House of Commons

Science and Technology Committee

Within REACH: The EU's new chemicals strategy

Sixth Report of Session 2003–04

Volume I: Report

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The Science and Technology Committee

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Contents

Report

Summary

The Proposals for new EU chemicals legislation published by the European Commission on 29 October 2003 attempt to bring tens of thousands of chemicals manufactured in or imported into the EU under a single regulatory regime. The process of Registration, Evaluation and Authorisation of Chemicals (REACH) aims to shift the burden of proof of the safety of chemicals on to manufacturers and make it easier to remove highly toxic chemicals from the market. It has proved controversial, largely because of fears that it could result in a disproportionate burden being placed on industry and an increase in the number of vertebrate animal experiments required by the Proposals.

A key issue has been the prioritisation of chemicals for Registration. Under the Proposals, Registration will take place in three stages over 11 years, with the highest production volumes taken first along with identified CMRs (carcinogens, mutagens and reprotoxins). We argue that in an ideal world the system would identify the chemicals that present the highest risk to humans and the environment and deal with those first. We consider this to be impractical and conclude that volume should form the basis for prioritisation. A single pre–Registration phase should be introduced and mass screening techniques used to identify high and low priority chemicals.

It is envisaged that Evaluation of the Registration dossiers will be conducted by Member States. While it is sensible to make use of their expertise and avoid a large new European structure, we believe that the proposed European Chemicals Agency should play a more dynamic role in ensuring that there is consistency across the enlarged EU and that Evaluations address the chemicals of highest concern in a timely fashion.

Environmental NGOs have expressed concern that the Authorisation process proposed does not have enough emphasis on requiring the substitution of chemicals of concern. We agree that there is little value in the legislation if it fails to limit the availability of toxic chemicals but consider the current wording to be sufficient. The subsequent interpretation of the text is of greater concern and we contend that substitution should be the norm but not the rule where there is a suitable alternative. Of equal concern to us is that useful chemicals with no apparent toxicity will be lost to the market because of the costs of testing.

It has been estimated that the Proposals will require the testing of 30,000 chemicals. While some test data may already exist and most chemicals will require little vertebrate animal testing, there are concerns that a substantial number of animal tests will be needed to comply with the legislation. We are concerned that the scale of animal testing has not been properly communicated and justified, in terms of human health and the environment, by either the European Commission or the UK Government. We are also concerned by the speed with which alternative, non–animal tests are being developed and validated.

The UK Government is advocating "one substance–one Registration" as a means of minimising animal testing and reducing costs and bureaucracy. We consider that the Commission's Proposals contain sufficient provision to avoid duplicate animal testing, provided that a single pre–Registration phase that requires the declaration of animal test

data is introduced. The Government's proposal requires the formation of compulsory consortia to provide a basis for data–sharing. We consider this to be problematic and believe that companies should be able to make the commercial decision of whether to incur extra costs to ensure confidentiality.

There has been dispute about the impacts on industry and the health and environmental benefits of the Proposals. Particular concerns relate to the indirect costs of the legislation. We consider it important that the legislation has the confidence of all parties to deliver its aims with the lowest possible impact on European industrial competitiveness. The legislation is unlikely to be agreed much before the end of 2005. There is sufficient time to conduct a further impact assessment, with methodology agreed by all stakeholders.

The Government has played an important part in the development of the legislation. We conclude that its stance is, for the most part, sensible and that it has made a welcome attempt to make the debate in the UK an inclusive and constructive one.

1 Introduction

1. On 29 October 2003, the European Commission[1] adopted Proposals for a new EU regulatory framework for chemicals known as REACH (Registration, Evaluation and Authorisation of Chemicals).[2] Its objectives were:

- Protection of human health and the environment;
- Maintain and enhance the competitiveness of the EU chemical industry;
- Prevent the fragmentation of the internal market;
- Increase transparency;
- Integrate with international efforts;
- Promote non–animal testing;
- Conform to EU international obligations under the WTO.

2. While these aims are not contentious, the means by which they are achieved is. There has been criticism from three main lobbies: industry, environmental NGOs and animal welfare groups. Industry argues that the Proposals threaten the competitiveness of the European chemical industry, with one study predicting the loss of over 2 million jobs in Germany alone. Environmental groups have predicted that REACH could save the UK £50 billion by reducing "modern diseases" associated with exposure to toxic chemicals. By demanding that many chemicals already on the market undergo new tests, animal welfare groups are concerned by the increased number of animals that will be used.

3. With huge potential benefits and costs, we decided to conduct an inquiry into how the impact of legislation can be optimised. Announced on 29 October, our inquiry sought to establish what, in order of priority, needed to be amended in the legislation, and what the implications would be if those amendments were not made. We were also interested in views on the role played by the UK Government[3] and what action it should take in the final stages of the legislative process.[4] Our inquiry took as its starting point the acceptance that REACH was the only system under discussion at this stage in the legislative process and that our energies could best be directed at identifying areas where the legislation could be modified to make it more workable and more effective. We will, however, comment on the process by which the Commission arrived at its Proposals.

1 Hereafter referred to as the Commission or EC.

2 COM (2003) 644 final 2003/0256 (COD) concerning a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}; and COM (2003) 644 final 2003/0257 (COD) Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals.

3 Hereafter referred to as the Government.

4 Press Notice No. 47, Session 2002–2003

4. We held four oral evidence sessions. We took evidence from environmental non–governmental organisations (WWF and Greenpeace), the retail industry (British Retail Consortium and Marks and Spencer) and the British Union for the Abolition of Vivisection on 19 January 2004. During a visit to Brussels on 2 February 2003, we took evidence from the EC Directorates General for Environment and Enterprise, including Erkki Liikanen, European Commissioner for Enterprise and Information Society. Our visit to Brussels also included briefings from Dr Michael Warhurst, Scientific Officer of WWF in Brussels and Mr Utz Tillman, Executive Director of CEFIC, the European Chemical Industry Council. On our return, on 9 February, we questioned a panel representing the UK chemicals industry, and heard evidence from the Government, including the Rt Hon Alun Michael MP, Minister of State for Rural Affairs and Local Environmental Quality. We received over 20 written submissions to the inquiry. We have drawn on submission's to the Commission's public internet consultation held in 2002, and the Government's consultation document, published in March 2004.

5. The new legislation is highly complex, in six volumes covering 1328 pages. This inquiry has not attempted an in–depth analysis of the legislation. Its aim has been to identify the important areas where there is disagreement between the campaign groups, the UK Government and the Commission in an effort to make recommendations to the UK Government about where it should try to further influence the legislative process.

2 Background

The EU chemicals industry

6. The turnover of the EU chemicals industry (excluding pharmaceuticals) was €417 billion in 2000, making up roughly 8% of EU manufacturing production. The overall value–added contribution of the EU chemicals industry (excluding pharmaceuticals) in 2001 was €107 billion, contributing 1.3% of total economy GDP.[5] In 2001 its sales exceeded €515 billion in Europe, accounting for 28% of world chemicals production.[6] The EU chemicals industry is mainly concentrated in four countries. Germany is the largest European producing country, accounting for over a quarter (26.2%) of EU production in 2000, followed by France (17%), the United Kingdom (13.5%) and Italy (11.6%). In 1981 there were approximately 100,000 chemicals in production in the EU. It is estimated that there are currently 30,000 substances whose annual production exceeds 1 tonne and 5,000 substances whose production exceeds 100 tonnes.

7. The UK chemicals industry is the sixth largest in the world, with approximately 3% of global production. In 2000, sales of chemicals (excluding pharmaceuticals) were worth £26.1 billion, representing £10 billion in added value (7% of UK total). This is equivalent to 1.2% of GDP. The UK is particularly strong in speciality chemicals.[7]

5 European Commission, *REACH Extended Impact Assessment*, October 2003, section 4.1

6 www.cefic.be

7 Department of Trade and Industry, *Enhancing the Competitiveness and Sustainability of the UK Chemicals Industry*, a report by the Chemicals Innovation and Growth Team, December 2002, pp 8–9

Existing legislation

8. Current chemical regulation distinguishes between "new" and "existing" (pre–1981) chemicals. Existing substances are regulated by Regulation (EEC) 793/93 and represent 99% of chemicals on the market. New substances are regulated under Directive 67/548/EEC; there are approximately 3,000 which have been tested and assessed for possible risks to human health and the environment before being marketed in volumes starting at 10 kg per year.

9. Existing substances are not subject to the same testing requirements that apply to new substances. Approximately 140 of the 30,000 substances manufactured in volumes over 1 tonne have been identified as priority substances and are subject to comprehensive risk assessment carried out by Member State authorities under Regulation (EC) 793/93.[8] Under Directive 76/769/EEC restrictions on the marketing and use of certain dangerous substances and preparations are applied where necessary. Risk assessments and adequate analyses of the costs and the benefits are required prior to any proposal or adoption of a regulatory measure controlling the marketing and use of chemicals. The proposed legislation will replace over 40 pieces of existing legislation, including these three.[9]

10. The Commission identified the following problems with the current legislation:

a) There is a general lack of knowledge about the properties and the uses of existing substances;

b) The risk assessment process is slow and resource–intensive and does not allow the system to work efficiently and effectively;

c) The allocation of responsibilities is inappropriate because authorities are responsible for the assessment rather than the enterprises which produce, import or use the substances;

d) Current legislation only requires the manufacturers and importers of substances to provide information, but not the downstream users (industrial users and formulators). Thus information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce; and

e) Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances.

8 Article 8(1) of Council Regulation (EEC) 793/93 states that: "On the basis of the information submitted by manufacturers and importers in accordance with Articles 3 and 4, and on the basis of the national lists of priority substances, the Commission, in consultation with Member Sates, shall regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their potential effects on man or the environment."; http://ecb.jrc.it/existing-chemicals/

9 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, p 8

Chemical regulation overseas

11. Useful comparisons can be made with the chemical regulatory systems in the USA and Japan. The Royal Commission on Environmental Pollution, in its June 2003 report on *Chemicals in Products*, discusses the differences in some detail.[10] The key features are outlined below. Both systems employ a risk–based approach to regulation and are cheaper than those currently in operation in the EU. There is also state funding for testing.

USA

12. Industrial chemicals are regulated by the 1976 Toxic Substances Control Act (TOSCA), which is administered by the US Environmental Protection Agency (EPA). Manufacturers or importers are obliged to notify the EPA if a new chemical is being introduced. There are four phases to the process:

- Chemistry review
- Hazard (toxicity) Evaluation
- Exposure Evaluation
- Risk assessment/risk management

13. There is no minimum data requirement for the notification, and often assessment of chemicals does not use toxicological data but employs QSARs (quantitative structure activity relationships) to infer the toxicological properties. On the basis of this information and any extra test results requested, the EPA will act to control the risk. A key difference with the REACH Proposals is that, under TOSCA, the burden of proof is on the EPA not on industry. The process is designed to remove substances of low risk from further consideration at the beginning of the process and to focus resources on substances of greater risk. The US system was criticised by the US General Audit Office in 1994 for providing ineffective protection.

Japan

14. The 1973 Chemical Substances Control Law regulates the manufacture of chemicals and provides a framework for the evaluation of toxicity. All chemicals, imported or manufactured, are subject to pre–market evaluation. Persistent chemicals with long–term toxicity are divided into two classes depending on the level of bioaccumulation. Of the 1,280 chemicals introduced between 1973 and 2002, 11 have been withdrawn and 13 are tightly controlled.

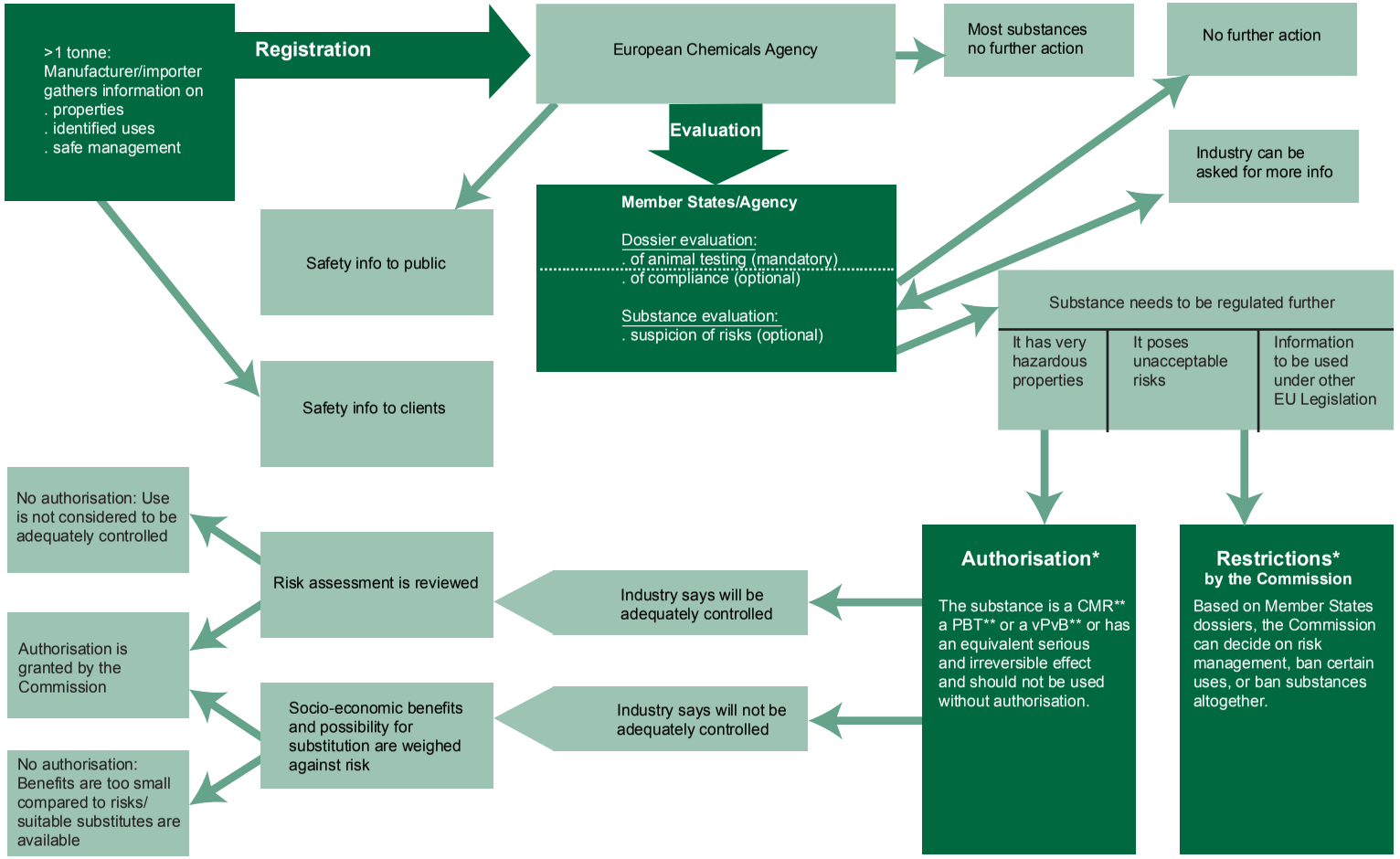
REACH principles

15. The REACH Proposals have three main phases: Registration, Evaluation and Authorisation. **Registration** is a comprehensive attempt to gather data on the chemicals manufactured in, or imported into, the EU. The data requirements vary according to

10 Royal Commission on Environmental Pollution, 24th Report, *Chemicals in Products: Safeguarding the Environment and Human Health*, Cm 5827, June 2003, Chapter 3

production volume and known toxicity. On the basis of the Registration data, **Evaluations** are to be undertaken to establish whether further tests are required and whether chemicals should be subject to the **Authorisation** process. Substances can be banned, their use restricted, or they can continue in production if they are adequately controlled, no suitable alternatives exist or there are socioeconomic implications. A flow chart summarising the process is shown in Figure 1.

Figure 1: The REACH process.[11]



* Substances do not have to be registered or evaluated to be placed under authorisation or restriction. They can be identified in other ways
** Can cause cancer or mutations, or is toxic to reproduction; or is persistent, bio-accumulative and toxic, or very persistent and very bio-accumulative

11 Source: europa.eu.int/comm/enterprise/chemicals/

Royal Commission on Environmental Pollution

16. In June 2003, the Royal Commission on Environmental Pollution (RCEP) published its report, *Chemicals in Products: Safeguarding the Environment and Human Health*. As well as an assessment of REACH, it outlined its own model for regulation. It has four steps:

a) Listing – compilation of a list of all chemicals;

b) Sorting – using modern techniques to determine key properties of the listed chemicals, for comparison with publicly accepted criteria;

c) Evaluation – further investigation of chemicals selected by the sorting process; and

d) Action – risk management based on use, including regulatory measures to restrict use and non–regulatory drivers of substitution.

Despite its criticisms of REACH (based on the White Paper), the RCEP's system has much in common with the Commission's Proposals. The RCEP claim that there would be no need for tiering based on tonnage in its model since a rapid sorting process would select the chemicals of concern for further evaluation.

History and process

17. The REACH Proposals can be traced back to an informal Environment Council of Ministers meeting held at Chester under the UK Presidency of the EU in April 1998. The meeting led to a review by the European Commission of the EU legislative framework for the management of chemicals. The Commission's report to EU Environment Ministers at the end of 1998 identified as the main issue the backlog of existing substances for which information about their potential to cause harm to the environment and human health was not available. The Commission held a "brainstorming" meeting with stakeholders: regulators, scientists, industry, environmental and consumer NGOs, and representatives from applicant countries – in February 1999.[12] In June 1999 Environment Ministers called on the Commission to consider measures that provide an efficient and integrated design of the various legal instruments for chemicals; place the main responsibility on industry for generating and assessing data; provide a more flexible approach to risk assessment with the aim of targeting assessments; and establish effective risk management strategies for certain chemicals that may cause threats of serious or irreversible damage to human health or the environment as a result of their inherent properties by giving appropriate weight to their use pattern and the possibility of exposure. The resultant work was conducted jointly by the Environment and Enterprise Directorates–General.

18. The result was a proposed chemicals policy detailed in a White Paper discussion document, entitled *Strategy for a future Chemicals Policy*, published in February 2001.[13] A White Paper is traditionally used by the European Commission to launch new policy initiatives. It may suggest changes to existing legislation or the introduction of new legislation, but it creates no legal obligations. The White Paper was considered by the

12 European Commission, Strategy for a future Chemicals Policy, COM(2001) 88 final, February 2001, pp 2–3

13 European Commission, Strategy for a future Chemicals Policy, COM(2001) 88 final, February 2001

House of Lords European Union Sub Committee D. Its report, published in February 2002, concluded that it was "unrealistically overambitious" and that combining new and existing chemicals in a single regime was unnecessary and would be "extremely complicated and contentious".[14]

19. Following the White Paper, the Commission developed a draft text for new legislation, which was posted on the internet for an 8–week public consultation in May 2003. The Commission presented its final Proposals for a Regulation on REACH in October 2003 alongside an Extended Impact Assessment it had conducted.

20. It is intended that the REACH Proposals enter EU law as a Regulation rather than a Directive. This means that the legislation will be directly binding on Member States and the only national legislation required will be to amend or repeal incompatible domestic legislation. The use of this legal instrument has in general been seen as necessary in order to achieve uniform application, legal certainty and the smooth running of the internal market.[15]

21. The Proposals will now be passed over to the scrutiny of the European Parliament and the Council, following the co–decision procedure. The first reading in the European Parliament and the Council is likely to take place in autumn 2004. The co–decision procedure, by which legislation is adopted both by the Parliament and the Council, is now underway and a working group of officials from Member States has begun to consider the Regulation in detail. It is expected that the European Parliament will return to this after the June 2004 elections. It is possible that the Council may agree a common position during the UK Presidency in the second half of 2005, with the conciliation process with the European Parliament to follow. The European Council of Ministers has agreed that it will be led by the Competitiveness Council. In the European Parliament it has now been agreed that the process will be handled jointly by three Committees: Environment, Industry and Legal Affairs. The Government suggests that Registration will begin in 2008–9.[16]

Lobbying positions

22. Three principal lobbying groups on REACH can be identified as follows:

a) The chemical industry. While the REACH principles are generally accepted, there are major concerns about the workability of the Proposals and their impact on the industry's competitiveness. The UK Chemical Industries Association (CIA) has been active, alongside its European equivalent, CEFIC (European Chemical Industry Council).

b) Environmental NGOs. These have been enthusiastic about the approach of the legislation but have expressed concerns that too many concessions are being made to industry. WWF has taken the lead; Greenpeace and Friends of the Earth have also been active.

14 Thirteenth Report of the House of Lords European Committee, Session 2001–02, *Reducing the Risk Regulating Industrial Chemicals*, HL 81

15 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 17

16 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 44

c) Animal welfare groups. Their principal concerns have been the increased animal testing required by the Proposals. They see the legislation as an opportunity to replace existing tests with non–animal alternatives. This is perhaps a bigger concern in the UK than elsewhere in the EU and the British Union for the Abolition of Vivisection (BUAV) has given the legislation a lot of attention.

Other interested parties have been downstream businesses, retailers and the EU's trade partners. The scientific community has also expressed its views, notably the Royal Society of Chemistry.

3 Registration

23. Registration of substances will involve the submission to a new European Chemicals Agency (ECA) of a technical dossier of information about the substance, including a testing package. The Regulation would prohibit the manufacture or importation of any substance which had not been registered. A substance is defined in Article 3 as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

24. Registration of "phase–in" substances (i.e. those already in production) will be in three stages over 11 years after the Regulation has come into force, on the basis of production volume. Registrants would have to carry out tests to acquire the information needed to ensure the responsible management of any risks that the substances in question may present. Registration would involve the submission of a technical dossier containing the necessary information, with more information being required as different tonnage thresholds are exceeded, to reflect the increased exposure potential: and, in the case of substances where the quantities involved exceeded 10 tonnes, it would also be necessary to provide a chemical safety report, documenting the choice of measures. The deadlines for Registration and the testing requirements vary, with more onerous demands on higher volume chemicals and carcinogens, mutagens and reprotoxins (CMRs):

- Year 3 for high production volume chemicals (1,000 tonnes or more per year per manufacturer or importer) and CMRs in volumes of 1 tonne or more;
- Year 6 for production volumes in the range of 100–1,000 tonnes;
- Year 11 for low production volume chemicals (1–100 tonnes).

25. Other Registration provisions include rules on data sharing in order to reduce animal testing; a requirement for information to be passed both up and along the supply chain by means of a safety data sheet; and an obligation on downstream users to consider the safety of their use of substances and to take appropriate risk management measures. A downstream user may use measures prepared by the manufacturer or importer, but these must be consistent with the use of the product. In cases where the use of a substance downstream is not covered by a manufacturer's safety assessment, a short report must be sent to the ECA, thus enabling any such use to be monitored.

Substances in articles

26. Provision for substances in articles is made in Article 6. It states that any producer or importer of articles shall submit a Registration to the Agency for any substance contained in those articles, if:

a) It is present in those articles in quantities totalling over 1 tonne per producer or importer per year (each article type will be considered separately);

b) It meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC; and

c) It is intended to be released during normal and reasonably foreseeable conditions of use.

Scope

27. Article 4 requires that all substances manufactured or imported in quantities over 1 tonne per manufacturer/importer be registered. There are some exemptions. The chemicals listed in Annexes II and III are exempt from Registration either because their risks or properties are considered to be well known or because of historical precedent in EU legislation. These include vitamin C, sucrose, limestone, water, castor oil and tallow. Minerals, ores or substances occurring in nature are exempt if they are not technically modified during their manufacturing, unless they are classified as hazardous according to Directive 67/548. Medicines, radioactive materials and cosmetics will not be included in REACH if they are covered by other EU legislation. Substances used solely in plant protection products and biocidal products that are already covered by current legislation will be considered as registered.

28. Non–isolated intermediates (chemicals used to make other chemical substances) are fully exempt. Isolated intermediates will have to be registered, but with simplified information requirements, although more data are required if the intermediates are transported.[17] The move by the Commission to reduce the requirements for intermediates has been welcomed by industry, although the Confederation of British Industry (CBI) notes that a risk–based approach to prioritisation would resolve the issue in any case since their exposure potential would not make them a priority.[18]

29. As a result of comments received on the draft proposals, polymers (large molecules consisting of repeating chemical units, such as plastics) will be exempt from Registration and Evaluation; but this may change if a "practicable and cost–effective way of identifying dangerous polymers on the basis of sound technical and valid scientific criteria" can be established.[19] This has been welcomed by the Government and the Scientific Alliance, "an independent non–profit membership–based organisation fostering rational discussion and debate on environmental issues", although less so by WWF.[20]

17 Articles 15 and 16

18 Ev 94

19 http://europa.eu.int

20 Ev 102; Q 13

30. It has been suggested to us that other chemicals should be exempted. The EEF argues that recycled materials should be exempted from REACH and says that the Proposals could clash with EU legislation, such as the End of Life Vehicles Directive, which require increased use of recycled materials.[21] We agree that this issue needs to be clarified. According to the Government's consultation document, "consideration needs to be given to whether products made from recycled or recovered material should be subject to restrictions". At present there is uncertainty as to the meaning of the term "placing on the market" used in the Proposals.[22] **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.**

31. The British Cement Association (BCA) argues that cement should be exempted on the grounds that "risks associated with cement are already known; additional testing, cost and bureaucracy required by the REACH proposals are an unnecessary duplication". It argues that cement can never have been intended to be included since the Commission referred to an annual global chemical production of 400 Mt (Megatonnes) in the White Paper, whereas the world cement industry manufactures 1,750 Mt per year. The BCA is also concerned that its components are classified as persistent, although this does not mean that cement poses any persistent risk.[23] Mark Strutt from Greenpeace criticised this approach. He argued that "If the cement manufacturers believe cement is safe then they have data to show that, so why would they be wanting to exempt themselves from the REACH process?" and stating that if the industry has the data then the costs to prove cement is safe will be minimal.[24] **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.**

32. The CBI believes that REACH could conflict with the already extensive legislation on worker protection and waste management. It would also like the situation clarified with regard to waste, minerals and ores, alloys and treated natural fibres and would like to see a single provision on scope at the beginning of the legislation. The Government is "broadly content with the general principle outlined in the European Commission's criteria for exemptions". It believes that material falling within the definition of "waste" is not a substance and therefore not within the scope of REACH.[25] We too are content with the criteria for exemptions but agree with the CBI that it is important that companies should be able to determine quickly and easily whether their products are affected by the legislation. **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.**

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21 Ev 65

22 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 126

23 Ev 88

24 Qq 10–11

25 Ev 92; DEFRA, UK Consultation paper on the New EU Chemicals Strategy – REACH, March 2004, para 55

Prioritisation

33. The prioritisation of substances in the Registration process is one of the most contentious elements in the Proposals. In general, they use production volume as the principal criterion for establishing the priority for Registration. There is widespread support in industry for a risk–based approach to prioritisation, in which both the intrinsic hazard of the chemical and its exposure to humans and the environment are factors. According to the CIA, "REACH should define the underlying scientific principles for determining the identification and prioritisation of substances for further, detailed Evaluation and allow exemptions for substances with exposures and hazards of low concern".[26] The Scientific Alliance argues that "While measures have been proposed to improve the extent to which the risk associated with any chemicals is measured more realistically, the legislation does not go far enough in this respect".[27]

34. The Royal Commission on Environmental Pollution is scathing about the risk–based approach: "many regulators and industry bodies continue to argue strongly that control must be on the basis of known risk, regardless of other indications of concern. This is in spite of the fact that problems continue to occur due to unforeseen risks and that the system is unable to react quickly to emerging concerns".[28] WWF also disagrees with risk–based prioritisation in the Registration process, for three main reasons:[29]

a) The process would not be robust as it could only be based on the sparse existing data;

b) It would result in a much more labour intensive process for the regulatory authorities; and

c) It would be open to numerous challenges by industry if chemicals with what might appear to be similar toxicity and exposure data were prioritised differently.

35. The Environment Directorate General also opposes greater prioritisation on the basis that Registration is intended to be a "comprehensive information–gathering exercise" and that much had been done to reduce the administrative burden in the Proposals.[30] Commissioner Liikanen indicated that he was "intellectually open" to the issue of prioritisation and suggested that this issue would get a lot of attention from the European Parliament and Council.[31]

36. One unresolved issue is to what extent volume is an effective proxy for risk, and if it is not, whether there is a better alternative. The EEF reports that while some elements of the EU Parliament accept that prioritisation based on production tonnages is not logical, it has not heard a good proposal for an alternative based on risk.[32] A further issue is the availability of data to permit a risk–based approach, since one of the driving forces for the

26 Ev 67

27 Ev 101

28 Royal Commission on Environmental Pollution, 24th Report, *Chemicals in Products: Safeguarding the Environment and Human Health,* Cm 5827, June 2003, para 3.206

29 Ev 79

30 Q 110

31 Q 173

32 Ev 64

legislation is the concern that there are insufficient data for chemicals introduced before 1981. The CBI does not see this as a problem: "There is sufficient information and agreement at European level on enough substances that are known to pose higher risks for these to be addressed in a practical way in the first time–frame envisaged under the regulation".[33] The lack of available data could be addressed by employing European Centre for Ecotoxicology and Toxicology of Chemicals's (ECETOC's) Targeted Risk Assessment tool. This involves the screening of substances for human and environmental exposure and basic hazardous properties. Following collation of these data, decisions can be made on the need for further risk assessment to achieve greater accuracy.[34] The Royal Commission on Environmental Pollution advocates a similar screening process using advanced computational techniques. The Environment Agency describes these as crude and advocates caution.[35]

37. Any system which seeks to introduce an element of risk assessment to the Registration process would require a comprehensive pre–Registration process. The CBI says this process could be simple, demanding only:

a) Company name (or representative);

b) Chemical name/CAS Number;[36]

c) Production volume;

d) What animal tests are available; and

e) Willingness to join consortia.[37]

38. The UK Government, in its consultation, "recognises the benefits of this approach and would be interested in developing such an approach as long as it does not introduce another layer of complexity".[38] The Proposals do provide for a pre–Registration for phase–in substances. Article 26 requires that Registrants wishing to use the phase–in provisions pre–register information on their substances so as to permit sharing of existing data. These data will form the basis of a Substance Information Exchange Forum. At present, there are two deadlines for pre–Registration; CMRs (carcinogens, mutagens and reprotoxins) and substances manufactured in volumes over 1000 tonnes must pre–register 18 months after the Regulation comes into force, while substances manufactured in volumes over 1 tonne can be pre–registered three years later.[39] Manufacturers and importers of substances in quantities of less than 1 tonne can contribute to the sharing of data voluntarily. The Government suggests a short pre–Registration phase, lasting perhaps only six months from the introduction of the Regulation.[40] We consider this an unnecessarily tight deadline. **We**

33 Ev 91

34 www.ecetoc.org

35 Royal Commission on Environmental Pollution. 24th report, 2003, paras 4.15–4.18; Ev 61

36 Chemical Abstract Service, a division of the American Chemical Society; www.cas.org

37 Ev 94

38 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 69

39 Articles 21, 26

40 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 80

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.

39. **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.**

40. We share WWF's concerns that decisions on prioritisation could be contested. While we welcome the view from Judith Hackitt of the CIA that any decisions would need to involve all stakeholders, we believe that the three tranches of Registration based on volume should remain but that the Registration of chemicals could be delayed or speeded up where there is sufficient data.[41] As Dr Colin Church from the Department of the Environment, Food and Rural Affairs (DEFRA) told us, a "balance of practicality and ideal" is necessary.[42] Some chemicals produced in low volumes are extremely hazardous and others produced in large volumes are known to be benign.[43] Many low–volume hazardous chemicals will be automatically subject to Authorisation and this could be extended. The UK Environment Agency wishes to see regulatory activity focused on the chemicals of highest concern and believes that more effort should be put into identifying such chemicals.[44] The reverse should also be the case. **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.**

Audit

41. Article 18 of the Proposals sets out the duties of the European Chemicals Agency (ECA) in auditing the Registration dossiers. It requires that it undertake a completeness check of each Registration. This would not comprise an assessment of the quality or the adequacy of any data or justifications submitted. This lack of quality control is of concern to some. WWF would like an evaluation of the quality of the dossiers, citing evidence that only 25% of EU safety data sheets were fully accurate.[45] It argues that all submissions

41 Q 236

42 Q 285

43 Ev 85

44 Ev 61

45 Ev 78

should be independently audited before submission to the ECA, with costs met by the registrant. Leigh's Paints is concerned that having generated so much data, there is only limited provision in the Proposals to check it.[46] The Royal Society of Chemistry regrets that only checking for completeness will encourage registrants to generate comprehensive datasets and increase the number of animals used in testing.[47] **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.**

Data sharing

42. The Proposals include a number of measures to encourage or insist on data sharing. For non phase–in chemicals, vertebrate animal test data must be shared and procedures put in place to allow the original registrant to claim for the cost of the test (Articles 24 and 25). Any summaries of studies submitted may be made freely available by the European Chemicals Agency to any other potential registrant after 10 years.

43. The issue is more complicated for phase–in substances. An area of contention is the amount of data already held by companies on the chemicals they currently produce or have produced in the past. David Thomas of the BUAV told us, "there is a huge amount of existing animal data which is there in companies' archives, which is not available to regulators or to the general public. It would be a huge step forward if that data had to be made available".[48] Craig Barker of Ciba Specialty Chemicals told us that "In many cases most of these chemicals have already gone through several Evaluations over their lifespan. We have had the existing chemicals legislation; we have had the HPV programmes running in the States and under the OECD initiatives. These have all gone through these types of chemicals and we are not using those to the best advantage of this legislation; they have just been ignored".[49] This is not strictly the case, as Article 12 provides that alternative methods may be used if the registrant can justify their suitability, for example for substances that were already manufactured or marketed outside the Community. A further problem is that a large proportion of this information has probably been obtained by using old protocols, and not according to current Good Laboratory Practice standards.[50]

44. The BUAV believes that, by ensuring that data sharing becomes mandatory under REACH, authorities will not only be able to prevent duplicate animal testing being carried out for the purposes of Registration and Evaluation of substances that are already on the market, but also improve systems of monitoring and coordinating test plans for new substances, so that the problem of duplicate animal testing is eliminated entirely. A similar point is made by the Royal Society of Chemistry, which argues that data from other

46 Ev 56

47 Ev 86

48 Q 95

49 Q 238

50 Combes R et al (2003) *An Overall Strategy for the Testing of Chemicals for Human Hazard and Risk Assessment under the EU REACH System*, Alternatives To Laboratory Animals vol 31, pp 7–19,

regulatory regimes, such as the US High Production Volume (HPV) system, should be acceptable to the ECA.[51] Dr Colin Church of DEFRA told us that the experience from HPV indicated that around 90% of test data on chemicals already existed and felt it was reasonable to extrapolate to REACH.[52] While a large number of chemicals to be registered will have been through the HPV programme, there is no requirement for Good Laboratory Practice, which could present problems in transferring data gathered under this programme.[53] A further problem is bringing data into REACH from overseas and from companies that no longer produce the chemical in question.

45. **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.**

One substance–one registration

46. Currently the Proposals encourage the formation of consortia, but this is not mandatory. The UK Government is presenting the case strongly for one substance–one Registration, which would require the compulsory sharing of data. The Government's proposals are set out in its consultation published in March 2004. The advantages, it argues, are:[54]

- Minimising animal testing through sharing of data in consortia;
- Reducing the cost of REACH to the economy by sharing costs of testing;
- Maximising the sharing of existing data and creating one data package per substance;
- Reducing the workload and simplifying the system for industry and Authorities;
- Aiding rapid decision making through the use of one registered data package; and
- Creating a level playing field for all registrants, including late entrants to the EU market.

47. A key element of the Government's proposals is a single pre–Registration phase, supported by the Substance Information Exchange Forum and run by the ECA. This would make possible the mandatory formation of consortia for joint Registration of chemicals.[55] Few would argue with the Government's aims. The CIA has produced a detailed critique of the workability of the proposals, particularly relating to the compulsory

51 Ev 85

52 Q 271

53 The Organisation for Economic Co–operation and Development Principles of Good Laboratory Practice set out managerial concepts covering the organisation of test facilities and the conditions under which pre–clinical safety studies are executed. Their purpose is to ensure the generation of high quality and reliable test data (in vitro and in vivo) related to the safety of chemicals and preparations in the framework of the Mutual Acceptance of Data.

54 Ev 53

55 This has been discussed above in paragraphs 33–40 in relation to the introduction of a risk–based approach to Registration

formation of consortia.[56] The Government itself recognises that several issues need to be resolved for one substance–one Registration to be workable:

- Identity of the substance;
- Cost–sharing;
- Timing;
- Access to consortia;
- New substances introduced after the phase–in process of Registration; and
- Commercial sensitivity.

48. The Government's proposals address the identity of a chemical but, as the CIA sets out, the situation is complicated by different companies producing the same substance to different levels of purity. The impurities will also differ according to the production process. The CIA points out that an impurity profile would indicate the process used and might reveal company secrets.[57] We also understand that there are some very similar chemicals with different uses which have the same CAS number.

Consortia

49. The Government argues that "in the interests of fair and open competition, companies must be able to join consortia". It suggests that industry should propose equitable cost sharing guidelines detailing the data sharing and charging requirements for late entrants. The issue of late joiners and free riders is of concern to industry when costs have been incurred, the outcome is known and the Registration has succeeded. [58] The CIA reports that late joiners to consortia of this kind are, on top of a share of the costs, charged a risk premium of 20–25% and interest. This is complicated by the fact that completed studies are a depreciating asset and that in theory a discount rate should be imposed. A further issue is the membership of consortia of organisation from different sectors with chemicals used for different purposes and in very different volumes.[59] The CIA points out that smaller producers will be disadvantaged as they would be forced to register earlier under the volume thresholds for Registration or pay consortia costs later even though they possess much of the Registration data already. This problem could be overcome by the introduction of a single pre–Registration deadline soon after the Regulation comes into force.[60] A further concern is that consortia tend to move more slowly than single companies.[61] However, the CBI concludes that the Government's proposal has many attractions, provided that the competition and confidentiality aspects can be managed and there is the flexibility for companies to operate outside consortia.[62] **While we do not doubt**

56 Ev 69–71

57 Ev 70

58 Ev 69–70

59 Ev 70

60 See paragraph 37–38

61 Ev 71

62 Ev 94

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.

50. The CIA questions the legality of DEFRA's suggestion that industry should not be made responsible for preparing guidelines for cost sharing. This issue needs to be resolved but we suspect that industry would rather draw up its own guidelines than have them forced upon them by the Commission or an ombudsman. The CBI expresses concern that some of the information required by REACH is "extremely commercially sensitive" and that competition law prevents companies from exchanging this information with others directly. It argues that further thought needs to be given to this issue with data held in a secure system and that company names should not be associated with some information.[63]

51. Mr John Kemp, Corporate Health, Safety and Environment Manager at Infineum International Limited, identified a further issue. He felt that it was important to distinguish between the generation of the physicochemical data and the data from animal testing; and information about end uses and the risks associated with end uses. He argued that for the first part, data–sharing should be maximised, but that the same chemical can have very different end uses and that trying to put all these factors together in one risk assessment would slow down the whole process and make it unworkable.[64]

52. While the Government seems keen to make one substance–one Registration a key element of its position, its enthusiasm is not shared by Commissioner Liikanen, who agreed with the suggestion that mandatory consortia formation, critical to ideas of one substance–one Registration, was a "dead duck".[65] Mr Michael responded that "One has to ask what he meant by that and what was meant by the question".[66] We see little scope for interpretation in Commissioner Liikanen's comments and are concerned that the Government's negotiating position could be undermined if it continues to take this stance. **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.**

Chemical Safety Reports and Safety Data Sheets

53. A chemical safety assessment (CSA) must be conducted and a chemical safety report completed for all substances produced in quantities over 10 tonnes. Where a substance is identified as dangerous the Chemical Safety Report (CSR) must also include an exposure assessment and risk characterisation. The CBI is pleased that the requirement to conduct a CSA has been removed in the Proposals for substances produced in quantities of below 10

63 Ev 92

64 Q 234

65 Q 197

66 Q 282

tonnes. It would still like to see more streamlining of the requirements of the CSA and CSR with current environmental and health and safety regulation.[67]

54. Under the Proposals, manufacturers or importers have to provide downstream users with a safety data sheet (SDS) for the purposes of managing their risk when using the substance. The SDS must be consistent with the CSA. The consultation text had indicated that CSRs would be necessary and this move has been welcomed by industry as reducing the burden on downstream users.[68] The Government also welcomes the European Commission's proposal to adopt the existing SDS mechanism to improve the communication along the supply chain. WWF describes the uses of SDSs as "an adequate way of passing information to downstream users".[69] We agree that the use of safety data sheets to improve communication down the supply chain is a useful introduction.

4 Evaluation

55. The Proposals outline two types of Evaluation, to be carried out by the competent authority in the Member State of production:

a) Dossier Evaluation (where the principal aim of preventing unnecessary animal testing would be achieved by Proposals being examined in advance) and

b) Substance Evaluation (which would enable an authority to require more information from industry).

56. Dossier Evaluation has two stages: a mandatory review of testing proposals and a voluntary compliance check of registrations. The Proposals suggest that the review of testing proposals will be carried out by Member States in order to assess whether the test proposed is necessary and, if so, whether the proposed test conditions are appropriate.[70] This is intended to avoid unnecessary animal testing. In addition, the Member State Competent Authority may check that any Registration complies with the registration requirements. The location of the registering company dictates which Member State will conduct the Dossier Evaluation.

57. For substance evaluation, the ECA would be required to develop guidance on the prioritisation of substances, in order to promote a consistent approach. Member States would then prepare rolling plans of the substances which they wished to evaluate. As with Registration, the new arrangements would be phased in, with testing for substances above 1,000 tonnes having to be completed within five years of the Regulation entering into force, and testing for those above 100 tonnes within seven years.

58. While the CBI welcomes the distinction between dossier and substance Evaluations, it regards the Evaluation system as "unnecessarily complex and burdensome". Particular concerns are the freedom of Member States to undertake Evaluation over and above

67 Ev 95

68 Ev 95

69 Ev 79

70 Article 43. This only applies to Annexes VII and VIII.

criteria set by the ECA and the need to harmonise the approach across the EU. The CBI is also concerned that the Evaluation process has no clear end point.[71]

59. A driving principle for the Commission has been the abolition of the distinction between "old" and "new" chemicals. The Scientific Alliance argues that the distinction could still have some value in the Evaluation process: "the Evaluation process for pre–1981 chemicals should be more reactive than proactive. A full Evaluation process should only be enacted to investigate the chemicals where evidence exists that they cause harm".[72] Greenpeace rejects this position: Mark Strutt told us that "history has shown us that chemicals that will be perceived to be safe at one point have subsequently proved to be risky; that exposure has taken place when it was denied that it would take place, and that exposure has had health or environmental impact".[73] We agree. Treating old and new chemicals the same is one of the strengths of the REACH Proposals.

60. Despite Dr Delbeke's insistence that the Evaluation process was risk–based, the Government describes concern that "the European Commission's proposal may not in practice result in all evaluations which are needed being carried out".[74] As drafted, the Proposals indicate that Member States are responsible for drawing up a rolling programme of Evaluation, although the ECA will develop criteria and propose priorities for Evaluation.[75] The UK Environment Agency argues that it will "be crucial to develop a system of prioritisation which will enable a quick screen of the information supplied at Registration to identify chemicals which may be of concern and for which Evaluation should be prioritised".[76] The WWF is concerned that the Proposals would allow some Members States to carry out no Evaluations at all and argues that each country should have to undertake a minimum number of Evaluations.[77]

61. While there are merits in leaving the Evaluation process with the competent authorities in Member States, it is naïve to think that this will result in the rapid identification of substances of concern unless the rolling programmes are subject to ratification by the Commission of the ECA. It is unclear what incentive there is for Member States to either develop or implement their rolling programmes. Member States, protective of their chemical industries, could easily be tempted to move at a pedestrian pace when more energetic progress is required. The Government says it is "considering whether the obligation to conduct substance evaluations should be moved from the Member States' Competent Authorities to the European Chemicals Agency".[78] While this has its attractions, we feel that expertise in Member States' Competent Authorities should be utilised. What is missing from the Proposals, we believe, is strong oversight by the ECA to ensure that a speedy and risk–based approach to Evaluation is employed by all Member States. **We recommend that Substance Evaluation remain the responsibility of Member**

71 Ev 96

72 Ev 102

73 Q 14

74 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 94, Q 136

75 Article 38

76 Ev 62

77 Ev 76–77

78 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 95

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.

5 Authorisation

62. For those substances which give rise to very high concern, REACH requires that their use and placing on the market would be subject to an Authorisation by the Commission, on a case–by–case basis. Chemicals of high concern are defined as:

a) substances meeting the criteria for classification as carcinogenic category 1 or 2[79];

b) substances meeting the criteria for classification as mutagenic category 1 or 2[80];

c) substances meeting the criteria for classification as toxic for reproduction (reprotoxins)[81]; and

d) substances which are persistent, bioaccumulative and toxic (PBT).[82]

e) substances which are very persistent and very bioaccumulative (vPvB)[83];

63. The Proposals state that "An Authorisation shall be granted if the risk to human health and/or the environment from the use of a substance … is adequately controlled … and as documented in the applicants' chemical safety report…[but that] an Authorisation may be granted if it is shown that socio–economic benefits outweigh the risk to human health and/or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies".[84]

64. If the Authorisation has been granted on the basis that the socio–economic benefits of the use of the substance outweigh the risks, Authorisations would normally be time–limited, subject to review, and the burden of proof would be put on the applicant. Downstream users would be able to use a substance for an authorised use, provided that they obtained it from a company which has been granted an Authorisation (and kept within its terms). The Authorisation decision will take into account substitution plans showing, for example, that the industry is researching substitutes. Third parties will also be able to provide information to the ECA about possible substitute substances or technologies.

65. The Government, while supportive of the Commission's criteria for Authorisation, has concerns that Authorisations can only be granted to an individual producer or importer. It comments that bureaucracy could be reduced if there was one Authorisation per substance per use with all known manufacturers and importers identified on the Authorisation.[85] We

79 According to Directive 67/548/EEC

80 As above

81 As above

82 In accordance with the criteria of Annex XII.

83 As above

84 Annex XIII

85 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 99

are sympathetic to this suggestion but it has obvious limitations where the chemical in question has a range of uses and as a result could pose very different levels of risk. Any proposals that could increase the rate at which substances are considered at Authorisation are welcome, however.

Substitution

66. The extent to which the Commission issues Authorisations rather than insist on the substitution of a substance is highly contentious. The industry has claimed that substitution already forms part of the strategies of chemical companies, that enforced substitution could diminish competitiveness and that substitutes might not necessarily be safer.[86] The CIA argues that inflexible imposition of substitution plans on EU producers would cause downstream users to switch sourcing of ingredients rather than cooperate with the substitution process.[87] The Royal Society of Chemistry is concerned that safe compounds may be withdrawn because they generate insufficient profit to cover the cost of testing. Leigh's Paints argues that the reformulation of products resulting from substitution would result in gaps in product availability and niche products might have to be withdrawn.[88] The CBI is content with the principle of substitution but argues that decisions must take "a holistic view of all relative hazards and risks on a case–by–case Evaluation" and be made in a transparent fashion.[89]

67. The environmental NGOs take a harder line and espouse the precautionary principle, as articulated by Mark Strutt from Greenpeace: "if it is possible to avoid any risk then that is what you should do … and particularly if that risk is imposed on the general public by industry".[90] WWF considers that the use of chemicals of very high concern should only be authorised when there is no safer alternative, and where there is an overwhelming societal need, and when measures to minimise exposure are in place. They are sceptical about the use of risk management strategies, suggesting that it is impossible to predict all possible scenarios.[91] The UK Environment Agency "wish to see every effort made to substitute substances of most concern with more acceptable alternatives".[92] Alun Michael's view is that "We are in favour of appropriate substitution… If you are too simplistic you say that if there is any risk at all there ought to be a substitute, but you need to be sure that there is a safe substitute".[93]

68. Greenpeace is scathing about the provision for "adequate control": "Are phthalates in toys 'adequately controlled'? When brominated flame retardants burn in an incinerator or landfill fire are they adequately controlled? If hormone disrupting chemicals are showing up in breast milk are they adequately controlled?".[94]

86 Ev 67

87 Ev 67

88 Ev 55–56

89 Ev 92

90 Qq 19–20

91 Ev 73–74

92 Ev 61

93 Q 288

94 Ev 57

69. A key issue is how socioeconomic benefit is assessed. Andrew Lee from WWF said that "of course there may be some cases where chemicals will be authorised because the risks outweigh the benefits, but many more cases where there are substitutes or where the purpose to which the chemical is put is perhaps non–essential; that it is nice to have, and there we think substitution should take place".[95] The use of flame retardants is a useful example as many are toxic yet their application will have saved many lives.

70. Dr Delbeke from the Commission's Environment Directorate General felt that there had been scaremongering over the substitution issue. He felt that it was good news for industry as it would provide market and public relations value by adding "a gloss to the substances or the products that they are producing". Equally, he believed that under the current Proposals "a lot of substitution is going to happen".[96]

71. The Government supports the principles of substitution but expresses concern as to how this would work in practice; for example how the Commission will determine what is a suitable alternative chemical, how socioeconomic need will be interpreted or whether the risk management plan submitted by the company is adequate. The Government suggests that there could be an independent review of available substitutes, which could be part of the socio–economic analysis, paid for by industry as part of the Authorisation fee, but carried out by a third party.[97] It also has concerns about legally enforceable substitution, recognising that:

a) There have been a number of well known examples where an apparently safer substitute introduced by legislation has led to different effects to those of the substituted substance but of equivalent concern;

b) Substitution is seldom a simple matter of substituting one chemical for another. It can be a costly process involving the consideration of a number of new substances and their full life–cycle impacts as well as changes to production processes.[98]

72. A lot centres on the term "adequate control". The term is defined in Annex 1, section 6. This states that for any exposure scenario, the exposures of humans and the environment can be considered to be adequately controlled if:[99]

a) The exposure levels do not exceed the appropriate derived no–effect levels or the predicted no–effect concentration;

b) The likelihood and severity of an event occurring due to the physicochemical properties of the substance is negligible.

73. WWF's concerns seem to stem from how adequate control has been interpreted previously: "past experience with the risk assessment process under the current legislation, suggests that what industry considers to be "adequate control of the risk" may fall below

95 Q 31

96 Q 135

97 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 109

98 As above, para 107

99 Annex 1, Section 6 (4)

the necessary level of health and environmental protection".[100] It argues that if the Commission accepts industry's arguments that the risks of such chemicals are adequately controlled, they must authorise the use of the chemical, even if a safer alternative is readily available.[101] WWF argues that "It is very difficult to ensure chemicals are properly controlled during their entire life cycle, and even good control measures can result in appreciable exposures".[102] The Government also has concerns over the interpretation of adequate control, on the basis that it relies on exposure ratios and that it is not clear whether such models can be applied to PBTs and vPvBs. It says that "The difficulties in defining 'adequate control' in PBTs and vPvBs could lead to inconsistencies, uncertainty for industry and, if large numbers of chemicals of high concern are authorised through the first track, a failure to protect human health and the environment from some of the most hazardous chemicals covered by REACH".[103]

74. WWF seems to have a lack of confidence in the Commission. It fears that it will accept everything that industry tells it and that substitution will never be demanded. We see little evidence to justify this fear since the legislation seems to have been initiated with high environmental ideals and the Proposals clearly state that "burden of proof is placed on the applicant to demonstrate that the risk from the use is adequately controlled or that the socio–economic benefits outweigh the risks".[104] Nevertheless, the Government's concern that the definition does not apply to PBTs and vPvBs is a genuine one and needs to be resolved.

75. A further concern is that considerations over the risk management of chemicals will result in the system "floundering".[105] This should be taken seriously but is not an excuse for making irrational decisions and refusing Authorisations when the health and environmental dangers are negligible. Instead, attention needs to be given to ensuring that the Commission's decision–making processes are rapid and transparent.

76. In an ideal world, highly toxic chemicals would not be produced, but companies must be able to argue that the risk of exposure is small during and after the lifecycle of the product. To insist that a substance is substituted in such cases could lead to a situation in which a company is disadvantaged without any health or environmental benefits. Nevertheless, the legislation's definition of adequate control needs to be tightened. WWF is concerned about the provisions for chemicals of concern for substances of "equivalent concern" in Article 54. This stems from an insertion stating that these need to have been "identified as causing serious and irreversible effects to humans or the environment" and WWF expresses concern that "there is a need to act on very persistent and very bioaccumulative chemicals, irrespective of currently known toxicity".[106] We believe these concerns to be misplaced. A previous section of Article 54 covers "substances which are very persistent and very bioaccumulative", which implies that this is indeed irrespective of

100 Ev 75

101 Ev 73–74

102 Ev 74

103 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 110

104 Proposals section 1.7

105 Ev 75

106 Ev 76

known toxicity. Thus we do not find WWF's argument convincing as REACH has been designed to identify chemicals of concern.

77. The CIA rejects the requirement for a substitution plan as a condition for Authorisation. It says also that substitution plans would need to engage downstream users.[107] **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.**

78. The WWF's hard line on substitution is weakened by Andrew Lee's own admission that "we know there are companies already diversifying, already getting out of the production of some of these chemical concerns, retailers are already demanding substitution of chemicals because of consumer pressures".[108] This implies that substitution could occur through market mechanisms alone.

79. A further issue relating to substitution was raised by David Thomas, a legal consultant to the BUAV. The environmental NGOs have focused on those chemicals which have proven toxicity. Mr Thomas argued that abstinence was an option, that if a chemical could not be proven safe using non–animal tests then "society has the ethical choice whether to allow that substance onto the market".[109]

80. Greenpeace complains that Article 57 allows for the issuing of an Integrated Pollution and Prevention and Control permit, which sets allowable discharge limits.[110] It argues that IPPC permits were not designed to deal with persistent and bioaccumulative chemicals and that the REACH Proposals should cover emissions from industrial processes. The UK Environment Agency and the Government also express concern about this exemption.[111] The Commission says that this decision was taken so as "not to interfere with such other competences and to avoid differences between the decisions taken under different regulatory regimes as well as the resources in examining an impact twice". **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.**

81. **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.**

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107 Ev 67

108 Q 37

109 Q 89

110 Ev 57; Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control

111 Ev 84; DEFRA, *UK Consultation paper on the New EU Chemicals Strategy – REACH*, March 2004, para 113

Review of Authorisations

82. The Proposals state that "Authorisations may be subject to conditions, including review periods and/or monitoring".[112] Greenpeace would like to strengthen this provision, arguing that all Authorisations should be temporary and not subject to renewal.[113] WWF agrees and suggests that Authorisations should be reviewed at least every five years.[114] While we appreciate that Greenpeace does not accept that a chemical can be adequately controlled, we conclude that if review and monitoring has been shown to be effective in controlling a chemical, it would be unreasonable not to renew Authorisations. This element of the Proposals could be strengthened to insist that all Authorisations should be subject to review at a stated time, at the discretion of the Commission. **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.**

Restrictions

83. A fourth element of the REACH Proposals is Restriction.[115] Annexes XVI and XVII contain a list of restrictions for substances on their own, in preparations or in articles. If listed they may not be placed on the market or used unless in compliance with the condition of the Restriction. Restrictions will be made in response to dossiers, which can be drawn up by the ECA at the Commission's request or by Member States. The process is largely uncontroversial. The CBI wishes to see "detailed criteria for the imposition of Restrictions drawn up as soon as possible in order to assist harmonisation".[116] The Government is seeking clarification about the inclusion of products made from recycled or recovered material and whether Restrictions can be challenged or reviewed. It expresses concern that Member States and the ECA could duplicate effort if working on the same substance. We discuss the functions of the ECA in more detail below but we believe that this could be easily resolved if Member States are obliged to notify the ECA before assembling a dossier.

6 Testing requirements

84. An important element of REACH is that substances introduced before 1981 should be subject to more rigorous testing and that what data there are should be in the public domain. This will impose a cost burden on industry but the main area of contention is the number of animal tests that will be conducted in ensuring compliance with REACH. The requirements are set out in detail in the annexes to the Proposals. The information requirements for testing are set out in Annexes V–VIII. Annex V consists of mainly non–

112 Article 57

113 Ev 57

114 Ev 77

115 Article 64

116 Ev 96

animal physicochemical tests, with the requirements in subsequent annexes being progressively increased with volume. Annex IX contains rules for adapting the standard testing requirements.

- Annex V: requirements for substances manufactured or imported in quantities of 1 tonne or more.
- Annex VI: additional requirements for substances manufactured or imported in quantities of 10 tonnes or more.
- Annex VII: additional requirements for substances manufactured or imported in quantities of 100 tonnes or more.
- Annex VIII: additional requirements for substances manufactured or imported in quantities of 1,000 tonnes or more.

Animal tests

85. This inquiry has considered the Commission's Proposals for chemicals legislation and we have not sought to form a collective view on the ethics of animal testing. There are, however, a number of issues relating to animal testing that we wish to address.

Number of animals

86. It has been generally concluded that the Proposals will lead to an increase in the amount of animal testing, at least in the short term, since many existing chemicals will not have been tested on animals to the standards required by the Proposals.[117] Animal testing is expensive and therefore demands for its minimisation are not restricted to the animal welfare groups. Leigh's Paints' evidence states that even with the provision for data sharing, there will need to be a massive increase in testing overall and a significant increase in animal testing.[118] Estimates of how many extra animals will be used are hard to come by, however. The Biosciences Federation (BSF) submission says that in 2002, 162,000 animals were used by industry for safety testing (6% of the 2.73 million total used in scientific procedures).[119] The BSF concludes that a "substantial portion" of the 30,000 chemicals expected to go through the Registration process will need further testing. It concludes that, on average, an extra 80,000 animals will be required each year in the UK alone.[120] The UK has 13.5% of the EU chemical industry, which suggests that around 500,000 animals would be required across the EU each year and thus 5.4 million for the duration of the 11–year phase–in period.

87. Following the publication of the White Paper in 2001, the then Department for the Environment, Transport and the Regions commissioned the Institute for Environment and Health at Leicester University "to inform policy development in relation to proposals in the European Commission White Paper". The authors calculated a worst–case scenario, based

117 Ev 58

118 Ev 56

119 Ev 59

120 Ev 59

on OECD requirements, that if testing were required for the full 30,000 chemicals then between 2.5 and 3.9 million mammals and fish would be needed.[121] The Government seems to be unable or unwilling to publish a more up to date estimate. In giving evidence, Dr Colin Church told us "that is a very difficult question to answer". He told us that approximately 2,000 chemicals would need the testing required by Annex VIII.[122] John Kemp from Infineum International Limited told us that each Annex VIII chemical (produced in volumes of over 1,000 tonnes per manufacturer/importer per year) would require 1,000 animals. On this basis, we can calculate that, assuming no data exist already, around 2 million extra animals will need to be tested for chemicals coming under Annex VIII as a result of REACH, across the EU.

88. In a written answer to Bob Spink MP, Mr Michael gave a partial answer. He said that there are likely to be 20,000 chemicals being produced or imported in quantities of less than 10 tonnes (Annex V). For this volume, the Commission requires 25 animals per chemical. Assuming again no duplication of testing, we arrive at a figure of 500,000.[123] This leaves approximately 8,000 chemicals produced in quantities between 10 tonnes and 1000 tonnes (covered in Annexes VI and VII). Dr Church estimated that 90% of the data already existed but it seems likely that less data exist for the later Annexes, given the more stringent requirements.

89. It is a pity that our rather crude estimates have not been supplemented with a more in–depth analysis by the Government and the Commission, since increased animal testing is a controversial and unfortunate by–product of the legislation. It is surprising that BUAV has not even attempted a calculation and states in its evidence merely that "the overall requirement is for data obtained through many millions of animal tests".[124] DG Environment is even less helpful. Dr Delbeke told us that the REACH Proposals would increase animal testing but "only marginally" due to the application of QSARs (quantitative structure activity relationships).[125] **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.**

One substance–one Registration

90. We have discussed the merits of one substance–one Registration above.[126] The first advantage, according to the Government, is the minimisation of animal testing. This is a noble aim so we asked the views of Commissioner Liikanen. His response was that the sharing of animal testing data was already compulsory, which also seems to be the

121 Institute for Environment and Health (2001) *Testing Requirements for Proposals under the EC White Paper 'Strategy for a Future Chemicals Policy': an update*

122 Q 271

123 HC Deb, 3 March 2004, Col 928W

124 Ev 106

125 Q 138

126 See paragraphs 46–52

understanding of the CIA.[127] Officials at DEFRA know better and, following our evidence session, we have been supplied with some scenarios in which data may not be shared:[128]

a) For phase–in substances, if data are available, the potential registrant and the study owner shall take steps to reach agreement on cost–sharing. If this is not possible, the potential registrant proceeds as if the test did not exist and further tests must be carried out .

b) If no test data exist then registrants who need the data "shall take all reasonable steps to reach agreement as to who is to carry it out on behalf of the other participants". If no agreement can be reached then duplicate testing will occur.

c) If a substance is produced both at high and low volumes, it is possible that if the latter manufacturer/importer has relevant data that is not available through the Substance Information Exchange Forum at the time of pre–Registration/Registration the former may conduct further tests.

d) For non–phase–in substances, if cost sharing cannot be agreed between registrants, the Agency, *on request*, will hand over study summaries for all the tests needed by the subsequent registrant, leaving open the possibility that the subsequent registrant will repeat the test. Also, only the study summary will be provided, and this may not be sufficient if the registrant wishes to use the data in another context, which could lead to repeat testing.

91. If we assume that DEFRA is correct, this raises the questions over the number of animals which are likely to be spared and the likely cost of achieving this as a result of mandatory consortia formation. We are concerned that the answer to the former is not many and the answer to the latter is quite a lot. **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.**

92. Most of the evidence we received expresses the view that animal testing should be reduced as far as possible, but without any clear articulation of the acceptance that the increased use of animal tests will improve human health and the environment. Mark Strutt from Greenpeace told us that "Most of our supporters would accept the need for some animal testing on many premises, not least because animals too in the wild are exposed to and affected by the type of chemicals".[129] Andrew Lee of WWF said "You talked about REACH driving up the number of tests but that is only because a proper testing regime is being put in. The reason the numbers are low at the moment is that most of these chemicals are not properly tested at all, and surely that is not acceptable".[130] Judith Hackitt of the CIA said that communicating the need to use animal tests was a shared role between industry and governments but that the Commission should have been doing more to

127 Q 234

128 Q 276, Ev 114

129 Q 49

130 Q 50

articulate this.[131] Dr Delbeke argued that the Commission had been making these points clearly.[132] This is not our impression and we sense a reluctance on that part of the Commission to be fully frank about the extent of animal testing required by REACH. The Minister, Alun Michael, told us that "animal testing is appropriate where it is necessary in order to be able to provide evidence that is needed". This case needs to be made more strongly and more often.[133]. The Government, the chemical industry, the Commission and the environmental NGOs need to say clearly and publicly that a large number of extra animals will be used and killed in testing, but that this is worth it to achieve the environmental and health benefits intended by the legislation, which aims to benefit animals too.

Non–animal tests

93. A major element of BUAV's argument is that animal testing does not give reliable information on which to base measures to protect human health.[134] It gives 10 reasons for this conclusion:[135]

i. The response to a chemical in the animal species/strain/gender used differs from that of humans or another test species;

ii. The absorption, distribution, metabolism or excretion of a chemical differ between species;

iii. The tissue effects are not the same at the macroscopic or microscopic level as in humans or are seen in different organs;

iv. Differences at the anatomical, physiological, cellular, subcellular or receptor levels cause varying susceptibilities to toxicity;

v. The dose required to produce toxic effects in animals may never be reached in humans;

vi. The target dose in humans cannot be achieved in test animals or the test is not sensitive enough;

vii. The potential synergy between many chemicals to which humans are exposed cannot be studied in animal tests;

viii. The test animals (i.e. inbred, genetically identical rodents) neither represent normal animals of their species nor the human population of concern;

ix. The experimental conditions may differ from test to test; and

131 Qq 224–225

132 Q 141

133 Q 265

134 Ev 106–107

135 *Chemical Safety and Animal Testing: A Regulatory Smokescreen?* A British Union for the Abolition of Vivisection (BUAV) report by Dr Gill Langley, March 2004

x. The experimental conditions are inappropriate to the human situation.

94. Europeans for Medical Advancement (EMA) also believes that many animal tests do not provide useful data. This group argues, for example, that 80% of cancers have an environmental cause and that environmental chemicals are a likely cause. It cites research by the US National Cancer Institute, which tested 12 anti–cancer drugs on mice that are currently being used successfully in humans. The scientists took mice that were growing 48 different kinds of human cancers and treated them with the 12 drugs. They found in two thirds of cases the drugs were ineffective in the mice and thus inaccurately predicted human response.[136] EMA argues that alternatives could provide at least as good an indication of the toxicity of chemicals to humans. It further believes that the REACH legislation would be better delayed by several years than passed with the existing set of animal tests.

95. The CIA does not feel that animal tests could be replaced yet. Judith Hackitt told us that "In the debate that has gone on thus far one of our concerns would be that there has been some misleading statements made about when and where you can substitute other means for animal testing … We do not believe—in fact we know—that those alternative test methods have a long way to go in many cases to being accepted as alternatives and that needs to be clear to people."[137]

96. The EMA evidence asserts that, in private, environmental NGOs agree with the arguments it is making, yet refuse to back the position publicly. Dr Ray Greek from EMA tells us that:[138]

> "We have spoken with numerous environmental groups who agree with us that the current REACH concept of using animals to test for effects of chemicals on the environment is misguided. The idea that testing chemicals on three or four species and obtaining from this, informative data for what the chemical will do to other species and the environment as a whole is specious. The green groups realise this but do not wish to bring this position to bear lest they lose what political influence they think they have achieved with this campaign."

In giving evidence to us, Andrew Lee told us that "WWF is in favour of substituting for animal tests wherever there are technologies and techniques available that can provide the data we need. But … we do not believe it is possible to provide the data to end the use of some of these chemicals of very high concern … without some animal testing data".[139]

97. Dr Greek argues that "to sacrifice principle, and in this case, in all likelihood, human and animal lives in order *not* to be perceived as being too radical is disingenuous at best and immoral at worst". This is a serious allegation, suggesting that the green NGOs are more interested in a political victory than protecting the environment. The tests are the foundation of the legislation; unless they have some validity, it becomes a pointless, bureaucratic exercise. As Emily McIvor told us, "I do not have very much faith that the

136 Ev 115

137 Qq 224–225

138 Ev 117

139 Q 2

REACH proposal… including the battery of tests, can do very much good at all in terms of improving chemicals regulation".[140] **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 continue promoting the legislation until these doubts have been resolved or better tests introduced.**

Development of new tests

98. The Royal Society of Chemistry describes the problems associated with new tests being incorporated into chemical regulation:[141]

> "New test methods will take time to develop, validate and gain acceptability by regulators. … In general companies prefer to use test methods that don't involve animals. However a company cannot use alternative tests until legislators and regulatory agencies have confirmed that they will accept the results. In the past it has taken many years of international validation studies before legislators and regulatory agencies would accept the results from alternative test methods."

Mike Barry from Marks and Spencer also feels that the introduction of alternatives has been too slow: "insufficient effort was put in ten years ago to start the programmes that we need now, so we are where we are. We would like to see the chemical agency and other bodies in Europe really driving forward a plan to look for alternatives".[142] Emily McIvor from BUAV told us that animal testing continued simply because it has always been done.[143] Dr Langley told us that she would not claim that all the non–animal tests are available but that there were enough "to allow substance prioritisation for substances, to allow regulation and better regulatory decisions to be made in the short term".[144]

99. One problem is the setting of appropriate standards. The European Centre for the Validation of Alternative Methods (ECVAM), part of the Commission's Joint Research Centre, is responsible for coordinating the independent evaluation of the relevance and reliability of tests for specific purposes, so that chemicals and products of various kinds, can be manufactured, transported and used more economically and more safely, while the current reliance on animal test procedures is progressively reduced. It has an annual budget of €35.2 million.[145] The EMA points out that none of the current animal tests has been subject to the demands being made for alternative methods. To retrospectively validate animal tests would be expensive and would in itself involve the extensive use of animals.[146]

140 Q 90

141 Ev 86

142 Q 75

143 Q 84

144 Q 86

145 Q 271

146 House of Lords Select Committee on Animals in Scientific Procedures, Session 2001–02, HL Paper 150–I, Appendix 3, p 64

100. Craig Barker of Ciba Specialty Chemicals told us that industry had a part to play in developing non–animal tests but that the legislators have to work in that direction too: "There does not seem to be enough emphasis on producing the alternatives to animal testing".[147] He told us that the US Toxic Substances Control Act requires alternatives to be used to identify if there is potential problem. Animal testing is only employed when alternative tests raise concerns about the substance.[148]

101. The House of Lords Select Committee on Animal Procedures reported that a 20% reduction in animal tests could be achieved through the harmonisation of test guidelines, reductions in the number of animals used in each test, and greater use of available alternative methods. A 50% reduction would require considerably more development and scientific research but was feasible within 10 years. A 90% reduction would probably take at least 20 years, and would need a major breakthrough in mathematical modelling and molecular biological techniques. The Report stated that,at the EU level, research funded by DG Research has not led to the development of any new tests.[149]

102. Annex IX sets out alternative methods of testing to those set out in Annexes V–VIII. This includes in–vitro methods and states that "Results obtained from suitable [according to internationally agreed test development criteria] in vitro methods may indicate the presence of a certain dangerous property". These tests can only be used, however, to prove the existence of a hazardous property, and a negative result requires that the standard tests are performed. ECVAM has a considerable budget; if it has been making progress there is little to show for it in the REACH Proposals.

103. **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.**

104. It is of concern to us that, first, non–animal tests should be developed and, second, the process for validation and adoption in legislation is rapid. The current UK budget for alternatives is small but progress needs to be made at a European level if it is to have an impact on chemicals legislation. The Government should play a bigger role in making sure that alternatives, where available, are incorporated into European legislation. Current research expenditure by the Government on alternatives is £280,000, from the Home Office.[150] The Lords Committee recommended that a national centre to promote alternative methods should be set up and Lord Sainsbury, Minister for Science and Innovation, announced on 17 October 2003 that the Government agreed with "the persuasive case put forward by the Select Committee".[151] Mr Michael made it clear that

147 Q 226

148 Q 229

149 House of Lords Select Committee on Animals in Scientific Procedures, Session 2001–02, HL Paper 150–I, Appendix 4, p 71

150 Q 271

151 HL Deb, 17 October 2003, Col 1228

funding for research into animal procedures was within the remit of the Home Office, which is entirely appropriate given that it is responsible for its regulation. **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.**

QSARs

105. Results obtained from quantitative structure–activity relationship models (QSARs) may indicate the presence or absence of a certain dangerous property. The Commission has set out when the results of QSARs may be used. Article 11 says the development of approaches such as QSARs shall be taken into account in any proposals to modify the information requirements for 1 to 10 tonne registrations. The CBI welcomes the provisions for QSARs but argues that their use should be extended beyond substances produced below the 10 tonne threshold.[152] The Government is seeking responses to this question as part of its consultation.

Testing capacity

106. Concerns have been expressed about the practicality of testing 30,000 chemicals within 11 years. The Crop Protection Association points out that evaluation work frequently takes longer than expected.[153]

7 European Chemicals Agency

Functions

107. The role of the ECA is set out in Title IX of the Proposals. Its principal functions will be to:

a) Run the databases necessary to operate the system;

b) Coordinate the Evaluation procedures and take any decisions to require further information from industry;

c) Provide advice to the Commission on priorities regarding treatment of substances and on issues linked to Authorisation; and

d) Run a number of technical committees advising, and drafting opinions for, the Commission.

The ECA will be based on the European Agency for the Evaluation of Medicinal Products, whose functions it will most resemble.[154] It will be sited in Finland with a planned annual

152 Ev 95

153 Ev 113

154 REACH Proposals, Volume 1, Section 1.9, p 16

budget of €30 million, funded mainly through fees charged for Registrations and Authorisations, and will have a staff of about 200.

108. Article 71 explains that the ECA has been set up with a coordinating function and not as a regulatory body, based on the principle of subsidiarity. There is widespread support for a stronger body, however. The Government says it would like to see the European Chemicals Agency taking more of a central role than that envisaged in the European Commission's proposal, in particular:

a) To act as arbitrator in disputes when setting up consortia for data sharing;

b) To carry out a screening of the Registration information in order to prioritise for further action under evaluation; and

c) To take responsibility for Evaluations to ensure they are carried out.

109. This view has support from industry, The CIA thinks the ECA should have full responsibility for all aspects of prioritisation, decision–making and management of the system. Currently this is just at the Registration phase. This would help, it says, to ensure consistency of enforcement and timely decision–making.[155] The British Cement Association agrees, concluding that the lack of a strong central ECA threatens "distortions in the internal market".[156] WWF wishes to see the ECA take on a stronger role in checking the accuracy of Registration dossiers and insisting on a minimum number of Evaluations to be undertaken by Member States.[157]

Structure and administration

110. The structure of the ECA is set out in Article 72. It will comprise:

a) A Management Board;

b) An Executive Director;

c) A Committee for Risk Assessment, which prepares the ECA's opinion on risks to human health and the environment under the Authorisation and restriction procedures;

d) A Committee for Socio–economic Analysis, which prepares the ECA's opinion on any question related to the socio–economic analysis of substances;

e) A Member State Committee, which coordinates work on Evaluation, classification and labelling and identification of substances of very high concern;

f) A Forum on exchange of information on enforcement, which coordinates a network of Member States' enforcement authorities;

155 Ev 67

156 Ev 89

157 Ev 56, 78

g) A Secretariat to support the Committees and the Forum and to execute the administrative parts of the REACH system; and

h) A Board of Appeal, which considers any appeals against the decisions of the ECA.

111. The Government says the Proposals for the ECA have been improved but is considering whether its administration could be further streamlined. One option would be to combine the committees for risk assessment and socio–economic analysis, which would have the benefit of ensuring that issues concerning substitution were not dealt with in isolation. The CBI is concerned about the proposed structure of the ECA, suggesting that there are too many decision–making bodies, which will lead to inefficiencies.[158] **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.**

112. The Royal Society of Chemistry has concerns about the resources and expertise needed by the ECA. A particular concern is that harmful chemicals could be classified into categories not intended for rapid Evaluation and slip through because the data are not properly scrutinised. The ECA, it says, will need considerable expertise "to counter the ability of registrants to finesse a dossier that could hide issues requiring more careful scrutiny".[159] It had originally been envisaged that the ECA would be based at Ispra in the Italian Lakes, the site of the European Chemicals Bureau and ECVAM. For reasons that seem to be political rather than rational, the ECA went to Helsinki as part of a deal which gave Parma the European Food Safety Authority. **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.**

113. **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.**

8 Impacts

114. A number of impact assessments have considered REACH since the White Paper in June 2001.[160] These can be divided into four types:

a) Testing and registration (direct) costs;

158 Ev 95

159 Ev 86

160 These are summarised in Presentations from Stakeholder Workshop held by the European Commission on 21 November 2003. europa.eu.int/comm/enterprise/chemicals/chempol/bia/index.htm

b) Impacts on downstream users (indirect costs);

c) Innovation effects;

d) Health and environmental benefits.

Industrial competitiveness

115. The direct costs incurred by industry as a result of REACH have been estimated by the Commission to be around €2.3 billion over 15 years, a €10.6 billion reduction on the calculations based on the consultation text.[161] These savings have been achieved by reducing the requirements for Chemical Safety Reports, the exclusion of polymers, increased use of QSARs, reduced requirements for production volumes between 1 and 10 tonnes and lighter requirements for transported intermediates.[162]

116. More contentious are the indirect costs. The European Commission now estimates the maximum overall cost of the revised Proposals to be €7.5 billion, significantly lower than the €18–32 billion previously estimated. A key issue for industry is that the REACH Proposals will impose costs on companies that will undermine their competitiveness. The Bundesverband der Deutschen Industrie (Federation of German Industries) commissioned a report from Arthur D Little, which claimed that job losses could be up to 2,350,000 in Germany. A similar French study found that up to 670,00 jobs could be lost.

117. The WWF denies that REACH will be economically damaging and cites Adair Turner, former Director General of the CBI, who states in his book, *Just Capital,* that "There is no evidence that increasing environmental constraints have slowed overall growth rates, and no evidence that higher environmental standards in some developed countries have disadvantaged them economically versus others". WWF points out that the costs will be spread over the phase–in period for REACH, representing 0.12% of the chemical industry's annual turnover.[163] It also argues that REACH will provide new markets for environmentally friendly products.[164]

118. WWF reports that the Arthur D Little report, commissioned by the Federation of German Industries, has been "severely criticised by a group of leading German economists, drawn together by the German Environment Agency" and concludes that industry groups have been "engaged in scare–mongering tactics", that the cost burden to industry has been used as "a barrier to moving forward" and described the chemical industry as a "dinosaur industry".[165] This seems to reflect a deep–seated hostility to chemical companies rather than a rational assessment of an industry, which has, according to Dr Delbeke of DG Environment, spent substantial amounts on tackling environmental problems.[166] Commissioner Liikanen described WWF as "more diplomatic in their tone" than other groups; nevertheless, insults and point–scoring are not consistent with constructive

161 Q 163

162 European Commission, REACH Extended Impact Assessment, October 2003, section 5.2

163 Ev 80

164 Ev 72

165 Ev 80, Q 6

166 Q 122

discussions about how to improve.[167] Mike Barry from Marks and Spencer has mixed feelings about the chemical industry:[168]

> "My greatest frustration is that the chemical industry is perhaps the greatest achievement of the UK in the twentieth century. It is one of our greatest success stories; and yet it is on the back foot every day of its life because systematically it has mismanaged the whole concept of trust in the last twenty years. To put itself on the front foot and access the benefits of the twenty–first century, it has got to re–build trust in itself, and REACH is a necessary compromise."

119. A report produced for WWF concluded that there was little evidence that environmental legislation had any impact on employment and that "the negative impacts on innovation, competitiveness and employment have been overstated in industry–funded studies, and that insufficient account has been taken of broader social and environmental benefits".[169] Dr Delbeke pointed out that the companies which had been producing CFCs were largely the winners when it became necessary to substitute them with HCFCs.[170] A further factor in the costs is the effect on liability. Commissioner Liikanen pointed out that REACH introduced a duty of care principle, which would protect companies from expensive liability suits.[171]

120. Judith Hackitt from the CIA told us, "I think it is all to do with whether legislation is well designed or not. Good legislation should not harm growth rates".[172] Mike Barry agreed that REACH would drive innovation in the chemical and retail industries if it was "done properly".[173] **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.**

121. The Environmental Industries Commission, a trade association for the environmental technology and services industry, points out that "the Proposals will require considerable analysis work – some of it on the environmental impacts of chemicals. UK environmental laboratories are well placed to undertake this work both in the UK and abroad. The REACH Proposals, therefore, will generate jobs and profits in a fast growing and highly skilled industry in which the UK has a strong market position". We agree with this conclusion, but it is important to recognise that job creation can sometimes result from unfortunate events.[174]

167 Q 155

168 Q 71

169 Ev 81

170 Q 114

171 Q 168

172 Q 222

173 Q 60

174 Ev 98

Competition from outside the EU

122. An argument has been made that EU producers will benefit in the long term owing to the added value that inclusion within the REACH Proposals will give them.[175] This is contested by the industry, the principal arguments being that the Proposals' provisions for chemicals in finished articles will not impose the same level of regulatory burden on non–EU producers. Dr Delbeke from DG Environment rejected these arguments and suggested to us that the complaints from industry reflected the painful process of restructuring in response to competition from China and other countries.[176]

Substances in articles

123. The CBI is concerned that the wording of Article 6 is open to subjective judgement and will be difficult to enforce.[177] The CIA says that it will be possible for articles (such as computers, household products, cars, toys, packaging and clothes) to be manufactured outside the EU using a wider choice of materials and with fewer controls. This, it is claimed, will lead to the migration of production outside the EU borders. Leigh's Paints reports "a growing concern that REACH will drive the chemical producers out of the EC, into regions where the costs of development and production are already low by EC standards. If this move takes place, there will be less and less incentive to register raw materials in Europe, and manufacturers who rely on chemicals – including all paint manufacturers – will themselves have to consider whether EC manufacture is a viable option".[178]

124. Commissioner Liikanen told us that the Proposals would not affect EU competitiveness since the same rules applied to imported goods.[179] Judith Hackitt felt that if imports were not adequately policed, manufacturing would move out of the EU in order to avoid some of the costs of testing.[180] Exporting companies will also be disadvantaged, according to John Kemp from Infineum. He told us that even a medium–sized company such as his exported 25% of its products outside the EU, and that he would be competing with products whose component chemicals may not have been tested to the same standards.[181]

125. The CIA and the CBI argue that the current Proposals place EU–manufactured finished articles (products) at a commercial disadvantage to the same article manufactured outside the EU.[182] As the legislation currently stands, it will be possible for articles to be manufactured outside the EU using a wider choice of non–EU registered chemicals and with fewer controls. The CIA believes that these articles would be cheaper than equivalent articles produced within the EU.[183] The EEF also argues that finished articles should come

175 Ev 81

176 Q 127

177 Ev 93

178 Ev 57

179 Q 187

180 Q 223

181 Q 223

182 Ev 68, Ev 92

183 Ev 68

within REACH and cites other EU legislation – the End of Life Vehicles Directive and the Cosmetics Directive – as examples where importers must require declarations from suppliers that components do not contain banned substances.[184]

126. Different requirements for EU and non–EU manufactured goods concern Mike Barry from Marks and Spencer. He told us that if he imported a suit into the EU containing 30 different chemicals, he was quite happy to declare what those chemicals were but "What I do not want to do is a separate scientific risk assessment to prove that just because they were made in China they are safe. I want to ensure that if that chemical is coming into the EU in this [suit], it has been properly risk–assessed against the REACH model… import is the biggest fundamental concern we have got".[185]

127. WWF also considers this to be a key issue: and is "extremely concerned that the current proposal will allow unregistered, dangerous, or banned chemicals to be brought into Europe from 'outside' the REACH system".[186] It argues that Article 6 should be amended so that any producer or importer of articles would have to submit a Registration to the Agency for any substance contained in those articles, if it was present in those articles in cumulative quantities over 1 tonne per producer or importer per year.[187] Even if this amendment were introduced, the issue of other chemicals used in the production process but not present in the finished article remains.

128. The Government identified its concerns about Article 6 in its consultation, in particular it says there could be confusion over what constitutes the same article type. It also questions whether the supplier of articles is best placed to make an assessment of whether the quantity of substance released may be of concern to human health or the environment.[188]

129. Conversely, there have also been complaints from outside the EU that the Proposals will discriminate against non–EU producers. In a letter to the EU in March 2004, Asia–Pacific Economic Cooperation (APEC), an inter governmental grouping with 21 members, including the USA and Japan, expressed serious concerns about the REACH Proposals:[189]

> "Smaller foreign producers, including specialty chemical suppliers and downstream suppliers simply do not have the capacity for the data generation required under REACH. As a result, there is a potential for EU importers to deselect imported supplies, which are not only chemical substances but also articles containing chemical substances. Thus, REACH may create an inherent bias in favour of domestic EU suppliers."

130. The issue of finished articles is particularly problematic. To treat imported goods in the same way as EU–manufactured articles could impose a huge burden on small importers in particular, and would be very difficult to police. The SMMT argues that the

184 Ev 64

185 Qq 72–73

186 Ev 77

187 Ev 77

188 DEFRA, UK Consultation paper on the New EU Chemicals Strategy – REACH, March 2004, para 52

189 www.apec.org

ideal solution is for REACH to become the norm internationally.[190] The CBI agrees that "The only effective solution is to ensure a globally harmonised system and the EU should seek to work on this".[191] This would have obvious advantages and we would be pleased to see the EU argue the benefits this could have on international trade. We must accept that a global REACH is not on the horizon, however.

131. **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.**

Availability of chemicals

132. Leigh's Paints believes that REACH will lead to the withdrawal of some products. It cites the example of the Biocidal Products Directive, which was associated with a fall in the number of available products from 1,600 to 350. The Commission estimates that 1–2% of substances currently on the market will be lost. The Royal Society of Chemistry argue that this may be a significant underestimation since there will be cases when a producer would have to spend a large amount of money to test a low economic value substance for the purposes of Registration.[192] Judith Hackitt of the CIA suggests that the figure could be in the range 20–40%.[193] WWF disagrees and Andrew Lee told us, "Our view at WWF is quite clear: that if there is a chemical which is safe, produced in very small volume and for which there is an overwhelming need because it has a unique property that is needed for something that is very important, the market will deliver the result because the price mechanism will operate. The consumer pays for the safety, if you like, and for the use of the chemical".[194] **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.**

Downstream users and distributors

133. Nigel Smith of the British Retail Consortium (BRC) said that there was a lot of confusion in the sector.[195] Mike Barry from Marks and Spencer told us that his company sold 34,000 products and that the effort of tracking these products across the globe imposed a huge burden. He wanted to see "one, trusted, robust system in the middle for us all to use and share the costs across".[196] Nigel Smith explained that retailers wanted certainty and that the BRC was trying to be proactive, ahead of REACH, by drawing up a

190 Ev 105

191 Ev 92

192 Ev 87

193 Speech to DEFRA's New EU Chemical Strategy Stakeholder Consultation Conference, 27 April 2004

194 Q 34

195 Q 61

196 Q 26

list of 25–30 chemicals that needed to be addressed in the supply chain.[197] Mike Barry explained that while consumer awareness of the legislation is "virtually nil", he is concerned by the prospect of an increasingly fickle consumer and he would rather spend now to put a trusted system of regulation in place than wait for a reaction in a few years' time. Mike Barry drew parallels with foot and mouth, for which the costs of addressing the problem were far in excess of the actual health risk.[198] He described REACH as "hugely imperfect [but] … the least bad option that people are offering me at this moment in time".[199]

134. The BRC, in its response to the Commission's internet consultation, believes that the obligations on retailers as downstream users and vendors of articles are likely to lead retailers towards reconsidering the manner in which they source products, switching their buying patterns in favour of EU importers rather than importing directly from manufacturers based outside the EU in order to ensure compliance with REACH at reasonable cost (leading to the increased cost of products to the consumer). The BRC sought clarification on whether retailers would be considered as downstream users. This would affect their REACH obligations.

135. The BRC states in its consultation submission that "If a substance is already registered in REACH it should be possible for other importers to make use of a very simplified Registration process, which demonstrates that use of the chemical is consistent with the rules, restrictions and purity of the existing Registration, but does not require submission of a chemical safety report or any additional data. This will reduce the burden of administration for the Agency and the importer, though careful consideration would be required on how to share costs with the original registrants".[200]

136. Leigh's Paints points out that the coatings industry operates on extremely low margins. It reports that the industry uses 10,000 chemicals to make 500,000 products and the company is concerned about the costs incurred in producing risk assessments in each case. It suggests that a single risk assessment could result in a document of up to 150 pages.[201] The Society of Motor Manufacturers and Traders (SMMT) reflects many of the concerns among downstream users of chemicals. It points out that they will be responsible for demonstrating the safety of chemicals and disclosing the information to the public. While it recognises the public's right to know the hazards associated with chemicals, it argues that the flow of information should impose as little burden on downstream users as possible. As an example, the SMMT points out that an average vehicle comprises 10,000 substances. [202] The SMMT has particular concerns about the need to specify uses of chemicals. Currently, the Proposals state that downstream users must either inform producers or importers of their intended uses or submit a Registration of their own. The

197 Q 63

198 Q 67

199 Q 68

200 British Retail Consortium Submission to Reach Regulation Public Internet Consultation, July 2003

201 Ev 56

202 Ev 104

SMMT would rather see standardised exposure categories used as it sees three problems with the proposed system:[203]

a) Confidentiality. Downstream users may not want their suppliers to know how a particular substance is used.

b) Flexibility. Downstream users may want to use a substance for a specific use not originally communicated to the supplier of chemicals.

c) Workability. A small European firm, which lacks relevant staff time and training, may find it impossible to communicate all the uses of a substance to an overseas importer of chemicals.

Accession countries

137. The turnover of the chemicals industry in the accession countries is estimated at some €16 billion (roughly 4% of the production of the EU15).[204] Opinion is divided over whether these countries are well prepared to implement this legislation. One view is that they already have regulatory mechanisms and bodies and that adapting to EU legislation will not cause too many problems. Conversely, there is concern that awareness is low. Public bodies from only three of them – Latvia, Lithuania and Poland – made a submission to the internet consultation. The Minister told us that the accession countries were "slightly nervous about REACH".[205] Dr Delbeke from DG Environment told us that "The accession states have a fairly limited chemical sector… But we know that generally, in the field of the environment, the higher your income is, the higher the concern is with your health… I would invite you to contribute your concern for that into the awareness raising and the general attitude towards the environment which is quite different there".[206] The implication is that the poor people in the accession countries are less concerned by health and the environment issues but this does not mean that EU law should not protect them. **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.**

Effects on innovation

138. Following the internet consultation, the Commission made new provisions for innovation. Article 7 states that substances used for product—and process–orientated research and development will be exempted for up to 5 years. There is no explicit exemption for scientific R&D below 1 tonne per year because production, import and use of substances is already outside the scope of the Registration obligation. The Commission lists on its website the ways in which the Proposals fulfil the objectives of REACH to promote R&D and innovation:

203 Ev 105

204 European Commission, REACH Extended Impact Assessment, October 2003, section 4.1

205 Q 298

206 Q 148

a) Uses of substances in product—or process–oriented R&D do not need to be registered for up to 5 years, renewable for a further 5 years (For substances used in medicinal products, the maximum total exemption is 15 years).

b) The REACH threshold for registration (1 tonne/year) is much higher than the 10 kg threshold for new substances under the existing legislation.

c) The costs of registering a new substance will be significantly lower than the current cost of notification.

d) Registration will be quicker than the current notification, thus reducing the time to market.

e) The requirements for Authorisation should encourage companies to increase their search for safer substitutes.

f) The discrimination against new substances versus existing substances will come to an end.

139. Despite this, concerns have been expressed about the likely impact of the Proposals on innovation. These fall into four categories:

- Loss of intellectual property rights;
- Cost of new Registrations;
- Restrictive provisions for R&D; and
- Decreased competitiveness will lead to reduced R&D investment.

140. Leigh's Paints argues that uncertainty over IPR will be a disincentive. It also points out that the protection of new chemicals only lasts while R&D is in progress, and thereafter when production is in small quantities. New chemicals will only be developed if the predicted market is likely to be large, it suggests. [207] The CIA believes that, under REACH, there are instances in which confidential information could become public: the classification and labelling inventory, the sharing of data within consortia, and in the Chemical Safety Report.[208] In principle we support a presumption of openness. Given current concerns about the impact of reduced IPR protection it is important that companies can withhold data in some cases. This should be subject to review.

141. The CIA argues that different regulatory environments give rise to contrasting levels of innovation. It points out that, between 1987 and 1996, EU companies notified 274 new chemicals per year, Japanese companies made 265 notifications annually, and the number of new chemical substances notified per annum in the USA was 1,720.[209] Few would dispute the potential impact of regulation on innovation but these figures should be used with caution. At the very least they present an argument for change, which is just what is happening.

207 Ev 56

208 Ev 69

209 Ev 68

142. Depending on the enforcement of substitution, REACH should provide increased pressure on producers to develop new chemicals.[210] According to the Environmental Industries Commission (EIC), this presents opportunities in R&D. These include work to:

a) Establish the properties of chemicals and formulations;

b) Establish the environmental fate and behaviour of chemicals and formulations;

c) Establishment of environmental quality standards;

d) Monitoring of chemicals in the environment;

e) Develop new test methods in environmental toxicology; and

f) Develop, validate and apply QSARs.

143. The CIA believes that the provisions for R&D into new chemicals are too restrictive: "Research and development substances should have neither weight thresholds nor time limits as long as specified criteria are met, documented and retained for future inspection".[211] The Royal Society of Chemistry is concerned that the Commission's Proposals to encourage innovation focus on substitution as a driver. It argues that substitution is unlikely to lead to truly innovative products that contribute to the profits needed to underpin sustainable development.[212] Andrew Lee from WWF insisted that "strong regulation will drive innovation because it will create a guaranteed market for safe chemicals in the future".

144. Little of the evidence we have received focuses on the impact of REACH in the context of existing legislation. Mike Barry from Marks and Spencer told us that the current regulation stifled innovation. While there were large numbers of chemicals the company would like to use in its products, it was unsure of the reaction from consumers.[213] The Department of Trade and Industry's (DTI's) Chemicals Innovation and Growth Team concluded that while the UK chemical industry has a long tradition of innovation, its recent record was less strong.[214] **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.**

145. The EIC concludes that the Government "should review spending of research and development to ensure the UK is well placed to make the most of this business opportunity". It suggests the formation of a UK Centre for Chemicals Management, established as a centre of expertise to help ensure that the UK benefits from the business opportunities provided by REACH. We agree with this suggestion. In addition, the Government should complement this with measures to strengthen academic chemistry

210 Ev 61

211 Ev 69

212 Ev 87

213 Q 54

214 Department of Trade and Industry, *Enhancing the Competitiveness and Sustainability of the UK Chemicals Industry,* a report by the Chemicals Innovation and Growth Team, December 2002, p 37

and chemical engineering. **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.**

Health and environment

146. There is increasing evidence that background pollution is having health and environmental effects. The EC's Extended Impact Assessment (EIA) noted that chemicals are linked with a considerable number of diseases including respiratory and bladder cancers, leukaemia, mesothelioma, skin disorders, respiratory diseases, eye disorders and allergies. It states, however, that there is frequently not enough information to be clear about the epidemiology, making it very difficult to link many so–called "modern diseases" to particular chemicals.[215]

147. The EIA found that while gaps in data prevented a comprehensive quantitative picture of the environmental impacts of chemicals, it concluded that "the impacts of chemicals on the environment are potentially large".[216] The Scientific Alliance expresses doubt over the projections for health improvement, based on assumptions made about the negative effects of chemicals and the economic benefit of reducing them.[217]

215 Q 109

216 European Commission, REACH Extended Impact Assessment, October 2003, section 6.2

217 Ev 101

Table 1: Examples of types of environmental impacts

Observation/impact	Species	Substance**	Association*
Large–scale effects			
Eggshell thinning	Guillemot, eagle, osprey, peregrine falcon	DDT/DDE	5
Reproduction	Seal, otter	PCB	4
Skeletal malformation	Grey seal	DDT, PCB	4
Pathological changes	Seal	PCB, DDT, metabolites	3
Reproduction	Mink	PCB	5
Reproductive disturbances	Eagle	DDT, PCB	2–3
Reproduction (M74 syndrome)	Salmon	Chlorinated substances	2
Imposex	Molluscs e.g. dog whelk	TBT	5
Impairments in wildlife in relation to endocrine disrupting chemicals			
Sperm quality, cryptorchidism	Panther		2–3
Population decrease	Mink, otter		2–3
Female reproductive disorders,	Seal		4–5
Eggshell thinning	Birds		4–5
Embryotoxicity and malformations			4–5
Reproductive behaviour			2–3
Microphalli and lowered testosterone	Alligators		3–4
Vitellogenin	Fish		4–5
Masculinisation			3–4
Reduced testis size			2–3
M74 and early mortality syndromes			1–2
Imposex	Molluscs		5

Source: Extended Impact Assessment, European Commission, {COM(2003)644 final}. Original data from European Environment Agency, 1998 (large–scale effects); Swedish EPA, 1998 (impairments in wildlife in relation to endocrine disruptors.

*1 = no observed association, 2 = suspected association, 3 = weak association, 4 = clear association, 5 = significant association.

**DDT = 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane; DDE = 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene; PCB = Polychlorinated Biphenyl; TBT = tributyl tin

148. The UK Environment Agency argues that REACH will help to generate data that are useful in targeting monitoring programmes. It is also concerned that existing systems will not prove adequate for identifying substances of concern to the environment.[218] **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.**

149. Most of the benefits arising from the REACH Proposals are expected to be as a result of a substantial reduction in occupational diseases. The WWF reports that "dangerous substances currently contribute significantly to the 350 million days lost through occupational ill health, and to the 7 million people suffering from occupational illnesses".[219] We have listed some of the health and environmental impacts in Table 1. WWF points out that the "full extent of the problem is unclear because adequate toxicity data are only available for a small percentage of the many thousands of chemicals in everyday industrial and domestic use".[220] A report commissioned by WWF concluded that the health benefits could result in savings of £180 billion across Europe, with £50 billion in the UK alone. (These estimates were based on the consultation text and the WWF says that the Proposals have been "watered down" to the extent that benefits on this scale will not be realisable.[221]) The Commission's extended impact assessment suggests that "the total health benefits would be in the order of magnitude of €50 billion over the next 30 years" based on a 0.1% reduction in the burden of disease. The Commission stresses that this figure is not an estimate of the benefits of REACH, but rather an illustration of their potential scale".[222]

150. CIA has "serious doubts about the magnitude of the benefits being claimed".[223] Calculations are necessarily dependent on the validity and reliability of the testing regimes.[224] The Scientific Alliance argues that projections for health improvements are extremely doubtful, both in terms of the dubious assumptions made about the negative effects of chemicals and the net economic benefit of reducing them.

Further impact assessments

151. Industry has expressed the view that the impact assessments performed so far have been inadequate and that a further study is necessary. The CBI argues that "The impact assessments performed to date … have taken a limited and closed view of the impact on European businesses" and that the extended impact assessment does not reflect:

a) the effects on downstream users of the loss of certain substances from the supply chain;

b) the effects of increased competition from outside the EU; and

218 Ev 62

219 Ev 81

220 Ev 22

221 Ev 82

222 European Commission, REACH Extended Impact Assessment, October 2003, section 6.3

223 Ev 68

224 See paragraphs 93–97

c) the increased costs associated with the implementation of the REACH system.[225]

152. The CIA agrees, arguing that an independent third party should conduct a new study.[226] We pressed the CIA about from whom such an independent study could be commissioned. Judith Hackitt told us that "I think there are any one of several consultants out there who could do the impact assessment. I think it is immaterial to us in industry who does that".[227] We do not doubt that many consultants have the competency to do such a study but our scepticism is based on the fact that the impact assessments conducted so far have tended to support, very conveniently, the views of the commissioning organisation. There is a real danger that any future impact assessment would be dismissed by anyone whose views it did not support. Commissioner Liikanen is right to suggest that it is first necessary to get broad agreement on the methodology to be employed before the study has started.[228] This begs the question as to why this was not done before the Commission's Extended Impact Assessment was undertaken. **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.**

153. In 1998 the Prime Minister announced that no proposal for regulation which has an impact on business, charities or voluntary bodies, should be considered by a Ministers without a regulatory impact assessment (RIA) being carried out. A "draft partial" RIA was published in March 2004 with the Government's consultation.[229] This estimates a direct cost to UK industry of £515 million, and £2.4 billion total for the EU as a whole.[230] This follows a first partial regulatory impact assessment by the Government on the White Paper published in May 2001.[231]

154. The WWF argues that, while there will be costs to industry, the benefits in terms of environment and health will outweigh this and cites studies concluding that the industry has overstated the costs.[232] The Commission estimates total current worst case costs of REACH, both for producers and downstream users, to be €5.2 billion spread over the phase–in period of REACH, with health benefits roughly estimated to be €50 billion over 30 years. A report commissioned by WWF, suggests that the value of the health benefits could be far higher, and easily exceed €100 billion.

155. Dr Delbeke from DG Environment told us that the Commission "sometimes feel a bit sorry that the debate is focusing too much about the costs and possible problems than about the benefits".[233] He went on to tell us that the Proposals were guided by the results of

225 Ev 91

226 Ev 68

227 Q 219

228 Q 169

229 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy—REACH*, March 2004, para 12

230 DEFRA, *UK Consultation paper on the New EU Chemicals Strategy—REACH*, March 2004, p 62

231 Q 259

232 Ev 80–81

233 Q 108

the cost analysis, in which case, it is not surprising that this has continued to be a source of contention.[234] It was pleasing to hear Dr Delbeke reveal that the subject was not closed and that the Commission would be establishing a round table involving all the players to establish a more sophisticated understanding of the impacts on industry.[235] We sympathise with suggestions that further impact assessments should be undertaken but endorse Commissioner Liikanen's comment that "the easiest political initiative is to say that you should do more counting".[236] **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.**

9 Role of stakeholders

The Commission

156. The Commission set out its policy on chemicals in its White Paper published in February 2001, following a number of stakeholder meetings. Mike Barry from Marks and Spencer felt that there was insufficient discussion beforehand: "the retail sector … was insufficiently consulted when REACH was being drafted. Since the REACH draft was put on the internet consultation has been very good but, in effect, the words had been written in tablets of stone by then".[237] This is confirmed by Dr Colin Church at DEFRA, who told us that he suspected that alternatives to REACH were not discussed widely before publication of the White Paper: "the Commission's openness to discussing this with Member States and other stakeholders has increased dramatically over the last three or four years from a position of traditional – if I may put it this way – 'It's our job, leave us to do it' to a much more open and engaged process".[238] Dr Delbeke from the Environment Directorate General told us that engaging with stakeholders was not easy as some players only start to take an interest when there are firm Proposals on the table. It took a while for downstream users to realise that there was an issue for them and make the effort to assess the impact for their companies.[239]

157. The consultation document published by the Commission in May 2003 attracted a large number of responses. Commissioner Liikanen told us that the changes as a result of the internet consultation were "the biggest ever in the Commission's history" and defied us to identify a piece of UK legislation for which there had been wider consultation.[240] As a result of the submissions, the Proposals are considered by many, including the UK Government, to have moved some distance in making the legislation workable.[241] Thus the

234 Q 118

235 Q 116

236 Q 169

237 Q 54

238 Q 293

239 Q 115

240 Qq 176–179

241 Ev 52, Ev 85

changes have been more welcome in industry quarters than among the environmental NGOs. The CBI says that "significant improvements have been made to the proposal since the '2003 internet consultation'".[242] The CIA says that the text in the consultation would result in an "unrealistic system [that] would seriously damage the EU's attractiveness as a location for the chemical industry and all its customer industries in the manufacturing supply chain. Whilst the revised legislation … demonstrates some progress towards a more sensible scope for the legislation, [the Commission has] not addressed the fundamental issue of workability".[243] Submissions from industry have generally indicated that more progress is needed. Leigh's Paints argues that "the measures set out in the White Paper are more likely to achieve the direct opposite of the stated objectives, despite efforts in the latest revision to 'tone down' some of the more onerous requirements".[244]

158. The WWF is less positive about the value of the consultation. Andrew Lee told us that it was industry that dominated and that "the cost and workability arguments have been given too much weight and the regulation has already been watered down to a level where it is in danger of not delivering what it needs to do".[245] Greenpeace says it is "concerned that in its current form it is unlikely to deliver any real benefits, either in terms of protection of health and the environment, or of stimulating innovation towards safe chemicals… as drafted, REACH will permit continued manufacture of toxic substances that accumulate in the human body even when a safer alternative is available".[246]

159. **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.**

Enterprise and Environment

160. The REACH legislation is unusual in Europe for having two Directorate Generals – Environment and Enterprise – involved. The missions of these Directorates are distinct:

- According to the Enterprise DG, "Our role is to help create an environment in which firms can thrive, for example by helping facilitate access to markets and promoting entrepreneurship and innovation".[247]

- The Environment DG's mission statement is:

— To promote sustainable development, preserving the rights of future generations to a viable environment;

242 Ev 91

243 Ev 66

244 Ev 55

245 Qq 41–42

246 Ev 57

247 europa.eu.int/comm/dgs/enterprise/index_en.htm

— To work towards a high level of environmental and health protection and improvement of the quality of life;

— To promote environmental efficiency; and

— To encourage the equitable use, as well as the sound and effective management, of common environmental resources.[248]

161. Dr Delbeke acknowledged that there were tensions between economic and environmental/health concerns and described the "heated discussions" with his opposite number in the Enterprise DG, particularly concerning impact assessments. There is a danger that Enterprise and Environment are seen, at least, as representing the interests of industry and the green NGOs respectively. Dr Delbeke indicated that there was some truth in this but that both DGs realised that it was important that they could buy into the same product and that compromises would have to be made.[249] Dr Delbeke's candour is welcome and gives us more confidence that his DG is showing admirable pragmatism in its approach to the legislation.

UK Government

162. The UK has played an important role in the development of the legislation. We have already noted that the process was initiated at the Council of Environment Ministers in Chester during the UK Presidency in 1998. DEFRA is the lead Department on the legislation and WWF congratulates it on having "invested much time, effort, and expertise, in co–ordinating the views amongst the different Government departments, and in synthesising the views of different stakeholders".[250] The WWF describes the Government as a "powerful positive force for change" but expresses concern about the DTI's "increasingly pro industry hard line". The EEF supports the DTI's downstream users' group but has complained that DEFRA has not included all industry groups in its consultations.

163. The Prime Minister has taken an interest in the legislation. On 20 September 2003, he wrote a joint letter, with President Jacques Chirac and Chancellor Gerhard Schröder, to Romano Prodi, President of the Commission. In particular, the letter expressed concerns that:

a) The legislation was too costly and bureaucratic;

b) There was insufficient prioritisation of the handling of chemicals.

164. The WWF argues that the Prime Minister's signature on the trilateral letter to the President of the Commission demonstrates that the UK is "prioritising the concerns of a

248 europa.eu.int/comm/dgs/environment/index_en.htm

249 Qq 130–131

250 Ev 83; Several other Departments have strong interests, including the DTI, the Health and Safety Executive, the DoH and the Environment Agency.

dinosaur industry over and above the needs of human health".[251] The trilateral letter is said to have had a significant effect on the development of the Proposals.[252]

165. WWF has expressed concern that the Department of Health and the Health and Safety Executive have given little support to the new legislation: "It is a well–known fact that the vast majority of substances traded in the EU do not have available adequate toxicity data to make even a basic risk assessment". WWF also laments the lack of visibility of the Department of Health.[253] Dr Church denied that these Departments' input had been inadequate and described a "series of concentric rings of interested departments and agencies". He said that "the HSE is part of the inner ring …, as is the Department of Health …[which] has been superb in offering us advice on some of the testing issues, some of the general public health issues. The Health and Safety Executive have a lot of experience because they run the new substances regime, so they have been giving us expertise there".[254]

166. Andrew Lee from Greenpeace told us "Whilst behind the scenes we hear a lot of very clear and good messages from DEFRA, when the Prime Minister intervenes we see criticism, with the government seeing this as a problem and a barrier".[255] We asked Mr Michael about the role different Departments have played, only to be accused of indulging in "the time honoured sport of trying to put pieces of cigarette paper between either the Prime Minister and other Ministers or between Government Departments". We fully admit to testing joined up Government: the Minister should recognise that presenting a disjointed and inconsistent negotiating position is unhelpful, not least if the Prime Minister expresses views that are distinct from the lead Department, if only in tone.

167. **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.**

10 Conclusion

168. Opinion is divided on the current Proposals. While industry continues to argue that they remain unworkable, environmental NGOs claim that further concessions to industry risk undermining the legislation's effectiveness while still imposing most of the burden. We have taken a pragmatic approach to this legislation, to look at how the current Proposals can be optimised in terms of health, environment and industrial competitiveness. REACH is not perfect but any regulation is a compromise between competing demands. We share the view that it is better than the current EU legislation. There are concerns that the more risk–based approaches to regulation in Japan and the USA have not been effective in protecting human health and the environment from toxic substances. We conclude that the Proposals offer a good basis for negotiation during the co–decision process and have highlighted areas of concern; for example, we would like to see a pre–Registration system

251 Ev 32

252 Q 117

253 Qq 43–44

254 Q 295

255 Q 40

to identify substances of high and low concern and prioritise their Registration accordingly. At the Evaluation stage, we would like to see stronger oversight by the European Chemicals Agency. We have not been convinced by the arguments of the environmental NGOs that the current Proposals create insufficient provision for the substitution of chemicals of concern. The predicted impact of the Proposals has been extremely contentious and we believe that a further impact assessment will be necessary to give all stakeholders confidence in the legislation.

169. We agree with the Minister for Rural Affairs and Local Environment Quality that "a number of changes have been made which are moving towards more workability but I think further improvements are necessary".[256] The UK Government has adopted, for the most part, a sensible position, which we attribute to a refreshingly objective stance to legislation. We urge it to argue its case strongly at the Council of the European Union and to use its influence when it assumes the Presidency in the second part of 2005.

256 Q 256

Conclusions and recommendations

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)

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)

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)

4. 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)

5. 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)

6. 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)

7. 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)

8. 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)

9. 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)

10. 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)

11. 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)

12. 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)

13. 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)

14. 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)

15. 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)

16. 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)

17. 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)

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

19. 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)

20. 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)

21. 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)

22. 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)

23. 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)

24. 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)

25. 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)

26. 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)

27. 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)

28. 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)

29. 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)

30. 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)

31. 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)

32. 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)

33. 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)

34. 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)

Formal minutes

Wednesday 5 May 2004

Members present:

Dr Ian Gibson, in the Chair

Paul Farrelly	Dr Evan Harris
Kate Hoey	Dr Brian Iddon
Mr Robert Key	Dr Desmond Turner

The Committee deliberated.

Draft Report (Within REACH: the EU's new chemicals strategy), proposed by the Chairman, brought up and read.

Ordered, That the Chairman's draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 169 read and agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.

[Adjourned till Wednesday 12 May at a quarter past nine o'clock.

Witnesses

Written Evidence

Reports from the Science and Technology Committee since 2001

Session 2003-04

First Report	Annual Report 2003	HC 169
Second Report	Chief Executive of the Medical Research Council: Introductory Hearing	HC 55
Third Report	The Work of the Biotechnology and Biological Sciences Research Council *(Reply HC 526)*	HC 6
Fourth Report	Office of Science and Technology: Scrutiny Report 2003	HC 316
Fifth Report	*Too Little too late?* Government Investment in Nanotechnology	HC 56

Session 2002–03

First Report	The Work of the Particle Physics and Astronomy Research Council *(Reply HC 507)*	HC 161
Second Report	Annual Report 2002	HC 260
Third Report	The Work of the Medical Research Council *(Reply Cm 5834)*	HC 132
Fourth Report	Towards a Non-Carbon Fuel Economy: Research, Development and Demonstration *(Reply HC 745)*	HC 55-I
Fifth Report	The Work of the Natural Environment Research Council *(Reply HC 1161)*	HC 674
Sixth Report	UK Science and Europe: Value for Money? *(Reply HC 1162)*	HC 386-I
Seventh Report	Light Pollution and Astronomy *(Reply HC 127, 2003-04)*	HC 747-I
Eighth Report	The Scientific Response to Terrorism *(Reply Cm 6108)*	HC 415-I
Ninth Report	The Work of the Engineering and Physical Sciences Research Council *(Reply HC 169, 2003-04)*	HC 936

Session 2001-02

First Report	Cancer Research – A Follow-Up *(Reply Cm 5532)*	HC 444
Second Report	The Research Assessment Exercise *(Reply HC 995)*	HC 507
Third Report	Science Education from 14 to 19 *(Reply HC 1204)*	HC 508-I
Fourth Report	Developments in Human Genetics and Embryology *(Reply Cm 5693)*	HC 791
Fifth Report	Government Funding of the Scientific Learned Societies *(Reply HC 53)*	HC 774-I
Sixth Report	National Endowment for Science, Technology and the Arts: A Follow-Up *(Reply HC 276)*	HC 1064
Seventh Report	The Office of Science and Technology: Scrutiny Report 2002 *(Reply HC 293)*	HC 860
Eight Report	Short-Term Research Contracts in Science and Engineering *(Reply HC 442)*	HC 1046