



House of Commons
Science and Technology
Committee

**Government Response
to the Committee's
Sixth Report, Session
2003–04, Within
REACH: the EU's new
chemicals strategy**

**Seventh Special Report of Session
2003–04**

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The Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Office of Science and Technology and its associated public bodies

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Seventh Special Report

On 12 May the Science and Technology Committee published its Sixth Report of Session 2003–04, *Within REACH: the EU's new chemicals strategy*. On 8 July 2004 the Committee received a memorandum from the Government which contains a response to the Report. The memorandum is published without comment as an appendix to this report.

Appendix

Introduction

The Government welcomes the Sixth Report of the House of Commons Science and Technology Committee 'Within REACH: The EU's new chemicals strategy'. The report provides conclusions and recommendations and detailed analysis of the elements of REACH, testing requirements, functions of the European Chemicals Agency, impacts and role of the stakeholders.

The Government has considered carefully all the conclusions and recommendations. We have set out the Government response as shown below. The Committee's recommendations are included in the body of the responses and are highlighted in bold and cross-referenced to the body of the Committee's report

List of recommendations and Government responses

1. We believe that the REACH legislation should not be allowed to inhibit the use of recycled materials in production and that it should be amended to provide that recycled materials should be exempt on the basis that their constituent substances will have already gone through the REACH. (Paragraph 30)

The Government agrees that REACH should not inhibit the use of recycled material nor should it duplicate the existing regulatory controls already imposed on such material. The European Commission has advised Member States that recycled material will be outside the scope of REACH, where that material is regulated under Waste Management Legislation.

2. We have sympathy with the view that cement should not be included within REACH but we are not persuaded that it should be exempt. We are in favour of high volume chemicals of demonstrably low risk being eligible for delayed Registration with less onerous testing requirements. (Paragraph 31)

We see little value in having two stages of pre-Registration for phase-in substances and recommend that a single, compulsory pre-Registration stage 1 year after the Regulation comes into force. The volume threshold for pre-Registration should be lowered to 10 kg to provide a clearer picture of the production of highly toxic substances. Such a move need not be burdensome and would allow prioritisation based on risk during Registration. (Paragraph 38)

In an ideal world REACH would embrace a system of prioritisation for Registration based purely on risk. However, we are concerned about the workability of such a system. While production volume is a crude proxy for risk, it is a useful starting point. We recommend that this approach remain, but that it is refined with the introduction of a single pre-Registration phase so that highly toxic low production volume chemicals can be dealt with more quickly and high production volume chemicals of low risk dealt with later by employing advanced computational techniques. We remain concerned about the 1 tonne threshold for carcinogens, mutagens and reprotoxins. The toxicity of these chemicals is such that we believe the volume threshold should be lowered to 10 kg. (Paragraph 40)

The Government welcomes the recommendation not to exclude cement from REACH. Cement is already considered a chemical substance under the existing legislation and as such should be subject to REACH. In addition, cement has a range of potential harmful health effects.

The Government supports the view that tonnage is a crude proxy for risk, but is a useful starting point for the purpose of registration. The Government recognises the potential benefits a prioritised approach to registration could offer, however there are concerns that it could introduce an additional layer of bureaucracy in order to demonstrate a substance is of low risk. In addition the Government would not want to see a delay in registrations while substances were prioritised and the order of registration agreed. The Government is open to considering further prioritisation tools if they can be demonstrated to be workable and will not result in a delay in registrations.

It should be noted that, although registration is limited to substances above 1 tonne, there is no threshold proposed for substances subject to the authorisation procedure. Therefore for substance of high concern and subject to authorisation – such as those classified as carcinogens, mutagens and toxic to reproduction categories 1 or 2 – there is no lower limit.

The Government is giving careful consideration to the best approach to pre-registration. A single, compulsory pre-registration stage appears to offer scope for simplification, but it would require lower volume suppliers to provide information earlier than the proposed two-stage approach. However, further thought is being given to this issue and in particular the impact it would have on smaller businesses.

3. Information on which substances are or are not covered is of great importance. We recommend that the scope of the legislation should be set out clearly and comprehensively to enable unambiguous understanding of what the legislation does and does not cover. (Paragraph 32)

The Government welcomes this recommendation and agrees that the scope of the Regulation should be clearly set out. The Government will take this into consideration in negotiating the Regulation.

4. We understand that the CIA has plans to establish a UK database of marketed chemicals. This is a welcome initiative and one that will enable UK be better prepared for the introduction of REACH. We recommend that the Government support this initiative and provide resources if necessary. (Paragraph 39)

A comprehensive and regularly maintained list of marketed chemicals would be a valuable tool. The Government welcomes the Chemical Industries Association's announcement that it has decided to develop and maintain a database of all chemicals marketed in the UK¹, and agrees that this could be a useful tool to prepare the UK for the introduction of REACH.

The Government has been in contact with the Association about its plans for the list and we are considering the scope for Government to support the development.

5. We agree that some audit of Registration dossiers is required. The WWF's suggestion that all submissions should be independently audited would bring the process to a halt, which is counterproductive. A better system would be a programme of spot checks, with a stated percentage of Registration dossiers checked for accuracy with sanctions for the submission of inaccurate data. (Paragraph 41)

The Government welcomes the recommendation for a process of spot checks and is currently giving further thought to how a workable system could be developed.

6. REACH is an excellent opportunity to draw together comprehensive chemical data to help the sharing of test data. This will form a valuable resource. We believe that the European Chemical Agency should augment this with resources to help improve the access to chemical data already held by national libraries and international and overseas bodies. (Paragraph 45)

The Government supports the sharing of test data and would expect to see as much relevant information as possible made publicly available whilst ensuring that concerns about commercial confidentiality are taken into account. The Government agrees that this should be augmented with data already held in national libraries and international and overseas bodies.

A key element of REACH is that it transfers the responsibility onto industry to obtain the necessary data to register their substance. While the Government recognises the European Chemicals Agency has a role in assisting in data sharing between companies, we would not wish for that to detract from its primary purpose in delivering REACH.

7. While we do not doubt the problems of late joiners and free riders on consortia formation, we consider that having identified the problems it should be possible to develop an equitable pricing formula. (Paragraph 49)

The Government shares the view of the Committee that the issue of agreeing cost sharing should not be insurmountable. Industry has already developed cost sharing guidance under existing initiatives such as that supported by the International Council of Chemical Associations (ICCA). As this is an inter-industry issue, companies and trade associations should take the lead in recommending solutions with appropriate scrutiny from the authorities.

¹ Chemical Industries Association, 22 January 2004

8. There is much to be gained from the promotion of one substance-one Registration. While the legislation could do more to provide incentives and encouragement to form consortia so that data sharing becomes the norm but not the rule, the mandatory formation of consortia is not workable. We consider the Government's position on this issue to be untenable. (Paragraph 52)

The Government continues to favour a system of 'one substance, one registration' and is pleased that a number of countries are increasingly interested in our proposals. It would ensure:

- rapid decision making by authorities;
- effective information exchange to downstream users and consumers;
- improved quality assurance through co-operative working;
- a reduced need for testing – and therefore less animal testing;
- a reduced impact on smaller businesses;
- anti-competitive practices that might otherwise be possible under REACH are avoided through fair, open-access and transparent arrangements for data sharing.

One way of realising such benefits would be by means of compulsory consortia, which was included as an option in an initial outline of the evolving 'one substance, one registration' proposal. We have indicated a willingness to consider other options that would achieve the same end. The Government notes the Committee's comments on compulsory consortia. We are giving further thought to this element of the 'one substance, one registration' proposal and will produce a revised suggestion following consideration of the responses to the consultation on REACH.

9. We recommend that Substance Evaluation remain the responsibility of Member States but their rolling programmes be subject to oversight by the European Chemicals Agency to ensure that Evaluations of chemicals are prioritised according to risk and rapidly undertaken. (Paragraph 61)

The Government agrees there should be a stronger role for the Agency at the evaluation stage and is considering whether a prioritised system of evaluation – coordinated by the Agency – to ensure a harmonised approach and focus on substances of concern first would be more streamlined. We also agree that Member State expertise in chemical assessment should continue to be used to the full in the evaluation process.

10. We do not find the Proposals' requirements for substitution excessively onerous. Where a substance of high concern is involved, it seems reasonable that any Authorisation should require that attention is given to the use of alternatives. We do not contest the fact that this imposes a burden on companies, but nor should they contest the importance of ending the production of substances of high concern. (Paragraph 77)

The Government notes the Committee's recommendation and agrees that the aim of the authorisation process should be to ensure that the risks from substances of high concern

are properly controlled and that these substances are eventually replaced by suitable substances or technologies with the aim of reducing risks to human health and the environment.

The concept of substitution – that chemicals of most concern should be systematically replaced by safer alternatives – is supported by the UK. However substitution is not a straightforward process. There have been a number of examples where an apparently safer substitute has been introduced in response to human health or environmental concerns only to turn out to have unintended or unexpected effects of equal or greater concern to those of the substituted substance. It will therefore be important that REACH facilitates a long term strategy on substitution by increasing our knowledge about the properties, uses and potential new applications of chemicals.

The UK considers that REACH should be designed to create a framework to stimulate innovation into finding safer substitutes to complement, as far as possible, the commercial pressures that already apply within markets, but especially where such pressures are weak.

The Government is currently considering the provisions relating to substitution to see whether they are likely to achieve the desired effect of acting as a sufficiently strong incentive – along with other incentives such as market pressure – for industry to innovate and develop new and safer substitutes.

11. It is sensible for REACH to be compatible with existing EU legislation. The Proposals replace around 40 existing Directives and it is not clear why one - the IPPC Directive - is unaffected when it allows the emission of hazardous substances. We recommend that risks from emission points be considered in the Authorisation process. (Paragraph 80)

We conclude that the current wording of the Proposals with regard to substitution is acceptable, provided that "adequate control" is interpreted so that the risks of exposure to humans or the environment are remote during and after the lifecycle of the product. Substitution is an important element of the legislation and must be encouraged but its enforcement must be pragmatic. (Paragraph 81)

The Government welcomes the fact that REACH simplifies the existing regulatory regime by replacing so many existing Directives, but wishes to give further consideration to certain exemptions from authorisation.

In its consultation paper, the Government has asked whether it would be more advisable to consider the risks from all emission points, including those covered by the Integrated Pollution Prevention and Control Directive as part of the REACH authorisation regime in order to fully assess whether a substance is adequately controlled or whether further controls are necessary.

The Government agrees that the definition of ‘adequate control’ is central to authorisation and the benefits expected to accrue from this process. Given that authorisation will apply to chemicals of most concern, it will be essential that the definition of ‘adequate control’ is clear, precise and reflects commitments under existing occupational health, public health and environmental legislation, otherwise this could undermine such authorisation decisions.

The potential difficulties in defining ‘adequate control’ for substances such as those that are persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) could lead to inconsistencies, uncertainty for industry and, if large numbers of chemicals of high concern are authorised this way, a failure to protect human health and the environment from some of the most hazardous chemicals covered by REACH.

12. The Government believes that decisions about what precise time limits should apply for Authorisations can only be made on a case-by-case basis, and would need to strike the balance between acting as an effective incentive while avoiding imposing deadlines which are unrealistic. This is a sensible approach and we believe that time-limited Authorisations should be made subject to these criteria. (Paragraph 82)

The Government is currently considering how time limited reviews could be applied to authorisation and welcomes the Committee’s support for its view that for any such approach a balance must be struck between incentives and costs.

13. We recommend that the Commission provide estimates of the number of animals likely to be used for testing as a result of the REACH Proposals and make clear statements that these animals' lives can be justified by the improvements to the environment and human health achieved by the new legislation. (Paragraph 89)

The Government welcomes the recommendation for a view from the Commission on the estimate of the number of animals likely to be used under REACH, however it recognises that this is not a straight forward task.

14. The Government has identified scenarios where there could be duplicate animal testing if one substance-one Registration is not imposed. While we sympathise with the desire to minimise testing, the response must be proportionate and that covering every eventuality could impose an unjustified burden on industry. (Paragraph 91)

Avoiding duplicate or unnecessary animal testing is one advantage of ‘one substance, one registration’. There are in addition a number of other significant benefits as set out in response to recommendation 10.

We only have to look at the pesticides approval regime to see the consequences of allowing multiple registrations. A Commission report on its operation stated that “many different dossiers were submitted for the same substances, unnecessarily multiplying the number of evaluations required. While every effort was made to encourage notifiers to create taskforces and to submit a single dossier per substance, it was not always possible to achieve this. For example, there were 35 notifiers for the active substance glyphosate and 11 dossiers were submitted.”²

15. The validity of the tests required by REACH is fundamental to its ability to protect the health and environment from toxic chemicals. If any party has any doubts about the application of the tests required by REACH, then we consider it to be dishonest to

² European Commission, DG SANCO, Evaluation of the Active Substances of Plant Protection Products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market), SANCO 822/2001 rev. 3, 2001

continue promoting the legislation until these doubts have been resolved or better tests introduced. (Paragraph 97)

We believe that the current rate of progress in developing and validating non-animal tests is too slow and that the European Chemical Agency must play a role in driving forward change. It is unlikely that animal tests can be replaced in the Regulation before it comes into effect but we believe that there should be a framework and a timetable for change embedded in the legislation. It will be several years before much of the test data is required. This provides a window of opportunity that should not be missed. (Paragraph 103)

The final testing requirements under REACH are still under discussion but where there is a requirement to generate information on intrinsic properties of substances they will need to be carried out in accordance with methods laid down in Annex X of the proposal. Annex X takes over the current testing methods currently contained in Directive 67/548/EEC. These methods will have been subject to validation and will be approved by the OECD and widely acceptable for regulatory purposes. Any new tests for inclusion in Annex X, including alternatives to tests using animals will need to be fully validated according to internationally agreed test development criteria.

The process of developing and validating alternatives to animal tests is inherently slow partly because it needs to be robust enough to ensure delivery of meaningful and reproducible data. The imperative is to avoid unnecessary testing.

The proposed European Chemicals Agency may well be able to play a role in driving change but it may be more appropriate to encourage the Commission to increase activities in this area independently of REACH and as a matter of urgency since animal testing and experimentation have wider implications.

16. Just as Lord Sainsbury, as Science Minister, has taken an interest in research into alternative, non-animal tests, the Minister of State for Rural Affairs and Local Environmental Quality should use his influence to ensure that this research funding is directed towards new and sensitive environmental toxicology tests. (Paragraph 104)

Both Ministers take an interest in all aspects of the REACH proposals and their potential impact. This has been welcomed by all stakeholders and has strengthened our hand in international discussions.

As a member of the Interdepartmental Group on the 3Rs (Replacement, Refinement, Reduction), Defra has a role in influencing activities on issues relating to the minimisation of the use of animals in experiments, including those required for the testing of chemicals. It was a supporter for the setting up of the Centre for the 3Rs for co-ordinating work in this area.

REACH is a major driver for developing alternative methods to using animals and Defra will be developing policy to influence this area and how research funding might best be channelled to meet environmental objectives. Defra will be looking into prioritising requirements for research in both short and long term goals for the 3Rs. A particular objective will be to see how modelling approaches can be optimised to reduce the

requirement for animal tests which will include the use of QSARs (Quantitative Structure Activity Relationships).

17. We agree with the suggestion that the European Chemicals Agency's committees for risk assessment and socio-economic analysis should be merged. As well as streamlining its work, the move would ensure that these issues are not dealt with in isolation. (Paragraph 111)

The Government is still considering the options for the structure of the European Chemicals Agency and its committees. While the Government welcomes ways to streamline the procedures, it is important that the committees should comprise of experts with relevant understanding of the issues involved.

18. We hope that locating the European Chemicals Agency at Helsinki rather than Ispra in Italy with the European Chemicals Bureau and the European Centre for the Validation of Alternative Methods does not affect its access to the necessary chemicals expertise. Without the necessary skills and experience, the EU's new chemical regulation cannot be fully effective. It is also vital that European Chemicals Agency attains the confidence of all stakeholders. To achieve this, it must operate in a transparent fashion and decisions must be consistent. (Paragraph 112)

The Government agrees that the European Chemicals Agency must have access to the necessary chemicals expertise and agrees that the Agency must secure the confidence of stakeholders and operate in a transparent and consistent way.

19. The European Chemicals Agency needs to be a powerful and authoritative body. While much of the Evaluation should be dealt with by Member States to make use of existing expertise and avoid unnecessary bureaucracy, strong direction and oversight will be required from the Agency to ensure that the Evaluation of substances is carried out promptly and rationally by Member States. (Paragraph 113)

The Government agrees with this recommendation and would like to see the European Chemicals Agency taking more of a central role than envisaged in the European Commission's proposal.

20. Conclusions on the impact of environmental legislation cannot be generalised and to do so confuses the arguments as to how REACH can be improved to optimise competitiveness and benefits to human health and the environment. (Paragraph 120)

The Government is currently consulting with all stakeholders and negotiating at EU level with other Member States. It will consider all stakeholders views before agreeing a UK Government position which will aim to minimise negative impacts.

21. We believe that the REACH Proposals could have a significant adverse impact on trade with the US and Asia. This should be borne in mind by the Commission, the European Chemical Agency and Member States in the assistance they give to industry complying with REACH. (Paragraph 131)

We note the Committee's recommendation. Maintaining or enhancing the competitiveness of the chemical industry is one of the Government's three overarching

objectives in negotiating the legislative proposals. REACH must be streamlined, workable and place the minimum regulatory burden on industry necessary to ensure the adequate protection of human health and the environment.

22. REACH may lead to the loss of products, at least in the short term. Given that one of its aims is to remove dangerous chemicals from the environment, this is not necessarily a bad thing. Of greater concern is that very useful products will be withdrawn by companies rather than being put through the Registration process, regardless of whether they pose any danger to human health or the environment. (Paragraph 132)

The Government is also concerned about the withdrawal of substances on cost grounds alone. The Government considers the lower production volumes – the 1 – 10 tonne band – may be most at risk of this. The Government's proposal for 'one substance, one registration' will help drive the cost of registration down by sharing the cost on a proportionate basis.

It is important to note that the European Commission's extended impact assessment suggested that a far smaller percentage of chemicals might be withdrawn from the market than earlier estimates – about 1-2%. However the Commission have also undertaken to carry out further impact studies to assess the impact and likelihood of product withdrawal.

23. We believe that the Commission should work harder to ensure that the accession countries are more fully and better prepared for the introduction of REACH. (Paragraph 137)

The Government agrees that Member States will need to be prepared for REACH. The European Commission has recognised the particular needs of the new Member States and has undertaken to carry out an impact assessment specifically to assess the impact of REACH on these States. The Minister of State, Alun Michael, took the opportunity of the WHO conference on Environment and Health in Budapest to have a very positive discussion with the Hungarian Environment Minister and to agree to joint working on issues regarding REACH.

24. The REACH Proposals are not perfect and will force change on the European chemical industry. The UK chemical industry has a poor record of innovation in recent years and REACH provides an opportunity to reverse this trend. British companies should see it as an opportunity, not a threat. (Paragraph 144)

The Government agrees that REACH provides a real opportunity for the UK chemicals industry and for industry more widely. The Government is actively engaged with UK industry to ensure that it, and other stakeholders, are prepared for REACH at an early date.

25. Academic chemistry in the UK has been suffering in recent years, with a string of closures of university chemistry departments. The Government must act to reverse this trend and support British industry in its attempts to compete successfully in the REACH environment. (Paragraph 145)

A key issue related to closures of some Chemistry departments is one of lack of demand for these courses. The Government already has a raft of measures in place to enthruse and

encourage school pupils to go on and do these courses at higher education such as the Science Ambassadors Scheme and the Student Associate scheme. The Government is also exploring with the funding bodies, universities and key stakeholders what further can be done to ensure balance in the supply and demand of strategically important subjects.

26. There is evidence that a number of chemical compounds are having significant environmental impacts but in too many cases the associations are poorly understood. If REACH is to be effective in protecting human health and the environment, it must be supported by good basic science and monitoring. We urge the Government and the Commission to give research in this area a high priority. (Paragraph 148)

The Government supports a strategic approach to research on the fate and behaviour of chemicals in the environment. This area of research is evolving and will be improved through the validation of predictive models and monitoring studies. Any future research programme on chemicals in products will build on methods that have been developed for chemicals with positive approval regulations such as pesticides and veterinary medicines. These are areas where research is ongoing to refine both fate and effects assessments to reduce the element of uncertainty that exists in assessing the risk of chemicals on organisms in the environment. Proposals for work towards the refinement of understanding of the fate and behaviour of chemicals in the environment will be made widely known following consultation with all interested and appropriate stakeholders.

27. A further impact assessment looks increasingly necessary if the legislation is to attain the confidence of all parties. It is unlikely that the European Parliament will give the legislation its first reading before the end of the year. This gives the Commission ample time to agree a methodology with interested parties and to undertake a further study which has widespread confidence. (Paragraph 152)

We accept that it is often difficult to quantify impacts, but establishing figures to a reasonable level of accuracy is important in getting the balance right between workability and environmental protection. We welcome the Commission's efforts to acquire a more sophisticated understanding of the complex chemical industry and the impact of REACH upon it. (Paragraph 155)

The Commission has carried out an impact assessment and has estimated the cost of REACH to industry to be €5.2bn and potential public health benefits of €50 billion over 30 years. Since then it has undertaken to carry out further impact assessment work under the guidance of a stakeholder group to consider:

- Impacts on the new Member States
- Impacts on innovation
- Impact on business through the supply chain.

We support the Commission's decision to carry out further impact assessment.

28. The Commission has made great strides in its openness and its responsiveness to suggestions. While we regret that alternative models to REACH were not considered in any detail before the White Paper was published, the Commission has shown itself

open to constructive criticism of the REACH Proposals. We hope that this continues during the co-decision process, as the legislation still needs improvement. (Paragraph 159)

The Government agrees that the Commission's openness to constructive suggestions has been most welcome. Like the Committee, we hope this will continue through the process, with the Commission prepared to consider alternative proposals such as those put forward by Member States to make positive changes that will lead to a workable piece of legislation.

29. The Government has played constructive and important part in the development of the legislation. The trilateral letter signed by the Prime Minister played an important role in making the Proposals more workable but the UK Government needs to keep up pressure to improve workability. (Paragraph 167)

The Government agrees that it is important to work with Member States, the Commission and the European Parliament at all levels to achieve a workable piece of legislation and will continue this effort through to the end of the process.

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