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# Summary of responses to the consultation on REACH enforcement between 13 March to 4 June 2007

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## 1. Introduction

1. From the 13 March to 4 June 2007 Defra in conjunction with the Devolved Administrations for Scotland, Wales and Northern Ireland held a consultation to gather stakeholder views on proposals for the UK enforcement of the new EU Regulation on chemicals – **REACH** (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals).
2. The consultation document, which included a partial regulatory impact assessment, was sent to 84 organisations and stakeholders as well as being made publicly available on the Defra website.
3. A total of 51 responses were received; a list of the organisations who responded to the consultation can be found in Annex A.
4. All respondents were asked if they were content for their views to be made public. A full set of the consultation responses can be obtained by contacting Defra's Information Resource Centre, Lower Ground floor, Ergon House, 17 Smith Square, London, SW1P 3JR.
5. We are grateful for the responses received. This summary paper aims to reflect the views offered, but inevitably it is not possible to describe all the responses in detail. A number of issues were made outside the scope of the consultation questions but still in relation to the REACH Regulation and these have been summarised in Annex B.
6. In undertaking this consultation and drawing up this summary, we have been guided, not only by the number of respondents expressing a particular view, but also by the arguments advanced by respondents in support of their views.

## 2. Summary of Responses

### General Themes

- The proposed approach to the enforcement of REACH in the UK was generally welcomed.
- There was common support of the Hampton Principles that enforcement should be effective and proportionate.
- There was general agreement for simplification of the regulatory environment and the principles of better regulation.
- It was felt important to utilise existing approaches where possible and ensure enforcement is fair, pragmatic, consistent, effective, and safeguards and promotes competitiveness of businesses.
- Compliance should initially be encouraged and then supported by more formal enforcement procedures.
- There must be fair and consistent enforcement across all European Union (EU) Member States. This would ensure that UK companies are not at a competitive disadvantage.

Respondents frequently raised issues that related to the practical operation of the enforcement regime by the various enforcement bodies in addition to the legal framework that was the focus of the consultation paper.

### **3. Consultation Questions Responses**

#### **Q1. Do you agree with this approach to enforcement?**

7. All but a couple of the respondents broadly supported the proposed approach to enforcement.

#### **Resources**

8. Many of the respondents stressed that greater resources must be made available to all the enforcers. There were concerns whether effective enforcement, including training of the enforcers, could occur using only existing resources and staff.

9. A specific concern was raised about recent reductions in inspection and enforcement at the Health and Safety Executive (HSE) and that inspecting for REACH would further dilute their other inspection activities.

10. A couple of respondents felt that HSE and the Environment Agency are unlikely to identify non-compliance as part of their normal Control Of Major Hazards (COMAH) or Pollution Prevention and Control (PCC) inspections.

#### **Selection of premises for inspection**

11. Some of the respondents requested further explanation of the risk based approach which would be used for the selection of premises for inspection. Respondents felt that enforcement could concentrate on those posing the lowest risk i.e. manufacturers of chemicals as the real environmental and occupation health and consumer risk would lie with the downstream users. It was suggested that the risk based approach to inspection should consider the risks from non-compliance, consequential risks from non-compliance and should not be based on size, process industry or the sector. Consideration should also be given to what is an unacceptable hazard or unmanageable risk.

12. Several respondents believed that the enforcing authorities may not focus on non-hazardous substances thus leading to non-enforcement of these substances. Concerns were also expressed that if inspection/ compliance checks are done on risk, companies that do not get a registration/authorisation would not be on the radar. One respondent suggested the most significant risks would come through market stalls and car boot sales.

13. Some respondents highlighted that a business already inspected by the authorities is more likely to be inspected for REACH than a business not currently inspected by any of the proposed enforcing authorities.

14. The majority of respondents believed that procedures and circumstances for inspection should be consistent across all the enforcers. A common set of risk-based methods for prioritising inspections and performing comparative assessments of the level of inspections should be adopted. It was suggested that this could be the responsibility of

the Competent Authority in issuing guidance to the enforcing bodies. Many respondents stressed the need for confidential information to be protected in the case of investigations and for this again to be consistent across the enforcers.

15. It was highlighted by one respondent that Trading Standards currently enforce regulations such as the Dangerous Substances and Preparations Regulations (2006) and this enforcement includes market surveillance. REACH may replace such regulations and thus there may be differences in enforcement depending on the product supplied. Enforcement should thus address both the so called 'paper trail' and the actual 'mode of use'. For this, a regulatory inspector would need to be very familiar with a substance.

### **Whistle blowing**

16. Several of the respondents expressed concerns over the practicalities of 'whistle blowing'. It was considered that 'whistle blowing' may lead to extra investigations by the enforcers against a backdrop of current responsibilities under other legislation. This was considered inconsistent with the statement in the consultation that there would be no more site visits than at the current level. Further details were requested on how HSE would organise/manage whistle blowing. It was suggested that the investigations should be targeted on a minimum level of evidence to establish non compliance.

17. It was felt that malicious reporting or reporting out of ignorance could seriously affect a manufacturer or downstream user. Without sufficient evidence Small and Medium Sized Enterprises (SMEs) may face a disproportionate number of investigations where resources are more scarce. However, there was a belief that occasional investigations may also encourage compliance. In addition, it was questioned how whistle blowing would be co-ordinated between the Member States.

### **Hampton Principles and better regulation**

18. One respondent thought that the proposed enforcement regime was not compatible with the Hampton principles.

19. One respondent thought that an opportunity had been missed to streamline existing arrangements.

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

#### **Role of HM Revenue and Customs (HMRC)**

20. There was a widespread view from respondents that the role of HMRC should be clarified and strengthened.

21. It was repeatedly emphasised that under the proposed enforcement regime imported substance would be less likely to be challenged and without this the competitiveness of UK based companies would be severely compromised. The consensus of the respondents was that there must be rigorous and effective inspection of all imports into the UK. If not, non compliance may then only be picked up further down the supply chain and it would then have to be traced back up to the importer.

22. One respondent gave the example of the EU controls on Active Pharmaceutical Ingredients which has strict enforcement in the EU but it is believed to be insufficiently enforced regarding imports which make up to 80% of the market.

23. Several respondents suggested that a statement of REACH compliance for all imported goods within scope could be inserted into the customs declaration at the point of entry or there could be the use of a signed statement/certificate of compliance with REACH registration of relevant substances within the goods. Investigations could then occur as part of a routine audit or where suspicion of non-compliance occurs.

24. Some of the respondents thought that due to the confidential nature of businesses full disclosure of exact compositional information would be resisted and cause confusion, delay and additional work for officials.

### **Control of substances outside of REACH**

25. A few respondents raised the need to monitor substances which can be exempt from REACH but when they are then used fall within the scope of REACH. Food grade stuffs have many non-food grade applications; these may be moved to non-food use after import into the EU, which would have implications for enforcement. It was felt unclear how enforcement at the point of importation would work if it could not be defined if the substance was subject to REACH until the point of use.

### **Areas of enforcement**

26. Some respondents questioned how encompassing the enforcement structure was. It was felt that further consideration should be made of enforcing the registration requirement so that substances within products, including articles, are appropriately identified and registered.

27. One respondents thought greater consideration was required of the phrase 'placing on the market' and how it would be enforced. Infringements could take place outside the UK where a substance is manufactured or where it is first imported into the UK, but the powers of the enforcement bodies stop at the borders.

28. Another respondent questioned how companies would face sanctions on data sharing obligations. If the data sharing, in particular of animal testing data, does not occur how it would enforcement be managed between the European Chemicals Agency (EHCA) and Member States.

### **Communications**

29. Several respondents considered that compliance would be increased if there was effective dissemination of information to ensure that all parts of the supply chain were aware of their obligations. In addition it was felt that SMEs may need additional assistance as they could be more likely to be unfamiliar with the implications. It was proposed that the publication of a communication strategy by Defra and HSE should be encouraged along with awareness raising activities.

## **Q2. Do you agree with the allocation of responsibilities?**

30. The majority of the respondents agreed with the allocation of responsibilities.

### **Formal enforcement policy working document**

31. The majority of respondents requested a formal (possibly legal) working policy document on how the enforcers would work together, their roles and responsibilities in enforcing REACH across the UK. It was considered that some form of mechanism is required to enable the regulating agencies work together efficiently and effectively, to avoid duplication and omission, share information and to ensure that there is a consistent approach with clear guidelines for the inspectors. A couple of respondents proposed that there may need to be liaison groups set up to produce protocols/procedures.

32. There was agreement that there also needs to be transparency on where the enforcement resources are being focused. Many respondents suggested that HSE should take a leading role in co-ordinating enforcement and monitoring consistency. HSE's role as the Competent Authority could ensure that UK enforcement does not disadvantage companies in their business in the EU.

33. One respondent believed that the propose allocation of responsibilities was complex and fragmented.

### **Widening remits of the inspectors**

34. Some respondents expressed the view that Local Authorities have little or no experience of regulating chemicals. It was also mentioned that there may be limitations to how Local Authority PPC officers would be able to enforce REACH in Part A and Part B premises, e.g. permits only relate to installations specified by law and not to a whole site. Therefore permits might need to be extended to cover a whole site, which would increase inspection times and place more burdens on industry.

35. A few respondents pointed out that the scope of the activities of the Scottish Environment Protection Agency (SEPA) may increase as some of the suggested aspects of chemical use enforcement in REACH are outside their current regulated functions of PPC sites.

36. One respondent considered REACH to be 'principally' health and safety legislation and that it would open the door for Local Authority regulation of factories for health and safety. This would lead to a blurring of HSE/Local Authority role as enforcing bodies.

37. Some respondents shared the view that enforcers must have the powers to take samples and have them analysed. These powers would be similar to those in the Health and Safety at Work Act 1974, Environmental Protection Act 1990 and Consumer Protection Act 1987.

### **Multiple site inspections**

38. Many respondents raised the need to ensure appropriate division of the enforcement activities and the need to avoid multiple site regulation. Some of the articles in Annex D of the consultation document could fall both with use related enforcement and supply chain enforcement.

39. It was mentioned that Trading Standards would often visit manufacturing plants, importers or the headquarters of a company to enforce the current Marketing and Use of Dangerous Substances Regulations; these companies are also visited by HSE as they are considered high risk because they supply safety regulated products. In addition Trading Standards operates the Home Authority Principle where one local authority (where the business is located) acts as the main contact for all trading standards matters. The working relationship with the Competent Authority as managing the 'intelligence' needs to be considered.

### **Training**

40. Several respondents would like to see a consistent level of training for all inspectors to ensure fair enforcement. In addition it was asked what arrangements would be made to ensure that there are sufficient numbers of appropriately qualified personnel.

### **Offshore inspections**

41. A respondent referred to the facts that currently the Environment Agency does not have a remit beyond 1 nautical mile (nm) in English territorial waters, and similarly SEPA does not monitor activities (other than those relating to radioactive discharges) in Scottish controlled waters (out to 3 nm). Therefore, there would be no regulatory body to ensure compliance by the offshore oil/gas sector with the 'environmental protection' aspects of REACH.

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

### **Charging for enforcement**

42. Many respondents had concerns about how enforcement would be funded. The consultation document made no reference to charges resulting from enforcement; however, there was a general view that if charges are introduced they should be compatible with enforcement and inspection charging schemes that already exist. Current charges such as the permitting functions for PPC and COMAH should not increase as a result of the additional requirement of REACH. This would be unfair where authorities are not inspecting in association with other charging regimes and could lead to market distortion.

### **Progress and performance**

43. Many respondents would like to see a mechanism in place which would monitor the progress and performance of REACH implementation and enforcement.

44. In a wider context, some respondents enquired as to what measures would be put in place to test whether the REACH regulation is effective in improving the protection of the environment and human health.

### **Defence exemption**

45. A couple of respondents requested that further information should be made available to those industries with an interest in how the Defence exemption would operate.

### **Connection with existing legislation**

46. There were some concerns expressed from the respondents on how existing legislation would be repealed and how the enforcement activities would be translated across from the repealed legislation to REACH. As an example, enforcement activities

under the Dangerous Substances and Preparations regulations are not allocated between different regulators as would be the case under REACH. Some respondents questioned where REACH would stop and Control of Substances Hazardous to Health (COSHH) begin and which legislation would take precedence in the event of a conflict.

### **Interaction with other Member States**

47. There was agreement that there needed to be formal procedures for liaising with other EU Member State's enforcement authorities for enforcement down the supply chain when substances cross Member State borders. The question was also raised how enforcement would apply to non-EU entities which used an "only Representative".

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

48. Several respondents suggested alternative arrangements which are detailed below.

### **Non Governmental Organisations (NGOs) and competitors**

49. One respondent suggested that NGOs and competitors are best placed to enforce REACH and would do this via informing the authorities of suspected non-compliances.

### **DTI- Marine environment**

50. The Department of Trade and Industry (DTI)'s Energy Development Unit (EDU) is already responsible for implementing the OSPAR Harmonised Mandatory Control Scheme (HMCS) under the Offshore Chemical Regulations 2002. (OSPAR is the Convention for the Protection of the Marine Environment of the North-East Atlantic.) The Scheme deals with assessment and control of the use and discharge of hazardous chemicals by the offshore oil and gas industry into the marine environment. Therefore, DTI should continue to be the recognised enforcement agency in this area. This would improve effectiveness and minimise the burden to industry by offering continuity while allowing a gradual integration of the HMCS into REACH.

### **Environment Agency**

51. There was a proposal to set up a Chemicals Safety Co-ordination Unit within the Environment Agency and its equivalent in the Devolved Administrations, as it was considered that the balance of policy attention on chemicals is driven by environmental and consumer safety than by occupational safety. This unit would be charged with managing and enforcing REACH and is likely to require new enforcement powers.

### **HSE**

52. Many respondents suggested various arrangements by which HSE could enforce REACH:

- obtain an extension of powers and more resources for chemicals enforcement under REACH.
- perform the bulk of the enforcement with supporting roles from Local Authorities/Trading Standards and HMRC, and the various Environment agencies.

- be the arbiter to which companies can turn to for advice and also in contested or appeal situations.
- as HSE covers the enforcement aspects of Globally Harmonised System of Classification and Labelling of Chemicals (GHS) down the supply chain so enforcement of REACH should entirely be with HSE.
- HSE and HSE Northern Ireland (HSENI) should regulate REACH at business premises. A Memorandum of Understanding could then be entered into with the environment agencies (Environment Agency, SEPA and Northern Ireland Environment and Heritage Service (EHSNI) to ensure that they are informed of any REACH issues relating to environmental aspects which might be identified during HSE inspections. Any enforcement activity would be undertaken by HSE and HSENI. At premises enforced by Local Authorities for both health and safety and environmental matters there would not be a conflict as no other regulators would be involved.

### **ECHA and Commission**

53. Several respondents suggested roles for the ECHA and European Commission (EC)

- A dual system between ECA and EC would be the primary enforcement bodies in the EU Member States with UK enforcement being the responsibility of the HSE and HSENI as the Competent Authority and Defra.
- An EU-wide based enforcement with harmonised customs controls and penalties.

### **HSE and Environment Agency**

54. All enforcement should lie with the HSE and Environment Agency.

### **Good Laboratory Practice Monitoring Authority (GLPMA)**

55. GLPMA could have a wider monitoring role in relation to compliance with the principles of 'good laboratory practice'.

### **Government Chemist**

56. The Government Chemist has a long-established remit under public protection legislation to help resolve or avoid disputes relating to analytical science, and maintain a level playing field for enforcement. The Government Chemist could thus be available to advise on appropriate provisions for a referee function relating to REACH enforcement;

### **Electronic Compliance Checks**

57. A few of the respondents felt that enforcement activity relating to data and dossier completeness could be conducted electronically and this could be done via e-mails and website visits. This would have the additional bonus of reducing the costs of physical inspections. It was suggested that electronic and recorded post checks would also facilitate the coverage of premises that are not usually covered by routine inspections.

58. Information should also be made available on what IT capacity companies may need to comply with REACH.

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

59. The respondents views of the type of penalties regime was very much mixed.

#### **Single penalties regime**

60. Some of the respondents were in support of a single penalties regime. It was considered that it would give transparency and would be more suitable for borderline cases. Enforcement for consumer products and industrial products would also be equal. As individual circumstances would play a significant role in determining the seriousness of an offence the application of different sizes of penalties was considered to remain best suited for consideration by the courts.

#### **A tiered penalty regime**

61. Some of the respondents were in support of having some form of tiered penalty regime. It was considered important to distinguish between the more and less serious offences in order to have a suitable deterrent. Lower level fines should be only for offences of a technical nature. Breaches for authorisations and restrictions were considered more serious and should attract higher fines.

#### **Proportionate penalties**

62. Many respondents felt that the penalty could be proportionate to the profit connected with the substance or a proportion of annual profits. A penalty that corresponded to the compliance cost and the time the product was illegally on the market was suggested. The penalties could also reflect the level of hazard/risk involved. It was recommended that offences to human health should be treated differently to offences to the environment and that they should not have equal weighting.

#### **Types of breaches**

63. Many of the respondents suggested that there were different types of breaches including repeated breaches, deliberate non-compliance and accidental non-compliance. The level of penalty should take into account the type of breach as well as its seriousness.

#### **Appeals process**

64. There was general agreement that there needed to be an appeals process. It was proposed that HSE could refer certain disputes over data sharing to the Home Office, being the department that licenses animal tests. It was believed that there should be recognition that a company may have a genuine belief and valid argument as to why it is compliant, but the agency inspector disagrees.

#### **Prosecutions**

65. A few respondents questioned whether prosecutions would be aimed at the organisation or an individual.

#### **Administrative penalties, enforcement notices, fixed penalty notices**

66. Several respondents thought that it would be useful to consider monetary and other administrative penalties as an enforcing tool. The use of fixed penalty notices and enforcement notices would enable the enforcement body to impose a more proportionate sanction where an offence had been committed but larger scale financial penalties or

prosecution was not warranted. Any administrative sanctions would need to be proportionate and provide incentives to comply.

67. Some respondents, however, questioned the practicality of consistent administrative penalties across all the enforcers.

68. A number of respondents shared the view that the enforcement regime would need to accommodate the outcomes of the Macrory review. In addition one respondent suggested that the results of Defra's recently commissioned project on environmental penalties should also be considered. A further respondent believed that government should aim at an approach harmonised with the 'environmental protection through criminal law' draft directive.

### **Consistency of penalties with other regulations**

69. Some respondents said that there needed to be consistency of enforcement between REACH, GHS and other regulations such as the Consumer Protection, Health and Safety at Work, Clean Neighbourhoods and Environment legislation. The General Product Safety Regulations 2005 could provide an example of a creative and structured approach to penalties.

### **Penalties across the EU Member States**

70. Considerable support was given to the application of the same level of penalties to be applied in all Member States to ensure a level playing field across the EU. This would prevent the movement of companies to 'penalty friendly' states. A legislative forum was suggested by one respondent to help all Member States ensure consistency of approach.

### **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?**

71. Approximately half of the respondents thought the levels of penalties proposed were sufficient to meet the requirement of "effective, proportionate and dissuasive". The other half of the respondents felt the penalties were not sufficient.

72. Many respondents agreed that the penalty should be an effective deterrent, proportionate to the seriousness of the offence, any financial gain from non-compliance, and the time period of non-compliance. Effective application of criminal law and financial penalties at least equivalent to the cost of compliance would act as an effective deterrent.

73. Some respondents felt that £5000 would be adequate for a less serious offence with the option of referral to the courts for a more serious offence where an unlimited fine could be levied. However, £5000 would not be seen to be dissuasive for large companies. Many respondents thought that penalties should be in line with those of existing legislation e.g. Health and Safety legislation provides for a fine of up to £20,000 to be levied in the Magistrates Court.

74. A couple of respondents suggested that the Office of Fair Trading could have a role in determining the degree of market distortion and the level of penalties.

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

75. There was overwhelming agreement that each enforcing authority should apply its current procedures for enforcing REACH. Any change may result in confusion.

76. Concerns were raised, however, that current procedures would not be able to cope with the extra burden of work. In addition, it would be important to demonstrate consistency across the different authorities.

77. A couple of respondents did, however, suggest that REACH-specific enforcement powers should be developed which would give better accountability and visibility. The use of enforcement notices for current regimes would mean that it would be difficult to monitor the level of compliance for REACH. Comprehensive data of all non-compliance would be essential to validate reporting to the Commission. Selective recording would make inter-state comparisons impossible.

78. There were shared views that the Competent Authority should work closely with the other enforcing authorities to ensure that procedures and circumstances for issuing enforcement notices are as coherent and consistent as possible.

**4. Partial Regulatory Impact Assessment Questions**

**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.**

79. Several of the respondents felt that the effectiveness of option 2 had been overestimated and from a cost perspective option 3 had not been fully explored so that a sufficient case had not been made for its rejection. It was acknowledged that a single enforcement agency would cost more but extra resources would also be required for all the regulators under option 2.

80. It was thought that a scheduled REACH compliance inspection might not coincide with a scheduled inspection for other regulatory requirements, and that as a result more specific REACH inspections would be required. This would bring the administrative costs of options 2 and 3 closer together.

81. Several respondents believed that double inspections may also be required as each regulator would only be an expert in its own field of competence.

82. Several respondents said that the proposed cost of enforcement to industry was a serious underestimate.

83. A couple of respondents stated that if the enforcement effort focused on chemicals which were newly subject to authorisation or restriction, then companies dealing with substances outside these parts of the regime could effectively ignore REACH because enforcement could not be undertaken.

84. One respondent felt that the times allocated did not appear to have taken into account a product formulator using hundreds of chemicals going to multiple end users. They also did not take into account an importer of articles who may not be aware of what substances they contain.

85. Many respondents recognised that many of the compliance checks would be coordinated with the ECHA and between EU Member States, and that electronic methods would therefore be crucial to the regulatory authorities.

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

86. A few respondents argued that many small companies may be using high volumes of chemicals. Therefore the presumption that the requirement to register would not impact on them until 2018 was incorrect.

87. It was suggested that some consideration should be given to the extent to which the task of complying with REACH would vary for companies of different sizes. Enforcement inspections may be quicker in the large manufacturing companies compared to the smaller, more diverse manufacturers, formulators, blenders importers and suppliers.

88. There were shared views that site visits may not be required for many aspects of enforcement. An electronic based compliance check system would mean that there could be a higher number of checks.

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

89. Many respondents stated that 90 minutes was an underestimate for the activities described and did not relate to the number of individual substances that may be used on any one site.

90. It was considered by many respondents that the 90 minutes did not reflect the need for preparatory activities for an inspection. Respondents believed that it could take up to 2 days to get ready for an inspection. Preparatory time could include activities such as the need to hire lawyers, search for papers or set up expert teams. It was pointed out that REACH documentation may also be stored in a central office rather than where an inspector might be at the operational site. Thus incorporation into routine site checks for other regimes would not cover some compliance checks.

91. It was also suggested that the 90 minutes also presumed that businesses had been ready for previous checks under other regimes. Several respondents believed that there had been very few enforcement checks/ notices issued under existing regulations (Existing Substances Regulations (ESR) and Notification of New Substances (NONS)) within the last 5 years and therefore companies would not already be prepared.

92. Small companies would also be inexperienced and they would require more time to prepare for enforcement checks. It was suggested that a REACH compliance certificate may be more appropriate for downstream users rather than checking registration numbers.

93. Some respondents had concerns that the 90 minutes stated did not take into account sampling and testing requirements which are an essential part of the enforcement mechanism. That activity would place extra burdens on inspectors and companies. If analytical process or product controls have been used to show compliance with authorisation conditions, inspectors would need to be sure that the data are genuine. The company may have to demonstrate the test method at a non-scheduled time in order to coincide with the visit. If so, an appropriate specialist may need to be involved for a significant period in order to initiate, stabilise and validate the measuring system, obtain data, carry out quality assurance and interpret the results. Additional time should also be factored in for any follow up activity by the company and inspectors after the inspection.

94. It was felt that if compliance is only checked via electronic data capture and recording then 90 minutes was possibly a reasonable estimate.

95. Several respondents suggested initiating pilot studies involving exploratory visits on a sample of industries of a range of sizes within various sectors.

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

96. There were mixed views from the respondents regarding the appropriateness of the wage rate used.

97. A few respondents thought that it was not clear how the wage rate had been decided as it was based on a mean figure derived from the two widely different wage rates quoted. The wage rate could vary according to the type of compliance check and did not take into account the cost of any sampling or testing requirements.

98. A concern was raised that the hourly rate for inspections was approximately a third of the rate which Local Authority Officers would anticipate charging at.

99. The person designated to be responsible for demonstrating compliance with REACH would need to be highly qualified; for a medium to large organisation this could be £35.40 per hour (wage rate plus overheads).

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

100. A minority of respondents commented that in order to assess compliance a much higher frequency of visits would need to take place. The consultation paper had not taken into account the possible role of electronic compliance checks.

101. The proposed frequency of sites visits for chemicals manufacturers was considered to be disproportionately high. Frequencies should be risk based and take into account existing levels of expertise and regulation. Some respondents felt that the chemical industry would be singled out compared to non-chemical companies although all UK businesses were subject to regulation.

102. Many respondents stated that the risk of non-compliance is likely to be higher for imported materials, therefore the proposed number of site visits for UK chemical manufacturers was disproportionately high compared with investigations of companies responsible for importing goods from outside the EU.

## **5. Next Steps**

103. The responses to the consultation paper will be carefully considered. This will be followed by the drafting of the Statutory Instrument for the enforcement of REACH, for which there will be further consultation in early 2008.

## **Annex A – list of respondents**

AMEC Earth and Environmental  
American Chemistry Council  
Arjowiggins Group  
Aromatherapy Trade Council  
Association of the British Pharmaceutical Industry  
British Aerosol Manufacturers' Association  
British Cement Association  
British Coatings Federation Ltd  
British Occupational Hygiene Society  
Chemical Business Association  
Chemicals Industries Association  
Confederation of British Industry  
Corus UK Limited  
Cumberland Ellis LLP  
DanGoods Training & Consultancy Ltd  
Department for Trade and Industry - Energy Development Unit  
EEF (the organisation for manufacturing, engineering and technology-based businesses)  
Environment Agency  
Federation of Small Businesses  
Food and Drink Federation  
Government Chemist  
Health and Safety Commission  
Hewlett Packard  
Imperial Tobacco Ltd  
Ineos Chlorvinyls  
Local Authorities Coordinators of Regulatory Services (LACORS)  
Lubrizol Limited  
Midland Joint Advisory Council for Environmental Protection  
Non Ferrous Alliance  
Picon  
Polartech Ltd  
Robert McBride Ltd  
Robinson Brothers Ltd  
Royal Commission on Environmental Pollution  
Royal Society of Chemistry  
Society of British Aerospace Companies (SBAC)  
S. Black Ltd  
Scottish Environment Protection Agency (SEPA)  
Solvents Industry Association  
Technical Committee of Petroleum Additive Manufacture in Europe (ATC)  
The Kennel Club and FRAME  
The Packaging Federation  
Trade Union Congress  
Trading Standards Institute  
UK Cleaning Products Industry Association  
UK Petroleum Industry Association  
Unite the Union - Amicus Section  
Unite (T & G Section)  
Vegetarian Economy & Green Agriculture (VEGA)

WSP Environmental Limited  
3M United Kingdom PLC

## Annex B – issues raised from respondents outside the scope of the consultation paper questions

### 1. Interpretation of the text of the REACH Regulation

- 1.1 Clarification was sought of the interpretation of the timescales in Articles 36 (1) and 26(3) - Article 36 (1) requires a company to keep all information relating to its REACH obligations for 10 years AFTER the last date of manufacture, import, supply or use of a substance. Article 26(3) requires the Agency to pass on the contact details of all registrants that had previously registered the same substance up to 12 years prior to the date of request by a potential new registrant.
- 1.2 Article 126 entered into force on the 1 June 07 therefore it was suggested that member state penalties and provisions should be put in place by this date, in particular in relation to infringements of the Safety Data Sheet where the REACH provisions take over from the current provisions.
- 1.3 Suggested changes were made to the following Information and Supply Chain obligations found in Annex D of the consultation document to avoid movement away from the REACH text.

- 1.3.1 Article 7- “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.”

Suggested change to - A **producer** of articles shall **notify the agency** in accordance with paragraph 4 if a substance contained in those articles meets the criteria in Article 57 and is identified in accordance with Article 59(1) if both the conditions in paragraph 2 are met [“Candidate list”].

- 1.3.2 Article 7- “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.”

Suggested change to - An importer of articles shall **notify the Agency** in accordance with paragraph 4 if a substance contained in those articles meets the criteria in Article 57 and is identified in accordance with Article 59(1) if both the conditions in paragraph 2 are met [“Candidate list”].

- 1.3.3 Article 7- “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.”

[Notification] shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer shall supply appropriate instructions to the recipient of the article.

- 1.3.4 Article 7- “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.”

[Notification] shall not apply where the importer can exclude exposure to humans or the environment during normal or reasonably foreseeable

conditions of use including disposal. In such cases, the importer shall supply appropriate instructions to the recipient of the article.

- 1.3.5 Article 33 - “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.”

Suggested change to - 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** on request with sufficient information to allow safe use of the article.

- 1.3.6 Article 5 – “No data no market. Not place on the market an article containing an unregistered substance requiring registration.”

It was suggested that this wording is more ambiguous than the REACH Regulation itself and would mean that all substances in imported articles need to be registered (paragraph 105).. This would take the definition beyond the requirements of REACH as it does not distinguish between substances in articles which are intended for release and those which are not.

Therefore it was proposed that the Annex should say: “substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.”

It was suggested that this would mean that substances in articles do not have to be registered if they are:

- not intended for release (in normal / foreseeable conditions of use)
- not hazardous

Imported articles may contain substances that are not intended for release in quantities greater than one tonne and are not hazardous. Under REACH such substances do not need to be registered.

- 1.4 There was a suggested change to the REACH implementation time line found in Annex B of the consultation document.

Article 7 registration and notification of substances in articles Deadline:1 December 2008.

Notification: 1 June 2011, Registration:

- a. pre-registered phase-in substances: depending on quantity and properties
- b. non phase-in substances/not pre-registered phase-in substances: 1 June 2008

2. The following points were suggested for inclusion in future communications with industry.

- 2.1 While distributors and professional users may have obligations relating to registration, they will not be required to register chemicals directly with ECHA.
  - 2.2 Restrictions can amount to banning chemicals that pose a serious hazard, but can also be used more flexibly, for example by focusing on particular applications.
  - 2.3 Substance evaluation will not necessarily be carried out by the Competent Authority of the lead registrant's Member State. This flexibility could help ensure a level playing field in the identification and prioritisation of substances for evaluation.
  - 2.4 Set out the revocation dates and transitional arrangements for UK legislation to be superseded as a result of REACH, for example the safety data sheet requirements under CHIP- Chemicals (Hazard Information and Packaging for Supply).
  - 2.5 Identify that it is the Secretary of State for Environment, Food and Rural Affairs on whose behalf the Competent Authority functions and who will be responsible for UK legislation to implement REACH.
  - 2.6 That the purpose of the REACH Regulations embraces "the promotion of alternative methods for assessment of hazards of substances".
  - 12.7 The definition of Monetary Administrative Penalties.
3. Proceedings have been issued by one respondent in the High Court of Justice for a judicial review of specific provisions of the REACH Regulation relating to polymers and preparations.
  4. It was suggested that there needed to be clarification of how 'Natural' substances should be dealt with under REACH. In addition further clarification was sought on 'articles', e.g. whether the regulation applied to finished 'articles' such as cigarettes or whether it included all forms of packaging such as the box, cellophane etc

## **Annex C – list of acronyms**

COMAH	Control Of Major Hazards
COSHH	Control of Substances Hazardous to Health
DTi	Department of Trade and Industry
EC	European Commission
ECHA	European Chemicals Agency
EDU	Energy Development Unit
EHSNI	Northern Ireland Environment and Heritage Service
ESR	Existing Substances Regulations
EU	European Union
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HMCS	Harmonised Mandatory Control Scheme
HMRC	HM Revenue and Customs
HSE	Health and Safety Executive
HSENI	HSE Northern Ireland
NONS	Notification of New Substances
OSPAR	The Convention for the Protection of the Marine Environment of the North-East Atlantic
PPC	Pollution Prevention and Control
SEPA	Scottish Environment Protection Agency
SMEs	Medium Sized Enterprises