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Government Response  
August 2004



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Presented to Parliament by the Secretary of State  
for Environment, Food and Rural Affairs  
and the Chief Secretary to the Treasury  
by Command of Her Majesty  
August 2004

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## Introduction

The Royal Commission on Environmental Pollution's Twenty-fourth Report, *Chemicals in Products, Safeguarding the Environment and Human Health*, was presented to Parliament in June, 2003. The report sets out new approaches to the assessment and management of chemicals, and argues for better information about chemicals on the market, more intelligent testing, better use of monitoring, and early and effective action at a European level and on substitution.

The Government is grateful to the Royal Commission for its report, which is a significant contribution to the work underway in the UK to make stakeholder dialogue on chemicals of concern effective through the UK Chemicals Stakeholder Forum, and to prepare, with our European partners, for new European chemicals legislation known as REACH.

The Government and the Devolved Administrations published their consultation document on the UK Chemicals Strategy in February of this year, and will shortly be publishing their full response to the responses received. As well as setting out options for the future of the Strategy, this consultation highlighted some of the Royal Commission Recommendations of particular relevance to the UK Chemicals Stakeholder Forum, and invited comments from consultees on them. Where these were received they have helped to inform the Government's response. The Government and the Devolved Administrations have recently sketched out the main features of the future Strategy, and these are outlined in the Summary of Responses to the consultation published on the Department for Environment, Food and Rural Affairs' website at [http://defraweb/corporate/consult/synthetic-chemicals/summary\\_responses.pdf](http://defraweb/corporate/consult/synthetic-chemicals/summary_responses.pdf)

The Government and the Devolved Administrations also consulted on REACH earlier this year, and will be publishing their response to this consultation in due course.

This document provides the Government's formal response to the Twenty-fourth Report. The response summarises action being taken and proposed as it relates to the Royal Commission's Recommendations. The response groups the Recommendations thematically to minimise to as great an extent as possible the need for repetition. The Royal Commission's Recommendations are given in bold throughout.

## **Information gathering, sorting, testing, evaluation and management of chemicals and publishing information: Recommendations 1-17, 21-23, 27, and 28.**

### ***1. The Government should compile and publish a list of all chemicals currently marketed in the UK (4.14).***

A comprehensive and regularly maintained list of marketed chemicals would be a valuable tool. The Government welcomes the Chemical Industries Association's (CIA's) announcement that it has decided to develop and maintain a database of all chemicals marketed in the UK by CIA member companies.<sup>1</sup> This could be a useful tool to prepare the UK for the introduction of REACH, particularly if it is developed to include all chemicals marketed by industry in the UK.

The Government has been in contact with the Association about its plans for the database and is considering the scope for Government to lend its support to the development of it.

### ***2. The Government should put in place now sorting procedures for dealing with the backlog of untested chemicals to select a more manageable number that can be studied in greater detail. The sorting procedures should be informed by data already available and be based extensively on computational approaches to hazard assessments, using the US EPA and Environment Canada procedures as models where applicable (4.17).***

### ***21. We foresee reluctance on the part of some authorities to move from the traditional and slow testing protocols to the much more rapid and in many ways simpler, computer-based systems we propose. Therefore we recommend that the UK government, jointly with like-minded Member States, should press for an EU-wide initiative to demonstrate and promulgate the effectiveness of these techniques, and to secure their international acceptance through OECD (4.46).***

The Government is keen for modern computational and rapid screening techniques to be used to assist the process of assessing the environmental safety of chemicals. We support the concept of methodologies which will enable the rapid identification of the properties of chemicals and provide a means of prioritisation of chemicals for action.

The Government is a strong advocate of moving away from animal testing for chemicals and therefore supports the development of alternative techniques to establish the hazards of chemicals, as well as for screening purposes. Computational techniques, such as genomics, proteomics, metabonomics and computational chemistry or biology offer much potential. However, we are aware that at the current time, such techniques are not available for wide use. For such systems to be helpful to both industry and regulators they will need to be validated, widely accepted by stakeholders here and abroad, evidence-driven, and based on sound scientific principles. It is likely to be some time before computational techniques alone will be sufficiently developed to facilitate robust decision making. QSARs appear to be more accurate for environmental hazard endpoints than for human health endpoints. These techniques are used in the United States to indicate where testing on new substances may be needed. Over a period of time it has been found that the experimental data developed under EU legislation has raised concerns about individual chemicals that were not picked up by the QSAR screening. The chemicals industry should remain vigilant in this area and support research to develop assessment tools.

<sup>1</sup> Chemical Industries Association, 22 January 2004.

**3. *The Government should publish all necessary toxicity, persistence and bioaccumulation data on the Internet for all chemicals on the UK market, using the list we recommend in 4.14 (4.22).***

The Government agrees that publishing on the Internet a list of these chemicals together with their persistence, bioaccumulation and toxicity (PBT) data would represent a significant step forward in addressing the lack of information about chemicals. We support the Commission's call for a mechanism to ensure the provision of PBT data on all marketed chemicals, whether on the basis of experimental or computational methods, and look to the CIA's development of a database of all chemicals marketed in the UK by its members as a first step in this direction. The development of the database is in keeping with REACH's aim of shifting responsibility for the provision of data onto industry, and the CIA should aim to include PBT data for the chemicals on its database as soon as possible, and, in any case, well ahead of the legislative deadlines under REACH. Such a database would help British industry to prepare for the forthcoming legislation by promoting data sharing and providing information valuable to downstream users and other stakeholders. It would also assist chemical users seeking to identify safer substitutes and stimulate innovation.

**4. *New legislation should prohibit the marketing of any chemical for which these basic environmental safety data have not been registered on the list (4.21).***

The introduction of "no data, no market" will be a key benefit of the REACH system and is an important element in increasing transparency under the new European legislation. The Government is working with the European Commission and its Member State partners to ensure that the registration system under REACH is appropriately robust. In anticipation of REACH, the Government is also working closely with industry to ensure that it becomes familiar with the requirements of the legislation prior to its implementation.

REACH is not expected to come into force for some time, and its implementation will be phased in over at least a decade. In the case of chemicals produced in quantities of 1-10 tonnes per year, for example, there will be an 11 year implementation period. Meanwhile, the existing regulatory regime will remain in force. Furthermore, given the data-gathering focus of REACH, it seems sensible to make every reasonable effort now to prepare for it, in terms of industry providing information about the chemicals they use. Such a preparatory initiative should in the long-term help smooth the path for compliance with REACH.

In this situation, the Government considers that the rationale for voluntary action to fill in the considerable gaps in our knowledge about chemicals remains persuasive. We will continue with this approach for identifying chemicals of very high concern taking into consideration advice from the UK Chemicals Stakeholder Forum and the Advisory Committee on Hazardous Substances. Where appropriate to do so, the Government will take action to manage the risks arising from the production and use of chemicals with these properties, as with the recent announcement that action is needed to phase out the use of PFOS in this country.

We doubt whether it would be practical to develop and agree a new interim system within the time-scales expected before the introduction of REACH. This would require new EU-wide legislation that would distract regulators and governments from their focus on the development of the new legislation for REACH.

**5. A key prerequisite in the sorting procedures is to define the standards on the basis of which a conclusion can be drawn that a chemical is 'of concern' (4.25). The standards should be reviewed regularly, through an inclusive process taking into account public views, and adjusted accordingly (4.26).**

Identification of criteria of concern has been part of the UK Chemicals Strategy. The UK Chemicals Stakeholder Forum, having examined work done in the EU and elsewhere, has developed criteria to identify such chemicals based on properties of persistence, bioaccumulation potential and toxicity. This includes criteria for very persistent and very bioaccumulative chemicals which might be expected to accumulate in the higher trophic levels of the food web. The Forum has published a list of high production volume chemicals meeting its criteria for concern. It has engaged with industry which has come forward with data on the properties and uses of the chemicals on the list. The list has also been used as a basis for drawing up a timetable for detailed consideration of chemicals leading to the provision by industry of detailed information about the chemicals as well as action to gather more data about the risks and hazards and to take risk management action. All of this has been done in an open and transparent manner with full publication of Forum papers on the Internet and meetings open to the public. This approach based on scientific evidence has been coupled with a full public consultation on the future of the UK Chemicals Strategy and the UK Chemicals Stakeholder Forum. The Government's consultation was, in part, in recognition of the fact that despite the dedicated work of Forum members, and the contribution of those industry stakeholders who have engaged with it, progress on individual chemicals has been slow. The Government's full response to its consultation is being published shortly, and an outline of the way in which the Government has decided to reorient the Forum's work on the basis of the consultation is found at the response to Recommendations 18 to 20 below.

**6. Once standards are defined, sorting of chemicals to identify those of concern becomes an automatic process. The resulting putative list of selected chemicals should be shared with other countries and their observations used to inform the process (4.27).**

The Government supports the sharing of appropriate information between countries in order to facilitate the management of chemicals. We believe that such measures should, to be most effective, be carried out at international level, for instance through cooperation at the EU, OECD and UN. The introduction of REACH will ensure that adequate information is available for chemicals produced and supplied in the EU above one tonne per year. In order to make progress towards achieving the sound management of chemicals globally, it will be important that appropriate information gathered under REACH is available to other jurisdictions. We therefore welcome the European Commission's proposal to include a specific provision to facilitate the sharing of information gathered under REACH between jurisdictions.

In the meantime, the Government is already actively contributing to several international efforts to coordinate and identify chemicals of concern including the Oslo and Paris Conventions' (OSPAR's) work on selection of PBTs (DYNAMEC), and the identification of PBT chemicals under the EU's Interim Strategy being coordinated by the European Chemicals Bureau.

***7. The Government should carry out the sorting process on the listed chemicals within three years, and annotate the list to show those exceeding the sorting criteria (4.28).***

As indicated above, the Government believes that the announcement by the CIA that it intends to produce a database of all chemicals marketed in the UK by its members represents an opportunity for industry to prepare for REACH by expanding this to be as exhaustive as possible and to include the hazardous properties of each as this information becomes available. In addition, the Government has decided to reorient the UK Chemicals Stakeholder Forum to engage with industry in a new way following its recent consultation. This is outlined in the response to Recommendations 18 to 20 below, and is expected to result in the speedier provision of missing data by industry.

***8. Chemicals found in unexpected environmental compartments or at unexpected concentrations, or associated with unusual biological phenomena, should be selected for further investigation (4.30).***

The Government agrees that chemicals found in unexpected locations or at unexpected levels should be selected for further investigation. This is already happening. For example, pentabromodiphenylether (pentaBDE) which has been detected in breast milk, and perfluorooctane sulphonate (PFOS) found in human blood samples, have been examined and the Government has recently announced that action is needed to phase out the use of PFOS in the UK.

The unintended presence of a substance in an environmental compartment or animal tissue should be sufficient to warrant further investigation, in particular collection of further data in order to identify its source, pathway and potential impact, and possibly information on trends over time. That said, presence alone would not generally be sufficient to prompt immediate regulatory control (such as its removal from the marketplace) without an assessment of the risk posed and consideration of risk management options, while taking a precautionary approach to avoid unnecessary delays.

***9. Chemicals selected by the sorting process or identified through environmental monitoring as 'of concern' should be categorised according to their degree of potential risk on the basis of agreed criteria, to determine the level of risk management or charge to which they should be subject (4.34).***

Once basic information is available on chemicals, the Government believes that there is a need to ensure that further evaluation of chemicals is prioritised so that those of most concern are investigated first. This is very important if we are to best use the limited resources available to both the authorities and industry.

The detailed evaluation under REACH of all of the approximately 30,000 chemicals supplied in quantities greater than 1 tonne in the EU would require vast amounts of resources compared to the benefits that this process would deliver and would not be achievable within an acceptable time-scale. There is, therefore, a need to focus the effort on those substances which, through

their continued use, may present a risk to human health or the environment and where further information may be necessary to assess the potential risks. This is the reason that the Government strongly supports a prioritised system of evaluations under REACH based on an initial screen of hazard, exposure and tonnage information supplied in the registration package. The initial screening would identify and prioritise chemicals for further action quickly and easily. Those of highest concern would move straight to authorisation, requiring specific permission for each use on the basis of the risks they present and societal need for them. Chemicals giving rise to a lower level of concern would progress to tiered risk assessment and, if necessary, risk management. We believe that, if adequate prioritisation is included in REACH, the system can be made workable and will deliver a rapid and efficient way of evaluating substances of most concern whilst delivering the benefits to human health and the environment that we want to achieve.

***10. All new chemicals should be considered as potentially harmful and evaluated with chemicals of concern (4.31). This would reflect the fact that they have not yet been released into the environment and we know little about them. The investigation of all in this category of concern would be overseen by the agency.***

We support the Royal Commission's desire to see new chemicals examined in-depth before going on to the market. All chemicals newly placed on the market are currently examined in far more depth than those which have been around for many years. There is a requirement to provide basic information (varying according to tonnage) on all new chemicals placed on the EU market in quantities greater than 10 kg per year. This compares to the majority of existing substances (i.e. those not covered by Regulation (EC) 793/93) where no basic information is required for continued supply. Although the current EU system for new chemicals is widely considered to be effective, there is a perceived imbalance of resources towards regulating new substances (which account for approximately 1% of the total tonnage of chemicals on the EU market). One of the aims of the REACH proposals is to ensure that all substances, whether new or existing, are subject to the same requirements.

***11. We recommend that the government should ensure that 90% of the chemicals selected by sorting have been evaluated and categorised within three years of selection (4.24) (4.35).***

As mentioned above, the Government strongly supports a prioritised system of evaluations under REACH, to allow chemicals of highest concern to proceed straight to authorisation. As well as working with our European partners to achieve the most rapid and efficient system of evaluating substances possible under REACH, the Government has recently announced changes to the way in which the UK Chemicals Stakeholder Forum examines the chemicals on its list of chemicals of concern. More on this change designed to make evaluation and agreement on voluntary risk management action effective in the UK in the run-up to REACH can be found in the response to Recommendations 18 to 20 below.

**12. In evaluating chemicals, all practicable steps should be taken to avoid the use of higher animals as test organisms, and decisions to move to such tests should be made on a case by case basis following transparent discussion (4.70).**

The Government shares the Commission's concern over the use of vertebrate animals in evaluating chemicals. There is a need to ensure that such testing has a sound scientific basis, using an intelligent rather than a 'tick-box' approach, and that every effort is made to minimise not only the amount of animal testing that is undertaken but also the suffering that is caused. An intelligent approach requires due consideration to be given to the use of existing data and the use of alternative approaches before any animal testing is considered.

With regard to REACH, the Government believes that vertebrate animal testing should be kept to the absolute minimum necessary to ensure that sufficient information is available for decision-making on health and environmental protection.

**13. We endorse the recommendation in the 2002 report by the House of Lords Select Committee on Animals in Scientific Procedures, that the government should be developing a strategy to fund the development and validation of replacements for animal tests (in vitro and in silico), possibly via a centre for the 3 Rs (4.71).**

The Government recognises the need for improved development, identification and dissemination of work that promotes the 3Rs. At the same time it acknowledges the necessity for validation of alternative methods and that this needs to be at international level. Both the European Centre for the Validation of Alternative Methods (ECVAM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) have made good progress in the validation of alternative methods.

The Government announced on 21 May 2004 the setting up of a national centre for the 3Rs and doubled funding to boost research on replacing, refining and reducing the use of animals in scientific research. The centre will be called The National Centre for the Replacement, Refinement and Reduction of Animals in Research and the lead responsibility will lie with the Office of Science and Technology. Funding for the 3Rs will be doubled from £330,000 to £660,000 for the current year with further increases expected thereafter. The Centre will have a board to provide strategic vision and direction and its first task will be to develop the centre's mission statement into a detailed action plan.

**14. The phase-out of animal tests for risk assessment of substances used in cosmetics and the international drive for acceptance of data derived from in vitro studies for cosmetic ingredients, using validated alternative methods as an initiative to gain regulatory acceptance of alternative methods on a global scale is welcomed. The government should press for wider application of this approach, using screening tests, existing data and computational techniques, together with in vitro studies, to describe the hazards of chemicals in all but exceptional cases (4.64).**

The Government fully supports effective alternative methods, such as screening tests, existing data, computational techniques and *in vitro* studies, that reduce the requirement for using animals for safety testing chemicals. Unfortunately, however, some vertebrate animal testing will still be necessary for some time for the safety assessment of chemicals, but the Government believes that it should be kept to the absolute minimum. We must ensure that sufficient hazard information is available on chemicals for decision making on the protection of human health and the environment, whilst at the same time avoiding unnecessary testing.

Any alternatives to the use of animals need to be adequately validated and accepted by regulatory authorities before they can be used as replacement tests. The Government supports the work in this context of the European Centre for the Validation of Alternative Methods (ECVAM) and their liaison with the International Co-ordinating Committee on the Validation of Alternative Methods (ICCVAM).

***15. Where synthetic chemicals are found in elevated concentrations in biological fluids such as breast milk and tissues of humans, marine mammals or top predators, regulatory steps should be taken to remove them from the market immediately (4.38).***

As stated above, in the response to Recommendation 8, the Government believes that the unintended presence of a substance in animal tissue should be sufficient to warrant the collection of further data to identify its source, pathway and potential impact, and possibly information on trends over time. That said, risk assessment and the consideration of risk management options, for example, as undertaken by the Government for pentabromodiphenylether (pentaBDE), need to be undertaken before decisions can be made on removing substances from the marketplace. A precautionary approach can be taken to avoid unnecessary delays.

***16. There will be some chemicals for which risk management action should be taken as a matter of urgency. The proposed chemicals safety co-ordination unit, (4.107-4.111), guided by a statutory advisory committee (4.45) and within a wider deliberate process (4.26), should indicate at an early stage, the criteria that will trigger a higher level of concern (4.39).***

The Government fully supports prioritisation as key to the functioning of an effective chemicals risk management programme, and has consulted on how to improve the efficiency with which the current regulatory structure in the UK operates. The UK Chemicals Stakeholder Forum criteria for chemicals of concern, as being persistent, bioaccumulative, and toxic; or very persistent and very bioaccumulative, guide its deliberations as predictors of the likelihood of environmental damage. These criteria were used by the Environment Agency to compile the Forum's list from a screen of the International Uniform Chemical Information Database (IUCLID), and the Forum's deliberations are aided by the technical expertise provided by the statutory Advisory Committee on Hazardous Substances. Employing these transparent criteria has led the Forum to recommend risk management action to Government on a number of substances and, while the process of agreeing action has proven slow, the recent changes to the way in which the Forum operates are discussed at Recommendations 18 to 20 below.

**17. The government should open discussions with other Member States with similar national approaches to chemicals management, and seek EU legislation to underpin a satisfactory listing, sorting and management scheme for chemicals (4.44).**

The Government is investing significant resources in working with its European partners and UK stakeholders to ensure that REACH is workable and efficient. As well as the importance of prioritisation under REACH, the Government is advocating one substance, one registration, in order to make the requirements of the system workable for both industry (and particularly small and medium-size businesses) and regulators.

While we believe that most of the Government's resources are best employed to influence the final shape of REACH, and at engaging with UK stakeholders on their hopes for and concerns about the legislation, we particularly welcome the announcement by the CIA of its intention to draw up a database of chemicals marketed in the UK. We believe this has the potential to prepare UK industry for the demands of REACH and be a significant tool for chemicals management in the future.

**22. The government should maintain pressure on the international community to achieve the goals of the Bahia Declaration leading to full arrangements for the exchange of information on hazardous chemicals regardless of their country of origin (5.100).**

The UK will continue to press for progress on the Bahia Declaration on Chemical Safety and the Priorities for Action beyond 2000 through the International Forum on Chemical Safety (IFCS). These high level agreements along with other international environmental agreements such as the Stockholm Convention on Persistent Organic Pollutants, the Rotterdam Convention on Prior Informed Consent, and the Basel Convention on the Transboundary Movement of Hazardous Waste, should form the basis of the strategic approach to international chemicals management.

**23. The government should continue to support and encourage greater international standardisation of testing and enhanced sharing of information in order to generate the required standard data set with minimal additional costs and animal test requirements. The government should also consider, together with other like-minded governments, whether to press for this work (and associated resources) to move from the OECD to a broader forum, perhaps UNEP (5.102).**

The Government supports the Royal Commission's views regarding the need for greater international standardisation of testing and information sharing. The UK Government is contributing to the development of agreed chemical assessments through both the OECD and UNEP and will continue to do so. We are also working to ensure that the already close co-operation between the two programmes is maintained. The OECD is the recognised international organisation for developing agreed test methods, and its "Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals" is recognised more broadly than amongst OECD Member Countries. It would therefore appear to offer the standard data set suggested by the Royal Commission, or, as a minimum, a good starting point. Given the OECD's positive track record, therefore, we do not see a case for moving the standardisation of testing to a broader forum such as UNEP.

**27. The chemicals safety co-ordination unit should commission and co-ordinate a programme of research to evaluate and keep under review rapid screening techniques to assess the environmental safety of synthetic chemicals. The chemicals industry, cooperating internationally, should play a central role in this work, including the provision of resources (4.117).**

As we stated in the response to Recommendations 2 and 21, the Government is keen for modern computational and rapid screening techniques to be used to assist the process of assessing the environmental safety of chemicals. We support the concept of methodologies which will enable the rapid identification of the properties of chemicals and provide a means of prioritisation of chemicals for action. The Government notes, however, that, at present, high-throughput screening techniques such as those used in the pharmaceutical industry are more effective at identifying substances that produce specific reactions, rather than the more complex issues surrounding the creation of assays relating to persistence, bioaccumulation, and chronic toxicity. We support the need for research in this area and would welcome industry taking a leading role. Such work might best be addressed as part of preparing for REACH.

**28. The chemicals industry should be encouraged to augment genomics research significantly, in a direction that will lead towards an understanding of the way that synthetic chemicals interact with biological organisms (4.119).**

The Government agrees with the Commission about the potential benefits of genomics to chemical risk management. The Government is participating in work by the OECD and the International Programme on Chemical Safety to explore the future application of toxicogenomics to test guidelines, chemicals, pesticides and biocides. Funding from the Department of Health has also helped to launch the UK Biobank Project, the world's largest study of interactions between genes and the environment in health and disease.

## **Administrative Arrangements: Recommendations 18, 19 and 20**

**18. The government should establish a chemicals safety co-ordination unit, by transferring resources (staff and budgets) from existing organisations dealing with chemicals safety to the Environment Agency (4.111).**

There is clearly scope for enhanced coordination and information sharing across administrations, departments and agencies dealing with risks from chemicals and we are taking steps to address this, for example, the recent decision to bring together work on pesticides and industrial chemicals within the same Directorate-General of Defra. However, it is not yet clear to us that some new single organisational structure is required to bring chemicals work together. Any such change would also need to accommodate arrangements for handling the new EU chemicals strategy. The Government has also not yet taken a view on whether the Environment Agency would be the correct home for such a body if it were to be created – we would need to look carefully at the degree of synergy with the Agency's other work and at how such a role might fit in with the Agency's wider strategy. The Government does, however, have an open mind on ways of further coordinating the full range of chemical issues and will take action to do so as appropriate.

**19. *The Chemicals Standards Forum should be mandated to provide advice on any topic within the unit's remit, and that the unit should be required to take such advice into account in making regulatory decisions about chemicals, or in advising Ministers or government departments on chemicals policy (4.113).***

The Government's consultation on the 1999 UK Chemicals Strategy and the future of the UK Chemicals Stakeholder Forum has examined the Forum's delivery of advice on the risk management of chemicals and chemicals policy generally to Ministers. The consultation period ended on 4 May 2004, and the Government has announced that it plans to reorient the Forum to provide advice to Ministers on REACH and to examine chemicals in groups. The aim of this reorientation is to ensure that the Forum's independent advice to Ministers across the range of chemicals issues is delivered as efficiently as possible in the future, and that the Forum has a voice in the important area of the new European chemicals strategy.

**20. *As part of the UK implementation of this statutory development, the Chemicals Stakeholder Forum should be reconstituted as a statutory advisory body to the chemicals safety co-ordination unit to enable it better to carry out the risk management role proposed in 4.29-4.35, and this should be reflected in a change of name to the 'Chemicals Standards Forum' (4.45).***

The Government does not believe that putting the UK Chemicals Stakeholder Forum on a statutory footing would enhance its ability to advise or the way in which that advice is taken forward. The Forum is comprised of a wide range of representatives of different organisations, many of whom bring their scientific expertise to its discussions, but it is not an expert group (The Forum can call on the resources of the Advisory Committee on Hazardous Substances for technical guidance). Since it was created, the Forum has been representative of the spectrum of views held in the UK on the issues it discusses, and its deliberations have been carried out in an open and transparent manner. The Government is currently reviewing the membership of the Forum to ensure that these qualities are retained in its changed role following the consultation.

## **Import of Substances and Preparations: Recommendations 24 and 25**

**24. *The government should press for a provision that all foreign manufacturers and importers who wish to import into the EU should be obliged to register the substances and preparations containing dangerous chemicals, and list what products these have been incorporated into, in precisely the same way as European manufacturers will be required to do (5.113).***

The Government supports the principles set out in the REACH proposal for treating imported substances and preparations in the same way as those manufactured in the EU.

We also believe that there is a need to consider finished products and articles produced and imported into the EU that potentially contain hazardous substances in the development of REACH. This is a contentious issue in relation to international trading obligations, and presents formidable enforcement difficulties. It is essential to find a solution that is proportionate to the risks, that is robust enough to deal with the legitimate concerns which we are seeking to address, and is the least burdensome for industry and regulators. The Government is actively working with stakeholders to develop solutions to this issue.

***25. The government should increase the resources available to customs authorities or agencies responsible for chemicals regulation, to identify and, where appropriate, restrict the import of products containing unregistered chemical substances (5.114).***

In order for Her Majesty's Customs and Excise to take action against goods entering the UK from third countries under the Customs and Excise Management Act 1979, there must be legislation in place creating a prohibition or restriction. This prohibition or restriction must be against the goods and must state that the importation of a particular good is prohibited. In this context, it is worth remembering that UK Customs are only able to take action against imports from countries outside the EU and have no control over intra-EU movement of goods. Some of the issues that would need to be addressed if Customs and Excise was to be given a more prominent role in the enforcement of rules governing products containing chemical substances include the identification of such products, the provision of relevant expertise, safe storage of any goods detained, funding, and health and safety.

## **WTO powers: Recommendation 26**

***26. In appropriate cases both the UK and the EU should make use of the powers already available under WTO rules to restrict the marketing or use of dangerous substances or products containing them even at the risk of challenges by overseas suppliers that such measures are indirectly discriminatory (5.115).***

The Government will consider any proportionate measures which are necessary to protect human health and the environment. We believe that these must not leave the EU exposed to challenges by another World Trade Organisation (WTO) member and, in the light of the WTO Doha Development Round Agenda, and in keeping with the principles of trade benefiting developing countries and poverty reduction, should aim to minimise problems for exporters in developing countries. Measures should not create barriers to imports to the EU, or disadvantage indigenous EU producers against imports and, equally important, should not create disadvantages for EU exporters. One of the Government's objectives in the REACH negotiations is to ensure that the new EU chemicals strategy is compatible with the EU's WTO and other trade obligations.

## Research: Recommendations 29 and 30

**29. We recommend that the Chemicals Safety Co-ordination Unit publish its strategic approach to research, setting out the steps it will take to ensure that it will be possible to predict with adequate confidence the fate and effects of synthetic chemicals released into the environment. It should report progress at 5-yearly intervals (4.121).**

The Government supports a strategic approach to research on the fate and behaviour of chemicals in the environment no matter where the specific responsibility for that may lie. This area of research is evolving and will be improved through the validation of predictive models. Monitoring studies will only augment this process. Future research programmes on chemicals will build on methods that have been developed for chemicals with positive approval regulations such as pesticides and veterinary medicines. These are areas where research is ongoing to refine both fate and effects assessments to reduce the element of uncertainty that exists in assessing the risk of chemicals on organisms in the environment. Proposals for work towards the refinement of understanding of the fate and behaviour of chemicals in the environment will be made widely known following consultation with all appropriate stakeholders.

**30. The Government should argue for a European central entity that takes on, as a main objective, the co-ordination of research into chemicals assessment and risk management (4.125).**

The European Commission's REACH proposal provides for the establishment of a European Central Agency to service the new strategy. The UK fully supports the creation of the Agency to ensure that REACH operates efficiently. We would, however, like to see the Agency taking more of a central role than envisaged in the proposal.

In providing secretariat functions to the REACH process the Agency will work closely with the European Commission and Council, Member State Competent Authorities and the chemicals industry (manufacturers, importers and downstream users). While we would not consider it to be its main objective, the Agency should certainly have a role in the co-ordination of chemicals related research and the dissemination of results.

## Monitoring: Recommendations 31, 32, 33, 34 and 35

**31. The Chemicals safety co-ordination unit, in co-ordinating monitoring as recommended, should direct effort towards reconnaissance monitoring and environmental epidemiology, using an integrated approach to detecting the presence or possible effects of chemicals in the environment as part of its risk management programme. Responsibility for carrying out publicly-funded monitoring should remain with the expert bodies (4.97).**

The Government carries out a significant amount of monitoring for chemicals in the environment, in food and in biota. Much of the monitoring currently carried out is in response to legislative requirements, and many of our commitments are established on an Europe-wide basis. Other UK programmes have been established to determine trends, environmental effects or even compliance issues. Better information on the production, use and disposal of chemicals will improve the targeting of monitoring programmes, help identify priorities, and will be essential to ensure the design of cost-effective monitoring programmes.

A closer linkage between biological and chemical monitoring (referred to in the Royal Commission report as reconnaissance monitoring) and the use of environmental epidemiology studies are already a feature of many environmental monitoring programs. This type of monitoring can play an important role in identifying possible environmental effects or exposure pathways – which are useful for risk management considerations. Any additional monitoring requirements would require a full consideration of the resource implications.

***32. Following the introduction of reconnaissance monitoring as recommended, the regulatory approval of chemicals should include requirements for post-approval monitoring by (or at the expense of) the producer or importer (4.101).***

We agree that the introduction of measures to facilitate specific post-approval monitoring by industry, where appropriate, should be encouraged as this would help assess the effectiveness of risk management measures. Under REACH, we would be interested in examining the possibility of requiring industry to fund monitoring to demonstrate that a substance has been 'adequately controlled' and to inform decision-making at a future authorisation renewal stage.

***33. Environmental epidemiological studies of human and animal populations should be used by the chemicals safety co-ordination unit to identify chemicals, and combinations of chemicals, with the potential to damage animal and human health (4.95).***

As outlined above, environmental epidemiology studies are already a feature of some monitoring programs. They may provide useful information regarding possible causes of health impacts via environmental exposure but they cannot be used in isolation to establish causal relationships. Specific epidemiology studies designed on a case-by-case basis are needed to provide definitive information and these are costly and take considerable time. Thus, they are only appropriate for priority cases.

***34. Monitoring activity related to the fate and effects of chemicals in the environment should be co-ordinated by the proposed chemicals safety co-ordination unit. However, the monitoring activity itself should continue to be carried out by the relevant expert organisations as at present (4.93).***

We agree that there is the need for more and better co-ordination of monitoring activities in the UK. The Government is currently considering ways in which Government Departments and Agencies with responsibility for large monitoring programs may work together more closely. Defra has already begun this process by producing a database of all UK monitoring activities and identifying the wide range of individuals and interests involved. We will continue to identify better approaches to enhance communication between the key players. In addition, the Environment Agency is developing a more effective approach to monitoring chemicals in the environment through its own Chemicals Strategy.

**35. *The chemicals safety co-ordination unit (or other relevant agency) should assess the feasibility of a 'yellow card' scheme for use by the public to report unusual environmental effects that might be related to chemical exposure (4.86).***

We recognise the importance of surveillance monitoring for chemicals and biota and of using the wealth of information on biota generated by voluntary organisations to identify the often unexpected impacts of chemicals. There are already some formal routes established for groups to report unexpected findings to the regulatory authorities and it may be possible to extend these more widely. The 'yellow card' scheme referred to in the Royal Commission report may not be the most appropriate mechanism for reporting unusual environmental effects as this system has been developed by the Department of Health for reporting possible health effects in individuals exposed to specific medical products rather than for unusual environmental events. Other options in this area could be considered, however.

## **Substitution of Safer Chemicals: Recommendations 36 and 44**

**36. *The UK government should adopt substitution as a central objective chemicals policy (5.18).***

The Government is committed to seeing substitution play a key role in chemicals management. That is why it was given prominence in the 1999 Chemicals Strategy, and why the Government is working with the European Commission and other Member State partners to ensure it is a prominent part of REACH.

**44. *The government should introduce a charging scheme to stimulate greater substitution. Categories of concern from our proposed testing regime for chemicals should be used to differentiate the levels of charge (5.70).***

The Government is committed to seeing effective substitution, and is exploring all methods of ensuring that the incentives reflect the need to replace hazardous substances with less hazardous ones.

## **Information through the supply chain: Recommendations 37, 38 and 40**

**37. *The Government should carry out work with users to investigate the flow of information up and down the supply chain (5.33).***

The Chemicals Innovation and Growth Team recognised the importance of good dialogue up and down the supply chain. It was concerned that the industry lacks the mechanisms for this, which will become more critical as speed to market becomes a key competitive factor. This work is being taken forward through a Business Process Intensification group under the Chemistry Leadership Council. DTI funding has been made available to establish some quick wins under the Britest (Best Route Innovative Technology Evaluation and Selection Techniques) programme. This programme will also consider the barriers to innovation that chemical supply chains experience.

**38. *The government should investigate means of improving the information provided on Safety Data Sheets in order to make them more user-friendly (5.34).***

**40. *The government should formulate legislation requiring all companies trading in chemicals to ensure that they receive all available information about any chemical substance or preparation when they obtain it, and supply full information about it when they sell it (5.36).***

The Government agrees that ensuring effective transmission of information through the supply chain is an important part of risk management. The existing safety data sheet legislation places a clear requirement on suppliers to ensure that users of chemicals have all the necessary information to safeguard health, safety and the environment. However, we recognise that these arrangements do not consistently work well as users, especially small and medium-sized enterprises, do not always take the right precautions. REACH provides a welcome opportunity to look closely at the flow of information down the supply chain with the aim of significant improvement. We agree that suppliers and users should be involved in that process. It will also be important to ensure that these improvements in Safety Data Sheets are harmonised with international developments in their production.

## **Public Information: Recommendations 39, 51, 52 and 54**

**39. *The government should review the role of commercial confidentiality and statutory protection of relevant intellectual property rights (5.35).***

The Government believes that the REACH legislation can be structured to ensure that adequate information is available on the risks posed by chemicals to human health and the environment. We are in dialogue with UK stakeholders to get the balance right between the legitimate and necessary requirement for commercial confidence, and the right to know. The Government's aim is for the maximum amount of transparency possible under REACH consistent with this requirement, and we are working with our European partners to achieve this.

**51. *The government should sponsor research with consumers to determine the most effective means of information transfer and the level of detail required on the hazardous substance content of finished articles (5.93).***

The Government believes that consumers should have access to information about the chemicals in the products they buy. Encouraging and enabling active and informed consumers who practice more sustainable consumption is a key objective of taking forward *Changing Patterns*, our Framework for Sustainable Consumption and Production. We are looking to find ways of making sustainable consumption more attractive to the consumer and labelling and information has an important role. However, we recognise the difficulty in making this information meaningful so as to help consumers make informed choices. Our work with retailers and other stakeholders has indicated that the issue of chemicals in products is often one of the top consumer priorities. However, consumers are unlikely to want detailed and complex information on chemical content on the products themselves. Consumers are much more likely to want to know that a particular retailer controls the use of chemicals in their products. The Government is working with stakeholders to develop solutions to this issue.

**52. *The proposed chemicals safety co-ordination unit (4.111) should put in place a means of providing information in response to queries from members of the public (5.94).***

The Government's 1999 UK Chemicals Strategy made openness a key objective. The UK Chemicals Stakeholder Forum deliberates in open session, and puts its agenda, papers, and minutes on the Internet. In addition, a large amount of additional information about chemicals of concern is published on the Forum's website, and an annual report produced outlining the Forum's work. The Forum adheres to Defra's accessibility commitment that sets standards for the accessibility of information, better information management, timeliness in meeting requests for information, and open consultation. Contact details for the Forum's Secretariat are provided on Defra's website, and the Secretariat regularly receives queries from members of the public interested in the Forum's work and the Government's Strategy more generally.

**54. *The UK government should argue strongly for adherence to the EU model (commercial confidentiality is the exception not the rule) despite pressure to the contrary from the US (3.141).***

We agree that commercial confidentiality should be the exception and not the rule. However, adequate controls on access to commercially sensitive data are essential to avoid stifling innovation.

## **Identification of Chemicals in Products: Recommendation 41**

**41. *A programme of random tests on the composition of chemical products, including imported products, should be carried out by the relevant authorities as part of their enforcement strategies, and the results made public (5.44).***

We agree with the Royal Commission's conclusion that the practicalities and cost involved in any comprehensive programme of finished product testing would outweigh any potential benefits. A programme of random testing of imported products might be a better approach, but it will still be necessary to demonstrate that the costs involved produce real enforcement benefits. A more direct strategy of identifying products for testing, through intelligence or consumer information, may be more beneficial. If testing of imported products is carried out it makes sense that that information should be shared with other Member States and made publicly available.

## **Incentives for Developing Safer Alternatives: Recommendation 42**

**42. *The government together with the chemical industry should continue to promote programmes for the development and promotion of green chemistry but with a new emphasis on its application to product design and use. We commend the establishment of annual green chemistry awards, but again there has been an undue emphasis on processes rather than products. We recommend that specific awards be developed for the application of green chemistry to products and services (5.54).***

The Government funded CRYSTAL Faraday Partnership aims to be the focus for the chemical industry in pursuing green chemistry routes to products and services. In addition, the Government has supported proposals under the Sustainable Technologies Initiative, and has supported a number of technology areas under the current Innovation Review and Technology Strategy including sustainable technologies. The Government continues to regard green chemistry as a major priority for the future of a sustainable chemical industry.

## **Sustainable Business Practices: Recommendation 43**

***43. One function of the chemicals safety co-ordination unit proposed in chapter 4 (4.111) should be to promote the adoption of chemicals management services in appropriate sectors (5.62).***

Chemicals Management Services (CMS) have been increasingly highlighted as a mechanism for improving resource efficiency. Green Alliance, in conjunction with the Chemical Strategies Partnership, held a workshop on CMS in March 2003 co-sponsored by the Department of Trade and Industry's Sustainable Technologies Initiative. The workshop brought together 56 representatives from 40 different organisations to hear presentations about the CMS model and its implementation in both the US and Europe. The conference was part of a broader Green Alliance research project, looking at the potential for the service model to improve the resource efficiency of the UK economy, in key sectors such as chemicals and energy. Green Alliance's work in this area has also been highlighted at the UK Chemicals Stakeholder Forum.

## **Consumer Protection Act: Recommendation 45**

***45. We recommend that wholesalers and retailers, as well as the manufacturer, should be jointly and severally liable under the Consumer Protection Act (5.72).***

Part I of the Consumer Protection Act 1987 implements the provisions of the Product Liability Directive (85/374/EEC) into UK law. The Directive makes producers strictly liable for death, injury, loss or damage to private property caused by unsafe products, whether or not they were negligent. The liability applies to all products including consumer goods and goods used in the workplace. Importers of goods into the Community are liable without prejudice to the liability of the producer. Distributors (e.g. wholesalers and retailers) are not liable under the Directive unless they fail to identify the producer or importer, when asked to do so by a person suffering damage.

It is already the position that retailers who sell "own brand" products attract the liability of a producer under the Directive. However, the Government has reservations as to whether it would be wholly appropriate – in all circumstances – to apply strict liability under the Directive to intermediary suppliers of products on the same basis as producers. While we have sympathy with the Royal Commission's wish to improve consumer protection in relation to the use of chemicals in products, we doubt whether the proposal for making producers and intermediary suppliers jointly and severally liable under Part I of the Consumer Protection Act would necessarily have the desired effect.

We do not believe that retailers, for example, would necessarily be aware that products contained hazardous chemicals. Also, creating different requirements in one particular area could raise problems in relation to the wider law on causation and civil liability. Given the high visibility of retailers compared to producers, it is likely that consumers would opt to sue the retailer in most cases. This together with the added cost of product liability insurance would represent a considerable burden for retailers that could well be beyond the means of small independent traders and would result in increased costs for consumers.

## **Product Liability Directive: Recommendation 46**

***46. We accept that, in the light of the judgement of the European Court of Justice in Commission v. France concerning the harmonising effects of the Product Liability Directive, governments may not have the power to introduce changes unilaterally to national legislation. If this is the case, then [w]e recommend the government promote the case for change to the Product Liability Directive in Europe (5.73).***

The Royal Commission's report notes that in a recent infraction case against France (C-52/00, 2002), the European Court of Justice ruled that the Directive sought to achieve total harmonisation and that the extent to which intermediary suppliers are liable is governed by the Directive. Therefore France, which had a strict liability regime in place covering both producers and intermediary suppliers before the Directive was introduced, was wrong to maintain its regime covering the latter.

Following the European Court of Justice judgment a Council Resolution was adopted in December 2002 inviting the Commission to assess whether the Directive should be amended in such a way as to allow for national rules on liability of intermediary suppliers on the same basis as the liability system in the Directive concerning liability of producers.

The Product Liability Directive places primary liability for a product on the person who by manufacturing it (or having it manufactured on his behalf) bears the responsibility for making the product safe. The Directive places liability on the importer where the producer is outside the Community or on the distributor where he does not identify his supplier or the producer. This takes account of the degree of responsibility of those in the supply chain extending liability pragmatically to suppliers and importers so that the person harmed is able to find a person against whom to seek redress. Any proposed changes to this would require careful examination.

However, it might be appropriate to consider whether distributors whose activities have affected the safety of a product (e.g. through incorrect storage) should be liable under the Directive. This would be consistent with their position under the General Product Safety Directive (92/59/EC) which regulates the safety of consumer products and gives rise to criminal sanctions. At present anyone suffering damage as a result of the activities of an interfering supplier can, of course, sue under national law, if they can prove negligence on the part of that supplier.

## **Liability for environmental damage from the use of products: Recommendation 47**

***47. The Government should ensure that the issue of liability for environmental damage from the use of products is given proper weight in current discussions on liability regimes at European Community level (5.74).***

The Government notes that, in its discussion leading to the above recommendation, the Commission suggests that current discussions at European Community level on civil liability for environmental damage have largely been focused on liability for emissions from manufacturing processes or waste disposal, rather than environmental damage caused by the use of products.

The Commission may wish to note that the Environmental Liability Directive, which was adopted in April 2004 and is now being implemented by Member States, does cover use of chemical and other products. Subject to a causal link with the activity, damage to land, water and biodiversity – as defined by the Directive – resulting from the use of ‘dangerous substances’, ‘dangerous preparations’, ‘plant protection products’, and ‘biocidal products’ will be subject to strict liability under the Directive.

## **Challenges to traditional civil liability concepts: Recommendation 48**

***48. The Government should fund a joint scientific / legal study in order to anticipate the moral, legal and practical challenges to traditional civil liability concepts posed by increasing knowledge of genetic susceptibilities to specific chemicals (3.195).***

We recognise the challenges identified by the Royal Commission with regards to the issue of individual susceptibilities and the potential impact on traditional civil liability concepts. Given the breadth of possible implications, including trade implications, we consider that this issue is best approached cautiously and at an international level. There are several international agreements, such as the draft Environmental Liability Directive and the Biosafety Protocol amongst others, which are already looking at international liability issues and we consider that the UK should continue to address these issues via these fora rather in isolation. We question the practical use of carrying out a study as recommended by the Royal Commission at this stage. However, we will keep this under review and commission UK specific work if appropriate in light of outcomes at the international level. That said, it is important to remain realistic about the complexity of the issues and about the time and effort needed to reach a common position which can form the basis of practical action.

## **Extending Producer Responsibility: Recommendation 49**

***49. We recommend that the government investigate further the effect of take-back legislation on product design (5.79).***

Existing producer responsibility legislation, such as the Packaging Regulations have been successful in increasing the recovery and recycling of packaging waste. By placing a tonnage recovery obligation on producers, the Regulations include a cost incentive for businesses to

minimise the amount of packaging they handle. It has been reported that this has led to producers considering ways to reduce packaging by examining both their packaging systems and individual packaging on goods. The Advisory Committee on Packaging has recently set up a task force to look at packaging minimisation and reuse.

Under the Packaging Regulations, the liability for recovery and recycling lies with producers. However, producers of specific items of packaging are not required to track down and recycle the very same items once they have become post-consumer packaging waste. In most cases, it would not be practicable for producers to collect and recycle the exact packaging they have placed on the market. The same can be said for other waste streams, such as waste electrical and electronic equipment. Here, the UK argued against true individual producer responsibility in the Waste Electrical and Electronic Equipment (WEEE) Directive on the grounds that the costs of separating out all products at the end of life and returning them to their manufacturers would be disproportionate, and there would be more vehicles on the roads transporting WEEE than necessary.

True individual producer responsibility also throws up a number of other problems. For example, there is the problem of 'orphan' products – products whose manufacturer cannot be identified. Industry have suggested that a significant number of WEEE products are unidentifiable at end of life, and are concerned about who would pay for the recycling of these products. Similarly, there is the issue of 'free riders' – companies that place goods on the market and then dissolve before the products become waste. There would then be no legal entity responsible for the recycling of these products. Who would pay for the recycling of these products? In the end, the other Member States agreed with the UK, and the wording was changed to allow for collective approaches. These approaches should discharge the obligations under WEEE just as effectively.

## **Encouraging substitution: Recommendation 50**

***50. We commend the initiative of the Chemicals Stakeholder Forum in promoting voluntary reduction of certain chemicals, but emphasise that in the longer term such a voluntary approach needs to be seen in the context of a more systematic promotion of regulatory and other instruments to encourage substitution (5.84).***

The Government shares the view that the UK Chemicals Stakeholder Forum has made a beneficial contribution to chemicals management, and agrees with the Royal Commission's assessment of the importance of substitution. Consistent with good practice, the Forum's remit has now been reviewed after its first three years as part of the overall consultation on the UK Chemicals Strategy launched in January of this year. Following the consultation on these proposals it has been decided that the Forum should take a more strategic approach to discussions with industry by examining substances of concern in groups of say 10 to 12 per Forum meeting. By taking this new approach, and fully utilising existing international chemical management activity, the Forum hopes to build a more effective and efficient relationship with industry for the provision of data on chemicals of concern. An approach which will, in turn, help to prepare UK industry for the requirements expected of it under REACH.

## Industry leadership: Recommendation 53

***53. The Chemistry Leadership Council and the Chemicals Innovation Centre should take a positive attitude to new regulations designed to address public concerns about the industry, by improving the information about and social management of existing chemicals, and by working to ensure that the new regulations act to stimulate innovation in a socially beneficial direction (5.138).***

The Chemistry Leadership Council has set up an Innovation Group, a Skills Network Group and a Futures Group to enable it deliver these objectives. Of particular relevance to this Recommendation is the work of the Futures Group. The Futures Group has agreed, as a priority, that the development of an approach to sustainable development is a key first step to improving the reputation of the chemical industry. The Futures Group is therefore developing a programme to engage all stakeholders as well as those in the industry, particularly its leaders, in this process.

The Futures Group is aware of new regulations designed to address public concerns about the industry, including the REACH proposals, and the Innovation Group is developing a blueprint for what a Chemicals Innovation Centre might look like.

The Government supports the Chemistry Leadership Council in taking its clear role on behalf of the chemicals industry in the UK. It is envisaged that elements of that leadership role will involve statements relating to regulation and sustainable development, and the importance of each in stimulating innovation.



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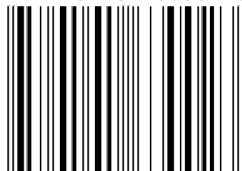
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