

## Summary: Intervention & Options

<b>Department /Agency:</b> <b>DEFRA</b>	<b>Title:</b> <b>Impact Assessment of the enforcement of REACH</b>	
<b>Stage:</b> Final	<b>Version:</b> 1	<b>Date:</b> 16 <sup>th</sup> September 2008
<b>Related Publications:</b> Consultation on the Enforcement of REACH in the UK June 2008		

Available to view or download at: <http://www.defra.gov.uk/corporate/consult/reach-enforce/index.htm>

**Contact for enquiries:** Fatima Olubodun

**Telephone:** 020 7238 1582

### What is the problem under consideration? Why is government intervention necessary?

REACH (Registration, Evaluation and Authorisation of CHemicals) is an EU Regulation which came into force on the 1 June 2007. Without effective enforcement firms may not have the adequate incentive to comply and the benefits of REACH may not be achieved.

### What are the policy objectives and the intended effects?

The policy objective is to ensure that firms comply with REACH and that potentially harmful impacts of hazardous substances are avoided. An effective regime will ensure greater compliance with the regulation and consequently improve protection for human health and the environment.

In accordance with Hampton principles, it is proposed to use existing enforcers to enforce REACH alongside their current activities, which minimises costs of enforcement and seeks to minimise the burden on businesses of additional inspections.

### What policy options have been considered? Please justify any preferred option.

Two options are being considered to enforce REACH.

- 1) No Enforcement regime is set up.
- 2) Existing enforcement agencies are used to enforce REACH alongside their current enforcement activities.

Option 2 is the preferred option, as it is the most cost effective means to enforce REACH, taking advantage of existing expertise and allowing for enforcement to be undertaken in conjunction with other regulatory regimes.

### When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Every five years Member States are required to submit to the Commission a report on the operation of the Regulation including a section on enforcement. The first report is due by 2010.

### **Ministerial Sign-off** For SELECT STAGE Impact Assessments:

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister:

..... Date:

## Summary: Analysis & Evidence

Policy Option: **2**

Description: Existing enforcement agencies are used to enforce REACH alongside their current enforcement activities

<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups'  Key costs are to business and enforcers. Using the Standard Cost Model, annual costs once REACH is fully in force have been estimated at £11k to £14k for large businesses, £216k to £264k for SMEs and £321k to £376k for enforcers. The total cost is in the range £541k – £661k with a mid point of £601k.
	<b>One-off</b> (Transition)	<b>Yrs</b>	
	£ 0		
	<b>Average Annual Cost</b> (excluding one-off)		
	£ 601k	30	<b>Total Cost (PV)</b> £ 11.3m
Other <b>key non-monetised costs</b> by 'main affected groups'			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups'  Benefits of increased compliance with REACH to human health. Potential benefits to human health of £43m over thirty years if 1% of producers comply as a result of an effective enforcement regime.
	<b>One-off</b>	<b>Yrs</b>	
	£ 0		
	<b>Average Annual Benefit</b> (excluding one-off)		
	£ 3.9m	10-30	<b>Total Benefit (PV)</b> £ 43m
Other <b>key non-monetised benefits</b> by 'main affected groups' Improvement to the environment as a result of less emissions of harmful substances. Effective competition – the benefits of providing a level playing field for businesses.			

### Key Assumptions/Sensitivities/Risks

It is assumed that putting an effective enforcement regime in place, coupled with effective inspections by the enforcement authorities, can result in significantly higher levels of compliance. Non-compliance will result in firms running the risk of facing criminal sanctions and losing their good reputation. The assumption that 1% of firms comply as a result of enforcement is likely to be conservative and gives an indication of the potential scale of benefits.

Price Base Year	Time Period Years	<b>Net Benefit Range (NPV)</b> £ 31 – 33m	<b>NET BENEFIT (NPV Best estimate)</b> £ 32m
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What is the geographic coverage of the policy/option?		The UK		
On what date will the policy be implemented?		1 <sup>ST</sup> December 2008		
Which organisation(s) will enforce the policy?		See Annex A		
What is the total annual cost of enforcement for these organisations?		£321k - £376k		
Does enforcement comply with Hampton principles?		Yes		
Will implementation go beyond minimum EU requirements?		No		
What is the value of the proposed offsetting measure per year?		£ 84,000		
What is the value of changes in greenhouse gas emissions?		£ N/A		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)*	Micro	Small	Medium	Large
Chemical Companies	£122	£122	£122	£121
(Non-Chemical Companies)	(£37)	(£37)	(£37)	(£36)

\* This represents the cost per inspection, not the average cost to all firms

Are any of these organisations exempt?	No	No	No	No
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<b>Impact on Admin Burdens Baseline</b> (2005 Prices)			(Increase - Decrease)	
Increase of	£ 337,000	Decrease of	£ 84,000	<b>Net Impact</b> £ 253,000

Key:

Annual costs and benefits: Constant Prices

(Net) Present Value

## Evidence Base (for summary sheets)

### Introduction

REACH (Registration, Evaluation and Authorisation of CHemicals) is an EU Regulation which came into force on the 1 June 2007. It requires that Member States must set a system of controls and penalties for breaches of the requirements of the Regulations. The aim of REACH is to ensure a high level of protection for human health and the environment from hazardous substances, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry. Government intervention in the form of enforcement is also necessary to ensure that firms comply with the Regulation and the potential benefits are realised.

The UK is required to notify the European Commission of its enforcement structure by no later than 1 December 2008. In line with Better Regulation practice, it is necessary that government identify what costs may be incurred by businesses and enforcers, or benefits that may accrue to them. The focus of the cost of enforcement is in confirming that businesses are complying with the REACH Regulation (i.e. preparation for an inspection and the inspection itself) and hence separates out the enforcement of the REACH Regulation from the REACH Regulation as a whole. A partial impact assessment was included in the initial consultation in 2007 on the options for the enforcement of REACH and in a second consultation in June 2008. This identified the administrative burden of enforcing REACH to businesses and the cost to enforcers. The present impact assessment is considering the revision of these enforcement burdens alongside any benefits in enforcing REACH. The main benefit of enforcement is that firms are more likely to comply with regulations due to actual enforcement or the threat of enforcement. More consistent compliance is of benefit to business, as well as human health and the environment. As well as potential punitive measures, firms also have the incentive to comply due to the risk of damage to reputation and the potential for more rigorous investigation in future due to a risk-based approach to inspections.

All the costs quoted in this Impact Assessment are based on when REACH is fully in force by 2018. For more information on this see the section below on phase in periods.

A partial regulatory impact assessment covering the sectors and groups affected and costs and benefits of the entire REACH Regulation as a whole was published in May 2006<sup>1</sup>.

### Existing Legislation

REACH will replace over 40 existing European Directives and Regulations and, as a consequence, the UK will repeal and amend the domestic legislation that implemented these Directives and Regulations. For example REACH principally replaces the Notification of New Substances Regulations 1993 (NONS) (SI 1993/3050), the Notification of Existing Substances (Enforcement) Regulations 1994 (ESR) (SI 1994/1806) and parts of the Chemicals Hazard Information and Packaging for Supply (CHIP) Regulations 2002 (SI 2002/1689). REACH also replaces the Controls on Dangerous Substances and Preparations Regulations 2006 (SI 2006/3311) and the Dangerous Substances and Preparations (Safety) Regulations 2006 (SI 2006 2916). Business will benefit from REACH through this replacement of the current patchwork of separate pieces of legislation with a single framework and consequently more effective enforcement.

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<sup>1</sup> <http://www.defra.gov.uk/environment/chemicals/reach/pdf/PartialRIACCommonPosition-May2006.pdf>

A substantial amount of the burden of the enforcement of REACH is offset through the replacement of this existing domestic legislation. It has not been feasible to obtain the offsetting costs due to the structure of the enforcement activities and ability to collect this information e.g. over 200 local authorities enforce the Dangerous Substances and Preparations (Safety) Regulations. The offsetting costs have therefore been assumed to be 25% of the costs to both enforcers and business.<sup>9</sup>

## Estimating the Cost of REACH Enforcement

This section provides a summary of the methodology for working out the costs and benefits associated with the enforcement of REACH. It covers definitional issues, the options, and then provides detailed analysis, including an estimate of the administrative burden of enforcement on businesses and an estimate of the costs of enforcement to Government.

### Definition

The administrative costs of regulation are defined as “the [recurring] costs of administrative activities that businesses are required to conduct in order to comply with the information obligations<sup>2</sup> that are imposed through central government regulation”<sup>3</sup>. Administrative costs are separate from compliance or policy costs which are directly attributable to the policy goal. In contrast, administrative costs represent the ‘red-tape burden’ of the policy.

In the case of REACH, the compliance and policy costs will include, for example, the one off costs of registration for individual chemicals (including the costs of any further tests needed to complete the registration dossier), the costs of compiling safety data sheets, and any continuing economic costs associated with the loss of the ability to use chemicals which are judged to be hazardous and are therefore restricted or banned. These costs follow directly from the REACH Regulation, and were covered by the regulatory impact assessment of May 2006 noted above.

For the purposes of this impact assessment, the focus is on the administrative burdens to business to confirm their compliance with the REACH Regulation (i.e. preparation for inspection and the inspection itself). This is likely to be the time taken, for example, to show that the chemicals being used in the business have been registered where this is required by the Regulation, that safety data sheets have been issued or received when required, or that chemicals are not being used outside the conditions of a restriction or authorisation. The impact assessment also assesses the cost to the public sector of carrying out the enforcement of REACH, through inspections and the new posts created in the enforcing agencies.

In accordance with guidance from the Department for Business, Enterprise and Regulatory Reform, this assessment deals only with the enforcement costs of REACH. If a business is found not to have complied with REACH, it is likely that they will face additional administrative costs associated with further dealings with the enforcing authority including prosecution. However, this is not covered within the scope of this impact assessment as non-compliance is an individual business decision and should not be assumed to exist for the purposes of policymaking.

### The Options

This impact assessment considers two options.

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<sup>9</sup> The figure of 25% is an assumption, based upon consultation with regulatory bodies.

<sup>2</sup> A duty to retain or submit information.

<sup>3</sup> <http://www.cabinetoffice.gov.uk/REGULATION/reform/simplifying/routes.asp>

1. No enforcement regime is set up and no enforcement occurs.
2. Existing enforcing agencies are used to enforce REACH, and enforcement takes place alongside current enforcement activities.

A third option was considered in the partial Regulatory Impact Assessment of March 2007 of a single agency enforcing all of REACH. This option was rejected following consultation as going against the principles set out by Hampton and putting a high administrative burden on business and excess burden on one enforcer.

### Option 1

The REACH Regulation would fail in its aims unless there is subsequent enforcement to ensure that it is being adhered to. Enforcement is essential in order to safeguard the initial investment in REACH by business, protect compliant businesses from unfair competition, and to safeguard the improvements in protection of human health and the environment.

If we were to follow this option, the UK would be in clear breach of the terms of the Regulation. There would be considerable cost to the public purse if the European Commission were to commence infraction proceedings, together with considerable political cost to Government. This option is therefore not considered further.

### Option 2

This is the preferred option as it uses existing structures, which will minimise costs for both business and for Government. It was supported by the responses to the first consultation in 2007. This approach takes advantage of existing expertise, and means that the majority of the work can be undertaken in conjunction with regulation of other regimes which relate to the safe use of chemicals. Option 2 is therefore a measured and proportional response which is in line with general Hampton Principles<sup>4</sup> that enforcement should be efficient. We believe that this approach is likely to be that which imposes the least burden on business. This option has been analysed and the headline results are given below.

### Cost of enforcement – total costs to business and enforcers annually after 2018 when REACH is fully in force

Table 1- a summary of the ongoing cost of enforcement to business and enforcers

	<b>Gross Costs Per Year (Range)</b>	<b>Net Costs Per Year (Range)</b>
Business (all)	£304,000 to £371,000	£227,000 to £278,000
- SMEs	£288,000 to £352,000	£216,000 to £264,000
- Large firms	£15,000 to £19,000	£11,000 - £14,000
Enforcers	£427,000 to £501,000	£321,000 to £376,000

Net costs are gross costs minus 25% - the assumed offsetting costs.

These burdens are based on the best evidence available to us, and collected through engagement with stakeholders and enforcers. However, the amount of evidence available is limited, e.g. in assessing the costs to businesses and authorities of operating existing enforcement regimes, which means that estimates have been made of the parameters used to calculate the burdens.

<sup>4</sup> [http://www.hm-treasury.gov.uk/budget/budget\\_05/other\\_documents/bud\\_bud05\\_hampton.cfm](http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm)

## General points

### **Different Types of Enforcement Obligations**

The enforcement obligations can be divided into 3 broad areas:

- registration related – demonstrating having a valid registration;
- supply chain – provision of information up and down the supply chain, such as safety data sheets and the keeping and making available of information; and
- use related – compliance with conditions imposed such as on the safe use and risk management measures.

The draft Statutory Instrument proposes that:

- Health and Safety Executive (HSE) and Health and Safety Executive Northern Ireland (HSENI) will enforce REACH alongside their wider day to day enforcement programmes in respect of health and safety in Great Britain.
- Environment Agency, Scottish Environment Protection Agency (SEPA), Department of the Environment Northern Ireland (DoENI) will enforce REACH alongside wider enforcement of environmental protection regulations.
- The Local Authorities will enforce REACH alongside wider enforcement of Health and Safety at Work and Consumer Safety legislation.
- Department for Business, Enterprise & Regulatory Reform (BERR) on behalf of the Secretary of State will enforce REACH alongside wider enforcement in respect of environmental protection offshore.

The enforcement regime will apply to all offshore installations (including fixed and floating platforms, floating production storage and off-loading systems, and floating storage units - but not ships) within the UK territorial sea and the Continental Shelf (UKCS). It is expected that the Harmonised Mandatory Control Scheme (HMCS) and REACH systems will run in parallel, with the HMCS approach to controlling offshore chemicals being gradually harmonised with the requirements of the EU Regulation. The proposed SI for the enforcement of REACH contains certain provisions from, and makes references to, the Offshore Chemicals Regulations (OCR) 2002, so effectively OCR (and hence the HMCS) will be the mechanism for supporting the application of the environmental protection aspects of REACH to offshore installations. However, it should be noted that BERR's existing regulatory regime for offshore chemicals does not extend to Scottish controlled waters and therefore, the same scenario will apply to BERR's enforcement of REACH. A list of the enforcing authorities can be found in Annex A

It is likely that at different times the enforcing authorities will want to devote more or less focus on REACH enforcement, depending on the levels of non-compliance experienced or their judgment of the relative importance of different risks to human health and the environment. For example, enforcement authorities might want to focus their effort on chemicals which have newly been subject to authorisation or restriction, which means that particular industry sectors might be more intensively covered at one time, and less so once it is clear that new rules are being satisfactorily complied with.

There are likely to be different total costs associated with enforcement activity under REACH depending on the subject matter of the enforcement. For instance, enforcement authorities have suggested that registration and supply-chain related enforcement is likely on a case-by-case basis to involve greater cost than use related enforcement. Registration and supply chain obligations may be more technical in nature and subject to exemptions which may need to be checked. However, the actual cost of enforcement will depend upon decisions on the level of activity which various enforcing agencies embark on in the years to come.

## **Monitoring and Evaluation**

Every five years Member States are required to submit to the Commission a report on the operation of the Regulation including a section on enforcement. The first report is due by 2010. The enforcing authorities will develop procedures to ensure enforcement information is appropriately recorded with the guidance of the UK REACH Competent Authority or the Enforcement Liaison Group which is comprised of all REACH enforcing authorities.

## **Small and Medium Enterprises (SMEs) and Large Firms**

This impact assessment takes into account the difference between the impact of enforcement on SMEs and impact on larger companies. For example, a SME will have a smaller number of employees and as a consequence a higher level staff member (e.g. finance director) may be required to prepare and deal with an inspection. Enforcement in relation to SME's will mainly be in conjunction with use related enforcement obligations such as the preparation of the Safety Data Sheet. In contrast a large multi-national company that is well resourced and has effective information systems may use a more junior member of staff to prepare and deal with an inspection. Inspections in the case of the large firms, will mainly be registration of chemicals and supply chain obligations.

Small Firms Impact Test – For the purpose of this impact assessment we have separated out the costs according to the size of firm. Although total costs fall largely on small firms, this is due to the population of firms, costs per firm inspected are calculated at approximately £120 for chemical firms and £40 for non-chemical companies.

## **REACH Phase-in-Periods**

The impact of the REACH regime will grow over time as its requirements are implemented in phases over a period of 11 years from June 2007 until 2018. Therefore the enforcement requirement will also develop progressively over this time. For example, the registration requirement will be enforced on different businesses at different times depending on the tonnage of substances that they produce or import.

Generally, registration enforcement requirements fall on the bigger businesses earlier. Companies which produce substances above 1000 tonnes per annum must register by 1 December 2010, and medium producers of substances above 100 tonnes per annum must register by 2013 while the SMEs that produce substances from 1-100 tonnes per annum may not be greatly impacted by REACH until 2018. Further details are included in Annex B.

We can expect some registration related enforcement from December 2008 e.g. related to the registration of substances new to the market and some supply chain related enforcement. (From 1<sup>st</sup> June 2007 it is already an obligation for businesses to provide information up and down the supply chain and comply with use related obligations). By 2010 onwards registration requirements for pre-registered substances come into force.



The authorisation and restriction parts of REACH enter into force on 1 June 2009, although the first authorisations are not likely to be issued until 2011, with the number initially small but growing over the following decade. The chemicals initially subject to restrictions are those already restricted under the current regime and therefore not initially a new burden for enforcement; new substances will only be added progressively after 2010.

The figures quoted in the impact assessment are an indication of the likely costs once REACH has a broad coverage of chemicals, including those used in moderate tonnages.

## **Cost to Business**

The costs to business are administrative burdens, as these are the costs associated with the legal requirements to comply with information obligations. The Standard Cost Methodology, a preferred Cabinet Office method for estimating administrative burdens, is the method used here in the calculation of the costs. This method calculates the administrative costs, by estimating the resource cost, time, population and frequency of the inspection and multiplying these together<sup>5</sup>. The estimates used for these parameters are based on the best information made available to us from stakeholders and various data sources, indicated as appropriate.

## **Parameters**

### Population and Frequency

The impact of REACH, although expected to be felt across a wide number of industries, will dominate in the chemicals manufacturing sector. Therefore, for this parameter we have split the population into two groups: chemical companies and other companies. We have suggested different enforcement frequencies for each.

Based on a risk assessment and intelligence-led approach, we assume that 10% of chemical companies and 2.5% of other companies will be subject to enforcement activity each year. Respective UK populations are 2,955 and 329,000<sup>6</sup>. These populations can be further broken down into SMEs and larger companies<sup>7</sup>:

Chemical companies	- Large 165 - SMEs 2,790
Other companies	- large 16,450 - SME's 312,550

Given that these frequencies and populations are key parameters, for which assumptions have had to be made, we think it is reasonable to employ a range of +/- 10%, in order to give a more representative picture of actual administrative burdens.

The initial Impact Assessment quoted 20% of chemical companies and 5% of other companies would be inspected. From the responses received to this initial assessment these frequencies were considered too high and have thus been adjusted.

As an aside, it is important to consider that administrative burdens might vary by Government Office Region, given the concentration of chemical companies in the North-West and South-

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<sup>5</sup> More detail of this methodology can be found on the Cabinet Office website.

<sup>6</sup> <http://stats.berr.gov.uk/ed/sme/smestats2006.xls#UK%20Whole%20Economy!A1>

<sup>7</sup> <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=13101>

East regions. Both of these regions account for more than 20% of UK total turnover from the manufacture of chemicals, chemical products and man-made fibres, and therefore might be expected to experience greater administrative burdens than other regions.

### Time

This is the time taken to enforce REACH, per visit. If businesses are ready for REACH checks, having had to be ready for previous similar checks (which are potentially no longer needed), then the additional time costs associated with REACH could be argued to be negligible. Alternatively, if REACH checks are quite different to existing checks, then the time parameter may be more significant.

An average time of 5 hours has been assumed for chemical companies, this includes 3 hours for preparing the information, and 2 hours to collect and provide the information on the day. An average time of 1.5 hours has been assumed for non chemical companies. This includes 1 hour for preparing the information, and 30 minutes to collect and provide the information on the day. The nature of enforcement for other companies will be mainly in respect to use enforcement and we believe it will not require the same length of time in preparation or for inspection.

The initial Impact Assessment quoted 90 minutes (60 minutes for preparing information and 30 minutes for the inspection). These times have been separated out and increased for chemical companies to reflect the responses received and the varying length of an inspection for different types of businesses.

At the level of the individual firm, the time taken to prepare for an inspection will vary according to business type and individual circumstances. We also consider that it is fair to assume that companies possess efficient and effective information retrieval systems for the other aspects of REACH. Although the enforcement requirements of REACH will grow over time as more chemicals are included in the regulations up to 2018, that means that the frequency that an individual business can expect an inspection is likely to reduce. Equally the time taken to prepare and the length of inspections may reduce with time as businesses become increasingly familiar with REACH processes and hence, enforcement costs on business may reduce over time.

### Resource cost

This is the wage rate, not including any overheads, of the person responsible for demonstrating compliance with REACH in a large firm. For a large company this has been estimated from the Annual Survey of Hours and Earnings in the UK<sup>8</sup> based on an Associate Professional and Technician who works in the Business and Public Service and gives an hourly rate of £18.63 (using the 75% percentile to assume they have good competence/ knowledge of REACH). For a SME this has been estimated from the Annual Survey of Hours and Earnings in the UK for a Corporate manager and gives an hourly rate of £18.80 (this figure is taken as the median wage rate due to the large number of SMEs included in the assessment ). As standard procedure we have then included 30% overheads to these figures, making the applied wage rates £24.22 per hour for a large company and £24.43 per hour for an SME.

The initial Impact Assessment quoted a resource cost of £41.48 for both business and enforcers and was felt to not accurately reflect resource costs to businesses based upon data collected by the Office of National Statistics – the wage rate for the 90<sup>th</sup> percentile of all employees, including overheads, is £30.25, significantly lower than the previously assumed resource cost.

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<sup>8</sup> [http://www.statistics.gov.uk/downloads/theme\\_labour/ASHE\\_2007/tab2\\_1a.xls](http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2007/tab2_1a.xls)

## Calculating the administrative burden

Table 2 – the administrative burden on business

	<b>Gross Costs Per Year (Range)</b>	<b>Net Costs Per Year (Range)</b>
Business (all)	£303,566 to £371,025	£227,674 – £278,269
- SMEs	£288,321 to £352,392	£216,241 - £264,294
- Large firms	£15,244 to £18,632	£11,433 - £13,974

Net costs are gross costs minus 25% - the assumed offsetting costs.

### Costs per Firm

This section provides an estimate of the average cost to a firm of being inspected, and a sensitivity where the inspection takes longer than assumed for the impact assessment. It should be noted that this cost will not apply to all companies, but only those who are inspected in any one year (we assume previously that 10% of chemical companies and 2.5% of non-chemical companies will be inspected in any one year). Table 3 gives an indication of the costs per firm inspected, assuming the average length of inspection. Table 4 provides a sensitivity, in the case where a firm requires double the length of time for preparation and an inspection. It is possible that this will occur in more complicated situations where companies are using a number of chemicals in a range of processes. Higher figures were suggested by a respondent in the consultation stage, however this is envisioned to be unlikely for companies that have efficient management systems and data storage.

Table 3 – administrative burdens per firm inspected

	Large Firms	SMEs
Chemical Firms	£121	£122
Non-chemical firms	£36	£37

Table 4 – sensitivity – administrative burdens per firm inspected with twice the time required

	Large Firms	SMEs
Chemical Firms	£242	£244
Non-chemical firms	£73	£73

## **Costs to Enforcers**

### Population and Frequency

The population and frequency to chemical companies and other companies is as described in the burden on businesses.

### Time

This is the time taken to carry out an inspection. Two hours has been assumed to carry out the inspection for chemical companies and 30 minutes for other companies. These are the same as the times allowed for businesses to collect and provide the information on the day. As at the level of the individual firm, time will vary according to business type and individual

circumstances. As it is proposed that enforcement takes place alongside existing regimes no additional time has been allocated for site travel or reporting.

### Resource Costs

We have considered two approaches in estimating the wage rate for the enforcers.

- i) The first approach has taken into consideration the wage rate, not including overhead costs, for the enforcers who will be enforcing REACH alongside existing legislation and thus are not expected to incur any extra costs in relation to overheads.
- ii) The second approach has taken into account enforcers who would be taking REACH on as a new enforcement duty and would therefore be subject to new overhead costs. It is envisaged that there will be new posts created in HSE connected with enforcement of registration and the Environment Agency and SEPA connected with enforcement outside Pollution Prevention and Control sites.

Wage rate excluding overheads – from data provided by HSE this would be equivalent to a Regulatory Inspector (Band 3), which gives a wage rate of £37.80/hr. Other enforcers provided higher wage rate costs that included full economic costs. We have assumed a rate which excludes overheads for the reasons given above.

New enforcement posts - Full economic costs of new posts have been quoted as

- HSE (1 post) - £54,445
- Environment Agency (2 posts) - £110,000
- SEPA (1 post) - £46,000

Enforcement offshore - Data provided by BERR has estimated that enforcement offshore will lie in the range of £57,000 and £95,000.

Training costs – there will be time costs associated with the training of inspectors and the preparation and dissemination of training materials. There will be ongoing costs of training arising from the need to train new inspectors in the provisions required under REACH – HSE have advised that the REACH training will be included in the early years training for inspectors, and as it is included alongside the other training received by a health and safety inspector, the costs are expected to be small relative to the overall costs of enforcement. Due to the small scale of these costs, we have not quantified them here.

There will also be an initial cost associated with the familiarisation of existing inspectors and the preparation and dissemination of training materials. It is expected that the preparation of training sessions and guidance documents will be part of the new posts created in the HSE and EA, so these costs are not additional and are already included above under the new enforcement posts. There is also a cost of the time for inspectors to attend workshops – this will not be an additional financial cost as it will be attended by existing enforcers, but there is an opportunity cost of the time of the inspectors. Following discussion with enforcing agencies, it is not felt that these costs are significant additional costs relative to the other costs of enforcement and in line with a proportionate approach these have not been quantified here.

The exact administrative burdens on enforcers will vary by agency, and will only be determinable in the long-run when the regulations are actually in place.

### Calculating the cost to enforcers

We estimate that the cost to enforcers, based on them enforcing REACH alongside current existing chemical regulation activities, to lie in the range of £160,013 – £195,571 per year.

The cost of the new posts created is estimated at £210,445

The cost of enforcing REACH offshore lies in the range of £57,000 and £95,000 per year.

The total net costs to enforcers lies in the range of £321,000 to £376,000 per year.

## **Benefits of REACH Enforcement**

The benefits of enforcement result from firms being more likely to comply with regulations due to actual enforcement or the threat of enforcement. As well as potential punitive measures, firms also have the incentive to comply due to the risk of damage to reputation and the potential for more rigorous investigation in future resulting from a risk-based approach to inspections. The benefits of enforcement form a sub-category of the total benefits of REACH. There are a number of reasons why firms comply with regulation, with enforcement and the threat of punitive action being an important one. Due to a lack of direct data on firms' behaviour and the complexity of the impacts, it is not possible to carry out a full quantitative assessment of the benefits arising as a result of enforcement. However, for illustrative purposes, a break even calculation has been carried out based upon illustrative estimates of the health benefits of REACH which suggests that a compliance rate due to enforcement of less than 0.5% would justify the costs of enforcement. Further details on estimating the benefits of REACH can be found in Annex E.

This break even calculation is based upon the total monetised health benefits of REACH as calculated in the Commission's extended impact assessment<sup>9</sup> which estimated the potential health benefits as being EUR 28bn.<sup>10</sup> The calculation is based upon expert estimates of the health impacts of REACH, but still only represents an illustrative example of the potential benefits as there is a great deal of uncertainty in these figures.

The illustrative figure is also likely to be an underestimate as it doesn't include a number of other benefits of REACH, such as reduced environmental risks as a result of the production, use and disposal of chemical substances.

There is further uncertainty surrounding the proportion of the potential benefits which are likely to occur in the UK. For the purposes of cost estimation, a central figure of 21.5% was used. This is the mid point between the UK chemical industry's output as a proportion of EU output (15%) and the proportion of notifications under the current Notification of New Substances regulations (NONS) by UK firms (28%). For the purposes of sensitivity analysis, the alternative figures are also displayed in the table below.

The costs of enforcement are calculated based upon Time, Resource Costs and Population and Frequency of visits, as calculated using the Standard Cost Model. Using the central estimate as detailed previously, these give an estimation of the total costs of enforcement as £0.6m per year, which is equivalent to £11.3m over 30 years (at a discount rate of 3% to match the Commission's calculations<sup>11</sup>)

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<sup>9</sup> Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

<sup>10</sup> This figure was estimated using Commission data on the health impacts combined with DfT guidance values for life years lost.

<sup>11</sup> The discount rate has been chosen for consistency – using the green book rate makes very little difference to the final result of the break even calculation (a difference of around 0.01%)

Combining the two figures above, in the central case, this gives a break even percentage for compliance with REACH due to enforcement of 0.26%.<sup>12</sup> This suggests that a very small percentage of compliance due to enforcement would be necessary for the costs of enforcement to be justified.

**Table 5-** break even points for enforcement of REACH

	<b>Sensitivity – proportion of UK benefits</b>		
	<b>Low</b>	<b>Central</b>	<b>High</b>
UK proportion of EU benefit	15%	21.50%	28%
Benefits to the UK	£3bn	£4bn	£6bn
Cost of Enforcement	£11.3m	£11.3m	£11.3m
Break Even Point	0.37%	0.26%	0.20%

### **1% Assumption of Compliance**

The break even calculation shows that a small proportion of additional compliance as a result of enforcement is necessary to justify the costs of enforcement. For the purposes of cost benefit analysis on the cover sheet, it has been assumed that 1% of compliance is as a result of the enforcement regime. Under this assumption, there is a potential benefit from enforcement of £43m over a 30 year period, or a net benefit of £32m after the costs are taken into account. Estimates from literature suggest that the assumption of 1% additional compliance resulting from enforcement is a conservative assumption and effective enforcement can lead to much higher levels of compliance.

### **Conclusion**

This impact assessment estimates the costs associated with the enforcement of REACH, separated out into the administrative burden on business of preparing for inspections and having inspections of their premises carried out, and the cost to the enforcement agencies of carrying out the inspections and the new posts specifically related to the enforcement of REACH.

The net costs of the enforcement of REACH are estimated to be between £550,000 and £650,000 per year. These costs are made up of administrative costs to business of between £230,000 and £280,000 and costs to enforcers of £320,000 and £370,000.

The impact assessment identifies a number of potential benefits associated with the enforcement of REACH, primarily the health and environmental benefits associated with an increase in the level of compliance with REACH as a result of having an effective and credible enforcement regime.

An illustrative example, based upon expert estimates of the potential health benefits of REACH, suggests that additional compliance of less than half a percent would lead to the costs of the enforcement of REACH being justified by the resulting health benefit. A net benefit figure of £32m has been estimated based upon the assumption of 1% additional compliance resulting from enforcement.

<sup>12</sup> NB these figures are all calculated using the EU discount rate of 3%. The calculations were repeated using the Green Book discount rate of 3.5% and the break even percentages were very similar (within 0.02%)



## Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.**

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	Yes	No
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

The specific impact tests can be found in Annex C



# Annexes

## Annex A – The Enforcing Authorities

- The Health and Safety Executive (HSE)
- The Health and Safety Executive of Northern Ireland (HSENI)
- The Environment Agency
- The Scottish Environment Protection Agency (SEPA)
- The Department of the Environment Northern Ireland (DoENI)
- Local Authorities
- The Secretary of State (SoS)

## Annex B – REACH Phases over 11 years and scaling of enforcement activities

Date	Activity	Enforcement Required
1 <sup>st</sup> June – 30 Nov 2008	Pre-registration for existing ('phase-in') substances	Existing enforcement Regulations e.g. dangerous substances/marketing and use continue
1 <sup>st</sup> June 2008	Registration for new ('non phase-in') substances starts	Existing enforcement structures continue
1 <sup>st</sup> Dec 2008	Registration for existing substances (that have not been pre-registered)	REACH enforcement commences. Enforcement initially will be similar to previous enforcement activities and increase as registrations take place
1 December 2010	Deadline for registration of substances supplied at $\geq 1000$ tonnes per annum (tpa)	Increasing enforcement activities as first tonnage deadline is passed
1 <sup>st</sup> June 2011	Earliest sunset date for authorisations	Earliest date for inclusion of enforcement activities relating to authorisations (substances of very high concern that may need to be authorised for specific uses)
1 June 2013	Deadline for registration of substances supplied at $\geq 100$ tpa	Greater enforcement activities as more registrations are completed
1 June 2018	Deadline for registration of substances supplied at $\geq 1$ tpa	Full enforcement of REACH

## Annex C

### OUTCOME OF 'SPECIFIC IMPACT TESTS' NOT REFERRED TO IN THE 'EVIDENCE BASE'

**NB: The effect on SMEs has been included within the main evidence base of this Impact Assessment**

### Competition Assessment

The proposal will allow for effective competition with the benefits of providing a level playing field for businesses between businesses.

### **Legal Aid**

The proposal creates some new criminal sanctions but we envisage these will have minimal impact on legal aid.

### **Sustainable Development**

The proposal to an extent is a simplification of existing legislation and should see short to long term impacts by reducing 'red tape' and burdens for business.

### **Carbon Impact Assessment**

The proposal will not have a significant effect on carbon emissions.

### **Other Environmental Issues**

The proposal will improve the environment as a result of less emissions of harmful substances.

### **Health Impact Assessment**

The proposal will improve human health as a result of less emissions of harmful substances.

### **Race /Disability/Gender**

There are no limitations on meeting the requirements of the proposal on the grounds of race, disability or gender.

### **Human Rights**

The proposal is consistent with the Human Rights Act 1998.

### **Rural Proofing**

The proposal has no direct impact on rural communities.

### **Annex D Acronyms**

BERR	Department for Business, Enterprise and Regulatory Reform
CHIP	Chemicals (Hazard Information and Packaging for Supply) Regulations 2002
DoENI	Department of the Environment Northern Ireland
HMCS	Harmonised Mandatory Control Scheme
HSE	Health and Safety Executive
HSENI	Health and Safety Executive of Northern Ireland
MoU	Memorandum of Understanding
OCR	Offshore Chemicals Regulations
PPC	Pollution Prevention Control
REACH	Registration, Evaluation and Authorisation of Chemicals
SCM	Standard Cost Model

SEPA	Scottish Environment Protection Agency
SIEFs	Substance Information Exchange Forum
SMEs	Small and Medium Enterprises
SoS	The Secretary of State
UK	United Kingdom

## Annex E

### Estimating the Benefits of REACH Enforcement

This annex provides further details on the benefits of enforcement and how the estimates have been obtained.

The benefit from enforcement arises as a result of firms becoming more likely to comply with regulations due to actual enforcement or the threat of enforcement. As well as potential punitive measures, firms also have the incentive to comply due to the risk of damage to reputation and the potential for more rigorous investigation in future due to a risk-based approach to inspections. The benefits of enforcement form a sub-category of the total benefits of REACH. There are a number of reasons why firms comply with regulation, with enforcement and the threat of punitive action being an important one. Due to a lack of direct data on firm behaviour and the complexity of the impacts, it is not possible to carry out a full quantitative assessment of the benefits arising as a result of enforcement. However, for illustrative purposes, a break even calculation has been carried out which suggests that a compliance rate due to enforcement of less than 0.5% would justify the costs of enforcement.

This break even calculation is based upon the total monetised benefits of REACH as calculated in the Commission's extended impact assessment<sup>13</sup>. The calculation is based upon expert estimates, but still only represents an illustrative example of the potential benefits and may be an underestimate as it doesn't include a number of other benefits of REACH. There is a great deal of uncertainty in these figures.

### General Approach

The framework for quantifying the benefit is a simple calculation which takes into account the total benefit of REACH and the proportion of firms who are complying with the policy as a result of enforcement.

Benefit of Enforcement = Benefit of REACH \* Proportion of firms complying because of enforcement.

### Benefits of REACH

The benefits of REACH are expected to accrue mainly in terms of reduced risks to human health, reduced risks of damages to the natural environment and benefits to the chemical industry in terms of improved reputation and competitive advantages. The quantification of costs to industry, especially the direct costs of registration, can be estimated with a reasonable degree of accuracy. That is because the information requirements for registration are clearly set out in annexes (V to VIII) to the Regulation. Direct costs may be less than estimated to the extent that, for example, industry already possesses much of the information, or some tests can be shown to be unnecessary due to limited exposure. In contrast, the quantification of the benefits of REACH is much more difficult to determine with any degree of accuracy. That is partly because the net beneficial effects of REACH for human health and the environment are difficult to identify precisely in relation to other causes of potential effects, and the benefits are likely to be long term, which itself creates uncertainty.

Nevertheless, it is possible to give indications of benefit, and these are illustrated in this section.

The benefits can be categorised as follows:

1. Reduction of environmental risks:

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<sup>13</sup> Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

- a. from the production process; and
  - b. the use and disposal of chemical substances.
2. Reduction of risks to human health:
- a. through occupational exposure;
  - b. through exposure via the environment; and
  - c. risks from use of consumer products.
3. Benefits for industry:
- a. improvement of the chemicals industry's reputation and improvement of the public's attitudes (and attached values) about chemicals and the chemicals industry (linked to a perceived higher degree of safety);
  - b. savings associated with a lightening of the regulatory burden for low production volume chemicals;
  - c. innovation associated with R&D to create substitutes and reformulated products; and
  - d. savings to downstream users associated with increased knowledge on chemicals.

### **Reduction of Environmental Risks**

In terms of environmental pollution, better information about the properties of chemicals (and subsequent risk management if required) may result in subsequent benefits. Quantification of these benefits in monetary terms would be extremely difficult, if not impossible. There are two primary reasons:

- although better information (and hence REACH) will help secure these benefits, the extent to which existing problems will be ameliorated is as yet unclear as is, in many cases, the existing baseline; and
- it will be very hard to value such benefits. There are economic valuation techniques (such as stated preference methods) that are increasingly used to elicit values of non market benefits including environmental benefits. However, it is a complex issue to present the environmental impacts in a way that can be properly understood and hence valued by the general public.

Although, it is thus not possible to attempt the valuation of potential environmental benefits of the REACH Regulation, it can be assumed that increased information on chemical substances could lead to enhanced risk management, specifically of those substances which are considered to present an unacceptable risk to the environment. The precautionary principle is thus of acute relevance here.

### **Reduction of Risks to Human Health**

The effects on human health, and thus the potential benefits of REACH, can be divided into occupational impacts and public health impacts. The latter includes the effects on children, the elderly and even embryos, all of which may be more vulnerable to exposure to certain substances. As noted above, it is very difficult to estimate how many of these illnesses and even deaths, can be associated directly with certain chemicals, i.e. to establish clear causation. This is partly because of problems of cocktail and multi-causal effects and the difficulty in obtaining robust dose-response functions to quantify the health impacts.

As is the case for the environmental benefits, it is very difficult to value potential human health benefits of REACH. The difficulties associated with attempting such a valuation include:

- the uncertainty over actual damage (i.e. how many of the illnesses and deaths can be linked to chemicals). For most chemicals it is not known how they pass through the environment (accumulated, dispersed or transformed), and how they affect living organisms at different concentrations (dose-response relationships – the relationship between a change in concentration level of a chemical substance and the health impacts).
- the lack of good statistical information on the total number of people affected by a certain disease.
- the absence of behavioural models showing how Government, other public bodies, industry and consumers would respond to the information provided by REACH, and how industry and users would then respond to the true costs of compliance. This means that there is also uncertainty about the effect REACH will have on reducing exposure to chemicals found to have damaging effects on human health, meaning that quantifying the risk reduction is impossible.

For these reasons, we have adopted a 'break even' approach, applying an illustrative estimate of the costs of REACH to the costs of enforcement to estimate the level of additional compliance necessary to outweigh the costs of enforcement.

The Commission has given an illustration of the potential long-term health benefits of risk reduction measures in their Extended Impact Assessment<sup>14</sup>. These have been tailored to the UK using data on the chemical market and valuations applied to UK policy:

- the proportion of all disease (based on World Health organisation figures and measured in Disability Adjusted Life Years – DALYs) due to agro-industrial chemicals and chemical pollution from diffuse sources is estimated to be between 0.6% and 2.5% in developed market economies. A conservative figure of 1.0% is therefore taken from this range.
- the proportion of this disease that will be identified and tackled by REACH is 10%.
- 30 DALYs are equivalent to 1 life saved.
- in line with a DfT guidance, a value per statistical life estimate of £1.2m was adopted<sup>15</sup>.
- the positive effects on public health would start to occur 10 years after REACH starts to be implemented, and persist for another 20 years.

The total health benefits would be in the order of magnitude of €28 billion (£20 billion) over the next 30 years. In other words, a 0.1% reduction in the burden of disease due to REACH would yield health benefits of €28 billion (£20 billion). The Commission stressed that this was not an estimate of the benefits of REACH, but rather an illustration of their potential scale.

### **A Break Even Approach to Estimating the Benefits of Enforcement**

Using the Commission's indicative estimates, combined with the enforcement cost estimates it is possible to carry out a break even calculation, to estimate the proportion of firms that would have to comply with REACH as a result of enforcement to justify the costs involved.

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<sup>14</sup> Extended Impact Assessment, Commissions Staff Working paper, SEC (2003) 1171/3, COM(2003) 644 final.

<sup>15</sup> The Department for Health is currently undertaking work to develop a standard value for this to be applied across government policy so this figure may change in future.

To estimate the proportion of benefits which will be accrued, a central figure of 21.5% has been used. This is the mid point between the UK chemical industry's output as a proportion of EU output (15%) and the proportion of notifications under the current Notification of New Substances regulations (NONS) by UK firms (28%).

Using the central estimate, the potential health benefit to the UK over a 30 year period is £4bn. On the cost side, the central estimate from earlier in the document has been applied, giving a net present value cost of enforcement over a 30 year period of £11.3m. In the central case, this implies that the break even percentage for compliance with REACH due to enforcement is 0.26%. This suggests that a very small percentage of compliance due to enforcement would be necessary for the costs of enforcement to be justified.

**Table 6-** break even points for enforcement of REACH

	<b>Sensitivity – proportion of UK benefits</b>		
	<b>Low</b>	<b>Central</b>	<b>High</b>
UK proportion of EU benefit	15%	21.50%	28%
Benefits to the UK	£3bn	£4bn	£6bn
Cost of Enforcement	£11.3m	£11.3m	£11.3m
Break Even Point	0.37%	0.26%	0.20%

### **1% Assumption of Compliance**

The break even calculation shows that a small proportion of additional compliance as a result of enforcement is necessary to justify the costs of enforcement. For the purposes of cost benefit analysis on the cover sheet, it has been assumed that 1% of compliance is as a result of the enforcement regime. Under this assumption, there is a potential benefit from enforcement of £43m over a 30 year period, or a net benefit of £32m after the costs are taken into account. Estimates from literature suggest that the assumption of 1% additional compliance resulting from enforcement is a conservative assumption and effective enforcement can lead to much higher levels of compliance.

### **Evidence on Compliance Behaviour**

There exists a body of literature on the subject of environmental regulation and enforcement which examines the link between the enforcement of regulations and the behaviour of companies.

Direct enforcement is where the firm is found to be in violation of regulations and is issued with penalties. This is the most direct mechanism for enforcement to impact on behaviour, but research has found that if only the direct incentives to comply are taken into account that firms tend to significantly over-comply with regulation, a phenomenon known as the Harrington paradox<sup>16</sup>. There are a number of potential explanations for this, some of which are included below.

Indirect deterrent effect is the benefit to the regulator of having a reputation for effective enforcement. Shimshack and Ward<sup>17</sup> found that “a single fine on one plant strongly enhances the regulator's credibility with all plants, amplifying that fine's impact.” This shows that an effective enforcement regime can lead firms to comply with the regulation even when they are not directly involved in enforcement.

<sup>16</sup> Helm (2000) “Environmental Policy, Objectives, Instruments and Implementation”, chapter 5, “Making things stick: enforcement and compliance”

<sup>17</sup> Shimshack and Ward (2003), “Regulator reputation, enforcement and environmental compliance”

A potential loss of image and brand reputation if a firm is found to be in violation of a regulation acts to strengthen the impact of a credibility regulatory regime. Reputational effects with the regulator are also a factor as non-compliance in one period may lead to a greater threat of enforcement in future and stronger punitive measures if found to be out of compliance on multiple occasions.

The literature finds that significant increases in compliance rates can be achieved as a result of effective enforcement regimes. The benefits of enforcement are shown to be wide-ranging, entailing more than just the risk to the firm of facing a fine with additional compliance resulting from the indirect deterrent effect and the potential damage to a firm's reputation (with both customers and regulators) as a result of being found to not be complying with regulations.

### **Concluding Remarks on the Benefit Estimation of Enforcement**

There is considerable uncertainty involved in estimating the benefits of REACH. However, the indicative figures for health benefits estimated by the Commission show that the total benefits of REACH in the UK could be in the region of £4bn. Relative to the enforcement costs as estimated using the standard cost model, it would need the additional compliance of a small proportion of firms for the benefits to outweigh the costs of enforcement.