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UK Chemicals Stakeholder Forum

Annual Report 2001–2002



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DEVELOPMENT



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Department for Environment
Food and Rural Affairs

UK Chemicals Stakeholder Forum

Annual Report 2001–2002

February 2003

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Foreword by the Chairman, The Earl of Selborne

I am pleased to present the second annual report of the Chemicals Stakeholder Forum.

The Forum has a key role in advising and assisting the UK Government, the devolved administrations and industry to meet their shared objective of delivering sustainable and safe production and use of chemicals. This is one of the most difficult and yet important challenges for sustainable development. The chemicals industry provides products on which we all depend and it would be very difficult to envisage how modern life would develop without them. But some chemicals can have unintended side effects, and bitter experience has taught us that we may need to take a precautionary approach. There are chemicals in production and in everyday use about which we have inadequate knowledge. This is not acceptable.

Decisions about how best to protect the environment and human health through the environment – which is the Forum's main focus – are far from easy. Banning chemicals that are known to be hazardous or about which there are insufficient data would certainly reduce risks, but may have great costs in terms of economic well being and lead to the loss of other benefits. Some chemicals, for example flame retardants, have safety applications and it is important that substitute chemicals or technology are identified before introducing a ban.

Ultimately it is for society to determine the level of risk which it considers acceptable: to balance the sometimes enormous benefits that individual chemicals bring against risks of potential damage to the environment and to human health through the environment. The Forum cannot pretend to represent society as a whole, but the broad membership of the Forum and our attempt to be as open as possible does reflect the principle that we all have a stake in these decisions. The varying views of individual Forum members about where the balance of risks and benefits should lie, has meant that decisions are rarely made on the basis of unanimous agreement. But, so far, we have managed to reach conclusions broadly acceptable to all even where some members were not actively supportive.

The Forum has explored in some detail how it might reflect broader public concerns about chemicals in the way it operates and makes decisions. In the early part of 2002, at the Forum's request, the UK Government commissioned research into the general public's view of chemicals policy and the work of the UK Chemicals Stakeholder Forum. In addition to recommending ways in which the Forum should communicate with the public, the researchers found that the membership of the Forum meets people's expectations and that the independence of the Forum is welcomed.

The second year of the Forum's existence has seen an acceleration in its work on individual chemicals. There has been active involvement from industry in providing information required for decision making. Our consideration of each chemical is based on an understanding of its risks and benefits, and the availability of alternatives to the use of the chemical. In October, Government and the devolved administrations accepted our recommendation to seek a formal voluntary agreement to control the risks from nonylphenol, octylphenol and their ethoxylates. In response to the Forum's statement of concerns, a group of industrial users of medium chain-length chlorinated paraffins have established, and are implementing, a risk reduction strategy.

Chemicals Stakeholder Forum

The Forum has continued to take a close interest in the new EU chemicals strategy, which we expect will eventually address many of the concerns that the Forum is now starting to tackle. However, we are disappointed that proposals for new legislation had not been published during the year as expected.

We strongly believe that animal testing should be kept to the minimum necessary to protect human health and the environment, and we are particularly concerned about the potential for the forthcoming EU legislation to increase animal testing. We have written to Government to make our views clear and recommend an approach to achieve the minimisation of animal testing.

After two years, the Forum is well established and we look forward in our third year to accelerating our work with industry in determining where precautionary risk management action needs to be taken. We are grateful for the contribution individual companies have already made to the Forum's work. As our work progresses I expect that we will increasingly be looking to industry to come forward with proposals for addressing our concerns.

Finally, in addition to the chemical companies who have helped with our work, I would like to thank Forum members and all others who have contributed to the successes of the past year. In particular I would like to thank the Secretariat for their support to all members and to me in particular throughout the year.

Introduction

This is the second annual report of the UK Chemicals Stakeholder Forum, which was created under the UK Government's Chemicals Strategy¹. The Strategy, published in December 1999, set out the Government's policies to prevent industrially produced and used chemicals harming the environment and (through environmental exposure) human health. The Strategy has three goals:-

- Make full information publicly available about the environmental risks of chemicals;
- Continue reduction of the risks presented by chemicals to the environment and human health while maintaining the competitiveness of industry; and
- Phase out early those chemicals identified as representing an unacceptable risk to the environment and human health.

The scope of the Chemicals Strategy is set out in Table 1.

Table 1 Scope of UK Chemicals Strategy	
The Strategy deals with:	The Strategy does not deal with:
<ul style="list-style-type: none"> • Risks to the environment and to human health through environmental exposure to commercially available chemicals; • The commercial production and use of such chemicals; and • Measures relating to controls on production and use. 	<ul style="list-style-type: none"> • Chemicals covered by positive approval procedures for pesticides, biocides and human and veterinary medicines; • Exposure to chemicals in the workplace; • Transport of dangerous chemicals or major accident hazards; • Chemicals added to food during processing; or • Measures relating to controls on emissions of chemicals to the environment.

The Strategy announced a new UK Chemicals Stakeholder Forum to promote a better understanding between stakeholders of the concerns which people have about chemicals in the environment. The Strategy envisaged that the Forum would, by providing advice to the UK Government and the devolved administrations, ensure that these concerns are fully reflected in the development of UK policy on chemicals and the environment.

This report covers the issues that we discussed between publication of our first annual report in November 2001 and our meeting in December 2002. We held five meetings during this period.

¹ Sustainable Production and use of chemicals – a strategic approach

Terms of reference

At our first meeting in October 2000, we agreed the following terms of reference:

- To advise Government on managing risks to the environment and (via the environment) to human health from chemicals entering the environment through commercial production and use in accordance with the 1999 Government paper *Sustainable production and use of chemicals – a strategic approach*, taking into account the views of interested bodies and the public, and European and international chemicals policy, and with due regard to sustainable development and the precautionary principle.
- To advise Government on the development of general policy on chemicals in the environment and, where appropriate, make recommendations for research and monitoring.

Membership

The Forum is chaired by the Earl of Selborne and has 19 members drawn from industry, environmental, animal protection and conservation organisations, trade unions, consumer groups and the scientific community. The organisations who are currently members are listed in Table 2.

Table 2 Membership of the UK Chemicals Stakeholder Forum (December 2002)

British Association for Chemical Specialities
British Coatings Federation Ltd
British Plastics Federation
British Retail Consortium
British Union for the Abolition of Vivisection
Chartered Institute of Environmental Health
Chemical Industries Association
English Nature
Friends of the Earth
GMB
Green Alliance
MRC Institute for Environment and Health
National Council of Women of Great Britain
NERC Centre for Ecology and Hydrology
Non-Ferrous Alliance
Royal Society of Chemistry
Transport and General Workers Union
Welsh Consumer Council
World Wildlife Fund -UK

Working methods

We aim to work as transparently as possible and we hold Forum meetings in public. Details of forthcoming meetings are advertised on the Forum's web site, and to facilitate maximum access to the Forum, meetings are held in various locations around the UK. In the period covered by this report we held meetings in Stockton on Tees, the centre of a major chemicals manufacturing region, the National Assembly of Wales in

Cardiff, and in Manchester as well as London. Anyone wishing to attend a meeting or receive papers is invited to contact the Secretariat. Meetings are held every three months.

All of the Forum's agendas, minutes and papers are published on our website:

www.defra.gov.uk/environment/chemicals/csf/

Advisory Committee on Hazardous Substances

The Stakeholder Forum is not an expert committee. We represent the views of a range of groups – technical and non-technical – who have an interest in chemicals and the environment. To provide scientific and technical input to the Forum, Government has made available to us support from its relevant scientific advisory groups. The most important of these for the work of the Forum is the Advisory Committee on Hazardous Substances (ACHS).

The ACHS is a statutory advisory committee. It was originally set up in 1991 to advise Government on proposals to restrict chemicals or to require information about chemicals under Sections 140 and 142 of the Environmental Protection Act 1990. Increasing activity at European level and changes in responsibilities within Government meant that the ACHS became much less active and eventually dormant.

The UK Chemicals Strategy identified a new role for the ACHS in supporting the Stakeholder Forum on prioritisation, ecotoxicology and risk assessment of chemicals. A new Committee – chaired by Professor Jane Plant, Professor of Geochemistry at Imperial College, London – was appointed in January 2001.

During the course of the last year the ACHS has provided advice to us on:

- guidance on the treatment of inorganic substances when using the Forum's safety net criteria for those chemicals which do not meet the Forum's PBT (persistence, bioaccumulation and toxicity) criteria but that are of concern (see Annex C);
- harmonisation of the Forum's criteria of concern with those of the European Commission and OSPAR;
- a screen of the IUCLID database of chemicals undertaken on the Forum's behalf by the Environment Agency to identify substances meeting the Forum's criteria of concern;
- whether the following chemicals meet the Forum's criteria for chemicals of concern: vinyl neodeconate, hexamethyldisiloxane, tetraethyl lead;
- a review of how medium chain-length chlorinated paraffins (MCCPs) meet the Forum's criteria for chemicals of concern, taking into account the further development of the safety net criteria;
- a review of the evidence of the presence of MCCPs in human breast milk; and
- whether naturally occurring organohalogens can be mistaken for MCCPs.

Assessors

Chemicals policy is an issue which cuts across many Government Departments and Agencies. These Departments and Agencies have sent assessors to Forum meetings and provided contributions to the Forum's work.

In particular the Environment Agency have provided advice on:

- The above mentioned screen of the IUCLID database, on which the ACHS also provided advice;
- Harmonisation of the Forum's criteria with those of OSPAR and the European Commission;
- The progress of the ICCA data gathering and hazard assessment programme.

The Environment Agency have also provided regular updates on the development of their Chemicals Strategy, and a number of us attended a workshop to discuss the approach that the Agency might take.

The Department of Trade and Industry informed us about the activities of the Chemicals Innovation and Growth Team. This was launched in January to help make the chemicals industry more sustainable and competitive. It was set up to work in partnership with key stakeholders, including Government, to tackle the key challenges facing the industry in the rapidly developing global chemicals market.

The environmental aspects of chemicals policy are also the responsibilities of the devolved administrations in Scotland, Wales and Northern Ireland, and officials from the administrations have attended Forum meetings.

Issues considered

7.1 Identification and review of chemicals meeting the Forum's criteria for potential concern

7.1.1 Programme of work on specific chemicals

In our last annual report we reported that the Forum had agreed criteria for identification of chemicals of concern. These are based on the properties of persistence, bioaccumulation and toxicity (PBT), with a safety net for chemicals which do not meet these PBT criteria but which are also of concern.

In June 2002 we received the results of a study conducted for the Environment Agency to screen the IUCLID database of high production volume chemicals against our PBT criteria. The database lists over 2,500 chemicals and, of these, over 100 met the criteria. One third of the PBT chemicals were identified on the basis of laboratory tests for these properties. For the remaining two thirds such test information was not available but computer modelling (quantitative structure-activity relationships) suggested that they would fall within the PBT criteria. The ACHS advised us that the study was robust and gave the following advice in terms of factors to take into account when prioritising chemicals for further investigation:

- the Forum should consider inorganic substances, not only the organic substances covered by the screening project;
- where data on hazards were not available but computer modelling (QSAR) showed that chemicals are likely to meet Forum criteria then these chemicals should be treated the same as those where analytical hazard data were provided. The underlying principle is that firms who have provided information should not be treated unfairly compared with those that had not;
- that it would be helpful to know if the Food Standards Agency and the Committees on Toxicity (CoT), Carcinogenicity (CoC) and Mutagenicity (CoM) had considered any of the chemicals on the list, and if so, if they had further information; and
- whilst UK production and commercial use were a useful indication of the likely level and significance of exposure of the UK environment and citizens it should be not be an overriding consideration for the Forum. This was because of the potential exposure through imports in products.

Taking into account these factors and also the availability of information on the chemicals, the Forum decided to look at ten chemicals in more detail during the remainder of 2002 and 2003. This programme of work is set out at Annex D. We have taken a flexible approach to the order in which we consider these chemicals to allow for the fact that information from other sources, for example the EU Existing Substances Regulation or from industry input, may be available earlier or later than anticipated. Out of the 10 chemicals we agreed on 10 June to review, four have been considered by the Forum (pentaBDE, vinylneodecanoate, hexamethyldisiloxane and alkyl leads). Further detail on our conclusions on specific chemicals are given below.

7.1.2 List of chemicals of potential concern

We acknowledge that there is *not* a scientifically robust way of prioritising consideration of chemicals on the list in order of hazard or risk, not least because there is insufficient information available in the public domain. (The word 'hazard' in this context applies to the dangerous properties intrinsic to a substance. The word 'risk' relates to the likelihood of harm and therefore depends on exposure, including the way the substances is used or is likely to reach the environment.) We decided to publish on our website the full list of chemicals identified by the study and to encourage companies producing, supplying or using these chemicals to come forward with more information about them. We are seeking further information both about the intrinsic properties of the substances as well as the patterns of use. The supply chain from manufacturer to end user can be complex. The flow chart at Annex F shows the complexity of the supply chain for just one sector, the coatings industry. So there are many routes that chemicals may reach the environment, and once in the environment, many routes through which it can be dispersed via and into air, water, soil, sediment, biota and the food chain.

The publication of the list of chemicals of potential concern will be accompanied by an explanation of what the list is for, how it relates to other lists of chemicals and what companies should do if chemicals they produce or use are on the list. The presence of a chemical on the list does not mean that it has been banned or is likely to be banned. Possible future legislative measures are discussed in more detail in Section 7.6 on the EU Chemicals Strategy. Chemicals will be removed from the list if it can be shown, to the satisfaction of the Forum, that:

- newly available information shows the chemical falls outside the PBT criteria; or
- all of its uses are covered by positive approval regimes which take into account both environmental and human health considerations; or
- it is not used or imported into the UK.

With reference to the last of these points we are concerned that articles imported into the UK may contain chemicals no longer used by UK manufacturers because of safety concerns. This undermines protection of the environment and human health and also the competitiveness of responsible UK manufacturing industry and chemical producers. This is an issue which we hope to see addressed by the new EU Chemicals policy (see Section 7.6).

The list as originally presented to us has been modified following consultation with regulators and scientific advisory bodies across Whitehall, including the ACHS. A separate list records a number of chemicals removed from our original list for the reasons given above. At the end of the period covered by the report the list included 111 chemicals of potential concern.

The European Commission has also developed an interim PBT strategy that requires the identification of PBT chemicals. A report is being prepared by the European Chemicals Bureau, based partly on the work of the Environment Agency. There will be consultation on this involving both EU industry and member state governments, and

there will be an opportunity for companies to submit additional data for consideration. The aim is to derive a list of candidate PBT substances that could be investigated further under the Existing Substances Regulation. The interim strategy proposes a risk avoidance approach to PBT and vPvB substances. Thus decisions for these substances will be made on the basis of a non-quantified risk taking account only of whether exposure occurs, and the measures needed to achieve a reduction.

7.1.3 New criteria for chemicals of potential concern

When the Forum first set out its criteria for chemicals of concern (December 2000) based on persistence, bioaccumulation and toxicity, and persistence and bioaccumulation without known toxicity. Our criteria, which are set out in Annex B, are modelled closely on EU guidelines of the time. Since then these guidelines, which are also used by the OSPAR Convention on release of chemicals into the North East Atlantic, have been further developed and refined. At our September 2002 meeting we agreed that the harmonisation of the Forum's criteria with those at EU level would make them simpler to understand and use. However, making such a change is not straightforward and in December we asked for further and clearer information on what such changes would mean before making a decision in 2003.

7.1.4 Safety net criteria for inorganic chemicals

We were advised by the ACHS on the identification of inorganic substances through our safety net procedures for chemicals not meeting our PBT criteria but that nevertheless give rise to concerns.

The ACHS advised that developing criteria for inorganic substances, particularly metals and metalloids was more difficult than for organic substances because some are essential for the health of humans, wildlife and ecosystems, and they are often naturally occurring. Traditional criteria such as persistence are inappropriate. Furthermore, metal and metalloid toxicity is dependent on the chemical speciation of the metal/metalloid. For example, chromium (III) is essential for health, whilst chromium (VI) is carcinogenic.

Moreover, some potentially harmful substances, for example barium, occur in minerals that are resistant to weathering and therefore of limited bioavailability i.e. they are less likely to be taken up and retained in living organisms. But some inorganic substances released into the environment in an inert form may be transformed to a more toxic form, for example the methylation of mercury.

The complexity of metals speciation and environmental behaviour points to the need for a flexible approach to the provision of safety net guidance for inorganic substances, in order to 'capture' inorganic substances that are of high concern due to possible adverse effects to the environment or human health via the environment. For these reasons, all inorganic substances selected by these guidelines will be considered by the ACHS on a case-by-case basis.

The Forum agreed that the ACHS advice be incorporated into the guidance on application of the safety net for chemicals of most concern. The advice is summarised at Annex C.

7.2 Consideration of specific chemicals

7.2.1 Nonylphenol, octylphenol and their ethoxylates

In our last annual report we reported that we had issued a statement encouraging industry to phase out most uses of nonylphenol, octylphenol and their ethoxylates. We recognised that current uses of octylphenol were not a substantial risk, but that it could become so in future if it were to be used as a substitute for nonylphenol.

Industry responses to the Forum's statement were considered at our sixth meeting in December 2001, and we were pleased that many of those companies contacted were aware of the proposed EU policy to severely restrict the marketing and use of nonylphenol and nonphenol ethoxyates. Many companies had either phased out the use of these substances altogether or were in the process of doing so. However, we were concerned that some companies that did not reply to the letter at all and of those that did, many did not give firm dates for phase out. Subsequently we decided that a second letter would be sent to companies requesting further information on this and on product stewardship.

At the eighth meeting, the we considered a summary of industry's response to our questions. Although we recognised the progress already made by industry to phase out the use of nonylphenol and its ethoxylates, we concluded that risk reduction needed to be accelerated. We were not convinced that the explanations by industry of the difficulties they were faced with in phasing out the use of nonylphenol and their ethoxylates justified their continued use. We concluded that risk reduction action should be taken ahead of the expected EU legislation as identified through the Existing Substances Regulation process. We therefore recommended that Government seek a formal voluntary agreement with industry to achieve a reduction in the risks ahead of the implementation of the proposed legislation, which is expected to take effect towards the end of 2005 or the first part of 2006.

On 18 October the UK Government announced its decision to accept our recommendation, and negotiations are now underway to establish a formal voluntary agreement.

7.2.2 Medium chain-length chlorinated paraffins

Medium chain-length chlorinated paraffins (MCCPs) meet the Forum's PBT criteria for potential concern. We considered them at some length during the year and discussed with the manufacturers of MCCPs and the industry Best Practice User Forum about how the risks from them could be reduced.

At our meeting on 10 September, we decided to call on industry to develop risk reduction proposals to reduce the risks to the environment. We issued a statement

which is reproduced at Annex E, and explains the basis of our conclusions on this substance. We agreed that further data were required to address the issue of a potential risk to human health through the presence of MCCPs in cows and human breast milk. The ACHS considered this data at its meeting in November 2002, and advised us that MCCPs were likely to be found in human breast milk and cows milk.

The MCCP Best Practice User Forum presented to the Forum's meeting in December 2002 a targeted risk reduction plan to address our concerns about these substances. This included a target to reduce emissions by 25% through best practice measures. We asked the MCCP Best Practice User Forum to proceed with the implementation of the plan with the addition of information on production and use of MCCPs. We also asked them to look at emissions from end of product life.

7.2.3 1,2,4 trichlorobenzene

We first considered this substance at our seventh meeting in March 2002, when it was identified as meeting our criteria of concern. However, further information submitted by the Chemical Industries Association indicated that this substance was no longer in use in the UK and Environment Agency monitoring showed levels in the environment decreasing. We therefore decided at our eighth meeting in June 2002 that we would give no further consideration to this substance.

7.2.4 Vinyl neodecanoate

Vinyl neodecanoate was identified as meeting our PBT criteria for chemicals of concern. We first discussed it in detail at our meeting in September 2002. Representatives from the main industry suppliers took part in the discussion and informed us about current initiatives to gather further information for risk and hazard assessment. In the absence of sufficient information on the properties of this chemical and its environmental exposure, we have called upon the manufacturers to provide further information for consideration at a later meeting. We will be discussing this chemical for a second time at our first meeting in 2003.

7.2.5 Pentabromodiphenyl ether

Pentabromodiphenyl ether (PentaBDE) meets our PBT criteria for concern and was considered at our ninth meeting in September 2002. The risk assessment carried out under the Existing Substances Regulation had identified risks for the environment, for sediment and soil and for secondary poisoning of top predators in the aquatic and terrestrial food chains. In relation to human health, the risk assessment concluded that further information was required to address a number of uncertainties relating both to human health hazards and human exposure. However, following agreement of these risk assessment conclusions for human health, as a result of discussions at a policy level, EU Member States agreed that in view of the uncertainties expressed regarding the risk characterisation of infants exposed via human breast milk, risk reduction measures should be considered without delay for the sources of this exposure.

A full risk reduction strategy prepared by the UK Government under the Existing Substances Regulation had concluded that EU wide marketing and use restrictions should be introduced. The strategy included an analysis of the advantages and drawbacks of the continued use of PentaBDE. Legislation banning the marketing and use of this chemical was adopted in December 2002, and we expect that it will come into force in mid 2004.

We agreed that although the risks from PentaBDE were being addressed at EU level, we should write to industry organisations seeking assurance that use in the UK would stop after next year. Responses received by the end of 2002 indicated that this was the case.

7.2.6 Hexamethyldisiloxane

Hexamethyldisiloxane (HMDS) meets our criteria for concern, although it does not meet our criteria for substances of highest priority. HMDS is mainly used as an intermediate in production processes although smaller amounts are used in personal care products. HMDS is also on the OSPAR list of priority substances (<http://www.ospar.org/eng/html/welcome.html>).

We considered HMDS for the first time in December 2002. The trade association representing the manufacturers (Centre Européen des Silicones (CES)) attended the meeting and presented valuable additional information about the risks and hazards of the substance. This answered a number of concerns raised by the ACHS during their consideration of the available data.

In conclusion, we decided to reconsider HMDS at a future meeting in the light of further information that was expected in a report to be presented by the OSPAR Priority Substances Group in October 2003. We also agreed to seek further information from key industry organisations in the UK.

7.2.7 Alkyl leads

We decided to consider alkyl leads at our meeting in June 2002. The available data suggested that there were three alkyl leads produced in high volumes in the EU. Further investigation revealed that of these three, tetraethyl lead and diethyldimethylplumbane were not manufactured or used in the UK. We therefore decided to concentrate on the third of the alkyl leads: tetraethyl lead (TEL)

We considered TEL in detail for the first time in December 2002. We were advised by the ACHS that TEL did not appear to meet the Forum's persistence criteria, but that it would break down in the environment to triethyl lead, which has the potential to bioaccumulate. TEL should therefore be considered under the Forum's safety net criteria.

Most TEL produced in the UK is exported to countries yet to complete the UNEP programme for phasing out its use in vehicle fuels. Releases from the manufacture of TEL are regulated in the UK under the Integrated Pollution Prevention and Control legislation and are therefore outside the Forum's remit.

Remaining UK uses of TEL in vintage cars and piston-engined aeroplanes are of concern, although we recognised that the volume used was comparatively low. We decided that at a future meeting (June 2003) we should consider these uses in more detail, the justification for them, possible substitutes and risk management measures already in place.

7.3 Performance Indicators for the UK Chemicals Strategy

The UK Chemicals Strategy required the Forum to develop indicators of environmental exposure to hazardous chemicals, including targets for reducing overall exposure of the environment.

We were involved in the preparation of a specification of a project to develop the indicators, and a contract was subsequently awarded to AEA Technology. The contractors worked with members of the Forum and the ACHS to produce a report covering the definition and scope of a range of indicators using the PRUEID (Production, Release, Use, Exposure, Impact and Dispersal) life-cycle based framework. The report, which was still under preparation at the end of the period covered by this report, will also include information on data sources, anticipated data costs, whether new data or manipulation of existing data are required, the frequency of data provision and a judgement on the robustness of data and indicator utility. We expect the report to be published early in 2003. It will be made available on our website:

www.defra.gov.uk/environment/chemicals/index.htm

The work to develop indicators has been undertaken alongside Defra work to improve the coordination of monitoring of chemicals in the UK environment. As a first step, Defra commissioned the "Collation of Information on Activities Related to Monitoring Chemicals in the Environment". The study, carried out by Risk and Policy Analysts Ltd was completed in July 2002 and the report and database of activities are publicly available on request. The database contains information on monitoring chemicals in air, water (surface, groundwater and marine), soil and food. It does not contain information on concentrations measured but provides details of where these can be found. Defra intends to commission an update of the database in 2005.

7.4 Animal testing

At our seventh meeting, in March 2002, we considered a report, commissioned by Defra, updating a previous report by the Institute for Environment and Health 'Testing requirements under the EC White Paper "Strategy for a future chemicals policy"'. This reassessed the number of animals that would be needed for tests under proposals for new legislation, taking into account new knowledge about the replacement of current animal tests with *in vitro* alternatives.

The report concluded that the number of animal tests could be reduced to a small extent by the use of available validated alternative *in vitro* tests, but only a radical change in the proposed chemicals testing policy could reduce numbers significantly.

After considering this report, and the conclusions of the House of Lords European Subcommittee D report on the EC White Paper, we decided to write to the UK Government expressing our concerns about the potential increase in animal testing that would result from a new EU chemicals strategy, and recommending an approach to achieve the minimisation of animal testing. The UK Government replied in support of our view and our recommended approach, agreeing that testing must only be required where it is needed and not just for the sake of filling data gaps. The UK Government will argue in responding to the EU White Paper that animals should only be used when opportunities for data sharing have been exhausted; when there is no acceptable non-animal alternative test available; and that all opportunities for minimisation and refinement of testing methods have been taken into account.

7.5 International Council of Chemical Associations (ICCA) hazard assessment programme

The UK Chemical Strategy recognised the importance of the International Council of Chemical Associations (ICCA) voluntary high production volume programme in providing the basic information necessary to decide whether or not a chemical is likely to be of concern. Under ICCA industry has committed to conduct hazard assessments of 1,000 high production volume chemicals by the end of 2004. These assessments are being audited by member countries of the OECD to ensure completeness and adequacy.

The progress of the programme is of particular interest to the Forum, since it is potentially an important source of data to inform our deliberations. We continued to receive regular updates of the progress of the assessments at our meetings. At the end of 2002 the UK had agreed to sponsor 64 substances within 14 groups. Two assessments had been submitted to the OECD for discussion.

7.6 EU Chemicals Strategy

In February 2001 the European Commission published a White Paper on a future chemicals policy. At the centre of these proposals is a new scheme for registering, evaluating and if necessary authorising the use of industrial chemicals (REACH). This would affect an estimated 30,000 chemicals currently in use in the EU and not covered by positive approval regimes.

Following publication of the White Paper, the Commission set up a series of working groups consisting of technical experts from Member States to contribute to the development of draft legislation. In our last annual report the Forum reported that four sub groups were to be set up to enable Forum members to feed in more detailed ideas to Commission working groups. The four sub groups were on:

- a) Testing and registration of chemicals;
- b) Authorisation and rapid risk management of chemicals of concern;
- c) Chemicals in products; and
- d) Interaction of downstream users with proposed EU mechanism.

Each working group met once and their contributions can be found on the Forum website (Annex to Paper CSF/01/INF/11, 6th meeting). Ideas from the Commission working groups are being used to inform the development of legislative proposals. These proposals were due to be published in the summer of 2002 but had not emerged by the end of the reporting period (December 2002). We were very disappointed at the lack of progress, and felt that this delay increased the importance of ensuring that the Existing Substances Regulation continues to be implemented as effectively as possible.

In March 2001 the House of Lords European Union Select Committee published its report on its inquiry into the European Commission's White Paper on a future chemicals policy. This can be found on the House of Lords website at:

<http://www.publications.parliament.uk/pa/ld200102/ldselect/ldcom/81/8101.htm>

Nearly all Forum members had given evidence during the inquiry. We thought that the report provided a full and useful discussion of the issues raised by the White Paper. The Forum shared the concerns of the House of Lords report on the potential increase in animal testing from the new REACH system (see Section 7.4 for more on this subject).

The Forum has encouraged the UK Government to come forward with its own thoughts on how the new legislation should work. At its tenth meeting in December 2002 the Forum discussed the broad approach the legislation might take with representatives from Defra and from Directorate General for Enterprise of the Commission. It will discuss the UK Government's position paper on the White Paper REACH proposals at its first meeting in 2003. This paper can be found at:

<http://www.defra.gov.uk/environment/chemicals/eufuture.htm>

The output of our sub groups assisted in the formulation of the Government's position paper.

Other EU states, as well as the Commission, have taken an interest in our work. We believe that we are the only body in Europe to bring such a wide range of stakeholders together to consider the risks presented by chemicals.

The UK Government's Position Statement on the White Paper supports moves to bring chemicals meeting vPvB and PBT criteria, once these have been agreed, under the most stringent controls. These would require any continuing uses to be authorised.

7.7 Public participation

In our first annual report we recorded our decision to take forward work on encouraging and reflecting the views of the general public in our work. We had, in our first year, agreed the objective of informing ourselves of public understanding and reactions to the work undertaken and planned by the Forum, and to contribute to the development of that work.

In February this year Defra commissioned research through the Central Office of Information on people's understanding of, and views about, chemicals and our work. Forum members were closely involved in discussions about the design of the project.

Chemicals Stakeholder Forum

The researchers ran a series of small discussion groups followed by larger workshops, and several members of the Forum were able to observe these. Their key objectives were to explore the public's awareness and attitudes to chemicals and the stability of these; to gauge what actions the public would like in the light of their unprompted and prompted views on chemicals; and to explore responses to the Forum and its remit. The research also collected the views of journalists working for national media organisations, as being representative of opinion formers.

The research found that chemicals and concerns about them are, for the general public, a subset of environmental and pollution concerns. People are re-assured by the existence of the Forum, although they wish us to have greater powers and resources. However, the researchers concluded that the general public do not see the Forum or its work as public facing. They thought that the tight remit of the Forum makes it unlikely that the general public would truly engage with it. They found that journalists did not believe that our role was newsworthy although they expressed interest in hearing about the successful withdrawal of any chemical found to be harmful.

The researchers recommended that we ensure that our website was accessible and that clear links are made with bodies with contiguous responsibilities. These recommendations are being implemented following review of our website undertaken by the Secretariat.

Wider links

Although the focus of our work is the safe production and use of chemicals in the UK, our activities have raised interest across Europe and beyond. The international nature of the industry has inevitably meant that our concerns have focused on the activities of companies whose interests in individual chemicals cross international borders. Our meetings have been attended by industry representatives from European trade bodies, from the Netherlands and from the United States.

The innovative nature of the Forum as a policy tool has also attracted the attention from outside the UK of those looking for new approaches to policy making.

Within the UK we have continued to maintain close contacts with the Royal Commission on Environmental Pollution (RCEP), who are due to conclude their study into the long term effects of chemicals in the environment in May 2003. In last year's annual report we reported that our chairman, the Earl of Selborne, briefed the RCEP on the work of the Stakeholder Forum. Over the past year, Forum members have provided written and oral evidence to support the Commission's study. The RCEP have continued to update the Forum on the progress of their study.

Annex A: Glossary

Bioaccumulation	The uptake of substances from the environment, and their concentration and retention by organisms, e.g. in fatty tissues.
Bioaccumulation factor (BAF)	<p>Bioaccumulation factor is a measure – made during laboratory testing – of the ratio of the concentration of a substance in an organism to the concentration in water, based on uptake from the surrounding medium and from food. It is derived in similar ways to the BCF (below), but the chemical exposure may be through food.</p> <p>BAF and BCF are considered among the most reliable predictors of the potential of a chemical to bioaccumulate.</p>
Bioconcentration factor (BCF)	Bioconcentration factor is a measure – made during laboratory testing – of the ratio of the concentration of a substance in an organism to the concentration in water, based only on uptake from the surrounding medium. For example, if a fish is exposed to a chemical in surrounding water and, after a defined period of time, is found to have a concentration of that chemical five hundred times greater than the surrounding water it would have a BCF of 500.
Carcinogenicity	A property of a substance that causes cancer.
Ecosystem	Living organisms, their physical environment, and their interrelationships within a particular part of the environment.
Ecotoxic	Harmful to ecosystems and/or the organisms within them.
Ecotoxicology	The scientific study of harmful effects caused by manufactured chemicals to the natural environment, especially effects on populations, communities, and ecosystems; an essential part of ecotoxicology is the study of the movement of potentially toxic substances through food webs and through the water cycle, etc.
Endocrine disrupter	Substance that interferes with the working of the endocrine (hormone) system.
Existing chemicals	Defined as those listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) between January 1971 and September 1981– a total of over 100,000. All other chemicals are ‘new chemicals’.
Hazard	In the context of this document ‘hazard’ refers to the dangerous properties intrinsic to a substance.

Hazard assessment	Assesses a chemical's potential to harm humans or the environment. This is an assessment of the intrinsic properties of a substance. It does not address the <i>likelihood</i> of harm (risk), which depends on exposure, including the way the substance is used or is likely to reach the environment. The hazard assessment is therefore only the first step towards an assessment of risk.
Hazard profile	Data on physical and chemical characteristics, acute and chronic toxicity, bioaccumulation, persistence and mobility in environmental media and other properties required for a hazard assessment of a chemical. Together with information on exposure, the hazard profile is used to assess risk.
High production volume (HPV)	The OECD defines an HPV chemical as one that is produced or imported into any single country in quantities of 1,000 tonnes per year or more. The US Environmental Protection Agency terms HPV chemicals as those produced or used in quantities of over one million lb. Per year, i.e. about 444 tonnes.
International Council of Chemical Associations (ICCA)	A body of trade associations representing chemical manufacturers world-wide. It provides a forum for regular meetings of executives from member associations. ICCA has announced a voluntary programme of accelerated testing and hazard assessments of about 1,000 high priority chemicals, to be completed by the end of 2004.
In vitro	<i>In vitro</i> means, literally, "in glass"; a biological or biochemical process occurring outside a living organism.
L(E)C₅₀	Lethal (Effective) Concentration is a measure of toxicity (see below). It is a statistically derived measure, made during laboratory testing, of the concentration of a substance that can be expected to cause death (L) or an effect (E) (e.g. reduction in growth) during exposure or within a fixed period of time after exposure in 50% of animals exposed for a specified time. The value is expressed as weight of test substance per standard volume (milligrams per litre).
L(E)D₅₀	Lethal (Effective) Dose is a measure of toxicity (see below). It is a statistically derived single dose of a substance that can be expected to cause death (L) or an effect (E) in 50% of dosed animals. The value is expressed in terms of weight of test substance per unit weight of test animal (e.g. milligrams per kilogram).
Lipophilic	Literally 'fat-loving'. Applied to substances that have an affinity for fat, a tendency to dissolve in fat-like (e.g. hydrocarbon) solvents and may readily accumulate in fat deposits in living organisms.

Log K_{ow} (Log P_{ow})	<p>Log K_{ow} is a measure, established from non-animal testing methods, used to predict, among other endpoints, the likelihood of a substance to bioaccumulate. It can be derived by observing the behaviour of a substance added to a mixture of water and an organic solvent. This will provide an indication of how lipophilic it is.</p> <p>A more precise technical explanation is that the partition coefficient, K, is defined as the ratio of the equilibrium concentrations of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, usually n-octanol and water (ow). The partition coefficient therefore is the quotient of two concentrations and is usually given in the form of its logarithm to the base 10 (Log K).</p>
No Observed Effect Concentration (NOEC)	<p>The No Observed Effect Concentration is a measure, made from laboratory tests, of the highest concentration level that living organisms are exposed to where no adverse treatment-related findings are observed.</p>
Mutagenicity	<p>A property of a substance which causes mutation of the genetic material of an organism exposed to it.</p>
New chemicals	<p>Defined as those not listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) between January 1971 and September 1981. Those on that list are the so-called 'existing chemicals'.</p>
OSPAR	<p>The Convention for the Protection of the Marine Environment of the North East Atlantic (the OSPAR Convention), to which the UK is a party, agreed a strategy to 'prevent pollution of the maritime area by continuously reducing discharges, emissions and losses of hazardous substances with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances.'</p>
Persistence	<p>The ability of a substance to remain unchanged in the environment. Persistent substances can become distributed world-wide, particularly in the marine environment or in the atmosphere.</p>

Precautionary principle	The precautionary principle is an approach to risk management that can be applied in circumstances of scientific uncertainty, reflecting a perceived need to take action in the face of a potentially serious risk without waiting for results of scientific research. The 1992 Rio Declaration on Environment and Development says: <i>'In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'</i>
Quantitative Structural Activity Relationship (QSAR)	The Quantitative Structural Activity Relationship approach is a computer modelling technique used to predict a chemical's properties – such as whether they are persistent, bioaccumulative, or toxic – by analysing its structure. It is not considered as being as reliable as other methods of establishing a chemical's properties but can be applied rapidly according to established rules. It is generally considered suitable for screening chemicals i.e. identifying chemicals that should be subject to further analysis and testing.
Risk	The likelihood of the hazardous properties of a chemical causing harm to people or the environment. Risk depends on exposure including the way the substance is used or is likely to reach the environment.
Risk assessment	The determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentration/doses to which people or parts of the environment may be exposed. Scientists compare the hazard profile and the exposure assessment to characterise the risk, they build in uncertainty factors to allow for uncertainty in predictions or exposures and for effects on different species. When assessing risks for humans, scientists include factors to take account of extrapolating information from tests on laboratory animals and variation in the human population. Detailed risk assessments have been carried out on relatively few chemicals.
$t_{1/2}$	This is the scientific notation for the half-life of a substances and is used as a measure of persistence in the environment. The half-life means the period it takes the concentration of a substance to be reduced by half, by transformation, in a medium (e.g. soil or water).
Teratogenicity	A property of a substance causing abnormalities in the embryo or foetus when administered to the mother or maternal organism.

Toxicity

Harmfulness to living organisms. Toxicity is the capacity of a substance to cause toxic effects to organisms or their progeny, such as reduction in survival, growth and reproduction, carcinogenicity, mutagenicity, teratogenicity, and endocrine disruption (see separate entries for these).

IUCLID

International Uniform Chemical Information Database – containing unvalidated property and hazard information for 2,604 EU high production volume chemicals, submitted under the Existing Substances Regulation, EC 793/93.

Annex B: criteria for identifying chemicals of concern

Introduction

The UK Government Chemicals Strategy – published in December 1999 – set out the Government's policies to prevent commercially produced and used chemicals from harming the environment or (via environmental exposure) human health. The Strategy sets out a fast track procedure for taking action on the chemicals of most concern. This requires the development of criteria which will enable chemicals that require a risk management strategy to be identified quickly. As a first step in this process the UK Chemicals Stakeholder Forum – established in September 2000 – was asked to agree criteria to identify the chemicals of greatest concern, taking into account the key properties of persistence, bioaccumulation and toxicity (PBT).

The Stakeholder Forum held an initial discussion on criteria at its first meeting on 2 October 2000. The Forum considered information on work in other fora (particularly that developed under the OSPAR Convention to prioritise action on substances which pose a threat to the marine environment) in reaching its conclusions on criteria for priority chemicals for the UK and for all environmental media.

An ad-hoc meeting of the Forum, held on 3 November, considered in more detail the implications of different sets of criteria. The discussion was based on a paper produced by the NERC Centre for Ecology and Hydrology, which looked at how different criteria selected substances from a sample of chemicals considered under OSPAR.

The Forum held a further discussion on 30 November 2000 and agreed to recommend to Government criteria which would enable all relevant information to be taken into account. The Forum received further information on an OSPAR exercise to identify the numbers of chemicals which might be selected by five different sets of criteria.

Stakeholder Forum recommendations on criteria (as agreed on 30 November 2000)

Persistence

$t_{1/2}$ water > 2 months OR
 $t_{1/2}$ soil or sediment > 6 months

The Forum recognised that such half life data may frequently not be available and that screening data such as the results of ready biodegradation testing may need to be used in the first instance.

Bioaccumulation

$\text{Log } K_{ow} \geq 5$ for the substances of highest priority, unless the experimental BCF < 5000

$\text{Log } K_{ow} \geq 4$ for other priority substances for the Forum, unless the experimental BCF < 500

Where experimentally derived bioconcentration factors (BCFs) were available these would be given precedence over $\text{Log } K_{ow}$.

Toxicity

Toxicity or ecotoxicity data that indicate potential for damage, in the immediate or longer term, and through direct or indirect effects. Such data may include acute and/or chronic aquatic toxicity data, with thresholds of $L(E)C_{50} \leq 1$ mg/l and long-term no observable effect concentration (NOEC) ≤ 0.1 mg/l respectively; and category 1 and 2 carcinogenic, mutagenic or reproductive toxins (CMR) and category 3 mutagens, or chronic toxicity data, with reference to the thresholds and provisions set out in EC Directive 67/548/EEC.

If no toxicity information is available from animal tests, QSAR or expert judgement, it would be assumed that the toxicity criterion was met.

Persistence and bioaccumulation without toxicity

If persistence and bioaccumulation criterion were met but the toxicity criterion was not, the Forum would not assume that the chemical was safe, but it would not be as high a priority as chemicals which met the toxicity criterion.

Annex C: Safety net procedures

In our first annual report, we reported advice received by the ACHS on the application of a safety net procedure that would apply where chemicals did not meet the PBT criteria but there were reasons to believe that the chemicals raised equivalent concerns.

We were advised by the ACHS that the following types of organic substances or scenarios could be subject to the safety net criterion. As a general principle the advice also applies to substances that break down or are transformed to products or compounds that meet the first tier criteria agreed by the Stakeholder Forum and the safety net:

- i. Substances that are very toxic (vT) to organisms in the aquatic or terrestrial compartments: for example, substances with acute toxicity $L(E)C_{50} < 0.1$ mg/L, NOEC < 0.01 mg/L ($L(E)D_{50} < 0.1$ mg/Kg, NOED < 0.01 mg/Kg). Such substances may not be sufficiently persistent or bioaccumulative to meet the PBT criteria, but due to their potent toxicity may still be a cause for concern, especially if they are continually released to the environment.
- ii. Substances which are actually or potentially very bioaccumulative (vB) by whatever mechanism (not necessarily just lipophilic compounds, but also those that accumulate in bone, bind to proteins etc). These may include, for example, substances with a $BCF > 10,000$ or substances with a $\log K_{ow} > 6$, respectively. The committee noted that BCFs must be determined in typical environmental concentrations to give an accurate indication. Bioaccumulation factors should also be used where available. These substances (especially if actually found in biota) may be of concern due to their bioaccumulation, even if their persistence and toxicity do not meet the Stakeholder Forum's criteria. Substances with a very high $\log K_{ow}$, however, may have reduced bioavailability to organisms as they may sorb very strongly to soils and sediments, and may not be freely available in water. Substances which are both bioaccumulative and toxic (i.e. B and T) also may be a cause for concern, especially if the substances are released regularly (i.e. the input load is greater than the degradation removal).
- iii. Organic substances that may persist in the environment for many years ($t_{1/2} > 10$ years), or for shorter periods where evidence suggests that adverse effects to the environment and human health may occur. Evidence of potential adverse effects may be identified by measurement via testing, by modelling predictions, or by monitoring. Adverse effects may include interference with biogeochemical cycles or toxicity to humans or other organisms*. The ACHS will continue to examine this issue and will advise further.

* The ACHS considered that dispersive uses of very persistent substances were in themselves a cause for concern, whether or not there was any evidence of harmful effects.

- iv. Substances that may cause adverse effects measured, or detected, as novel toxicity endpoints. Such substances may cause sub-lethal effects that might result in population level effects for exposed species, and could include endocrine-disrupting chemicals, for example. Further scrutiny on a case-by-case basis may be required to determine whether or not a particular substance should be included in the safety net.
- v. The safety net will consider additional substances identified on other appropriate priority lists such as OSPAR, which apply to the UK as a consequence of our European and/or international commitments. If these substances comply with one or other of the proposed safety net criteria, they will be retained. If not, they will be considered further to determine if they require inclusion in the safety net due to some unforeseen potential hazard or whether they should not form part of the safety net list.

In December 2001 the ACHS advised that the following inorganic substances should be included in the safety net:

- vi. Substances that are very toxic to organisms in either the aquatic or terrestrial compartments. Toxicity thresholds for inorganic substances could be those with acute toxicity of $L(E)C_{50} < 0.1$ mg/L(Kg), or point estimate (or NOEC/D) < 0.01 mg/L(Kg); and/or
- vii. Substances that are actually or potentially very bioaccumulative in organisms, by whatever mechanism. These may include, for example, substances with a BCF/BAF $> 5,000$. Note that to eliminate the bioaccumulation concern BCF/BAF data should only be used if the experiments were conducted at environmentally relevant concentrations.

Substances identified under the safety net criteria would require case-by-case consideration by the ACHS prior to the Chemicals Stakeholder Forum's consideration for risk management.

Annex D: Timetable for consideration of individual chemicals

UK Chemicals Stakeholder Forum – Programme of Review of Specific Chemicals (as at November 2002, subject to further changes)

September 2002	December 2002	1st Meeting 2003	2nd Meeting 2003	3rd Meeting 2003
1st discussion- vinyl neodecanoate	1st discussion – Alkyl leads	1st discussion on tetrabromo-bisphenol A	1st discussion – Dodecophenol, mixed isomers	1st discussion – Tert-dodecanethiol
Concluding discussion – MCCPs	1st discussion – Hexamethyl-disiloxane (HMDS)	1st discussion Hexabromocyclo-dodecane	2nd discussion – tetrabromo-bisphenol A	1st discussion – N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine
1st discussion – PentaBDE	Review work on individual chemicals	2nd discussion – vinyl neodecanoate	2nd and concluding discussion – Hexabromocyclo-dodecane	2nd discussion – Hexamethyl-disiloxane (HMDS)
	2nd and concluding discussion – PentaBDE		2nd discussion – alkyl leads.	2nd discussion – Dodecylphenol, mixed isomers
			Concluding discussion – vinyl neodecanoate.	Concluding discussion – tetrabromo-bisphenol A
				Review work on individual chemicals

Annex E: Chemicals Stakeholder Forum statement on medium chain-length chlorinated paraffins

At its meeting on 10th September 2002, the UK Chemicals Stakeholder Forum (CSF) concluded that medium chain-length chlorinated paraffins (MCCPs) present substantial risks to the environment. The Forum has called on industry to take voluntary action to address these risks in the UK. The Forum will also be looking at the evidence of possible risks to human health via the environment when more information becomes available.

The main use of MCCPs is in the manufacture of PVC. MCCPs also have significant uses in other plastic/rubber products (as flame retardants), as well as in sealants, paints, metal cutting/working fluids, leather fat liquors and carbon-less copy paper. MCCPs are mainly used in industrial processes but are also found in some products used directly by consumers.

The decision to take this action followed extensive consideration by the CSF and its scientific advisory body, the Advisory Committee on Hazardous Substances (ACHS). MCCPs are also being considered under EU regulations and much of the evidence considered was taken from the Existing Substances Regulation (ESR) process. MCCPs are persistent, potentially bioaccumulative, and toxic to aquatic organisms. The ESR Risk Assessment concluded that MCCPs do present a risk to both aquatic and terrestrial ecosystems, particularly from some uses in the plastics, metal working and leather industries. It is also recognised that some uses do not currently lead to an environmental concern (e.g. formulation and use of sealants).

The Forum has asked industry's MCCP Best Practice User Forum to come up with a practical, achievable plan that will reduced risks to the environment in the UK in advance of any action at EU level. The plan should be targeted, looking at where advances can be made quickly, rather than seeking to be completely comprehensive. It should include proposals on how the success of the plan could be monitored and should not only focus at "end of pipe" solutions.

The Forum will be seeking regular updates on progress from the MCCP Best Practice User Forum.

Further information on discussions on MCCPs at the Chemical Stakeholder Forum and Advisory Committee on Hazardous Substances can be found on the internet at:
www.defra.gov.uk/environment/chemicals/csf/ and
www.defra.gov.uk/environment/chemicals/achs/index.htm

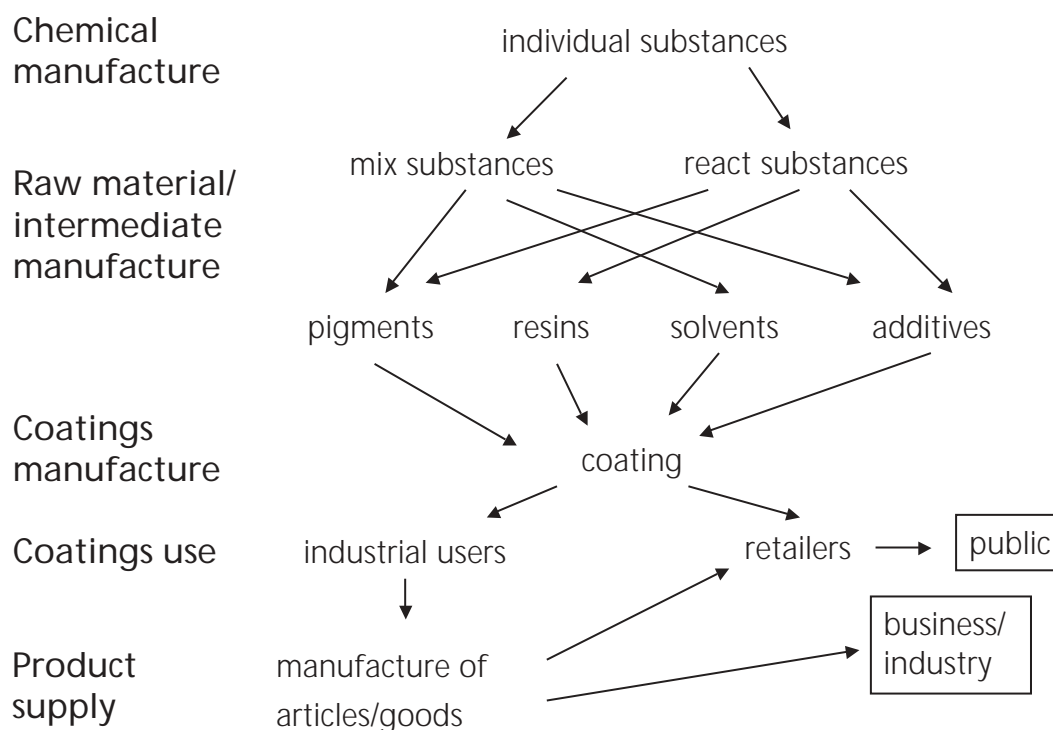
Contact the CSF Secretariat for further information at:
chemicals.strategy@defra.gsi.gov.uk.

November 2002

Annex F: Coatings: cycle of use

Simplified flow chart of the major steps involved in the manufacture, supply and use of coatings

(See Section 7.1.1)



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