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# Consultation on the enforcement of REACH in the UK

June 2008



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# Section 1- About the Consultation Paper

## 1.1 Purpose

This United Kingdom (UK) wide consultation paper seeks views on the draft Regulations and administrative arrangements for the enforcement in the UK of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals referred to in this consultation as REACH. This is the second and final consultation; an initial consultation was held in March 2007 on the various options for UK enforcement.

The scope of this consultation is focussed only on the draft Regulations and administrative arrangements for the proposed UK enforcement of REACH. It sets out how the Government proposes to meet the enforcement requirement in a proportionate manner i.e. by ensuring that compliance and enforcement burdens on businesses and the regulators are no greater than is strictly necessary. This consultation does not cover the nature of REACH which has been the subject of a previous consultation<sup>1</sup> nor does it cover how businesses are expected to comply with REACH.

This consultation paper initiates a 12 week period during which we would like to hear the views of any stakeholders interested in the enforcement of REACH. All responses will be carefully considered so we can decide whether amendments are needed to the Regulations and administrative arrangements.

## 1.2 Responding

This consultation has been issued by Defra with the Department for Business, Enterprise and Regulatory Reform (BERR) and the Devolved Administrations (DAs) for Scotland, Wales and Northern Ireland (together referred to as Government throughout this consultation paper).

If you would like to comment please email your response by **25<sup>th</sup> August 2008** to:

Email: [necs@defra.gsi.gov.uk](mailto:necs@defra.gsi.gov.uk)

Alternatively if you do not have access to email you can send your response to:

Fatima Olubodun  
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17, Smith Square  
London  
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<sup>1</sup> ['UK Consultation on the New EU Chemicals Strategy – REACH'](#).

Fax: 020 7238 1602

Respondents in Scotland, Wales and Northern Ireland may wish to copy their responses to the relevant Devolved Administration.

For Scotland:

Sandra Allan, Scottish Government, Area 1-J North, Victoria Quay, EH6 6QQ  
[Sandra.J.Allan@scotland.gsi.gov.uk](mailto:Sandra.J.Allan@scotland.gsi.gov.uk)

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Martin McVay, Welsh Assembly Government, c/o SUW, Environment Agency  
Wales, Cambria House, 29 Newport Road, Cardiff, CF24 0TP  
[Martin.McVay@Wales.gsi.gov.UK](mailto:Martin.McVay@Wales.gsi.gov.UK)

For Northern Ireland

Barry McAuley, Environmental Policy Division, AEQ, Department for the  
Environment, 20-24 Donegall Street, Belfast, BT1 2GP  
[Barry.Mcauley@doeni.gsi.gov.uk](mailto:Barry.Mcauley@doeni.gsi.gov.uk)

When responding please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

The Secretary of State for Environment, Food and Rural Affairs is the data controller, as defined in Section 1 of the Data Protection Act 1998 (DPA), in respect of any "personal data" that you provide to Defra in response to this consultation exercise. "Personal data" is information about an individual such as their name, contact details and opinions.

In line with Defra's policy of openness, at the end of the consultation period copies of the responses we receive may be made publicly available, in whole or in part. The information they contain may also be published in a summary of responses. If you do not wish all or part of your response (including your identity) to be made public, you must state in the response which parts you wish us to keep confidential. Any confidentiality disclaimer generated by your IT system in e-mail responses will not be treated as such a request. You should also be aware that there may be circumstances in which Defra will be required to communicate information to third parties on request, in order to comply with its obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004.

The Defra Information Resource Centre, Lower Ground Floor, Ergon House, Horseferry Road, London SW1P 2AL will supply copies of consultation responses to personal callers or in response to telephone or e-mail requests (tel: 020 7238 6575, e-mail: [defra.library@defra.gsi.gov.uk](mailto:defra.library@defra.gsi.gov.uk)). Wherever possible, personal callers should give the library at least 24 hours' notice of their requirements. An administrative charge will be made to cover photocopying and postage costs.

Comments or complaints about the consultation process (as opposed to comments about the issue which is the subject of the consultation) should be addressed to Marjorie Addo, Defra's Consultation Coordinator, Area 7D Nobel House, 17 Smith Square, London SW1P 3JR, email: [consultation.coordinator@defra.gsi.gov.uk](mailto:consultation.coordinator@defra.gsi.gov.uk).

## Section 2- Executive Summary

REACH is a new European Community Regulation on chemicals and their safe use ([EC 1907/2006](#)). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH). REACH became applicable in the UK (and across EU member States) on 1 June 2007. Not all of the provisions are currently in force<sup>2</sup>. REACH replaces a number of existing European Directives and Regulations which will result in amendments to, or revocation of corresponding secondary UK legislation.

REACH aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. It will make those who place chemicals on the market responsible for understanding and managing the risks associated with their use. As such it aims to enhance the innovation and competitiveness of the EU chemicals industry.

The benefits of REACH will only be realised if its application in the UK is effectively implemented and enforced against any companies that breach it. As the REACH provisions will be phased-in over 11 years the enforcement requirements will grow over time to 2018 as more chemicals fall within its scope, based on quantity (in tonnes) manufactured or imported, or action is taken to reduce the impact of the most hazardous substances.

The Government's aim is that REACH should be effectively enforced, but in ways which minimise the burden of verifying compliance for both businesses and for public authorities. REACH requires that Member States set up a Competent Authority(ies) that can advise business on their obligations and encourage compliance (see Section 3.3).

From the first consultation there was widespread agreement that existing enforcing agency or agencies should be used to enforce REACH, with REACH enforcement taking place alongside current enforcement activities<sup>3</sup>.

### The Regulations

The proposed Regulations in this consultation set out the legislative framework within which the enforcement authorities will operate. The Regulations establish in UK law the set of offences, and the penalties which the courts may impose, which can arise from non-compliance with certain provisions of the REACH Regulation. It imposes on a number of existing organisations a duty to enforce the Regulation, and gives powers to enable them to do this – for example to enter premises or ask for information. It also gives them powers to take prosecutions or issue a range of enforcement notices, to help secure compliance with the Regulation and it lays down the various offences and penalties should the requirements of the notices not be met.

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<sup>2</sup> Article 141 of REACH sets out when various provisions come into force.

<sup>3</sup> <http://www.defra.gov.uk/environment/chemicals/reach/index.htm>

The proposed enforcement authorities are those currently responsible for occupational health and safety, environmental protection, and consumer safety respectively, in the various parts of the United Kingdom (including territorial waters and the UK Continental Shelf (UKCS)).

### **Administrative Arrangements**

At an operational level the enforcing authorities will need to have arrangements on how they will work together. This is set out administratively using a Memorandum of Understanding. This memorandum will ensure that the Regulation can be enforced effectively but also that the burden on business is kept to a minimum by avoiding any potential overlaps in enforcement duties.

### **Impact Assessment**

A revised partial Impact Assessment is also being published alongside this consultation document and we welcome your views on the costs of enforcement to Government and businesses. The annual administrative burden on business and enforcers once REACH is fully in place (thus after 2018) 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.

The Government welcomes comments on the draft Regulations, administrative arrangements and the revised partial Impact Assessment. Any comments will be carefully considered so we can decide whether amendments need to be made to the Regulations or the administrative arrangements. Under Article 126 of REACH, Government must inform the European Commission of its enforcement provisions by 1 December 2008 and to meet this deadline will include the laying of Regulations in Parliament, by November 2008.

## Section 3- Introduction and Background

### 3.1 Background to REACH

The aim of the REACH Regulation ([EC 1907/2006](#)) is to ensure, across the EU, 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.

REACH will help fill a significant knowledge gap about chemicals in the environment, and to which humans are exposed. Around 30,000 chemicals are made, sold and used in significant amounts, but the current system has generated proper assessments on only a few hundred. Chemicals bring real benefits to everyday life. But some chemicals can also bring significant problems.

The Regulation aims to address a number of serious shortcomings with existing legislation. Central to these is the lack of available information on risks to human health and the environment for the majority of chemical substances on the EU market and the slow nature of the current system in dealing with substances which are identified as hazardous. This not only makes it difficult to assess the risks from chemicals but also affects the competitiveness of chemicals businesses due to distortions of the internal market inherent in the current fragmented legislative regime.

### 3.2 Summary of Key Features of REACH and Application in the UK

REACH is a European Regulation; as a Regulation it is directly applicable in all Member States without the need for transposition into domestic law. The Regulation became operative in the UK (in part) on 1 June 2007. The remainder of its provisions will progressively come into force between now and June 2018, see Table 1.

REACH forms the EU's framework legislation for the management, control and use of chemicals, and will replace much of the current patchwork of over 40 separate pieces of legislation over the phase-in period. This consultation paper sets out the draft Regulations for enforcement in the UK, the administrative arrangements of how the proposed enforcing authorities will work together and a revised partial Impact Assessment detailing the proposed costs to Government and businesses relating to enforcement.

REACH requires that each Member State must, under Article 125, set up a system of official controls and other activities as appropriate to the circumstances. Further, under Article 126 the UK must-

- lay down provisions on penalties for breaches of the requirements in the Regulation;
- take all measures necessary to ensure that they are implemented; and
- ensure the penalties provided for are effective, proportionate and dissuasive.

The UK must notify its provisions to the European Commission by no later than 1 December 2008.

REACH will apply to any business which manufactures, imports, distributes, sells or uses chemicals throughout the supply chain. REACH obligations could therefore potentially fall upon any business of any size in any part of the UK.

Manufacturers, importers, distributors and professional users who market or use chemicals must ensure those chemicals (in quantities of 1 tonne per year or more) are registered with the new European Chemicals Agency (ECHA) in Helsinki, which will coordinate the operation of REACH throughout the EU. Before a chemical can be registered, the applicant must provide information about the characteristics and hazards, if any, associated with that chemical.

REACH requires information about the risks associated with chemicals to be set out and provided to users in 'safety data sheets'. The manufacture, marketing or use of those chemicals which pose particularly serious hazards may be restricted (either in part or entirely), or may only be permitted following the grant of a specific "authorisation".

**Table 1: Key deadlines in the implementation of REACH**

<b>Date</b>	<b>Activity</b>
1 <sup>st</sup> June – 30 November 2008	Pre-registration for existing substances (substances already manufactured - includes those on the European Inventory of Existing Commercial Chemical Substances)
1 <sup>st</sup> June 2008	Registration for new substances starts
1 <sup>st</sup> December 2008	Registration for existing substances (that have not been pre-registered)
1 <sup>st</sup> June 2009	REACH restrictions enter into force
1 December 2010	Deadline for registration of substances supplied at $\geq 1000$ tonnes per annum (tpa) plus those which are carcinogenic, mutagenic or toxic to reproduction.
1 <sup>st</sup> June 2011	Earliest sunset date for 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
1 June 2018	Deadline for registration of substances supplied at $\geq 1$ tpa

The basic components of the REACH process are set out below:

- A single **pre-registration phase** of 6 months intended to encourage data sharing and help minimise any additional testing requirements. Pre-registration

information must be submitted to the European Chemicals Agency between 1 June 2008 and 30 November 2008.

- **Registration with ECHA** on a central database of all substances which any individual company manufactures or imports into the EU in quantities greater than 1 tonne per year (unless they fall within the scope of exemptions i.e. covered by existing legislation). There are arrangements, dependent on pre-registration, to phase in registration for substances currently manufactured or placed on the market, based on tonnage. Registration requires the submission of a technical dossier which may contain proposals for testing of a chemical to fill knowledge gaps. Once registered, substances will be assigned a registration number.
- **Dossier evaluation** which consists of a mandatory review of testing proposals submitted (primarily for substances supplied or manufactured in quantities greater than 100 tonnes per year) and a mandatory compliance check of at least 5% of registration dossiers. Dossier evaluation will be carried out by the European Chemicals Agency.
- **Substance evaluation** which consists of further evaluation of substances where it is felt these may pose a risk to human health or the environment but further information is needed. Substance evaluation will be co-ordinated by the European Chemicals Agency. Member States' competent authorities will carry out the evaluation.
- **Authorisation** - for substances of high concern, where alternatives cannot be substituted, businesses will need to apply for authorisation for specific uses where the risks can be adequately controlled or where there is a socio-economic case for continuing with the use of the substance. All other non-authorised uses of authorisable chemicals will be prohibited.
- **Restrictions** on manufacture, marketing and use of substances where the risks to human health and the environment are deemed to be unacceptable.

REACH applies to substances on their own, or in preparations (i.e. mixtures) and, in some circumstances, articles.

### 3.3 The Competent Authorities in the UK

REACH requires that member States set up a Competent Authority or Authorities<sup>4</sup>. In the UK the Competent Authorities are-

- in England, the Secretary of State, and so far as the matter comes within devolved competence;
  - in Wales, Welsh Ministers,
  - in Scotland, Scottish Ministers
  - in Northern Ireland, the Department of Enterprise, Trade and Investment and the Department of the Environment acting alone or jointly.<sup>5</sup>

For matters not within devolved competence, the Secretary of State is the Competent Authority.

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<sup>4</sup> Article 121

<sup>5</sup> S.I. 2007/ 1742

The functions of these Competent Authorities have been delegated to the Health and Safety Executive (HSE). HSE have set up a helpdesk where businesses can access advice on what is required of them by REACH. The helpdesk can be contacted by email [UKREACHCA@hse.gsi.gov.uk](mailto:UKREACHCA@hse.gsi.gov.uk), telephone 0845 408 9575 or post

UK REACH CA Helpdesk  
2.3 Redgrave Court  
Bootle  
Merseyside  
L20 7HS

The Competent Authority will be able to advise businesses of their obligations and encourage compliance. The web-site and helpdesk of the European Chemicals Agency can also provide advice (see email contact details below).

### **3.4 Role of European Chemicals Agency in Relation to Enforcement**

There is likely to be significant interaction on enforcement-related tasks between ECHA and national authorities i.e. the Competent Authority. The tasks of the ECHA include ensuring effective management of the technical, scientific and administrative aspects of the REACH system. The ECHA will perform completeness checks of registrations and assign registration numbers or where necessary reject registrations. When the ECHA performs compliance checks it may become necessary to require registrant(s) to submit further information. The ECHA will therefore have to rely on the national enforcement authorities to ensure that companies submit further information. If a registrant does not provide the information required, this may lead to the ECHA cancelling a registration (number) which may have previously been allocated.

There is extensive guidance on REACH procedures on the ECHA website <http://echa.europa.eu/>

A “Forum for Exchange of Information on Enforcement<sup>6</sup>” under the ECHA will aim to spread good practice and highlight problems at Community level, co-ordinate harmonised enforcement projects and joint inspections, develop working methods/tools for inspectors, identify enforcement strategies and best practice in enforcement.

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<sup>6</sup> The REACH Regulation Articles 76 and 77

## Section 4- The Proposal and Draft Regulations

### 4.1 The UK REACH Enforcement Regime

Between March and June 2007 Defra in association with the Devolved Administrations consulted on different potential enforcement regimes. Following that consultation a decision was made to enforce REACH through existing enforcement mechanisms. The enforcement regime thus developed takes into account differences with the legal systems and administrative structures across the UK. That means REACH will be enforced in the UK-

- by enforcing authorities who carry out existing functions in the areas covered by REACH; and
- as far as possible with their current enforcement powers.

The preferred approach to provide the legal basis for the UK enforcement of REACH is a Statutory Instrument made under Section 2(2) of the European Communities Act 1972. We propose that administrative arrangements using a Memorandum of Understanding deal with the operational aspects of enforcement.

In the design of the enforcement approach the following factors were key:

- Enforcement must be effective – it being recognised that failure to comply with REACH can have serious consequences for the environment or health.
- The first aim of enforcement is to ensure compliance. Where compliance is not occurring, the enforcing authorities should have the necessary powers to try to ensure compliance without the need for prosecution. Therefore, the enforcing authorities should all have powers to serve notices setting out any non-compliance or anticipated non-compliance. Failure to comply with a notice will be a criminal offence.
- Prosecutions are to be regarded as a measure of last resort.
- There are effective and dissuasive penalties for a breach of the Regulation.
- Where possible enforcement minimises the burden of checking compliance for both businesses and for enforcing authorities.
- The enforcement regime is compliant with Hampton principles of inspection and enforcement.
- A consistent approach is achieved (in so far as possible) throughout the UK.

### 4.2 The Regulations

The Regulations consist of seven Parts and ten Schedules, these are:

Part 1	Introduction
Part 2	Enforcement
Part 3	Exemptions
Part 4	Enforcement powers and civil proceedings
Part 5	Offences and penalties
Part 6	Appeals against notices and service of documents

Part 7            Revocations and amendments

Schedule 1	Table of REACH provisions
Schedule 2	Functions of enforcing authorities
Schedule 3	Health and safety enforcement arrangements
Schedule 4	Defence exemption and certificates
Schedule 5	Marketing and use of leaded paint
Schedule 6	Powers of enforcement
Schedule 7	Authorisations
Schedule 8	Appeals
Schedule 9	Service of documents
Schedule 10	Revocations and amendments

#### **4.3    The Enforcing Authorities**

Regulation 2 sets out the proposed enforcing authorities, they are:

- 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)

The enforcing authorities are proposed on the basis of their existing expertise in health and safety, environment matters and consumer safety, and their enforcement of similar legislation. REACH replaces some existing legislation including the Control of Dangerous Substances and Preparations Regulations 2006 and the Dangerous Substances and Preparations (Safety) Regulations 2006.

HM Revenue and Customs (HMRC) will provide assistance to the enforcement authorities by detaining goods at Import, either when requested to do so or in the event that HMRC suspect that goods may be imported which are in breach of REACH. Memoranda of Understanding will be introduced to allow HMRC to assist criminal investigations by the enforcers.

**Q.    Do you have any comments relating to the proposed enforcement authorities?**

#### **4.4    The REACH Provisions**

Regulation 2(1) of the draft Regulations defines a "listed REACH provision". This is a provision listed in the REACH table at Schedule 1. The table sets out those provisions in REACH which will be enforced in the UK. The Government believes that the articles of REACH included in Schedule 1 comprise all those provisions of

REACH which is appropriate to enforce in the UK to make REACH work. The table also lists the enforcing authority or authorities who are responsible for enforcement of these provisions. It therefore does not include all REACH provisions. The table was compiled by matching existing enforcement functions/responsibilities of proposed enforcers to provisions of REACH requiring enforcement.

The provisions can be divided into three broad areas: Registration, Supply Chain and Use

#### **4.4.1 Registration Related Provisions**

These provisions concern having a valid registration. Invariably they include a requirement on manufacturers or importers of substances on their own, in preparations or in articles to have a valid registration. There is also an equivalent responsibility on an 'only representative' (an EU based agent who will act to register substances for a company outside the EU). A valid registration also includes submitting the correct information on tonnage/change in tonnage and the completion and keeping up to date of a chemical safety report. The provision of any incorrect information could lead to an invalid registration. If a manufacturer places a substance or article on the market without a valid registration then it will be a criminal offence. Duties concerning dossier or substance evaluation are included under this heading as they relate to the validity of the registration in question. Examples of registration type articles include articles 5, 6, 7, 9, 14, 22 and 24.

#### **4.4.2 Supply Chain Related Provisions**

These provisions concern supply of information up and down the supply chain. Examples of such provisions include no. 31, 32, 34 and 37. They include: giving to recipient's safety data sheets; ensuring the information present is consistent with the chemical safety assessment; passing on of information by distributors; and keeping and making available information. There are also requirements on actors in the supply chain, including downstream users, to update and report information up the supply chain and to the Competent Authority and ECHA; this information may also relate to authorisations.

#### **4.4.3 Use Related Provisions**

These provisions concern using substances in accordance with the control measures identified by the registration process to ensure the protection of human health and the environment. There is also a requirement that a use of a substance complies with any authorisation or restrictions applied. Examples of such provisions include no. 37, 56, 60 and 67.

There are, however, some provisions of REACH that are not covered in the draft Regulations, for reasons explained below; these relate to animal testing (see 4.5 below) and Substance Information Exchange Forum (SIEFs) (see 4.6 below). There are also some other duties whereby if an applicant fails to discharge them they will result in an invalid registration. For example this might be in relation to an incorrect tonnage level.

## 4.5 Animal Testing

A key theme of REACH is the need to minimise the use of animals in testing and where possible to use suitable non-animal alternative methods. The long term aim is that where possible animal testing should be phased out altogether. The UK Government fully supports these aims. The key articles in the REACH Regulation that relate to animal testing are 13(1), which encourages information on the intrinsic properties of substances to be generated “*whenever possible by means other than vertebrate animal tests...*”, and 25(1) and 26(3), which state that animal testing should only be undertaken as a matter of last resort and that studies involving vertebrate animals shall not be repeated.

In the UK, the Animals (Scientific Procedures) Act 1986 (ASPAs) regulates any experimental or other scientific procedures applied to a ‘protected animal’ that may have the effect of causing that animal pain, suffering, distress or lasting harm. The Act defines protected animals as any living vertebrate, other than humans, and *Octopus vulgaris*. The Act also specifies in section 5(3) the permissible purposes for which animals may be used. The permissible purpose relevant to the conduct of animal tests for REACH is the protection of the natural environment in the interests of the health or welfare of man or animals, which also accords with the main aim of REACH.

The Act requires that regulated procedures can only be authorised and performed if there are no scientifically suitable alternatives that replace animal use, reduce the number of animals needed, refine the procedures used in order to cause less suffering, or involve animals of the lowest degree of neurophysiological sensitivity. The resultant likely benefits must also be weighed against the likely welfare costs to the animals.

This Act is administered in Great Britain by the Home Office and in Northern Ireland by the Department of Health, Social Services and Public Safety.

ASPAs has a three-level licensing system. The practical aspects of ASPAs controls on animal testing that would also apply to REACH are:

- Those carrying out the regulated procedures for the testing of chemicals under REACH, e.g. dosing and sampling of animals etc., must hold personal licences, which ensures that they are qualified;
- A project licence must be in place authorising the programme of work; in the case of REACH this would be for the testing of chemicals using internationally recognised test methods such as the Organisation of Economic Co-operation and Development (OECD) test guidelines;
- The establishment where the animal tests are to be carried out, e.g. a Contract Research Organisation (CRO), must hold a Certificate of Designation.

The Home Office and The Department of Health, Social Services and Public Safety in Northern Ireland enforce this system of Regulation mainly through unannounced inspections of designated establishments, such as CROs, to check compliance with

their licence and certificate authorities, and the conditions applied to them. Any person found guilty of an offence under ASPA is liable, in the worst case, to imprisonment or a fine, or both.

The Home Office has confirmed that if necessary licences would be amended to ensure REACH compliance is taken into account when CROs agree projects for the conduct of animals tests with customers and appropriate conditions added to licences so that meaningful and informative records of such tests are maintained and made available for inspection by Home Office inspectors.

In the Government's view, the provisions of the 1986 Act, together with the enforcement arrangements of the licensing system and programme of inspections, provide a suitable mechanism for ensuring that the requirements of REACH with regard to animal testing are satisfactorily met. In the light of this, separate enforcement provisions within the REACH enforcement Statutory Instrument for articles 13(1) and 25(1) are unnecessary.

#### **4.6 Substance Information Exchange Forum**

The REACH registration process encourages the joint submission of data for registration purposes. Dutyholders, who for example wish to register a similar substance, can form a Substance Information Exchange Forum (SIEF). SIEFs aim to reduce the number of individual submissions received by the Agency and encourage the early sharing of data and identification of data gaps. In addition, they aim to prevent duplication of testing strategies and limit the cost of registration. They require parties to "make every effort" to reach agreement about the sharing of studies or the cost of studies. We believe it would be impractical and inappropriate to enforce such provisions using criminal sanctions, except for those provisions related to avoiding unnecessary tests using animals. The rights and obligations which are created by these provisions are matters for civil law to resolve as and when appropriate.

**Q. Do you believe that all appropriate REACH provisions have been included for enforcement in the UK?**

#### **4.7 Enforcement Duties**

Regulation 3- (1) 'An enforcing authority must enforce a listed REACH provision where it is named against that provision in a column under the heading "Enforcing authority" in the REACH table'. This provision places a duty to enforce on the enforcing authorities. Regulation 3 (5) provides that the enforcing authorities will only be required to enforce to the extent they are dealing with issues related to their existing functions as set out in Schedule 2. How enforcing authorities carry out the duty placed on them is at their discretion. The draft Regulations do not specify any particular level of activity for the enforcing authorities and this will depend on their enforcement programmes and resources.

##### **4.7.1 Registration Related Enforcement**

We propose that articles relating to registration are enforced by HSE throughout Great Britain. This proposal is based on HSE having access to the

ECHA database.<sup>7</sup> The REACH Regulation requires that the Competent Authority is notified by the European Agency when information on a registration from a UK based registrant is available. This information can be used to check suspected instances of non-compliance throughout the supply chain.

In Northern Ireland HSENI will be formally responsible for enforcing these provisions, although drawing on HSE officers.

#### **4.7.2 Supply Chain Related Enforcement**

We propose that articles relating to the supply chain up to the point of the sales are enforced by HSE throughout Great Britain and HSENI in Northern Ireland. From previous Regulations such as Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) (CHIP governs the supply of dangerous chemicals in the UK) enforcement has been successful when there has been a single regulator regardless of site specific responsibilities. The number, and type, of sites in any given supply chain can vary considerably with different sites potentially covered by different regulators. If a site specific approach is taken on supply chain issues there would be potential difficulty in identifying which link in the chain is actually responsible for a given breach of REACH due to the different regulators involved and which enforcer should take enforcement action.

There may be instances in registration and supply chain enforcement that require environmental advice e.g. article 14(3)(c) and 14(3)(d) on an environmental hazard assessment and a persistent, bioaccumulative and toxic and very persistent and very bioaccumulative assessment. The administrative arrangements in the Memorandum of Understanding address how HSE and HSENI will obtain this advice from the Environment Agency, SEPA, SoS, and DoENI respectively in relation to any enforcement action.

#### **4.7.3 Use Related Enforcement**

The Government proposes that articles relating to use are enforced by the Environment Agency, SEPA, HSE, HSENI, DoENI, the Secretary of State (BERR) and Local Authorities. Local Authorities will be carrying out two functions in relation to REACH enforcement. First, health and safety and secondly, consumer safety.

In the initial consultation we proposed that REACH enforcement relating to environmental breaches from the use of chemicals in premises outside of regulated Pollution Prevention and Control (PPC) A(1) installations could be enforced by Local Authorities (A2 and B sites). However, in England and Wales there is already environmental expertise in the enforcement of chemicals legislation within the Environment Agency, reflected in the current enforcement of the Control of Dangerous Substances and Preparations Regulations 2006 which REACH replaces.

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<sup>7</sup> See 3.3 CA functions have been delegated to HSE.

It also ties in with Environment Agency responsibilities under the Water Framework Directive<sup>8</sup> and with enforcement campaigns which the Environment Agency runs.

In light of the above, it appears to the Government to suggest that the Environment Agency rather than Local Authorities enforce environmental breaches in England and Wales at A(2) and part B sites and beyond. Adopting this approach appears likely to provide a more logical, practical and cost-effective method of enforcement. Enforcement of this type is not envisaged to be on a proactive basis but rather a reactive basis. Thus environmental breaches of use-related provisions in England and Wales will all be enforced by the EA, wherever they occur.

In Scotland, SEPA currently has a wider remit with respect to PPC installations than the Environment Agency in England and Wales and will enforce environmental breaches in relation to part A and B processes. SEPA may extend their remit outside PPC processes based on the agreement for Local Authorities to provide intelligence and information at these sites. In Northern Ireland the DOE will enforce environmental breaches beyond PPC sites.

REACH is a process driven system and offences will not clearly relate to risks to health and safety or the environment. At an operational level there might be practical cases where more than one enforcing authority could have a power to enforce 'use' provisions, and there would also be 'grey' areas which could relate to both health and safety and the environment (e.g. the use of an unauthorised substance). Subject to the enforcement authorities acting in relation to their existing functions it will be for the Memorandum of Understanding to set out clear administrative arrangements by which the enforcement authorities will cooperate to enforce a particular provision.

**Q. Do you agree that the proposed enforcement authorities acting within their existing functions can adequately enforce REACH?**

#### **4.8 Enforcement 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 UKCS. HSE currently enforce maritime Health and Safety Regulations which apply to offshore installations and BERR currently regulate the use / discharge of chemicals by enforcing the Offshore Chemicals Regulations 2002 (OCR 2002) which implemented the OSPAR Harmonised Mandatory Control Scheme (HMCS) for controlling offshore chemicals (OSPAR - The Convention for the Protection of the Marine Environment of the North-East Atlantic).

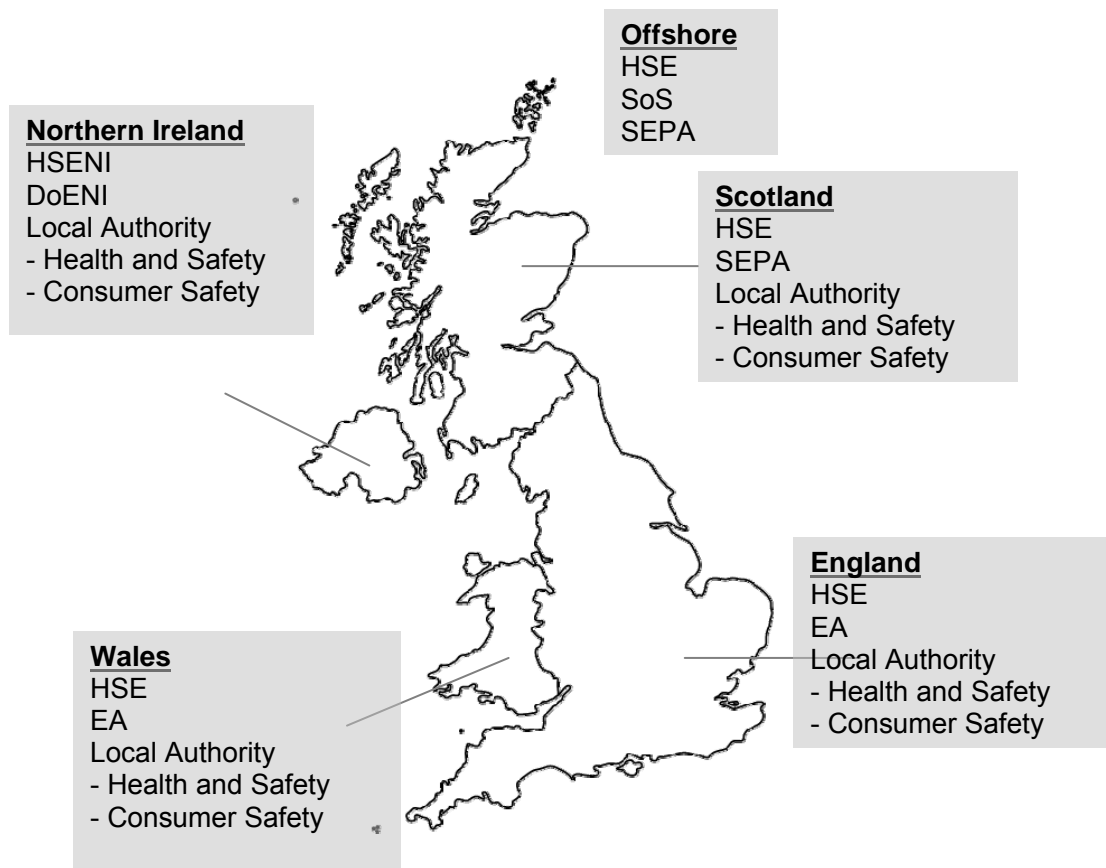
In order to ensure a consistent regime, the Government proposes that offshore enforcement of REACH is carried out by those who are currently familiar with enforcement requirements in similar circumstances to that required by REACH. Therefore, it is proposed that HSE and BERR should enforce offshore aspects of REACH enforcement (using their respective offshore inspectors to check compliance with the relevant provisions).

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<sup>8</sup> <http://www.defra.gov.uk/environment/water/wfd/index.htm>

In this context, it is expected that the 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 Regulations for the enforcement of REACH contain certain provisions from, and makes references to, the OCR 2002 so effectively OCR (and hence the HMCS) will be the mechanism that BERR intends to use for supporting the application of the environmental protection aspects of REACH to offshore installations. However, it should be noted that BERR's regulatory regime for offshore chemicals does not extend to Scottish controlled waters and therefore, in so far as this area is concerned, REACH will be enforced by an authorised body (i.e. SEPA) on behalf of the Scottish Executive. The appropriate articles for offshore enforcement and by which body are detailed in the offshore column of Schedule 1: Table of REACH provisions.

## Map showing the enforcement authorities in the UK



### 4.9 Scope of Enforcement Activities

The Government has aimed to provide as much clarity as possible to the regulators and business on the scope of the enforcement duties. The Government proposes to follow current divisions of responsibilities which have been created between HSE and Local Authorities in relation to the enforcement of health and safety matters. Therefore, where a local authority and HSE are both named as an enforcer of a listed REACH provision, responsibility will be ascertained by reference to the Health and Safety (Enforcing Authority) Regulations 1998 for England and Wales and similarly for Northern Ireland the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999. With some necessary changes this is reflected in Regulation 6 and Schedule 3 to the draft Regulations. The enforcing authority regulations present a steer for a particular situation for the correct enforcing body. Broadly speaking Local Authorities enforce in respect to retail premises and HSE enforcers everywhere else.

**Q. Do you have any comments on the scope of the enforcement duties?**

#### **4.10 Co-operation and Information Sharing**

The framework proposed may appear rigid with enforcing authorities only acting within legal remits and geographic areas. To allow flexibility and the capability to deal with novel circumstances the Government is proposing Regulations 4 and 5. Regulation 4 requires the enforcing authorities to co-operate with each other to assist compliance with, or the effective enforcement of, REACH. It proposes that the enforcers co-operate with each other, the equivalent of an enforcing authority in another Member State, and a competent authority in the UK or another Member State. Where reasonable, enforcing authorities must also disclose information to each other in relation to REACH enforcement activities.

It is likely, due to the nature of the chemical industry and range of downstream users affected by REACH in the EU that enforcement activities will occur across Member States. Thus it is important that information is shared, for example in relation to the tonnage levels manufactured or imported by a company. Interactions with the ECHA will probably occur via HSE as the delegated agent of the UK Competent Authority.

#### **4.11 Enforcement Arrangements**

Regulation 5 gives the enforcement authorities power to agree arrangements with another enforcing authority to facilitate the carrying out of an enforcement duty, or part of it. The Regulations also set out the process by which this can be achieved. This power means that the most appropriate enforcement authority can carry out enforcement in any particular case. Regulation 5(5)b allows for the cancelling of an enforcement transfer by the transferor or a transferee in 60 days notice in writing to the other party.

**Q. Do you believe that this approach on the transferring of enforcement responsibility and the co-operation and sharing of information between the enforcing authorities provides enough or too much flexibility? Do you believe that 60 days is sufficient time for the cancelling of an enforcement transfer?**

#### **4.12 Defence Exemption**

There are some matters which the enforcing authorities will not enforce as a listed REACH provision. Article 2(3) of the REACH Regulation gives Member States the power to allow exemptions from the Regulation to be made in specific cases for certain substances, where necessary in the interests of defence. The provision does not spell out what the circumstances for an exemption might be, or the type of substances involved. The Government expects application of an exemption to be the exception not the rule.

In the UK, the Ministry of Defence (MoD) will deal with exemptions in the sense of (a) the SoS deciding whether a person should have the benefit of the exemption and (b) providing evidence of that decision so that the enforcing authorities know that a person is exempt from enforcement. The draft Regulations deal with how the enforcing authorities will know that a person is exempt from enforcement. If a person has the benefit of the defence exemption it will be evidenced by a written certificate.

Schedule 4 sets out how the exemption may be applied, the contents of certificates and the persons to whom a certificate must be produced if required. The circumstances in which the SoS produces a certificate are not covered by this Statutory Instrument.

The Policy Statement on Safety, Health and Environmental Protection issued by the Secretary of State for Defence which can be found on the MOD website [www.mod.uk](http://www.mod.uk) stipulates that where the MoD has been granted specific exemptions, disapplications or derogations from legislation, international treaties or protocols, the MoD undertakes to introduce internal standards and management arrangements that are, so far as reasonably practicable, at least as good as those required by the legislation.

In accordance with this policy, the MoD will introduce a management system to mirror the main principles of the REACH regime. This system will be administered on behalf of the MoD by Defence Equipment and Support (DE&S) and applications for an exemption will be scrutinised on a case-by-case basis by a senior board within DE&S, who will make a recommendation to the Defence Secretary for the granting of a certificate. It is proposed that certificates should be time limited, depending on the use, and reviewed regularly. An annual report will be provided to the SoS and the UK competent authorities. The exemption certificates will be linked to the appropriate safety information containing the same level of detail that would be covered under the normal REACH arrangements.

#### **4.13 Maintained on Marketing and Use**

Article 67 and Annex XVII of the REACH Regulation will replicate, with some modifications, the annex to the EU Marketing and Use Directive 76/769/EEC. The UK continues to wish to make use of the derogation permitted to Member States to allow marketing and use of leaded paints in limited circumstances e.g. in the maintenance of certain historic buildings. Regulation 8 and Schedule 5 carry forward the existing arrangement in the UK in this new context.

N.B. Exemptions from the obligation to register can be found in Annexes IV and V of the REACH Regulation. These are substances on which sufficient information is known and they are considered to cause the minimum risk because of their intrinsic properties. These are universal exemptions across the EU and it is not appropriate to repeat them in these Regulations.

#### **4.14 Powers of Enforcement**

Regulation 9 and the relevant parts of Schedule 6 give each enforcing authority the suite of powers it will need to enable it to carry out its responsibilities. In each case the powers are carried forward from those already used in their existing enforcement activities. Using existing powers minimises the need for additional training and the risk of inappropriate actions by inspectors unfamiliar with new powers. It also means that businesses should already be familiar with the procedures being followed by inspectors when assessing compliance. This will minimise the overall burden of enforcing REACH on both business and the enforcing authorities.

#### **Table 2: Powers of enforcing authorities**

<b>Schedule 6</b>	<b>Enforcing Authority</b>	<b>Powers</b>
Part 1	Environment Agency, the Scottish Environment Protection Agency and the Department of the Environment Northern Ireland	These powers are as similar as possible to those under the Environment Act 1995.
Part 2	Health and Safety Executive and the Health and Safety Executive for Northern Ireland.	These powers are as similar as possible to those under the Health and Safety at Work Act 1974 and the Health and Safety at Work (Northern Ireland) Order 1978.
Part 3	Local (consumer safety) authorities and local (health and safety) authorities.	These powers are as similar as possible to those under the Consumer Protection Act 1987, the Health and Safety at Work Act 1974 and the Health and Safety at Work (Northern Ireland) Order 1978.
Part 4	The Secretary of State (BERR)	These powers are as similar as possible to those under the Offshore Chemicals Regulations 2002.

All enforcing authorities can authorise anyone to act for them in carrying out their enforcement duty.

#### **4.15 Appeals Against Notices**

Regulation 20 and Schedule 8 provides for the appeals process against a notice that has been issued by an enforcer. There are various types of notice available to the enforcing authorities in most part following the types of notice they currently use. The existing appeals procedures that apply to notices issued by an enforcing authority under other legislation are applied for the purposes of REACH enforcement. Those procedures are set out in Schedule 8 with minor drafting modifications. Businesses can therefore deal with appeals on the same basis that they would have done if the same enforcing authority had served a notice on them under other legislation. This may reduce their administrative burden.

**Q. Do you agree with the proposed powers and appeal routes against notices?**

#### **4.16 Offences and Penalties**

Regulation 11 provides that it is an offence for a person to contravene a provision of REACH listed in Schedule 1- the table of REACH Provisions. Failure to comply with REACH can have serious consequences for the environment and human health and it is necessary to have significant dissuasive penalties available to the courts. There could be some significant economic advantages to be obtained from supplying chemicals otherwise than in accordance with the requirements of REACH and, therefore, the penalties need to be sufficiently punitive to avoid this risk.

Accordingly, the breach of a listed REACH provision will be deemed to be an offence and, if found guilty criminal penalties will apply. There will be no distinction in the level of criminal penalties for breach of the provisions and it will be up to the courts to decide the level to apply in any particular case.

Accordingly, Regulation 12 sets out that a breach of each provision may be tried summarily or on indictment and provides that the same potential maximum penalty will apply for each provision, namely up to the maxima permitted under s2(2) European Communities Act 1972. These are currently three months imprisonment / £5,000 fine in Magistrates' Court or two years imprisonment / unlimited fine in the Crown Court. The maximum penalties for a breach will be the same irrespective of which authority is enforcing the provision in a particular case. In Scotland the majority of offences would be dealt with through the Sheriff Court which can issue penalties the same as those of the magistrate's court or the crown court depending on how the case is prosecuted. The Government acknowledges that there will be different levels of penalties between for instance Health and Safety offences and REACH offences. The approach for using those penalties permissible under s2(2) European Communities Act 1972 allows the same penalty for each REACH offence regardless of the enforcing authority.

Regulation 13 sets out supplementary criminal offences. These include obstruction of enforcement authorities, providing false statements, failure to comply with powers of enforcement, failure to comply with notices, prevention of a person from appearing before an authorised person and falsely pretending to be an authorised person. The supplementary offence will also be the subject of criminal penalties which are consistent with those in regulation 12 (for breaches of a listed Reach provision).

**Q. Should the penalties for offences under regulation 11 (a provision of REACH) and 13 (supplementary offences) be the same?**

If the enforcing authority is of the opinion that proceedings against a person for an offence would afford an ineffectual remedy against that person, the enforcing authority may take civil proceedings against that person for the purpose of seeking such remedy as the enforcing authority believes is appropriate in the circumstances, this is set out in regulation 10.

Regulations 18 and 19 put in place limitations on the power to institute criminal proceedings in England, Wales and Northern Ireland. No criminal proceedings for an offence may be instituted except by an enforcing authority or with the consent of the Director of Public Prosecutions (DPP). The Government believes that it would not be in the public interest for a private prosecution to be initiated without prior approval of

the DPP. The Government believes that, in the context of REACH, the public interest is served by imposing a requirement to obtain the consent of the DPP before a prosecution is brought than to rely on the power of the DPP to bring a prosecution to a close. It is likely that less time and resource will be needed to consider a request for consent to a prosecution than to bring an existing prosecution to a close.

#### **4.16.1 Administrative Financial Penalties**

Administrative penalties have been considered. However at present only the Environment Agency makes use of administrative financial penalties in some of its enforcement roles, but the Health and Safety Executive does not. As stated above, in order to ensure effective and consistent enforcement, it is important that a business should be subject to the same potential penalties whichever enforcement authority it is dealing with.

The Regulatory Enforcement and Sanctions Bill, currently before Parliament, takes forward key recommendations from the Macrory review by proposing to provide for Monetary Penalties. The powers will be made available as a menu to regulators on an 'opt-in' basis by means of affirmative Statutory Instrument. However, until the Bill becomes law and the scope of such penalties and the procedures to introduce them become clearer, it would be inappropriate to include a range of Macrory Penalties in the REACH enforcement Regulations.

The availability of Macrory Penalties will be kept under review in order that they may be available at a future date, if it is felt that they will materially contribute towards the effective enforcement of REACH.

**Q. Do you agree with the proposed penalties?**

#### **4.17 Revocations and Amendments**

REACH replaces a number of existing European Directives and Regulations. Repeals of the European legislation are detailed in Article 139 of the REACH text and are summarised as follows:

- Directive 91/155/EEC, the Safety Data Sheet Directive is already revoked.
- Directives 93/105/EC and 2000/21/EC, regarding information requirements for technical dossiers and for dangerous substances and preparations respectively. Both to be revoked with effect from the 1 June 2008.
- Regulations (EEC) No 793/93 regarding the evaluation and control of existing substances and (EC) No 1488/94, which lays down the principles for the assessment of risks to man and the environment of existing substances according to 793/93/EC. Both to be revoked with effect from 1 June 2008.
- Directive 93/67/EEC, which lays down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548/EC on dangerous substances. To be revoked with effect from 1 August 2008.

- Directive 76/769/EEC (Marketing and Use Directive), the legislative framework by which dangerous substances are currently restricted or banned. To be revoked with effect from 1 June 2009.

These Directives and Regulations were implemented in Great Britain by Statutory Instruments and by Statutory Rules in Northern Ireland. The equivalent provisions in REACH have legal effect in their own right; they are directly applicable in the UK. The UK will need to ensure that its domestic law is amended to remove any legislative provisions which are replicated as a result of REACH. In some cases, restrictions under the Directives were subject to discretionary exceptions which the UK decided to apply. Some of those exceptions are still permitted under REACH.

The instruments listed in Schedule 10 will be revoked from the date shown in that Schedule. These instruments include:

- SI 2006/3311 The Control of Dangerous Substances and Preparations Regulations 2006
- SI 2006/2961 The Dangerous Substances and Preparations (Safety) Regulations 2006
- S.I. 1994/1806 The Notification of Existing Substances (Enforcement) Regulations 1994
- S.I. 1993/3050 The Notification of New Substances Regulations 1993

**Q. Are there any other comments that you would like to be considered in respect of the Regulations?**

## Section 5 - Administrative Arrangements

### 5.1 Memorandum of Understanding

The Regulations show that there are many aspects of REACH that are relevant to more than one enforcing authority. For example, a use-related offence may have adverse implications for human health as well as the environment. At an operational level the enforcing authorities will need to have procedures on the working arrangements between them. This is set out administratively using a Memorandum of Understanding (MoU) between all the enforcing authorities (except Local Authorities, see below). These administrative arrangements will:

- Promote good standards of co-operation between the enforcement authorities to fulfil their duties under the Regulations.
- Ensure effective co-ordination between the enforcers where there are joint enforcement responsibilities.
- Ensure enforcement is consistent, transparent, targeted and proportionate.
- Ensure REACH is effectively enforced, whilst minimising the burden of checking compliance for both businesses and for public authorities.
- Avoid conflicting requirements being placed on dutyholders.

Where existing memoranda, concordats, partnership agreements and similar agreements exist between the parties to the MoU, the working arrangements set out in this MoU are without prejudice to those existing arrangements.

A single Memorandum of Understanding has been agreed by HSE, HSENI, Environment Agency, SEPA, EHSNI and BERR. It is believed that sufficient arrangements already exist between central government and Local Authorities both in relation to Health and Safety and the environment. These are referred to in the MoU and will be followed by the relevant authorities in respect of REACH enforcement. They are:

'Working Better Together'

<http://www.wlga.gov.uk/uploads/publications/469.pdf>

'Local authorities and HSE working together'

<http://www.hse.gov.uk/lau/pdfs/worktog0305.pdf>

The administrative arrangements cover:

#### 5.1.1 Enforcement Liaison Group

It is proposed to establish an Enforcement Liaison Group to help ensure co-operation and co-ordination between the enforcers. The group will be comprised of representatives of all the enforcing authorities. The group will:

- Discuss enforcement issues e.g. practical issues, areas of uncertainty.
- Determine the substances and/or issues that are a priority for enforcement.
- Advise on appropriate arrangements for informing industry of REACH developments; and
- Contribute to UK participation in enforcement of REACH outside of the UK.

The UK representative at the European Chemicals Agency Forum for exchange of information on enforcement will also be a member of the Enforcement Liaison Group.

### **5.1.2 Effective Enforcement where there is Joint Responsibility**

There are cases where more than one enforcing authority is responsible for the enforcement of a provision. For instance, where the use of a substance presents a risk in terms of work related health and safety and the environment. In cases such as these the decision on which enforcing authority will take the operational lead will be made locally by the relevant field inspectors and on a case by case basis to ensure that between them the provision is effectively enforced.

### **5.1.3 Information Exchange**

The MoU details the procedures by which enforcers will share information between each other. These include

- That which is outside the enforcement responsibility of an enforcement authority.
- Information in relation to inspection campaigns.
- Notification to the competent authority where there is evidence that a substance, preparation or article is being placed on the market without a valid registration.
- Where the ECHA or competent authority is aware of imposed conditions or restrictions they will share these with the enforcing authorities; and
- The provision of information from the ECHA database via the competent authority for the purpose of enforcement.

### **5.1.4 The Provision of Specialist Advice**

The arrangements by which specialist advice will be provided such as the provision of environmental advice in relation to supply chain enforcement undertaken by HSE or HSENI. Environmental advice will be from the Environment Agency, SEPA or DoENI as appropriate. From the competent authority this will be in areas such as toxicology and occupational hygiene.

### **5.1.5 Recording Enforcement Information**

The mechanisms by which the enforcing authorities will report on enforcement progress and performance. This is necessary to fulfil the UK's obligations under article 117 of the REACH Regulation which requires Member States to submit to the European Commission every 5 years a report on the operation of REACH in their respective territories, including enforcement.

#### **5.1.6 Resolving Disagreements**

The process that will be used if disagreements occur between the enforcing authorities. Initially disagreements should be resolved bilaterally however, if this is not possible the issue will be referred to the Enforcement Liaison Group and then the Competent Authority Steering Committee if necessary.

#### **5.1.7 Review**

The practical implications and effectiveness of the MoU will be reviewed after its first year and any amendments agreed by all parties.

**Q. Do you agree with the administrative arrangements as set out in the Memorandum of Understanding? Do you think there should be additional operation issues included?**

## Section 6 – Revised Impact Assessment

The revised partial Impact Assessment provides information on the costs and benefits associated with REACH enforcement.

It provides a detailed analysis which includes an estimate of the costs to business of preparing for and demonstrating compliance to enforcement authorities and the costs of enforcement to Government.

The partial Impact Assessment covers the key monetised costs by main affected groups (chemical companies, other companies and draws out small and medium enterprises). It also covers the benefits of increased compliance to human health and improvement to the environment along with effective competition.

The annual administrative burden on business and enforcers once REACH is fully in place (thus after 2018) 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.

**Q. Could the assessment of the enforcement costs to business and the enforcement authorities be further improved? If so, how?**

## **Section 7 – Summary of Questions and Next Steps**

### **7.1 The Regulations**

- Q. Do you have any comments relating to the proposed enforcement authorities?
- Q. Do you believe that all appropriate REACH provisions have been included for enforcement in the UK?
- Q. Do you agree that the proposed enforcement authorities acting within their existing functions can adequately enforce REACH?
- Q. Do you have any comments on the scope of the enforcement duties?
- Q. Do you believe that this approach on the transferring of enforcement responsibility and the co-operation and sharing of information between the enforcing authorities provides enough or too much flexibility? Do you believe that 60 days is sufficient time for the cancelling of an enforcement transfer?
- Q. Do you agree with the proposed powers and appeal routes against notices?
- Q. Should the penalties for offences under regulation 11 (a provision of REACH) and 13 (supplementary offences) be the same?
- Q. Do you agree with the proposed penalties?
- Q. Are there any other comments that you would like to be considered in respect of the Regulations?

### **7.2 The Administrative Arrangements**

- Q. Do you agree with the administrative arrangements as set out in the Memorandum of Understanding? Do you think there should be additional operation issues included?

### **7.3 The Impact Assessment**

- Q. Could the assessment of the enforcement costs to business and the enforcement authorities be further improved? If so, how?

### **7.4 Next Steps**

Consultees have 12 weeks to send in their comments. All responses to the consultation will be considered carefully. A summary of responses, including the next steps will be published as soon as possible after the closure of the consultation. Paper copies as well as a large print version will be available on request.

## Section 8 List of Consultees

- Agricultural Industries Confederation
- Alliance of Industry Associations
- Amicus
- ARENA Network
- Association for Instrumentation, Control, Automation and Laboratory Control (GAMICA)
- Association of British Pharmaceutical Industry
- Association of Manufacturers of Domestic Appliances (AMEDA)
- BMT Cordah
- British Aerosol Manufacturers Association (BAMA)
- British Association for Chemical Specialties
- British Cement Association
- British Chamber of Commerce
- British Coatings Federation Ltd
- British Footwear Manufacturers Association
- British Furniture Manufacturers
- British Geological Survey (BGS)
- British Hardware and Housewares Manufacturers' Association
- British Plastics Federation
- British Printing Industries Federation
- British Retail Consortium
- British Rubber Manufacturers Association
- British Surface Treatment Suppliers Association
- British Union for the Abolition of Vivisection
- British Wood Preserving & Damp Proofing Association
- CBI
- CBI Wales
- Centre for Ecology & Hydrology
- Centre for Environment, Fisheries and Aquaculture Science (CEFAS) - Offshore Chemical Notification Scheme (Chemical Submissions & Enquiries)
- Centre for Environmental Strategy
- Chartered Institute of Environmental Health
- Champion Technologies
- Chemical Business Association
- Chemical Industries Association
- Chemlaw UK

- CIA / Rhodia
- Confederation of British Industry
- Confederation of British Wool and Textile Manufacturers
- Confederation of Paper Industries
- Convention of Scottish Local Authorities (COSLA)
- Component Obsolescence Group (COG)
- Countryside Council for Wales
- Defence Aviation Repair Agency
- Engineering Employers Federation (EEF)
- Environment Agency Wales
- European Coalition to End Animal Experiments (ECEAE)
- European Oilfield Specialty Chemicals Association (EOSCA)
- Federation of Small Businesses
- Federation of Small Businesses (Scotland)
- Food Standards Agency Scotland
- Fisheries Research Services
- Friends of the Earth
- GMB
- Green Alliance
- Greenpeace
- Greenspace Scotland
- Hallibuton
- HSE
- Institute of Metal Finishing
- Intellect
- International Association of Drilling Contractors
- Local Authorities Coordinators of Regulatory Services (LACORS)
- MRC Institute for Environment & Health
- National Federation of Women's Institutes
- National Microelectronics Institute (NMI)
- NAVS/Animal Defenders International / Lord Dowling Fund for Humane Research
- Non-Ferrous Alliance
- Oil & Gas UK
- Packaging & Industrial Films Association
- Paint Research Association
- People for the Ethical Treatment of Animals
- Performance Textile Association
- Resource Efficiency Knowledge Transfer Network

- Royal Commission on Environmental Pollution
- Royal Society for the Prevention of Cruelty to Animals (RSPCA)
- Royal Society of Chemistry
- Scientific Alliance
- Scottish Chambers of Commerce
- Scotch Whisky Association
- Scottish Business in the Community
- Scottish Committee of the Chemical Industries Association
- Scottish Engineering
- Scottish Enterprise
- Scottish Environment Protection Agency
- Scottish Federation of Small Businesses
- Scottish Manufacturing Advisory Service
- Scottish Power
- Society of Chemical Industry
- Society of Dyers & Colourists
- Society of Motor Manufacturers & Traders Ltd (SMMT)
- Solvents Industry Association
- The British Electro-technical & Allied Manufacturers (BEAMA)
- The Franchised Distributors of Electronics Components (AFDEC)
- Trades Union Congress (TUC)
- Trading Standards Institute
- Transport & General Workers' Union (TGWU)
- UK Cleaning Products Industry Association
- UK Steel Association
- Union of Shop, Distributive & Allied Workers (USDAW)
- Wales Environment Trust
- Welsh Local Government Association
- Wood Panel Industries Federation
- WWF - UK

## Section 9 List of Acronyms

ASPA	Animals (Scientific Procedures) Act 1986 ASPA
BERR	Department for Business, Enterprise and Regulatory Reform
CHIP	Chemicals (Hazard Information and Packaging for Supply) Regulations 200213
CRO	Contract Research Organisation
DAs	Devolved Administrations
DE&S	Defence Equipment and Support
DoENI	Department of the Environment Northern Ireland
DPP	Director of Public Prosecutions
ECHA	European Chemicals Agency
EHSNI	The Environment and Heritage Service
EU	European Union
HMRC	HM Revenue and Customs
HSE	Health and Safety Executive
HSENI	Health and Safety Executive of Northern Ireland
MoD	Ministry of Defence
MoU	Memorandum of Understanding
OECD	Organisation of Economic Co-operation and Development
PPC	Pollution Prevention Control
REACH	Registration, Evaluation and Authorisation of Chemicals
SEPA	Scottish Environment Protection Agency
SIEFs	Substance Information Exchange Forum
SoS	The Secretary of State
UK	United Kingdom
UKCS	UK Continental Shelf