Scoping Study for the Evaluation of EU REACH and CLP Regulations

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by

Risk & Policy Analysts Limited,
Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT
Tel: 01508 528465 Fax: 01508 520758
E-mail: post@rpaltd.co.uk

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Report Prepared by:	Meg Postle, Director Jan Vernon, Technical Director Philip Holmes, Technical Director Nigel Tuffnell, Senior Consultant Anne Thorell, Senior Consultant
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1. INTRODUCTION

1.1 Background

Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) places specific requirements on Member States, the European Chemicals Agency (ECHA), the European Commission (EC) and industrial organisations to report on the implementation and operation of REACH.

Defra (as lead UK-government department for REACH) has developed a strategy that will enable the collection, collation and assessment of all relevant information in a manner to enable not only the timely completion of its first report to the EC but to also provide the UK-government with additional insight into the operation of REACH within the UK context. This strategy is based upon a number of staged activities that are to be undertaken during the course of 2009:

- Scoping study;
- Design of evaluation questionnaire;
- Possible design/development of database; and
- Data assessment and gathering.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP), also places requirements on Member States to report on the enforcement of the provisions of CLP to ECHA and for ECHA, supported by Member States, to study the impact of labelling under CLP on the safe use of chemicals by consumers. The UK reporting requirements under CLP are primarily the responsibility of the HSE. In addition, the HSE has obligations to review the predictions in the UK Impact Assessment (UK IA) prepared by the HSE during the consultation period prior to the introduction of CLP.

CLP will be implemented in parallel with REACH and there are several overlaps between the two pieces of legislation. This study therefore seeks to integrate the evaluation and reporting of REACH and CLP.

The current study constitutes only the initial scoping element for the evaluation of both REACH and CLP. It provides an outline specification for a monitoring programme over the longer-term that is suitable to meet information needs for the future periodic reporting to ECHA and the EC as well as the UK-government's more general requirements for information on the impacts of REACH and CLP in its territory.

1.2 The Study Objectives

The specific objectives of the scoping study are to:

- ascertain the feasibility of obtaining information on how the principal objectives of REACH and CLP are being delivered, and how baselines for each of these may be established for evaluation purposes;
- identify possible options for data-gathering methodologies suitable to meeting the requirements for REACH and CLP; and
- propose possible options for longer-term monitoring, evaluation and reporting of REACH and CLP impacts on the UK.

To meet these objectives, it was also important to bear in mind the activities being proposed at the EU level for evaluation of REACH.

1.3 Approach to the Study

The approach to the study comprised five main tasks:

- Task 1: Inception meeting with Defra and HSE to clarify the requirements of the study in relation to REACH (following inclusion of the consideration of CLP in the study, a scoping meeting to address this aspect was also held);
- Task 2: Identification of the aims and objectives of REACH and CLP and baselines;
- Task 3: Identification of possible sub-objectives and review of potential indicators and data sources – including a consultation phase;
- Task 4: Screening and prioritisation of indicators; and
- Task 5: Development of evaluation proposals.

The approach was agreed with the Steering Group as the work progressed and, in some cases, this led to modifications of the approach to ensure that it fully met the requirements of the Defra and HSE and that the results would be robust. In particular, there was an increase in the level of consultation with various stakeholders, as an important way of checking data availability.

In addition, there were several iterations in the work carried out under Tasks 3 to 5, to reflect changes in information on the likely availability and usefulness of different data sources, stakeholder views on indicators, and to incorporate consideration of CLP requirements into the study (including limited specific consultation on this aspect with stakeholders of particular relevance).

More details on the work undertaken in Tasks 2 to 5 are provided in the main sections of the report.

1.4 Organisation of the Report

The remainder of this report has been organised as follows:

- Section 2 provides further discussion on the context to this study, including key issues likely to affect any future evaluation in relation to setting the baseline, defining the counterfactual and disentangling impacts due to other confounding economic or policy factors;
- Section 3 sets out the conclusions of our review of the key aims for the evaluation of REACH and CLP;
- Section 4 summarises, for each of the main aims of REACH and CLP, the potential objectives and sub-objectives that have been identified, with further details on the scoring of indicators and potential data sets provided in Annexes 2 and 3, respectively;
- Section 5 presents the output from the detailed critical assessment of each indicator;
- Section 6 presents the proposals developed to meet the scoping studies main objective of establishing – in outline – options for the monitoring and evaluation of the impact of REACH and of CLP in the UK; and
- Section 7 provides details of the time-line against which various actions should be considered.

Annex 1 details the organisations consulted, Annex 2 contains tables with data sources for all indicators and Annexes 3 and 4 set out the scores used to inform the assessment of each indicator for the evaluation of REACH and CLP respectively.

2. THE STUDY CONTEXT

2.1 The REACH Regulation

2.1.1 Introduction

EC Regulation No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was adopted on 18 December 2006 and entered into force on 1 June 2007.

The overall aim of REACH is to achieve:

- a high level of protection of human health and environment;
- free movement of substances on their own, in preparations, and in articles; while
- enhancing competitiveness and innovation.

2.1.2 Main Obligations and Timescales

The key steps involved in REACH are:

- **registration** of all chemical substances placed on the EU market in amounts greater than 1 tonne per year (per manufacturer or importer);
- **evaluation** of registration dossiers (for completeness and compliance, vertebrate animal testing plans) and prioritisation of substances for further evaluation;
- **authorisation** of substances of very high concern, aimed at progressive replacement by alternative substances or technologies where viable; and
- **restriction**, aimed at addressing risks not adequately controlled on a Community wide basis.

Although entering into force in 2007, for practical reasons reflecting the complexity of the considerations required, the number of stakeholders involved and resource constraints (not just on regulatory authorities but also on industry), REACH is to be implemented in stages up to June 2018 (Table 2.1 shows the timescale for the main activities under REACH).

Table 2.1: Timescale for Main Activities under REACH

Date	Activity
From 1 June 2008	Manufacturers and importers must register new substances, or those not pre-registered
1 December 2008	Manufacturers and importers complete pre-registration of existing substances
1 January 2009	The European Chemicals Agency (ECHA) publishes a list of pre-registered substances on its web site
From 1 January 2009	All potential registrants who have pre-registered will become part of a Substance Information Exchange Forum (SIEF)

Table 2.1: Timescale for Main Activities under REACH	
Date	**Activity**
1 June 2009	ECHA will make its first recommendations for substances to be included in Annex XIV (The candidate list was published in October 2008)
30 November 2010	Substances produced/imported in volumes over 1000 t/y, CMR category 1 and 2 substances in amounts of 1 t/y or more, and substances classified as R50/53 in amounts of 100 t/y or more must be registered by their manufacturers/importers
By first delivery after 1 December 2010 of a substance to be registered by 2010	Manufacturers/importers must provide a safety data sheet compiled in accordance with Annex II of REACH[1], which may include an exposure scenario
From 1 June 2011	Producers or importers of articles must notify ECHA if an article contains a substance identified according to Article 59.1 above a concentration of 0.1%
Within 12 months of receiving a safety data sheet	Downstream users must apply the appropriate conditions within the safety data sheet
Deadline 31 May 2013	All other substances produced/imported in amounts of 100 tonnes per year or more must be registered by manufacturers/importers
By first delivery after 1 June 2013 of a substance to be registered by 2013	Manufacturers/importers must provide a revised safety date sheet, which may include an exposure scenario
Deadline 31 May 2018	All other substances produced/imported in amounts of 1 tonnes per year or more must be registered by manufacturers/importers
By first delivery after 1 June 2018 of a substance to be registered by 2018	Manufacturers/importers must provide a revised safety date sheet, which may include an exposure scenario
Note 1: Where no safety data sheet is required (under Article 31 of REACH), the supplier must provide the registration number(s) of the substance(s), indicate where the substance(s) is subject to authorisation or any restrictions, and any other available and relevant information to enable risk management measures to be applied (see Article 32 of REACH)	

2.1.3 Factors Leading to the Development of REACH

Prior to the inception of REACH, control of the chemicals used industrially and in consumer products within the European Union had been largely achieved by two regulations, Council Regulation (EEC) No 793/93 of 23 March 1993 which established the requirements for the evaluation and control of the risks of existing substances (the so called Existing Substances Regulation, ESR) and the Notification of New Substance Regulations 1993 (NONS).

The NONS regulations implemented part of the Seventh Amendment Directive (92/32/EEC) and replaced the earlier Notification of New Substances Regulations 1982.

ESR provided for the EC or Member States to undertake data gathering and risk assessments, and to develop proposals for risk reduction where there was considered cause for concern, for any chemical included in the European

Inventory of Existing Commercial Chemical Substances (this contained details of commercial substances which were present on the market in the EC at some time between 1 January 1971 and 18 September 1981). Substances on this list were exempt from the NONS regulations.

Together, ESR and the NONS Regulation were intended to protect human health and the wider environment from the possible harmful effects of substances and, particularly in the case of new substances, to create a 'single market' across the EU. The risk assessment process for chemicals covered by these regulations was co-ordinated by the European Chemical Bureau (ECB). Requirements on producers to provide data on existing substances were light, while the level of information required on chemical characteristics and hazard potential in order to introduce a new substance onto the market varied depending on the quantities to be produced, increasing incrementally from a minimal data set at 10 kg per year to quite extensive requirements at annual productions of 1000 tonnes or greater.

Particular issues with the NONS Regulation and ESR were that the onus to undertake risk assessments, and produce periodic updates as new information became available for chemicals already on the market, was placed upon regulatory authorities rather than the organisation marketing the chemical. Furthermore, the scope of the data requirements for the marketing of both new and existing chemicals did not fully address some important toxicological and environmental endpoints; exposure assessment requirements were also limited in scope. These factors, in particular the extensive burden on regulatory bodies to undertake any assessment of risks, limited the rate of progress in reviewing existing substances and may have acted as a disincentive to companies to innovate and bring forward new products.

In order to address such concerns, in October 2003 the EC adopted a proposal to address the management of chemicals that provided for the unification of requirements for new and existing substances through the creation of the REACH system. Following much discussion and negotiation, the REACH Regulation (No. 1907/2006) was adopted on 18th December 2006.

2.2 The CLP Regulation

2.2.1 Introduction

On 20 January 2009, the CLP Regulation entered into force with the intention of aligning existing EU legislation with a Globally Harmonised System (GHS) developed by the United Nations (UN).

The overall aims of CLP are:

- to ensure a high level of protection of human health and the environment;

- to ensure the free movement of chemical substances, mixtures and certain specific articles; while
- enhancing competitiveness and innovation.

2.2.2 Main Obligations and Timescales

Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP) also places reporting obligations on Member States relating to enforcement activities, which may overlap with Member State obligations for reporting of REACH implementation and enforcement.

Article 46(1) requires Member States to submit a report to ECHA *every five years by 1 July on the results of the official controls, and other enforcement measures taken. The first report shall be submitted by 20 January 2012.* Furthermore, it is clear from Article 46(2) that the Member State Enforcement Forum formed under REACH will also act as the Enforcement Forum under CLP. In the UK, the HSE will be responsible for preparing and submitting this report to ECHA.

In addition to reporting on enforcement activities, Article 34(1) requires ECHA to *carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. This study shall be carried out in consultation with competent authorities.* Therefore, it is likely that HSE will have to collect and collate information on the safe use of substances and mixtures, which may overlap in some areas with the reporting requirements associated with REACH implementation.

In addition to its reporting obligations, the HSE has plans to review the impact of CLP in the run up to two key milestones: 1 December 2010, the date from which all substances should be classified according to CLP; and 1 June 2015, the date from which all mixtures should be classified according to CLP. This evaluation is expected to involve chemical suppliers, enforcing authorities and downstream users, through both existing stakeholder networks and those established for evaluation purposes.

After a transitional period, CLP will replace current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). Together with CLP, the European Parliament and the Council adopted two related acts which adapt further Community acts to the new rules on classification and labelling, Directive 2008/112/EC and Regulation (EC) No 1336/2008.

Provisions under Community legislation other than CLP (downstream legislation) may be triggered by the classification of a substance or mixture. The relevant acts are listed in Table 2.2.

Table 2.2: Community Legislation that may be Triggered by the Classification of a Substance or Mixture
REACH
Control of major-accident hazards involving dangerous substances (Seveso II): Council Directive 96/82/EC of 9 December 1996
Plant protection products: Council Directive 91/414/EEC (PPPD) of 15 July
Biocidal products: Directive 98/8/EC (BPD) of 16 February 1998
Chemical agents at work: Council Directive 98/24/EC of 7 April 1998
Carcinogens and mutagens at work: Directive 2004/37/EC 29 April 2004
Young people at work: Council Directive 94/33/EC of 22 June 1994
Pregnant and breastfeeding women at work: Council Directive 92/85/EEC of 19 October 1992
Health and safety signs at work: Council Directive 92/58/EEC of 24 June 1992
Cosmetic products: Council Directive 76/768/EEC of 27 July 1976
Toy safety: Council Directive 88/378/EEC of 3 May 1988 as amended by Directive 93/68/EEC
Detergents: Regulation (EC) No 648/2004 of 31 March 2004
Eco-label award scheme: Regulation (EC) No 1980/2000 of 17 July 2000
Aerosol dispensers: Council Directive 75/324/EEC of 20 May 1975. CLP Article 14 (2c) takes account of the Aerosols Directive Article 8 (1a)
Limitation of emissions of volatile organic compounds: Council Directive 1999/13/EC (VOCD) of 11 March 1999 and Directive 2004/42/EC of 21 April 2004
Ambient air quality assessment and management: Council Directive 1996/62/EC of 27 September 1996
Export and import of dangerous chemicals: Regulation (EC) No 689/2008 of 17 June 2008
Hazardous waste: Council Directive 91/689/EC of 12 December 1991, including Commission Decision 2000/532/EC of 3 May 2000
Batteries and accumulators: Council Directive 91/157/EEC of 18 March 1991
End-of-life vehicles: Directive 2000/53/EC of 18 September 2000
Waste electrical and electronic equipment (WEEE): Directive 2002/96/EC of 27 January 2002

Other Community legislation will, over time, be amended to refer to CLP rather than to Directive 67/548/EEC (hazardous substances) or Directive 1999/45/EC (hazardous mixtures).

The key dates for CLP are:

- 20 January 2009: CLP Regulation entered into force
- 1 December 2010: Substance classification and labelling to be consistent with the new rules; and
- 1 June 2015: Mixture classification and labelling to be consistent with the new rules.

2.2.3 Development of CLP

Following a decision in 1992 by the UN Conference on the Environment and Development (UNCED), the UN has been working to develop a Globally Harmonised System of Classification and Labelling of Chemicals (GHS), to provide a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures.

The UN anticipates that once fully implemented, GHS will act to:

- enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
- provide a recognized framework for those countries without an existing system;
- reduce the need for repeat testing (including animal testing) and evaluation of chemicals for classification and labelling purposes; and
- facilitate trade in chemicals whose hazards have been properly assessed and identified on an international basis.

In Johannesburg in September 2002, the World Summit on Sustainable Development adopted an implementation plan to encourage countries to implement this harmonised system. Subsequently, the European Commission and its Member States endorsed the UN recommendation to implement GHS into domestic law.

Like REACH, the introduction of CLP has as a principal aim to ensure a high level of protection of human health and the environment. CLP also aims to maintain the overall current level of protection of human health and the environment provided by Directive 67/548/EEC (Dangerous Substances Directive), as well as Directive 1999/45/EC (Dangerous Preparation Directive).

The EU CLP Regulation thus contributes to the UN GHS aim that the same hazards will be described and labelled in the same way around the world. By using internationally agreed classification criteria and labelling elements, it is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals. This Regulation thus complements the REACH Regulation.

2.3 Costs and Benefits of REACH

Prior to the announcement of its proposals, the EC carried out studies to understand the business and other impacts of its proposals. Following the launch of the 2003 proposals, the EC commissioned a further series of impact assessment studies, covering issues such as the macroeconomic impacts of REACH, impacts on low value and low volume substances, impacts on SMEs and impacts on health and the environment.

This led to a wide range of other impact assessments being carried out at the national level and by various non-governmental bodies. The UK undertook its own impact assessment work during this period, including preparation of a partial RIA and commissioning of a study to understand supply chain effects.

2.3.1 Potential Costs of REACH

A key focus of the impact assessments prepared for the EC and by the various industry bodies and associations was the impact that REACH would have, not only on manufacturers and importers of chemicals but also on downstream users of chemicals. This is likely to be a key area of on-going interest for Defra and HSE in relation to the UK chemicals industry and its supply chain; it includes not only impacts on individual operators but also on industry sectors as a whole.

The impact assessment studies highlighted a wide range of potential effects on the chemicals industry, on traders in and downstream-users of chemicals throughout the supply chain. This includes implications for the retail sector.

The main **direct** costs that we have identified from a review of available studies which are relevant to UK companies are summarised in Table 2.3.

Table 2.3: Direct Costs of REACH to Business	
Pre-registration	• administrative costs of collating data and submitting pre-registration form; • may also include contractual negotiations with a third party representative
Registration	• representation at a SIEF; • supply chain communication to identify exposure scenarios; • data gathering and collation and potentially purchase of data from other members of the SIEF; • preparation of the chemical safety report or contributing to the costs of preparing the shared components of a registration dossier; these costs may vary depending on the complexity of the supply chain, the ability to use QSARs and other read-across methods, and the extent to which risks have already been assessed due to other regulatory drivers; • undertaking any testing necessary following evaluation of testing proposals; • producing an extended safety data sheet; • supply of revised safety data sheet to downstream customers
Evaluation	• provision of further information upon the request of authorities
Authorisation	• responding to Candidate List consultations; • preparation of chemical safety assessment sooner than required under phase-in provisions for non-Annex XV substances; • assessment of alternatives; • preparation of socio-economic assessment (as appropriate); • preparation of justification for authorisation, including details of research and development activities; and • responding to Committee opinions on application
Restrictions	• responding to Member State requests for data; • preparing own submissions of a SEA or input to one; and • responding to Committee opinions

Pre-REACH estimates of the likely effects vary across all of the above cost items, with many of these variations stemming from differences in assumption as to what exactly will be required by a 'typical' company. Cost estimates

also vary depending on the size of companies (with reduced fees for SMEs) and by tonnage of the chemical of concern.

Undertaking an evaluation of REACH in relation to the direct costs set out above would effectively be an *ex post* assessment of the degree to which the predicted costs of REACH were reliable estimates. It is understood from discussions with the Steering Group that this is not the main aim of this study, although it may be one important aspect of REACH evaluation.

Also of interest are some of the potential **indirect** effects that may arise from REACH, as they may affect the structure of industry and hence provide an indication of the impacts of REACH on the free movement of chemicals and on competitiveness and innovation within the UK (and the EU more generally). The main indirect costs that we have identified from the various impact assessments are listed in Table 2.4.

Table 2.4: Indirect Costs/Effects of REACH

- Substance withdrawal for economic reasons, and the consequent impacts on supply chains. This may be associated with either:
  - low value products;
  - low volume products; or
  - substances produced as a by-product or through recycling and which are of variable composition over time, making registration prohibitively costly.
- Substance withdrawal for risk reasons (e.g. substances that are only produced as a by-product of another substance's manufacturer, with production of the main substance ceased for hazard or other reasons);
- Dissemination of sensitive business information (e.g. in relation to monomers in polymers);
- Supply chain effects, whereby the loss of substances or the increased cost of substances has an impact on activities in the remainder of the value chain, impacting on levels of manufacturing and other activities.
- Re-location of certain activities outside of the EU, due to
  - increases in costs of chemical inputs due to REACH requirements;
  - withdrawal of chemicals from EU market but which remain available elsewhere;
  - inability to demonstrate safe use and hence to register the chemical for the processes of concern; or
  - shift of some links in the value chain for above reasons leads to other links in the chain also relocating to enable 'just in time' delivery/working, etc. to continue.
- Research and development, with potential impacts including:
  - reduction in spend due to diversion of resources towards registration activities, reducing innovation in the short term and hence global competitiveness;
  - redirection of spend towards 'green chemistry' initiatives, leading to greater innovation rates and improved competitiveness.

Interestingly, none of the direct or indirect costs identified in the various impact assessments reflect impacts that may arise in relation to the free movement of chemicals, preparations and articles. This is an aim of much EU legislation and is linked to the justification for the EC taking action. As requirements for registering manufacture and import of chemicals existed pre-REACH under the ESR, it is not surprising that no 'new' costs were identified in relation to achievement of this aim.

2.3.2 Potential Benefits of REACH

The benefits of REACH are expected to accrue mainly in terms of reduced risks to human health, reduced risks of damage to the natural environment and benefits to the chemical industry in terms of improved reputation and competitive advantages. There are also provisions, such as the increase in the tonnage threshold for the registration of new substances that should lead to direct cost savings.

Predicting and quantifying these benefits was a major difficulty in the impact assessment work preceding formal adoption of REACH. This was partly because of the difficulty of separating the effects of REACH from other factors such as other regulations, market trends and developments, etc. It also stemmed from the fact that such benefits will arise from additional controls being placed on substances which are found by REACH to present risks to man or the environment – risk on which we currently have no or very limited information and thus cannot easily predict the value of if they are reduced.

The main anticipated benefits identified to date are summarised in Table 2.5:

Table 2.5: Main Anticipated Benefits of REACH

- Reduction of environmental risks:
  - from production processes; and
  - use and final disposal of chemical substances.
- Reduction of risks to human health:
  - through occupational exposure;
  - through exposure via the environment; and
  - from use of consumer products.
- Benefits for industry:
  - improvement of the chemical industry's reputation and in the public's attitudes (and attached values) towards chemicals and the chemical industry (linked to a perceived higher degree of safety);
  - savings associated with a lightening of the regulatory burden for registration (notification) of new low production volume chemicals;
  - innovation associated with R&D to create substitutes and reformulated products; and
  - savings to downstream users stemming from an increased knowledge on chemicals. Savings may also result from decreases in special disposal or other requirements

2.4 Costs and Benefits of CLP

Prior to the finalisation of CLP, the HSE commissioned a Regulatory Impact Assessment (RIA) on the proposed new regulation (HSE, 2007a). The focus of the RIA was on the potential costs and benefits to UK industry. As the EU had a well established system of classification and labelling prior to the introduction of CLP, it was not considered likely that its introduction would result in significant impacts to human health or the environment.

The RIA notes that the enhancement of international trade may be impaired by the non-harmonised 'building block' approach to the world-wide adoption of GHS; this was a particular concern of industry.

The RIA identified six main affected groups: chemical manufacturers, downstream businesses, wholesalers, retailers, the public authorities and retail consumers of chemical products. It also differentiated impacts by company size.

2.4.1 Potential Costs of CLP

The potential costs of CLP to different affected groups identified by the UK RIA are summarised in Table 2.6. The costs to industry are all predicted to occur during the transition period over which the CLP will be implemented.

Table 2.6: Potential Costs of CLP to Different Groups

Affected Group	Impacts
Manufacturers	• Replacement or updating of information technology (IT) systems to produce new labelling; • Staff training and familiarisation to familiarise employees with CLP; • Reclassification of chemicals, with costs from: - the reassessment of hazard data to reclassify; - the potential use of a conversion table for reclassification; - the potential for 'higher' classifications (For example, may result in many cleaning and detergent products being classified for skin irritation and skin corrosion for the first time); and - the use of bridging principles, and other alternatives to additional testing; • Re-labelling of chemicals; • Stock losses; • Informing consumers and downstream users of chemicals about CLP; and • Proposing new harmonised hazard classification
Downstream businesses	• Staff training and familiarisation to familiarise employees with CLP; • Reviewing labels; • Undertaking new risk assessments relating to chemicals classified under CLP; • Stock losses; and • Informing consumers and downstream users of chemicals about CLP
Wholesalers and retailers	• Staff training and familiarisation to familiarise employees with CLP; • Stock losses; and • Informing consumers about CLP
Public sector	• Training and familiarisation of enforcement officers; and • Training and familiarisation of emergency services staff (paramedics)
Retail consumers of chemical products	• Consumers taking time to familiarise themselves with CLP

2.4.2 Potential Benefits of CLP

The main economic benefits to the UK are predicted to arise from an enhancement of the international trade in chemicals. These benefits relate to:

- reduced costs for complying with different hazard classification and communication systems (with cost reductions from the reduced need for different testing, labelling, packaging and safety data sheets); and
- increased ease of access to world chemical markets due to the reduced need for expertise in multiple classification systems.

These benefits may in turn lead to increased international competition in chemical products, giving rise to increased innovation, productivity and lower prices.

These benefits to industry are expected to arise over the longer term and will be dictated by the pace at which the UN GHS is applied throughout the world; they will also depend on the degree of harmonisation between the GHS-based systems adopted.

Some of the hazard categories included in the UN GHS go beyond the scope of the Dangerous Substances Directive. These have not been adopted under CLP. Therefore, classification for hazard categories in addition to those under CLP may be necessary to facilitate export to some countries outside the EU. In addition, there were elements of CHIP incorporated into the CLP which are not (yet) included in the UN GHS, for example the additional EU hazard class "Hazardous to the ozone layer" (R 59). These differences between CLP and the GHS that may be adopted by non-EU countries may limit the benefits to international trade predicted for GHS and CLP.

2.5 Setting Baselines for Evaluation Purposes

2.5.1 Baselines from the Impact Assessments

The REACH and CLP impact assessments provide a wealth of data that could be used to set the baseline for any evaluation exercise. This includes:

- **Basic assumptions**: numbers, types and sizes of companies, numbers of chemicals to be registered by tonnage band, numbers of PBT substances, numbers of carcinogens, numbers of uses for chemicals placed on the market in different tonnages per manufacturer or importer, etc.;

- **Assumptions underlying key calculations of costs and benefits**: likely levels of substance withdrawal by tonnage, availability of data, average costs of testing for each Annex, costs of preparing a registration dossier, costs of preparing exposure scenarios, numbers of SVHC, costs of reclassification, costs of updating IT systems, costs of stock losses, costs

from provision of information, costs of stock disposal, benefits from increased international trade, benefits to competitiveness and innovation, benefits to human health and the environment;

- **Assumptions on the functioning of REACH and CLP**: numbers of manufacturers joining in consortia, numbers of breakaway consortia, costs of participating in a consortium or SIEF, numbers of companies seeking authorisations, numbers of applications for harmonised classification, numbers of restrictions dossiers to be prepared per annum, costs to MS of meeting REACH and CLP obligations, etc.

Unfortunately, some of this information was generated for earlier proposals on REACH and the final legislation may have changed to an extent that the assumptions or the manner in which they were combined is no longer valid. In addition, the assumptions are just that – assumptions based on the best available information, but assumptions nevertheless; thus, they are not a true baseline.

However, it should still be possible to carry out an ex post assessment along the same lines as some of the predictions presented in the impact assessments. Even if some of the assumptions change, it may be possible to follow similar calculation approaches for comparison purposes.

In addition, it should be possible to follow-up on some of the case study work that was undertaken to examine whether impacts were as expected, different in nature, or higher or lower in magnitude. For example, RPA and London Economics[1] undertook a study for Defra and BIS (then DTI) which looked at the potential impacts of REACH on three chemicals supply chains: can coatings; semiconductors; and fragrances. These case studies include predictions on, for example, the number of substances that might be removed from the supply chain, the costs that would be passed on by manufacturers in the form of price increases, impacts on innovation, etc. It also looked at the potential implications for these sectors as a whole within the UK. Other similar work was undertaken by some of the industry associations (e.g. the British Coatings Federation did some work to predict the impacts of REACH in terms of substance withdrawal). These case studies provide both baseline information for the situation in 2004/5 and also predictions as to the impacts of REACH. It should therefore be possible to revisit such assessments, bearing in mind that the provisions in the Regulation that was finally adopted vary from those in the proposals being discussed in 2004/5.

In other cases, the impact assessment work would be of no use in setting a baseline, but would be of value for a comparison of ex ante and ex post estimates of costs. For example, during the REACH negotiations phase, RPA

[1] RPA & LE (2005): Project to Assess the Impact of the New EU Chemicals Strategy and to Develop a Model, prepared for Defra

developed a computer model to predict the number of organisations that would join in consortia in response to the introduction of the "one substance, one registration" requirement. This model made assumptions on the number of companies that might pre-register and then fully register a substance (with predictions being probabilistic, using a combination of a random number generator and Monte Carlo analysis). However, even in this probabilistic model it was not assumed that more than say 100 companies would be registering the same substance (even in the >1000 t/y tonnage band). In reality, there would appear to be numerous cases of far higher numbers of companies pre-registering chemicals. For example, it is understood that over 5000 companies pre-registered for zinc metals, with over 7000 companies pre-registering copper metals. Even if only 10% of these companies go on to full registration, they are much larger numbers than expected and this will have an impact on the administrative costs associated with REACH (although the costs per company may be the same as assumed, the higher number of companies means that total costs would have been underestimated).

2.5.2 Baselines from Other Data

For some of the other variables of concern, setting the baseline is likely to be more straightforward, for instance where it is possible to use environmental or occupational health monitoring data from the year in which REACH came into force (and which is prior to the entry into force of CLP). Progress could then be measured against these data, looking at changes between 2006 figures (or 2008 for CLP) and those for (say) 2011.

A baseline for the application of provisions relating to new substances may be provided by data relating to NONS. Similarly, for CLP a baseline may be provided by data relating to the situation in the UK under CHIP.

It is not always clear cut, though, how the baseline should be set. Some indicators have definitive annual baselines against which any perturbations can be clearly attributable as an impact of REACH or CLP. For other indicators, however, the baseline data set may be poor (or absent), or confounding factors may also separately impact on the indicator, decreasing the level of confidence which can be placed in its value as reflecting impacts of REACH or CLP (confounding factors are treated separately and described in greater detail below). In other cases, the issue may be more as to what constitutes a suitable data collection period or frequency of collection in order to judge the extent of any impact of REACH or CLP.

An example of a case where the impact of REACH might be expected to be seen quickly is the costs of SIEF formation and registration dossier preparation, as such information should become available as the first phase-in deadline of 1 December 2010 approaches. Similarly, there are historic examples where taking measures to safeguard occupational health has led to measurable short- to medium-term improvements. For example, Danish legislation approved in 1983 reduced the content of water-soluble chromate to

below 2 ppm in cement. This was followed by a noticeable decrease in the prevalence of allergic eczema (from 8.9% in 1981 to 1.3% in 1987) in Danish cement workers (CSTEE, 2002). Impacts such as this should show up fairly quickly in the annual occupational health data collected by HSE; although they would need to be adjusted to reflect only those disease burdens that can be attributed to REACH (rather than to on-going action to reduce disease burdens associated with exposures to chemicals already known to cause a particular illness/health effect). In contrast, impacts related to other health endpoints, such as changes in cancer rates, can only be expected to show a response over much longer time-scales.

Most of the costs of CLP are predicted to coincide with implementation of its provisions on substances (by 1 December 2010) and on mixtures (by 1 June 2015). However, the benefits are expected to occur over a much longer timescale. The monitoring of international trade, innovation, productivity and prices are therefore likely to need to continue well beyond 2015.

For industry, the current economic climate may be the most important influence on its response to REACH or CLP. However, it may be feasible to identify indications of the extent to which REACH and CLP has impacted on the EU through comparison with trends in the chemical industries of non-European jurisdictions and with other European business sectors (e.g. has turnover in the chemicals industry reduced by a disproportionate amount compared to other primary industrial sectors). The REACH Baseline Study, commissioned by the EC, identified the chemical industry as one of the main drivers in economic growth (CARACAL, 2009). More specifically, it was determined that "The growth of Gross Domestic Product (GDP) as a measure of economic growth correlates with the volume growth of chemical production. In addition, the growth of toxic chemicals or even CMR chemicals (carcinogens, mutagens and reproductive toxicants) is following this trend". Thus, the economic performance of the chemical industry, expressed as a proportion of GDP, may provide a measure of performance that is relatively independent of the prevailing economic climate.

2.6 Establishing an Evaluation Counterfactual

In order to correctly estimate the impact of REACH or CLP, it is also important to consider what the 'state of the world' would have been had REACH or CLP not been put into place, i.e. establishing what is termed as the counterfactual or the situation in the absence of the policy.

The aim of developing a counterfactual is to provide the basis for evaluating the 'outturn' of a policy compared to what was predicted and to what would have happened in any event (i.e. the alternative state – or states - without the

policy)[2]. This type of approach is important to understanding the role of REACH or CLP compared to other legislation that may have impacts similar those of REACH or CLP.

2.6.1 Counterfactual to REACH

With regard to REACH, legislation such as the Water Framework Directive would still have been implemented and thus have contributed towards a reduction of chemicals in the water environment, whereas other effects might have taken much longer to take place or never taken place at all. This is highlighted in Figure 2.1 taken from a Eurostat report, which provides an illustration of the potential difference between the post REACH state and a without REACH state.

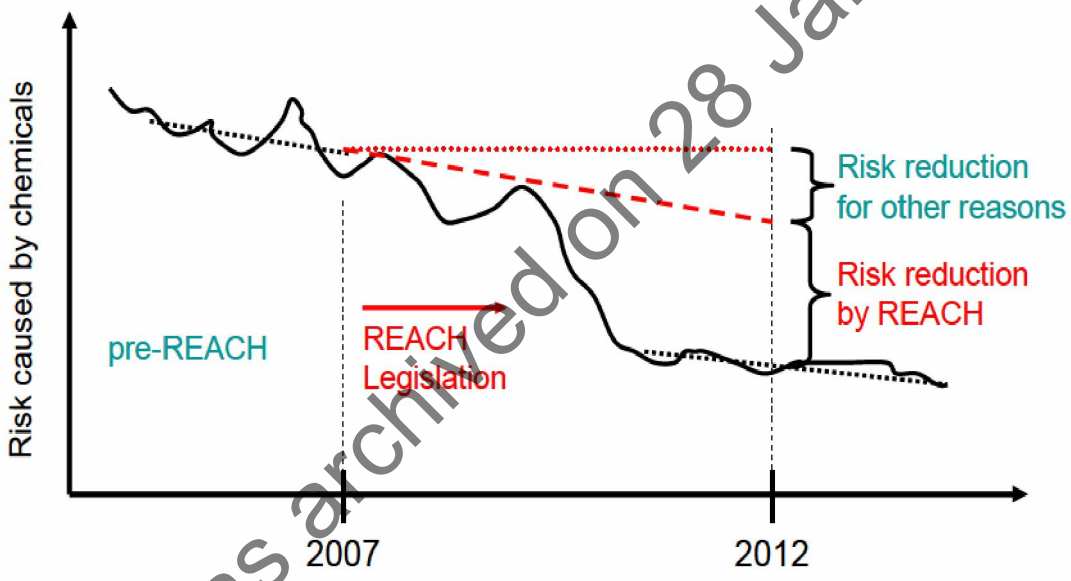

Figure 2.1: Possible Future Evolution of the Risk Caused by Chemicals (Source: Eurostat, 2009b)

Thus, the aim of an ex post evaluation should be to assess what the impacts of REACH have been, how these compare with the ex ante assessments of impacts and how these compare to what might have taken place in any event (i.e. one or more counterfactuals).

One approach to assessing what would have happened in the absence of REACH would be through the use case studies of, for example, particular chemicals on which action was taken because of REACH; these would compare the real outcome with the most likely outcome under the previous regulatory framework. This is similar to the methodology applied in the

[2] See also the Treasury "Green Book: Appraisal and Evaluation in Central Government" (2003), HM Treasury, London.

assessment of REACH's predicted impact on health and the environment, as carried out by RPA and BRE for DG Environment (RPA & BRE, 2003). This project looked at four chemical case studies to examine the damages that had arisen over time due to the failure to control the risks associated with a given substance. This was then compared to the most likely outcome had REACH already been in place, i.e. the case studies attempted to identify whether REACH would have:

- required the same level of test data as required under ESR or other regulatory regimes;
- identified the same endpoints and risk compartments as those identified (historically) and controlled by the existing legislative arrangements; and
- if so, whether the risk reduction measures recommended by the retrospective application were likely to be similar to those implemented at the time.

The study identified four key advantages of REACH over the previous system, namely that:

1. REACH has the potential to identify a hazard before (substantial) damage occurs by assessing the properties of substances and thereby making information available more quickly rather than waiting for monitoring (which is slow and underfunded) to provide evidence of harm;

2. It may allow effective risk management measures to be identified, by providing data in a systematic manner, thus enabling risks to be assessed rigorously;

3. It enables industry (chemicals manufacturers and downstream users) to take voluntary action in response to stakeholder pressure and/or their own policies because of the availability of information on risks; and

4. It provides a basis for quicker regulatory action for the most hazardous substances (e.g. through authorization).

This methodology would naturally have to be reversed to carry out a counterfactual analysis of REACH; the starting point would be what happened under REACH and the analysis would then focus on applying the old legislation (and making further assumptions on prioritisation for risk assessment and risk management) to the same chemicals to see how the outcome might have differed.

For example, there were numerous initiatives underway to improve the protection of human health and the environment from the impact of chemicals even before REACH was first proposed. The OECD introduced the High Production Volume Programme and several member states had their own programmes or policies too, such as Germany (VCI Initiative) or Sweden (which was the driving force behind substitution). In the UK, there was a

Chemicals Strategy and government agencies such as the Environment Agency had their own chemicals strategies with specific focus on their work areas. These programmes would have continued even in the absence of REACH and any counterfactual-based evaluation of the impact of REACH would therefore have to allow for the changes that would have happened under these programmes[3].

However, REACH does offer further protection of health and the environment beyond what these programmes offered. For instance, it covers other endpoints than the OECD (such as for instance endocrine disruption) and also makes certain tests (like sensitisation) obligatory where they were a voluntary requirement under OECD. In addition to this, REACH is the only chemical strategy or policy to reverse the burden onto industry.

2.6.2 Counterfactual to CLP

Prior to the introduction of the CLP, the classification, labelling and packaging of substance was regulated across the EU by the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD). In the UK, these directives were implemented as the Chemicals Hazard Information and Packaging for Supply Regulations (CHIP). Therefore, the standard of classification, labelling and packaging of substances is not expected to change. Genuine impacts of CLP will therefore be those that would not have occurred under the last version of CHIP before the introduction of CLP.

CHIP and CLP are conceptually similar in that they deal with classification, hazard communication through labelling and packaging. CLP is aimed at workers and consumers, and covers the supply and use of chemicals. It does not cover the transport of chemicals, although testing for physical hazards is largely driven by the UN Recommendations on the Transport of Dangerous Goods. Classification for transport is covered by the Framework Directive (2008/68/EC) implementing the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN).

[3] Allowances are made for many of these programmes in the Business Impact Assessments carried out for REACH; for example, reducing the costs of preparing registration dossiers due to the fact that similar dossiers would have been prepared for submission to the OECD, etc. Thus, the previous impact assessment work is likely to be of value to establishing a counterfactual. Indeed, the first "preliminary" Regulatory Impact Assessment carried out on REACH for Defra in 2001 contained assumptions as to what would have been required under the UK Chemicals Strategy, including a fairly simply based set of cost estimates and more limited information on benefits.

CLP adopts those hazard classes from the UN GHS which most closely match the DSD/CHIP categories of danger. However, while the overall scope of classification under CLP is comparable with CHIP, the number of hazard classes has increased, in particular for physical hazards (from 5 to 16), leading to a more explicit differentiation of physical properties.

Unlike CHIP, the classification of mixtures under CLP is for exactly the same hazards as substances and bridging principles can be used for the determination of some health and environmental hazards, using data on similar tested mixtures. Furthermore, the formulae used for the classification of mixtures often differ from those used under CHIP and the application of expert judgement and weight of evidence determination are more explicit in the legal text of CLP.

CLP replaces the CHIP risk phrases, safety phrases and symbols with the mostly equivalent hazard statements, precautionary statements and pictograms. CLP also introduces two signal words, 'Danger' and 'Warning', to indicate the severity of a hazard as a new feature in EU legislation.

DSD and CLP both have provisions for the harmonised classification of particular substances of very high concern. However, under CLP it is now possible for manufacturers to make proposals for such classifications. Both CHIP and CLP require companies to classify the substances and mixtures that they supply. Under CLP, companies will have to notify ECHA of the substance classifications and labelling that they use. Suppliers of the same substance should seek to reach agreement on the classification of that substance. It is intended that this will lead to greater harmonisation of the classification and labelling and the increased transparency may also lead to more rigorous classification of substances.

2.7 Addressing Confounding Factors

In assessing the impacts or effects of REACH or CLP, there will be several confounding factors which must be taken into account since neither REACH nor CLP were agreed against a static socioeconomic backdrop, and a range of other policy initiatives and legislative changes will be introduced over the prolonged period of their implementation. These can be expected to either directly or indirectly influence many of the indicators against which REACH and CLP will be assessed.

In seeking to attribute an effect to the impact of REACH or CLP, it will therefore be important to consider what other confounding factors may also have caused or contributed to that effect, such as other legislation which may have come into force or common practises which may have changed thus contributing towards the effect.

2.7.1 Confounding Factors to REACH

As highlighted above, a number of other regulations and directives also exist within the EU which regulate certain classes of chemicals, such as agrochemicals, biocides, food-packaging materials and pharmaceuticals; the introduction of REACH has not significantly affected these. In addition, chemicals considered hazardous at work are covered by various legislation, such as the COSHH regulation (which also addresses the control of hazards from other potential occupational sources such as gases, fumes, dusts and biological agents).

Other international initiatives that predate and have been progressed alongside the development of REACH include the voluntary initiative co-ordinated since 1998 by OECD and the International Council of Chemical Associations (ICCA) to collate information on, and conduct risk assessments on, a priority list of 1000 HPV chemicals (referred to above in relation to the counterfactual). A similar initiative in the US, the EPA High Production Volume (HPV) Challenge Program is intended to make health and environmental effects data publicly available on chemicals produced or imported in the United States in high volumes. Although not having regulatory status, these initiatives are governed by authoritative bodies and have generated a considerable amount of data that can be used to support the registration of existing HPV chemicals under REACH.

Changes in the state of the economy, in technical or scientific innovations and in the demand for particular goods or services may also be relevant. For example, monitoring may indicate that there has been an effect in the environment such as reduced levels of a given chemical in the water environment. This may be the result of REACH or may stem from changes in best practise, the development of new technologies which reduce net emissions through recycling, or a switch to another chemical or process (that was not driven by the substitution principle under REACH).

Such factors would therefore have to be identified for each indicator and taken into account before attributing any impacts to REACH. The presence of such confounding factors does not mean that REACH has had no impact, only that it may be important to attribute only a share of any change to REACH.

Examples of expected confounding factors include:

- responses by industry due to the anticipated implementation of REACH. For example, once the intention to require the registration of chemicals and to require demonstration of 'safe use' was proposed, industry may have sought to act early to replace potential SVHCs or to streamline their product portfolios so as to obtain a commercial advantage;

- implementation of policies designed to reduce the impact of chemicals on health and the environment (e.g. Control of Substances Hazardous to

Health, Chemical Agents Directive, Water Framework Directive, the Marine Strategy Framework Directive, the Biocides and Pesticides Directives, Integrated Pollution Prevention and Control, the proposed Directive on Industrial Emissions, and waste legislation. For instance, the Waste Framework Directive may change the definition of waste, and substances which were previously classified as waste - and therefore not covered by REACH - may soon be classified as reclaimed, and thus be covered by REACH);

- introduction of other (non-chemical) health related policies which may impact on the incidence of particular diseases which may be adopted as indicators of REACH's impact;

- other non-legislative factors that could affect the endpoints used to assess the impacts of REACH (e.g. changing demographics, climate change);

- changing consumer attitudes (e.g. previous work by RPA indicates that consumer concerns/NGO pressure may lead to withdrawal of substances from consumer products even in the absence of evidence of risks);

- general economic factors, such as the current recession, which may have an impact on the viability of individual companies, on their product portfolios, on the ability to fund R&D, etc. Such impacts may also affect others in the value chain, with the potential for wider shifts in manufacturing demand, etc.; and

- factors influencing the competitiveness of industry in general or the chemical industry (or sectors thereof) in particular, such as changes in prices of raw materials and in the relative cost of labour, or the impact of any changes in chemicals regulation that may be introduced by competitor economies.

2.7.2 Confounding Factors to CLP

CLP covers substances and mixtures in general but for certain chemicals, such as cosmetics or flavourings, the labelling elements introduced through CLP may be complemented by further elements which are required by the relevant product-specific legislation. The impacts of CLP on the export and import of Dangerous Chemicals, Regulation (EC) No 689/2008, may also impact on any enhancement of trade. Therefore, in addition to confounding effects from REACH and other chemicals legislation, the impacts of CLP on international trade will also be influenced by changes in the economic climate.

2.7.3 REACH and CLP: Mutual Confounding Factors

It was the intention to implement CLP within the EU in parallel to REACH, with the timetable for CLP relating to key dates in the implementation of

REACH. For example, the deadline for the reclassification of substances under CLP is the same as that for the first phase-in deadline under REACH and the deadline for the reclassification of mixtures was calculated from this important REACH date. CLP amends the sections of REACH that refer to DSD or DPD to relate to itself and removes any reference to 'dangerous' substances or preparations, replacing these with references to CLP hazard classifications.

The UK RIA predicts that most, if not all, of the costs of CLP will occur during the initial period of transition from CHIP. Given that key points in this transition are expressly linked to key points in the implementation of REACH it is likely that impacts to industry from one will be confounded by impacts from the other. For example, data from REACH registration dossiers may be used to re-classify substances under CLP thus reducing the impact of CLP alone. The UK Competent Authority and enforcement agencies for CLP will be the same or closely linked to those for REACH. Therefore, costs from the management and enforcement of CLP are likely to be reduced.

Given the extent of the overlap between certain aspects of REACH and CLP, it is likely that one will result in significant confounding of the other. However, through the evaluation of REACH and CLP together it is hoped that each evaluation will provide data for the correction of confounding to the other.

3. IDENTIFICATION OF REACH AND CLP AIMS AND OBJECTIVES

3.1 Introduction

The initial focus of the study was to confirm the overarching aims and objectives suitable for the evaluation of REACH and CLP through a review of key source documents, the expert knowledge of the team based on its previous work on the development of the REACH and CLP legislation and supporting guidance documents, and in discussions with the client. Work was also undertaken to establish the anticipated reporting format requirements for Member State quinquennial reports to the Commission.

The key sources of information used for these purposes were as follows:

- relevant articles of the REACH and CLP Regulations;
- the Eurostat Baseline Study (for REACH);
- output from the recent first meeting of the Competent Authorities for REACH and CLP (CARACAL) on the MS Reporting under REACH Project (ENV.D.1/SER/2008/0095r);
- Final report of the Forum for Exchange of Information on Enforcement for the Working Group 'Member States Report to the Commission';
- reporting and evaluation obligations under Regulation (EC) No 1272/2008;
- UK Regulatory Impact Assessment on CLP; and
- initial considerations developed by Defra.

Relevant information drawn from these source documents is summarised below, with full citations given in the References section.

3.2 Reporting Obligations under REACH

Obligations of stakeholders are detailed in the REACH Regulation. In particular, the obligations on Member States to report are defined within Articles 117 (Reporting) and 127 (Report) of the REACH Regulation. The requirements of Article 117 are set out in Table 3.1.

Article 117(4)(a) of REACH obliges the Commission to publish a general report on experience with the operation of REACH. Paragraphs 1 to 3, together with Article 127, set out the reporting obligations for Member States and ECHA to the EC, in relation to this report. Each Member State is required to submit a report to the EC every five years on the operation of REACH in its territory, with the first such report due by 1 June 2010. However, the articles do not provide detailed descriptions of the reporting that will be required, and efforts are still underway at the European level to develop detailed specifications and a standardised reporting and submission mechanism.

Table 3.1: Reporting Obligations under REACH Article 117

Article 117

1. *Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127. The first report shall be submitted by 1 June 2010.*

2. *Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11[4] and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 June 2011.*

3. *Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation. The first report shall be submitted by 1 June 2011.*

4. *Every five years, the Commission shall publish a general report on:*
   a) *The experiences acquired with the operation of this Regulation, including the information referred to in paragraph 1, 2 and 3 and*
   b) *The amount and distribution of funding available by the Commission for the development and evaluation of alterative test methods.*

   The first report shall be published by 1 June 2012.

5. *Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127. The first report shall be submitted by 1 June 2010.*

6. *Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11[5] and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 June 2011.*

7. *Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation. The first report shall be submitted by 1 June 2011.*

8. *Every five years, the Commission shall publish a general report on*
   a) *The experiences acquired with the operation of this Regulation, including the information referred to in paragraph 1, 2 and 3 and*
   b) *The amount and distribution of funding available by the Commission for the development and evaluation of alterative test methods.*

   The first report shall be published by 1 June 2012

Article 127

The report referred to in Article 117(1) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum

[4] Article 11 refers to the responsibilities of registrants of chemicals to submit certain information

[5] Article 11 refers to the responsibilities of registrants of chemicals to submit certain information

3.3 Reporting Obligations under CLP

The reporting obligations on Member States in relation to the CLP Regulation are somewhat more limited than those specified under REACH. Specific reporting requirements are defined under Articles 34, 45 and 46 of the Regulation and are set out in Table 3.2. In particular, Article 46 places the principal requirement on Member States for reports to be submitted to ECHA at five yearly intervals, the first being due on 20 January 2012.

Within the UK, the Competent Authority for CLP is the same as for the REACH regulation (HSE). This offers considerable opportunities for the efficient gathering of data and reporting on the impacts of each regulation. In particular, it is likely that HSE will be tasked with the collection and collation of information on the safe use of substances and mixtures, and that this will overlap in some areas with the reporting requirements for REACH implementation.

It is also clear from Article 46(2) that the Member State Enforcement Forum under REACH will also act as the Enforcement Forum under CLP. Furthermore, hazard communication is a key overlapping feature of REACH and CLP and it may be that the REACH Competent Authority and Helpdesk will, therefore, take up the responsibilities of Competent Authority and Helpdesk for CLP.

Article 45 of CLP imposes a requirement on the UK government to establish a body with responsibility for gathering information from manufacturers and importers of mixtures, holding it in a secure manner and using the data to support the preparation of advice of a medical nature that may be required in cases of exposure to such mixtures. This body/ies will also be responsible for supplying data to allow the UK government to decide if there is a need to improve risk management measures. Although it may be anticipated that the HSE will be ultimately responsible for some aspects of this function, the manner of delivery and the extent to which other departments and agencies may be involved has yet to be fully defined. It is however it is considered likely that Article 45 will be implemented in the UK by Health Protection Agency (HPA) and the National Poisons Information Service (NPIS) on behalf of the HSE.

Thus, while it appears that the HSE will be in an excellent position to collect and collate much of the information on the safe use of substances and mixtures, particularly with regard to those areas where there are overlaps in reporting requirements with REACH, in a number of areas there remain issues as to which other government bodies may also be involved in the various processes and activities.

Table 3.2: Reporting Requirements of CLP
Article 34 (1)
The Agency shall carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. This study shall be carried out in consultation with competent authorities
Article45
1. Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24. *2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used:* *(a)to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; and* *(b)where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed. The information shall not be used for other purposes.* *3. The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible.* *4. By 20 January 2012 the Commission shall carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review, and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission may adopt a Regulation adding an Annex to this Regulation*
Article 46
Member States shall submit a report to the Agency every five years by 1 July on the results of the official controls, and other enforcement measures taken. The first report shall be submitted by 20 January 2012. The Agency shall make those reports available to the Commission, which shall take them into account for its report under Article 117 of Regulation (EC) No 1907/2006

3.4 Eurostat Baseline Study

3.4.1 Types of Indicators

Eurostat has recently completed the initial development of approaches to data collection and modelling to inform on the impacts of REACH. It commissioned a baseline study to develop a 'snap shot' of data for 2007 that will be used for future comparisons (Eurostat, 2008 & 2009b). These systems

are intended to address many, but not all, aspects relating to REACH implementation (Table 3.1). It is intended that a range of metrics will be produced on the implementation and operation of REACH processes, on the degree of transparency and consumer awareness, and on a series of indicators addressing health and environmental aspects.

This baseline study is designed around three main sets of indicators (Eurostat, 2009b):

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

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

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

These indicators are focused on the overall European situation. Those relating to the availability and quality of the chemical data sets (and the consequences with regard to the degree of confidence as to the 'safety' of a chemical) will draw on a small subset of chemicals. There are approximately 30,000 substances which fall within the scope of REACH. Eurostat considered it unmanageable to address all these substances, so a stratified subset of 237 substances has been randomly selected from the approximately 10,000 existing substances of known high, medium and low production volume chemicals and some Substances of Very High Concern (SVHC). Eurostat considers this subset large enough to detect changes in the risks and the quality of the databases for chemicals. Information to determine the impact on consumer safety is largely drawn from pre-existing reporting systems in Germany (BfR consumer products database) and Scandinavia (SPIN data).

The extent to which the Eurostat exercise is of relevance to assessing the UK-specific situation is uncertain. Importantly, the Eurostat system does not address the competitiveness of the chemical industry or fragmentation of internal markets. Table 3.3 sets out the objectives of REACH as interpreted by the Eurostat Baseline Study and the relevant indicator types.

Table 3.3 Objectives of REACH as Interpreted by the Eurostat Baseline Study			
Central elements & objectives of REACH	**Baseline Study Indicator System**		
	Administrative indicators	**R&Q indicator system**	**Supplemental indicators**
Registration of chemicals	ü		
Evaluation of chemicals	ü		
Authorisation and restriction of chemicals	ü		
Establishment of a central agency	(indirect)		
Protection of human health and the environment		ü	ü
Improvement of knowledge on properties and safe uses of chemicals		ü	ü
Assessment of existing and new chemicals in a single, coherent system			ü
Increased transparency and consumer awareness			(ü)
Promotion of alternative methods for assessment of hazards of chemicals			ü
Maintenance and enhancement of the competitiveness of the EU chemical industry	Not within the scope of the Baseline Study		
Prevention of fragmentation in the internal market	Not within the scope of the Baseline Study		
Conformity with EU's international obligations under WTO	Not within the scope of the Baseline Study		

Source: Eurostat (2008)

3.4.2 Administrative Indicators

The administrative indicators involve the monitoring of basic REACH metrics such as the number of registrations. As data for these indicators will only become available with the application of REACH, the baseline was taken to be zero. These indicators will be calculated from data provided by ECHA.

3.4.3 Risk and Quality Indicators

The purpose of REACH, as set out in Article 1, is to ensure a high level of protection of human health and the environment. Thus, the change in human and environmental risk from exposure to chemicals would be an important indicator of the impact of REACH. To measure such a change, exposure and a toxicity assessments were undertaken for the sample of 237 substances (including two substances identified as having endocrine disrupting properties). From these assessments, each substance was awarded a risk score of between 1 and 1000 (or more). Changes in these scores over time will be taken as indicators of change in risk.

One way that REACH is intended to ensure a high level of protection is by ensuring that information of sufficient quality to prepare accurate risk assessments is available throughout the supply chain. It was assumed that the

implementation of REACH should result in more complete testing of toxicological properties, better data from alternative test methods, improved reporting and better quality exposure data. The data sources used to produce the risk scores described above were therefore each given a score of between 1 (very good data quality) and 100 (very poor data quality). Changes in these scores over time will be taken as indicators of changes in data quality. However, while noting that REACH is expected to result in an increased number of substances classified as dangerous, Eurostat (2009b) also recognises that changes arising from CLP will have an influence.

3.4.4 Supplementary Indicators

A number of additional or 'supplementary' indicators were identified. These indicators will be derived from existing statistics and other data sources that may be available at the Member State level rather than the EU level. The supplementary indicators are:

- changes in quality of safety data sheets;
- availability of hazard data;
- availability of use and exposure data;
- changes in use patterns in Scandinavia and Germany;
- changes in classification and labelling;
- registration of new chemicals;
- production of toxic chemicals;
- toxic chemicals in households;
- cross-border transport of toxic chemicals;
- occupational skin diseases; and
- use of alternative methods (non-testing and non-animal testing methods).

Chemicals were separated by their current classification for toxicity under Directive 67/548/EEC or Directive 1999/45/EC into:

- carcinogenic, mutagenic and reprotoxic (CMR);
- chronic toxic chemicals;
- very toxic chemicals;
- toxic chemicals;
- harmful chemicals; and
- chemicals not classified under any of the classifications above.

3.4.5 Outstanding Issues Identified by the Eurostat Baseline Study

While many of the indicators and supporting data sets intended to be used in the Baseline study by Eurostat are now well established, a number of issues still remain which may impact on the availability and value of the proposed indicator sets. Those particularly highlighted by Eurostat (2009b) include:

- arrangements for administrative indicator data gathering have to be established with ECHA;

- many indicators are currently informed by IUCLID 4 but in future Eurostat will seek to establish access to IUCLID 5;
- a formal agreement between Eurostat and the German Federal Ministry for the Environment has yet to be established to obtain output from the BfR database to inform the 'Toxic chemicals in households' indicator;
- identified data limitations and gaps have cast doubt on the suitability of the proposed indicator on occupational skin disease, so alternative approaches are to be sought;
- a formal agreement between Eurostat and the Nordic Council of Ministers, Chemicals Group has yet to be established to enable access to output from the SPIN database for the 'use patterns in Scandinavia' indicator;
- confirmation of intended frequency of publication of statistics on animal testing has to be sought from DG Environment;
- the absence of adequate baseline data for year 2007 on animal testing has to be addressed; and
- further work on indicators to inform on endocrine disrupting chemicals and persistent or bioaccumulative chemicals may be necessary.

3.5 Working Group of the Forum for Exchange of Information on Enforcement

3.5.1 Thematic Areas for Reporting

DG Environment is currently developing detailed specifications of the reporting requirements for Member States to meet the requirements of Article 117(1) of REACH. An electronic tool is also under development by the Commission that is to assist Member States with their submissions.

These development activities are being overseen by a Working Group of the Forum for Exchange of Information on Enforcement. Although the recommendations from the Working Group have not yet been finalised, and it will ultimately be for the Commission to determine the overall format of the Article 117(1) report, some insights as to the probable scope and nature of the reporting requirements have started to emerge. The following summary draws in particular on the outputs from the recent first meeting of the Competent Authorities for REACH and CLP (CARACAL) on the MS Reporting under REACH Project (ENV.D.1/SER/2008/0095r) and from the recent (January 2009) Final Report of the Forum for Exchange of Information on Enforcement for the Working Group 'Member States Report to the Commission'.

It is believed that information requirements will be structured around ten thematic areas. These are detailed below, together with brief summaries of the aspects that would fall within each.

Theme 1: Competent Authority. This theme focuses on basic information on the Member State and its Competent Authority (CA), such as the numbers and skill sets of the staff at the CA and other co-operating institutions, in order to establish that adequate resourcing has been made available.

Theme 2: Co-operation and communication with other Member States, the Agency and the Commission. The focus here is on capturing data on the level of contribution made by the CA to meetings and other appropriate fora about REACH and also details of any provisional, unilateral measures that the Member State may have introduced (in order to protect human health or the environment) during the period covered by the report.

Theme 3: Operation of the National Helpdesk and provision of communication to the public of information on risks of substances. The theme covers the operation of the National Helpdesk (e.g. numbers of staff working on the Helpdesk on a yearly basis, the number of enquiries received, extent of participation in REHCORN) and public awareness raising activities (e.g. number of awareness raising activities undertaken, usage data on websites and feedback received, etc.).

Theme 4: Promotion of the development, evaluation and use of alternative test methods. This theme seeks to gain an insight into the activities undertaken to raise awareness of alternative test methods, the extent of contributions made by the Member State to EU and OECD test method development activities (in terms of man-hours expended) and other contributions made that are of relevance to this subject.

Theme 5: Participation in ECHA Committees and Fora. This theme comprises the collection of data (mainly in terms of man hours or financial expenditure) on the level of Member Sate participation in various ECHA activities. The fora identified to date include the ECHA Forum and its Committees on Member States, Risk Assessment, Socio-economic Analysis and Co-operation.

Theme 6: Evaluation activities and draft decisions prepared. This theme address the number of institutions involved in evaluations and the amount of commenting and related activities that have been undertaken by the Member State. It is proposed that the information will be recorded in terms of numbers of dossiers and other document types handled and the amount of resources expended.

Theme 7: Annex XV Dossiers. Similarly to Theme 6, this will report on the resources (in terms of man-hours) spent on Annex XV production or in commenting on submissions by others.

Theme 8: Enforcement Activities. It is anticipated that Member States will be asked to provide the following details under this theme:

- ***General information:*** all the enforcement authorities in the Member State and their roles and responsibilities. There may also be an option to report on those with duties under REACH.

- ***Enforcement strategy:*** the overall strategy of the Member State for enforcement and clarification as to whether this reflects that arising from the Commission Forum. Where no strategy has yet been implemented, details of any plans to do so, and the state of their progress will be required.

- ***Co-ordination, co-operation and information exchange:*** details of the mechanisms established to ensure good co-operation and exchange of information across Enforcement Authorities and the Competent Authority within the Member State and evidence that these mechanisms are functioning adequately in practice.

- ***Enforcement activities:*** the sanctions available to Enforcement Authorities where contravention of REACH is detected, the types and numbers of inspections, investigations and formal enforcement actions undertaken, with scope and outcome of these actions (including numbers and types of legal action taken and if these lead to convictions). This will include reporting on the basis for undertaking each investigation and information on the duty holders (including role in supply chain and size of company) that were subject to such inspections or actions. Optional reporting of the methodologies and techniques used during the various inspections and investigations may also be possible.

There will also be a requirement to report any requests for enforcement arising from ECHA or other Member States and any other measures that were taken during the reporting period under Articles 125 or 126 of REACH.

Theme 9: Effectiveness of REACH on the protection of health and the environment, and the effects of REACH on Innovation and Competitiveness. This theme is to address two quite distinct aspects, firstly, the effectiveness of REACH in protecting human health and the environment and secondly the effects of REACH on business innovation and competitiveness.

For human health, the theme will be supported by information on the level of human and environmental protection that has been achieved and to report any evidence of a reduction in, or potentially accumulation of, chemical exposures.

Assessment of the impact of REACH on business is likely to include the ex post evaluation of the costs that have been incurred in producing registrations dossiers, and the extent to which this has impacted on the availability and costs of chemicals. The relative performance of the EU chemical industry compared to competitor regions is also to be considered, including the need for indicators

on the relative level of innovation (e.g. in terms of new products and chemicals).

Theme 10: Other Issues. Information on any general aspects that are not covered by the other themes will be collated. The scope and nature of reporting requirements under this theme have not yet been defined.

3.6 Anticipated Reporting Requirements for REACH

Based on consideration of the reporting requirements in the REACH Regulation and available outputs from Eurostat and the Working Group on the Member States Report to the Commission, it appears that the EC's criteria for judging the success of REACH primarily relate to administrative matters. An important aspect of this is to demonstrate adequate operation of the central European bodies (particularly the EC and ECHA).

At the Member State level, the focus of EC reporting requirements appears to be on the extent to which Competent Authorities (and other contributing departments and agencies) have met their obligations under REACH, and the degree of success they have had in assisting industry in understanding their obligations under REACH.

A further aspect will be for the Competent Authority to demonstrate the adequacy of its enforcement systems and to show proof of activities in this area. Since this responsibility will apply to the Competent Authorities across Member States, and there is expected to be a standard Commission report format, Member States may tend over time to adopt a common data gathering and reporting approach. However, differences in the organisation of responsibilities among governmental bodies across Member States exist and this may restrict the scope for implementation of a truly standardised data collection system.

Each of the various themes that have been adopted by the Forum for Exchange of Information on Enforcement could be considered analogous to the term "Objective" as used in this report:

- Themes 1 to 3 and 5 to 8 focus is on the process-driven aspects of REACH implementation, with the intention being to report the inputs and achievements by the Member State, in numeric terms wherever possible.

- Theme 4 will include quantification of effort, mainly in terms of resource expenditure rather than the achievements or progress made.

- Since the nature of requirements for Theme 10 have yet to be confirmed, no conclusions can yet be reached on its intended scope.

- For Theme 9, while reporting of some elements (e.g. numbers of new chemicals produced and costs associated with registration) will be addressed in terms of simple metrics, other aspects may involve more complex analysis and assessment reporting requirements.

Other issues – particularly relating to environment and human health (where historically approaches have shown marked differences between Member States) – are currently to be reported in a manner determined by each Member State. This is particularly the case for human health and environmental effects for which chemical exposure is only one factor of uncertain relative importance compared to other environmental or socioeconomic factors. For such issues, the focus of concern is likely to vary considerably between Member States or even at a regional level within a State.

3.7 Indicators Identified by Defra Relating to REACH

In the original Study Specifications, Defra identified a series of objectives and potential evaluation indicators relevant to REACH that it considers might meet not only the immediate needs for information to prepare quinquennial reports to the EC, but that might also address the UK Government's wish to understand the consequences of the introduction of REACH. The main objectives and indicators identified are shown in Table 3.4.

It was noted that these suggestions constituted Defra's initial thoughts as to potential indicators and sources of data. In many cases, the suggestions also implied potential sub-objectives (for example on maintaining competitiveness, implied sub-objectives include benefiting small businesses through reduced fees, effective operation of SIEFs, substitution of substances).

3.8 UK Regulatory Impact Assessment on CLP

The UK RIA on the CLP regulation identified a number of issues that may warrant consideration in the establishment of appropriate indicators to support future evaluation of the impact of CLP in the UK.

As detailed in Section 2.4, the UK RIA predicts that the implementation of CLP will result in costs to industry and consumers during and shortly after its phased implementation. The UK RIA also predicts benefits to industry over the longer term from the enhancement of the international trade in chemicals.

Table 3.4: Indicators relating to REACH Identified by Defra

- Protection of human health and environment, including:
  - identification of possible baselines for both public and occupational health impacts and indicators of improvements through REACH, e.g. usage of REACH-format Safety Data Sheets (SDSs); and
  - Identification of possible indicators of the environmental impact of REACH and appropriate baselines from which to measure them.
- Maintaining industry competitiveness and encouraging innovation, including;
  - What, why, how many substances withdrawn from market (i.e. not due to direct regulatory action; too hazardous (e.g. not adequately controlled); too expensive to register, etc.)
  - Has the reduced SME registration fee structure been of benefit to small businesses?
  - How have SIEFs operated in practice especially with respect to competition between members (e.g. recovered waste producers and primary manufacturers)?
  - Can conclusions be drawn on the effects of REACH on wider UK and EU recycling/waste recovery/sustainability agendas?
  - Evidence of substitution arising from REACH (e.g. from consumer pressure; changing supplier; increase in new substance registrations); and
  - Differences in impact on different social groups (different areas of the UK, industrial or business sectors, large companies versus SMEs, etc.).
- Increased transparency of information, including:
  - Use of REACH-format SDS; and
  - Levels of customer/consumer requests for information.
- Minimise animal testing including:
  - Home Office statistics on numbers of animals/tests;
  - ECHA statistics from registration test proposals; and
  - ECHA/Home Office data on promotion of non-animal alternatives.
- Identify the extent to which REACH costs and benefits set out in the original Impact Assessment can be evaluated (i.e. compare ex-ante and ex-post impacts).
- Awareness-raising/communication strategy with results measured by:
  - Numbers of pre-registrations (possibly available from ECHA via CA);
  - Numbers of enforcement actions (low if good awareness leading to pre-registrations); and
  - Defra-commissioned awareness telephone surveys.
- Operation of the CA including:
  - Participation in ECHA committees;
  - Evaluation of hazardous substances (from ECHA);
  - Annex XV dossiers prepared;
  - Comments on other MS' Annex XV dossiers;
  - Operation of Helpdesk – statistics, achievement of response targets; feedback from industry, etc.
  - Awareness-raising (CA-specific, but link with above awareness point);
  - Information to general public – Risk Communication Network, etc.; and
  - CA contacts with other MSCAs/ECHA/Cion, and levels of cooperation.
- Annual budgets for REACH implementation work, comprising:
  - CA budget; and
  - Defra budget.
- REACH enforcement (to be provided by Enforcement Forum reporting), including:
  - Explanation of arrangements;
  - Numbers and types of enforcement actions;
  - Possible impacts of enforcement, e.g. increased levels of compliance, such as registrations; and
  - UK participation in ECHA Enforcement Forum

Any major improvements to human and environmental health in third countries from the adoption of CLP may result in a more level trading environment for EU exporters. However, in addition to confounding effects from REACH and other chemicals legislation, international trade will also be influenced by changes in the economic climate. The impacts of CLP on the export and import of Dangerous Chemicals Regulation (EC) No 689/2008 may also impact on any enhancement of trade.

Public authority costs identified in the RIA were limited to the training of enforcement and emergency staff and familiarisation with the provisions of CLP relevant to them. However, the development, and oversight of CLP will require additional public authority resources, including UK contribution to the formulation, implementation, oversight and update of CLP in the EU and within the UK. For example, there will be costs associated with the establishment and running of the UK CLP Competent Authority, whether or not this is combined with that for REACH. There will also be the costs to establish and maintain the provisions relating to emergency actions as set out in Article 45 of CLP.

HSE is interested in exploring the feasibility of evaluating the predictions of the UK RIA in addition to any evaluation or reporting commitments set out in CLP.

3.9 Outcome of the Review on REACH and CLP Aims and Objectives

3.9.1 REACH Aims

Based on the review of the above data sources, the aims and main objectives of REACH to be carried forward are:

- ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals;
- promote alternative methods for assessment of hazards of substances;
- ensure the free circulation of substances on the internal market; while
- enhance competitiveness and innovation.

While these high level objectives should form the basis for reporting, many of the recitals[6] to REACH stress the importance of communication in the supply chain in order to achieve the effective implementation of each of the three aims stated in Article 1(1). Therefore, "***Increase the availability and transparency of information***" would appear to be a further implied aim for the evaluation of REACH.

[6] In particular see Recitals 17, 56, 57, 62 95, 97 and 119.

In order for the identified aims of REACH to be realised, its provisions need to be implemented in the UK. An additional aim has therefore been identified for the evaluation of REACH, namely to "***Ensure the efficient implementation of REACH requirements***".

It should be noted that there are some inconsistencies in the interpretation and communication of the aims of the REACH regulation between different documents. For instance, the REACH regulation has the stated aim to 'ensure a high level' of protection of human health and the environment. In contrast, an ECHA summary of the regulation on their website states that REACH aims to 'improve' protection of human health and the environment. Clearly, there could be a significant difference in the outcome of an assessment depending on whether one is assessing performance against 'ensuring a high level of' or 'improving' protection, especially given the current variable extent of knowledge about the nature of different types of chemicals and of the level of 'protection' that may or may not exist.

Similarly, the ECHA website does not address the aim of REACH of enhancing innovation. For these reasons, the potential relevance of particular objectives was assessed against the REACH regulation itself, as the definitive information source, and the additional suggestions of Defra as presented in the Study Scope.

The review process also highlights that the anticipated scope and nature of the Member State reporting requirements to the EC are minimal compared to the types of indicators suggested as relevant by Defra. This study has therefore adopted a scope that extends well beyond expected Member State reporting requirements to try and identify a range of possible options for future UK specific reporting. The implications of this for future options for the proposed Defra monitoring programme that is intended to support both, the Member State report to the Commission and the wider requirements of the UK government, are considered in Section 7.

3.9.2 CLP Aims

Like REACH, CLP has the express purpose to "***ensure a high level of protection of human health and the environment***". Recital 8 of CLP also expresses the intention to maintain the overall current level of protection of human health and the environment provided by Directive 67/548/EEC, as well as Directive 1999/45/EC. However, due to the relatively minor differences between CHIP and CLP, the UK RIA predicted that there would be no human or environmental health impacts from CLP. It is however noted that the introduction of CLP may result in substances and mixtures being reclassified with higher or lower classifications which may impact human and environmental health. Some, limited, evaluation of this aim may therefore be justified as part of the evaluation of the UK RIA.

The second expressed purpose of CLP is to "***ensure the free movement of chemicals (while enhancing competitiveness and innovation)"***. Due to the similarities between CHIP and CLP there are unlikely to be significant impacts on the free movement of chemicals within the EU. However, the UK RIA predicts benefits from the enhancement of international trade while noting that these may be impaired by the non-harmonised 'building block' approach to the world-wide adoption of GHS. It also predicts secondary benefits from the encouragement of innovation resulting from increased competiveness in the international market for chemicals.

In addition to the expressed purpose of the CLP, Recitals 40 and 42 make it clear that the labelling provisions are intended to be important tools for the communication of chemical hazards to both workers and consumers. This communication is seen as supplementing the provisions for safety data sheets set out in REACH and might indicate relevancies of the implied REACH aim to ***increase in the availability and transparency of information*** to the evaluation of CLP. However, given the similarities between CHIP and CLP, this is unlikely to have the same importance for the evaluation of CLP as it has for REACH. The submission of classification and labelling details to the classification and labelling inventory may, however, encourage a more harmonised and rigorous approach to the classification and labelling of substances.

It was intended that CLP should take account of ***promoting alternative methods*** for the assessment of hazards of substances and mixtures to generate information (Recital 27) and that it should reduce the need for repeat testing and evaluation of chemicals. However, such considerations are secondary to the expressed purposes of CLP.

In order for the identified aims of CLP to be realised, its provisions need to be implemented in the UK. An additional aim has therefore been identified for the evaluation of CLP, namely to "***ensure the efficient implementation of CLP requirements"***. This aim would include objectives needed to evaluate the cost predictions made by the UK RIA, however it would also include others such as, 'Encourage the efficient operation of the REACH and CLP process by UK Industry' which go beyond the scope of the UK RIA. The analysis clearly identifies any evaluation of CLP beyond the that needed to meet the reporting requirements set out in the regulation, or that needed for the an evaluation of UK RIA.

3.9.3 REACH and CLP Objectives

Table 3.5 sets out the aims and objectives to be carried forward for the evaluation of REACH and CLP in the UK.

Some of the objectives listed in the table apply wholly or mostly to REACH rather than CLP. However, only those of relevance to CLP are included in any option for the evaluation of that Regulation.

Table 3.5: The Aims and Objectives Carried Forward for the Evaluation of REACH and CLP	
Evaluation Aims	**Objectives**
Ensure a high level protection of human health and the environment from the risks that can be posed by chemicals	Reduce the negative health impacts arising from occupational exposure to chemicals
	Reduce the negative impacts on public health of exposure to chemicals
	Reduce the negative impacts on the environment arising from chemicals
Enhance competitiveness and innovation	Maintain the competitive position of the UK chemical sector
	Minimise adverse structural changes to UK industry
	Minimise adverse effects on the pattern of industrial activity in the UK
	Maximise the potential for innovation
Increase the availability and transparency of information on chemicals	Encouraging the dissemination and utilisation by stakeholders of information sources and advice relating to chemicals
	Ensuring the provision of high quality information and advice about chemicals
Promote alternative methods for assessment of hazards of substances	Promote the development of alternative (especially non-vertebrate) test methods
	Promote the use of alternative (especially non-vertebrate) test methods
	Minimise the usage of vertebrates in the testing of chemicals that fall within the scope of REACH or CLP
Ensure the efficient implementation of reach requirements	Support the efficient operation of the REACH and CLP processes by UK government and governmental organisations
	Ensure the adequacy of the UK government resource base to meet REACH and CLP obligations
	Encourage the efficient operation of the REACH and CLP process by UK Industry
	Encourage the provision of an adequate resource base by UK industry with which to meet REACH obligations

4. IDENTIFICATION OF POSSIBLE SUB-OBJECTIVES, INDICATORS AND DATA SOURCES

4.1 Overview

Sub-objectives, indicators and data sources that might be of potential value in evaluating the success of the primary aims and objectives of REACH and/or CLP were sought through a staged approach involving:

1) initial identification of sub-objectives;
2) identification of indicators and data sets; and
3) repeated iterations of these two activities.

Detailed comments were also received from the Steering Group on some of the indicators being proposed, on alternatives to these and on further indicators that could be considered or included in the list.

4.2 Initial Identification of Sub-Objectives

The initial step in establishing the identity of relevant sub-objectives was to review the REACH Regulation and the REACH Technical Guidance Documents to gain additional insights as to possible sub-objectives that might support the established aims and objectives of REACH (together with the other sources considered in the first task). A number of the pre-implementation REACH impact assessments were also consulted for these purposes (including work carried out for the European Commission (DG Enterprise and Environment) in the period spanning 2002 to 2006, by NGOs such as the European Trade Unions Congress, and for the UK both pre- and during Presidency (which was also the period for final negotiation of the Regulation[7]).

This step was then extended by a review of the CLP Regulation and the UK RIA to gain insights as to the possible sub-objectives that might support the evaluation of CLP. This included the re-evaluation of sub-objectives identified for their relevance to REACH, as well as the identification of additional sub-objectives where required.

From these reviews, an initial draft list of sub-objectives was developed. This was then supplemented through searches which drew wherever possible on readily available sources (such as Internet sites) and through in-house searches

[7] Note that not all of the assessment work carried out during the Presidency period would have been published as it was aimed at informing Defra on a day-to-day basis on the implications of proposals for amendment of the then draft Regulation and whether these should be promoted or discouraged. For example, work was undertaken to understand different permutations in the requirements for substances of very high concern.

(due to the extent of the impact assessment work carried out pre-Regulation, RPA holds an extensive range of studies, position papers, and other documents related to both REACH and CLP). The searches covered as wide a range as possible of potential sources of information. These included but were not restricted to:

- Government departments, agencies and committees, such as:
  - BIS; Defra, Department of Health (DH), Environment Agency, Health and Safety Executive (HSE); Health Protection Agency; Home Office; NIEA SEPA; and
  - Chemical Stakeholder Forum, Joint Nature Conservation Committee.
- Industry associations and trade unions, such as:
  - Chemical Industries Association; and
  - European Trade Union's Congress.
- NGOs, such as
  - Chemtrust; and
  - RSPCA.
- Authoritative statistical data sources, such as:
  - Eurostat; and
  - UK National Statistics.

While not intended to be exhaustive or to identify all possible indicators or monitoring activities that are currently being considered (or are underway), the intention was to establish an initial 'general picture' of the nature, types and extent of monitoring and other relevant activities that have been or are being carried out.

Additional insights were subsequently gained by undertaking targeted searches based on information available from the above and earlier sources. This was supplemented by additional searches to follow-up suggestions arising during the consultation process (see Section 4.4).

In addition, the list of sub-objectives was reviewed at intervals during the search process to establish any gaps that might exist either in the list of main objectives or in the sub-indicators already identified. For example, one of the underlying philosophies of REACH is the precautionary principal, whereby action should be taken to minimise the potential impacts of a chemical's use even though hazardous effects have not yet been proven (e.g. vPvB substances). It was therefore recognised as essential to consider not only issues and particular substances for which there is already concern and for which monitoring is already being carried out, but also to include an element of 'blue sky' thinking on how other insights into the wider impacts of REACH might be assessed. Regular consultation with the Steering Group ensured that the relevance to the needs of the UK-government of the various potential sub-objectives could be established with a high degree of confidence.

4.3 Identification of Indicators and Data Sets

4.3.1 Introduction

Once a consolidated list of sub-objectives had been developed and discussed with the Steering Group, the various information sources were reviewed to establish possible indicators that might inform on the sub-objectives and to determine the current and likely future availability of data sets that could serve to support such indicators. During this review, particular attention was given to establishing for each data set:

- the nature, quality and source of the data set;
- the extent to which the continued availability of the data set was assured;
- whether suitable baseline information is currently available or if this would need to be established;
- the extent to which the data set might be subject to confounding by factors other than those related to REACH or CLP; and
- the frequency of recording of the data.

The list generated through this process was further supplemented through application of the expert knowledge and personal contacts of the project team and from suggestions and ideas arising during the course of the consultations.

In line with the guidance received from the Steering Group, only limited consideration was given to delineating the essentially administrative information on processes involved in REACH or CLP implementation (e.g. number of staff employed by Competent Authority, budgets and time spent on REACH/CLP-related tasks). Nonetheless, some of these 'process' focused aspects were included where it was considered that they might potentially aid in the evaluation of the wider impacts of REACH or CLP and the extent to which each fulfils its aims. Such sub-objectives and indicators are generally reported under the aim of "Efficient implementation of REACH or CLP requirements".

Finally, a gap analysis was carried out to ensure that each aim and objective had available a range of potential sub-objectives and indicators, and that possible supporting data sources had been identified for each. Where gaps were identified, more targeted searches or consultation were undertaken in order to attempt to identify suitable indicators and/or data sources.

Details of the comprehensive list of sub-objectives, indicators and data sets are presented in Section 4.5.

A highly iterative approach was adopted during the information gathering phases of this study, including consultation with key stakeholders. In some cases, the scope and focus of the sub-objectives and indicators were modified, although none were discarded; i.e. all identified sub-objectives and indicators were considered during the assessment phase (see Section 5).

All information sources consulted during the various searches are presented in the References section.

4.3.2 Identification of Stakeholders of Relevance to REACH and CLP

An important issue for the evaluation of both REACH and CLP is the clear and consistent identification of different types of industry stakeholder. One possibility is to use the SIC codes used by the UK Office of National Statistics (ONS). The latest 2007 SIC codes exactly match the internationally used NACE codes and the 2007 PRODCOM categories match NACE classification to the first four digits (but have a lower level fifth digit unique to the UK).

Unfortunately, SIC (or NACE) codes were not designed with REACH or CLP in mind and they are therefore not an exact match for the different industry types of interest to an evaluation of REACH or CLP. However, it is possible to use an understanding of the sectors concerned to determine the type of industry most approximated by different SIC codes or PRODCOM categories. This issue is also addressed in the UK RIA, which details the approximations made to match SIC codes with relevant CLP stakeholder industry sectors.

A major revision of both SIC and PRODCOM codes to match updated NACE codes became effective on 1 January 2007 but the UK RIA of CLP and other baseline data relate to the 2003 (or earlier) SIC codes. The industry definitions used for the 2003 SIC codes and PRODCOM categories do not match those used for the 2007 codes and categories in every respect but an almost exact comparison between the two is possible to construct with care.

Table 4.1 sets out 2003 and 2007 SIC codes alongside respective industry types of relevance to the evaluation of REACH or CLP.

Table 4.1: SIC Codes of Relevance to REACH or CLP

2007 SIC Codes and Descriptions	**Nearest 2003 SIC Codes**	**Industry Type of Relevance to:**	
		REACH	**UK RIA of CLP**
A01 – Crop and animal production, hunting and related service activities	A01	DU (M/I)	Downstream businesses
C13 – Manufacture of Textiles			
C13.1 – Preparation and spinning of textile fibres	DB17.1	DU	Downstream businesses
C13.2 – Weaving of textiles	DB17.2	DU	
C13.3 – Finishing of textiles	DB17.3	DU	
C13.9 – Other textiles	DB17.52 to 17.54	DU	
C17.1 – Manufacture of pulp, paper and paperboard	DE21.1	DU	
C19 - Manufacture of coke and refined petroleum products			
C19.1 - Manufacture of coke oven products	DF23.1	M/I	Not included
C19.1.0 - Manufacture of coke oven products	DF23.10	M/I	Not included
C20 - Manufacture of chemicals and chemical products			
C20.1 - Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	DG24.1	M/I (DU)	Chemical Manufacturers

Table 4.1: SIC Codes of Relevance to REACH or CLP			
2007 SIC Codes and Descriptions	**Nearest 2003 SIC Codes**	**Industry Type of Relevance to:**	
		REACH	**UK RIA of CLP**
C20.1.1 - Manufacture of industrial gases	DG24.11	M/I	
C20.1.2 - Manufacture of dyes and pigments	DG24.12	M/I (DU)	
C20.1.3 - Manufacture of other inorganic basic chemicals	DG24.13	M/I	
C20.1.4 - Manufacture of other organic basic chemicals	DG24.14	M/I	
C20.1.5 - Manufacture of fertilisers and nitrogen compounds	DG24.15	M/I (DU)	
C20.1.6 - Manufacture of plastics in primary forms	DG24.16	DU	
C20.1.7 - Manufacture of synthetic rubber in primary forms	DG24.17	DU	
C20.2 - Manufacture of pesticides and other agrochemical products	DG24.2	Exempt from REACH	
C20.2.0 - Manufacture of pesticides and other agrochemical products	DG 24.20	Exempt from REACH	
C20.3 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	DG24.3	DU	
C20.3.0 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	DG24.30	DU	
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	DG24.4	Excempt from REACH and CLP	
C20.4 - Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	DG24.5	DU (Exempt from REACH)	
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	DG24.51	DU (Exempt from REACH)	
C20.42 - Manufacture of perfumes and toilet preparations	DG24.52	DU (Exempt from REACH)	
C20.5 - Manufacture of other chemical products	DG24.6	M/I (DU)	
C20.5.1 - Manufacture of explosives	DG24.61	M/I (DU)	
C20.5.2 - Manufacture of glues	DG24.62	DU	
C20.5.3 - Manufacture of essential oils	DG24.63	M/I (DU)	
C20.5.9 - Manufacture of other chemical products n.e.c.	DG24.64 to DG24.66	DU (M/I)	
C20.6 - Manufacture of man-made fibres	DG24.7	DU	
C20.6.0 - Manufacture of man-made fibres	DG24.70	DU	
C22 - Manufacture of rubber and plastic products			
C22.1 - Manufacture of rubber products	DH25.1	DU (M/I)	Downstream businesses
C22.1.1 - Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	DH25.11 & DH25.12	DU (M/I)	
C22.1.9 - Manufacture of other rubber products	DH25.13	DU (M/I)	
C22.2 - Manufacture of plastics products	DH25.2	DU	
C22.2.1 - Manufacture of plastic plates, sheets, tubes and profiles	DH25.21	DU	
C22.2.2 - Manufacture of plastic packing goods	DH25.22	DU	
C22.2.3 - Manufacture of builders' ware of plastic	DH25.23	DU	
C22.2.9 - Manufacture of other plastic products	DH25.24	DU	
C23 - Manufacture of other non-metallic mineral products			
C23.1 – Manufacture of glass and glass products	DI26.1	DU (M/I)	Downstream

Table 4.1: SIC Codes of Relevance to REACH or CLP			
2007 SIC Codes and Descriptions	**Nearest 2003 SIC Codes**	**Industry Type of Relevance to:**	
		REACH	**UK RIA of CLP**
			businesses
C24 – Manufacture of basic metals	DJ27	DU (M/I)	Not included
C25 – Manufacture of fabricated metal products, except machinery and equipment	DJ28	DU	Not included
C25.4 – Manufacture of weapons and ammunition	DK29.6	Exempt from REACH	Downstream businesses
C26 - Manufacture of computer, electronic and optical products	DL30, DL33	DU	Not included
C27- Manufacture of electrical equipment	DL31, DL32 & DL33	DU	
C28 - Manufacture of machinery and equipment n.e.c.	DL31, DL32 & DL33	DU	
C29- Manufacture of motor vehicles, trailers and semi-trailers	DM34	DU	
C30 - Manufacture of other transport equipment			
C31 - Manufacture of furniture	DN36.1	DU	Downstream businesses
C32 - Other manufacturing	DN36 (not DN36.1)	DU	
E38.3 - Materials recovery	DN37	DU	
E38.31 - Dismantling of wrecks	DN37.1	DU	
E38.32 - Recovery of sorted materials	DN37.2	DU	
G46.75 - Wholesale of chemical products	G51.55	Dis (M/I)	Wholesalers of chemicals
G46.77 - Wholesale of waste and scrap	G51.57	M/I (Dis)	Not included
G47.1 - Retail trade, except of motor vehicles and motorcycles			
G47.11 - Retail sale in non-specialised stores with food, beverages or tobacco predominating	G52.11	Dis (M/I)	Retailers
G47.19 - Other retail sale in non-specialised stores	G52.12	Dis (M/I)	
G47.52 - Retail sale of hardware, paints and glass in specialised stores	G52.46	Dis (M/I)	
* Key to types of REACH actor: M/I: Manufacturers and/or importers. DU: Downstream users. Dis: Distributors. (): Less prominent type of stakeholder and potential confounding factor.			

The impacts of REACH or CLP are likely to be felt to different extents by companies of different sizes, even where such companies fall within the same SIC code. Therefore, an evaluation of REACH and CLP must also attempt to differentiate impacts to companies of different sizes, as defined by Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC).

In addition, it is understood that the possibility of differentiating industry data by UK regions might be of value to the evaluation of REACH but not to CLP. It is therefore recommended that any surveys or case studies include companies distributed across the UK wherever possible. However, it is possible that not all industry associations will be able to differentiate the data

that they collect or supply by region. Furthermore, it is likely that data provided from one address (i.e. a head office) may represent the position of many separate sites.

4.4 Consultation

During the early development of ideas on suitable sub-objectives that might support the main aims and objectives of the evaluation, representatives of a limited number of government departments and agencies were contacted and asked to provide initial comments and observations.

Subsequently, after consultation with the Steering Group, the scope of the consultation exercise was extended to include additional government departments and agencies (including the devolved administrations), some non-governmental public bodies, a number of non-governmental public interest organisations (NGOs addressing areas of particular relevance), Trade Unions, and several major UK industrial associations. Limited consultation of academics was also included. The organisations consulted are listed in Annex 1.

An initial email outlining the objectives and scope of the study, the focus of the consultation and, where appropriate, a summary of the main objectives, sub-objectives, indicators and data sources identified to date was sent to the identified representative of each organisation. In some cases, the original recipient considered that they were not the most appropriate person to address the issues raised. In these cases, a cascade approach was used to identify and contact a more appropriate alternative. In a very limited number of cases, a suitable person was not identified or was unavailable during the time window for consultation.

The initial email contact was followed by a teleconference in which the study's aims and approach were described. The representative was then asked for their opinions on the relevance of objectives, sub-objectives and indicators and the nature and availability of data sources. Where appropriate, discussion also sought to establish the robustness of available data, its frequency of collection and the suitability of data for use as a baseline. Views on possible confounding factors and the extent to which allowance could be made for them during data analysis were also discussed. Opportunity was provided for representatives to suggest alternative approaches and/or data sources. Information on the costs of data collection was also sought, although feedback on this was generally limited and qualitative in nature.

Following the interview, short notes detailing the issues discussed were sent to the representative for their comment and approval.

Where considered appropriate, suggestions as to additional indicators and/or data sources were included within the comprehensive lists and relevant

opinions incorporated into discussions set out in subsequent sections of this report. Due to concerns regarding confidentiality, detailed transcripts of the consultation discussions are not presented in this report. However, brief summaries of key findings are presented below, on a sectoral basis.

A number of non-UK organisations was identified that might also provide valuable information and, although not consulted for this study, it may be useful to discuss particular issues with such organisations at a later stage

4.4.1 UK Government Departments and Agencies

There was general support for the proposed evaluation of REACH and CLP implementation by Defra across the various Departments and Agencies, although some concern was expressed that the burden on resources should not be onerous, particularly given existing Better Regulation targets. Thus, in several areas it was suggested that proposals should include careful consideration of cost and benefits, and that there might be a need to agree budget allocations between departments. The Devolved Administrations were in favour of this exercise but were content to see it progressed by central government. Support also came from the various government expert committees consulted.

Particular concerns were expressed as to the extent to which the impacts of REACH or CLP could be distinguished from those of other legislation and the wider socioeconomic and environmental factors. This was most apparent with regard to the evaluation of the human and environmental health impacts of REACH. Here there was general agreement that, while the identified data sets probably were the best available, they would be subject to significant confounding factors and, particularly in relation to human health, the issue of disease latency would be difficult to address. Therefore, a focus on alternative approaches was suggested, such as evidence of withdrawal of chemicals because of safety concerns or other types of response by industry that would indicate a reduction of exposures to potentially harmful chemicals. It was also suggested that great care would be needed to distinguish the economic impacts of REACH or CLP from the cumulative impact of regulation (i.e. again confounding factors were seen as a problem). Thus, it was suggested that the focus should be on those aspects of REACH or CLP that had only limited interaction with other factors, and that an approach which focused on the key sectors likely to be particularly affected by REACH or CLP be adopted.

Some of these concerns, particularly regarding the confounding effect of overlapping legislation, may be somewhat reduced by adoption of a single evaluation system for REACH and CLP (although other confounding factors will remain). Consideration of CLP also highlighted that issues regarding the assignment of roles for certain aspects of its implementation are outstanding.

4.4.2 Independent Government-supported Bodies

Various bodies were consulted but, while generally being supportive of the initiative, the extent to which they could assist was limited. The Government Chemist indicated that it does not currently hold data of relevance but intends to mount future case-study investigations on REACH implementation. However, these may be in quite specialised areas and it was noted that the Government Chemist would need to ensure that it maintains its impartiality. In contrast, the Office of National Statistics has indicated that it would be able to provide a data set specific to the needs of this study, at limited cost.

4.4.3 Industry Associations

The majority of the industry associations consulted expressed an interest in and willingness to co-operate with this exercise. There was, however, a general concern regarding confidentiality/data protection issues, which would mean that some surveys may need to be organised through and feedback reported by the relevant associations. It was suggested that there was still a lack of awareness by some sectors (e.g. small businesses) of the potential impacts of REACH and CLP and that this may lead to serious problems as substances are registered (and eSDS produced) or withdrawn from the market. Some industry sectors were so focused on the requirements of REACH that associations felt that their members would have little interest in providing information on CLP at the current time. It was anticipated that this would change as the demands of CLP began to be felt, but that CLP data may be obtained beforehand if combined with requests for data on REACH.

In contrast some, but not all, representatives of the waste recovery and non-ferrous metals sectors stated that their membership did not, at this time, regard REACH and CLP as a issues of concern and were unlikely to be interested in co-operating. Other highly specialised sectors – while willing to co-operate – noted that their membership was perhaps more concerned about other incoming legislation (such as the Cosmetics Regulations and Aerosols Dispenser Directive) than REACH or CLP.

Although most sectors were more concerned with the impacts of REACH than CLP, concerns were expressed about the more stringent thresholds at which various classifications would be applied and with regard to difficulties implicit in toxicity data interpretation due to the need to undertake route-to route extrapolations in relation to aerosol products. Concerns were also expressed as to the extent to which industry would be able to provide robust comprehensive estimates of the costs incurred in meeting the demands of REACH or CLP, since there were felt to be significant 'invisible' costs that might be difficult to capture.

4.4.4 Environmental and Animal Rights Organisations

The NGOs consulted were generally supportive of the need for an evaluation exercise. Furthermore, they were realistic as to the extent to which it would be practical to show direct evidence of changes in human health, environmental status or in animal testing practices as a result of REACH, particularly in the short- and mid-term. However there was an expectation that other indicators of REACH (and, by inference, of CLP) impacts might be more valuable, such as evidence of withdrawal of potentially hazardous chemicals from, for example, consumer products in the UK. Such expectations echo advice provided by relevant government departments and agencies.

Interest was expressed in the extent of UK industry and government use of, and support for the development of, alternatives to animal tests. Respondents noted that the UK government has been a leader in Europe on the development/use of alternative testing and expressed hope that this position will be maintained in the future. Others commented that, at this time, their focus on animal rights had changed from REACH to seeking to influence the course of the European testing directive. A number of NGOs noted that, while they do not monitor specific costs related to REACH, they would be willing to provide estimates and wider feedback with regard to the effects of REACH or CLP. Unfortunately, because of resource limitations, CHEMTrust was unable to contribute at this time.

4.4.5 Academic Institutions

The academic institutions consulted did not have data of direct relevance to the evaluation of REACH or CLP. However, they were willing to provide, or facilitate the provision of, expert comment. In some cases a limited administrative cost may be charged.

4.4.6 Trade Unions

Trade Union contacts were, in most cases, willing to provide qualitative data and comment regarding the impacts of REACH or CLP, although it was generally felt that this should be sought via the TUC rather than from individual unions.

4.5 Summary of Objectives and Sub-Objectives

The objectives and sub-objectives identified for each of the main aims for the evaluation of REACH or CLP are summarised in Table 4.2. For each of the identified objectives and sub-objectives, a number of potential indicators have been developed. These and possible supporting data sources are detailed and discussed in the sections that follow.

Table 4.2: The Objectives and Sub-Objectives Considered to Support the Aims of the Evaluation REACH and CLP	
Objective	**Sub-objective**
Ensure a High Level Protection of Human Health and the Environment from the Risks that can be Posed by Chemicals	
Reduce the negative health impacts arising from occupational exposure to chemicals	Reduce the incidence of chemical-related occupational dermatitis and other skin diseases. Reduce the incidence of chemical-related occupational respiratory disease. Reduce the incidence of chemical-related occupational cancers. Reduce the incidence of chemical-related industrial injuries. Reduce or eliminate exposure to chemicals of concern in the workplace
Reduce the negative impacts on public health of exposure to chemicals	Reduce the incidence of chemical-related conditions in the general public. Reduce the level of public exposure to chemicals of concern. Promote withdrawal of substances of concern from the market. Increase substitution of substances by less hazardous alternatives. Implement national emergency action under Article 129 to ensure rapid safeguarding of human health in UK
Reduce the negative impacts on the environment arising from chemicals	Increase population levels of species susceptible to chemical pollution. Reduce the extent of chemical-induced effects in wildlife species. Reduce the level of chemicals of concern present in abiotic environmental media. Reduce the level of chemicals of concern present in wildlife. Implement national emergency action under Article 129 to ensure rapid safeguarding of the environment in UK
Maintain the assessment of hazards to human and environmental health	Maintain the current high standard of hazard classification
Enhance Competitiveness and Innovation	
Maintain the competitive position of the UK chemical sector	Maintain the competitive position of UK substance producers and downstream users. Maximise the ease of export of chemicals from the UK Maximise the ease of import of chemicals into the UK
Minimise adverse structural changes to UK industry	Minimise adverse structural changes to the UK chemicals sector. Minimise adverse structural changes to the UK downstream user sector. Minimise adverse structural changes to the UK chemicals trading sector. Minimise adverse structural changes to the UK recycling sector
Minimise adverse effects on the pattern of industrial activity in the UK	Avoid damaging increases in input prices. Maintain competition in the supply of chemicals. Minimise costs associated with loss of substances. Minimise withdrawal of substances for non risk-related reasons

Table 4.2: The Objectives and Sub-Objectives Considered to Support the Aims of the Evaluation REACH and CLP	
Maximise the potential for innovation	Maximise innovation by UK substance producers. Maximise innovation by UK downstream users
Increase the Availability and Transparency of Information on Chemicals	
Encourage the dissemination and utilisation by stakeholders of information sources and advice relating to chemicals	Encourage the dissemination of information by the UK CA. Encourage the dissemination of information by industry. Encourage the dissemination of information from all sources
Ensure the provision of high quality information and advice about chemicals	Ensure the availability of high quality information from the UK CA. Encourage the availability of high quality information from industry. Encourage the availability of high quality information to consumers
Promote Alternative Methods for Assessment of Hazards of Substances	
Promote the development of alternative (especially non-vertebrate) test methods	Promote the development, evaluation and validation of alternative methods for chemical testing
Promote the use of alternative (especially non-vertebrate) test methods	Promote the replacement of existing vertebrate test methods. Encourage the use of non-animal approaches in REACH and CLP risk assessments
Minimise the usage of vertebrates in the testing of chemicals that fall within the scope of REACH and CLP	Promote minimisation of use of vertebrates in the testing of chemicals for REACH and CLP
Ensure the Efficient Implementation of REACH Mechanisms	
Support the efficient operation of the REACH and CLP process by UK government and governmental organisations	Efficient participation in REACH implementation process by UK government
Ensure the adequacy of the UK government to meet REACH and CLP obligations	Ensure adequate resourcing by UK government
Encourage the efficient operation of the REACH and CLP process by UK Industry	Encourage participation of UK industry in REACH and CLP processes. Minimise the regulatory burden and maximise benefits. Minimise adverse impact on competitiveness. Establish economic benefits from improvements to human and environmental health. Minimise adverse impacts on recycling and waste recovery

Table 4.2: The Objectives and Sub-Objectives Considered to Support the Aims of the Evaluation REACH and CLP	
Encourage the provision of an adequate resource base by UK industry with which to meet REACH and CLP obligations	Encourage provision of an adequate scientific and technical resource base for UK industry to meet REACH and CLP Obligations

5. SCREENING AND PRIORITISATION OF INDICATORS

5.1 Overview of the Approach

A list of possible indicators was developed with the potential to inform each of the sub-objectives set out in Section 4. All indicators were developed for their potential relevance to the evaluation of REACH and for their potential relevance to CLP (except for environment). Therefore, when data are gathered, it will be necessary to differentiate between data relating to REACH and those relating to CLP.

Once the long list of possible indicators was developed, some means of screening these and prioritising those for future consideration was required. To aid this process, a simple scoring and weighting system was developed to allow the different indicators to be compared against one another in a consistent and transparent manner.

This involved the following stages[8]:

1. criteria were defined against which all of the indicators were to be assessed;
2. the indicators were then scored, using a Likert scale of 1 to 5[9], against each criterion;
3. weights were assigned to each of the criteria to reflect a subjective judgement on their importance to the end priority that should be given to each in developing an evaluation and monitoring framework for the UK;
4. weighted scores were derived for each indicator;
5. sensitivity analysis was undertaken, in particular on the weights assigned to the different criteria; and
6. the results were converted to a set of reporting priorities for each of the main objectives.

The professional judgement of the study team was applied to both the scoring and weighting exercise and to the subsequent prioritisation of indicators for the evaluation of REACH or CLP.

Each indicator was assigned to one of four options for frameworks for the evaluation of REACH and CLP. This is described in greater detail in Section 7, but the four options are:

- **Option 1**: Indicators representing the minimum needed to meet the evaluation requirements of REACH or CLP respectively;

[8] See also **Multi-criteria analysis: a manual**, dated January 2009, published by Department for Communities and Local Government, Eland House, Bressenden Place, London.

[9] Except for one criterion for which a scale of 0 – 5 was used, as described in Section 5.2.

- **Option 2**: Indicators that offer valuable data for the evaluation of REACH or CLP respectively, at a low to moderate cost (except indicators needed for Option 1);
- **Option 3**: Indicators that offer useful data for the evaluation of REACH or CLP respectively, at a moderate to high cost (except indicators needed for Option 1); and
- **Option 4**: All indicators that do not meet the requirements of the other options but have the potential to provide data of some use to the evaluation of REACH or CLP. Also included are indicators which were not needed for Option 1 (i.e. not a reporting requirement), and that would have been considered for other options but would require very expensive data gathering.

5.2 Results of the Scoring and Weighting Exercise

Four criteria were chosen against which to score each indicator, namely:

1. **Specificity**: how closely does the indicator match to the sub-objective at the UK level?

2. **Quality of Information**: is the data robust based upon its source and the extent of quality control that is apparent within data sets?

3. **Confounding Factors**: how extensive and significant are the confounding factors, and to what extent can these be addressed?

4. **Cost**: how easy will it be to collect the data and what will be the extent of additional analysis required?

The professional judgement of the study team was used to assign a score between 1 and 5 to each indicator against the four criteria. Each indicator was scored separately for the evaluation of REACH or CLP. However, it was found that although the factors underlying the criteria 'Quality of information', 'Confounding factors' and 'Cost' did differ slightly with regard to the evaluation of REACH or CLP, such differences were not sufficient for the scores to differ significantly for any indicator. The scores produced for 'Specificity' were found to be significantly different for REACH and CLP and these were used as a guide to the relative importance of each indicator to the two separate evaluation processes. In addition, to allow for indicators that had no relevance to either REACH or CLP, a score of zero was introduced for 'Specificity'.

The definitions used in assigning the scores are summarised in Table 5.1 provided on the next page.

Summaries of the reasoning behind the assigned scores were recorded for each indicator (other than where a score of one or five was assigned, where the

rational was considered self-evident from the definition) and used to inform the further analysis of each indicator.

In addition to the scoring, four different systems of weights were applied to each criterion to assess the importance of each indicator for the evaluation of REACH or CLP:

- with equal weight for each criterion but regardless of cost – **System A**;
- with equal weight for each criterion including cost – **System B**;
- with priority given to 'Specificity' and 'Quality of information' – **System C**; and
- with priority given to 'Cost' and 'Confounding' – **System D.**

The weights applied to each criterion under systems A to D are set out in Table 5.2 below.

Table 5.1: The Definitions Used in Assigning Scores to each Criterion			
Specificity: how closely does the indicator match to the sub-objective at UK level?	**Quality of information:** is the data source robust?	**Confounding factors:** how significant are the confounding factors and how easily can these be addressed?	**Cost:** how easy will it be to collect the data and extent of additional analysis required?
0. **Irrelevant**: of no relevance to the evaluation of REACH or of CLP, as appropriate			
1. **Questionable**: tenuous fit with the sub-objective and will inform on a non-UK level only	1. **Unreliable**: no apparent quality control in place	1. **Very high confounding**: many confounding factors that it will be difficult to address	1. **Very high**: requires collection of new data through extensive monitoring/analysis (possibly development of new methodologies) or extensive surveys specifically to gather data
2. **Limited**: limited fit with sub-objective and may inform only on a non-UK level	2. **Borderline**: collecting organisation has some quality control measures in place, but no cross-checking is possible	2. **Some confounding**: some confounding factors with limited potential for correction	2. **High**: requires collection of new data through additional monitoring/analysis using existing methodologies, or surveys in co-operation with other organisations
3. **Moderate**: reasonable fit with sub-objective but may inform only on a non-UK level	3. **Reasonable**: some independent cross-checking of information is possible	3. **Moderate confounding**: some confounding factors but with some potential for correction	3. **Medium**: requires collection of new data (monitoring or surveys) but this will be undertaken at little or no cost to Defra, or may involve addition of some questions to existing questionnaire survey
4. **Good fit**: reasonable fit with sub-objective and relates to UK relevant data,	4. **High**: information collected by authoritative source, but quality control unspecified	4. **Little confounding:** some confounding factors but they can be largely corrected	4. **Moderate**: data already collected, but significant additional analysis required
5. **Specific**: excellent fit for the sub-objective and relates to UK specific data	5. **Robust**: information collection by authoritative source and is subject to recognised quality control	5. **No confounding:** no confounding factors	5. **Very low**: already collected on ongoing basis in a usable format, from a reliable source, with no data protection issues. May need some reformatting or limited additional analysis.

Table 5.2 The Weights Applied under Systems A to D				
Criterion	**Weighting**			
	System A	**System B**	**System C**	**System D**
Specificity	1	1	60	10
Quality of Information	1	1	60	10
Confound Factors	1	1	10	40
Cost	0	1	10	100

To allow comparison of the results from each of these four systems, the results were normalised by presenting them as the percentage of the maximum available points obtained under each system, so that obtaining 15/20 points under System A is equivalent to obtaining 600/800 points under System D.

Viewing the results of the different weightings together allows some sensitivity analysis to be carried out, for instance to determine how changing the emphasis placed on different criteria affected the relative importance of the indicators. The different sets of scores produced under the different scoring systems were then used to inform (but not dictate) the subsequent prioritisation of indicators for the evaluation of REACH and for the evaluation of CLP (provided in Section 6).

Sections 5.3 – 5.9 set out the potential indicators for each objective and sub-objective, the possible confounding factors and the results of the assessment of the suitability of each indicator with respect to the evaluation of REACH or CLP.

For brevity, the scores given to each indicator for each criterion, as well as the total scores under each of the four scoring systems, have not been reproduced here, but are included in tables given in Annex 3 and 4. The main findings of the scoring and weighting exercise are summarised below, however.

The results are presented in tables, and the final column of these sets out which option each indicator might be expected to be assigned to, based on a combination of legal requirements, results of the scoring and weighting and application of expert judgement. Additional detail about potential sources of data and the nature of available baselines can be found in Annex 2.

5.3 Objective: Reduce the Negative Health Impacts Arising from Occupational Exposure to Chemicals

5.3.1 Indicators

HSE, in association with other government bodies, has for many years supported an extensive array of monitoring programs designed to quantify the UK's occupational health burden. This covers both occupational diseases with short latency (e.g. dermatitis and asthma) and others with latency periods measured in decades (e.g. chronic obstructive pulmonary disease (COPD) and cancer). Other identified government-supported datasets provide information on the level and severity of injury suffered by UK workers and the relationship of such injuries to the use of chemicals.

While many of the chemicals responsible for some 'classical' occupational-diseases are known (e.g. asbestos) and are already the subject of separate control measures outside of either REACH or CLP, there remains a significant UK occupational disease burden that has yet to be attributed to particular chemicals or other agents. Indicators and data collection systems have therefore been identified that could potentially inform on the impact of the introduction of controls on previously unrecognised chemical hazards, which may be identified as a result of REACH or to a somewhat lesser extent by CLP. Furthermore, these indicators and the supporting datasets are the same or similar to many of those used in the pre-implementation REACH impact assessments, such as those for the Commission or other bodies (e.g. Pickvance *et al*., 2005; RPA, 2002). Inclusion of such indicators might therefore allow an ex post evaluation of the impact of REACH.

Other indicators, suggested by the HSE, which could indirectly inform on workers' exposure to chemicals associated with the common occupational diseases of dermatitis or occupational asthma, comprise:

- changes in the levels (or strength) of prescriptions for those diagnosed with occupational dermatitis or asthma during the period immediately following implementation or REACH (and CLP), since a change in these indicators could be inferred to indicate that worker exposure to the causative chemicals had been influenced by REACH (or CLP); and

- changes in expenditure by industry on protective gloves (both numbers and types purchased) or on local or general ventilation equipment may inform on the level of concern about the potential dermal or respiratory effects of chemicals and thus indicate positive action by industry to increase worker safety as a result of increasing information availability through REACH.

Other indirect indicators that would imply increased worker safety could include the withdrawal or substitution of hazardous chemicals by industry (either as a result of regulatory action or voluntarily). However, because of their wider potential significance, these have been included in the

consideration of possible indicators of public health, rather than specifically within an occupational context.

Two further indicators specific to CLP have been identified that inform on the changing classification profile of chemicals in the workplace. Such changes may arise as a result of the review of available data for substances or mixtures because of the implementation of the CLP regulations.

5.3.2 Confounding Factors

Although the occupational diseases and their data sources recorded in Table 5.3 are probably the best available indicators of occupational health available in the UK, any fluctuations in incidence patterns would be extremely difficult to ascribe specifically to either REACH or CLP, because of the high level of potential confounding that exists. A further problem with the disease indicators (except for dermatitis and asthma) is that any effect of REACH or CLP is very unlikely to be detectable within a reasonable timeframe because of the prolonged latency periods for these conditions.

In the case of occupational asthma and skin disease, particularly dermatitis, use of incidence figures for these diseases as an indicator for the combined effect of CLP and REACH would have some attraction, since jointly considering the impact of these two closely related regulations would somewhat reduce the extent of confounding. However, the remaining confounding factors are still considered to be extensive (indeed many of the recognised causative agents for these indicators are of a biological rather than chemical nature) casting doubt on their value for the purposes of this study. The extent of difficulties surrounding the use of incidence data is exemplified by the recent withdrawal of occupational skin disease from consideration as an indicator from the Eurostat REACH baseline study (Eurostat, 2009).

For the possible indicators addressing industrial injury compensation, the types of disease that are linked with compensation provisions are very limited and related to specific causative chemicals that are already closely defined. It is highly questionable whether REACH or CLP, either separately or combined, will result in the identification of any previously unrecognised chemicals with sufficiently robust information on cause-effect relationships to justify the inclusion of such a chemical-disease linkage within the existing legal compensation framework.

The possible indirect indicators of prescription practice by physicians treating occupational cases of dermatitis or asthma have the benefit of drawing on a pre-defined study population using established data collection networks and structures. However, these may be subject to significant confounding factors – such as changes in medical practice or the influence of other legislation outside of the combined effects of REACH and CLP. Similarly, the requirement to meet occupational exposure limits for particular chemicals introduced outside the REACH or CLP regulations and, importantly, the

general economic climate may influence any changes in industrial expenditure on worker protective measures such as PPE and ventilation.

Changes in the indicators relating to the reclassification of substances will be essentially driven by the CLP process and will be derived from the C & L database, so should represent robust information and be subject to relatively few confounding factors. While some external factors may influence the data, for example withdrawal of chemicals from the market as a result of economically-based decisions, these can be allowed for to some extent from insights gained by the survey of industry.

5.3.3 Results of Indicator Assessment

Recommendations have been made for the assignment of each of the occupational health indicators to one of the four options. Table 5.3 presents the assessment of each indicator against each of the four criteria described above. The full set of scores arising from the scoring and weighting exercises can be found in Annex 3.

Impacts on occupational health are likely to be of little relevance to the evaluation of CLP. However, consideration is given to two indicators that are highly CLP-specific; these relate to the numbers of substances and mixtures that are subject to reclassification to higher or lower categories. These have been assigned to Option 2, rather than Option 1, as they are not specific to either the CLP or REACH minimum evaluation requirements.

For a number of the remaining occupational health indicators, however, reservations have been identified as to their ultimate usefulness in reliably informing on the impacts of REACH and/or CLP. A small number of other more promising indicators have been assigned to the higher tiers of the option scenarios considered, largely because of concerns regarding cost. These issues are discussed further in Section 6.

5.3.4 Results of Scoring and Weighting

For the occupational health indicators, there was little difference in the unweighted scores with or without consideration of anticipated cost, except for those indicators relating to the incidence of occupational diseases. Adoption of these was favoured by inclusion of cost, since they are derived from readily available governmental information produced on a yearly basis for other purposes. For the same reason, the aggregate score for the indicator 'change in numbers claiming compensation because of industrial injuries attributable to chemicals' showed a marked rise when cost was included in considerations.

The ranking of indicators under System C (in which specificity and quality of information were given priority) was very similar to that under System A although there were small differences between the indicators relating to the number of mixtures or substances reclassified and those relating to

occupational disease incidence. The score for 'numbers claiming compensation because of industrial injuries attributable to chemicals' was higher than for System A, reflecting the high quality of the data source that would be used to support this indicator.

Under the scenario with priority given to cost and the degree of confounding factors present (System D), the indicators on numbers of mixtures and substances reclassified showed a slight fall in relative ranking compared with System C, reflecting the anticipated costs of extracting and analysing data from the C&L database. Nonetheless, they remain high scoring indicators. Although readily available at little cost, the anticipated extensive confounding factors in the data sources for the indicators relating to occupational disease incidences significantly reduced their value. In contrast, the anticipated costs relating to the development and performance of studies to ascertain if there are changes in prescription practice for sufferers of selected occupational disease (together with some concern as to confounding) affected the relative ranking of the associated indicators.

Table 5.3: Objective: Reduce the Negative Health Impacts Arising from Occupational Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Reduce the Incidence of Chemical-related Occupational Dermatitis and other Skin Diseases					
Change in incidence of chemically-related occupational skin disease (short- to medium-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Occupational incidence data derived directly from UK government sources that are subject to rigorous quality assurance procedures	Wide range – including other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice.	Data are already collected and collated. Minimal costs will be incurred to extract and format required data.	Addresses legal minimum requirement of REACH so required for Option 1. Recommended for Option 2 for CLP
Change in number of prescriptions for chemically-related occupational dermatitis (short-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Can use collection systems under HSE control so good quality data can be expected	Wide range – including changes in medical practice, general improvements in occupational hygiene, changes in industrial practice. Could be addressed by careful study design	High, as will require generation of new data from survey of appropriate health professionals but cost can limited by using established HSE data gathering systems	Potentially a novel and informative indicator on occupational health.. Recommended for Option 3 for REACH and CLP
Change in incidence of work-related chemically-induced skin disease (short- to medium-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Quality of data likely to be limited because of source and imprecise nature of end-point being investigated.	Wide range – including misreporting, impacts of other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice - background trend data only	High, as targeted surveys of workers in industrial sectors considered at particular risk would be required.	Will provide limited background trend data; monitoring at REACH and CLP deadline dates may provide some indication of overall progress in occupation health and safety. Not carried forward for REACH or CLP
Sub-objective: Reduce the Incidence of Chemical-related Occupational Respiratory Disease					
Change in incidence of chemically-related occupational asthma (short- to medium-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Occupational incidence data derived directly from UK government sources that are subject to rigorous quality assurance procedures	Wide range – including other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice Provides background trend data only	Data are already collected and collated. Minimal costs will be incurred to extract and format required data	Addresses legal minimum requirement of REACH so required for Option 1. Recommended for Option 2 for CLP

Table 5.3: Objective: Reduce the Negative Health Impacts Arising from Occupational Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Change in incidence of chemically-related occupational chronic obstructive pulmonary disease (COPD) (long-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Occupational incidence data derived directly from UK government sources that are subject to rigorous quality assurance procedures	Time course over which disease develops suggests level of confounding would be considerably greater than that for asthma or dermatitis. Provides background trend data only	Data are already collected and collated. Minimal costs will be incurred to extract and format required data	Low cost and ready availability would suggest but significant limitations and extensive latency period suggest that consideration be given to use of alternative indicators
Change in number of prescriptions for occupational asthma (short-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Can use collection systems under HSE control so good quality data can be expected	Wide range – including changes in medical practice, general improvements in occupational hygiene, changes in industrial practice. Could be addressed by careful study design	High, as will require generation of new data from survey of appropriate health professionals but cost can limited by using established HSE data gathering systems	Potentially a novel and informative indicator on occupational health.. Recommended for Option 3 for REACH and CLP
Change in incidence of work-related chemically-induced respiratory disease (timescale of indicator dependent on conditions under consideration)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Quality of data likely to be limited because of source and imprecise nature of end-point being investigated.	Wide range – including misreporting, impacts of other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice - background trend data only	High, as targeted surveys of workers in industrial sectors considered at particular risk would be required.	Monitoring at REACH and CLP deadline dates may provide limited indication of overall progress in occupation health and safety. Not carried forward for REACH or CLP
Sub-objective: Reduce the Incidence of Chemical-related Occupational Cancers					
Change in incidence of chemically-related occupational respiratory cancers (long-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Occupational incidence data derived directly from UK government sources that are subject to rigorous QA procedures	Wide range –.level of confounding would be considerably greater than that for asthma or dermatitis background trend data only	Data are already collected and collated. Minimal costs to extract and format required data	Not carried forward for REACH or CLP
Change in incidence of chemically-related occupational skin cancers (long-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Occupational incidence data derived directly from UK government sources subject to rigorous QA	Wide range –level of confounding would be greater than that for asthma or dermatitis. Background trend data only	Data are already collected and collated. Minimal costs to extract and format required data	Not carried forward for REACH or CLP

Table 5.3: Objective: Reduce the Negative Health Impacts Arising from Occupational Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Reduce the Incidence of Chemical-related Industrial Injuries					
Change in the number of chemical incidents involving exposure of workers (short- to medium-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Draws on data from UK central and local government sources so expected to be robust	Wide range – including other legislation, general improvements in occupational hygiene, technological changes in industrial practice. Background trend data only	Data are already collected but will require additional collation, formatting and analysis	Potential for Option 3 for REACH or CLP. However, limitations suggest that consideration be given to use of alternative indicators. Not carried forward for REACH or CLP
Change in the number of the workers affected by chemical incidents (short- to medium-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Draws on data from UK central and local government sources so expected to be robust	Wide range – including other legislation, general improvements in occupational hygiene, technological changes in industrial practice. Background trend data only	Data are already collected but will require additional collation, formatting and analysis	Potential for Option 3 for REACH or CLP. However, limitations suggest that consideration be given to use of alternative indicators. Not carried forward for REACH or CLP
Change in rates of serious worker injury or death attributable to chemicals (short-term indicator)	Directly relevant to occupational health but not particularly specific to REACH or to CLP	Draws on data from UK central government sources so expected to be robust	Wide range; dataset on which any analyses would be based will be small. Provides background trend data only	Data are already collected but will require some collation, formatting and analysis	Significant limitations therefore not carried forward for REACH or CLP
Change in numbers claiming compensation because of industrial injuries attributable to chemicals (long-term indicator)	Directly relevant to occupational health but not specific to REACH or to CLP	Draws on data from UK central and local government sources so expected to be robust	Wide range – including other legislation, general improvements in occupational hygiene, technological changes in industrial practice. Background trend data only	Data are already collected but will require additional collation, formatting and analysis	Potential for Option 3 for REACH or CLP. However, limitations suggest that consideration be given to use of alternative indicators. Not carried forward for REACH or CLP
Sub-objective: Reduce or Eliminate Exposure to Chemicals of Concern in the Workplace					
Change in industry expenditure on protective gloves (short-term indicator of improvement in worker exposure)	Directly relevant to occupational health and could be linked to varying extents to REACH and/or CLP	Quality of data likely to be limited because of source and nature of end-point being investigated.	Wide range – including other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice, overall economic conditions.	High cost – would require targeted surveys of industrial sectors considered to be at high risk of relevant diseases	Would potentially provide a novel background trend indicator on the impact of REACH and CLP on occupational health. Recommended for Option 3

Table 5.3: Objective: Reduce the Negative Health Impacts Arising from Occupational Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
			Background trend data only		for REACH and CLP
Change in industry expenditure on local and general ventilation equipment (short-term indicator of improvement in worker exposure)	Directly relevant to occupational health and could be linked to varying extents to REACH and/or CLP	Quality of data likely to be limited because of source and nature of end-point being investigated	Wide range – including other legislative changes, general improvements in occupational hygiene, technological changes in industrial practice. Background trend data only progress in occupation health and safety	High cost – would require targeted surveys of industrial sectors considered by HSE to be at high risk of relevant occupational diseases	Would potentially provide a novel background trend indicator on the impact of REACH and CLP on occupational health. Recommended for Option 3 for REACH and CLP
Number of substances/ mixtures reclassified with a 'higher' classification	CLP specific indicator	Draws on data from the ECHA C& L database so considered of high quality	Very few confounding factors	Based on an established EU dataset so only minimal costs for extraction and formatting of the required data	This indicator is not considered appropriate for REACH. Recommended for Option 2 for CLP
Number of substances/ mixtures reclassified with a 'lower' classification	CLP specific indicator	Draws on data from the ECHA C& L database so considered of high quality	Very few confounding factors	Based on an established EU dataset so only minimal costs for extraction and formatting of the required data	This indicator is not considered appropriate for REACH. Recommended for Option 2 for CLP

5.4 Objective: Reduce the Negative Impacts on Public Health of Exposure to Chemicals

5.4.1 Indicators

The scope for direct indicators of the impacts of REACH or CLP on public health is very limited. Other than in the case of acute chemical poisoning incidents, the extent to which the health of the general public is affected by environmental chemical exposure is very poorly understood; this is particularly true at background exposure levels. Probably the best characterised understanding of the health effects of chemicals on the general population is in respect of air pollution, where the principal concerns relate to substances generated through combustion or photochemical reactions. These pollutants fall outside of the scope of either REACH or CLP.

A number of measures of health endpoints have been identified but their relevance and sensitivity to REACH and CLP are highly questionable. The HPA has also suggested establishing (e.g. through surveys) changes in public opinion on the perceived risks associated with chemicals, the strength of available regulation and the degree to which ill-defined worries over the adverse consequences of chemical exposure persist. However, we believe that this aspect is most relevant to the objective of increasing the availability and transparency of information on chemicals, as it relates to perception rather than actual risk.

Other indicators may provide some insights into the influence of the REACH or CLP Regulations on public exposure to chemicals of concern and on the amount of information available on these chemicals. A monitoring programme to inform on changes in the residue levels of chemicals identified as of concern under REACH in the UK population is likely to be a legal requirement. A number of more indirect markers of public exposure to chemicals, such as levels of chemicals in environmental media, are considered below in relation to assessing environmental risks.

Any national emergency action by the UK government to ensure public health, as permitted under REACH Article 129 (the safeguard clause), could be taken as a demonstration of the increased flexibility provided by REACH to act in response to newly-identified risks. Similarly, evidence of enforcement actions taken under REACH would represent a potential measure of increased public protection; these aspects would not inform on CLP. However, consideration will need to be given as to the interpretation/presentation of trends over time. In particular, there is likely to be an increase in enforcement action over the initial period of REACH implementation – as failures by industry to meet the stricter regulatory requirements are identified by the inspection systems. During later stages of implementation, numbers of such actions are likely to fall, as industry adjusts to and meets the new regulatory requirements.

5.4.2 Confounding Factors

While data from public health monitoring schemes (e.g. poisoning incidents or congenital abnormalities) are robust data sets, they are collected for purposes other

than either REACH or CLP. The numbers of chemical incidents occurring in the UK, and the resultant numbers of individuals exposed to particular chemicals, depend on a very wide range of factors. Many of these will be quite independent of the level of knowledge about the hazard potential or the nature of the classification and labelling of the chemical(s) involved. Thus the extent to which indicators based upon these endpoints will inform on a reduction in public risk as a consequence of the CLP or REACH Regulations, combined or separately, is open to question. In addition, indicators such as levels of congenital abnormalities occurring in the UK population are unlikely to be influenced by CLP and are unlikely to show particular sensitivity to the impacts of REACH, at least within the time frame of REACH implementation, because of the extensive confounding factors (e.g. economic status, genetics, life-style, nutrition and infection) to which they are subject.

It is therefore suggested that the main focus for indicators of the effect of REACH on public health should be to establish evidence of a greater level of knowledge of the hazard potential of chemicals and an associated reduction in the extent of public exposure to chemicals of concern. Demonstration of trends in such metrics could provide reassurance to the public that the government is actively enforcing the regulation and that it is leading to concrete changes to the nature of chemical use within the UK. A number of government departments and agencies, trade unions and NGOs expressed agreement with this approach during the consultation process.

Many of the possible public health indicators identified are unrelated to CLP and no indicators specific to CLP were identified. Indicators on the level of knowledge of the properties of chemicals, and consequent changes in use of chemicals in products to which the public may be exposed, are suggested for inclusion in the CLP evaluation process. Although these will be subject to considerable confounding factors, utilising them as indicators of the combined impact of REACH and CLP will help to address this.

5.4.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.4.

For REACH, the selected indicators include four that are considered necessary to meet legal requirements (Option 1); these are:

- emergency actions undertaken under REACH to protect human health;
- change in number of substances selected for monitoring produced or marketed in the UK;
- change in number of substances of very high concern in articles on the UK market; and
- levels of chemicals of concern in body tissues within the UK population.

None of these are considered of relevance to CLP.

Most of the other REACH-relevant indicators are recommended for Option 3 with the exception of ‘introduction of alternative substances’ which was only recommended

for Option 4, because of concerns regarding quality of information, level of confounding factors and cost. However, a number of the indicators assigned to Option 3 are considered to have significant limitations which suggest that it might be preferable to use alternatives wherever these are available (this is discussed further in Section 6).

Of the four available CLP indicators, none are specific to CLP alone although 'numbers of substances withdrawn from the UK market because of concerns regarding human health' was considered to be particularly relevant to both REACH and CLP combined. Overall scores for this and 'change in usage of chemicals of concern in consumer products' were identical. Given that the latter indicator was considered to be influenced slightly more by REACH than by CLP, it is proposed that the indicator 'numbers of substances withdrawn from the UK market because of concerns regarding human health' is adopted for Option 1 of CLP, in order to meet the minimum evaluation and reporting requirement.

5.4.4 Results of Scoring and Weighting

The assessment summarised in Table 5.4 provides the basis on which scores were assigned to each of the criteria used to judge the value of the indicator. The full set of scores arising from the scoring and weighting exercises can be found in Annex 3.

As indicated above, for REACH, the selected indicators include four that are considered necessary to meet the legal requirement and hence should be assigned to Option 1; none of these relate to CLP. Other REACH-relevant indicators tended to have similar scores irrespective of the weighting scenarios considered, with the exception of 'introduction of alternative substances', which was recommended only for inclusion in Option 4 because of concerns regarding quality of information, level of confounding factors and cost.

Only four of the identified indicators were considered relevant to CLP, all of which are co-indicators of the impact of REACH (for which they have been assigned to Option 3). Most of these scored similarly when cost was not included in the considerations (System A and C). While the expected cost of these indicators were not dissimilar, the levels of specificity and confounding factors varied.

Table 5.4: Objective: Reduce the Negative Health Impacts on Public Health of Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Reduce the Incidence of Chemical-related Conditions in the General Public					
Change in the numbers of the public affected by chemical incidents (short- to medium-term indicator)	Directly relevant to public health but not particularly specific to REACH or to a lesser extent CLP	Draws on data from UK central and local government sources so expected to be robust	Wide range – including other legislation, general improvements in industrial practice. Background trend data only.	Relatively low - data are already collected but will require additional collation, formatting and analysis	Potential for Option 3 for REACH or CLP. However, limitations suggest that consideration be given to use of alternative indicators. Not carried forward for REACH or CLP
Change in the level of congenital abnormalities in the UK public that can't be attributed to causes other than chemicals (medium- to long-term indicator)	Directly relevant to public health but not particularly specific to REACH and unlikely to be a valid indicator for CLP	Draws on government funded data sources so reasonable quality, but may be subject to changes in recording practices and coverage of UK population not universal	Wide range – including co-exposure to other agents, life-style factors, other legislative changes, general improvements in occupational hygiene, technological changes	Significant - data are already collected but will require additional collation, formatting and analysis	As above
Sub-objective: Reduce the Level of Public Exposure to Chemicals of Concern					
Change in usage of chemicals of concern in consumer products (short- to medium-term indicator)	Informative of public exposure to chemicals of concern; any changes are likely to be related to the implementation of both REACH and CLP	Proposed data set for draws upon non-UK government source (also to be used in Eurostat REACH Baseline Study) so expected to be of high quality	Some uncertainty as to how representative the data may be of the UK situation. Careful study design (and investigation to confirm relevance) should reduce this.	Data derived from existing robust source but will require additional manipulation and analysis to establish and improve relevance to UK.	Recommended for Option 3 for CLP and REACH
Change in the number of chemical incidents involving exposure of the public (short- to medium-term indicator)	Directly relevant to public health but not particularly specific to REACH or, to a lesser extent, CLP	Draws on data from UK central and local government sources so expected to be robust	Wide range – including other legislation, general improvements in industrial practice. Background trend data only	Low - data are already collected but will require additional collation, formatting and analysis	Potential for Option 3 for REACH or CLP. However, limitations suggest that consideration be given to use of alternative indicators. Not carried forward for REACH or CLP

Table 5.4: Objective: Reduce the Negative Health Impacts on Public Health of Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Change in tissue levels of chemicals of concern in the UK population (anticipated EU core reporting requirement)	Monitoring for targeted substances selected for monitoring in the UK population will be highly REACH specific. No relevance for CLP	Some tissue archives already exist, access to tissues would have to be negotiated and quality criteria agreed	Wide range. Could be limited by careful study design	Could be very high, depending on range of chemicals considered and extent of monitoring required.	Addresses legal minimum requirement for REACH so needed for Option 1 for REACH. Not recommended for CLP
Sub-objective: Promote Withdrawal of Substances of Concern from the Market					
Numbers of substances withdrawn from the UK market because of concerns about human health, restrictions or other reasons under REACH or CLP	Highly specific indicator for both regulations	Draws on data from authoritative sources but will require additional survey information	Wide range of economic factors and overlapping influences of CLP and REACH (can be reduced by considering combined impact).	Some data will be readily available but potentially-costly surveys, additional collation, formatting and analysis will be needed.	Recommended for Option 3 for CLP and needed for Option 1 for REACH
Change in numbers of chemicals of concern produced or marketed in the UK	Addresses a REACH-specific endpoint. Not relevant to CLP	Draws on data from authoritative sources	Wide range of economic factors. Provides background trend data only	Data already collected. Minimal costs to extract and format required data	Addresses legal minimum requirement for REACH so needed for Option 1 for REACH. Not recommended for CLP
Change in number of substances of very high concern (SVHC) in articles on UK market	Addresses a REACH-specific endpoint. Not relevant to CLP	Draws on data from authoritative sources, although no existing baseline data	Wide range of economic factors. Provides background trend data only	Data already collected. Minimal costs to extract and format required data	Addresses legal minimum requirement for REACH so needed for Option 1 for REACH. Not recommended for CLP
Sub-objective: Increase Substitution of Substances by Less Hazardous Alternatives					
Introduction of alternative substances to replace chemicals of concern under REACH	Addresses a REACH-relevant endpoint although strength of association with public health may be difficult to establish. Not relevant to CLP	Quality of data questionable because of source, method collection method and limitations implicit in end-point being investigated	Wide range of economic factors. May be possible to partly correct through use of case studies	High cost for new data collection. Some savings may be possible by combining surveys for several indicators	Of only limited value for REACH and not a CLP indicator. Not carried forward for REACH or CLP

Table 5.4: Objective: Reduce the Negative Health Impacts on Public Health of Exposure to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Implement Emergency Action under Article 129 to Ensure Rapid Safeguarding of Human Health in UK					
Number of national emergency actions taken relating to human health (under Article 129) (anticipated EU core reporting requirement)	Addresses a specific REACH-relevant endpoint. Not relevant to CLP	Draws on data from authoritative UK government sources	No applicable	Minimal costs for inclusion of information in report, and discussion of implications	Addresses legal minimum requirement for REACH so needed for Option 1 for REACH. Not recommended for CLP

5.5 Objective: Reduce the Negative Impacts on the Environment arising from Chemicals

5.5.1 Indicators

Progress on this objective would ideally be demonstrated by linking REACH activities to measurable changes in significant markers of environmental health. These could include specific (non-lethal) markers of toxicity in wildlife (e.g. anatomical or patho-physiological changes in some species exposed to chemicals with particular endocrine activities), alterations in population levels for species that are particularly susceptible to chemicals or in overall biodiversity of particular environmental media. Possible indicators also relate to the levels of chemicals of concern in key abiotic and biotic media. Other indicators that may provide more indirect evidence of the influence of the REACH on the potential for the release of chemicals into the environment include any safeguard actions taken by the UK government because of concerns regarding environmental protection.

5.5.2 Confounding Factors

In practice, it is considered extremely doubtful that any changes in wildlife indicators could be attributed to a single cause, because of the subtle nature of some changes (e.g. loss of genetic diversity within a species or population). The multitude of potential confounding factors (e.g. habitat loss, climate change) would make attribution of any changes to REACH questionable.

Measuring the level of chemicals of concern in environmental media may be subject to practical limitations. Establishing a robust pan-UK picture of pollutant levels across the entire range of environmental media, regions and habitats of concern would be extremely costly as well as scientifically and technologically challenging. There are also practical uncertainties, such as what chemicals should be monitored in which media.

REACH focuses on persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) chemicals. Monitoring of river sediments (both suspended and deposited) and biota might be most appropriate, because such chemicals tend accumulate in sediments and biota. However, such monitoring is more complex and expensive than sampling of water bodies. Various sampling strategies and analytical approaches might be adopted. Developing a time-series of sample archives for the key media might be of particular value since this would provide the material on which any future targeted analyses to address chemical specific issues could be undertaken, at moderate cost.

Indicators on the potential for chemical release into the environment would be valuable. However, changes in the amounts released might arise for many reasons, for example where a company decides to stop producing or using a substance because it is not registered or because it is a by-product from the

production of a non-registered substance or one that is restricted under REACH. In order to link a reduction in releases directly to REACH, it would be necessary to establish the underlying causes for the change. In many instances, though, it is likely that multiple factors will have contributed.

5.5.3 Results of Analysis

The results of the analysis of the indicators are shown in Table 5.5. All the environmental indicators have been proposed for one of the four options, as they all relate to different environmental compartments or effects and therefore tell a different part of the story.

5.5.4 Results of Scoring and Weighting

The assessment summarised in Table 5.5 provides the basis on which scores were assigned for each of the criteria used to judge the value of the indicator. The full set of scores arising from the scoring and weighting exercises can be found in Annex 3.

The unweighted scores for the environmental indicators, with or without consideration of cost, were identical in terms of indicator importance ranking. However, there were significant differences depending on the weighting criteria considered. This was largely due to the influence of costs on the overall scores, particularly for System D in which cost was weighted highly.

For example, there is potentially a very high cost associated with establishing and maintaining extensive monitoring programmes for the presence of chemicals in environmental compartments (air, water and sediment, sludge and soil). However, there is an overall legal requirement to establish indicators of 'regional accumulation of chemicals in environmental compartments'. This set of indicators scored very highly when specificity and quality of information were given priority (System C). As a result, options for developing a more cost-effective monitoring programme are outlined in Section 6.

Soil biodiversity is only a moderately specific indicator for this sub-objective and thus had a lower score under System C. However, data collection systems are already being actively considered by Defra, thus making its anticipated cost very low, so it obtained a much higher score in System D.

Under weighting System C, eight indicators scored less than 400 points (mainly due to high costs), as such, would be included only in Option 4. However, they could be included in the lower cost options by undertaking a more basic monitoring programme for all or some of the environmental compartments (see Section 6.1).

Table 5.5: Objective: Reduce the Negative Impacts on the Environment Arising from Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Increase in Populations Levels of Species Susceptible to Chemical Pollution					
Change in population numbers of species with established susceptibility to chemical pollution	Specific to REACH in the UK. The species have already been identified as having susceptibility to chemical pollution No relevance to CLP	Biodiversity indicator data from Defra and government agencies, but information on different species will be collected by different organisations.	Wide range – e.g. co-exposure to non-REACH chemicals (pesticides etc.), habitat loss, climate change.,. Background trend data only	Data is already collected, but some additional analysis and possibly formatting of data will be required therefore medium overall cost	Recommended for Option 3 for REACH. Not carried forward for CLP
Sub-objective: Reduce the Extent of Chemical-induced Effects in Wildlife Species					
Change in population levels of chemical induced non-lethal effect in wildlife species	Indicator is specific to REACH in the UK No relevance to for CLP	Would draw from existing programmes but information on different species will be collected by different organisations so quality may vary.	Wide range – including co-exposure to non-REACH chemical agents, habitat loss, climate change, other legislation, Background trend data only	Data is already collected, but some additional monitoring and analysis and possibly formatting of data will be required - medium overall cost	Recommended for Option 3 for REACH. Not carried forward for CLP
Sub-objective: Reduce the Level of Chemicals of Concern Present in Abiotic Environmental Media					
Change in levels of selected chemicals in ambient air samples (anticipated EU core reporting requirement)	Monitoring for the right substances across the UK will be REACH specific No relevance to CLP	Sampling and analysis to be carried out by government organizations – high degree of quality control	Wide range – e.g. other legislation, improvements in industrial hygiene, changes in industrial practice. May be addressed by study design	A full scale monitoring programme will entail very high costs, but modified, less costly versions could be adapted.	Fulfils a legal requirement so will have to be included in Option 1 for REACH despite the high costs. Costs can be reduced by limiting the extent of the monitoring programme. Not carried forward for CLP
Change in levels of selected chemicals in water and sediment samples (anticipated EU core reporting requirement)	Monitoring for the right substances across the UK will be REACH specific No relevance to CLP	Sampling and analysis to be carried out by government organizations – high degree of quality control	Wide range – e.g. other legislation, improvements in industrial hygiene, changes in industry practice. May be addressed by study design	A full scale monitoring programme will entail very high costs, but modified, less costly versions could be adapted.	Fulfils a legal requirement so will have to be included in Option 1 for REACH despite the high costs. Costs can be reduced by limiting the extent of the monitoring programme. Not carried forward for CLP

Table 5.5: Objective: Reduce the Negative Impacts on the Environment Arising from Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Change in levels of selected chemicals in soil samples (anticipated EU core reporting requirement)	Monitoring for the right substances across the UK will be REACH specific No relevance to CLP	Sampling and analysis to be carried out by government organizations – high degree of quality control	Wide range – e.g. other legislation, improvements in industrial hygiene. May be addressed by study design	A full scale monitoring programme will entail very high costs, but modified, less costly versions could be adapted.	Fulfils a legal requirement so will have to be included in Option 1 for REACH despite the high costs. Costs can be reduced by limiting the extent of the monitoring programme. Not carried forward for CLP
Change in levels of selected chemicals in waste sludge samples	Monitoring for the right substances across the UK will be REACH specific No relevance to CLP	Sampling and analysis to be carried out by government organisations – high degree of quality control	Wide range – e.g. other legislation, improvements in industrial hygiene. May be addressed by study design	A full scale monitoring programme will entail very high costs, but modified, less costly versions could be adapted.	Different monitoring programmes could be used for each option, depending on funding available. Not carried forward for CLP
Sub-objective: Reduce the Level of Chemicals of Concern Present in Wildlife					
Change in levels of selected chemicals in tissue samples of terrestrial species (anticipated EU core reporting requirement)	Monitoring especially for selected substances covered by REACH and all samples are UK based, so specific. No relevance to CLP	Sampling and analysis to be carried out by government organisations – high degree of quality control	Wide range – e.g. habitat loss, climate change, other legislation, May be addressed through study design	Some substances are likely to require new testing methodologies so costs may be very high	Scores highly on specificity and quality of information, but high cost Recommended for Option 4. Not carried forward for CLP
Change in levels of selected chemicals in tissue samples of aquatic species (anticipated EU core reporting requirement)	Monitoring especially for selected substances covered by REACH and all samples are UK based, so specific. No relevance to CLP	Sampling and analysis to be carried out by government organisations – high degree of quality control	Wide range – e.g. habitat loss, climate change, other legislation May be addressed through study design	Some substances are likely to require new testing methodologies so costs may be very high	Scores highly on specificity and quality of information, but high cost Recommended for Option 4. Not carried forward for CLP
Change in soil biodiversity	UK specific, but looking at indirect effects so only moderate specificity to REACH No relevance to CLP	Sampling and analysis to be carried out by government organisations – high degree of quality control	Wide range – e.g. climate change, other legislation, May be addressed through careful study design	Very low – existing data	Fulfils a legal requirement at minimal cost, so should be included in Option 1. Not carried forward for CLP

Table 5.5: Objective: Reduce the Negative Impacts on the Environment Arising from Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Implement Emergency Action by UK under Article 129 to Ensure Rapid Safeguarding of the Environment in UK					
No. national emergency actions taken under article 129 (anticipated EU core reporting requirement)	UK and REACH specific but no relevance toCLP	Information collated by UK government with suitable quality control,	Not applicable	Very low	Fulfils a legal requirement at minimal costs and needed for Option 1 for REACH. Not carried forward for CLP

5.6 Objective: Maintain the Competitive Position of the UK Chemicals Sector

5.6.1 Indicators

The potential indicators are designed to measure the overall competitive position of the UK chemicals sector and the downstream user sectors. The relevance of these indicators is then assessed for the evaluation of REACH or CLP.

The indicators draw primarily on data available in regularly-published statistics from ONS on output, volume and value of imports and percentage contribution to GDP. As these statistics are collected continuously, they also provide baseline data. HMRC Customs Trade statistics and the Annual Business Inquiry are important sources of trade data which feed into the ONS database. The categories used and the publication frequency of ONS publications may not always fit the requirements of REACH reporting[10]. As highlighted in Section 4, an important issue for the indicators based on ONS statistics will be the selection of the SIC codes (for production and GDP data) and PRODCOM categories (trade data) for which statistics should be sought.

ONS does not produce statistics on the profitability of companies within particular sectors; some data are collected by BIS and by industry associations and it may be possible to draw on these.

WRAP would be able to provide data relating to the plastics, aggregates and metals sectors including:

- overall output of recovered product;
- volume and value of imports of waste and recovered product;
- volume and value of exports of waste and recovered product;
- percentage contribution to GDP;
- profitability;
- number of companies;
- size distribution of companies (large, medium, small and micro);
- employment;
- change in price of waste inputs (compared to overall industry inputs); and
- percentage change in price of waste outputs (compared to non-waste outputs).

A range of market research reports is also produced by commercial organisations. However, these may not be published on a regular basis, they can be costly to purchase and the robustness of the data is not always clear. Industry is unlikely to be

[10] However, it is possible to download the business enquiry data for a fee, with limited additional data requests free of charge. Alternatively, ONS could prepare all available data to pre-specified requirements. To do this ONS would levy an hourly charge£70 for the first hour and £35 for each subsequent hour involved in preparing the data. It is likely to only require a few hours of time to pull together the data identified here.

able to provide exact figures but may be willing to estimate the effect of REACH on specific sectors and the chemical industry as whole.

The UK RIA of CLP identified potential benefits to UK industry from enhanced international trade. The four indicators associated with import and export are therefore of particular value to the evaluation of CLP, especially over the longer term.

5.6.2 Confounding Factors

The potential indicators for changes in relative competitive position provide indirect trend data rather than measuring the impacts directly, as many other factors can affect competitive position, including the general state of the UK economy compared to those of its markets and suppliers. Nevertheless, the data may show changes that coincide with the different stages of implementation of REACH or CLP. If so, this could be an indicator of the effects of REACH or of the effects of CLP.

Due to the overlapping nature of scope and implementation of REACH and CLP, there is potential for the impacts of one on the UK economy to act as a confounding factor to assessment of the impacts of the other. This will be difficult to address from statistical data alone. A key date for both REACH and CLP will be 1 December 2010 so it will be difficult to disentangle early impacts from these pieces of legislation. However, later key dates differ sufficiently for some correction to be attempted in subsequent assessments.

5.6.3 Results of Indicator Assessment

Table 5.6 sets out the results of assessment of the indicators. For two of the indicators, 'overall output of UK chemical industry' and 'profitability', CLP is expected to have such a marginal impact compared to other confounding factors that it is not recommended that they be used for its evaluation.

It is likely that, REACH will have the greater impact on these indicators due to its wide-ranging scope. However, with the exception of the 'overall output of UK chemical industry' and 'profitability', the indicators will be equally relevant to the evaluation of REACH and CLP.

5.6.4 Results of Scoring and Weighting

The assessment summarised in Table 5.6 provides the basis on which scores were assigned for each criterion. A full set of scores for each indicator under Systems A to D are detailed in Annex 3.

Apart from identifying two indicators of no value to the evaluation of CLP, the indicators generally scored similarly with respect to the evaluation of REACH and CLP. This applied whichever scoring system was used. The only further differentiation resulted from 'profitability' requiring industry data rather than ONS statistics. This resulted in a lower score for 'quality of information' and 'cost' criteria.

Table 5.6: Objective: Maintain the Competitive Position of the UK Chemicals Sector					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Maintain the Competitive Position of UK Substance Producers and Downstream Users					
Overall output of UK chemical industry	UK specific and of relevance to REACH as key chemicals legislation. Of little relevance to the evaluation of CLP (score 0)	Data from ONS and subject of rigorous quality assurance control	Will be impacted by other chemical legislation including CLP and economic conditions. Consideration of industry trends and CLP may allow some correction	Data already collected and provided by ONS at limited cost	High quality, low cost indirect indicator of value to the evaluation of REACH. Recommended for Option 2 for REACH only
Profitability	As above	Data from industry of variable quality and QA control	As above	Cooperation with data gathering promised; costs will arise from data preparation, distribution, collection and analysis	High quality indicator of relatively low cost. Recommended for Option 3 for REACH only
Percentage contribution to GDP	As above	Data from ONS and subject of rigorous quality assurance control	As above	Data already collected and provided by ONS at limited cost	High quality, low cost indirect indicator of value to the evaluation of REACH and CLP. Recommended for Option 2 for CLP and Option 1 for REACH (as it is the best low cost indicator for 'Relative performance compared with competitor regions')
Sub-objective: Maximise the Ease of Export of Chemicals from the UK					
Value of exports	UK specific and of relevance to REACH as key chemicals legislation. Of equal relevance to the evaluation of CLP	As above	As above	As above	High quality, low cost indirect indicator of value to the evaluation of REACH and CLP. Recommended for Option 2 for REACH and Option 1 for CLP (as a key benefit predicted by the UK RIA)
Value of imports	As above	As above	As above	As above	As above

Table 5.6: Objective: Maintain the Competitive Position of the UK Chemicals Sector					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Maximise the Ease of Import of Chemicals into the UK					
Volume of exports	As above	As above	As above	As above	As above
Volume of imports	As above	As above	As above	As above	As above

5.7 Objective: Minimise Adverse Structural Changes to UK Industry

5.7.1 Indicators

The aim of the indicators is to identify any pattern of adverse changes to the structure of the UK industry sectors most likely to be affected by REACH or CLP, where this includes substance manufacturers, downstream users, chemicals traders and the recycling industry (which has indicated particular concern about the effects of REACH). The focus is on the number of companies (to identify any impacts on consolidation), their size distribution (to identify any reduction in the number of SMEs) and levels of employment, plus information for the recycling sector on volumes of materials recycled and use of recycled products.

The source of data for many of the indicators is ONS statistics which will provide both baseline and indicator data. For some indicators, it may be necessary to rely on other sources, such as information from industry associations or WRAP (which collects data on its specific targets, including diversion of waste from landfill and use of recyclate in manufacturing). Data are also collected by various regional development agencies but, in many cases, these will not cover the whole UK.

5.7.2 Confounding Factors

While they do not directly measure the impacts of REACH or CLP and are subject to a wide range of confounding factors, the potential indicators may flag up trends that could be investigated further.

The same issue applies here as for the previous objective in terms of identifying the relevant SIC codes for substance manufacturers and downstream users. Chemical traders are included within S46.75 – wholesale of chemical products; but there are particular issues with identifying the appropriate SIC codes for the recycling sector.

5.7.3 Results of Indicator Assessment

It is felt that CLP will have so little impact on these indicators compared to confounding factors that these should not be used for the CLP evaluation. However, consideration of CLP will be of value to minimising the impact of confounding factors for the evaluation of REACH.

5.7.4 Results of Scoring and Weighting

The assessment summarised in Table 5.7 provides the basis on which scores were assigned for each criterion. Full sets of scores for each indicator under Systems A to D are detailed in Annex 3. It is of note that all indicators scored equally for all criteria and under all scoring systems for REACH (with none proposed for CLP).

Table 5.7: Objective: Minimise Adverse Structural Changes to UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Minimise Adverse Structural Changes to UK Industry (Chemicals Sector C20, Downstream Users, Distributors and Waste Recycling Sectors)					
Number of companies	UK specific and of relevance to REACH as key chemicals legislation. Of little relevance to the evaluation of CLP (score 0)	Data from ONS and subject of rigorous quality assurance control	Will be impacted by other chemical legislation including CLP and economic conditions. Consideration of industry trends and CLP may allow some correction	Data already collected and provided by ONS at limited cost	High quality, low cost indirect indicator of value to the evaluation of REACH. Recommended for Option 2 for REACH only
Size distribution of companies	As above	As above	As above	As above	As above
Employment	As above	As above	As above	As above	As above
Volume of materials recycled/recovered	As above	As above	As above	As above	As above

5.8 Objective: Minimise Adverse Effects on the Patterns of Industrial Activity in the UK

5.8.1 Indicators

The aim of the indicators for this sub-objective is to determine whether the concerns expressed by industry about the potential adverse economic effects of REACH or CLP have been realised in practice. It will also test the extent to which the various impact assessments on REACH or CLP anticipated the actual effects (although the timing of the impact assessments, carried out at different stages in the development of the REACH regulation will need to be taken into account). The UK RIA for the CLP did not identify any economic costs beyond the implementation period.

The indicator, 'percentage change in price of chemical inputs', does not directly measure the impact of REACH or CLP and suffers from many confounding factors; however, it may provide useful background data on how input prices change over time during the implementation of REACH and of CLP, to a lesser extent. It will be possible to draw some relevant data on this from ONS statistics but it may also be necessary to use BIS or industry sources.

Information on the number of substances on the UK market post-REACH can be based on the number registered, assuming all registered substances are available in the UK. However, the baseline is more difficult to determine. Although the IUCLID IV database provides some information, it is widely acknowledged as incomplete. Industry also challenged estimates in the various impact assessments of the numbers of substances on the market prior to REACH and the numbers of manufacturers. The number of pre-registered substances may provide a better indicator of the numbers actually on the market, though this may be affected by issues of substance identity. Data on registrations and pre-registrations will be available to the HSE via REACH-IT. Information on the numbers of preparations on the UK market is likely to be harder to obtain, but it should be possible to identify PRODCOM categories that approximate to preparations, for which data on value rather than volume would be available.

A survey is suggested to test the reasons for withdrawal of substances; this will require information on the identity of pre-registrants that did not proceed to registration; otherwise, a wider pre-survey will be necessary to identify such companies. As many companies have pre-registered substances with no intention to register, such a survey will be essential to assess the number of substances actually withdrawn.

5.8.2 Confounding Factors

All other indicators for this objective rely on case-studies or surveys. By definition, these will provide only a partial picture of the impacts of REACH or CLP on economic activity, although they should give the opportunity to explore the reasons for impacts in more detail. One approach would be to select the same sectors or even companies that were used for case studies in the impact assessments (for example,

RPA's work for Defra on supply chain impacts) in order to provide a comparable baseline. As these case studies were focused on sectors where REACH was expected to have the greatest impact, this may result in a biased sample. However, it could also explore whether the fears of the sectors were realised.

5.8.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.8. Only one indicator is recommended for the evaluation of CLP, 'reasons for withdrawal of substances'. Should data from this indicator show a major influence from CLP, then this may signal that other indicators of economic cost are more relevant to the evaluation of CLP than predicted by the UK RIA. However, for indicators with low specificity for CLP that are useful for the evaluation of REACH, the data gathered could be used for the evaluation of CLP at a later stage.

One indicator, "hazard characteristics of withdrawn substances" would have relevance to the evaluation of REACH if it could be combined with data on the identity of withdrawn substances to identify whether or not withdrawals were focused particularly on hazardous substances. As this information can be provided by other, more relevant indicators it has not been considered further.

The other indicators have a high level of specificity for the evaluation of REACH. Two, relating to the total number of substances and preparations on the market, are expected to provide particularly high quality information and the indicator on substances would provide data at a lower cost than others (via REACH-IT). The remaining indicators will require more costly case studies but these could provide information across many indicators, including those assessed under different aims.

5.8.4 Results of Scoring and Weighting

The scoring identified three indicators that were of no relevance to CLP and these were only carried forward for the evaluation of REACH. One of these 'risk characteristics of withdrawn substances' also scored very low for specificity to REACH. 'Percentage change in price of chemical inputs' scored significantly lower under each system than other indicators of relevance to REACH or CLP. All other indicators had low scores for specificity to CLP except 'reasons for withdrawal of substances', which scored a maximum for both REACH and CLP.

Two indicators, 'total numbers of substances' and 'total number of preparations' scored particularly highly under System C for REACH, indicating both have high specificity and quality of information. However, both have significantly lower scores under System D due to a high level of confounding factors. The remaining indicators scored moderately highly (around 70%) under System C and System D. However, one indicator 'number products removed from market due to unsupported uses' outscored the others as it had a maximum score for specificity.

Table 5.8: Objective: Minimise Adverse Effects on Patterns of Industrial Activity					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Avoid Damaging Increases in Input Prices					
Percentage change in price of chemical inputs (compared to overall industry inputs)	UK specific and of relevance to REACH as key chemicals legislation and to evaluation of UK RIA of CLP	Data from industry of variable quality and QA control	Many, e.g. other chemical legislation including CLP and economic conditions such as commodity prices. Comparison with industry trends may allow some correction	Cooperation with data gathering has been promised but costs will arise from preparation, distribution, collection and analysis of data	Only recommended for further consideration under Option 4 for REACH and CLP because it is only indicator for this sub-objective
Sub-objective: Maintain Competition in the Supply of Chemicals					
Total number substances available on UK market and comparison with EU	UK specific and of relevance to REACH as key chemicals legislation. Of limited relevance to the evaluation of CLP	High quality data from REACH-IT data with high level of quality control	Many, e.g. other chemical legislation including CLP and economic conditions such as commodity prices. Consideration of industry trends may allow some correction	Data readily available but some extraction and analysis needed	Needed for Option 1 for REACH. Not considered further for the evaluation of CLP
Total no. preparations available on UK market	UK specific and of relevance to REACH as key chemicals legislation. Of little relevance to the evaluation of CLP	ONS data with high level of quality control	As above Value data used as approximation of volume	Relatively high: will require consultation with industry combined with readily available ONS data	Needed for Option 1 for REACH. Not considered further for the evaluation of CLP
Percentage change in number of suppliers per DU company	UK specific and of relevance to REACH as key chemicals legislation. Of little relevance to the evaluation of CLP	Case study data subject to some independent cross-checking	Economic factors will confound but REACH is likely to be a major impact. Some correction from case-studies	Cooperation with data gathering has been promised but costs will arise from preparation, distribution, collection and analysis of data	Recommended for Option 3 for REACH. Not considered further for the evaluation of CLP
Sub-objective: Minimise Costs Associated with Loss of Substances					
Percentage change in DU product portfolios	As above	As above	As above	As above	As above
Number of product reformulations carried out	As above	As above	As above	As above	As above
Number of products removed	As above	As above	As above	As above	Needed for Option 1 for

Table 5.8: Objective: Minimise Adverse Effects on Patterns of Industrial Activity					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
from market due to unsupported uses					REACH. Not considered further for the evaluation of CLP
Number of process changes carried out	As above	As above	As above	As above	As above
Sub-objective: Minimise Withdrawal of Substances for Non Risk-related Reasons					
Reasons for withdrawal of substances	High degree of specificity for REACH and CLP (Score 5)	As above	Confounding factors largely accounted for by REACH and CLP focused case study questions	As above	Needed for Option 1 for REACH. Recommended for Option 2 for CLP.

5.9 Objective: Maximise the Potential for Innovation

5.9.1 Introduction

The aim of the indicators for this objective and its sub-objectives is to identify whether REACH has provided a driver for innovation by industry. It also aims to test the concern identified in some impact assessments that REACH could divert resources from innovation to registration and other REACH activities.

5.9.2 Indicators

Data on R&D expenditure by substance manufacturers and downstream users provides only a background indicator which may show trends related to the various REACH or CLP implementation dates. Some data may be available from BIS but it is likely that these data will be available only via selected case studies sourced with the aid of industry associations. Case studies should also seek to differentiate between expenditure due to REACH and that due to CLP.

The number of new substances registered under REACH may appear to fall compared with notifications under NONS, due to the increased tonnage threshold under REACH (and because non-UK companies made NONS notifications in the UK). The number of PPORD exemptions sought will provide an alternative indicator though and may provide some validation of any trends. The reasons for such exemptions will provide for a further level of evaluation of REACH while allowing for an assessment of the R&D impact of CLP.

We have suggested including an indicator on 'value of REACH-related services' to capture the extent to which companies are providing REACH advice and assistance to their customers, moving from product to service business models.

5.9.3 Confounding Factors

The other potential indicators rely on case studies and are subject to the limitations described earlier in this section. The case studies for the two objectives of 'REACH/CLP related R&D expenditure' and 'value of REACH/CLP-related services' could be combined (and, potentially, could also provide insight to other objectives) to increase their cost-effectiveness.

5.9.4 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.9. Two indicators were assessed to have no relevance to the evaluation of CLP.

The remaining indicators would appear to be of equal value for the evaluation of REACH. Four of these indicators are relevant to the evaluation of REACH and CLP. However, the remaining three indicators mostly inform and evaluation of REACH and are not considered further for the evaluation of CLP.

5.9.5 Results of Scoring and Weighting

Two indicators, one relating to new substance registrations and the other to PPORD exemptions, scored the maximum for specificity for the evaluation of REACH but scored zero for the evaluation of CLP. These both had significantly higher scores under System C and System D as they both would provide high quality data at a moderate (but not low) cost for the evaluation of REACH.

All indicators had low scores for confounding factors (score 2), except 'value of REACH/CLP-related services' (score 3) and most had moderate costs (score 3) and would provide moderate quality data (score 3).

5.10 Objective: Encouraging the Dissemination and Utilisation by Stakeholders of Information Sources and Advice Relating to Chemicals

5.10.1 Indicators

The primary responsibility for the dissemination of information lies with the UK Competent Authority (CA) for REACH and CLP. Therefore, a number of indicators relate to the methods of information provision by the CA.

Consumers have the right to request information necessary for the safe use of an article containing a substance on the candidate list for authorisation or included in Annex XIV to REACH. Based on past experience with the Cosmetics Directive, some industry representatives have expressed concern that they could face significant costs in preparing information for requests that may never arrive. The number of such requests received is therefore an indicator of the effectiveness of this provision.

The level of information and guidance made available to industry by the UK government also informs the REACH aim "Ensure the Efficient Implementation of REACH Mechanisms".

5.10.2 Confounding Factors

The CA does not currently record data for all indicators but would have no difficulty doing so in the future. Other data are routinely recorded. Data on consumer requests will require surveys of relevant industry sectors. The CA for REACH and CLP are likely to be one integrated body or closely related, therefore the activity of the CA will relate to the operation of both REACH and CLP.

Table 5.9: Objective: Maximise the Potential for Innovation					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Maximise Innovation by UK Substance Producers and Downstream Users					
REACH/CLP related R&D expenditure as percentage turnover for selected sectors (manufacturers and DUs)	Maximum specificity for both REACH and CLP	Variable data quality but cross-checking across case studies could address this	Many confounding factors primarily economic. Some correction possible from case studies	Medium costs for case studies. Costs shared between many indicators	Needed for Option 1 for both REACH and CLP
REACH/CLP related R&D expenditure as percentage of total R&D for selected sectors (manufacturers/DUs)	As above	As above	As above	As above	As above
Number of new substances registered (UK sites) (manufacturers and importers)	Maximum specificity for REACH but of no relevance to CLP	High quality data from REACH-IT	As above	Relatively high costs for collation and analysis of REACH-IT data	Needed for Option 1 for REACH. Not considered further for the evaluation of CLP
Number of PPORD exemptions sought with reasons (UK sites) (manufacturers and importers)	Maximum specificity for REACH and relevant to innovation benefits from UK RIA of CLP	As above	No confounding factors for REACH. Indirect indicator of R&D activity for CLP therefore high level of confounding	As above	Needed for Option 1 for both REACH and CLP
Value of REACH/CLP-related services provided to customers (manufacturers, importers and DUs)	Maximum specificity for both REACH and CLP	Variable data quality but cross-checking across case studies could address this	Availability of alternative advice/ information sources will reduce value	Medium to high costs for case studies. Costs shared between many indicators	Recommended for Option 2 for both REACH. Needed for Option 1 for CLP
Number of high-risk substances substituted (and cost) by downstream users	Maximum specificity for REACH but of little relevance to CLP	As above	Many confounding factors primarily economic. Some correction from case studies	As above	Recommended for Option 3 for REACH. Not considered further for the evaluation of CLP
Reasons for substitution by downstream users	Maximum specificity for both REACH and CLP	As above	As above	As above	Recommended for Option 3 for both REACH and CLP
Number of new products developed by downstream users using lower risk	Maximum specificity for REACH but of little relevance to CLP	As above	As above	As above	Recommended for Option 3 for both REACH. Not considered further for the

Table 5.9: Objective: Maximise the Potential for Innovation					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
substances					evaluation of CLP
Value of new products developed by downstream users using lower risk substances	Maximum specificity for REACH but of little relevance to CLP	As above	As above	As above	Recommended for Option 3 for REACH. Not considered further for the evaluation of CLP

5.10.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.10. The indicators that are assessed as least useful for CLP relate to the activity of the expected combined REACH/CLP Competent Authority. They are therefore relevant to CLP but do not inform the reporting requirements under CLP or the evaluation of the UK RIA; thus, none of these indicators will be considered further for the evaluation of CLP. It will, however, be necessary to assess the CLP contribution to these indicators to remove the confounding factor of CLP when these indicators are used to evaluate REACH.

Apart from one indicator regarding consumer requests, all indicators are specific and provide high quality information with no confounding factors at low cost. These indicators all relate to the working of the REACH/CLP Competent Authority; three are needed for Option 1, the others are recommended for Option 2.

The indicator, "number of consumer requests for information regarding SVHCs in articles" is very specific to the application of REACH and has few confounding factors, but the quality of information provided is likely to be low and the cost may be relatively high. However, this is the only indicator under this objective that relates to the impact of REACH on consumers. Therefore, this is considered a valuable indicator for the evaluation of REACH and is recommended for Option 2.

5.10.4 Results of Scoring and Weighting

All indicators scored a maximum for specificity for the evaluation of REACH but scored zero or only 2 for the evaluation of CLP. Apart from one indicator regarding consumer requests, all indicators scored a maximum 100% under each of the scoring systems.

Table 5.10: Objective: Encourage the Dissemination and Utilisation of Information Sources and Advice Relating to Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Encourage the Dissemination of Information by the UK CA					
Number of visits to UK CA website	UK data specific to the application of REACH. Of relevance to the application of CLP but not to the evaluation under consideration here	Government data with high level of QA.	No confounding factors except the contribution of CLP. Consideration of impact of CLP therefore needed for correction	Government data already available or could easily be collected.	Required for Option 1 for REACH. Not considered further for the evaluation of CLP
Number of guidance items downloaded from CA website	As above	As above	As above	As above	As above
Number of subscriptions to CA e-Bulletin	As above	As above	As above	As above	Recommended for Option 2 for REACH. Not considered further for the evaluation of CLP
Number of CA helpdesk enquiries	As above	As above	As above	As above	Required for Option 1 for REACH. Not considered further for the evaluation of CLP
Number of information events (CA and other government bodies)	As above	As above	As above	As above	Required for Option 1 for REACH. Not considered further for the evaluation of CLP
Sub-objective: Encourage the Dissemination of Information by Industry					
Number of consumer requests for information regarding SVHC in articles	UK data specific to the application of REACH. Not relevant to the evaluation of CLP	Data likely to be incomplete and no cross-checking possible	Not able to correct but few confounding factors	New data from survey of retailers shared with only one other indicator. However, survey very limited and industry cooperation promised	Only indicator under this objective informing on consumer impacts. Recommended for Option 2 for REACH. Not considered further for the evaluation of CLP

5.11 Objective: Ensuring the Provision of High Quality Information and Advice about Chemicals

5.11.1 Indicators

The CA is charged with overseeing the effective implementation of REACH; this function is likely to be extended to include the implementation of CLP. The indicators consider the quality of information provided from two main sources; the CA website and the helpdesk.

A major feature of REACH is the transfer of responsibility for the control of risk from the regulator to the supplier. Therefore, the quality of information provided by suppliers can only be assessed in terms of that provided through the supply chain via (e)SDS and the information made available to consumers. CLP is concerned with the accurate classification of the hazards of substances and mixtures and the communication of those hazards (with relevant precautionary advice) is regulated through the CLP provisions relating to labelling and packaging. However, the impact of CLP on communication in the supply chain is expected to be limited, with the relevance of these indicators to the evaluation of the CLP therefore being limited.

5.11.2 Confounding Factors

Consultation with industry associations could provide a way to validate information provided by the CA on the quality of the information available via the website and the helpdesk.

In terms of the indicators related to SDS, there are few confounding factors other than the potential need to control for CLP when assessing the impacts of REACH.

Data on the level of consumer knowledge of REACH in general, and the right to demand information on substances in articles, may only be available through a consumer survey specifically conducted for this evaluation. However, it may be possible to identify a small subset of key stakeholders for each indicator that may be asked for their qualitative feedback. The percentage of respondents with knowledge of the right of consumers to request information has been chosen as the basis for two indicators, to provide specific and quantifiable data.

Those indicators directly relating to the functioning of the CA involve the collection of data on CA activities relating to both CLP and REACH. Correction will be needed to remove the confounding factor of REACH to CLP and vice versa.

5.11.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.11. No indicators except 'number of substance and mixture labels meeting CLP requirements' will be considered further for the evaluation of CLP. This indicator will not be considered further for the evaluation of REACH.

The indicator 'percentage of retailers with knowledge of their customers' right to request information' will have relatively high costs and a high level of confounding factors. However, consultation indicates that a lack of retailer knowledge of such rights may lead to requests not being forwarded appropriately. This indicator would therefore provide some useful background information (and is included in Option 4).

5.11.4 Results of Scoring and Weighting

All but one of the indicators scored a maximum of five for specificity to the evaluation of REACH and zero or two for CLP. One of these indicators 'number of (e)SDS failing legal requirements' scored 99% under System C and 95% under System D. The other indicators, except one, each scored around 89% under System C and around 70% under System D. The remaining highly specific REACH indicator 'percentage of retailers with knowledge of their customers' right to request information' scored significantly lower under System C and System D with scores of 66% and 44% respectively.

The remaining indicator 'number of substance and mixture labels meeting CLP requirements' scored zero for the evaluation of REACH but three for CLP. This indicator scored well under all other criteria with a score of 81% under System C and 85% under System D.

5.12 Objective: Promote the Development of Alternative (Especially Non-vertebrate) Test Methods

5.12.1 Indicators

The development and validation for regulatory purposes of alternative approaches to hazard assessment is not a UK-specific function. It takes place at the European level led by the European Centre for Validation of Alternative Methods (ECVAM) and in the wider international arena through the activities of the Organisation for Economic Co-operation and Development (OECD). Routinely, a new alternative test method validated by ECVAM will be submitted to the OECD for approval. Exceptionally, if there is "undue delay" in the OECD process, DG Environment (on behalf of the Commission) may decide to progress the approval process at the European level only so that it may be used for REACH purposes.

The UK government is an active participant in the various bodies involved in such decisions and it is therefore appropriate to include indicators of the level of UK resource committed. Various UK government departments and agencies, including Defra, provide funding for basic and applied research intended to develop novel hazard and risk assessment approaches. The UK government also makes contributions to the debate over testing approaches, thus helping to raise awareness of the issue and it is therefore important to include indicators that document these contributions. Indeed, evidence to indicate the level of UK-government support for these aspects is expected to be included in the core Member State reporting requirements.

Table 5.11: Objective: Ensure the Provision of High Quality Information and Advice about Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Ensure the Availability of High Quality Information from the UK CA					
Quality of CA website information	UK data specific to the application of REACH. Of relevance to the application of CLP but not to the evaluation under consideration here	Good - qualitative data from CA with case-studies for cross checking	No confounding factors	New data from case studies but costs shared between many indicators	Required for Option 1 for REACH. Not considered further for the evaluation of CLP
Completeness of CA website information	As above	As above	As above	As above	As above
Relevance of CA website information	As above	As above	As above	As above	As above
Quality of CA helpdesk responses	As above	As above	As above	As above	Recommended for Option 2 for REACH. Not considered further for the evaluation of CLP
Completeness of CA helpdesk responses	As above	As above	As above	As above	As above
Relevance of CA helpdesk responses	As above	As above	As above	As above	As above
Sub-objective: Encourage the Availability of High Quality Information from Industry					
Number of (e)SDS failing legal requirements	UK data specific to the application of REACH. Of no relevance to the CLP evaluation under consideration here	UK enforcement data with quality control	Key confounding factor is CLP, for which full correction may not be possible	UK enforcement data already collected or could be collected at limited cost	Recommended for Option 2 for REACH. Not considered further for the evaluation of CLP
Number of SDS meeting DU requirements	UK data specific to the application of REACH. Of relevance to the application of CLP but not to the evaluation under consideration here	Good, due to cross-checking from case studies	As above	New data from case studies shared between many indicators	. Recommended for Option 4 for REACH. Not considered further for the evaluation of CLP
Number of substance and mixture labels meeting CLP requirements	Of no relevance to REACH. Of particular relevance to the effective	Professional CHCS data of high quality.	No confounding factors.	Further CHCS surveys may require funding if frequency required for	Not considered further for the evaluation of REACH. Recommended for Option 2

Table 5.11: Objective: Ensure the Provision of High Quality Information and Advice about Chemicals					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
	working of CLP but falls outside of the evaluation under consideration here			evaluation differs from CHCS survey plans	for CLP despite being outside of the CLP evaluation under consideration here
Percentage of retailers with knowledge of their customers' right to request information	UK data specific to the application of REACH. Maximum score of 5. Relevant to the application of CLP but not to this objective	Moderate: only limited survey possible but some cross-checking. Can be carried out	Many confounding factors with limited possibility of correction	Relatively high: new data from limited survey of retailers shared with only one other indicator	Recommended for Option 4 for REACH. Not considered further for the evaluation of CLP
Sub-objective: Encourage the Availability of High Quality Information to Consumers					
Percentage of consumers with knowledge of right to request information on SVHCs in articles	UK data specific to the application of REACH. Of no relevance to the evaluation under consideration here	Only limited cross-checking possible	No confounding factors	. Could be incorporated into existing consumer survey at moderately low cost	Only indicator for this objective related to consumer impacts of REACH. Recommended for Option 2

An additional set of indicators that is non-UK specific has also been identified. While the UK-government is not in a position to make final decisions on the validation of tests for international regulatory purposes, as a leading contributor to such work it is in an excellent position to promote adoption of alternative test methods by these bodies. Thus, it is important to include an indicator which captures the numbers of alternative tests adopted by the lead organisations in order to assess the extent to which the UK's efforts have resulted in progress. The need for such evidence is supported by feedback from consultation with independent organisations (such as NGOs) active on the issue of animal testing.

5.12.2 Confounding Factors

Many of the identified indicators will draw on resource utilisation records of the UK government departments and agencies in relation to clearly defined activities (such as attendance at specific committees) or will utilise readily accessible published information from ECVAM and OECD. As such, the burden of collection and collation and the extent to which confounding factors will affect interpretation is generally limited. However, some aspects, such as the funding of primary research on alternative test approaches, may be influenced by other factors, for example changes in the overall levels of governmental discretionary spending.

5.12.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.12. The indicators have been assessed only for their potential value to the evaluation of REACH; none are considered of relevance to CLP.

Three of the indicators (UK Government contribution to EU and OECD work on alternative testing methods and guidance, UK Government contribution to the development of alternative test methods (UK focus only), and UK Government's alternative testing awareness raising activities) are anticipated to fall within the minimum (legal) reporting requirements and so have been assigned to Option 1 for REACH. The other indicators, although varying in the extent of data analysis or investigation that may be required to address confounding factors and inform interpretation, are considered of value. Given the likely active political interest in this aspect of REACH, they have therefore been assigned to Option 2 for REACH.

5.12.4 Results of Scoring and Weighting

Given the ready availability of data, these indicators score highly with regard to quality of data and cost of collection. Issues remain, however, with regard to the specificity of the information for some and the level to which confounding factors (particularly other legislation) may limit interpretation or require further analysis or investigation to assess their relevance.

Table 5.12: Objective: Promote the Development of Alternative Test Methods					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Promote The Development, Evaluation And Validation Of Alternative Methods For Chemical Testing					
UK Government contribution to EU and OECD work on alternative testing methods and guidance (anticipated EU core reporting requirement)	Activity driven by REACH and other legislation but not relevant to CLP	Derived from UK government data on staff utilisation so considered robust	Activity also driven by other legislation and UK policy initiatives - could be clarified through discussion with relevant departments.	Data are already collected but will require limited additional collation and formatting	Addresses legal minimum requirement for REACH so recommended for Option 1. Not considered to be a CLP indicator
UK Government contribution to the development of alternative test methods (UK focus only) (anticipated EU core reporting requirement)	Activity driven by REACH and other legislation but not relevant to CLP	Derived from UK government budget data so considered robust	Data will include funding of research into tests t intended for non-REACH related areas; influenced by general governmental expenditure levels. Will require careful consideration of tests funded	Data are already collected but will require limited additional collation and analysis	Addresses legal minimum requirement for REACH so recommended for Option 1. Not considered to be a CLP indicator
UK Government's alternative testing awareness raising activities (anticipated EU core reporting requirement)	Activity driven by REACH and other legislation but is not relevant to CLP	Derived from UK government budget data so considered robust	As above	Data are already collected but will require limited additional collation and analysis	Addresses legal minimum requirement for REACH so recommended for Option 1. Not considered to be a CLP indicator
Number of alternative (non-vertebrate) test methods subject to validation at European level	Directly relevant to issue of alternative testing but not specific to REACH or the UK Not relevant to CLP	Data readily available from robust data source (ECVAM TSAR database)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Number of ECVAM validated alternative (non-vertebrate) test methods	Directly relevant to issue of alternative testing but not be regarded as specific to REACH or the UK Not relevant to CLP	Data readily available from robust data source (ECVAM TSAR database)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator

Table 5.12: Objective: Promote the Development of Alternative Test Methods					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Number of alternative tests adopted by EU	Directly relevant to issue of alternative testing but not specific to REACH or the UK Not relevant to CLP	Data readily available from robust data source (ECVAM TSAR database)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Number of alternative (non-vertebrate) test methods subject to validation at OECD level	Directly relevant to issue of alternative testing but not specific to REACH or the UK. Not relevant to CLP	Data readily available from robust data source (OECD via Home Office)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs will be incurred to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Number of OECD validated alternative (non-vertebrate) test methods	Directly relevant to issue of alternative testing but not specific to REACH or the UK Not relevant to CLP	Data readily available from robust data source (OECD via Home Office)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator

5.13 Objective: Promote the Use of Alternative Test Methods

5.13.1 Indicators

As previously noted, the formal validation for regulatory purposes of alternative approaches to hazard assessment is an international, not a UK-specific, function. Similarly, the UK can promote - but not enforce - the withdrawal of 'traditional' test guidelines where suitable alternatives are available. Measures such as the number of 'traditional' tests withdrawn at European or OECD level do, however, represent a benchmark against which UK efforts to promote their withdrawal will be judged by stakeholders. Some UK-specific measures are available, since the UK will withdraw project licenses for test methods where clear alternative designs (addressing reduction, refinement or replacement) exist. Inclusion of such UK action thus provides a useful UK specific indication of government support for this REACH aim.

Some other possible indicators have been identified that may inform on the extent to which alternative approaches (such as use of waiving, read-across, computational models and non-vertebrate testing) are being adopted by registrants submitting dossiers to ECHA. It may be possible to compare overalls trends against dossiers in which UK industry is involved to inform on the willingness of UK industry to adopt alternative approaches to vertebrate testing.

5.13.2 Confounding Factors

The ECHA database's dossier entry system for submissions should allow ECHA/Eurostat to derive statistics on the use of non-animal approaches, QSARs and other computation approaches and read-across or waiving of test requirements, including identifying submissions that involve a UK organisation. However, the ease with which the UK competent authority will be able to extract such information from the ECHA database is at present unclear.

5.13.3 Results of Indicator Assessment

Table 5.13 presents the results of the assessment. These indicators have been assessed only for their potential value to the evaluation of REACH; none are considered of relevance to CLP.

Indicators relating to the withdrawal by OECD or the EU of traditional vertebrate test methods are easy to collect, highly relevant to the aim of REACH. Although subject to some confounding factors relating to the influence of other legislation, they provide valuable information. Since they are not anticipated to fall within the legal requirement they have been recommended for inclusion in Option 2. A further indicator 'Number of project licenses withdrawn in UK because of availability of alternative test methods' has many similar properties but benefits from relating specifically to action taken by the UK government; it is also recommended for Option 2.

The value of indicators on the use of alternative approaches (such as use of waiving, read-across, computational models and non-vertebrate testing) by registrants will be largely dependent on the ease of extraction of data from the REACH-IT database and the extent to which the roles played by UK companies can be determined. Because of this, and since they are not anticipated to form part of the legal minimum reporting requirements, they have been recommended for Option 2 for REACH. It may be appropriate to re-examine the relative ease of collection at a later time to ascertain if any of the indicators are easier to collect (e.g. as a result of the database structure) or provide more robust or easier to interpret data. In this case, such indicators can be given preference during the final selection of the REACH evaluation indicator sets.

5.13.4 Results of Scoring and Weighting

The assessment summarised in Table 5.13 provides the basis on which scores were assigned for each of the criteria used to judge the value of the indicator. The full set of scores arising from the scoring and weighting exercises can be found in Annex 3.

Indicators relating to the withdrawal of test methods are easy to collect, highly relevant to the aim of REACH and have scored highly as a result. Similarly, the indicators relating to the extent of use of alternative approaches in submissions to ECHA have also scored highly. However, there is a larger degree of uncertainty as to the robustness of the scoring, particularly in relation to the ease of data extraction and how far the roles played by UK industry will be ascertainable. Some caution is therefore necessary in relation to the assessment of these indicators.

Table 5.13: Objective: Promote the Use of Alternative Test Methods					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Promote the Replacement of Existing Vertebrate Test Methods					
Number of withdrawn EU test methods that involved use of vertebrate animals	Directly relevant to issue of alternative testing but not be regarded as specific to REACH or the UK Not relevant to CLP	Data readily available from Home Office based upon information received from European Commission	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Number of withdrawn OECD test methods involving use of vertebrate animals	Directly relevant to issue of alternative testing but not be regarded as specific to REACH or the UK Not relevant to CLP	Data readily available from robust data source (OECD via Home Office)	Decisions not in control of UK government but UK can promote progress	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Number of project licenses withdrawn in UK because of availability of alternative test methods	Directly relevant to issue of alternative testing and is UK specific, but not be regarded as specific to REACH per se. Not relevant to CLP	Data readily available from Home Office	Decisions largely driven by EU, but does represent direct action by UK government	Data readily available. Minimal costs to extract and format required data	Recommended for Option 2 of REACH. Not considered to be a CLP indicator
Sub-objective: Encourage the Use of Non-Animal Approaches in REACH Risk Assessments					
Number of REACH dossiers involving UK companies that include use of read-across as alternative to proposing vertebrate testing	Directly informs on adoption of alternative approaches and is specific to REACH. May also be possible to inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	Possible issues in establishing the roles played by UK companies in joint submissions but could be addressed by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional effort will be needed to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered a CLP indicator
Number of REACH dossiers involving UK companies including use of computational test methods as alternative to proposing vertebrate testing	Directly informs on adoption of alternative approaches and is specific to REACH. May also be targeted to inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	Possible issues in establishing the roles played by UK companies in joint submissions but could be addressed by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional effort will be needed to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator

Table 5.13: Objective: Promote the Use of Alternative Test Methods					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Number of REACH dossiers involving UK companies including use of non-vertebrate test methods as alternative to proposing vertebrate testing	Directly informs on adoption of alternative approaches and is specific to REACH. May also be targeted to inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	Possible issues in establishing the roles played by UK companies in joint submissions but could be addressed by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional effort will be needed to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator
Number of REACH dossiers involving UK companies for which (exposure-based) waiving is allowed as opposed to vertebrate testing	Directly informs on adoption of alternative approaches and is specific to REACH. May also be targeted to inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	Possible issues in establishing the roles played by UK companies in joint submissions but could be addressed by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional effort will be needed to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator

5.14 Objective Minimise the Use of Vertebrates in the Testing of Chemicals that Fall within the Scope of REACH and CLP

5.14.1 Indicators

These indicators relate mainly to the evaluation of REACH. However, two more general indicators of animal use have been identified that might be of value for evaluating CLP.

Indicators on the level of vertebrate use in the UK and the proportion of overall European testing that is conducted within the UK draw on readily available and robust data sources. Data are also available on the UK use of more refined methods where several exist (e.g. the local lymph node assay rather than the guinea pig maximisation test to investigate the sensitization potential of a chemical). Other indicators address UK industry involvement in proposals to ECHA for the use of vertebrate testing and the potential savings in animal use from the joint registration procedure encouraged by REACH.

One aspect for which robust indicators could not be identified was the extent to which industry use lower invertebrate species instead of vertebrate tests during research and development. There are no available mechanisms for recording or reliably estimating the extent of lower invertebrates use in testing of chemicals; they are not covered by the Animals (Scientific Procedures) Act.

5.14.2 Confounding Factors

There is some uncertainty about the proportion of vertebrate tests on chemicals in the UK that are undertaken specifically for chemicals falling under REACH. The Home Office advises that the data on toxicity testing of chemicals provide a sufficiently good approximation of REACH-related use to allow valid assessment of trends. This database has the benefit of allowing direct comparison with extensive baseline information and has no cost.

The confounding factor of the Cosmetics Directive ban on testing on products, ingredients or combination of ingredients is an issue for many of the indicators. However, the extent of testing undertaken in support of cosmetic substances is expected to be much smaller than that required under REACH. In addition, the UK has not allowed the testing of cosmetic products or substances specific to cosmetics use on animals since 1998. The Home Office might consider modification of the categories if specifically requested by Defra, although this could be costly and would involve disruption and delay and the loss of a robust baseline dataset. Such a request would also have to be judged against the Division's Better Regulation target for reduction of burdens.

Two of the indicators considered ('Number (by species) of vertebrate used for testing of chemicals in UK' and 'Relative proportion of traditional to more refined test methods using vertebrate animals in the UK') are also potentially relevant to CLP, although REACH will be the main driver. For these purposes, it has been assumed

that they are relevant to REACH but may also be a co-indicator for CLP (to overcome the risk of confounding).

The indicator on the proportion of vertebrate testing conducted in the UK compared with the rest of Europe will require careful interpretation, as the UK has a significant proportion of total EU testing capacity. For example, in 2005 the EU used 96,000 animals in the testing of chemicals of which 25% (24,000) were used in the UK. This is largely a reflection of the UK's of extensive contract toxicology testing facilities which may rise over the period of REACH. However, the UK has amongst the highest standards for animal welfare in the world, ensuring that testing is conducted to minimise suffering and distress.

5.14.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.14. The indicators have been assessed only for their potential value to the evaluation of REACH; none are considered of key relevance to CLP. The majority of indicators are REACH specific; most are based on relatively-robust data sources, although some manipulation or further investigations may prove necessary.

The value of indicators on the extent of use of alternative and traditional testing approaches by registrants will largely depend on the ease of extraction of data from the REACH-IT database and whether the roles played by UK companies can be determined. Since they are not anticipated to form part of the legal minimum reporting requirements, they have been suggested as suitable candidates for inclusion in REACH Option level 2. It may be useful to re-examine their relative ease of collection at a later date to ascertain if any are easier to collect (e.g. as a result of the database structure) or provide more robust or easier to interpret data. If this is the case, the more economic indicators can be given preference during the final selection.

5.14.4 Results of Scoring and Weighting

Most indicators scored highly across all the scenarios. High scores were achieved for the indicators relating to changes in the pattern of animal usage within the UK. Two of these were also considered suitable to potentially informing on the impact of CLP on animal usage.

The indicators on changes in the pattern of reliance between traditional and alternative approaches in the submissions to ECHA scored highly. However, there is a larger degree of uncertainty as to the robustness of these scores. The lowest scores were for the indicator 'Estimated savings of animal numbers for ECHA approved tests due to operation of SIEFs/Joint registrations involving one or more UK companies' because of concerns about the quality of data, the costs and, in particular, the ability to adjust for confounding factors.

Table 5.14: Objective: Minimise the Use of Vertebrates in the Testing of Chemicals that Fall within the Scope of REACH and CLP					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Promote Minimisation Of Use Of Vertebrates In The Testing Of Chemicals For REACH and CLP					
Number (by species) of vertebrate used for testing of chemicals in UK	Data highly specific to UK and relevant to REACH (subject to some limitations) Targeted survey of licensees could provide additional information	Draws on Home Office Animal use records so expected to be robust	Data will include tests for non-REACH- and non-CLP requirements. Other legislation may also have an impact. Home Office is confident that expert judgement will be able to address this	Basic datasets are readily available . Minimal additional costs for questioning of licensees Targeted survey of licensees could be more expensive	Recommended for Option 2 of REACH Potentially relevant to CLP but not considered a prime indicator
Change in proportion of total EU usage of animals conducted by UK	Information includes that specific to UK but also reliant on data submitted by other Member States. Should inform on REACH	Draws on European Commission Animal use records for Member States collected under Directive 86/609/EEC so reasonably robust, but may differ across Member States.	Variation in classification systems and reporting practices of MSs. Changes in testing capacity of different MS may also influence proportions over time. Careful study design should clarify this	Data are already collected but will require additional collation, formatting and analysis	Recommended for Option 2 of REACH. Not considered a CLP indicator
Relative proportion of traditional to more refined test methods using vertebrate animals in the UK	Data highly specific to UK and relevant to. However, is subject to some limitations	Draws on Home Office Animal use records so expected to be robust	Data will include tesets non-REACH- and non-CLP requirements. Other legislation may also have an impact. Home Office is confident that expert judgement will be able to address this	Basic datasets readily available. Minimal additional costs for questioning of licensees Targeted survey of licensees could be more expensive	Recommended for Option 2 of REACH. Potentially relevant to CLP but not considered a prime indicator
Numbers of REACH dossiers including vertebrate test proposals involving one or more UK companies	Directly informs on adoption of alternative approaches and is specific to REACH. May also inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	May be issues regarding the roles of UK companies in joint submissions; could be addressed by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional cost to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator

Table 5.14: Objective: Minimise the Use of Vertebrates in the Testing of Chemicals that Fall within the Scope of REACH and CLP					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Proportion of vertebrate test proposals agreed to by ECHA involving one or more UK companies	Directly informs on adoption of alternative approaches and is specific to REACH. May also inform on approaches being adopted by UK companies	Derived from REACH-IT via CA, so expected to be robust.	Possible issues regarding the roles of UK companies in joint submissions; could be addressed by careful study design and/or, case studies. Decision to accept test proposal is made by ECHA not UK.	May be possible for CA to readily extract information. Additional cost will be incurred to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator
Estimated savings of animal numbers for ECHA approved tests due to operation of SIEFs /Joint registrations involving one or more UK companies	Directly informs on role of REACH in limiting number of tests undertaken, but decision is made at the EU level. May also inform on approaches being adopted by UK companies	Basic source data derived from REACH-IT via CA, so expected to be robust, but would then require use of series of assumptions to derive final indicator data	May be issues regarding establishing the roles of UK companies in joint submissions but could be addressed by careful study design and/or case studies	May be possible for CA to readily extract information. Additional cost will be incurred to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 3 of REACH. Not considered to be a CLP indicator
Number of UK stakeholder submissions in favour and against acceptance of vertebrate testing involving UK companies	Directly informs on views of UK stakeholders on use/reliability of alternative test strategies and is specific to REACH	Derived from REACH-IT via CA, so expected to be robust. Could be supplemented by case studies	May be issues regarding establishing the roles played by UK companies in cases of joint submissions but should be possible to address by careful study design and, if necessary, case studies	May be possible for CA to readily extract information. Additional cost will be incurred to clarify role of UK companies and analyse data (or conduct case studies)	Recommended for Option 2 of REACH (or Option 3 because of increased costs if case studies are required). Not considered to be a CLP indicator

5.15 Objective: Support the Efficient Operation of the REACH and CLP Process by UK Government and Governmental Organisations

5.15.1 Indicators

A series of indicators has been identified on the contribution made by UK government bodies towards the REACH and CLP implementation processes. These are largely quantitative measures, such as staff days expended (and associated staff and non-staff costs incurred) in support of various activities at the European, international or national level, numbers of key documents prepared/reviewed, etc. The indicators reflect the requirements envisaged under several of the Themes (especially 2, 3, and 4) proposed by the Working Group for the Forum for Exchange of Information on Enforcement. Relevant activities are likely to include:

- at the European level, participation in/support of REHORN, RHEP, Enforcement forum, CARACAL, ECHA SEA committee, ECHA risk assessment committee, ECHA consultations/events; numbers of Annex XV dossiers prepared/commented on, numbers of documents prepared/commented on (substance evaluations, restriction dossiers, etc) and other relevant EU activities;
- at the national level, numbers of UK enforcement actions, resource expenditure in support of enforcement co-ordination and other relevant UK-based activities, scale of REACH awareness/promotion events supported by UK government (in terms of budget, number of events, number participants etc.); and
- international activities in support of REACH and CLP beyond European fora (such as OECD test method support and UN GHS development support).

Obtaining information on these indicators should not be particularly onerous although data capture systems may have to be introduced across a number of government organisations.

The extent of activities undertaken in support of the ESR/NONS regulatory framework may provide a baseline for REACH. Similarly work undertaken in support of CHIP may provide a baseline for CLP. One possible option is to develop the baseline from the contribution of the UK government during the negotiation of the REACH and CLP regulations. However, this is considered unsuitable as it would have been distorted by the fact that UK held the presidency during the negotiation stages for REACH and much of the later negotiation regarding CLP took place within fora set up for the implementation of REACH.

5.15.2 Confounding Factors

CA data are routinely recorded so are readily available. However, one of the levels of enforcement, local authorities (LAs), have no legal obligation to report on their REACH activities, including enforcement activities. LA data would have to be obtained by a survey of LAs. These data are likely to be fragmentary at best and expensive to obtain. Therefore, it is not recommended that evaluations include such data.

There is significant overlap between work undertaken to implement REACH and that undertaken to implement CLP. However, this confounding factor should be largely overcome by the integrated evaluation of REACH and CLP proposed here.

5.15.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.15. Five of the indicators were identified for Option 1 for CLP and three indicators were identified for Option 1 for REACH. All but one of the indicators are of high quality and the data are obtainable at low cost; where not needed for Option 1, they are therefore recommended for Option 2 for REACH and CLP as relevant. The remaining indicator 'cost to HPA from adapting emergency response guidance in the light of CLP' would have been recommended for Option 3 for CLP but will be needed for Option 1. This indicator is not of relevance to the evaluation of REACH.

5.15.4 Results of Scoring and Weighting

All of the indicators scored highly for specificity to the evaluation of REACH and CLP except for two indicators referring to the Health Protection Agency (HPA) and the National Poisons Information Service (NPIS) respectively, which only inform CLP.

All indicators scored highly under Systems A and C demonstrating that they are of high quality and specificity. In addition, most scored highly under Systems B and D demonstrating that they had few confounding factors and could be obtained at low cost. The only exception was 'cost to HPA from adapting emergency response guidance in the light of CLP' for which there would be more confounding factors because adaptations are ongoing and likely to occur for many reasons other than CLP.

Table 5.15: Objective: Supporting the Efficient Operation of the REACH and CLP Process by UK Government and Governmental Organisations					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Efficient Participation in REACH and CLP Implementation Process by UK Government					
Cost of training of emergency service staff	Not relevant to the evaluation of REACH. Highly relevant to the evaluation of CLP	High quality data from UK ambulance services	Some confounding factors as CLP training is likely to be part of other training but can be corrected	Low - data available but collation and analysis needed	Not considered further for the evaluation of REACH. Would have been recommended for Option 2 for CLP but needed for Option 1
Cost of training of enforcement officers	Highly relevant to the evaluation of REACH and CLP	High quality data from UK enforcement bodies	As above	As above	Recommended for Option 2 for REACH and needed for Option 1 for CLP
Cost saving from having a common CA and enforcement for REACH and CLP	As above	As above	No confounding factors	As above	Recommended for Option 2 for REACH and CLP but may be needed for Option 1 for CLP
Cost to emergency response bodies from adapting emergency response guidance in the light of CLP (CLP Article 45)	Not relevant to the evaluation of REACH. Highly relevant to the evaluation of CLP	High quality data from UK government	Adaptations are ongoing but it is anticipated that impacts due to CLP may be differentiated	As above	Not considered further for the evaluation of REACH. Included in Option 2 for CLP but may be needed for Option 1
Number of emergency health responses by emergency response bodies regarding mixtures (CLP Article 45)	As above	As above	Where no alternative name is requested, the composition and hazards may be apparent without reference to Article 45 of CLP	As above	As above
Format of data held by emergency response bodies (CLP Article 45)	As above	As above	No confounding factors	As above	Not considered further for the evaluation of REACH. Recommended for Option 2 for CLP but may be needed for Option 1
Nature of data held by emergency response bodies (CLP Article 45)	As above	As above	No confounding factors	As above	As above

Table 5.15: Objective: Supporting the Efficient Operation of the REACH and CLP Process by UK Government and Governmental Organisations					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Number of requests for statistical analysis submitted to emergency response bodies (CLP Article 45)	As above	As above	No confounding factors	As above	As above
Number of preventative or corrective measures prepared by emergency response bodies (CLP Article 45)	As above	As above	No confounding factors	As above	As above
Nature of preventative or corrective measures prepared by emergency response bodies (CLP Article 45)	As above	As above	No confounding factors	As above	As above
Number of proposals for harmonised classification (from UK government with reason)	Highly relevant to the evaluation of REACH and CLP	As above	No confounding factors	Low - data available and little analysis needed.	Recommended for Option 2 for REACH and CLP
Numbers and nature of REACH and CLP enforcement actions	As above	As above	As above	Relatively low - data available but collation and analysis needed	Would have been recommended for Option 2 for REACH but needed for Option 1. Recommended for Option 2 for CLP but may be needed for Option 1
Person days for REACH and CLP awareness/ promotion events (CA and other government bodies)	As above	As above	As above	Low - data available and little analysis needed	Recommended for Option 2 for CLP and needed for Option 1 for REACH
Person days of CA helpdesk activity	As above	As above	As above	As above	As above
Person days of REACH and CLP website development (CA and	As above	As above	REACH and CA website development by bodies other than CA may be part	Relatively low - collation and analysis of data needed	Recommended for Option 2 for REACH and CLP

Table 5.15: Objective: Supporting the Efficient Operation of the REACH and CLP Process by UK Government and Governmental Organisations					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
other government bodies)			of wider website development		
Person days of REACH and CLP activity at EU level by type (CA and other government bodies)	As above	As above	No confounding factors	Low - data available and little analysis needed	As above
Person days of REACH and CLP activity at UK level by type (CA and other government bodies)	As above	As above	As above	As above	As above

5.16 Objective: Ensure the Adequacy of the UK Government Resource Base to Meet REACH and CLP Obligations

5.16.1 Indicators

In order to facilitate the efficient implementation of REACH and CLP, UK government departments will require sufficient resources to fulfil their responsibilities. The majority of the indicators identified require basic costs and numbers that should be readily available from departmental records. The adequacy of the skill sets of staff assigned to government bodies will need to be obtained through interviews with departmental managers.

5.16.2 Confounding Factors

Demand for the skills identified is likely to be highest six to twelve months prior to each REACH phase-in registration deadline, with the greatest demand likely to be prior to the first deadline of 1 December 2010. This is also the deadline by which substances should be classified according to CLP. Therefore, monitoring should be put in place for each indicator as soon as possible.

5.16.3 Results of Indicator Assessment

The results of the assessment are set out in Table 5.16. All indicators except 'adequacy of skill sets of staff assigned to REACH' and 'CLP activities and Budget for REACH and CLP work' are needed for Option 1 for the evaluation of the UK RIA for CLP. A further four indicators are needed for Option 1 for REACH.

5.16.4 Results of Scoring and Weighting

All indicators are high quality, low cost indicators recommended for Option 2 for REACH and CLP where not required for Option 1.

Table 5.16: Objective: Ensuring the Adequacy of the UK Government Resource Base to Meet REACH and CLP Obligations					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Ensure Adequate Resourcing by UK government					
Adequacy of skill sets of staff assigned to REACH and CLP activities (CA and other government bodies)	Highly relevant to the evaluation of REACH and CLP	High quality data from UK government	No confounding factors	Low - data available and little analysis needed	Recommended for Option 2 for CLP and needed for Option 1 for REACH
Budget for REACH and CLP work (CA and other government bodies)	As above	As above	As above	As above	Recommended for Option 2 for CLP and REACH
Cost of CA helpdesk	As above	As above	As above	As above	Recommended for Option 2 for REACH and CLP but may be needed for Option 1 for CLP
Cost of CA website	As above	As above	As above	As above	As above
Cost of REACH and CLP activity at EU level by type (CA and other government bodies)	As above	As above	As above	As above	As above
Cost of REACH and CLP activity at UK level by type (CA and other government bodies)	As above	As above	As above	As above	As above
Cost of REACH and CLP awareness/ promotion events supported by CA	As above	As above	As above	As above	As above
Numbers of staff assigned to REACH and CLP activities (CA and other government bodies)	As above	As above	As above	As above	Recommended for Option 2 for REACH and CLP. May be needed for Option 1 for CLP and needed for Option 1 for REACH

5.17 Objective: Encourage the Efficient Operation of the REACH and CLP Process by UK Industry

5.17.1 Indicators

Indicators have been identified for the extent of involvement by UK companies in REACH processes, including pre-registration, registration, notifications and authorisations.

If REACH is operating efficiently, the regulatory burden on industry should be kept to a minimum. Indicators for the sub-objective 'Minimising Regulatory Burden' therefore include measures of the costs to industry of meeting its obligations. These can be compared to the costs predicted in the UK and other impact assessments. REACH includes measures designed to reduce compliance costs to industry, through data sharing in SIEFs and joint registrations and indicators are therefore included for these. The burden on SMEs was of particular concern during the development of REACH, and a number of indicators have been included which are specifically aimed at measuring the impacts on SMEs. Gathering data on costs will require surveys (potentially conducted jointly with industry associations) or case studies. These could be combined with the case studies for the objective 'Enhance Competitiveness and Innovation'.

An additional aspect that should be considered are cost savings associated with any reduced impacts of chemicals on occupational health and the environment. Indicators have been identified with the aim of capturing the financial or economic value of any changes in the incidence of occupational ill-health or public ill-health, or in the costs of addressing environmental damages (with these linked to the objectives on 'ensuring a high level of protection of human health and the environment from the risks that can be posed by chemicals').

The UK RIA made a range of predictions about the impact on UK industry from the implementation of CLP. Where the indicators for impacts on industrial activities identified for the evaluation of REACH were also relevant for CLP, a combined REACH and CLP indicator has been adopted. Additional indicators were added to inform the evaluation of the CLP RIA where needed. The majority of the impacts from the CLP will occur as part of its implementation and therefore many of the indicators set out here are likely to be critical to its evaluation.

5.17.2 Confounding Factors

It is likely that there will be changes over time in the patterns of response by various sectors of UK industry, reflecting the staged nature of REACH implementation.

Baselines for industry involvement with REACH or CLP processes may be drawn from the REACH implementation assessments, the Eurostat baseline initiative and predictions made by various industry associations. However, additional information may be required to establish UK–specific baselines, for example from case studies.

For many of the indicators, data will have been recorded under regimes predating REACH, such as ESR, NONS, IPPC and discharge consent controls. Data recorded under CHIP will be of relevance to CLP. However, there is likely to be considerable difficulty in establishing a robust baseline and ascribing subsequent trends or changes to REACH or CLP, given the large number of regulatory initiatives over recent years that may have influenced the chemical industry, changes in activity levels by industry over the period between the inception and implementation of REACH and then CLP, and the significant changes that have occurred in the general global economy. In particular, establishing the profitability of various sectors and company types would require detailed interviews to identify the contribution specifically attributable to REACH and CLP.

Many of the suggested data sources for these indicators are similar to those for other objectives, in particular 'Enhancing Competitiveness and Innovation'. The use of combined surveys or case studies should help to ensure consistency across different objectives and costs will be kept to a minimum.

5.17.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.17. Two of the indicators are needed for Option 1 for REACH and 15 for Option 1 for CLP. This reflects the relative importance of implementation impacts to the evaluation of CLP.

Eleven indicators are of no relevance to the evaluation of REACH and will be carried forward for the evaluation of CLP only. Thirteen indicators were of no relevance to the evaluation of CLP and will be carried forward for the evaluation of REACH only.

Of the twelve remaining indicators, two ('savings in environmental management costs due to better information on chemicals used' and 'savings in occupational health costs due to better information on chemicals used') were found to have only limited relevance to either evaluation. However, in both cases the quality of the data was high and the cost of obtaining that data was low, so they were recommended for Option 4.

5.17.4 Results of Scoring and Weighting

The assessment summarised in Table 5.17 provides the basis on which scores were assigned to the indicators. The full set of scores arising from the scoring and weighting exercises can be found in Annex 3.

Table 5.17: Objective: Encourage the Efficient Operation of the REACH and CLP Processes by UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Encourage Participation of UK industry in REACH and CLP processes					
Number of authorisation applications (UK based)	Highly specific indicator for REACH. Not relevant to the evaluation of CLP	High quality REACH-IT data	Not always clear whether data are UK specific	Low - data readily available but will require collation and analysis	Recommended for Option 2 for REACH. Not considered further for CLP
Number of phase-in registrations by each deadline (UK based) by manufacturers and importers	As above	As above	As above	As above	Recommended for Option 2 for REACH but needed for Option 1. Not considered further for CLP
Number of manufacturers and importers (UK based)	Background indicator for REACH; provides some background information of relevance to CLP	High quality REACH-IT and ONS data	As indicator	As above	Recommended for Option 2 for REACH and Option 3 for CLP
Number of notifications of SVHCs in articles by UK based companies	Highly specific indicator for REACH. Not relevant to the evaluation of CLP	High quality REACH-IT data	As above	As above	Recommended for Option 2 for REACH. Not considered further for CLP
Number of proposals for harmonised classification (from industry, with reason)	Highly specific indicator for REACH and CLP	REACH-IT data plus industry reported data with limited cross-checking	No confounding factors	Low - readily available data. Little analysis needed	Recommended for Option 3 for REACH and CLP but needed for Option 1 for CLP
Number of notifications of classification and labelling under CLP by UK based companies	Not relevant to the evaluation of REACH. Highly specific indicator for CLP	High quality REACH-IT data	As above	Low - rata readily available but will require collation and analysis	Recommended for Option 2 for REACH and CLP but needed for Option 1 for CLP
Sub-objective: Minimise the Regulatory Burden and Maximise Benefits					
Cost of stock disposal due to CLP changes	Not relevant to REACH. Highly specific indicator for CLP	Some cross-checking across industry consultation	Needs correction for normal business activity without CLP	Moderate - new survey required but costs shared between many indicators	Not considered further for REACH. Recommended for Option 3 for CLP but needed for Option 1
Expenditure by industry informing customers of	Highly specific indicator for REACH and CLP	As above	Needs correction for normal business activity	As above	Recommended for Option 3 for REACH and CLP but

Table 5.17: Objective: Encourage the Efficient Operation of the REACH and CLP Processes by UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
changes due to REACH and CLP			without REACH or CLP		needed for Option 1 for CLP
Expenditure by industry on relabelling due to CLP (set-up and ongoing)	Not relevant to the evaluation of REACH. Highly specific indicator for CLP	As above	Needs correction for normal business activity without CLP	As above	Recommended for Option 3 for REACH and CLP but needed for Option 1 for CLP
Expenditure by industry on repackaging due to CLP (set-up and ongoing);	As above	As above	As above	As above	Recommended for Option 3 for REACH and CLP but needed for Option 1 for CLP
Expenditure by industry on updating and/or replacement of IT systems due to REACH and CLP	Highly specific indicator for REACH and CLP	As above	Needs correction for normal business activity without REACH or CLP	As above	Recommended for Option 3 for REACH and CLP but needed for Option 1 for CLP
Expenditure on by industry on staff training due to REACH and CLP	As above	As above	Needs correction for normal business activity without REACH or CLP	As above	Recommended for Option 3 for REACH and CLP but needed for Option 1 for CLP
Expenditure on REACH authorisation	Highly specific indicator for REACH. Not relevant to the evaluation of CLP	As above	No confounding factors	As above	Recommended for Option 2 for REACH. Not considered further for CLP
Expenditure on REACH registration	As above	As above	As above	As above	Recommended for Option 2 for REACH but needed for Option 1. Not considered further for CLP
Expenditure on reclassification of mixtures due to introduction of CLP	Not relevant to the evaluation of REACH. Highly specific background indicator for CLP	As above	As above	As above	Not considered further for REACH. Recommended for Option 2 for CLP but needed for Option 1
Expenditure on reclassification of substances due to introduction of CLP	As above	As above	As above	As above	As above

Table 5.17: Objective: Encourage the Efficient Operation of the REACH and CLP Processes by UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Consumer confidence in chemicals industry	Good level of specificity for REACH and CLP article 34	High level of quality control but data based on opinion only	Many confounding factors with limited possibility for correction	High - new consumer survey shared between few indicators	High cost indicator with many confounding factors. Not considered further for REACH or CLP
Cost of changes to obligations under downstream legislation triggered by CLP	Not relevant to the evaluation of REACH Highly specific indicator for CLP	Some cross-checking will be required through industry consultation	Few confounding factors and scope for correction	Moderate - new data from survey shared between many indicators	Not considered further for REACH. Recommended for Option 3 for CLP
Cost savings from using REACH registration data for reclassification of substances	As above	As above	No confounding factors	As above	Not considered further for REACH. Recommended for Option 3 for CLP
Costs of updating SDS due to REACH and CLP	Highly specific indicator for REACH and CLP	As above	As above	As above	Recommended for Option 3 for REACH and CLP
Level of consumer understanding of hazard labels under CLP as compared to hazard labels under CHIP	Not relevant to REACH Highly specific background indicator for CLP	High level of quality control but data based on opinion only	Consumer opinion of chemicals affected by many experiences and campaigns	Moderate - new consumer survey shared between few indicators	Recommended for Option 2 CLP but needed for Option 1 for CLP. Not considered further for REACH
Number of campaigns by NGOs and trade unions on chemicals use	Highly specific background indicator for REACH and CLP	Simple data needed that may be gathered with high level of quality control	Campaigns on chemical issues other than REACH or CLP. Scope for correction	High - new survey with no sharing between indicators. Limited data needed and easily obtained	Recommended for Option 2 for REACH and CLP
Number of joint registrations versus individual registrations	Highly specific indicator for REACH No relevance to the evaluation of CLP	Some cross-checking required through industry consultation	May be valid business reasons for individual registrations	As above not from REACH-IT??	Recommended for Option 3 for REACH. Not relevant to CLP
Number of REACH dossiers updated for classification changes (with reason for change)	Highly specific indicator for REACH and CLP	As above	As above	As above??	Recommended for Option 3 for REACH and CLP
Number of separate lists of prohibited substances	Background indicator for REACH but limited	As above	The preparation of lists can have many reasons	High - new survey with little sharing between	Recommended for Option 4 for REACH. Not relevant to

Table 5.17: Objective: Encourage the Efficient Operation of the REACH and CLP Processes by UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
prepared by retailers	relevance to CLP		outside of operation of regulations	indicators.	CLP
Number of SMEs reducing manufacture/import to below 1t/y to avoid registration costs	Highly specific indicator for REACH. No relevance to the evaluation of CLP	As above	Many confounding factors and limited scope for correction	Moderate - new data from survey shared between many indicators	As above
Number of SMEs taking advantage of reduced registration fees	As above	High quality REACH-IT data	No confounding factors	Low – although some analysis needed	Recommended for Option 2. Not considered for CLP
Number of substances (and mixtures) reclassified using Annex VII alone	Not relevant to REACH. Highly specific indicator for CLP	Industry data with no cross-checking possible	As above	Moderate - new data from survey shared between many indicators	Not relevant to REACH. Recommended for Option 2 but needed for Option 1
Problems encountered with SIEFs	Highly specific indicator for REACH, not relevant to CLP	As above	As above	As above	Recommended for Option 2 for REACH. Not relevant to CLP
Savings in data costs due to SIEFs	Highly specific indicator for REACH. Limited relevance to CLP (cost of classification using REACH data)	As above	As above	As above	As above
Time taken by consumers to familiarise themselves with CLP	Not relevant to REACH. Highly specific indicator for CLP	Some cross-checking form survey but very subjective	No confounding factors	High - new consumer survey shared between few indicators	Not relevant to REACH Recommended for Option 3 but needed for Option 1 for CLP
Sub-objective: Establish Economic Benefits from Improvements to Human and Environmental Health					
Savings in environmental management costs due to better information on chemicals used	Limited relevance to REACH or CLP	As above	Costs affected by many factors other than REACH or CLP	As above	Recommended for Option 4 for REACH
Savings in occupational or public health costs due to better information on	As above	As above	As above	As above	As above

Table 5.17: Objective: Encourage the Efficient Operation of the REACH and CLP Processes by UK Industry					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
chemicals					

5.18 Objective: Encourage the Provision of an Adequate Resource Base by UK Industry with which to meet REACH and CLP Obligations

5.18.1 Indicators

In order for industry to be able to fulfil its obligations, it will require skilled personnel including toxicologists, ecotoxicologists and risk assessors for chemical safety assessments. Consultation undertaken as part of this study has found that industry has concerns about the availability of sufficient skilled personnel. As a result, indicators have been included to monitor the number of skilled personnel available and the adequacy of the resource base, as perceived by chemical companies.

5.18.2 Confounding Factors

The current survey of the UK's toxicology and ecotoxicology capacity, sponsored by Defra, is particularly timely for establishing a robust baseline and consideration should be given to conducting similar surveys for other disciplines (such as environmental scientists and risk assessors) needed to support the regulatory process.

Baseline estimates of overall testing requirements under REACH were derived for the various national and EU impact assessments and these included evaluation of the testing capacities needed to support them. Within the UK context it would be important to ascertain the extent of in-house and contract laboratory capacity, and the extent to which individual organisations are able and willing to undertake testing for REACH and CLP.

5.18.3 Results of Indicator Assessment

The results of the assessment are summarised in Table 5.18. All the indicators were highly relevant to the evaluation of REACH but of little relevance to the evaluation of CLP. Therefore, none of these indicators will be carried forward for CLP.

5.18.4 Results of Scoring and Weighting

Each indicator scored a maximum five for specificity to the evaluation of REACH but only one for specificity to CLP. All indicators scored two for confounding factors and three for cost. The quality of the data did not greatly differ between the indicators but did drop from four to three for 'adequacy of scientific and technical resource base available to industry for demands of REACH and CLP'. This indicator therefore scored significantly worse than the others under System C while scoring almost identically under System D.

Each is recommended for Option 4.

Table 5.18: Objective: Encouraging the Provision of an Adequate Resource Base by UK Industry with which to meet REACH and CLP Obligations					
Indicator	**Specificity**	**Quality of Information**	**Confounding Factors**	**Cost**	**Recommendation**
Sub-objective: Encourage Provision of Adequate Scientific and Technical Resource Base for UK Industry with which to meet REACH Obligations					
Adequacy of scientific and technical resource base available to industry for demands of REACH and CLP (FTEs, skill set and reasons)	Highly specific indicator for REACH. Limited relevance to evaluation of CLP	Industry data of unknown quality. Some cross-checking possible	Many confounding factors from other legislation and economic factors	New data from survey of manufacturers and users shared between many indicators	Recommended for Option 4 for REACH. Not considered further for CLP
Capacity of UK contract laboratories and extent of involvement in REACH support activities (FTEs, skill set and reasons)	As above	Data from open invitation survey only of labs. Limited opportunity for quality control	As above	Data available but collation and analysis needed	As above
Numbers of toxicologists/ ecotoxicologist and risk assessors based in the UK	As above	As above	As above	As above	As above

6. DATA SOURCES AND COSTS

6.1 Introduction

The costs of obtaining data will depend to a large extent upon the ease of data collection, extraction and analysis. This section sets out the data sources of relevance to the evaluation of REACH or CLP, identifies the data held by these sources (data sets) and provides estimates of the costs that may be incurred in collecting these data in a form appropriate to these evaluations. The costs set out here are estimates based on past experience and provide an indication only of the potential evaluation costs. Significant additional work would be required to develop more detailed and reliable cost estimates.

6.2 Competent Authority and other Governmental Bodies

The records of the Competent Authority/ies for REACH and CLP (CA) and other governmental bodies will provide data for a number of indicators. Much of the data will be being recorded and readily extractable for use. In such cases the cost of obtaining data is assumed to be essentially zero. However, from consultation it is clear that other data, although recorded, may not be held in a form that is readily extractable from the available recording systems while others may need to be recorded for the first time and hence would require the establishment of procedures in the relevant departments. Staff time will therefore be needed in order for these systems to be created and the data to be provided. It is estimated that this personnel time may amount to between one half day and two days per organisation.

Twenty six government departments, agencies and other government bodies have been identified as being of relevance:

- Centre for Environment, Fisheries & Aquaculture Science (Cefas);
- Competent Authority (within HSE);
- Competent Authority Enforcement Group;
- Department for Business Innovation and Skills (BIS, formerly BERR);
- Department for Business Innovation and Skills, Chemicals Regulatory Forum (BIS CRF);
- Department for Environment Food and Rural Affairs (Defra);
- Department for Environment Food and Rural Affairs, Chemicals Stakeholder Forum (Defra CSF);
- Department of Environment Northern Ireland (DOE);
- Department of Health (DH);
- Environment Agency (EA);
- Government Chemist at LGC;
- Health Protection Agency (HPA);
- Health and Safety Executive (HSE) – Enforcement Group;
- Health and Safety Executive (HSE) – Epidemiology Group;
- Health and Safety Executive (HSE), International Chemicals Unit (ICU);

- Home Office Animals In Scientific Procedure Division (Policy);
- National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs);
- National Educational Network for Ambulance Services (NENAS);
- Northern Ireland Environment Agency (NIEA);
- Scottish Environmental Protection Agency (SEPA);
- Scottish Executive;
- Welsh Assembly Government.

It is assumed that the REACH-IT database is available to CAs. If data are easily extracted, the required data might be gathered in between one half and two days at a cost of between £250 and £1000. However, the structure and functionality of the REACH-IT system is as yet uncertain and should data extraction prove difficult (or require significant manual review or manipulation) then costs might rise to £20,000 or more. It is likely that the time and cost of extracting data from REACH-IT will fall somewhere between the two extremes and therefore an estimate of £10,000 has been adopted.

It is understood that the data available from WRAP are in a form readily usable for the evaluation of REACH or CLP. It is therefore estimated that the time taken to obtain this data will be two days for each round of data gathering at a cost of about £1000 in staff time.

Many of the remaining bodies are identified as sources of very specific data only such as Cefas (monitoring data) and NENAS (training costs). Other bodies are sections within other departments (e.g. the ICU within HSE) which are costed under their parent department. The personnel time needed to obtain data from the remaining organisations is therefore estimated to be between seven days and fourteen days at a cost of between £3500 to £7000.

The costs detailed above would be incurred each time data are collected. Governmental activity in support of the implementation of REACH or CLP is likely to be highest up until and shortly after the first phase-in deadline for registration (1 December 2010). It is therefore suggested that data be collected annually. However, should it be found that activity levels have settled to a more or less constant value, then consideration could be given to collecting data at five yearly intervals.

6.3 Surveys of Industry and Case Studies

Following consultation undertaken as part of this study, it is expected that industry associations will help to facilitate surveys and case studies involving industry stakeholders.

Both surveys and case studies will need to be designed, consultees will need to be sourced and contacted and findings will need to be clarified and reported. From experience of undertaking such consultation, it is estimated that a UK-wide survey of industry could cost in the range of £45,000 to £60,000 for the first reporting period. It

is assumed that less time would be needed to set up follow-up surveys so it is estimated that these may cost between £25,000 and £40,000. Undertaking case studies across the UK could cost between £35,000 and £50,000 for the first reporting period, falling to between £20,000 and £30,000 thereafter. However, these are preliminary estimates only and the exact cost will depend on the scope and specific design of the survey and the organisation by which it is carried out. There may also be additional costs in interpreting and reporting the information gathered.

Surveys and case studies should include representatives of suppliers, downstream users and retailers from a range of industry sectors and company sizes. The lower costs provided here relate to consultation exercises of specific industry sectors (e.g. the waste recovery sector) conducted in isolation. The higher costings relate to consultation exercises that cover a wider range of industry sectors of interest.

If a limited survey of retailers was combined with a wider industry survey, it is estimated that this may cost an additional £10,000 to £15,000. However, if such surveys were to be conducted separately the total cost would be significantly higher.

Should it be necessary to survey UK laboratories and risk assessment companies providing REACH related services, this would involve entirely different companies from those already considered. In addition, companies would need to be identified and contacts sought without the aid of trade associations. It is estimated that such a survey might cost in the region of £45,000 to prepare and conduct, with reductions in cost of £5000 for subsequent rounds of data gathering.

6.4 Office of National Statistics, Eurostat

The Office of National Statistics (ONS) makes available a great deal of data via its standard publications. However, the categories used and the frequency of publications may not always fit the requirements of REACH or CLP evaluation and reporting.

Business enquiry data may be downloaded from the ONS Internet site for one 'project' for £125 plus VAT, with limited additional data requests free of charge. Alternatively, ONS could prepare all available data to the requirements of REACH and/or CLP evaluation. For this service ONS would charge £70 for the first hour and £35 for each subsequent hour; it is estimated that ONS may need no more than one or two hours to prepare the data package. These estimates are for the first reporting period but costs are not expected to alter significantly in the future.

Limited data will also need to be downloaded from the Eurostat Prodcom database. It is estimated that this would take no more than one half day and cost approximately £250 in staff time, for the first and each subsequent reporting period.

6.5 National Centre for Social Research

A survey would be needed to provide data on the level of consumer understanding of the right to request information about SVHCs in articles. Conducting a consumer survey purely to provide data for the evaluation of REACH or CLP is estimated to cost in the region of £100,000. It is therefore suggested that a question(s) should be added to an existing survey.

A consumer survey could be undertaken as part of the British Social Attitudes survey (BSA) undertaken by the National Centre for Social Research (NatCen). The BSA is undertaken in the summer of each year and one to five questions may be added for approximately £5000 per survey round. Alternatively, questions may be included in the NatCen Omnibus survey. The Omnibus survey is conducted quarterly and questions may be included at a cost of £2025 per question per survey round.

With regard to the evaluation of REACH the first report must be submitted to the Commission by 1 June 2010. Therefore, data gathering for the next BSA will be too late to be of use for this report. However, NatCen will be gathering data for the Omnibus Survey in the first months of 2010 for which data will be available in March 2010. Such data would be in time for inclusion in the first UK REACH report. NatCen have indicated that to be included in this first 2010 Omnibus survey, questions would need to be provided to them before the Christmas holidays for 2009.

6.6 Trade Unions and NGOs

The TUC, UNITE and GMB are the three trade union organisations identified as potentially having data of relevance to reporting under REACH or CLP. From consultation, it is understood that the TUC may respond on behalf of the other parties but this would need to be confirmed prior to any data collection.

It is expected that discussions, collection of data and reporting would take between three and five days for Defra or HSE personnel and cost between £1500 and £2500 in their staff time for the first reporting period. It is not clear how much staff time would be involved for the trade union organisations, although they indicated a willingness to provide available information. It is expected that the level of effort involved for both Defra and the trade unions would fall for subsequent reporting periods.

The British Union for the Abolition of Vivisection (BUAV), the Fund for the Replacement of Animals in Medical Experiments (FRAME), the Royal Society for the Prevention of Cruelty to Animals (RSPCA), Greenpeace UK and ChemTrust are the NGOs identified as potentially having data of relevance to reporting under REACH or CLP. It is expected that discussions, collection of data and reporting would take between five and eight days and cost between £2500 and £4000 for Defra in the first reporting period. Again, it is not clear how much staff time might be required of those in the above organisations. It is expected that the level of effort required would fall for subsequent reporting periods.

6.7 Academic and Professional Organisations

Although not identified as being needed for any of the indicators, consultation has suggested that a number of academic and professional organisations may have valuable opinions and insights to add to the findings of each UK report. An additional sum of £10,000 to £20,000 might therefore be allocated to obtain data from these organisations (e.g. through a workshop or expert forum)

Academic and professional organisations that may be consulted include:

- Green Chemistry Centre of Excellence, University of York;
- Institute of Chemical Engineers (IChemE);
- Royal Society of Chemistry (RSC);
- Royal Society of Chemistry, Green Chemistry Network (RSC, GCN);
- University of Birmingham, Division of Environmental Health and Risk Management, School of Geography, Earth and Environmental Sciences; and
- Queens University Belfast, Polymer Processing Research Centre.

6.8 Environmental Monitoring Costs

6.8.1 Overview

The costs of carrying out the environmental monitoring needed to evaluate the impact of REACH could vary by orders of magnitude depending on how extensive a sampling and analysis programme is instituted (with such monitoring not relevant to the evaluation of CLP).

The least costly option is to limit requirements to the establishment of a minimal archive bank of samples drawn from one or more of the relevant environmental compartments which are (after appropriate processing) then stored against possible future analysis requirements, such as to demonstrate changes in environmental levels of a particular chemical. Progressively more costly options might involve increasing the range of compartments considered, the number and frequency of sampling sites and the extent of chemical analyses undertaken.

The following illustrative costs have been developed based on experience from past projects and the limited consultations undertaken for this study. They are not intended to be definitive costs but rather to provide indicative estimates of the range and extent of monitoring that might be achieved at varying resource levels.

6.8.2 Air Quality Monitoring

Establishing a Sample Bank

In relation to air quality monitoring in order to minimise resource requirements, it is proposed that samples are taken in conjunction with Defra's existing air quality sampling network which consists of about 115-120 sites. However, it might not be

necessary to sample at all these sites, since the legal reporting requirement under REACH requires samples to be taken by MS at a regional level. In the case of the UK, this might be interpreted as only at the country level (England, Northern Ireland, Scotland and Wales). In addition, samples might be taken at rural and urban areas and highland and lowland regions. Thus, an absolute minimum of ten sampling sites might be adequate.

If passive air samplers were used to collect samples over three-month periods, at a cost of £120 each, then this would entail equipment costs of approximately £1200 per campaign. The cost of the sampling process itself would be minimal, since sampling is taking place at these sites for air quality purposes. It is suggested that the passive air sampling would be undertaken twice yearly (e.g. summer and winter). A nominal staff time has been included to allow for any additional effort/co-ordination involved. The samples would be extracted, at an estimated processing cost of around £800. Extracted samples would then be stored deep-frozen pending possible analysis requirements; the estimated cost of storage might be £5000 over a five-year reporting period. The total cost for establishing this archive bank for air quality samples would therefore be approximately £8000 over the first reporting period.

Sampling costs may be slightly lower for subsequent report periods as the passive samplers are already in place (although equipment would need maintenance and eventually replacing). However, storage costs would be cumulative as more and more samples are added so this element of the cost would double for the second and subsequent reporting periods.

Options for Air Quality Measurement

Establishing a sample bank would be highly desirable as a source for future reference. However, to satisfy our current understanding of the legal requirements for REACH reporting, some analysis will have to be carried out.

A Minimum Air Quality Monitoring Programme (to fit Option 1) might consist of sampling only 10 sites, twice a year and analysing these samples for a maximum of ten substances.

The numbers sampled and level of analysis would be adjusted to develop monitoring programmes suitable for Options 2-4 (i.e. Minimum Plus, Comprehensive and Extensive). The following examples are based on the number of sites and substances detailed in Table 6.1.

Table 6.1: Proposed Air Quality Monitoring Programmes for each Option (1-4)

Option information	Minimum (Option 1)	Minimum plus (Option 2)	Comprehensive (Option 3)	Detailed (Option 4)
No. of sampling sites	10	20	40	60
Sampling frequency / year	2	2	2	2
Number of substances analysed	10	20	50	200
Number of new analytical methods required	0	0	25	100

The Minimum programme contains just enough sites to cover the UK in terms of geographical regions, and to provide a very limited mix of urban and rural sampling sites. However, this scenario would not be extensive enough to allow for a thorough analysis of differences between rural/urban, highland/lowland or inland/coastal sites, etc. Limiting analysis to ten substances (each with analytical methods already developed) also means that it would be necessary to carefully select which chemicals to monitor for.

The Minimum Plus programme suggests twice as many sampling sites which would allow for a better distinction between geographical areas and analysing for 20 substances to enable a more robust picture to be developed. However, this estimate is still based only on substances for which analytical methods are already in place.

A Comprehensive Programme might look at 40 sites, thus allowing for a fair distribution between areas of different social and geographical character. Testing for 50 substances would also allow monitoring for a wider range of chemical types; it has been assumed that 25 of these might require method development.

The Detailed programme is based on undertaking analysis of 200 chemical analyses; this appears a reasonably high number based on the Eurostat Baseline Study list of 237 chemicals. The option, however, assumes half of these will require new analytical methods. Increasing the number of sites to 60 will allow a thorough analysis of differences within the UK. The additional sites under this detailed programme could include sites in areas with a specific industry cluster, to monitor on changes due to a reduction in the use of certain chemicals in that industry (e.g. chemical related industries in the North-East compared to another region where this industry is not present, such as the Highlands of Scotland). It is also sufficiently large to allow some sampling at a local rather than regional level. For instance, near a site using certain chemicals (e.g. near an industrial site using PVC plasticizers and stablisers).

Numerous variations are possible within each of these options. For instance:

- samples could be analysed for a lower number of chemicals straight away and the rest of the samples could be stored against a future need to retrospectively determine baselines and trends;
- sampling sites outside of the existing network may be added, although this would add considerably to costs for locating and renting the site etc.; or
- sampling frequency could be reduced to once per year but that would not allow detection of seasonal variations.

Assumed Costs

A purchasing cost of £120 per passive sampler has been assumed. Only a minimal allowance has been included for collection of the samples as these sites are visited anyway (under the existing monitoring programme).

The sample analysis costs used (£80 per sample) is based on an estimate of likely cost for chemicals for which an established analytical method is already in place. In addition to this, we have assumed £500 in set-up (method development) costs for substances where new methods are required. A storage cost of £25 per sample for a 5-year period has been used to allow for purchasing of freezers, physical storage place, electricity, etc.

A limited number of days have been allowed for reporting once the analytical data are available – the actual number of days allocated to each example would depend on how many samples and substances they involve and what level of analysis was required by Defra.

Based on the illustrative programmes and costs outlined above, the estimated costs of the air quality monitoring programmes for each option are listed in Table 6.2.

Table 6.2: Cost of the four Air Quality Monitoring Programme Options for the First Reporting Period (£k)

Item	Minimum (Option 1)	Minimum plus (Option 2)	Comprehensive (Option 3)	Detailed (Option 4)
Sampling equipment	1.2	2.4	4.8	7.2
Sampling - staff time	2.5	5	10	15
Storage	5	20	100	600
Analysis	16	64	320	1920
Start up cost per substance with new methods	0	0	12.5	50
Reporting	0.5	1.5	4	7.5
Total estimated cost	**23.7**	**89.9**	**445.3**	**2590.7**

6.8.3 Monitoring Other Environmental Compartments

We have estimated the cost for the other environmental compartments based on that of air. Actual cost will depend on factors such as number of sampling sites, chemicals tested for, actual testing cost for each substance, etc. In particular, it is noted that extraction and analysis from some matrices other than air can be much more complex and resource demanding. We have therefore presented only outline costs based on multiples of the above air monitoring costs, assuming:

- water monitoring cost may be the same as air and that there are several existing monitoring programmes and sites in place which may be used to support this activity, and cost for sampling, analysis and storage may be similar;
- sediment monitoring cost estimated at 2.5 times that for air, as it is more costly to obtain and analyse the samples. Also, sampling would have to be done for both suspended sediments and bottom sediments adding further complexity;
- soil monitoring is estimated at half the cost of sediment monitoring (e.g. 1.25 the cost of air monitoring) as the challenges of sampling and analysis are similar to sediment but there is only one type sample (i.e. not suspended and bottom); and
- sludge monitoring is the same as for soil.

Based on these multipliers, the environmental monitoring for these compartments are estimated at between £173,000 and £18.7 million, as indicated in Table 6.3.

Table 6.3: Overall Cost for Environmental Monitoring under each Option for the First Reporting Period (£k)

Environmental Compartment	Minimum	Minimum Plus	Comprehensive	Detailed
Air (= 1)	24.7	93.9	455.3	2,670.7
Water (= 1)	24.7	93.9	455.3	2,670.7
Sediment (= 2.5)	61.8	234.8	1138.3	6,676.8
Soil (= 1.25)	30.9	117.4	569.1	3,338.4
Sludge (=1.25)	30.9	117.4	569.1	3,338.4
Total	**172.9**	**657.3**	**3187.1**	**18,694.9**

For subsequent reporting periods, the proportion of substances requiring new analytical methods may be reduced as suitable methods will already have been developed for a lot of the substances of concern. However, the storage cost will be cumulative.

6.8.4 Wildlife Effects Monitoring

As a basic option, wildlife monitoring could rely on existing wildlife monitoring programmes, meaning the cost would be minimal (or zero).

A more extensive programme might involve tissue collection and analysis of top predators or other sensitive species. However, to be financially viable, it is likely that this would have to be incorporated into existing programmes such as those looking at raptors and cetacea.

Thus, provided agreement could be reached to incorporate such activities into suitable existing programmes, additional costs might be limited to those associated with the extension of the suite of chemicals to be analysed and some additional allowance for management and reporting. Examples of candidate programmes that might be used include the following

Marine and Terrestrial Predatory Birds

The Predatory Bird Monitoring Scheme (PBMS; see: http://pbms.ceh.ac.uk/) is being undertaken by the Centre for Ecology and Hydrology (CEH) with joint funding by Natural England, the Environment Agency and the Campaign for Responsible Rodenticide Use (CRRU). This long-term, national monitoring scheme seeks to quantify contaminant levels in the livers and eggs of predatory and fish-eating birds in Britain. The suitability of the programme to support REACH monitoring should be discussed with the principal contact at the Predatory Bird Monitoring Scheme.

Marine Mammals

In 1988 Defra established a 'Collaborative UK Marine Mammal Strandings Project' to monitor the health status of marine mammals and marine turtles in UK waters. This includes sampling of pollutant levels. However, it is believed that in recent years the extent of Departmental funding may have been significantly reduced. Therefore, before a firm decision is taken on inclusion of this aspect within the REACH monitoring program, its status should be clarified with Defra's Marine and Freshwater Biodiversity Division.

Soil Biodiversity

The minimum suggested level of monitoring of environmental health would include information on soil biodiversity. Since Defra is currently supporting the field evaluation of a suite of indicators (see: http://www.defra.gov.uk/environment/land/soil/research/indicators/bio-indicators.htm) by Centre for Ecology and Hydrology, Cranfield University and the Macaulay Institute to determine if these indicators are suitable to inform on soil biodiversity across the UK.

The Department's intentions with regard to possible implementation of a long term monitoring program is not yet clear and should therefore be discussed with Defra's Soil Policy Team as soon as possible to determine if this is a viable approach.

More Rigorous Wildlife Population Studies

In addition to the above activities to establish changes in chemical pollution levels in key wildlife species and in soil biodiversity, case studies could be used to inform on changes at a population level, for instance, in fish in certain rivers. This might be most economically achieved through funding of a number of PhD students per reporting period and then repeating (within the academic confines implicit for this approach) the study for the next reporting period, thus allowing and trends to be identified. Estimating the cost of a PhD-studentship at £60-100k , and allowing three such "case studies" (e.g. one fish, one bird and one mammal) over each reporting period, would suggest a total cost of £180-300k for each reporting period.

6.9 Monitoring of the UK Human Population

The minimum reporting requirements appear to include a requirement to demonstrate changes in levels of chemicals in a Member State's population. This represents a potentially costly requirement and may raise ethical issues, so the exact requirements should be established with the Commission as soon as possible.

It appears that the most comprehensive and secure source of human tissue samples for the UK will be the MRC-led Biobank project. This is a 30-year epidemiological study jointly funded by Department of Health, MRC, Wellcome Trust and Scottish Executive. The project is seeking to collect tissue samples and information on the

health and lifestyle of 500,000 UK volunteers so as to gather data on the genetic and environmental factors that cause or prevent human disease.

The availability of samples for the purpose of REACH evaluation is uncertain because of possible ethical constraints and this aspect would require discussion with the MRC and/or the hosting organisation the Manchester Cancer Research Centre Biobank, University of Manchester. It is unclear what alternatives may exist if this option proves impracticable but, were it to involve establishing a specific project, then costs could be considerable.

7. PROPOSALS FOR A MONITORING AND EVALUATION FRAMEWORK

7.1 Approach to Developing the Proposed Framework for REACH and CLP

The indicator assessment summarised in Section 5 resulted in each indicator being assigned to one of four options for the evaluation of REACH and / or the CLP. These are:

- **Option 1**: Indicators representing the minimum needed to meet the evaluation requirements of REACH or CLP respectively;
- **Option 2**: Indicators that offer valuable data for the evaluation of REACH or CLP respectively, at a low to moderate cost (not including indicators needed for Option 1);
- **Option 3**: Indicators that offer useful data for the evaluation of REACH or CLP respectively, at a moderate to high cost (not including indicators needed for Option 1); and
- **Option 4**: All indicators that do not meet the requirements of the other options but have the potential to provide data of some use to the evaluation of REACH or CLP respectively. Also included are indicators, not needed for Option 1, that would otherwise have been considered for other options but would involve high data gathering or analysis costs.

The indicators and costs presented under Options 2 to 4 are intended as being **additional** to those recommended for inclusion in the previous option(s) (i.e. Option 2 would also include all indicators (and costs) from Option 1, while Option 3 would also include all indicators (and costs) from Options 1 and 2).

7.2 REACH Option 1: Minimum Requirements

Indicators identified as suitable for Option 1 were selected based on the need to fulfil the anticipated reporting obligations set out in the REACH Regulation and the recording requirements agreed between Member States and the Commission in excess of these. Indicators with the potential to supply the information likely to be required to respond to enquiries on the impact of REACH from audiences, such as Parliamentary Committees and industry, were also considered for Option 1. Where more than one indicator was available to meet a minimum requirement, the highest scoring indicator was selected. Table 7.1 sets out the indicators proposed to meet these minimum reporting requirements.

Table 7.1: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Reporting Requirements under REACH	
Categories	**Indicators**
Competent Authority	
Name of Competent Authority & contact details	No specific indicator needed
Numbers of staff at CA	Numbers of staff assigned (CA and other gov. bodies)
Skill set of the staff at the CA	Adequacy of skill sets of staff assigned (CA and other gov. bodies)
Numbers of staff at co-operating institutions	Numbers of staff assigned (CA and other gov. bodies)
Skill set of the staff at co-operating institutions	Adequacy of skill sets of staff assigned (CA and other gov. bodies)
Co-operation and communication	
Level of contribution (man-hours or euro/annum) made by the CA (including preparation, participation & follow-up)	Cost of activity to Government for activities at EU level by type
Details of any national (i.e. provisional, unilateral measures) introduced to protect human health or the environment during the period covered by the report.	Number of measures introduced relating to environment protection under Article 129. Number of emergency actions taken relating to human health under Article 129
Operation of the National Helpdesk/communication with public	
Contact details of the helpdesk.	No specific indicator needed
Number of staff working on the Helpdesk per annum	Person days of CA helpdesk activity
Number of enquiries received by Helpdesk each year	Number of CA helpdesk enquiries
Participation in REHCORN (man-hours per year)	Cost of activity to Government for activities at EU level by type
Public awareness raising activities supported by UK Government	Person days for REACH awareness/ promotion events
Number of awareness raising activities supported by CA	Number of REACH awareness/ promotion events
CA websites usage	Number of CA website guidance items downloaded. Number of visits to CA website
Quality of CA website information Feedback received on CA website information	Completeness of CA website information. Quality of CA website information. Relevance of CA website information
Development, evaluation and use of alternative test methods	
Contributions by Member State to EU test method development activities - i.e. man-hours/year expended in support of relevant EU committees	UK Government contribution to EU and OECD work on alternative testing methods and guidance
Contributions by Member State to OECD test method development activities – i.e. man-hours/year expended in support of OECD committees	UK Government contribution to EU and OECD work on alternative testing methods and guidance
Contribution to development of alternative test methods – taken as research funding of alternative test development	UK Government contribution to the development of alternative test methods

Table 7.1: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Reporting Requirements under REACH	
Categories	**Indicators**
Other contributions of relevance to subject – e.g. awareness raising activities	UK Government's alternative testing awareness raising activities
Participation in ECHA Committees and Forum Member Sate participation (man-hours or euro/annum) in ECHA activities (preparation, participation & follow-up) including:	
Evaluation activities and draft decisions prepared	
Number of institutions involved in evaluations	No specific indicator needed
Amount of commenting and related activities undertaken (As numbers of dossiers/other document types handled)	Cost of REACH and CLP activity at EU level by type (CA and other government bodies). Cost of REACH and CLP activity at UK level by type (CA and other government bodies)
Amount of commenting and related activities undertaken (As resources expended, man-hours or euros/annum).	Cost of REACH and CLP activity at EU level by type (CA and other government bodies) Cost of REACH and CLP activity at UK level by type (CA and other government bodies)
Annex XV Dossiers	
Number of institutions involved in evaluations	No specific indicator needed
Amount of commenting and related activities undertaken (As numbers of dossiers/other document types handled)	Cost of REACH and CLP activity at EU level by type (CA and other government bodies) Cost of REACH and CLP activity at UK level by type (CA and other government bodies)
Amount of commenting and related activities undertaken (As resources expended (man-hours or euros/annum).	Cost of REACH and CLP activity at EU level by type (CA and other government bodies) Cost of REACH and CLP activity at UK level by type (CA and other government bodies)
Enforcement Activities	
Details of all enforcement authorities in the Member State and their roles and responsibilities.	
Overall strategy of enforcement (If no strategy yet implemented, details of any plans to do so, and their state of progress will be required)	No specific indicator needed
Details of the mechanisms to ensure co-operation and exchange of information across Enforcement Authorities and the Competent Authority	No specific indicator needed
Evidence that mechanisms are functioning adequately.	No specific indicator needed
Details of the sanctions available to Enforcement Authorities where contravention of REACH is detected	No specific indicator needed
Type and number of inspections, investigations and formal enforcement actions undertaken (with details of procedures)	Numbers and nature of REACH and CLP enforcement actions
Outcome of inspections, investigations and formal enforcement actions	Numbers and nature of REACH and CLP enforcement actions
Details of numbers and types of legal action taken and if led to convictions	Numbers and nature of REACH and CLP enforcement actions

Table 7.1: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Reporting Requirements under REACH	
Categories	**Indicators**
Reason for each investigation	Numbers and nature of REACH and CLP enforcement actions
Information on duty holders (including position in supply chain and size of company) subject to inspections or actions.	Numbers and nature of REACH and CLP enforcement actions
Any requests for enforcement from ECHA or other Member States	Numbers and nature of REACH and CLP enforcement actions
Any other measures taken under Articles 125 or 126 of REACH.	Numbers and nature of REACH and CLP enforcement actions
Effectiveness of REACH on the protection of health and the environment	
Level of human protection achieved	Number of emergency actions taken relating to human health under Article 129 Change in incidence of chemically-related occupational asthma Change in incidence of chemically-related occupational skin disease
Level of environmental protection achieved	Number of emergency actions taken relating to environment protection under Article 129. Change in soil biodiversity
Evidence of reduction in, or potentially accumulation of, chemicals in human and environmental compartments	Number of emergency actions taken relating to human health under Article 129. Number of emergency actions taken relating to environment protection under Article 129. Numbers of substances withdrawn from the UK market because of concerns regarding human health. Change in number of substances of very high concern (SVHC) in articles on UK market. Change in quantities of chemicals of concern produced or marketed in the UK
Evidence of UK regional accumulation of chemicals in human and environmental compartments	Change in levels of selected chemicals in ambient air samples. Change in levels of selected chemicals in water and sediment samples. Change in levels of selected chemicals in soil samples. Change in tissue levels of chemicals of concern in the UK population. Change in levels of selected chemicals in tissue samples of aquatic species
Effects of REACH on Innovation and Competitiveness	
Ex post evaluation of the costs incurred in producing registrations dossiers	Actual expenditure on REACH registration. Number of phase-in registrations by each deadline (UK based) by manufacturers and importers. Number of new substances registered (UK sites) (manufacturers and importers)
Extent to which costs have impacted on the availability and costs of chemicals.	Reasons for withdrawal of substances. Number products removed from market due to unsupported uses. Total number of substances available on UK market. Total number preparations/mixtures available on UK market

Table 7.1: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Reporting Requirements under REACH	
Categories	**Indicators**
Relative performance compared with competitor regions	Percentage contribution to GDP (C20) (Comparative GDP data for other nations from BIS)
Level of innovation (e.g. new products and chemicals).	Number of new substances registered (UK sites). Number of PPORD exemptions sought with reasons (UK sites). REACH/CLP related R&D expenditure as a proportion of total R&D for selected sectors (manufacturers and DUs). REACH/CLP related R&D expenditure as percentage turnover for selected sectors (manufacturers and DUs)

The data sets that will be required are:

- Records of CA authority (including REACH-IT) and other government bodies: first round @ £9,500 as a minimum and subsequent rounds @ £7,000;
- Office of National Statistics: first and subsequent rounds @ £1,000;
- UK Disease Registry records: first and subsequent rounds @ £4,000;
- Air monitoring data: first round @ £32,000 and subsequent rounds @ £10,000;
- Soil monitoring data: first round @ £40,000 and subsequent rounds @ £21,000;
- Water and sediment monitoring data: first round @ £111,000 and subsequent rounds @ £34,000;
- Tissue sample data – aquatic species: first and subsequent rounds @ £32,000;
- Tissue sample data – human: first and subsequent rounds @ £32,000;
- Survey of manufacturers and downstream users: first round @ £60,000 and subsequent rounds @ £40,000; and
- Case studies of manufacturers and downstream users: first round @ £40,000 and subsequent rounds @ £25,000.

The cost of Option 1 is estimated to be approximately £362,000 for the first round of data gathering (5 years) including that for the gathering of baseline data. The cost for subsequent rounds of data gathering is estimated to be approximately £206,000 (5 yearly).

7.3 Options 2, 3 and 4 for the Evaluation of REACH

The proposed assignment of indicators to Options 1, 2 and 3 for REACH is presented in Table 7.2.

The costs for each environmental indicator across four different monitoring levels have been described in detail in Section 6. However, for simplicity only one value per indicator has been used here. These values were based on the estimates provided in Section 6 and combined with our expert judgement on the level of detail each monitoring programme should reasonably entail (i.e. a mid-point estimate) under each option.

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
a: Human health – occupational health[2]	Number of substances/ mixtures reclassified with a 'higher' classification	Change in number of prescriptions for chemically-related occupational dermatitis (short-term indicator)	
		Change in number of prescriptions for occupational asthma (short-term indicator)	
		Change in the number of chemical incidents involving exposure of workers (short- to medium-term indicator)	
		Change in the number of the workers affected by chemical incidents (short- to medium-term indicator)	
		Change in numbers claiming compensation because of industrial injuries attributable to chemicals (long-term indicator)	
		Change in industry expenditure on protective gloves (short-term indicator of improvement in worker exposure)	
		Change in industry expenditure on local and general ventilation equipment (short-term indicator of improvement in worker exposure)	
b: Human health – public health[2]		Change in the numbers of the public affected by chemical incidents (short- to medium-term indicator)	Introduction of alternative substances to replace chemicals of concern under REACH
		Change in the level of congenital abnormalities in the UK public that can't be attributed to causes other than chemicals (medium- to long-term indicator)	
		Change in usage of chemicals of concern in consumer products (short- to medium-term indicator)	
c: Environment		Change in population numbers of species with established susceptibility to chemical pollution	Change in levels of selected chemicals in waste sludge samples
		Change in population levels of chemical induced non-lethal effects in wildlife species	Change in levels of selected chemicals in tissue samples of terrestrial species (anticipated EU core reporting requirement)
			Change in levels of selected

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
			chemicals in tissue samples of aquatic species (anticipated EU core reporting requirement)
Cost	**First and subsequent rounds £0** (No additional data sets)	**First and subsequent rounds £300,000** (Monitoring costs) **First and subsequent rounds £50,000** (Disease Records)	**First and subsequent rounds £350,000** (Additional monitoring costs)
Competitiveness and innovation	Overall output of UK chemical industry	Profitability (manufacturers, importers and DUs)	Percentage change in price of chemical inputs (compared to overall industry inputs)
	Value of exports	Percentage change in number of suppliers per DU company	
	Value of imports	Percentage change in DU product portfolios	
	Volume of exports	Number of product reformulations carried out	
	Volume of imports	Number of high-risk substances substituted (and cost) by downstream users	
	Number of companies (manufacturers, importers and DUs)	Reasons for substitution by downstream users	
	Size distribution of companies (manufacturers, importers and DUs)	Number of new products developed by downstream users using lower risk substances	
	Employment (manufacturers, importers and DUs)	Value of new products developed by downstream users using lower risk substances	
	Volume of materials recycled/recovered		
	Value of REACH/CLP-related services provided to customers (manufacturers, importers and DUs)		
Cost	**First and subsequent rounds £1000** (Additional WRAP data)	**First and subsequent rounds £0** (No additional data sets)	**First and subsequent rounds £0** (No additional data sets)
Availability and transparency of information	Number of subscriptions to CA e-Bulletin		Percentage of retailers with knowledge of their customers' right to request information
	Number of consumer requests for information regarding SVHC in articles		
	Quality of CA helpdesk responses		
	Completeness of CA helpdesk responses		
	Relevance of CA helpdesk responses		
	Number of (e)SDS failing legal		

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
	requirements		
	Number of SDS meeting DU requirements		
	Percentage of consumers with knowledge of right to request information on SVHCs in articles		
Cost	**First and subsequent rounds £10,000** (Consumer survey questions via NatCen)	**First and subsequent rounds £0** (No indicators)	**First and subsequent rounds £12,500** (Retailer survey if added to industry survey)
Alternative methods	Number of alternative (non-vertebrate) test methods subject to validation at European level		
	Number of ECVAM validated alternative (non-vertebrate) test methods		
	Number of alternative tests adopted by EU		
	Number of alternative (non-vertebrate) test methods subject to validation at OECD level		
	Number of OECD validated alternative (non-vertebrate) test methods		
	Number of withdrawn EU test methods that involved use of vertebrate animals		
	Number of withdrawn OECD test methods involving use of vertebrate animals		
	Number of project licenses withdrawn in UK because of availability of alternative test methods		
	Number of REACH dossiers involving UK companies that include use of read-across as alternative to proposing vertebrate testing		
	Number of REACH dossiers involving UK companies including use of computational test methods as alternative to proposing vertebrate testing		
	Number of REACH dossiers involving UK companies including use of non-vertebrate test methods as alternative to proposing vertebrate testing		
	Number of REACH dossiers involving UK companies for which (exposure-based)		

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
	waiving is allowed as opposed to vertebrate testing		
	Number (by species) of vertebrate used for testing of chemicals in UK		
	Change in proportion of total EU usage of animals conducted by UK		
	Relative proportion of traditional to more refined test methods using vertebrate animals in the UK		
	Numbers of REACH dossiers including vertebrate test proposals involving one or more UK companies		
	Proportion of vertebrate test proposals agreed to by ECHA involving one or more UK companies		
	Estimated savings of animal numbers for ECHA approved tests due to operation of SIEFs /Joint registrations involving one or more UK companies		
	Number of UK stakeholder submissions in favour and against acceptance of vertebrate testing involving UK companies		
Cost	**First round £5,500 Subsequent rounds £3,000** (Additional collation and analysis from existing data sources)	**First and subsequent rounds £0** (No indicators)	**First and subsequent rounds £0** (No indicators)
Efficient implementation	Cost of training of enforcement officers	Number of proposals for harmonised classification (from industry with reason)	Level of consumer understanding of hazard labels under CLP as compared to hazard labels under CHIP
	Cost saving from having a common CA and enforcement for REACH and CLP	Actual expenditure by industry informing customers of changes due to REACH and CLP	Number of separate lists of prohibited substances prepared by retailers
	Number of proposals for harmonised classification (from UK government with reason)	Actual expenditure by industry on relabelling due to CLP (set-up and ongoing)	Number of SMEs reducing manufacture/import to below 1t/y to avoid registration costs
	Person days of REACH and CLP website development (CA and other government bodies)	Actual expenditure by industry on repackaging due to CLP (set-up and ongoing);	Savings in environmental management costs due to better information on chemicals used
	Person days of REACH and CLP activity at EU level by type (CA and other government bodies)	Actual expenditure by industry on updating and/or replacement of IT systems due to REACH and CLP	Savings in occupational health costs due to better information on chemicals used

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
	Person days of REACH and CLP activity at UK level by type (CA and other government bodies)	Actual expenditure on by industry on staff training due to REACH and CLP	Adequacy of scientific and technical resource base available to industry for demands of REACH and CLP (FTEs, skill sets and reasons)
	Budget for REACH and CLP work (CA and other government bodies)	Costs of updating SDS due to REACH and CLP	Capacity of UK contract laboratories and extent of involvement in REACH support activities (FTEs, skill sets and reasons)
	Cost of CA helpdesk	Number of joint registrations versus individual registrations	Numbers of toxicologists/ ecotoxicologist and risk assessors based in the UK
	Cost of CA website	Number of REACH dossiers updated for classification changes (with reason for change)	
	Cost of REACH and CLP awareness/ promotion events supported by CA		
	Number of authorisation applications (UK based)		
	Number of manufacturers and importers (UK based)		
	Number of notifications of SVHCs in articles by UK based companies		
	Number of notifications of classification and labelling under CLP by UK based companies		
	Actual expenditure on REACH authorisation		
	Number of campaigns by NGOs and trade unions on chemicals use		
	Number of SMEs taking advantage of reduced registration fees		
	Problems encountered with SIEFs		
	Savings in data costs due to SIEFs		
Cost	(Additional collation and analysis from existing data sources accounted for above) **First and subsequent rounds £6500** (Survey of NGOs and Trade Unions)	**First and subsequent rounds £0** (No additional data sets)	**First round £45,000 Subsequent rounds £40,000** (Survey of UK labs and risk assessment companies)

Table 7.2: Proposed Indicators for Different Options for the Evaluation of REACH			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
Total Additional Cost of Option	**First round £23,000 Subsequent rounds £20,500**	**First and subsequent rounds £350,000**	**First round £408,000 Subsequent rounds £403,000**
Cummulative Cost of Option plus Previous Options	**First round approximately £390,000 Subsequent rounds approximately £230,000**	**First round approximately £740,000 Subsequent rounds approximately £580,000**	**First round approximately £1,100,000 Subsequent rounds approximately £1,000,000**

Notes.
1. The aims of REACH were identified as:
- Ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals;
- Enhance the competitiveness and innovation of the EU chemicals industry;
- Increase the availability and transparency of information on chemicals;
- Promote alternative methods for assessment of hazards of substances; and
- Ensure the efficient implementation of reach mechanisms.

2. For reasons of practicality the first aim was divided into three sub-aims: a) Human health – occupational health; b) Human health – public health; and c) Environment

7.4 CLP Option 1: Minimum Requirements

The indicators identified as fulfilling the limited legal reporting obligations as set out in CLP Articles 34, 45 and 46 were considered for inclusion in Option 1 are listed in Table 7.3.

Table 7.3: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Evaluation Requirements for CLP	
Categories	**Indicators**
Article 34: Assessment of Communication of Information to the General Public	
Adequacy of chemical labels of the communication of the safe use of chemicals to consumers	Number of substance and mixture labels meeting CLP requirements (Labels may be deficient due to non-compliance). Level of consumer understanding of hazard labels under CLP as compared to hazard labels under CHIP
Article 45: Body/ies Responsible for Receiving Information Relevant to an Emergency Human Health Response	
Name of body or bodies appointed to receive information	No specific indicator needed
Functioning of body or bodies likely to be relevant to Commission review	Format of data held by emergency response body/ies (CLP Article 45)
	Nature of data held by emergency response body/ies

Table 7.3: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Evaluation Requirements for CLP	
Categories	**Indicators**
	(CLP Article 45)
	Number of requests for statistical analysis submitted to emergency response body/ies (CLP Article 45)
	Number of preventive or corrective measures prepared by emergency response body/ies (CLP Article 45)
	Nature of preventative or corrective measures prepared by emergency response body/ies (CLP Article 45)
Article 46: Enforcement Activities	
Overall strategy of enforcement (If no strategy yet implemented, details of any plans to do so, and their state of progress will be required)	No specific indicator needed
Details of the mechanisms to ensure co-operation and exchange of information across Enforcement Authorities and the Competent Authority	No specific indicator needed
Evidence that mechanisms are functioning adequately.	No specific indicator needed
Details of the sanctions available to Enforcement Authorities where contravention of CLP is detected	No specific indicator needed
Type and number of inspections, investigations and formal enforcement actions undertaken (with details of procedures)	Numbers and nature of REACH and CLP enforcement actions
Outcome of inspections, investigations and formal enforcement actions	Numbers and nature of REACH and CLP enforcement actions
Details of numbers and types of legal action taken and if led to convictions	Numbers and nature of REACH and CLP enforcement actions
Reason for each investigation	Numbers and nature of REACH and CLP enforcement actions
Information on duty holders (including position in supply chain and size of company) subject to inspections or actions.	Numbers and nature of REACH and CLP enforcement actions
Any requests for enforcement from ECHA or other Member States	Numbers and nature of REACH and CLP enforcement actions

From discussions with the HSE it became clear that the actual reporting requirements under Articles 34 and 45 are very unclear at the present time and these have therefore been excluded from the basic requirements included in Option 1. Furthermore, the HSE anticipate little or no change in the enforcement of CLP compared to the enforcement of CHIP. Therefore, any reporting requirements under Article 46 have also been removed from Option 1.

With legal reporting obligations removed, Option 1 includes indicators selected as the minimum needed for the evaluation of the UK RIA of CLP. Where more than one

indicator was available to meet the minimum requirement, the highest scoring indicator was selected. Table 7.4 sets out the proposed indicators.

Table 7.4: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Evaluation Requirements for CLP

Categories	Indicators
Evaluation of UK RIA	
Costs to manufacturers from: • Replacement or updating of information technology (IT) systems to produce new labelling; • Staff training and familiarisation to familiarise employees with CLP; • Reclassification of chemicals, with costs from: - the reassessment of hazard data to reclassify; - the potential use of a conversion table for reclassification; - the potential for 'higher' classifications (For example, may result in many cleaning and detergent products being classified for skin irritation and skin corrosion for the first time); and - the use of bridging principles, and other alternatives to additional testing; • Re-labelling of chemicals; • Stock losses; • Informing consumers and downstream users of chemicals about CLP; and • Proposing new harmonised hazard classification	Actual expenditure by industry on updating and/or replacement of IT systems due to REACH and CLP. Actual expenditure on by industry on staff training due to REACH and CLP Number of substances (and mixtures) reclassified using Annex VII alone Cost of changes to obligations under downstream legislation triggered by CLP (particularly REACH, BPD, PPPD and Seveso II) Actual expenditure on reclassification of mixtures due to introduction of CLP Actual expenditure on reclassification of substances due to introduction of CLP Cost savings from using REACH registration data for reclassification of substances Actual expenditure by industry on relabelling due to CLP (set-up and ongoing) Actual expenditure by industry on repackaging due to CLP (set-up and ongoing) Actual cost of stock disposal due to CLP changes Actual expenditure by industry informing customers of changes due to REACH and CLP Value of REACH/CLP-related services provided to customers (manufacturers, importers and downstream users) Number of proposals for harmonised classification (from industry with reason) Number of notifications of classification and labelling under CLP by UK based companies
Costs to downstream businesses from: • Staff training and familiarisation to familiarise employees with CLP; • Reviewing labels; • Undertaking new risk assessments relating to chemicals classified under CLP; • Stock losses; and • Informing consumers and downstream users of chemicals about CLP	Actual expenditure by industry on updating and/or replacement of IT systems due to REACH and CLP Actual expenditure on by industry on staff training due to REACH and CLP Actual expenditure by industry on relabelling due to CLP (set-up and ongoing) Actual expenditure by industry on repackaging due to CLP (set-up and ongoing) Costs of updating SDS due to REACH and CLP Actual cost of stock disposal due to CLP changes Actual expenditure by industry informing customers of changes due to REACH and CLP Value of REACH/CLP-related services provided to customers (manufacturers, importers and downstream users)
Costs to wholesalers and retailers from: • Staff training and familiarisation to familiarise employees with CLP;	Actual expenditure on by industry on staff training due to REACH and CLP Actual cost of stock disposal due to CLP changes

Table 7.4: Option 1 - Indicators Recommended as the Minimum Necessary to Meet Evaluation Requirements for CLP	
Categories	**Indicators**
• Stock losses; and • Informing consumers about CLP.	Actual expenditure by industry informing customers of changes due to REACH and CLP
Costs to the public sector from: • Training and familiarisation of enforcement officers; and • Training and familiarisation of emergency services staff (paramedics)	Cost of training of enforcement officers Cost of training of emergency service staff *Cost saving from having a common CA and enforcement for REACH and CLP *Cost to HPA from adapting emergency response guidance in the light of CLP *Cost of CA helpdesk *Cost of CA website *Cost of REACH and CLP activity at EU level by type (CA and other government bodies) *Cost of REACH and CLP activity at UK level by type (CA and other government bodies) *Cost of REACH and CLP awareness/ promotion events supported by CA *Numbers of staff assigned to REACH and CLP activities (CA and other government bodies)
Costs to retail consumers of chemical products from Consumers taking time to familiarise themselves with CLP	Level of consumer understanding of hazard labels under CLP as compared to hazard labels under CHIP
Benefits to UK industry from the enhancement of the international trade in chemicals	Value of exports Value of imports Volume of exports Volume of imports
Benefits to UK industry from increased international competition in chemical products leading to increased innovation, productivity and lower prices	REACH/CLP related R&D expenditure total R&D for selected sectors (manufacturers and DUs) REACH/CLP related R&D expenditure as percentage turnover for selected sectors (manufacturers and DUs) Percentage change in price of chemical inputs (compared to overall industry inputs) Number of PPORD exemptions sought with reasons (UK sites) (manufacturers and importers)
Note * Indicators suitable for Option 1, not to be carried forward at the current time	

A number of items identified as being suitable for the evaluation of costs to the public sector from the CLP relate to the costs of the CA. From discussions with the HSE it is understood that such costs are currently under review and should not be included in Option 1 at the present time and these have therefore been transferred to Option 2, for possible consideration at a later date.

The data sets that will be required are:

- National Centre for Social Research (First and subsequent rounds £10,000);
- UK Ambulance Services Records (First and subsequent rounds £1,000)
- Office of National Statistics (First and subsequent rounds £1,000);

- Survey of manufacturers and downstream users: first round @ £60,000 and subsequent rounds @ £40,000; and
- Case studies of manufacturers and downstream users: first round @ £40,000 and subsequent rounds @ £25,000.

The minimum cost of Option 1 is estimated to be approximately £112,000 for the first round of data gathering (5 years), including that for the gathering of baseline data. The cost for subsequent rounds of data gathering is estimated to be £77,000 (5 yearly).

7.5 Options 2, 3 and 4 for the Evaluation of CLP

The proposed assignment of indicator to Options 1, 2 and 3 for CLP is presented in Table 7.5.

Table 7.5: Proposed Indicators for Different Options for the Evaluation of CLP

Aim[1]	Option 2: Minimum Plus	Additional Indicators for Option 3: (Plus Option 2)	Additional Indicators for Option 4 (Plus Option 3)
a: Human health – occupational health[2]	Change in incidence of chemically-related occupational skin disease (short- to medium-term indicator)	Change in number of prescriptions for chemically-related occupational dermatitis (short-term indicator)	
	Number of substances/ mixtures reclassified with a 'higher' classification	Change in incidence of chemically-related occupational asthma (short- to medium-term indicator)	
	Number of substances/ mixtures reclassified with a 'lower' classification	Change in number of prescriptions for occupational asthma (short-term indicator) Change in the number of chemical incidents involving exposure of workers (short- to medium-term indicator)	
		Change in the number of the workers affected by chemical incidents (short- to medium-term indicator)	
		Change in numbers claiming compensation because of industrial injuries attributable to chemicals (long-term indicator)	
		Change in industry expenditure on protective gloves (short-term indicator of improvement in worker exposure)	

Table 7.5: Proposed Indicators for Different Options for the Evaluation of CLP			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
		Change in industry expenditure on local and general ventilation equipment (short-term indicator of improvement in worker exposure)	
b: Human health – public health[2]		Change in the numbers of the public affected by chemical incidents (short- to medium-term indicator)	
		Change in the level of congenital abnormalities in the UK public that can't be attributed to causes other than chemicals (medium- to long-term indicator)	
		Change in usage of chemicals of concern in consumer products (short- to medium-term indicator)	
		Numbers of substances withdrawn from the UK market because of concerns about human health, restrictions or other reasons under REACH or CLP	
Cost	**First and subsequent rounds £4000** (UK Disease Registry records)	**First and subsequent rounds £50,000** (Additional UK Disease Records)	**First and subsequent rounds £0** (No indicators)
Competitiveness and innovation	Percentage contribution to GDP	Reasons for substitution by downstream users	Percentage change in price of chemical inputs (compared to overall industry inputs)
	Reasons for withdrawal of substances		
Cost	**First and subsequent rounds £0** (No additional data sets)	**First and subsequent rounds £0** (No additional data sets)	**First and subsequent rounds £0** (No additional data sets)
Availability and transparency of information	Number of substance and mixture labels meeting CLP requirements		

Table 7.5: Proposed Indicators for Different Options for the Evaluation of CLP			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
Cost	**First and subsequent rounds £10,000** (CHCS survey)	**First and subsequent rounds £0** (No indicators)	**First and subsequent rounds £0** (No indicators)
Efficient implementation	Cost of CA helpdesk	Number of manufacturers and importers (UK based)	Savings in environmental management costs due to better information on chemicals used
	Cost of CA website	Cost of changes to obligations under downstream legislation triggered by CLP (particularly REACH, BPD, PPPD and Seveso II)	Savings in occupational health costs due to better information on chemicals used
	Cost of REACH and CLP activity at EU level by type (CA and other government bodies)	Cost savings from using REACH registration data for reclassification of substances	
	Cost of REACH and CLP activity at UK level by type (CA and other government bodies)	Costs of updating SDS due to REACH and CLP	
	Cost of REACH and CLP awareness/ promotion events supported by CA	Number of REACH dossiers updated for classification changes (with reason for change)	
	Cost saving from having a common CA and enforcement for REACH and CLP		
	Cost to emergency response bodies from adapting emergency response guidance in the light of CLP (CLP Article 45)		
	Format of data held by emergency response bodies (CLP Article 45)		
	Nature of data held by emergency response bodies (CLP Article 45)		
	Nature of preventative or corrective measures prepared by emergency response bodies (CLP Article 45)		
	Number and nature of REACH and CLP enforcement actions		
	Number of emergency health responses by emergency bodies regarding mixtures (CLP Article 45)		
	Number of preventative or corrective measures prepared by emergency response bodies (CLP Article 45)		
	Number of proposals for harmonised classification (from UK government with reason)		

Table 7.5: Proposed Indicators for Different Options for the Evaluation of CLP			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
	Number of requests for statistical analysis submitted to emergency response bodies (CLP Article 45)		
	Numbers of staff assigned to REACH and CLP activities (CA and other government bodies)		
	Person days for REACH and CLP awareness/ promotion events (CA and other government bodies)		
	Person days of CA helpdesk activity		
	Person days of REACH and CLP website development (CA and other government bodies)		
	Person days of REACH and CLP activity at EU level by type (CA and other government bodies)		
	Person days of REACH and CLP activity at UK level by type (CA and other government bodies)		
	Adequacy of skill sets of staff assigned to REACH and CLP activities (CA and other government bodies)		
	Budget for REACH and CLP work (CA and other government bodies)		
	Number of campaigns by NGOs and trade unions on chemicals use		
Cost	**First round £15,000 Subsequent rounds £10,000** (Collation and analysis from existing government data sources) **First and subsequent rounds £6500** (Survey of NGOs and Trade Unions)	**First and subsequent rounds £5000** (Additions to industry survey)	**First and subsequent rounds £5000** (Additions to industry survey)
Total Additional Cost of Option	**First round £35,500 Subsequent rounds £30,500**	**First and subsequent rounds £55,000**	**First and subsequent rounds £5000**

Table 7.5: Proposed Indicators for Different Options for the Evaluation of CLP			
Aim[1]	**Option 2: Minimum Plus**	**Additional Indicators for Option 3: (Plus Option 2)**	**Additional Indicators for Option 4 (Plus Option 3)**
Total Cost of Option plus Previous Options	**First round approximately £150,000 Subsequent rounds approximately £110,000**	**First round approximately £200,000 Subsequent rounds approximately £160,000**	**First round approximately £210,000 Subsequent rounds approximately £170,000**

Notes.
1. The aims of REACH were identified as:
- Ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals;
- Enhance the competitiveness and innovation of the EU chemicals industry;
- Increase the availability and transparency of information on chemicals;
- Promote alternative methods for assessment of hazards of substances (no indicators for CLP); and
- Ensure the efficient implementation of reach mechanisms.

2. For reasons of practicality the first aim was divided into three sub-aims: a) Human health – occupational health; b) Human health – public health; and c) Environment (no indicators for CLP)

7.6 Cost Savings from the Joint Evaluation of REACH and CLP

The data sources identified for the evaluation of REACH are largely the same as those contributing to the evaluation of CLP. Therefore, there is the potential to share the costs of gathering data from these sources. Table 7.6 sets out the data sets and costs associated with each option for the evaluation of REACH and includes, where relevant, an indication of the lowest CLP option needing these data sets.

Table 7.6: REACH Data Sets and Costs of Relevance to the Evaluation of CLP		
REACH Option	**REACH Data Sets and Costs**	**Lowest CLP Option Needing Data Set**
Option 1	Records of CA authority (including REACH-IT) and other government bodies: first round £9,500 and subsequent rounds £7,000	Option 2
	Office of National Statistics: first and subsequent rounds £1,000	Option 1
	UK Disease Registry records: first and subsequent rounds £4,000	Option 2
	Air monitoring data: first round £32,000 and subsequent rounds £10,000	
	Soil monitoring data: first round £40,000 and subsequent rounds £21,000	
	Water and sediment monitoring data: first round £111,000 and subsequent rounds £34,000	
	Tissue sample data (aquatic species): first and subsequent rounds £32,000	
	Tissue sample data (human): first and subsequent rounds £32,000	
	Survey of manufacturers and downstream users: first round £60,000 and subsequent rounds £40,000	Option 1
	Case studies of manufacturers and downstream users: first round £45,000 and subsequent rounds £25,000	Option 1
Potential costs shared with CLP Option 1 (First round of data gathering)		*£106,000*
Potential costs shared with CLP Option 1 (Subsequent rounds of data gathering)		*£66,000*
Potential costs shared with CLP Options 1 and 2 (First round of data gathering)		*£119,500*

Potential costs shared with CLP Options 1 and 2 (Subsequent rounds of data gathering)		*£77,000*
Option 2	WRAP data: first and subsequent rounds £1,000	
	National Centre for Social Research: first and subsequent rounds £1,000	Option 1
	Additional records of CA authority (including REACH-IT) and other government bodies: first round £5,500 and subsequent rounds £3,000	Option 2
	Survey of NGOs and Trade Unions: first and subsequent rounds £6,500	Option 2
Potential costs shared with CLP Option 1 (First round of data gathering)		*£116,000*
Potential costs shared with CLP Option 1 (Subsequent rounds of data gathering)		*£76,000*
Potential costs shared with CLP Options 1 and 2 (First round of data gathering)		*£141,500*
Potential costs shared with CLP Options 1 and 2 (Subsequent rounds of data gathering)		*£96,500*
Option 3	Environmental monitoring: first and subsequent rounds £300,000	
	Additional UK Disease records: £50,000	
No further costs shared with CLP		*£0,000*
Option 4	Additional environmental monitoring costs: first and subsequent rounds £350,000	
	Retailer survey added to industry survey: £12,500	
	Survey of UK laboratories and risk assessment companies: first round £45,000 and subsequent rounds £40,000	
No further costs shared with CLP		*£0,000*

Table 7.7 sets out the data sets and costs associated with each option for the evaluation of REACH and includes an indication of the first CLP option needing these data sets.

Table 7.7: CLP Data Sets and Costs of Relevance to the Evaluation of REACH

CLP Option	**CLP Data Sets and Costs**	**Lowest REACH Option Needing Data Set**
Option 1	National Centre for Social Research: first and subsequent rounds £10,000	Option 2
	UK Ambulance Services Records: first and subsequent rounds £1000	
	Office of National Statistics: first and subsequent rounds £1000	Option 1
	Survey of manufacturers and downstream users: first round £60,000 and subsequent rounds £40,000	Option 1
	Case studies of manufacturers and downstream users: first round £45,000 and subsequent rounds £25,000	Option 1
Potential costs shared with REACH Option 1 (First round of data gathering)		£106,000
Potential costs shared with REACH Option 1 (Subsequent rounds of data gathering)		£66,000
Potential costs shared with REACH Options 1 and 2 (First round of data gathering)		£116,000
Potential costs shared with REACH Options 1 and 2 (Subsequent rounds of data gathering)		£76,000
Option 2	UK Disease Registry records: first and subsequent rounds £4000	Option 1
	CHCS labelling survey	
	Records of CA authority (including REACH-IT) and other government bodies: first round £15,000 and subsequent rounds £10,000	Option 1 Option 2
	Survey of NGOs and Trade Unions: first and subsequent rounds £6500	Option 2
Potential costs shared with REACH Option 1 (First round of data gathering)		*£119,500*
Potential costs shared with REACH Option 1 (Subsequent rounds of data gathering)		*£79,500*
Potential costs shared with REACH Options 1 and 2 (First round of data gathering)		*£141,500*
Potential costs shared with REACH Options 1 and 2 (Subsequent rounds of data gathering)		*£96,500*
Option 3	No additional data sets	
No further costs shared with CLP		*£0,000*
Option 4	No additional data sets	
No further costs shared with CLP		*£0,000*

The maximum costs that may be shared by the joint evaluation of REACH and CLP are in the region of £140,000. However, it should be noted that the extent of the data sets required for the two separate evaluations may not be identical nor will be the importance of different data sets. The exact nature of shared costs will therefore need to be negotiated at a later stage.

Costs will be incurred from setting up and maintaining a system for data handling which may also be shared between the two separate evaluations. Such costs are considered in Section 8 of this study. Further costs would be expected from the writing of reports and these costs have not been estimated as part of this study.

7.7 Outstanding Issues

For the majority of indicators, the scoring and weighting exercise proved a robust and transparent means by which to assign the indicators to an option. However, there is a small number of topic areas (identified in the tables above) where it has not been possible to reach a firm decision as to which (if any) indicator should be included or what approach should be adopted to obtain supporting data if the indicator is included.

For most of these, further clarification of policy requirements and budgetary possibilities would be required to reach a decision. Views would also need to be sought from those government departments or agencies with responsibilities in these areas. The areas affected by such uncertainty are discussed below.

7.7.1 Ensure a High Level of Protection of Human Health and the Environment from the Risks Posed by Chemicals

A range of indicators of occupational health (e.g. occupational incidences of skin and respiratory diseases and cancers, or numbers affected by incidents) or public health (e.g. congenital abnormalities and impacts of chemical incidents) have been identified that are readily available in useable form, since data are already routinely collected and reported for other purposes. However, though generally recognised as the **best available** measures of direct changes in the health, these indicators should be regarded, at most, as providing information on general trends in human health in the UK rather than being REACH or CLP specific in nature. This is because of the non-specific nature of many of these endpoints and the wide range of confounding factors, many of which may exert significantly greater influence than any effect REACH might have.

Departments and Agencies with an interest in occupational and public health have suggested a number of potential alternative or surrogate metrics that might inform on the public and occupational health impacts of REACH. Examples include monitoring industrial expenditure on protective equipment and more indirect measures, such as the withdrawal of chemicals because of health or environmental concerns or changes in public opinion on the risks associated with chemicals. Most of these, however, are not yet recorded, are of uncertain specific relevance to REACH and would potentially involve significant data collection costs. Establishing the costs associated with the

burden of (REACH-) chemical related ill-health would also be susceptible to confounding factors, for similar reasons. Since there is a minimum reporting requirement of 'level of human protection achieved', there is an obvious need to include some indicators to support this. However, a final decision may only be possible after clarification of precise requirements in this area with the EC and other Member States.

Similarly, there is a minimum requirement to report on the 'level of environmental protection achieved' and a number of simple indicators have been suggested that may inform on this to some extent. However, Defra should consider whether there is an established policy need for the UK government to be able to demonstrate improvements in wildlife health as a result of REACH, and the scope and extent of monitoring of wildlife populations that might be appropriate to support such a need.

The minimum report requirements (Option 1) include evidence of reduction in chemicals in human and wildlife compartments. There is also a need to present information to demonstrate that (presumably within-UK) regional accumulation of chemicals is not occurring in either of these compartments. While these requirements indicate that regional monitoring of contaminant levels in both humans and abiotic and biotic environmental compartments may be necessary, the scope of monitoring and analysis that may be required is, as yet, unclear.

Selecting Chemicals for Monitoring

As discussed in Section 2, Eurostat has recently completed its initial development of approaches to data collection and modelling so as to inform on the impact of REACH. This has included a baseline exercise taking a 'snap shot' of data for 2007 that will be used for future comparisons (Eurostat, 2008). This baseline survey draws on a small subset of chemicals (237 substances randomly selected from known high, medium and low production volume chemicals and Substances of Very High Concern (SVHC)). This set is considered large enough to detect with sufficient sensitivity changes taking place in the risk and quality of the databases for chemicals.

The selection of chemicals for monitoring is primarily an issue for the evaluation of REACH. Should it be decided to extend the evaluation to include possible impacts of the CLP, priority would naturally be given to those chemicals whose level of hazard classification had changed as a result of the introduction of CLP. However, we would expect this to provide little additional value at an extensive cost and therefore do not recommend this at the current time.

Monitoring the full range of substances covered by REACH across all environmental compartments is clearly unrealistic and prioritisation of the chemicals to be monitored will therefore be necessary. This could be achieved using a number of approaches:

1. **Chemicals authorised/restricted under REACH:** monitor only those chemicals for which authorisation is required or which have been restricted under REACH.
2. **ECHA candidate list:** This is a list of substances that have been identified as potentially of very high concern (SVHC) because of their potentially serious

effects on human health or the environment and their persistence in the environment. These substances may subsequently be subject to authorisation under REACH, so early monitoring might provide a baseline against which to determine the impact of REACH in regulating these chemicals. The candidate list currently contains 17 substances.

3. **Eurostat Baseline list:** The Eurostat Baseline survey (which was discussed in Section 2) draws on a random selection of 237 chemicals chosen from each of the production volume ranges and of the SVHC list as a basis for their monitoring programme, and the same list could be used for the UK monitoring.
4. **SIN (Substitute it Now) list:** This is a list of substances developed by a group of NGOs, which the NGOs believe are of very high concern and require urgent substitution for less hazardous ones. These organisations propose to update the listing continuously as new data emerges but the current version (SIN 1.0) contains 220 CMRs, 17 PBTs and 30 substances of equivalent concern (according to the NGOs assessment).
5. **ETUC list:** 306 that are claimed to meet the REACH criteria for classification as SVHCs (CMRs cat.1, 2 or 3 (from 67/548/EEC), carcinogens cat. 1, 2A or 2B (from IARC), PBTs (OSPAR Convention), known and suspected endocrine disruptors (Community Strategy for Endocrine Disruptors[11]), plus neurotoxic substances (Vela et al (2003)) and sensitizers (67/548/EEC). In addition, this list ranks chemicals by reference to their intrinsic toxicological properties and seeks to identify those recognised at EU level as potential causes occupational diseases. Chemicals are scored for each of the criteria above and the European Risk Ranking Method (EURAM) has been adapted to enable chemicals to be prioritised for authorisation under REACH.
6. **Random selection of chemicals:** Adopt a similar approach to the methodology used by EUSES in selecting chemicals for risk and quality monitoring (i.e. random selection from stratified production volume bands).
7. **Combination of the above:** For instance, producing a comprehensive list drawn from all the above or randomly selecting a number of substances from each list or from the combined list.

There are advantages and disadvantages with each of these options. Table 7.6 outlines some of the options, but a more thorough assessment would be required prior to a policy decision on prioritisation.

[11] "Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife" (COM (1999) 706) and (COM (2001) 262), as well Commission Staff Working Document on the implementation of the "Community Strategy for Endocrine Disrupters" (SEC (2004) 1372).

Table 7.6: Advantages and disadvantages of different approaches to prioritising chemicals for monitoring

Approach	Advantages	Disadvantages
Chemicals authorised/ restricted under REACH	Targeted monitoring where results are expected to be seen Smaller set of substances so costs likely to be lower	Does not account for other impacts of REACH, such as reduced releases of substances which are not subject to authorisation due to better risk management. Monitoring could not begin until substances are added subject to authorisation/control; likely to be a slow process
ECHA candidate list	Targeted monitoring to provide a baseline for assessing the impacts of future authorisation/restrictions Relatively small set of substances	Does not account for other impacts of REACH, such as reduced releases of substances which are not considered SVHC, due to better risk management. Could result in monitoring of substances not subsequently subject to authorisation/ restrictions, diluting monitoring effort
Eurostat baseline list	Allows comparison between UK and EU	Less flexibility for UK to select its own substances for monitoring. Fixed at 237 substances, which may be more or less than UK would like to sample and may not include the substances for which REACH is likely to have the greatest impact
SIN list	Extensive list of chemicals of concern to NGOs and, possibly, the public	Based on NGO opinions which have not been subjected to rigorous scientific assessment. Potential for frequent changes to list depending on NGO priorities
ETUC list	Extensive list of chemicals, including those of increasing concern such as endocrine disrupters. Includes potential causes of disease as well has high volumes to prioritise for risk. Prioritisation scores may allow for evaluation to focus on chemicals with highest score	Selection criteria go beyond that currently adopted for REACH and may include chemicals never addressed by REACH. Many chemicals to monitor if full list is used
Random selection	Allows selection of the number of substances to be monitored, which can be matched to available resources	May miss out some of the chemicals where environmental reduction has been extensive, thus underestimating the impacts on REACH. May lead to excessive monitoring where little or no change is expected
Combination of the above	Allows selection of the number of substances to be monitored, which can be matched to available resources	May include all of the disadvantages above

Given that the substances for monitoring have not yet been selected, the monitoring programmes may range from a minimal sampling strategy that addresses a limited set of compartments and a restricted set of chemicals (which is likely to incur only moderate cost) to increasingly complex and extensive monitoring programmes (of

steadily increasing costs) encompassing a wide range of environmental and human tissue compartments.

For instance, the following monitoring scenarios might be considered in addition to the monitoring proposed under Option 1:

- Option 2: include more substances for which analytical methods already exist or sample at increasingly diverse geographical sites and include limited analysis of potentially more expensive compartments such as sediment;

- Option 3: further extension of the list of substances (possibly including some requiring novel analytical method development) and increase the frequency of sampling or use more robust sampling approaches; or

- Option 4: establish a robust monitoring programme focused on a wide range of substances (relevant to REACH) at more locations and with increased frequency.

As for the indicators of human health, there is a need to establish EC expectations regarding the extent of information to be reported, as well as any additional UK government requirements, before detailed specifications can be developed. However, given the level of current uncertainty on which chemicals should be monitored (and that the range of chemicals of particular concern can be expected to change over the course of REACH implementation), it may be more appropriate to establish archiving systems to collect, at intervals, human and wildlife tissues and environmental media samples (possibly involving sample extraction and, for example, deep-freezing of extracts) in order to ensure a suitable time-series of samples are available to support any future requirements. In this way, the samples could be analysed for specific chemicals in future, with analysis targeted at those chemicals where a real reduction in environmental or human tissue levels may be expected or where problems have been identified. This approach might have financial benefits compared to expending resources on analyses where no impacts might be expected.

7.7.2 Promote Alternative Methods for Assessment of Hazards of Substances

While a number indicators of very low cost are available for use in Option 1, additional indicators of similar cost are also presented under Option 2 and there are a few slightly more costly indicators (e.g. UK contract laboratory capacity and estimates of savings in animal numbers due to joint registrations under REACH) that might also be considered of particular value to the UK government and therefore warrant consideration for inclusion, even if resource available for the evaluation exercise are limited.

7.7.3 Relevant Industrial Sectors

The industrial sectors relevant to the evaluation of REACH or CLP have been identified by SIC codes used by the UK Office of National Statistics (ONS). ONS and Eurostat data will be available for all such industry sectors. However, where data are to be obtained by consultation with industry (surveys or case studies) it may be

sufficient to focus on manufacturers and downstream users (CLP RIA: downstream businesses) within C20 plus waste companies (E38 and G36) and distributors/retailers in G47.

The impacts of REACH or CLP are likely to be felt to different extents by companies of different sizes, even where such companies fall within the same SIC code. Therefore, the questions asked when data gathering (ONS or industry consultation) should allow data to be differentiated by company size, as defined by the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC).

In addition, it is understood that the possibility of differentiating industry data by UK regions would be of value to the evaluation of REACH (but not to CLP). It is therefore recommended that any industry surveys or case studies be distributed across the UK, where possible. However, it is possible that not all industry associations will be able to differentiate the data that they collect or supply by region.

Should it be necessary to survey UK laboratories and risk assessment companies providing REACH related services this would involve entirely different companies from those already considered. In addition, companies would need to be identified and contacts sought without the aid of trade associations.

8. WAY FORWARD

8.1 Different Data Sources

The indicators considered in this report will, if progressed, require collection of data from the sources outlined here.

- **UK Government Departments** (data sets available for collation and analysis): Relevant departments will need to be contacted to arrange for data provision and to establish responsibilities for and extent of required data collation/analysis that will be needed.

- **UK Devolved Administrations** (data sets available for collation and analysis): The devolved administrations will need to be contacted to arrange for data provision and to establish responsibilities for and extent of required data collation/analysis that will be needed.

- **UK Government Agencies** (e.g. Health and Safety Executive (including the Competent Authority), the environment agencies (including those of the devolved administrations) and the Health Protection Agency): These organisations will need to be contacted to arrange for data provision and to establish responsibilities for and the extent of the required data collation/analysis that will be needed. In addition, the opinions and assistance of relevant agencies will be needed to establish appropriately tailored monitoring programmes on human health and the environment, including levels of chemicals in relevant environmental compartments.

- **Non-governmental public bodies:**

  - **Statistical data sources** (Office of National Statistics (ONS) and Eurostat): ONS will be able to provide data sets tailored to the needs of the evaluation of REACH or CLP (or both). The contents and format of such information need to be agreed with ONS, and the costs involved in preparation agreed. Procedures will need to be put in place and personnel allocated to the collection of non-UK data from Eurostat;

  - **UK Disease Registries** (data sets available for collation and analysis): If government departments or agencies are unable to provide appropriately targeted data (i.e. adjusted to improve relevance to the evaluations of relevance), the disease registers should be contacted to ascertain if they are able to provide such information. Registries may therefore need to be contacted to arrange for data provision;

  - **National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs): NC3Rs** The NC3Rs **s**hould be consulted to ascertain if it would be appropriate to include information on their activities and resource utilisation when reporting on government support for alternative testing;

- **Medical Research Council MRC** (human tissue samples): MRC should initially be consulted to ascertain if it would be possible to utilise their tissue collections to support any requirements with regard to measurement of levels of chemical in the public. If such a use is not possible, other potential sources in the NHS and the wider academic sector should be consulted;
- **WRAP** (waste related data): WRAP will be able to provide data relating to the recycling and recovery sectors. Procedures will need to be put in place and personnel allocated to the collection of data.

- **Chemical industry** (case studies of a range of sectors and company size and industry sector surveys): Industry associations will need to be contacted to aid in the selection of organisations for the case studies. Case studies will then need to be agreed and interviews arranged. The most valuable approach may be to initiate these in the near future so as to collect baseline data (and potentially to inform the counterfactual), given that it is likely that the case studies will take time to set up. In addition, there are some indicators where a survey of industry is likely to be the best method of collection. There may be merit in discussing the aims and scope of these surveys with industry organisations in the near future, as they will require decisions to be made at Board level and this could take several months.

- **Retailers** (survey): The British Retail Consortium can assist in sourcing consultees. Any survey will need structuring to include a range of retail sectors, regions and company sizes. Companies will need to be contacted, time will elapse for responses to be received and data will need to be analysed. Data collection could start with developing information on the baseline, to be followed by one or more subsequent surveys. Thus, there may be value in initiating this work in the near future.

- **Consumers** (survey): Consumer survey questions may be added to existing surveys undertaken by the National Centre for Social Research (NatCen). The next round of data collection for the British Social Attitudes Survey will be in the summer of 2010 which will be too late for inclusion in the first REACH report due by 1 June 2010. The next data gathering for the Omnibus survey will be in the first quarter of 2010, with data being available by March. To be included in this Omnibus survey questions would have to be submitted to NatCen before the Christmas period 2009. Therefore if required, this should be progressed in the near future.

- **Trade Unions:** Trade unions may collect data on changes in occupational situations which may be of relevance. They may also be able to comment on issues such as the value of extended SDS, the degree to which there is better communication of risk information, etc. It is likely that such information could be collected within a relatively short time period and thus putting in place tools for collecting the relevant information is less immediate than for the other groups indicated above.

- **NGOs:** Depending on their areas of interest, NGOs are likely to have views on the availability of information, specific chemical substitution issues or other issues

such as levels of animal testing. There is less immediacy in putting in place tools to collect such information.

It should be noted that all indicators have been assessed separately for their potential relevance to the evaluation of REACH and for their potential relevance to CLP (except for environment). Therefore, when data are gathered this must be differentiated between data relating to REACH and data relating to CLP.

8.2 Data Collection, Storage and Access

Although it would be desirable to directly collect information required for production of the Member State reports to ECHA in a form suitable for automated submission, there remains considerable uncertainty as to the final format and structure of the submission system that eventually will be implemented by ECHA.

Discussions arising from the Meetings of Member States Competent Authorities for REACH and CLP (CARACAL) suggest that consideration may be being given to a model in which existing data collated from existing sources within Member States will be submitted (under the various Themes discussed in Section 2) into a REACH reporting tool where it will be held pending subsequent compliance checking before being used for analysis. A presentation to the first meeting of CARACAL included a summary schematic apparently based upon these principles (Figure 8.1).

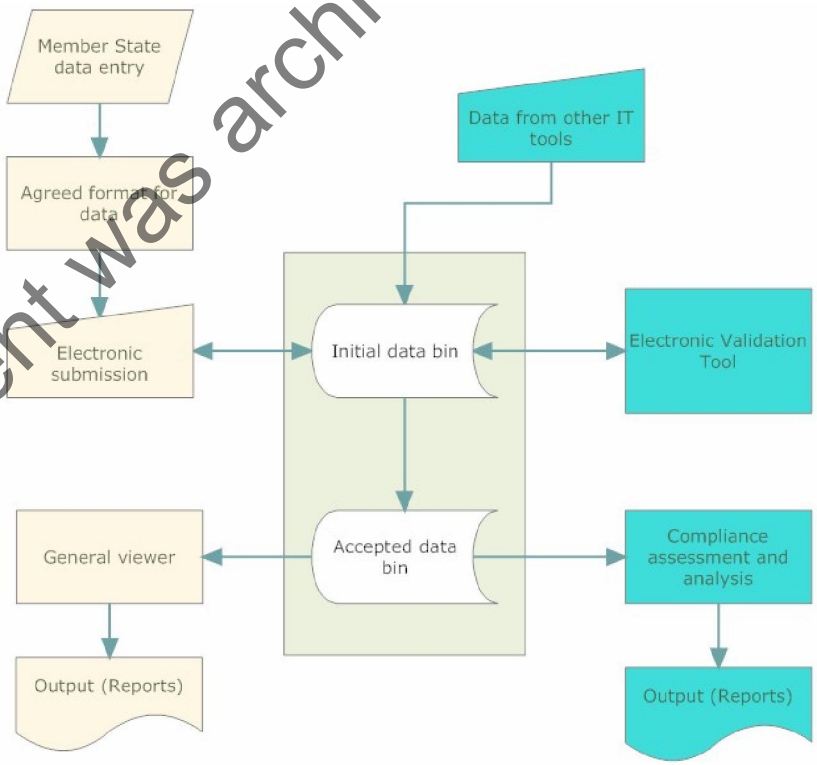

Figure 8.1: REACH reporting tool (adapted from WRC (2009))

There is some indication that 'ReportNet' may be considered as a suitable model structure for this given its use for managing the environmental reporting obligations of EEA member countries to DG Environment and its extensive use in Water Framework Directive reporting. However, the final outcome of the deliberations are, as yet, unknown.

As part of this study, we were asked to consider what type of data collection and reporting system might be required for the UK. As a starting point, consideration was given to the development of a comprehensive database, designed around the type of data to be gathered and the format in which that data would be submitted and analysed. However, there is currently too much uncertainty regarding the final submission process to the Commission for REACH including, the supporting software system and data formats that will be required. In addition, the reporting and evaluation requirements for CLP are understood to be very different to those for REACH and both regulations are under periodic review which may result in new evaluation needs in the future. Hence, any data collection system should be straight forward to adapt for future requirements. This warns against the creation of a database at this point in time, as it can be technically complex and time consuming to make modifications to the structure of a database, once it has been designed and partially populated.

Therefore, it is suggested that data handling for the evaluation of REACH and/or CLP is not undertaken by a database at the current time. Rather, to allow maximum flexibility, it is suggested that consideration be given to creating a web-based information hub for the purpose of collecting and storing the information required to report on REACH and CLP progress.

These systems have a number of advantages, such as:

- **Low cost:** monthly subscription rates may start from as little as £30 per month, going up to around £90 depending on the amount of storage space required (10-50 GB in the price examples listed above);

- **Multiple reporting formats:** any type of file can be uploaded, so some information may be submitted in Excel sheets or Word documents as is most appropriate to the data being provided. The reporting format could be standardised for each type of data but there would be the flexibility to change the reporting format once the ECHA format has been determined;

- **Easy to update:** can be updated directly by those reporting, without a need to submit information to the body managing the hub which then has to update an internal system (which would be the case for a PC-based system). The extent to which outside bodies can update the hub can be controlled;

- **Confidentiality:** different groups can be set up within the hub and access and privacy setting can be set for each member to determine what content they can access. Thus, some organisations may just be able to upload information, others may also be able to view and download information; and

- **Archive:** possibility to archive old files.

User names would have to be created and linked to specific e-mail addresses. In order to prevent having to change this if the specific person leaves their post; separate e-mail addresses with generic user names could be set up for this purpose.

There are several such software packages on the market and further consideration should be given to the advantages and disadvantages of each before making a final decision on which one to use, however this link to a provider's website is useful as an example and for further information on how they work (http://basecamphq.com/tour).

8.3 Timescales for the Evaluation of REACH

Under REACH, the UK is required to submit an initial report by 1 June 2010 and then every five years thereafter. Figure 8.2 displays the due dates for these reports in relation to key dates in the REACH implementation process.

Figure 8.2 emphasises the shortness of the timescale between the completion of this scoping study and the first reporting deadline. There is therefore some urgency to progress the task of setting up the framework for data gathering and to start collating data. This is because the first round will require not just the establishment of data collection systems for the selected indicators but will also involve the need to establish baseline information for each, including those that might require carrying out industry or consumer surveys or establishing an environmental monitoring programme.

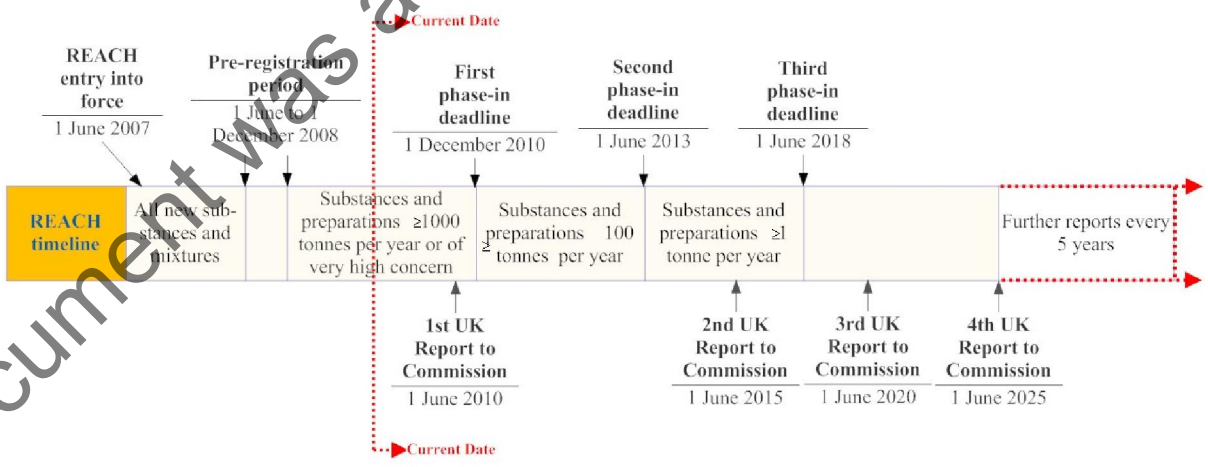

Figure 8.2: Key Dates for REACH Implementation and Evaluation

It is anticipated that any data that might inform indicators relevant to human health or environment would be most unlikely to show changes by the time of the first report, given that implementation of REACH is still at a very preliminary stage. Indeed, for

many of the direct measures of human health, the nature of the diseases considered are such that the lag between chemical exposure and manifestation of disease is likely to mean that detection of even significant changes might require several decades. In the case of chemical pollutant levels, the rate of change in compartmental pollutant levels would also be very variable depending on the sources and routes of exposure and the physiochemical properties of particular chemicals. Similar, restrictions apply to the ability to demonstrate wider environmental effects.

The lack of relevance of such indicators to the first report does not, however, negate the need to establish suitable indicators and metrics that might inform on the impacts of REACH over the longer term and to then seek to establish baseline information now. For this reason, while it may take some time to determine which chemicals should be monitored and in which media, it may be advisable to carry out some wide ranging monitoring to establish an archive of data to facilitate any future analysis needs.

8.4 Timescale for the Evaluation of CLP

Article 46 of CLP requires UK to submit an initial report on enforcement by 1 January 2012, followed by a second report by the 1 July 2017 and then on 1 July every five years thereafter. This is the only ongoing reporting requirement stipulated by CLP and the responsibility for its submission lies with the HSE. Figure 8.3 displays the due dates for these reports in relation to key dates in the CLP implementation process.

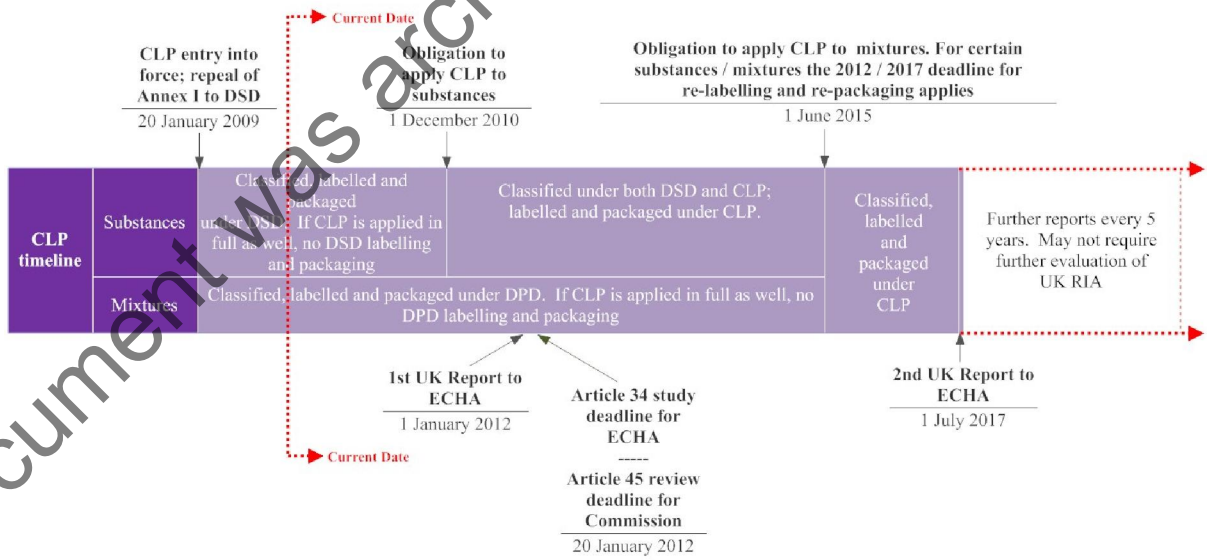

Figure 8.3: Key Dates for CLP Implementation and Evaluation

Article 34 of CLP requires ECHA, in consultation with Competent Authorities and stakeholders, to carry out *a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels*. ECHA must complete this study by 20 January

2012 but will require information from the UK Competent Authority, presumably during the second half of 2011.

Under Article 45 of CLP, the European Commission must carry out a review of the information collection and analysis undertaken in relation to preparation for an emergency response. Again this review must be conducted by 20 January 2012. In this case, it will require the provision of information from the HSE and the emergency response bodies appointed to fulfil the UK's obligations under Article 45. It is anticipated that these bodies will be the Health Protection Agency (HPA) and/or the National Poisons Information Service (NPIS). This information may be required by the Commission during the second half of 2011.

The nature of the reporting requirements under Articles 34 and 45 are currently unclear. However, should it be decided to make provision in anticipation of requests for information from ECHA or the Commission there is some urgency with regards to setting up the framework for data collection; this is particularly true if it is to be done in conjunction with REACH (and thus take advantage of the potential considerable cost savings). This may be of particular relevance to the gathering of consumer data in support of Article 34.

8.5 Way Forward: REACH

In summary, it is recommended that in order to meet the June 2010 reporting deadline for REACH, the next steps for Defra should include:

- agreeing which indicators (or part of options), in addition to those falling under Option 1, to include in the evaluation of REACH. This will include agreeing the environmental and human health indicators to be adopted and beginning monitoring work so as to set an environmental baseline (which could then be built on through on-going annual monitoring activities);
- establishing the framework and approach for the industry/retailer surveys/case studies needed for any selected indicators, and to agree timing of this work;
- agreeing and establishing data gathering procedures with government departments, agencies and other public bodies;
- agreeing and establishing the preparation of tailored ONS data sets;
- agreeing with NatCen the questions to be asked of consumers as part of the first 2010 Omnibus survey (questions to be submitted before Christmas 2009);
- agreeing to what extent it may be advantageous to include trade union and NGO involvement in the evaluation process and to facilitate that involvement;
- agreeing the extent of joint data gathering with the evaluation of CLP; and
- ensuring the provision of resources for the collation and analysis of data, as well as for the drafting of the first report.

8.6 Way Forward: CLP

In summary, it is recommended that the next steps for HSE should include:

- agreeing which indicators (or part of options), in addition to those falling under Option 1, to include in the evaluation of CLP;
- establishing the framework and approach for the industry/retailer surveys/case studies needed for any selected indicators, and to agree timing of this work;
- agreeing and establishing data gathering procedures with government departments, agencies and other public bodies;
- agreeing and establishing the preparation of tailored ONS data sets;
- agreeing with NatCen the questions to be asked of consumers as part of the first 2010 Omnibus survey (questions to be submitted before Christmas 2009);
- agreeing to what extent it may be advantageous to include trade union and NGO involvement in the evaluation process and to facilitate that involvement;
- agreeing the extent of joint data gathering with the evaluation of CLP; and
- ensuring the provision of resources for the collation and analysis of data, as well as for the drafting of any report.

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