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Summary of responses to the second consultation on REACH enforcement: 3 June - 25 August 2008

November 2008



Llywodraeth Cynulliad Cymru
Welsh Assembly Government



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SCOTTISH EXECUTIVE



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The consultation document on the REACH enforcement is available on the Defra website at:

<http://www.defra.gov.uk/corporate/consult/reach-enforce/index.htm>

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1. Introduction

1. From 3 June to 25 August 2008 Defra, in conjunction with the Devolved Administrations for Scotland, Wales and Northern Ireland, held a consultation to gather stakeholder views on the draft Regulations and administrative arrangements for the UK enforcement of the new EU Regulation on chemicals – **REACH** (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals). This was the second and final consultation; an initial consultation was held in March 2007 on the various options for UK enforcement.
2. The consultation document, which included a partial regulatory impact assessment, was sent to 102 organisations and stakeholders as well as being made publicly available on the Defra website.
3. A total of 23 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

Q1. Do you have any comments relating to the proposed enforcement authorities?

7. Of those respondents who commented there was broad agreement to the proposed enforcement authorities.

Consistency

8. Several respondents stressed that consistency of enforcement across the enforcing authorities and the UK was essential. There were suggestions that the need for a clear understanding of the division of enforcement required further consideration in order to ensure uniformity of enforcement and avoid duplication of efforts.

Role of HMRC

9. A number of respondents considered the proposed role of HMRC to be inadequate. Concerns were that importers would have an advantage over UK manufacturers. One respondent proposed that a signed statement of compliance with REACH requirements be required for all non-EU imports of relevant substances within goods at their point of entry. It was also commented that adequate resources towards training for officials of Revenue and Customs should be made available to ensure that routes of entry into the EU market were properly controlled.

Q2. Do you believe that all appropriate REACH provisions have been included for enforcement in the UK?

10. The majority of respondents who answered this question agreed that all appropriate REACH provisions had been included for enforcement in the UK.
11. One respondent explicitly expressed their agreement that it would be impractical and inappropriate to enforce provisions related to Substance Information Exchange Fora as these are matters for civil law to resolve amongst parties when appropriate.
12. Two respondents were concerned that the actual mechanism for enforcement was not clear and would have liked to have seen more information regarding the proposed system for enforcement. It was noted that good co-ordination by the HSE as the primary holder of information would be key.
13. One respondent considered that all of the REACH provisions should be included under existing enforcement regimes.

Animal Testing

14. One respondent expressed disappointment that the Animals (Scientific Procedures) Act 1986 was considered sufficient to meet the needs of REACH. They recommended that the Home Office should introduce measures to ensure that data sharing is compulsory and commented that if this was not enforced properly then REACH had the potential to substantially increase the number of duplicated animal experiments. It was considered that the proposal failed to set implementation and enforcement measures to ensure that all existing data is shared without exception.
15. One respondent agreed that it was appropriate for the Home Office to continue to control testing that is required under REACH, also expressing agreement that the SIEF process should remain a civil issue between partners. The respondent noted that evaluations as to whether read across data are adequate or not is for the European Chemicals Agency and the SIEFs to determine. They welcomed the recording of those *in vivo* tests that would be required, in order that the impact on animal numbers, particularly vertebrates, could be apportioned among all companies in complying with the Regulation.

Division of provisions

16. One respondent considered that the division of the provisions into the three broad areas of 'Registration', 'Supply Chain' and 'Use' related did not do justice to the widespread and various chemical uses that are regulated under REACH and provided the example of chemicals used in service industries and those that are distributed and sold.

Q3. Do you agree that the proposed enforcement authorities acting within their existing functions can adequately enforce REACH?

17. All respondents who specifically answered this question, except for one, expressed agreement that the proposed enforcement authorities acting within their existing functions could adequately enforce REACH.

Enforcement of pre-registration

18. One respondent believed that registration related enforcement should also include enforcement related to pre-registration.

Whistle blowing

19. One respondent stressed the importance of whistle blowing in the enforcement of REACH and noted that there were no legal requirements on the Competent Authority to investigate any whistle blowing. The respondent stated that this was required in order to ensure a level playing field both within the UK and across Europe.

Resourcing

20. One respondent was concerned that the regulations added powers to existing enforcing authorities without thought to the provision of resource. The respondent stressed that they would like to see more inspections, not fewer, and that this is the way to ensure a level playing field and avoid penalising law-abiding firms.
21. One respondent was concerned that the role of HMRC within the REACH process may result in extra burden being placed upon the other enforcing authorities. Another respondent commented that training for Officials of Revenue and Customs was essential and that, in general, training for all inspectors was vital.

Division of responsibilities

22. One respondent was concerned that all enforcement authorities should be clear on what requirements exist under REACH and which of these requirements they had responsibility for enforcing. They suggested that Schedule 2 ('Functions of enforcing authorities') should be removed from the text of the regulations in order to avoid accusations of an enforcing authority acting *ultra vires*. It was suggested that the functions of enforcing authorities should instead be set out in the Memorandum of Understanding.

23. Another respondent referred to section 4.7 of the consultation document - 'how enforcing authorities carry out the duty placed on them is at their discretion' - and suggested that additional guidance from Government on how these duties are to be carried out would be welcomed. This, they considered, would ensure a consistent approach between different regulators within the terms of their respective enforcement policies.

Reviews of enforcement arrangements

24. One respondent stated that the arrangements between regulators, over information sharing and the most appropriate regulator taking forward individual breaches of REACH requirements, needed to be constantly reviewed to ensure effective and efficient enforcement.

Q4. Do you have any comments on the scope of the enforcement duties?

25. The majority of respondents had no comments on the scope of the enforcement duties. Those comments that were received are summarised below.

Consistency

26. One respondent was concerned that there should be greater harmonisation between the different enforcing authorities and suggested that Schedule 6 to the Regulations, assigning different powers to different enforcing authorities, would lead to inconsistencies. They commented that it would be better to prepare harmonised REACH enforcement powers.
27. Another respondent also had concerns about consistency and stated that advice, information and enforcement can vary both within and between agencies leading to confusion and increased use of the appeals system. They recommended the model used to enforce the Transport of Dangerous Goods regime, which is enforced by HSE, the Police and the Vehicle Operator Standards Agency (VOSA). This includes a Memorandum of Understanding, an enforcement forum and enforcement guidance to cover issues across the agencies. The respondent suggested that the forum should discuss issues between themselves and with industry and then write internal enforcement guidance to apply 'lessons learned' across all authorities.

Transparency

28. One respondent suggested that there should be a central database maintained and published to show what action has been taken and the outcome. The respondent believed that non-sensitive information such as number of visits, type of notices served, appeals raised and outcome, and number of prosecutions should be reported.

Targeting

29. One respondent believed that enforcement would be weakened if it relies only on an 'intelligence lead approach'. They believed that companies were unlikely to whistle-blow unless they were severely inconvenienced by the actions of another company.

Enforcement by Trading Standards Officers

30. One respondent believed that enforcement by Consumer Protection Officers at retail level only would diminish current enforcement practice.

Data sharing

31. One respondent considered that further information was required concerning the working relationships between the European Chemicals Agency, the European Commission and the Competent Authorities of Member States. They considered that it was unclear how enforcement of data sharing would be accomplished across the EU without some responsibility being assumed at Member State level. They suggested that a dual system of data sharing, both at Member State and EU level should be put in place; the scope of the enforcement duties should include minimising animal testing as far as possible.

Enforcement of Scottish Controlled Waters

32. One respondent noted that Section 4.8 of the consultation paper stated regulation of offshore chemicals in Scottish Controlled Waters would be carried out by SEPA rather than BERR. However, the respondent considered that this is outside the present constituency of SEPA.

Q5. Do you believe that this approach on the transferring of enforcement responsibility and the co-operation and sharing of information between the enforcing authorities provides enough or too much flexibility? Do you believe that 60 days is sufficient time for the cancelling of an enforcement transfer?

33. The majority of respondents did not provide a response to this question.

Length of time allowed for an enforcement transfer.

34. Three respondents believed that 60 days was too much time to allow for cancellation of an enforcement transfer. They recommended 14 days, 30 days and 28 days respectively.

Monitoring

35. One respondent believed that transfer of enforcement responsibility and co-operation and sharing of information between the enforcing authorities was a key part of consistent enforcement. They recommended active co-ordination, monitoring and review of problems and inconsistencies, which would need to involve representatives of all stakeholder groups.

Q6. Do you agree with the proposed powers and appeal routes against notices?

36. The majority of respondents agreed with the proposed powers and appeal routes against notices. There were a number of respondents who did not express an

opinion and only one respondent who did not agree with the proposed powers and appeal routes.

37. One respondent suggested that clarity on the nature of the appeal process for the different enforcing authorities was needed to ensure fairness in all areas of REACH enforcement.
38. The respondent who did not agree with the proposals believed that penalties should distinguish between more and less serious offences, with a breach of data sharing obligations included among those that would incur a higher maximum penalty.

Q7. Should the penalties for offences under regulation 11 (a provision of REACH) and 13 (supplementary offences) be the same?

39. A number of respondents expressed specifically that they agreed that the penalties for offences under regulations 11 and 13 should be the same.
40. One respondent stated that it seemed logical for offences under regulation 13 to be more severe since these were deliberate attempts to evade the law. They commented that the eventual outcome should remain consistent with similar existing regulations.
41. One respondent commented that if offences are 'supplementary' the inference is that they are additional and, to an extent, of less importance. They stated that, for consistency, if offences are categorised in two ways then penalties should be as well.

Q8. Do you agree with the proposed penalties?

42. The majority of respondents did not provide a response to this question. Three respondents expressed their agreement. A number of respondents pressed for differentiation between deliberate and accidental non-compliance. Another respondent was concerned about the potential for the use of administrative penalties in the future.

Deliberate and accidental non-compliance

43. A number of respondents considered that there was a need to differentiate between deliberate non-compliance and inadvertent non-compliance. It was considered that such a complex and wide reaching piece of legislation as REACH should not criminalise companies or individuals for accidental non-compliance when unaware of the detailed provisions. It was also suggested that a duty holder may interpret the regulations in a different way to the regulators due to ambiguities in the text and that, in such cases, they should suffer no penalties provided that they had a documented rationale for their action.
44. Another respondent believed that the scope of the penalties was too broad and should be restricted to the act of 'knowingly' breaking the REACH regulations. They noted that many companies would be relying on information from further up the supply chain that confirmed that the substance they had purchased was 'REACH compliant' and would have no means of determining otherwise.

45. Another respondent stated that, in order to be dissuasive, penalties for deliberate non-compliance must take account of the financial advantages a company may have gained by avoiding the costs of registration.

Q9. Are there any other comments that you would like to be considered in respect of the Regulations?

46. The majority of respondents had comments to add and those that have not already been covered are summarised below.

Article 126 of the REACH Regulation

47. One respondent believed that Defra had misinterpreted the provisions of REACH Article 126, where Member States are required to lay down provisions on penalties. The respondent stated that the date by which this should have been done was 1 June 2007, when Title XIV came into force and when some requirements of REACH, such as the Safety Data Sheet requirements, first came into force.

Leaded Paint

48. Two respondents did not agree that the derogation on the marketing and use of leaded paint should be carried forward into the Statutory Instrument concerning the enforcement of REACH.

Product Safety

49. One respondent had concerns that the implementation of consumer safety-related provisions in REACH was not sufficiently clear and that certain areas of protection would be weakened.

Pre-registration

50. One respondent was concerned that for phase-in substances there would be a period of time before registration is required during which those that import or manufacture a substance might do so unchecked. They suggested that the placing on the market of any substance not pre-registered be a criminal offence. They also suggested a mechanism to verify the status of imported substances at the point of entry into the Community.
51. Another respondent commented that pre-registration was an important component of making REACH workable and believed that there should be a clear link between failure to pre-register and enforcement.

Q.10 Do you agree with the administrative arrangements as set out in the Memorandum of Understanding? Do you think there should be additional operational issues included?

Consistency

52. Stakeholders and Enforcement Authorities generally supported the administrative arrangements but called for consistency in enforcement between importers and EU manufacturers. To achieve this, clarification and strengthening of the role of HMRC has been called for – see paragraph 9 above.

Transparency

53. One respondent recommended that, for transparency, a central database be available to publish enforcement actions taken. They welcomed good information exchange between the enforcement authorities and arrangements for accessing the ECHA database.

Clarity

54. One respondent suggested a clearer outline of an overall enforcement strategy in the MOU detailing minimum enforcement activity for all the enforcing bodies for the various aspects of REACH across the UK. One other respondent suggested that Article 31 of the MOU should read as 'The provision of a single point of contact in each organisation will be made'.

Resourcing

55. One respondent requested that the response time of a request to the Competent Authority database be shortened to three working days. Another respondent recommended 30 days for the cancellation of an enforcement transfer in order to focus the authority's resources and attention more efficiently.

Q.11 Could the assessment of the enforcement costs to business and the enforcement authorities be further improved? If so, how?

Cost Estimation

56. Generally, stakeholders supported the approach to assessing the impact of REACH. However, one respondent did not agree with the estimated time taken by business to prepare for inspection. Another queried the estimate of wage rates of employees and noted that IT retrieval work had not been accounted for.

It should be noted that the preparation time estimate has increased from 1 hour in the previous RIA of enforcement in 2007 to 3 hours in the current RIA, based upon the responses from a number of stakeholders to the first consultation. In addition, the 75th percentile used for large companies is for associate professionals as opposed to professionals, hence it is lower than suggested by the response to the consultation. The impact assessment notes that the time taken for firms is likely to vary depending on the number of chemicals used and the information retrieval systems; however, this represents a best estimate of the average time taken.

SMEs

57. One stakeholder suggested that the cost allocated to SMEs was too low, the argument being that a company director of an SME should earn more than a junior member of staff in a large multinational.

The Department, from the Annual Survey of Hours and Earnings in the UK, considered that the role of an Associate Professional and Technician in a large company may be equivalent to that of the Corporate manager in an SME, assuming that they have equal competence and knowledge of REACH, and this informed the hourly rates used. It should be noted that the median wage rate is used for SMEs due to the large number of firms which are included in the assessment. The Department has made these estimates based on the best information made available to us from stakeholders and various data sources, indicated as appropriate.

Other Costs

58. One respondent commented that the formulating industry will be subject to the use provisions and duties on companies to collect chemical safety reports and exposure scenarios and pass them along the supply chain (section 4.7.3). They believed that this had not been covered in the Impact Assessment.

The Department has identified these obligations within the Impact Assessment as the supply chain and use related enforcement obligations and these are included in the administrative costs considered. Defra would like to note that the Impact Assessment concerned the costs associated with the *enforcement* of REACH only. The prior Regulatory Impact Assessment of May 2006 gave an estimate of the overall compliance and policy costs associated with REACH.

Training

59. Some respondents suggested that training of inspectors should be considered as an essential part of the enforcement of REACH. A few suggested the provision of manuals.

The Government is considering possible training needs for the Enforcement Authorities in order to achieve an efficient and effective enforcement regime in the UK. The preparation and provision of training is already included as a part of the cost of new posts created for the enforcement of REACH. However, the time taken for inspectors to attend training and familiarise themselves with the requirements of REACH was not included, and an estimate of this has been added to the impact assessment.

3 Subsequent steps

60. In light of the responses received, and with due consideration to the number of respondents expressing a particular view as well as the arguments put forward, the following steps have been taken. Where a number of respondents have expressed a particular view, but a decision has been taken not to take any further action, an explanation is provided.

The Role of HMRC

61. The role of HMRC has been clarified subsequent to the consultation. The Statutory Instrument has also been revised to specifically provide for transfer of information

held by Customs officials and for the detention of goods. HMRC will also be a party to the Memorandum of Understanding between the enforcement authorities. HMRC will be included on the Enforcement Liaison Group, which will greatly assist co-ordination between HSE and HMRC.

The use of customs declarations to signal compliance with REACH requires action at an EU level because of its potential implications for World Trade Organisation rules. However, this has been raised in the European Chemicals Agency Enforcement Forum and we will continue to take opportunities to support it.

Consistency of Enforcement

62. The Enforcement Liaison Group is established as part of the MoU to ensure general co-operation amongst enforcers. The Department and enforcing authorities look forward to close communication with stakeholders as enforcement under REACH begins and progresses.

Enforcement of pre-registration

63. The REACH Regulation does not require enforcement to commence in Member States until 1st December 2008, by which time the window for pre-registration will have come to an end. It is not appropriate to prosecute retrospectively any actions which took place before the regulations came into force. In addition, pre-registration is a voluntary action under REACH. However, from 1 December a company which is placing a substance on the market for which it has neither a pre-registration nor a valid registration will potentially be subject to enforcement action.

Due diligence defence

64. A number of respondents referred to 'accidentally' or 'non-deliberately', or conversely to 'knowingly' or 'deliberately', breaching the regulations. It is a general principle that ignorance of the law is not a defence, and REACH will be no exception. However, an enforcement authority will take into account the circumstances of each case when deciding what enforcement action it is appropriate to take. The Government has endeavoured to ensure that all groups are aware of their obligations under REACH, and has continued its awareness raising through the internet, radio, and stakeholder events.

Scottish Controlled Waters

65. Enforcement on offshore installations within Scottish Controlled Waters will now be the responsibility of SEPA, with BERR taking responsibility beyond those waters. However, given the location of the offshore installations, practical enforcement will remain the responsibility of BERR.

Annex A – list of respondents

ATC
British Coatings Federation Ltd
British Lime Association (QPA)
British Plastic Federation (BPF)
CEMEX UK Ltd
Champion House
Chemical Business Association
Chemical Industries Association
DanGoods
Alan Donnelly
Engineering Employers Federation (EEF)
Environment Agency
Federation of Small Businesses (FSB)
FRAME
Health and Safety Executive (HSE)
Laboratory of Government Chemists (LGC)
Local Authorities Coordinators of Regulatory Services (LACORS)
Lubrizol
Royal Society of Chemistry
S. Black Ltd
Scottish Environment Protection Agency
The Association of Manufacturers of Domestic Appliances (AMDEA)
The Kennel Club
The Trading Standards Institute
Trades Union Congress (TUC)
UK Cleaning Products Industry Association (UKCPI)
WRc Plc

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

66. One respondent is seeking clarification of the status of the documents detailing more broadly the process of LA work with other enforcing authorities and current effectiveness of the liaison between them.
67. One respondent was concerned about lack of clarity on the differentiation between a finished article and a substance or preparation in a container. They expressed concern that this would not be interpreted in a consistent manner by the enforcement authorities across the Community market and that this could have implications for the level playing field between different countries.
68. One respondent stated that they did not believe that there should be transfer of responsibility between Member States and that there needed to be safeguards and limits on the type of information to be shared. They also stated that when the exchange of inspectors according to REACH article 77(4) takes place any enforcement by the non-UK inspector should follow the UK legislation and procedures.
69. One respondent stated that the penalties applied by Member States should be the same across the EU to ensure a level playing field within the Community. They argued that UK-based companies should not find themselves more severely punished than competitors elsewhere in the Community and that significant differences would not be conducive to the good functioning of the internal market.
70. One respondent said that they would like to see a formal strategy for the collection and review of comparative information on the nature of enforcement between different regulatory regimes in Member States and supported the sharing of information on best practice.
71. One respondent described the use of production volume within REACH as arbitrary and expressed concern that animal testing would be conducted routinely rather than intelligently.

Annex C – list of acronyms

AMDEA	The Association of Manufacturers of Domestic Appliances
COMAH	Control Of Major Hazards
COSHH	Control of Substances Hazardous to Health
BERR	Department for Business, Enterprise and Regulatory Reform
EC	European Commission
ECHA	European Chemicals Agency
EDU	Energy Development Unit
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
LGC	Laboratory of Government Chemist
MOU	Memorandum of Understanding
NONS	Notification of New Substances
OSPAR	The Convention for the Protection of the Marine Environment of the North-East Atlantic (from the preceding Oslo and Paris Conventions)
PPC	Pollution Prevention and Control
SEPA	Scottish Environment Protection Agency
SMEs	Small and Medium Sized Enterprises
SoS	The Secretary of State
UKCPI	UK C LEANING Products Industry Association