

Consultation on the enforcement of REACH in the UK

March 2007

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Purpose

The purpose of this consultation is to gather stakeholder views on proposals for the UK enforcement of the new EU Regulation on chemicals – **REACH** (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals)

Responding

This consultation has been issued by Defra with the Devolved Administrations (DAs) for Scotland, Wales and Northern Ireland.

If you would like to comment please email your response by **4 June 2007** to:

Email: necs@defra.gsi.gov.uk

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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 in response to this consultation exercise. "Personal data" is information about an individual such as their name, contact details and opinions.

All responses to this consultation will be made publicly available, unless specifically requested in the response. The information contained in your response and any supporting documents will be shared with other officials in government, the Devolved Administrations and regulatory bodies such as the Environment Agency.

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Your response to this consultation document may be made publicly available in whole or in part at the Department's discretion. 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. Where confidentiality is not requested, responses may be made available to any enquirer, including enquirers outside the UK, or published by any means, including on the internet.

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 through the Defra Information Resource Centre, Lower Ground Floor, Ergon House, 17 Smith Square, London SW1P 3JR. The information they contain may also be published in a summary of responses.

If you do not consent to this, you must clearly request that your response be treated confidentially. 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.

The Information Resource Centre 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). 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.

This consultation document should adhere to the six criteria outlined in the Cabinet Office Code of Practice:

- Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
- Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
- Ensure that your consultation is clear, concise and widely accessible.
- Give feedback regarding the responses received and how the consultation process influenced the policy.
- Monitor your department's effectiveness at consultation, including through the use of a designated consultation coordinator.
- Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

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.

Following the consultation, we will publish a summary of responses and an outline of how we plan to take the proposals forward.

Introduction and Summary

The European Union has recently adopted a new system to control the risks which chemicals may pose to human health and the environment. The REACH Regulation (**R**egistration, **E**valuation, **A**uthorisation and restrictions of **C**hemicals) will come into force on 1 June. It will form the EU's framework legislation for the management, control and use of chemicals, replacing much of the current patchwork of over 40 separate pieces of legislation over a phase-in period. This consultation paper is about how REACH will be enforced in the UK.

REACH will be introduced progressively, starting in June this year until 2018. In summary, manufacturers, importers, distributors and professional users who market or use chemicals must ensure those chemicals are registered with the new European Chemicals Agency in Helsinki, which will oversee 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.

The Regulation also requires information about the risks associated with chemicals to be set out and provided to users in 'safety data sheets'. Those chemicals which pose a serious hazard may be banned (i.e. "restricted"), or may be used only following the grant of a specific "authorisation".

REACH will therefore apply not only to chemical manufacturers or suppliers, but to any business which uses chemicals – so a wide range of businesses will need to take account of REACH and may be affected by the enforcement arrangements proposed in this consultation document.

REACH is a European Regulation, which means it is part of our law without the need for transposition. However, REACH requires that each Member State must set up a system of controls and penalties for breaches of the requirements in the Regulation and take the necessary measures to implement those penalties. This consultation paper is about these enforcement aspects, where we need to supplement REACH with national legislation to ensure that it can work as intended.

The Government's aim is that REACH should be effectively enforced, but in ways which minimise the burden of checking compliance for both businesses and for public authorities.

An effective enforcement system requires:

- A body or bodies that are responsible for enforcing the requirements in REACH; these requirements may be allocated to different enforcement bodies.
- Adequate powers are given to these bodies to carry out their tasks (e.g. the ability to obtain information, to inspect premises and property, to collect evidence and to give enforcement notices requiring certain action to be taken or ceased).
- Effective, proportionate and dissuasive penalties for breach of the requirements in REACH and in connection with enforcement powers (e.g. failure to comply with an enforcement notice, obstruction of an inspector acting for an enforcement body).

An option would be to set up a new body or bodies. However, we consider this is not necessary if the existing regulators can enforce REACH within the range of their current functions. We believe that they can. We are satisfied that the regulators can establish arrangements between themselves whereby information they gather can be shared and that the most appropriate regulator takes forward a possible breach of a REACH requirement.

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We have also considered whether new powers of enforcement are required or whether existing powers available to these regulators are adequate in terms of the requirements under REACH. We believe that the existing powers are adequate in relation to the functions of the regulators and no new powers are needed.

In terms of penalties, we have considered whether the requirements under REACH are covered by existing legislation and penalties under that legislation. However, although there is some overlap of REACH with other legislation, to rely on existing penalties would risk inconsistencies and gaps in enforcement. There would also be a lack of clarity for both regulators and for business concerning the consequences of a breach of a REACH requirement.

Therefore, we propose that a breach of a REACH requirement will be made an offence and carry criminal penalties. However, we do not propose to introduce new penalties in connection with enforcement powers (e.g. failure to comply with an enforcement notice, obstruction of an inspector acting for an enforcement body). We believe that the existing range of penalties is adequate and sufficiently consistent. To introduce such new penalties would also cause practical problems for both the regulators and business. The consequences of, for example, failure to comply with an enforcement notice would possibly differ depending on whether a REACH or other legal requirement covering a similar matter was being enforced. This could lead to uncertainties for business and possible additional work for the regulators.

The requirements under REACH fall into two broad categories: (a) registration and information in the supply chain and (b) use of chemicals (Annex D describes which Articles in REACH fall within each category).

We propose that the requirements concerning registration and information in the supply chain will be enforced by the Health and Safety Executive (and the equivalent body in Northern Ireland). This broadly mirrors the current responsibility they have for enforcing the provisions on labelling chemicals.

We propose the requirements concerning the use of chemicals will be enforced by:

- The Health and Safety Executive (HSE), in Great Britain.
- The Health and Safety Executive of Northern Ireland (HSENI).
- The Environment Agency (EA) in England and Wales.
- The Scottish Environment Protection Agency (SEPA).
- The Northern Ireland Environment and Heritage Service (EHSNI).
- Local authorities.

These bodies will continue to act within the scope of their existing functions:- for HSE and HSENI this means dealing with health and safety in the workplace, for EA, SEPA and EHSNI this means environmental protection and for local authorities this means consumer protection, and health and safety in the workplace and environmental health for certain premises.

These bodies already enforce similar matters with existing legislation and in doing so visit premises and request information. So far as possible the enforcement of REACH will be carried out in conjunction with these other matters and therefore it is not intended that businesses will see any more site visits than they currently experience nor visits from different regulators than those they deal with now.

We have estimated, on the basis of initial assumptions, that the total cost to all businesses affected by the regulations of demonstrating compliance to enforcement officers may be around £1 million per year, but we would welcome any additional information to assess this cost further.

The Government will welcome comments on these proposals. Any comments will be carefully considered so we can decide whether the proposals should be amended in any way before we go forward. The next step will be to prepare a draft of the regulations, which will need to be in place during 2008 to meet the deadline set in the REACH Regulation. We envisage that there will be an opportunity to comment on the specific details of those regulations before they are finalised.

1 Introduction

1.1 Structure of the consultation

1. Section 1 sets out the scope and background to the consultation and the approach we have taken in developing the proposals.
2. Section 2 considers the roles of the enforcement authorities.
3. Section 3 considers the legislative approach including the penalties regime.
4. Annexes A – D provide additional information including a partial regulatory impact assessment of the proposals (**Annex A**).
5. You are invited to comment on the proposals in general but specific questions where we are seeking views are highlighted in the text.

1.2 REACH

6. The REACH Regulation was agreed by the European Parliament and the Council of Ministers on 18 December 2006, and published in the Official Journal on 30 December¹. The Regulation will enter into force on 1 June 2007. However, the requirements of REACH themselves are phased. The timings for the implementation of REACH are summarised in **Annex B**.
7. The UK is required to have an enforcement and penalties regime in place no later than 1 December 2008.

1.3 Scope

8. The scope of this consultation is focussed only on proposals for the enforcement of the REACH Regulation in the UK including proposals for a penalties regime. It does not cover the nature of the Regulation itself which has been the subject of a previous consultation² nor does it cover how businesses are expected to comply with REACH³. The impact of the Regulation as a whole has been assessed in a partial regulatory impact assessment⁴.
9. REACH is a European Regulation directly applicable in all Member States without the need for transposition into domestic law. However, Member States are required to provide for enforcement of the legislation and to set up a penalties regime which is “effective, proportionate and dissuasive”⁵. This consultation sets out how the Government proposes to meet this requirement while minimising burdens on business and the regulators.

1.4 Background to REACH

10. The aim of REACH 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.

¹ The final version of the text can be found at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf.

² ‘UK Consultation on the New EU Chemicals Strategy – REACH’.

³ The Government is working with the Competent Authority to develop a communications strategy to raise awareness of the REACH Regulation and its principle requirements. The Competent Authority also provides a helpdesk that may be contacted on 0845 408 9575 or via email at ukreachca@hse.gsi.gov.uk.

⁴ <http://www.defra.gov.uk/environment/chemicals/reach/pdf/PartialRIACCommonPosition-May2006.pdf>

⁵ REACH Regulation, Title XIV Enforcement, Article 126.

11. 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. 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.

12. 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 too.

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

- A single **pre-registration phase** of 18 months following entry into force of REACH on 1 June 2007, intended to encourage data sharing and help minimise any additional testing requirements. Pre-registration information must be submitted to the European Chemicals Agency within a period beginning 1 June 2008 and ending on 1 December 2008.
- **Registration** 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. There are special arrangements to phase in registration for substances currently manufactured or on the market, based on tonnage.
- **Dossier evaluation** – registration requires a technical dossier that may contain proposals for testing of the chemical to fill knowledge gaps. Dossier evaluation 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** – this consists of further evaluation of substances where these may pose a risk to human health or the environment. Substance evaluation will be co-ordinated by the 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 use of the substance. All other non-authorised uses of authorisable chemicals will be prohibited.
- **Restrictions** on marketing and use of substances where the risks to human health and the environment are deemed to be unacceptable (REACH will carry forward the existing EU restrictions regime, with the Agency to play a co-ordinating role in the examination of proposals for new restrictions).

14. There are requirements regarding information in the supply chain. It is an intention of the REACH Regulation that all available and relevant information on substances on their own, in preparations and in articles should be collected to assist in identifying hazardous properties, and recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary.

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15. There are also requirements regarding classification and labelling. A classification and labelling⁶ inventory shall be established in the form of a database and the information held will be publicly accessible.

16. 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.

17. REACH establishes a central European Chemicals Agency ("the Agency") to co-ordinate the system, while Member States are responsible for a degree of the work and enforcement. The Agency will be located in Helsinki, Finland.

18. REACH will replace 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.
- Directives 93/105/EC and 2000/21/EC, regarding information requirements for technical dossiers and dangerous substances and preparations respectively.
- 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.

Provisions in these Directives had to be implemented in the UK by Statutory Instruments in order to have legal effect – often referred to as "transposition". The equivalent provisions in REACH have legal effect in their own right and accordingly must not be transposed. The UK will need to ensure that its domestic law is amended to remove requirements in its legislation which will have legal effect under REACH itself. 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. We have begun a review to identify which existing Statutory Instruments should be revoked or amended, and whether there are any specific provisions which need to continue.

⁶ A Globally Harmonised System (GHS) of classification and labelling is currently under negotiation (HSE are the UK lead). REACH has been designed so that this system will co-ordinate with it when agreed.

1.5 UK responsibilities

19. Each Member State will be responsible for enforcement of the Regulation in their own country, and will also appoint a 'Competent Authority' to fulfil a number of domestic requirements. In the UK the Health and Safety Executive (HSE) will be performing the functions of the Competent Authority for REACH on behalf of the Secretary of State and the Devolved Administrations. The UK will be represented on the various committees set up under REACH to continue development of EU chemicals policy, help prioritise and assess chemicals for the authorisation and restriction processes and maximise consistency of implementation across the EU.

20. There are a number of new obligations for businesses under REACH, and one of the primary aims of the enforcement regime will be to help them to comply with the new Regulation. One of the roles of the Competent Authority is to provide a helpdesk where businesses will be able to access advice on what is required of them by the Regulation. Although REACH has not yet come into force, an interim helpdesk has been set up, and it can be contacted on 0845 408 9575 or via email at ukreachca@hse.gsi.gov.uk.

21. Not all of the obligations set out in REACH will be enforced by the UK authorities, particularly when they concern interaction with the European Chemicals Agency. The Agency will be responsible for issuing registrations, for example, and if an applicant fails to comply with the requirements of applications for registration, the Agency may simply reject the application. However, it will be an offence to submit fraudulent information and this will be enforced by UK authorities.

22. Examples of activities where UK enforcement is needed are:

- The manufacture, import, sale, supply or use of substances without the appropriate registration.
- Using a hazardous substance outside the terms of an authorisation or contrary to a restriction.
- Failure to provide required information up and down the supply chain.
- Failure to comply with other duties regarding information, e.g. workers' or consumers' rights of access to information.
- Failure to comply with the duty to apply recommendations, e.g. in safety assessments.
- Failure to comply with the duties to co-operate and to supply information (in a timely manner).

23. Some of the provisions create enforceable obligations between parties, for example Article 53 concerning cost sharing for tests without an agreement between registrants and/or downstream users, which requires a business to pay a share of costs of a study in certain circumstances. These are matters for civil law and the UK authorities will have no role in enforcing them.

24. The Regulation gives Member States the power to allow for 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. These aspects will be the subject of further discussion between the relevant Government departments and the Competent Authority.

25. The Government intends to use secondary legislation, made under Section 2(2) of the European Communities Act 1972 to provide the legal basis for the implementation of REACH enforcement. This route allows for legislation to be in place within the timescale required but use of these powers does impose some limits, for instance on the maximum penalties available.

1.6 UK approach to enforcement of REACH

26. The benefits of REACH will only be realised if it is effectively implemented. An enforcement approach which encourages compliance can be very effective in achieving the aims of a regulation, supported by more formal enforcement procedures where necessary. Such an approach also helps to reduce the enforcement costs to business. An example of this type of approach is provided by the HSE's enforcement of health and safety legislation:

HSE enforces health and safety legislation for some industry sectors in the UK, covering factories, building sites, mines, farms, fairgrounds, quarries, chemical plants, offshore and nuclear installations, schools, hospitals and some other places where there is work activity. HSE inspectors normally enforce health and safety standards by giving advice on how to comply with the law. Sometimes inspectors must order people to make improvements by issuing them with a notice, either an Improvement Notice which allows time for the recipient to comply or a Prohibition Notice which prohibits an activity until remedial action has been taken. If necessary, HSE may prosecute recipients for non-compliance with a notice.

27. The UK will aim to follow this approach in enforcing REACH. Initial enforcement action may be to advise businesses of their obligations and encourage compliance, followed if necessary by the use of enforcement notices. Prosecution would only be used as a last resort. However, Government recognises that failure to comply with REACH can have serious consequences for the environment or health and it is necessary to have significant dissuasive penalties available to the courts. Similarly such penalties will ensure that non-compliance does not become 'economically viable', ensuring a level playing field for business. This is discussed in more detail below.

28. Enforcing authorities will have the responsibility for deciding how enforcement is put into practice in order to deliver the requirements of the Regulation, within a framework of enforcement policy agreed across the Government.

29. In summary, for the reasons outlined in the remainder of this document, the proposals are that enforcement will be undertaken by existing enforcing authorities, using the powers generally provided to inspectors of their authority, alongside current regulatory activities. It is proposed that the HSE and HSENI enforce the information and supply chain related obligations of REACH and that HSE, HSENI, EA, SEPA, EHSNI and Local Authorities enforce the use related requirements of REACH.

1.7 Hampton principles of inspection and enforcement

30. In 2005 Philip Hampton's report, "Reducing administrative burdens: effective inspection and enforcement"⁷, was published by the Treasury. The report set out a number of ways in which Government should aim to reduce the administrative burden imposed by regulation. This included a number of principles to be considered when developing a regulatory framework. These are shown in full in **Annex C**. Careful consideration has been given to all of these principles and how they should apply to REACH enforcement.

31. In developing proposals for enforcement of REACH we have aimed to minimise any additional burden by improving on, and maintaining consistency with, existing approaches rather than developing completely new enforcement structures.

32. As noted in the previous section one of the key aims of REACH enforcement will be to provide advice and encourage businesses to fulfil their obligations under REACH so that further punitive action is not required. The Competent Authority helpdesk is a key element in this approach.

33. The Government proposals will provide a legislative framework within which enforcement can operate. Prioritisation within that framework will be for the enforcing authorities to determine and co-ordinate using a risk based approach.

34. The proposals aim to minimise any additional inspections or information requirements and the overall administrative burden by maximising the utility of existing systems. This is in accordance with the principle that no new regulator should be created where an existing one can do the work. The estimate of the administrative burden to business of the enforcement approach described in this document is in the range of £960,000 to £1.17 million per year (see **Annex A**).

35. No single regulator with responsibility for the areas covered by REACH has enforcement responsibility across all businesses in the UK because each regulator has been given different functions. However, existing regulators are together able to provide enforcement for REACH and therefore there is no case for creating a new single chemicals regulator.

36. There are also significant practical difficulties with either of these approaches. REACH does not replace all existing chemicals regulation and there would inevitably be overlap between the responsibilities of any new or extended regulator and the existing ones leading to multiple inspections. Setting up a new regulator or expanding the functions of an existing one could not be achieved within the timeframe set out in the Regulation and the costs associated with such an approach are likely to be disproportionate. The administrative burden to business of expanding the functions of a single regulator is estimated to lie in the range of £1.60 million to £1.96 million per year (see **Annex A**).

37. Any enforcement approach needs to be supported by appropriate sanctions to ensure its success and this is indeed a requirement of the Regulation. This is discussed further in **Section 3** below.

⁷ <http://www.hm-treasury.gov.uk/media/A63/EF/bud05hamptonv1.pdf>

2 Enforcement roles

2.1 The UK enforcement landscape

38. REACH has two main objectives – the protection of human health (including both workers and consumers) and the protection of the environment, whilst also promoting competitiveness and the free movement of goods in the internal market. The individual obligations in REACH are not specifically directed at one outcome or another.

39. The UK enforcement landscape is complex – the UK has historically created different enforcement regimes for different objectives.

40. For example, a large manufacturer in England may be subject to two separate regimes: one to protect people affected by work activities (under the Health and Safety at Work etc. Act 1974⁸) and another to protect the environment (under the Environmental Protection Act 1990⁹ and the Environment Act 1995¹⁰ and subordinate Legislation). For each regime there is a different enforcing body (HSE and the Environment Agency, respectively) which has its own functions and separate powers available to it to fulfil those functions. Further, the enforcement regimes have their own range of penalties.

41. Regulatory regimes also differ across the UK, and across different sectors of industry. Local authorities, for example, have responsibility for health and safety regulation for many businesses, and also enforce consumer protection legislation. Roles in enforcing REACH also potentially exist for a number of smaller specialist regulators, and for HM Revenue and Customs to enforce import/export controls at the external frontier. In addition, supply chains cross regulatory, sectoral and geographical boundaries.

42. This landscape can appear complicated, but it has evolved to deal with specific issues of regional or national importance, and has proven effective. Although there are a number of potential enforcement authorities for REACH their individual functions are set out in legislation and enforcement responsibilities are clearly demarcated. These bodies already cooperate successfully on enforcement of a number of different regimes, including some of those which will be replaced by REACH. Indeed REACH will simplify some of these arrangements as they relate to the chemicals industry in the UK and across Europe.

43. The challenge for Government is therefore how best to use and improve these existing structures to enforce REACH effectively, maximising environmental and health benefits and minimising burdens on business. The proposals set out below address this challenge.

2.2 REACH enforcement proposals

44. Enforcement of chemicals regulation in the UK is shared between HSE and HSENI, EA, SEPA and EHSNI and local authorities depending upon the regulation in question and the nature of the business being regulated. The authorities with remits to protect human health, consumer safety, and the environment are primarily:

- Health and Safety Executive (HSE)¹¹
- Health and Safety Executive Northern Ireland (HSENI)

⁸ <http://www.healthandsafety.co.uk/haswa.htm>

⁹ http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900043_en_1.htm

¹⁰ http://www.opsi.gov.uk/acts/acts1995/Ukpga_19950025_en_1.htm

¹¹ HSE covers Great Britain (England, Scotland and Wales)

- Environment Agency (EA)¹²
- Scottish Environment Protection Agency (SEPA)
- Northern Ireland Environment and Heritage Service (EHSNI)
- Local Authorities (LAs)
 - health and safety
 - environmental protection
 - trading standards

45. The requirements of REACH which need enforcement can be divided into two parts as indicated below. The provisions that apply in each case are outlined in **Annex D**.

- **Information and supply chain related enforcement** – this includes requirements to submit information to the Agency, for example registrations and up-to-date tonnage information. In addition, information such as safety data sheets and, where these are not required, details of registration and any other available and relevant information about a substance that is necessary to enable appropriate risk management measures to be identified and applied, must be communicated up and down the supply chain. Businesses are also required to hold certain information, for example any downstream users required to carry out a chemicals safety assessment covering their use of a substance must keep the resulting chemical safety report up-to-date and available.
- **Use related enforcement** – this includes the provisions for downstream use, and issues such as safe onsite use of chemicals, including the requirement that use of a substance complies with any authorisation or restriction applied.

2.2.1 Information and supply chain related enforcement

46. Chemicals within the scope of REACH cannot be manufactured or placed on the market unless they have been registered in accordance with the Regulation. This is to ensure that a certain level of information on the hazards and risks of the substance is known and available. As stated in paragraphs 21 and 23, not all of these provisions will be enforced by the UK authorities, particularly some of those that concern interaction with the European Chemicals Agency. However, registration itself is of little value unless the information gained is passed appropriately along the supply chain to ensure suitable risk management measures can be taken.

47. The registration process and the transfer of information through the supply chain place new burdens on business. It is therefore important that these aspects of REACH are enforced in such a way as to ensure a level playing field for business.

48. 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. This is true of the supply chain issues particularly as some of the requirements depend upon other actors in the supply chain to have fulfilled their obligations to communicate information, whereas safe on-site use is a clear responsibility of the individual business concerned.

¹² EA covers England and Wales

49. Similar issues arose with the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002¹³ (CHIP) and were successfully resolved by making a single regulator, the HSE¹⁴, responsible for enforcement in the supply chain up to the point of retail regardless of site specific responsibilities.

50. We therefore propose that HSE (in Northern Ireland HSENI) be the enforcing authority for the information and supply chain aspects of REACH.

51. HSE, with its responsibilities and the information it will hold as delegated Competent Authority, is best placed to fulfil this role for REACH. The 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.

52. Enforcement will be risk based but will have a significant intelligence led component. It is expected that information on suspected non-compliance will be passed on to the HSE by inspectors on the ground. A significant amount is also likely to come from “whistleblowing” – industry itself is likely to quickly identify situations where companies are potentially not complying with REACH duties in an attempt to gain competitive advantage. Other groups such as environmental NGOs may also be monitoring the behaviour of companies they suspect of not complying with REACH. HSE, in performing the functions of the Competent Authority, will set up mechanisms to receive and investigate such intelligence.

53. The major difference in this approach from HSE’s former role in enforcing chemicals regulations may be where regulators are required to visit purely office sites to gather information when such sites would usually be regulated by LAs for health and safety.

54. The Environment Agency will be providing technical advice and support to the Competent Authority to enable it to fulfil the environmental aims of REACH. This technical support will also be valuable to HSE as it carries out its responsibilities of enforcing information and supply chain requirements.

2.2.2 Use related enforcement

55. In order to minimise the burden of enforcement on businesses, the Government proposes that the obligations in REACH related to specific sites and the use of chemicals on them should be enforced by inspectors from the regulators identified above in paragraph 44 in the course of their normal business, rather than by creating any new structures or by requiring new inspection regimes. Use related enforcement includes activities such as establishing that substances are not being used outside of the specifications of a restriction or authorisation.

56. Regulatory activity would continue to be risk based in line with best practice. The risk of non-compliance with REACH will be considered alongside other existing factors when enforcing authorities select premises for inspection.

57. For simplicity Government proposes to impose a duty on each of the enforcement authorities listed in paragraph 44 to enforce the relevant REACH obligations (see **Annex D**). However, enforcing authorities will only have specific powers to enforce REACH over those businesses or premises where

¹³ <http://www.opsi.gov.uk/si/si2002/20021689.htm>

¹⁴ HSENI in Northern Ireland.

they already have responsibilities under other legislation. The enforcing authorities will therefore only be able to enforce REACH within the scope of these existing functions. For example the current balance of responsibilities for inspecting individual sites between HSE and Local Authorities will remain and the Environment Agencies will not be able to enforce on health and safety issues.

58. The roles of the various enforcing authorities are outlined in **Table 1** below.

Table 1

Enforcement authority	Proposed enforcement role
Health and Safety Executive (HSE), Health and Safety Executive Northern Ireland (HSENI)	Enforcement of REACH in conjunction with wider day to day inspection and enforcement programmes e.g. for Control of Substances Hazardous to Health (COSHH). This would include all businesses and premises according to Schedule 1 of The Health and Safety (Enforcing Authority) Regulations 1998 ¹⁵ not covered by Local Authority health and safety enforcement (see below). Enforcement of REACH in conjunction with day to day inspection and enforcement of the Control of Major Accident Hazards Regulations 1999 ¹⁶ and in Northern Ireland the Control of Major Accident Hazards Regulations (Northern Ireland) 2000 SR No. 93 ¹⁷ .
Environment Agency (EA), Scottish Environment Protection Agency (SEPA), Department of the Environment Northern Ireland (DOENI); the Chief Inspector	Enforcement of REACH in conjunction with routine regulation of A(1) installations under the Pollution Prevention and Control Regulations ¹⁸ . In Scotland in conjunction with day to day inspection and enforcement of Pollution Prevention and Control (Scotland) Regulations 2000 – Part A and B processes ¹⁹ . In Northern Ireland in conjunction with day to day inspection and enforcement of Industrial Pollution Control Order (NI) 1997 ²⁰ and Pollution Prevention and Control Regulations (NI) 2003 ²¹ – Part A and B processes. Power to enforce REACH on premises entered as a result of a pollution incident.
Local Authorities (LAs)	Enforcement of REACH in conjunction with wider day to day inspection and enforcement of health and safety legislation on those premises covered by Local authorities according to Schedule 1 of The Health and Safety (Enforcing Authority) Regulations 1998. This includes most offices, shops, retail and wholesale distribution. Enforcement of REACH in conjunction with wider day to day inspection and enforcement of Integrated Pollution and Prevention Control A2 and B sites (not applicable in Scotland; Northern Ireland: Pollution Prevention and Control Regulations (NI) 2003 – Part C Processes). Enforcement of REACH in conjunction with wider day to day inspection and enforcement of the Consumer Protection Act by Trading Standards officers.

¹⁵ <http://www.opsi.gov.uk/si/si1998/19980494.htm#sch1> Some areas of ambiguity between HSE and LA responsibility are further clarified at <http://www.hse.gov.uk/lau/lacs/23-15.htm>

In Northern Ireland the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999 SR No 90 apply.

¹⁶ <http://www.opsi.gov.uk/si/si1999/19990743.htm>

¹⁷ <http://www.opsi.gov.uk/sr/sr2000/20000093.htm>

¹⁸ <http://www.opsi.gov.uk/si/si2000/20001973.htm#sch1>

¹⁹ <http://www.opsi.gov.uk/legislation/scotland/ssi2000/20000323.htm>

²⁰ <http://www.opsi.gov.uk/SI/si1997/19972777.htm>

²¹ Northern Ireland Pollution Prevention and Control Regulations: www.opsi.gov.uk/sr/sr2003/20030046.htm

59. With this approach business will continue to see inspectors from the authorities with whom they normally deal – at least in the first instance, who will deal with any REACH issues as part of their work. Also, a breach of REACH may well occur alongside a breach of another regulation, for example COSHH, and this approach will ensure that business will see a consistent enforcement approach across the whole case. In this way the burden on business may be reduced by, for example, avoiding separate appeals routes for REACH and non-REACH aspects.

2.2.3 Co-ordination of enforcement

60. As with existing regimes, the enforcing authorities will agree between themselves and within the framework of wider Government arrangements how to deal with situations in which a business is potentially subject to inspection by more than one of the authorities. In the majority of cases the demarcation of responsibilities on such sites already exists and will continue to be followed. The aim will be to ensure that REACH can be effectively enforced, but in ways that the burden of inspection on businesses is minimised in accordance with the Hampton principles. Enforcing authorities will also be expected to share intelligence with each other and with the Competent Authority in relation to information and supply chain issues (see section 2.2.1 above).

61. The enforcing authorities will also cooperate to promote consistent approaches to enforcement, so that where there are different enforcement options open to an inspector (e.g. warning, improvement notice, prosecution) broadly similar approaches are adopted. The enforcing authorities will also take account of the approaches used under other chemical enforcement regimes – such as COSHH – to ensure that so far as possible similar obligations are interpreted in similar ways. There is, in addition, a need to ensure that environmental priorities are reflected in the enforcement of supply chain issues. HSE will have an ongoing role in monitoring the level of consistency.

2.2.4 Import controls

62. In the REACH Regulation import is deemed as ‘placing on the market’ and is subject to all the provisions in REACH which control this. Where imported goods are identified as part of an onsite inspection or as part of an investigation into a supply chain breach they will be dealt with by the enforcing authorities as identified above.

63. It is proposed that the role of HM Revenue and Customs (HMRC) should remain as currently provided for in existing legislation. For example, the Health and Safety at Work Act 1974 allows HMRC, where appropriate, to provide assistance to the enforcing authorities by detaining articles and substances and to authorise disclosure of information. It is not proposed to give HMRC a day to day inspection role for chemicals.

Q1. Do you agree with this approach to enforcement?

Q1a. Are there any additional issues that you would like to be considered further?

Q2. Do you agree with the allocation of responsibilities?

Q2a. Are there any issues that you would like to be considered further?

Q2b. Do you wish to suggest an alternative arrangement? If so, please detail your rationale.

3 Enforcement legislation

64. The REACH Regulation Article 126 requires that Member States create penalties applicable to the infringement of the provisions in the Regulation and that these penalties must be “effective, proportionate and dissuasive”.

3.1 Penalties

65. It will be made an offence to fail to comply with the requirements of the REACH Regulation. A maximum penalty will be identified for the offence. The maximum penalties for a breach of a REACH obligation will be the same irrespective of which authority is enforcing the Regulation in a particular case.

66. The Government has considered a penalty regime based on two levels for breaching an obligation of REACH, where a higher maximum penalty would apply for those obligations where a breach could potentially lead to a significant health or environmental incident. A lower level of maximum penalty would apply to the remaining obligations which primarily cover requirements around the transfer of information to the European Chemicals Agency or within the supply chain. However, the communication up and down the supply chain is integral to the success of REACH, and failure to comply with information requirements could in fact result in serious consequences to health and the environment.

Q3. Should there be a single penalties regime or is it appropriate to distinguish between the more and less serious offences?

67. It will be up to the courts to decide the level of penalty to apply, within the limits set out in the legislation. Penalties for similar offences currently stand at a maximum of £5,000 and three months imprisonment if prosecuted at the magistrates court. If prosecuted at the Crown court there is a maximum penalty of two years imprisonment and no limit to the maximum fine. These are the maximum penalties that can be imposed for an offence created by an order under Section 2(2). The Scottish courts system is different, here the majority of offences would be dealt with through the Sheriff Court which can issue penalties the same as those of the magistrates court or the crown court depending on how the case is prosecuted.

Q4. In your view do you consider these levels of penalty sufficient to meet the requirement of “effective, proportionate and dissuasive” and to remove any economic benefit of non-compliance?

3.2 Administrative penalties

68. The Macrory Review of Regulatory Penalties²² was published on the 28 November 2006. The review made a number of recommendations that aimed to make sure that regulators have access to a flexible set of modern fit for purpose sanctioning tools that are consistent with the risk based approach to enforcement outlined by Philip Hampton. Recommendations included wider use of Monetary Administrative Penalties. The Scottish Executive recently consulted on ‘Strengthening and Streamlining: The Way Forward for the Enforcement of Environmental Law in Scotland’²³, which tackles some similar issues to the Macrory review. At around the same time the Government’s Review of Enforcement in Environmental Regulation suggested a range of ideas for improving the fairness and effectiveness of environmental enforcement, including a role for administrative sanctions in strengthening proportionality, and incentives to comply. Variable administrative penalties could have the effect of normally taking responsible operators out of the criminal system. The Government is currently considering how to take forward these Reviews’ conclusions.

²² http://www.cabinetoffice.gov.uk/regulation/documents/pdf/macrory_penalties.pdf

²³ <http://www.scotland.gov.uk/Publications/2006/11/22152827/0>

69. This process will be running in parallel with the development of the regulations to implement REACH. It will therefore be difficult to incorporate any reforms, at least at this stage. The Government therefore proposes to base the REACH regulation on the current regulatory systems. Once policy proposals for improving enforcement have been developed more generally then the Government will consider how they should be applied specifically to REACH, taking account of the stage reached by each of the REACH enforcement authorities in adapting their enforcement processes to accommodate new approaches.

3.3 Enforcement powers

70. Officers of the enforcing authorities need to have a number of powers, for example to enter premises, collect evidence, or demand information. The Government proposes that enforcing officers use powers equivalent to those generally provided to inspectors of their authority. This would mean, for example, that officials from HSE would use powers under the Health and Safety at Work act when enforcing REACH.

71. Mirroring existing powers of inspectors within the individual organisations minimises the need for additional training and the risk of inappropriate actions by inspectors unfamiliar with any new powers. This will minimise the additional overall burden of enforcing REACH on both business and the enforcing authorities.

72. By following this approach the powers used in a given circumstance may differ slightly according to which authority an inspector comes from, but this does mean that in the course of a visit an inspector will not need to switch between subtly different powers for different parts of his or her inspection. This will minimise the burden of cost and likelihood of confusion on both the inspector and the business being inspected.

3.4 Enforcement notices

73. HSE, EHSNI, EA, SEPA and local authority inspectors have powers to issue 'enforcement notices' in a variety of circumstances under current regimes. Providing information and an opportunity to correct any issues, rather than immediate prosecution, may deliver more beneficial outcomes in terms of educating regulated businesses of their responsibilities while still ensuring risks are dealt with effectively. It is therefore proposed to ensure that the enforcing authorities have powers to issue enforcement and improvement notices for breaches of some requirements of REACH. This has proven to be a very effective and practical way of promoting compliance with statutory obligations for other regimes. An example of a breach of REACH where an improvement notice may be appropriate would be where an inspector finds that a manufacturer is not applying a measure identified in a chemical safety report in order to control risk during the manufacturing process.

74. There are two possible approaches available to Government concerning enforcement notices for REACH. These are:

- To develop REACH specific arrangements for the use of enforcement notices.
- To provide for the different enforcing authorities to issue enforcement notices in line with their current procedures.

75. The first approach would ensure that whichever enforcing authority identified the breach of REACH, procedures for enforcement notices, including those for appeal would be the same. However, these procedures would potentially differ from those for other regimes covered by that enforcing authority. The situation could therefore arise for example where a breach of REACH which contributed to a pollution incident would require the issuing of two separate enforcement notices each with their own procedures and appeals for essentially the same substantive issue. This would be complex to follow through for both the business and the enforcing authority involved.

76. The second approach would mirror that outlined above for more general powers, i.e. under REACH each enforcing authority would utilise its current arrangements for issuing enforcement notices. This would mean that depending on which enforcing authority identified the breach of REACH the procedure for the enforcement notice and appeals may be different. However, any additional issues related to other regimes could be dealt with by the same notice and the business and enforcing authority would only have to follow one procedure throughout.

77. Considering the potential administrative burdens associated with these two approaches, the second approach of using existing arrangements clearly has the lesser burden for both business and the enforcing authorities involved.

78. The Competent Authority would work closely with the enforcing authorities to ensure that procedures and circumstances for the issuing of enforcement and information notices were as coherent as possible across the different enforcing authorities.

Q5. Do you agree with each enforcing authority applying its current procedures for enforcement notices for REACH?

Estimating the Administrative Burden of REACH Enforcement

The aim of this note is to provide information on the costs and benefits associated with REACH enforcement. It covers definitional issues, the options, and then provides the detailed analysis, including an estimate of the administrative burden of enforcement on businesses and, finally, an estimate of the costs of enforcement to Government. A partial regulatory impact assessment covering the sectors and groups affected and costs and benefits of the REACH Regulation as a whole was published in May 2006¹, this also included a small firms impact test and competition assessment.

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 obligations² that are imposed through central government regulation”³. 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 the tests needed to comply to the dossier required) and the costs of compiling safety data sheets, as well as 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 noted above.

For the purposes of this RIA, the focus is on the cost of confirming that the business is complying with the REACH Regulation. This is likely to be the time taken for example to show that the chemicals being used in the business have been registered if the Regulation requires this, that safety data sheets have been issued or received when required, or that chemicals are not being used outside of a restriction or the conditions of an authorisation.

For registration issues, this will mainly depend on assembling the necessary documentation, or demonstrating that the business has a robust management system in place. For other issues, it could involve a physical check on production processes to ensure that authorisation conditions (e.g. on the prevention of losses) are being followed.

In accordance with the Cabinet Office guidance, 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, but this is not covered within the scope of this RIA as non-compliance is an individual business decision and should not be assumed existent for the purposes of policymaking.

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

² A duty to retain or submit information.

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

Annex A: Partial Regulatory Impact Assessment of Proposals for the Enforcement of REACH

Options

As a basis for analysis, this assessment considers three options.

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.
3. A single existing agency (HSE) enforces all of REACH.

Option 1

The REACH Regulation would be futile unless there is subsequent enforcement to ensure that it is being adhered to, and enforcement is essential in order to safeguard the initial investment in REACH. The costs and benefits of the REACH Regulation have already been estimated in the Partial RIA, and these benefits will be lost if there is no subsequent enforcement regime. In addition, compliant organisations would face unfair competition from other businesses

If we were to follow this option, the UK would be in breach of the terms of the Regulation, and would be subject to infraction proceedings which would be costly. 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. As described in the consultation document, the HSE⁴ will be responsible for enforcement of information and supply chain obligations, HSE, HSENI, EA, SEPA, EHSNI and local authorities will enforce obligations put on users of chemicals.

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 Principles⁵ that enforcement should be efficient. This option has been analysed and the headline results are given below⁶.

We believe the proposed split described in the consultation document is likely to be that which imposes the least burden on business.

Administrative burdens to business associated with option 2 lie in the range of £960,000 to £1.17 million per year, using the range for the population parameter used in the analysis. This is based on the best evidence available to us, and collected through engagement with stakeholders.

Q.RIA 1 We would welcome views as to whether any fine tuning concerning the proposed split between enforcing agencies outlined in the consultation document would improve the effectiveness and minimise the burden.

⁴ HSENI in Northern Ireland.

⁵ http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

⁶ Note that this analysis is discussed in more detail in the following section.

Option 3

This option would put additional administrative burdens on HSE, as it would bring more businesses under HSE control than at present, although it is not possible to estimate this figure this unfamiliarity is important. This option would create extra administrative burdens due to additional activities such as sending out letters to inform businesses of the HSE's new responsibilities and through the HSE covering all enforcement, rather than just the businesses it usually covers under existing regulations.

The administrative burdens to business from this option, assuming an extra hour of time is needed per visit (as the visit would be specific to REACH, additional time would be taken in duplication of activities that would be required when being regulated under other regimes), lie in the range of £1.60 million per year to £1.96 million per year. This option is not considered further due to higher administrative burdens on business and excess burdens on HSE.

Table of estimated administrative burdens from enforcement for all businesses affected by the regulations:

Option	Time (minutes)	Estimated administrative burden on all business
2	90	£960,000 – £1.17million
3	150	£1.60million – £1.96million

General points

The actual cost of enforcement will depend on decisions on the extent and pattern of activity which various enforcing agencies make in the years to come. The regulation will empower them to enforce the REACH Regulation, but does not specify any particular level of activity. It is likely that at different times the enforcing authorities will want to devote more or less effort to REACH enforcement, depending on the level of non-compliance experienced and their judgment of the relative importance of different risks to human health and the environment. It is possible, for example, that at any particular time the enforcement effort might want to focus on chemicals which have newly been subject to authorisation or restriction, and this means that particular industry sectors might be more intensively covered at one time, and less intensively once it is clear that new rules have been applied.

Moreover, the impact of the REACH regime will grow over time. The phase-in period for existing chemicals lasts until 2018, so many smaller users of chemicals may not be greatly impacted by REACH until then. 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 subject to the current regimes for enforcement, so not a new burden), and new substances will only be added progressively after 2010.

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

Administrative burden on business

Standard Cost Methodology is the preferred Cabinet Office method for estimating administrative burdens, and is used here. This method calculates the administrative costs by estimating the resource cost, time, population and frequency of the regulation and multiplying these together⁷. Business as usual costs then need to be deducted from this estimate⁸. The estimates used for these parameters are based on the best available information, made available to us from stakeholders and various data sources, indicated as appropriate.

Q.RIA 2 We would welcome any further information that may be useful to improve the accuracy of these estimates.

Time

This is the time taken to enforce REACH, per visit. The specific activities required to demonstrate compliance were discussed earlier, and this covers the time necessary to cover all these activities. 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 will be more significant. In time, the true additional costs of REACH enforcement will be represented by the figure left after existing administrative costs that are saved due to replacement of previous regulations with REACH are offset.

For the purposes of this RIA, a time of 90 minutes has been assumed. This includes one hour for preparing the information, and 30 minutes to collect and provide the information on the day. At the level of the individual firm, time will vary according to business type and individual circumstances, however 90 minutes appears a reasonable estimation based on initial stakeholder consultation though comments from other stakeholders are welcomed.

The enforcement requirements of REACH will grow over time as more chemicals become included in the regulations up to 2018, based on tonnages of chemicals. However, enforcement costs on business may reduce over time as businesses become increasingly familiar with REACH processes. Given this uncertainty around whether time will be larger or smaller over time, we have assumed that costs are constant year on year.

Q.RIA 3 We would welcome views as to whether the estimate of 90 minutes for the activities described is considered reasonable.

Resource cost

This is the wage rate, plus overheads (heat, lighting, travel etc.) of the person responsible for demonstrating compliance with REACH. According to consultation with the HSE, this person would be equivalent to a Senior Executive Officer (Band 3), which gives a total resource cost to business (wage rate plus overheads) of £21.01 per hour, based on supplementary information provided for the Standard Cost Model on the Cabinet Office website.⁹ Consultation with LACORS returned a

⁷ More detail of this methodology can be found on the Cabinet Office website.
<http://www.cabinetoffice.gov.uk/REGULATION/reform/simplifying/scm.asp>

⁸ Note in this case that business as usual costs are zero, as this is new regulation and all costs are additional.

⁹ www.cabinetoffice.gov.uk/regulation/documents/scm/scm_annexes.pdf

wage rate plus overheads of £61.94 per hour, which is a significantly larger figure. In order to calculate the burdens we use an average of these figures, which gives £41.48 per hour as an average hourly resource cost for enforcers. To note, we assume a similar level of proficiency is needed from both business and enforcers, therefore we use this resource cost for both the calculation on business and enforcers¹⁰.

Q.RIA 4 We would welcome views on whether the wage rate used for the estimate is considered reasonable.

Population and Frequency

The impact of REACH regulations, 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 with different enforcement frequencies.

Based on a risk assessment and intelligence-led approach, we assume that 20% of chemical companies and 5% of other companies will be enforced per year. Respective UK populations are 3,500 and 329,000¹¹. 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.

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

Q.RIA 5 We would welcome views as to whether the frequencies used are considered adequate.

Calculating the administrative burden

Using the above parameters, administrative burdens to business lie in the range of £960,000 to £1.17 million per year, using the range given for the (population * frequency) parameter.

This is based on the best evidence available to us, collected through engagement with stakeholders.

Costs on enforcers

In determining how REACH will be enforced, identifying costs to Government, and how they can be minimised, is an important additional part of the consideration. These costs are considered as best as possible here, and reflect consultation with stakeholders.

¹⁰ To note however, resource costs may be greater in smaller companies where there is no designated person in charge of compliance, and instead it is an additional part of a senior manager's job. However, here an average is assumed.

¹¹ http://www.sbs.gov.uk/SBS_Gov_files/researchandstats/SMEStatsUK2004.xls

Annex A: Partial Regulatory Impact Assessment of Proposals for the Enforcement of REACH

In terms of calculating the administrative burden on business we assume option 2 is pursued. We further assume that the parameters for population, frequency and resource cost will be the same as those for business. However, the time parameter will be different. As discussed above, times for business were dependent on one hour preparation time, and 30 minutes to collect and provide the information on the day. It is only the 30 minutes therefore that is relevant to this calculation.

Using these parameters, we would expect administrative burdens on enforcers to lie in the range of £320,000 to £391,000 per year.

Within the Statutory Instrument, different enforcement roles can be placed on various agencies. Therefore, 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. At this stage however, it is useful to provide a qualitative description of what differences we might expect by agency.

HSE, HSENI – It is expected that HSE and HSENI will enforce REACH alongside their wider day to day enforcement programmes, e.g. Control of Substances Hazardous to Health (COSHH).

EA, SEPA, DoENI – It is expected that EA, SEPA and DoENI will enforce REACH alongside wider enforcement of Pollution Prevention and Control regulations.

LAs – It is expected that Local Authorities will enforce REACH alongside wider enforcement of Health and Safety legislations on those premises covered by LAs. This includes most offices, shops, retail and wholesale distribution. Actual enforcement conducted by LAs will depend on individual council decisions about where priorities lie, e.g. dangerous dogs, chemicals, fireworks etc.

Annex B: REACH Implementation Timeline

REACH will apply in stages, taking account of its complexity, the need for industry to adjust accordingly, and to allow a phased transition from the existing regulatory regime to the new regulatory regime under REACH.

The Regulation consists of 15 Titles covering the principal elements of REACH, within which specific provisions are contained. Half of the Titles will apply from the entry into force date, with the other half of the Titles applying from one year after entry into force.

The table below sets out the implementation timeline for REACH, showing when the Titles apply, and the dates on which specific provisions, reviews, and repeals of existing legislation take effect, or deadlines by which specific actions must be completed.

2007	
Entry into force of REACH	1 June 2007
Titles applying: I – Scope, definitions IV – Information in supply chain IX – Fees and Charges (though fees are not required to be paid until an application for registration, authorisation etc is submitted to the Agency – the fees payable will be specified in a Commission regulation to be adopted through comitology by 1 June 2008 – see under Article 74 below) X – European Chemicals Agency XIII – Competent Authorities XIV – Enforcement XV – Transitional arrangements	1 June 2007.
Article 31 – provision of information down the supply chain on substances requiring a safety data sheet	1 June 2007
Article 32 – provision of information down the supply chain on substances not requiring a Safety Data Sheet.	At first delivery of such substances after 1 June 2007.
Article 115 – harmonisation of classification and labelling at Community level for CMRs cat. 1, 2, and 3, and respiratory sensitisers.	From 1 June 2007.
Repeal of: Directive 91/155/EEC (Information to be included in safety data sheets).	1 June 2007.
Deletion of: Article 14 (provision of safety data sheets) of Directive 1999/45/EEC (Classification, packaging, and labelling of dangerous preparations).	1 June 2007.

Annex B: REACH Implementation Timeline

2008	
Titles applying: II – Registration III – Sharing of Data V – Obligations of Downstream Users VI – Evaluation VII – Authorisation XI – Classification and Labelling Inventory XII – Information	1 June 2008.
Article 74 – European Commission Regulation specifying REACH fees and charges adopted.	By 1 June 2008.
Article 118(3) – practical application to REACH of Regulation (EC) No 1049/2001 (regarding public access to European Parliament, Council, and Commission documents).	By 1 June 2008.
Article 128 – free movement of goods within scope of REACH.	1 June 2008.
Article 136 – transitional measures regarding existing substances.	1 June 2008.
Article 138(4) – Commission review of REACH Annexes I, IV, and V.	By 1 June 2008.
Article 28 – pre-registration of phase-in (existing) substances of 1 tonne+ per year.	1 June 2008 until 1 December 2008.
Repeals of: Directive 93/105/EC (Information required for Technical Dossiers); Directive 2000/21/EC (amending the Dangerous Substances Directive); Regulation (EEC) No 793/93 (Evaluation and control of the risks of existing substances); Regulation (EC) No 1488/94 (principles for risk assessment of existing substances).	1 June 2008.
Article 135 – transitional measures regarding notified substances.	1 August 2008.
Article 7 – registration and notification of substances in articles.	1 December 2008.
Article 126 – Member States’ provision on penalties for non-compliance with REACH.	By 1 December 2008.
Article 138(5) – Commission review of REACH Annex XIII (adequacy of criteria identifying PBT and vPvB substances).	By 1 December 2008.
2009	
Title applying: VIII – Restrictions	By 1 June 2009.
Article 58(3) – European Chemicals Agency’s first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation).	By 1 June 2009
Article 67 – compliance with existing Marketing and Use restrictions for substances listed in Annex XVII (Requirement to comply with restrictions or bans under Directive 76/769/EEC continues until 1 June 2013)	From 1 June 2009 until 1 June 2013.

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2009 (continued)	
Article 67(3) – Commission to compile and publish an inventory of existing and more stringent restrictions maintained by any Member State in relation to Annex XVII.	By 1 June 2009.
Article 137(3) – Commission to incorporate into Annex XVII any amendments to Directive 76/769/EEC restrictions adopted from 1 June 2007.	1 June 2009.
Repeals of: Directive 93/67/EEC (Risk assessment for new notified substances); Directive 76/769/EEC (Restrictions on the marketing and use of certain dangerous substances and preparations).	1 June 2009.
Annex XVII – List of restricted substances and conditions of restriction.	1 June 2009.
2010	
Article 117(1) – First of 5-yearly Member State reports to Commission on the operation of REACH.	By 1 June 2010.
Article 23(1) – registration provisions for phase-in substances for CMR (cat 1 or 2) over 1 tonne per year and toxic (R50/53) over 100 tonnes per year, and other substances over 1000 tonnes per year.	1 December 2010.
Article 116 – transitional arrangements for obligations in Article 113 to notify the Agency of substances subject to registration and/or dangerous substances classified as such under existing legislation.	1 December 2010.
2011	
Article 117(2) – First of 5-yearly European Chemicals Agency reports to Commission on operation of REACH.	By 1 June 2011.
Article 117(3) – First of 3-yearly European Chemicals Agency reports to Commission on use of non-animal testing strategies.	By 1 June 2011.
Article 44(2) – European Chemicals Agency to prepare first draft 3-year Community rolling action plan of substances to be evaluated each year.	1 December 2011.
2012	
Article 117(4) – First of 5-yearly general report by Commission on operation of REACH, and funding for development and evaluation of alternative test methods.	By 1 June 2012.
Article 138(3) – Commission review of registration requirements for substances of 1-10 tonnes per year, for Article 117(4) reports.	By 1 June 2012.
Article 138(6) – Commission review of scope of REACH, to avoid overlaps with other legislation.	By 1 June 2012.
Article 43(2)(a) – European Chemicals Agency to prepare draft decisions for testing proposals in registrations received by 1 December 2010, complying with Annexes IX and X.	By 1 December 2012.

Annex B: REACH Implementation Timeline

2013	
Article 23(2) – registration provisions for phase-in substances of 100 tonnes or more per year.	1 June 2013.
Article 67(3) – Member States must end any existing and more stringent restrictions in relation to Annex XVII, as listed in the inventory of such restrictions to be published by the Commission by 1 June 2009.	By 1 June 2013.
Article 138(7) – Commission review of whether to exclude endocrine disrupting substances from “adequate control” authorisations.	By 1 June 2013.
2014	
Article 138(1) – Commission review of whether to require chemical safety assessments for CMRs cat. 1 or 2.	By 1 June 2014.
2016	
Article 43(2)(b) – European Chemicals Agency to prepare draft decisions for testing proposals in registrations received by 1 June 2013, complying with Annex IX only.	By 1 June 2016.
2018	
Article 23(3) – registration provisions for phase-in substances of 1 tonne or more per year.	1 June 2018.
2019	
Article 138(1) – Commission review of whether to require chemical safety assessments for substances exempt from REACH, or in quantities of less than 10 tonnes per year.	By 1 June 2019.
Article 138(8) – Commission review whether to extend duty to communicate information on substances in articles to other dangerous substances, in addition to CMRs, PBTs, vPvBs, and endocrine disruptors already covered.	By 1 June 2019.
Article 138(9) – Commission review of reproductive toxicity testing requirements (Annex VIII, section 8.7), to ensure minimisation of animal testing.	By 1 June 2019.
2022	
Article 43(2)(c) – European Chemicals Agency to prepare draft decisions for any testing proposals in registrations received by 1 June 2018.	By 1 June 2022.

Annex C: Hampton principles

- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most.
- Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.
- All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all interested parties should be consulted when they are being drafted.
- No inspection should take place without a reason.
- Businesses should not have to give unnecessary information, nor give the same piece of information twice.
- The few businesses that persistently break regulations should be identified quickly, and face proportionate and meaningful sanctions.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.
- Regulators should be of the right size and scope, and no new regulator should be created where an existing one can do the work.
- Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

Information and Supply Chain Related Obligations

	Article Number	Article Title	Paragraph	Potential Obligation
	Title II – Registration			
1	Article 6	General obligation to register substances on their own or in preparations	(1)	A manufacturer of a substance requiring registration on its own or in a preparation in a quantity greater than 1 tonne per year shall submit a registration to the Agency .
2	Article 6	General obligation to register substances on their own or in preparations	(1)	An importer of a substance requiring registration on its own or in a preparation in a quantity greater than 1 tonne per year shall submit a registration to the Agency .
3	Article 6	General obligation to register substances on their own or in preparations	(3)	A manufacturer of a polymer shall submit a registration to the Agency for the monomer of any other substances that have not been registered further up the supply chain if both the conditions in paragraph 2 are met.
4	Article 6	General obligation to register substances on their own or in preparations	(3)	An importer of a polymer shall submit a registration to the Agency for the monomer of any other substances that have not been registered further up the supply chain if both the conditions in paragraph 2 are met.
5	Article 7	Registration and notification of substances in articles	(1)	A producer of articles shall submit a registration to the Agency for the substance contained in those articles if both the conditions in paragraph 1 are met.
6	Article 7	Registration and notification of substances in articles	(1)	An importer of articles shall submit a registration to the Agency for the substance contained in those articles if both the conditions in paragraph 1 are met.

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	Article Number	Article Title	Paragraph	Potential Obligation
	Title II – Registration (<i>continued</i>)			
7	Article 7	Registration and notification of substances in articles	(2)	A producer of articles shall notify the Agency in accordance with paragraph 4 if a substance contained in those articles meets the criteria for authorisation (Articles 56 and 58(1)) and both the conditions in paragraph 2.
8	Article 7	Registration and notification of substances in articles	(2)	An importer of articles shall notify the Agency in accordance with paragraph 4 if a substance contained in those articles meets the criteria for authorisation (Articles 56 and 58(1)) and both the conditions in paragraph 2.
9	Article 7	Registration and notification of substances in articles	(3)	The producer shall provide appropriate instructions to the recipient of the article in accordance with Article 32(4) where paragraph 2 does not apply as exposure can be excluded under foreseeable conditions.
10	Article 7	Registration and notification of substances in articles	(3)	The importer shall provide appropriate instructions to the recipient of the article in accordance with Article 32(4) where paragraph 2 does not apply as exposure can be excluded under foreseeable conditions.
11	Article 7	Registration and notification of substances in articles	(5)	A producer of articles is required to register if required by the Agency for substances in articles which meet the requirements set out in paragraph 5.
12	Article 7	Registration and notification of substances in articles	(5)	An importer of articles is required to register if required by the Agency for substances in articles which meet the requirements set out in paragraph 5.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
	Title II – Registration (<i>continued</i>)			
13	Article 8	Only representative of a non-community manufacturer	(2)	Only representative of a non-community manufacturer shall comply with the obligations of importers .
14	Article 8	Only representative of a non-community manufacturer	(2)	Only representative of a non-community manufacturer shall maintain the information identified in paragraph 2.
15	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(2)	For the purpose of exemption outlined in paragraph 1, the manufacturer shall notify the Agency of the information set out in paragraph 2.
16	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(2)	For the purpose of exemption outlined in paragraph 1, the importer shall notify the Agency of the information set out in paragraph 2.
17	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(2)	For the purpose of exemption outlined in paragraph 1, the producer of articles shall notify the Agency of the information set out in paragraph 2.
18	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(4)	Requirement for the notifier to provide additional information to the Agency .
19	Article 11	Joint submission of data by multiple registrants	(1)	Manufacturers and/or importers must submit information together. The other registrants must also submit certain information themselves, however. In certain cases they can decide themselves whether they will submit certain information together or individually.

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	Article Number	Article Title	Paragraph	Potential Obligation
	Title II – Registration (<i>continued</i>)			
20	Article 12	Information to be submitted depending on tonnage	(2)	A manufacturer shall inform the Agency of a change in tonnage and provide the required additional information.
21	Article 12	Information to be submitted depending on tonnage	(2)	An importer shall inform the Agency of a change in tonnage and provide the required additional information.
22	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(1)	Requirement to complete a chemical safety assessment and report for a substance manufactured in quantities of 10 tonnes or more.
23	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(1)	Requirement to complete a chemical safety assessment and report for substances imported in quantities of 10 tonnes or more.
24	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(7)	A manufacturer shall keep a chemical safety report available or up to date.
25	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(7)	An importer shall keep a chemical safety report available or up to date.
26	Article 17	Registration of on-site isolated intermediates	(1)	A manufacturer shall register an on-site isolated intermediate requiring registration.
27	Article 18	Registration of transported isolated intermediates	(1)	A manufacturer shall register a transported isolated intermediate requiring registration.
28	Article 19	Joint submission of data on isolated intermediates by multiple registrants	(1)	Registration by one manufacturer or importer on behalf of all. See Article 11, paragraph 1.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title II – Registration (<i>continued</i>)				
29	Article 22	Further duties of registrants	(1)	A registrant shall update their registration in a timely manner in any of the circumstances outlined in paragraph 1.
30	Article 22	Further duties of registrants	(2)	Obligation to update registration at the Agency's request.
31	Article 22	Further duties of registrants	(4)	Obligation for individual registrants to submit information separately in case of joint registration.
32	Article 24	Notified substances	(2)	Provision of information if threshold exceeded.
Title III – Data sharing and avoidance of unnecessary testing				
33	Article 25	Objectives and general rules	(1)	Unnecessary testing on vertebrate animals and duplication of animal tests must be avoided.
34	Article 26	Duty to inquire prior to registration	(1)	A potential registrant for a non phase-in substance or phase-in substance not pre-registered shall inquire from the Agency if a registration has already been submitted for the same substance.
35	Article 26	Duty to inquire prior to registration	(3)	Tests on vertebrate animals shall not be repeated.
36	Article 27	Sharing of existing data in the case of registered substances	(6)	A potential registrant shall request information on vertebrate tests from a previous registrant.
37	Article 27	Sharing of existing data in the case of registered substances	(6)	A potential registrant shall pay for information on vertebrate tests from a previous registrant.
38	Article 30	Sharing of data involving tests	(1)	A SIEF participant shall inquire if relevant studies are available before performing tests on vertebrate animals.

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	Article Number	Article Title	Paragraph	Potential Obligation
Title III – Data sharing and avoidance of unnecessary testing (<i>continued</i>)				
39	Article 30	Sharing of data involving tests	(2)	Only one study may be conducted for all SIEF participants together.
40	Article 30	Sharing of data involving tests	(3)	A SIEF participant shall pay for information on vertebrate tests from a previous registrant.
41	Article 30	Sharing of data involving tests	(6)	A study owner shall provide the study or proof of cost as referred to in paragraph 3 and 4.
Title IV – Information in the supply chain				
42	Article 31	Requirements for safety data sheets	(1)	A supplier shall provide a recipient with a properly compiled safety data sheet where required according to paragraph 1.
43	Article 31	Requirements for safety data sheets	(2)	An actor in the supply chain who has been required to perform a chemical safety assessment shall ensure that the information in the safety data sheet is consistent with the information in the assessment.
44	Article 31	Requirements for safety data sheets	(3)	A supplier shall provide a recipient with a safety data sheet when requested for a preparation meeting the requirements set out in paragraph 3.
45	Article 31	Requirements for safety data sheets	(4)	A supplier shall provide a downstream user or distributor with a safety data sheet when requested for a preparation meeting the circumstances set out in paragraph 4.
46	Article 31	Requirements for safety data sheets	(5)	The safety data sheet must be supplied in the language of the Member States concerned.
47	Article 31	Requirements for safety data sheets	(6)	A safety data sheet shall contain the information set out in paragraph 6.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title IV – Information in the supply chain (continued)				
48	Article 31	Requirements for safety data sheets	(7)	An actor in the supply chain required to prepare a chemical safety report shall place the information outlined in paragraph 7 in an annex to the safety data sheet.
49	Article 31	Requirements for safety data sheets	(7)	A downstream user shall include the information outlined in paragraph 7 in their safety data sheet.
50	Article 31	Requirements for safety data sheets	(7)	A distributor shall include or pass on information outlined in paragraph 7 in their safety data sheet.
51	Article 31	Requirements for safety data sheets	(9)	A supplier shall update the safety data sheet without delay on the occasions outlined in paragraph 9.
52	Article 32	Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required	(1)	A supplier of a substance on its own or in a preparation, who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the information outlined in paragraph 1.
53	Article 32	Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required	(2)	Requirement to supply the information within the timeframe set out in paragraph 2.
54	Article 32	Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required	(3)	A supplier shall update the information without delay on the occasions outlined in paragraph 3.

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	Article Number	Article Title	Paragraph	Potential Obligation
	Title IV – Information in the supply chain (<i>continued</i>)			
55	Article 32	Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required	(3)	A supplier shall provide all previous recipients with updated information .
56	Article 33	Duty to communicate information on substances in articles	(1)	A supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59 in a concentration greater than 0.1% (w/w) shall provide the recipient with sufficient information to allow safe use of the article .
57	Article 33	Duty to communicate information on substances in articles	(2)	A supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59 in a concentration greater than 0.1% (w/w) shall provide the consumer with sufficient information to allow safe use of the article.
58	Article 34	Duty to communicate information on substances and preparations up the supply chain		An actor in the supply chain of a substance or preparation shall communicate information outlined in paragraph 1 to the next actor or distributor up the supply chain.
59	Article 34	Duty to communicate information on substances and preparations up the supply chain		A distributor shall pass on the information identified in paragraph 1 to the next actor in the supply chain.
60	Article 35	Access to information for workers		An employer shall grant workers or their representatives access to information provided in accordance with Article 31 and 32 in relation to substances or preparations which they may use or be exposed to in the course of their work.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title IV – Information in the supply chain (continued)				
61	Article 36	Obligation to keep information	(1)	A manufacturer shall assemble and keep all the information required by the Regulation for at least 10 years after last manufacturing, importing, supplying or using a substance or preparation.
62	Article 36	Obligation to keep information	(1)	An importer shall assemble and keep all the information required by the Regulation for at least 10 years after last manufacturing, importing, supplying or using a substance or preparation.
63	Article 36	Obligation to keep information	(1)	A downstream user shall assemble and keep all the information required by the Regulation for at least 10 years after last manufacturing, importing, supplying or using a substance or preparation.
64	Article 36	Obligation to keep information	(1)	A distributor shall assemble and keep all the information required by the Regulation for at least 10 years after last manufacturing, importing, supplying or using a substance or preparation.
65	Article 36	Obligation to keep information	(1)	A manufacturer shall submit or make available the information to the competent authority or Agency upon request.
66	Article 36	Obligation to keep information	(1)	An importer shall submit or make available the information to the competent authority or Agency upon request.

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	Article Number	Article Title	Paragraph	Potential Obligation
Title IV – Information in the supply chain (continued)				
67	Article 36	Obligation to keep information	(1)	A downstream user shall submit or make available the information to the competent authority or Agency upon request.
68	Article 36	Obligation to keep information	(1)	A distributor shall submit or make available the information to the competent authority or Agency upon request.
69	Article 36	Obligation to keep information	(2)	Obligation to provide the competent authority or the Agency with information on request.
Title V – Downstream users				
70	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(2)	A downstream user shall pass on sufficient information for use by a manufacturer, importer or downstream user who supplied the substance for the purpose outlined in paragraph 2.
71	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(2)	A distributor shall pass on the information identified in paragraph 2 to the next actor or distributor in the supply chain.
72	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(3)	A manufacturer shall comply with the obligations in Article 14 before next supplying a substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2.
73	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(3)	An importer shall comply with the obligations in Article 14 before next supplying a substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title V – Downstream users (continued)				
74	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(3)	A downstream user shall comply with the obligations in Article 14 before next supplying a substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2.
75	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(4)	A downstream user shall prepare a chemical safety report for a use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.
76	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(7)	A downstream user shall keep their chemical safety report up-to-date and available.
77	Article 38	Obligation for downstream users to report information	(1)	A downstream user shall report information to the Agency specified in paragraph 2 in the cases outlined in paragraph 1.
78	Article 38	Obligation for downstream users to report information	(3)	A downstream user shall update information without delay in the event of a change.
79	Article 38	Obligation for downstream users to report information	(4)	A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.
80	Article 39	Application of downstream user obligations	(1)	A downstream user shall comply with the requirements of Article 36 within the timescale set out in paragraph 1.

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	Article Number	Article Title	Paragraph	Potential Obligation
Title V – Downstream users (<i>continued</i>)				
81	Article 39	Application of downstream user obligations	(2)	A downstream user shall comply with the requirements of Article 37 within the timescale set out in paragraph 1.
Title VI – Evaluation				
82	Article 40	Examination of testing proposals	(3)	Obligation for registrant or downstream user to carry out a test proposed by the Agency.
83	Article 40	Examination of testing proposals	(4)	The registrant shall submit the information required to the Agency by the deadline set.
84	Article 40	Examination of testing proposals	(4)	The downstream user shall submit the information required to the Agency by the deadline set.
85	Article 41	Compliance check of registrations	(4)	The registrant shall submit the information required to the Agency by the deadline set.
86	Article 46	Requests for information and check of information submitted	(2)	A registrant shall provide information required by the agency by the deadline set.
87	Article 49	Further information on isolated on-site intermediates		The national competent authority may require the registrant to provide information on on-site isolated intermediates.
88	Article 50	Registrants and downstream users rights	(2)	Obligation for the registrant to inform the Agency of cessation of manufacture or import.
89	Article 50	Registrants and downstream users rights	(3)	Obligation for the registrant to inform the Agency of cessation of manufacture or import.
90	Article 50	Registrants and downstream users rights	(4)	Obligation to provide the competent authority with information for preparing a dossier in accordance with Annex XV (on CMR substances).

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title VI – Evaluation (<i>continued</i>)				
91	Article 53	Cost sharing for tests without an agreement between registrants and/or downstream users	(3)	A registrant or downstream user conducting a study shall provide each of the others concerned with a copy of the full study report.
92	Article 53	Cost sharing for tests without an agreement between registrants and/or downstream users	(4)	Requirement to pay a share of costs of a study or to hand over a full study report.
Title VII – Authorisation				
93	Article 61	Review of authorisations	(1)	A holder of an authorisation granted in accordance with Article 60 shall submit an update of any substitution plan .
94	Article 65	Obligation of holders of authorisations		The holder of an authorisation shall include the authorisation number on the label before the substance or preparation is placed on the market.
95	Article 65	Obligation of holders of authorisations		A downstream user referred to in Article 56(2) shall include the authorisation number on the label before the substance or preparation is placed on the market.
96	Article 66	Downstream users	(1)	A downstream user using a substance in accordance with Article 56(2) shall notify the Agency within three months of first supply.

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	Article Number	Article Title	Paragraph	Potential Obligation
Title XI – Classification and Labelling Inventory				
97	Article 113	Obligation to notify the agency	(1)	A manufacturer or group of manufacturers who place on the market a substance within the scope of Article 111 shall notify the Agency with the information outlined in paragraph 1.
98	Article 113	Obligation to notify the agency	(1)	An importer or group of importers who place on the market a substance within the scope of article 111 shall notify the Agency with the information outlined in paragraph 1.
99	Article 113	Obligation to notify the agency	(3)	The notifier in paragraph 1 shall update information listed under the circumstances identified in paragraph 3.

Use Related Obligations

	Article Number	Article Title	Paragraph	Potential Obligation
Title II – Registration				
100	Article 5	No data no market	(1)	Not manufacture an unregistered substance requiring registration.
101	Article 5	No data no market	(1)	Not manufacture a preparation containing an unregistered substance requiring registration.
102	Article 5	No data no market	(1)	Not manufacture an article containing an unregistered substance requiring registration.
103	Article 5	No data no market	(1)	Not place on the market an unregistered substance requiring registration.
104	Article 5	No data no market	(1)	Not place on the market a preparation containing an unregistered substance requiring registration.
105	5	No data no market	(1)	Not place on the market an article containing an unregistered substance requiring registration.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
Title II – Registration (<i>continued</i>)				
106	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(6)	The manufacturer shall comply with any conditions imposed by the Agency in accordance with paragraph 4.
107	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(6)	The importer shall comply with any conditions imposed by the Agency in accordance with paragraph 4.
108	Article 9	Exemptions from the general obligation to register for product and process orientated research and development (PPORD)	(6)	The producer of articles shall comply with any conditions imposed by the Agency in accordance with paragraph 4.
109	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(6)	A manufacturer shall identify and apply appropriate measures to control the risks identified in the chemical safety assessment.
110	Article 14	Chemical safety report and duty to apply and recommend risk reduction measures	(6)	An importer shall identify and apply appropriate measures to control the risks identified in the chemical safety assessment.
Title V – Downstream users				
111	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(5)	A downstream user shall identify or apply or where suitable recommend, measures to adequately control risks identified in the sources set out in paragraph 5.
112	Article 37	Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures	(6)	Where a chemical safety report is not prepared a downstream user shall identify or apply appropriate risk management measures to ensure that the risks to human health and environment are adequately controlled.

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	Article Number	Article Title	Paragraph	Potential Obligation
	Title VII – Authorisation			
113	Article 56	General provisions	(1)	A manufacturer shall not place a substance included in Annex XIV on the market for use when the exemptions in paragraph 1 do not apply.
114	Article 56	General provisions	(1)	A manufacturer shall not use a substance included in Annex XIV when the exemptions in paragraph 1 do not apply.
115	Article 56	General provisions	(1)	An importer shall not place a substance included in Annex XIV on the market for use when the exemptions in paragraph 1 do not apply.
116	Article 56	General provisions	(1)	An importer shall not use a substance included in Annex XIV when the exemptions in paragraph 1 do not apply.
117	Article 56	General provisions	(1)	A downstream user shall not place a substance included in Annex XIV on the market for use when the exemptions in paragraph 1 do not apply.
118	Article 56	General provisions	(1)	A downstream user shall not use a substance included in Annex XIV when the exemptions in paragraph 1 do not apply.
119	Article 56	General provisions	(2)	A downstream user may only use a substance that meets the criteria of paragraph 1 in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
120	Article 60	Granting of authorisation	(10)	Obligation for authorisation holders to minimise exposure.

Annex D: Provisions relating to information and supply chain requirements and use related requirements

	Article Number	Article Title	Paragraph	Potential Obligation
	Title VIII – Restrictions			
121	Article 67	General provisions	(1)	A substance on its own subject to a restriction shall not be manufactured unless it complies with that restriction.
122	Article 67	General provisions	(1)	A substance in a preparation subject to a restriction shall not be manufactured unless it complies with that restriction.
123	Article 67	General provisions	(1)	A substance in an article subject to a restriction shall not be manufactured unless it complies with that restriction.
124	Article 67	General provisions	(1)	A substance on its own subject to a restriction shall not be placed on the market unless it complies with that restriction.
125	Article 67	General provisions	(1)	A substance in a preparation subject to a restriction shall not be placed on the market unless it complies with that restriction.
126	Article 67	General provisions	(1)	A substance in an article subject to a restriction shall not be placed on the market unless it complies with that restriction.
127	Article 67	General provisions	(1)	A substance on its own subject to a restriction shall not be used unless it complies with that restriction.
128	Article 67	General provisions	(1)	A substance in a preparation subject to a restriction shall not be used unless it complies with that restriction.

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	Article Number	Article Title	Paragraph	Potential Obligation
	Title VIII – Restrictions (<i>continued</i>)			
129	Article 67	General provisions	(1)	A substance in an article subject to a restriction shall not be used unless it complies with that restriction.
130	Article 67	General provisions	(3)	A substance shall not be placed on the market in breach of more stringent UK restrictions prior to the date identified in paragraph 3.
131	Article 67	General provisions	(3)	A substance shall not be manufactured in breach of more stringent UK restrictions prior to the date identified in paragraph 3.
132	Article 67	General provisions	(3)	A substance shall not be used in breach of more stringent UK restrictions prior to the date identified in paragraph 3.

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