



defra

Department for Environment
Food and Rural Affairs

Advisory Committee on Hazardous Substances

Sixth Annual Report 2001–2002



**SUSTAINABLE
DEVELOPMENT**



Advisory committee on hazardous substances

Sixth annual report

Department for Environment, Food and Rural Affairs

January 2003

Department for Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 6000
Website: www.defra.gov.uk

© Crown copyright 2003

Copyright in the typographical arrangement and design rests with the Crown.

This publication (excluding the logo) may be reproduced free of charge in any format or medium provided that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as Crown copyright with the title and source of the publication specified.

Further copies of this publication are available from:
Defra Publications
Admail 6000
London
SW1A 2XX
Tel: 08459 556000

This document is also available on the Defra website.

Published by the Department for Environment, Food and Rural Affairs. Printed in the UK, January 2003, on material containing 75% post-consumer waste and 25% ECF virgin pulp (cover and text).

Product code PB 7826

Foreword by the Rt Hon Michael Meacher, Minister for the Environment

I am pleased to note in this first Annual Report of the reconstituted Advisory Committee on Hazardous Substances, that it has already made a substantial contribution in support of the work of the Chemicals Stakeholder Forum.

The heart of the Forum's work is to identify chemicals that may potentially harm the environment and the ACHS has during its first year of operation endorsed a list of substances of concern. This represents an important prelude to our long term objectives of investigating, addressing and eliminating risks to the environment and to human health from the production and use of industrial chemicals.

The re-establishment of the Advisory Committee on Hazardous Substances in 2001 has been particularly important in providing broad technical advice to the Chemicals Stakeholder Forum which was established in October 2000 to take forward proposed new policies on the control of risks posed by chemicals to the environment and to human health via the environment.

The Government is already doing much to implement the Freedom of Information Act. Defra is also committed to following the Office of Science and Technology Code of Practice for Scientific Advisory Committees. I pleased that the ACHS are going to be addressing these issues and look forward to the time when their meetings will be open to the public and their papers available on the Internet for anyone to read.

A handwritten signature in black ink that reads "Michael Meacher". The signature is written in a cursive style with a large initial 'M'.

MICHAEL MEACHER

Foreword by the chairman

The sixth annual report of the Advisory Committee on Hazardous Substances (ACHS) comes in the wake of a new generation of regulatory measures governing the management of hazardous chemicals in the environment and in the products we buy and consume. The government is implementing new policies on hazardous substances, especially in the light of proposals for a new system of chemicals control in the EU. It is now more necessary than ever for expert knowledge and advice from groups such as the ACHS to be available for input into the policy making process.

The ACHS was formed in 1991 to advise the Secretary of State on the exercise of his powers under Section 140 and 142 of the Environment Protection Act 1990. The ACHS undertook this role until 1996. Then, in 2001, the ACHS was reconstituted to provide statutory advice and information to the Secretary of State, and also to provide technical knowledge and advice to a new advisory body, the Chemicals Stakeholder Forum chaired by the Earl of Selborne. The Chemicals Stakeholder Forum was established by Government in October 2000 and comprises representatives from the scientific community, industry, business organizations, consumer groups and environmental groups. The Forum provides a means for the public and other stakeholders to be involved directly in the policy making process for chemical substances.

The ACHS comprises scientific and advisory specialists from private and public sector backgrounds, industry groups and non-governmental organisations. The ten scientists involved include experts in such fields as toxicology, ecotoxicology, chemistry, medicine, environmental geochemistry, risk assessment and biology. The ACHS provides objective, impartial advice, free from commercial or political bias.

In its 2001-2002 session the ACHS has been involved in advising the Chemicals Stakeholder Forum on a range of issues concerning the identification and hazard assessment of chemicals, and their prioritisation in terms of the risks they pose to humans and to the environment. Advice has also been given to the Secretary of State on several national and global issues related to the release and use of hazardous chemicals and their management in the environment. This report provides details of these important activities.

A handwritten signature in black ink, appearing to read 'Jane Plant', written in a cursive style.

Professor JANE PLANT

Contents

Foreword by the Minister for the Environment	iii
Foreword by the Chairman	iv
Introduction	
Terms of reference	1
Membership of the ACHS	1
Terms and conditions of office	2
Financial statement	3
The work of the ACHS (April 2001–March 2002)	
A summary of the Committee's work	4
Advice to the UK Chemicals Stakeholder Forum:	
Identification of chemicals of concern	5
Scrutiny of a draft list of substances that meet the first tier criteria	7
Guidance criteria for the safety net	7
Safety net criteria for inorganic substances	7
Development of second tier criteria	7
Advice on the presence of MCCPs in human breast milk	8
Advice to Government under S140 of the EPA:	
Development of a research specification for environmental indicators	9
New ozone depleting substances regulations	9
Restrictions on use of lead shot	9
Further information	10
Abbreviations used in the report	10
Reading list	
Background reading	11
Issues considered by the Committee – published sources	11
Issues considered by the Committee – Defra papers	12
Index	13
Annex	
Annex A: Environmental Protection Act 1990	14
Annex B: Declaration of Members Interests	18
Annex C: ACHS advice on the development of the safety net criteria for chemicals of greatest concern	19
Annex D: Guidance on criteria for selecting inorganic substances for the Chemicals Stakeholder Forum's safety net	21
Annex E: ACHS Advice on the development of the second tier criteria for chemicals of concern	23
Annex F: Advice from the ACHS on Medium Chain–Length Chlorinated Paraffins (MCCPS)	26

Annex G: Specification for a research project to develop indicators of hazardous substances	30
Annex H: Highlights of the new EC regulation on ozone depleting substances	35
Annex I: UK Chemicals Stakeholder Forum's first tier criteria for identifying chemicals of greatest concern	38

1. Introduction

1.1 Terms of reference

The Advisory Committee on Hazardous Substances (ACHS) was established in 1991 under Section 140(5) of the Environmental Protection Act 1990 (EPA 90), by the Advisory Committee on Hazardous Substances Order 1991 (S.I. 1991 No 1487) and by the Advisory Committee on Hazardous Substances (Terms of Office) Regulations 1991 (S.I. 1991 No. 1488). Extracts from the EPA 90 are presented in Annex A. Details of other documents referred to in the text are given in the reading list on page 12.

Under Sections 140(6) and (7) of the EPA 90, the ACHS must be consulted by Government on any proposal to introduce Regulations under that section to control injurious substances or articles. Under Section 142(3) it must similarly be consulted on any proposal to introduce Regulations under that Section requiring information about potentially hazardous substances. The Committee need not be consulted if there appears to be a risk that the delay could cause serious pollution of the environment.

Sections 140 and 142 of the EPA 90 are expected to be used mainly to implement controls agreed at EU level. The Government seeks the Committee's advice on proposed EU measures and on their implementation in the UK.

The ACHS was reformed in 2001 with the following terms of reference:

- to advise the Secretary of State for the Environment, Food and Rural Affairs, the Minister of the Environment, Northern Ireland, the Scottish Ministers, and the First Minister, National Assembly Government for Wales and other Ministers (hereafter collectively known as "the Ministers") as appropriate on the exercise of the power to make Regulations under Section 140 of the EPA 90 to prohibit or restrict the importation, use, supply or storage of specified substances or articles,
- to advise the Ministers on the exercise of the power to make Regulations under Section 142 to obtain information about potentially hazardous substances,
- to advise the UK Chemicals Stakeholder Forum and other bodies as appropriate on criteria, prioritisation and risk assessment of potentially harmful substances, and
- to advise the Ministers, the UK Chemicals Stakeholder Forum and other bodies as appropriate on research needs and the development of relevant indicators.

The ACHS provides objective advice free from commercial or political bias.

1.2 Membership of the ACHS

Schedule 12 of the EPA 90 states that the ACHS shall include scientists and advisers representing bodies concerned with environmental protection, protection of users, and industry. This is designed to ensure a broad mixture of specialists with varied backgrounds including private and public sector bodies, and professional and other non-governmental organisations.

The ACHS consists of ten scientific and advisory specialists in the fields of toxicology, ecotoxicology, chemistry, medicine, environmental geochemistry, risk assessment and biology. The Committee is chaired by Professor Jane Plant, Chief Scientist of the British

Geological Survey and Professor of Geochemistry at Imperial College, London. The Committee also has eight assessors representing Government Departments and Agencies. The main function of assessors is to provide the Committee with access to expertise and information on developments in other areas, and to contribute, where appropriate, to the Committee's discussions.

Membership of the ACHS (at March 2002)

Professor Jane Plant (Chairman)	British Geological Survey
Dr Stuart Dobson	Centre for Ecology and Hydrology
Dr Gev Eduljee	SITA Ltd
Dr Paul Harrison	MRC Institute for Environment and Health
Professor Roy Harrison	University of Birmingham
Professor Gabrielle Hawsworth	University of Aberdeen
Ms Gwynne Lyons	WWF-UK
Dr Lorraine Maltby	University of Sheffield
Professor James Readman	Plymouth Marine Laboratory
Professor David Williams	Cardiff University

Assessors on the ACHs (at March 2002)

Keith Butler	Food Standards Agency
Peter Evans	Health and Safety Executive
Robin Fielder	Department of Health
Chris Mee	Department of Trade and Industry
Isobel Moore	National Assembly for Wales
Vera Nararatnam	Home Office
Ken Pugh	Scottish Environmental Protection Agency
Steve Robertson	Environment Agency

1.3 Terms and conditions of office

The Advisory Committee on Hazardous Substances (Terms of Office) Regulations 1991 set out terms and conditions of appointment. Members are appointed for a period of up to three years ending on 31 December. Appointments may be renewed for further three-year periods. Members may resign earlier, or appointments may be terminated earlier.

The Government is committed to a fair and just society in which all citizens have an equal opportunity to play a full and active part. When inviting nominations to fill any vacancies on the Committee, Defra will draw the Government's concern to the attention of organisations whom it is consulting. It will normally ask them to offer a short list of individuals whom the Secretary of State might consider appointing, with relevant background information and, if possible, their opinion as to the person with the best combination of relevant skills and experience.

The Chairman is eligible to be paid a fee of £193 and the members a fee of £145 for each meeting attended in accordance with rates set by the Treasury. All members are paid travel and subsistence expenses, and Defra provides a working lunch during Committee meetings. Defra provides administrative support to the Committee.

While the Committee necessarily relies for its expertise on members with a close working knowledge of chemicals, their production and use, and their effects on the environment and human health, it is equally careful to safeguard the integrity and impartiality of the advice it provides to Government. Members are therefore required to make a declaration of any personal interests when first appointed, and additionally at meetings when specific subjects where conflicts of interest could arise. Having declared any interests, members can then speak on issues where they have expertise to offer.

Details of the declaration of personal interests made by members can be seen in Annex B (see "Further Information", page 10). These include any subsequent changes notified to the secretariat, and any oral declarations of interests in specific agenda items made at individual meetings.

1.4 Financial statement

Between 1 April 2001 and 31 March 2002 the following costs were incurred by Defra on behalf of the ACHS:

Travel and subsistence expenses for members	£10661.22
Secretariat staff costs	<u>£0</u>
Total	£10661.22

Support provided by other Government officials in producing and/or presenting papers or attending in the role of Assessor is excluded from the above costs.

2. The work of the ACHS (April 2001–March 2002)

2.1 A summary of the committee's work

Figure 1 entitled “Main sources of scientific advice to the government on hazardous chemicals” shows in simplified form the context in which the ACHS provides advice to Government on matters concerning the management of hazardous chemicals.

Assessment and control of hazardous chemicals is increasingly carried out at regional and international level, the main Agencies impacting on the UK being the European Union through its operating executive the European Commission (EC), and the Organisation for Economic Co-operation and Development (OECD). In February 2001 the EC adopted a White Paper on a far-reaching future chemicals strategy, which proposed that there should be a single system for the registration, evaluation and authorisation of new and existing substances, phased in over a period of time.

In anticipation of a new generation of regulatory measures governing the management of hazardous chemicals in the environment and in the products we buy and consume, Government published its UK Chemicals Strategy¹ in December 1999. The Strategy has three goals:

- to make full information about the environmental risks of chemicals publicly available;
- to continue to reduce risks from chemicals to the environment and human health while maintaining the competitiveness of industry; and
- to phase out early those chemicals that represent an unacceptable risk to the environment and/or human health as soon as possible.

To further the Chemicals Strategy, a UK Chemicals Stakeholder Forum was set up in October 2000, by the then Department of the Environment, Transport and the Regions (DETR) and the Scottish Executive, comprising representatives from industry, the public sector and non-governmental organisations. The remit of the Forum is to promote a better understanding between industry and the public about chemicals in the environment. The Chemicals Strategy envisaged that the Forum would, by providing advice to the Government, ensure that the views of the public are reflected in the development of UK policy on chemicals and the environment. Further information on the UK Chemicals Stakeholder Forum can be found in the annual report (Reading List) and on the website (www.defra.gov.uk/environment/chemistrat/stakehol/index.htm).

Between April 2001 and March 2002 the work of the reconstituted ACHS has primarily focused on providing advice to the UK Chemicals Stakeholder Forum, and to a lesser extent advising Government on the control of substances under Section 140 of the EPA. A summary of issues and outcomes is presented in Table 1, under these two areas of activity. More detailed information is provided in the sections below.

¹ Sustainable Production and use of chemicals – a strategic approach. (See document 9 in the reading list).

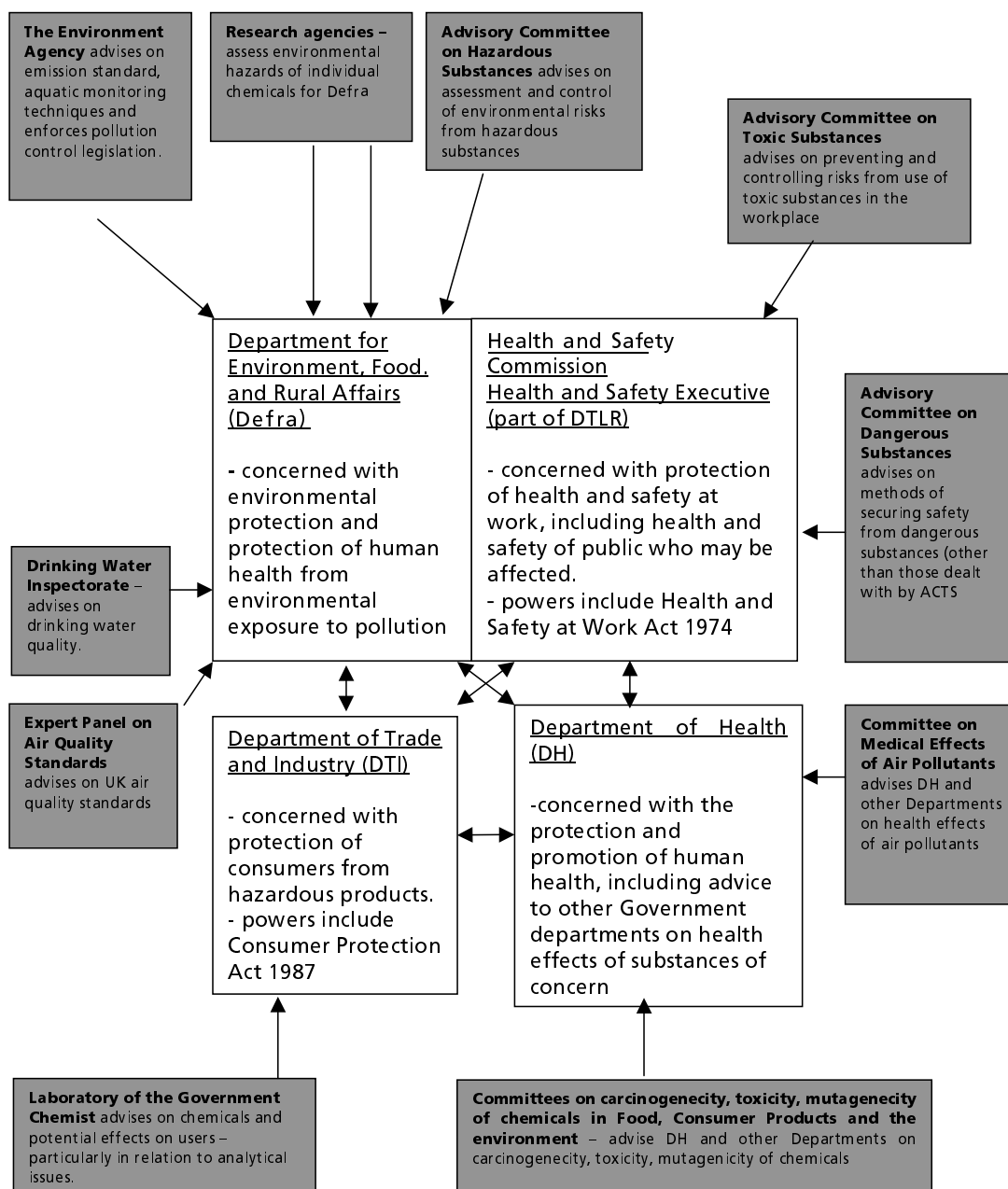


Figure 1: Main sources of scientific advice to the government on hazardous chemicals
This is a very simplified chart. In particular, the role of the devolved administrations in Scotland and Wales and the Northern Ireland Office who carry out some of these functions and sometimes have their own advisers are not included nor is the role of local Government in controlling pollution. Pesticides, veterinary medicines and biocides are dealt with by their own legislation. The chart does not show other Defra industrial and scientific panels such as those on acidic emissions, biotechnology, radioactive waste etc.

2.2 Advice to the UK Chemicals Stakeholder Forum

Identification of chemicals of concern:

The major role of the UK Chemicals Stakeholder Forum is to make recommendations to Government on risk reduction measures for hazardous substances that pose an unacceptable risk to the environment or to human health via the environment. A prerequisite task, therefore, is the identification of chemicals of concern.

Table 1: Summary of the issues and outcomes of the ACHS from April 2001 to March 2002

Summary of the Committee's Work		
Issue considered by Committee	Committee's views and Actions by March 2002	Where covered in report
I. Advice for the Chemicals Stakeholder Forum:		
Scrutiny of a draft list of substances that meet the Chemicals Stakeholder Forum's first tier criteria for substances of greatest concern.	Reviewed and endorsed the approach taken by consultants to compile a list of substances that meet the Forum's criteria for substances of greatest concern.	Section 2.2
Guidance criteria for a safety net for substances of greatest concern.	Advised that substances of equivalent concern to those meeting the first tier criteria (i.e. those of greatest concern), but for which standard (PBT/CMR) criteria are inappropriate, should be considered on a case-by-case basis by the Committee.	Section 2.2
Safety net criteria for inorganic substances of greatest concern.	Advised that inorganic substances should be considered by the Committee on a 'case-by-case' basis.	Section 2.2
Second tier criteria for organic substances of concern (but not greatest concern).	Criteria developed based on very Persistent and very Bioaccumulative (vPvB), persistent, bioaccumulative and toxic (PBT), and carcinogenic, mutagenic and toxic to reproduction (CMR) properties.	Section 2.2
Advice on the likely presence and possible consequences of Medium Chain-length Chlorinated Paraffins (MCCPs) in human breast milk.	Advised the Forum that MCCPs met the Forums First Tier Criteria and that MCCPs are likely to be found in human breast milk; that MCCPs have not been identified as naturally occurring organohalogens; and that it could not comment on the likely effects of MCCPs on human health.	Section 2.2
II. Advice to Government under the Environmental Protection Act 1990:		
Development of a research specification for environmental indicators of hazardous substances.	Provided advice on a specification for the development of indicators of hazardous substances. The work is underway. The Committee will take part in the steering group for the project.	Section 2.3
New Ozone depleting substances regulations.	The Committee endorsed new ozone depleting substances regulations, enabling the UK to ratify the Montreal Protocol (to reduce and eliminate the use of ozone depleting substances).	Section 2.3
Restrictions on the use of lead shot (with regard to the shooting of certain species of wildfowl in certain sites).	The Committee endorsed the removal of unnecessary sites and the addition of other SSSI sites to the 1999 Regulation. It recommended however, that further consideration be given to the proposal to remove the snipe and golden plover from their protected status.	Section 2.3

The Stakeholder Forum has sought advice from the ACHS on several issues relating to the identification of hazardous substances, including: scrutiny of a draft list of substances that meet the first tier criteria; the development of guidance for safety net criteria to identify substances of greatest concern (for which the standard criteria are not appropriate); the development of a second tier of criteria to identify substances of concern; the presence of MCCPs in human breast milk.

Scrutiny of a draft list of substances meeting the first tier criteria

A screen of the European Union, International Uniform Chemical Information Database (IUCLID) by consultants resulted in a draft list of substances meeting the Stakeholder Forum's first tier criteria. The first tier criteria are based on the persistence, bioaccumulation and toxic (PBT) properties of chemicals. Of the 1068 organic substances identified from the screen, thirteen met the requirements of the Forum's first tier criteria. A preliminary peer review of the screening study and the lists of chemicals that meet the first tier criteria was conducted by the Environment Agency to ensure quality of data. The ACHS reviewed this paper at its second meeting on the 3rd September 2001. The ACHS agreed that the work to date by the consultants was valid but the majority view of the ACHS was that further validation of the data was necessary to ensure that the final list of substances was based on sound science.

Guidance for the development of safety net criteria

The ACHS provided the Chemicals Stakeholder Forum with advice on guidance for a safety net, to select substances of greatest concern, so that the Forum could consider such substances for risk assessment and management. The purpose of the safety net guidance was to identify substances for which the standard criteria for identification of hazardous properties would be inappropriate. The ACHS subsequently held discussions at their first and second meetings and provided the Stakeholder Forum with guidance advice (Annex B). In summary the ACHS recommended that the safety net be designed to include those substances that meet any two of the three first tier criteria of persistence, bioaccumulation and toxicity, or are known to be very toxic. The ACHS recommended that the safety net be flexible and include substances other than those that meet the main criteria, where such substances might be a cause for concern. Finally it was recommended that the safety net be based on the precautionary principle. All substances meeting the ACHS's safety net guidance criteria should be subject to ACHS expert review to decide whether or not it would be appropriate to pass them on to the Chemicals Stakeholder Forum.

Safety net criteria for inorganic substances

The application of the safety net to metals/elements and inorganic chemical substances was discussed, and it was agreed that there are particular difficulties in dealing with them. Many occur naturally and are distributed in the environment in different ways governed by local geology and other factors. According to the particular chemical species of these substances they may be beneficial or essential to health, and not necessarily harmful in all scenarios. Case by case examination will, therefore, always be required. It is not possible to apply the Forum's criteria broadly. Guidance on the application of the safety net to these substances is given in Annex C.

Development of Second Tier criteria

The ACHS held an initial discussion on the development of a Second Tier of criteria to identify chemicals of sufficient concern to identify them for everyone (including downstream users and retailers). The ACHS discussed these criteria at its first and second meetings (27th March and 3rd September 2001), and presented interim advice to the Chemicals Stakeholder Forum at its fourth meeting (28th June 2001). The conclusions of that meeting are presented in Annex D. In summary, criteria were agreed for persistence and bioaccumulation and toxicity with less stringent thresholds than those of the first tier criteria (i.e. more substances are identified).

Advice on the presence of MCCPs in human breast milk

The Chemicals Stakeholder Forum is considering the medium chain-length chlorinated paraffins (MCCPs) with a view to agreeing risk management strategies with industry and users. MCCPs are currently going through the European Union's Existing Substances Regulation, where risks to the aquatic environment have been identified. There is considerable uncertainty, however, on other aspects of the risk assessment. The Stakeholder Forum, therefore, requested advice from the ACHS on several issues, including the likely presence and potential consequences of MCCPs in human breast milk, and whether MCCPs are naturally occurring substances. Based on the data placed before the Committee, expert judgement was given (Annex E). In summary, the ACHS decided that: MCCPs meet the Forum's first tier criteria for substances of greatest concern; MCCPs are likely to be present in human breast milk; and that MCCPs have not been identified as naturally occurring organohalogenes. The ACHS could not comment on the likely effects to human health of the presence of MCCPs in breast milk, based on available data. (refer to Text Box 1 below for further information)

Medium chain-length chlorinated paraffins

Medium Chain-Length Chlorinated Paraffins (MCCPs) are used to make a wide range of products in every day use. These include PVC plastics, metal working fluids, paints, sealants and glues, flame retardants, rubber and leather goods. MCCPs are released into the environment when these products are manufactured, used or disposed of (for example, the disposal of metal working fluids to the wastewater system).

It is thought that MCCPs in the environment are absorbed by animals and humans via water, soil and food. There are uncertainties about the properties of MCCPs. Information on their persistence, bioaccumulation and toxicity is not fully known. However, it is thought that MCCPs are persistent, meaning they remain in the environment for a long period of time without breaking down into inert products. Studies have failed to show that MCCPs accumulate in the bodies of animals or that concentrations of MCCPs increase in the food chain. Experiments have shown that high concentrations of MCCPs are harmful to fish and rodents, though the effects on humans are unknown.

There are still many uncertainties about MCCPs and their possible effects on human health and the environment. Companies that use or manufacture MCCPs are making efforts to find out more information with new studies being performed and have set up a Best Practise User Group. This user group meets to share practical ideas on how to reduce the risks of MCCPs. In summary, the jury is still out on what sort of action is justified in light of the risks from MCCPs.

The UK has completed a draft risk assessment for MCCPs. The risk assessment identifies where there is the possibility of harmful effects on human health or the environment and suggests things to be done to prevent harmful effects. The risk assessment identified a risk to the aquatic environment and raised concerns about the findings of a human breast milk study that showed MCCPs in human breast milk. The EU is performing a risk assessment of MCCPs at the moment, the results of which are expected to be published later in the year.

2.3 Advice to government under S140 of the EPA

Development of a research specification for environmental indicators

The UK Chemicals Strategy recommended that the Government should develop indicators of environmental exposure to hazardous chemicals, including targets for reducing overall exposure of the environment. The ACHS considered this issue at its first meeting in March 2001. Subsequently, an *ad hoc* 'indicators' group was formed from members of the UK Chemicals Stakeholder Forum, the ACHS, the Environment Agency and Government departments to develop a specification for the selection of suitable indicators. The specification was finalised by the ACHS at its second meeting in September 2001 (Annex F).

The specification stated that a suite of indicators should be developed for hazardous substances. These should include both PERFORMANCE and STATE indicators. Performance indicators are linked to a target or goal and show how far the indicator is from the target. State indicators describe what is happening to the environment. The specification was put out for competitive tender in December and the consultants selected began work in March 2002. The consultants will seek guidance from, and keep the Committee informed of, development of the project.

New ozone depleting substances regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer was adopted in 1987 and aims to reduce and eventually eliminate emissions of man-made ozone depleting substances. In order for the UK and the EU to ratify the latest two adjustments made in Montreal (1997) and Beijing (1999), a new Regulation (EC Regulation 2037/2000) was necessary. Details of the EC policy are provided in Annex G. Within the UK, a new Statutory Instrument enforcing the new EC Regulation is required and will create the necessary offences and penalties relating to the importation, use, supply, and storage of controlled substances. The ACHS endorsed the regulations, although concern was expressed that the enforcement measures could allow substances imported illegally to be re-exported.

Restrictions on the use of lead shot

The ACHS was invited to consider and comment on the draft revisions to amend Schedules 1 and 2 of Statutory Instrument 1999 No. 2170 Environmental Protection, the Environmental Protection (Restriction for the Use of Lead Shot)(England) Regulations 1999. A Government working group recommended revisions to the Schedules of the Regulations proposed to amend the list of sites covered and to remove the Common Snipe and Golden Plover from the scope of the regulations' required legislation under Section 140 of the Act.

The ACHS endorsed the removal of unnecessary Sites from Schedule 1 and added other SSSI's that are used by wildfowl. The ACHS asked that further consideration be given to the conservation consequences of the proposal to remove the Golden Plover and Common Snipe from Schedule 2 and recommended that there be an assessment of the potential adverse effects of alternatives to lead before they are allowed to be used as replacements. The ACHS also recommended that lead and the alternatives be formally monitored in habitats where shooting takes place, (cost recovery charges for monitoring could be considered in this respect).

Further information

Further information on the work of the Committee can be obtained on the web page, www.defra.gov.uk/environment/chemicals/achs/index.htm or from Dr John Garrod, at Defra Chemicals and GM Policy Division, Zone 3/E5 Ashdown House, 123 Victoria Street, London SW1E 6DE, telephone 0207 9445254. Press enquiries should be sent to Matt Conway, room 724, Nobel House, 17 Smith Square, London SW1P 3JR, telephone 0207 238 5334.

The reading list on page 12 provides more details of documents referred to in this report.

Abbreviations used in this report

ACHS	Advisory Committee on Hazardous Substances
CMR	Carcinogens, Mutagens and Reproductive toxins
Defra	Department for Environment, Food and Rural Affairs
DH	Department of Health
DTI	Department of Trade and Industry
DTLR	Department for Transport, Local Government and the Regions
EC	European Commission
EINECS	European Inventory of New and Existing Chemical Substances
EPA	Environmental Protection Act 1990
ESR	Existing Substances Regulation (793/93/EEC)
EU	European Union
HSE	Health and Safety Executive
IEH	Institute for Environment and Health
IPCS	International Programme on Chemical Safety
IUCLID	International Uniform Chemical Information Database
MCCPs	Medium Chain-length Chlorinated Paraffins
MRC	Medical Research Council
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
POPs	Persistent Organic Pollutants
QSAR	Quantitative Structure -Activity Relationship
SSSI	Site of Special Scientific Interest
vPvB	Very Persistent, Very Bioaccumulative

The report uses the commonly-used names of substances.

Reading list

The documents below can be read in the Defra Library at 2 Marsham Street, London SW1P 3EB (please give at least a day's notice) unless stated otherwise. Some can be ordered from HMSO or from bookshops.

Document (and ordering details, if published)

1. Background reading

- 1). **1st Annual Report of the Advisory Committee on Hazardous Substances 1991-92**
(HMSO ISBN 0 11 752638 X)
- 2). **2nd Annual Report of the Advisory Committee on Hazardous Substances 1992-93**
(HMSO ISBN 0 11 752858 7)
- 3). **3rd Annual Report of the Advisory Committee on Hazardous Substances 1993-94**
(HMSO ISBN 0 11 753047 6)
- 4). **4th Annual Report of the Advisory Committee on Hazardous Substances 1994-95**
(HMSO ISBN 0 11 753183 9)
- 5). **5th Annual Report of the Advisory Committee on Hazardous Substances 1995-96**
(HMSO ISBN
- 6). **Environmental Protection Act 1990**
(HMSO ISBN 0 10 544390 5)
NB. Sections 140 and 142 are reproduced at the end of this Report
- 7). **SI 1991, No. 1487 Advisory Committee on Hazardous Substances Order 1991**
(HMSO 1991 ISBN 0 11 014487 2)
- 8). **SI 1991, No. 1488 Advisory Committee on Hazardous Substances (Terms of Office) Regulations 1991**
(HMSO 1991 ISBN 0 11 014488 0)
- 9). **Sustainable production and use of chemicals – a strategic approach**
December 1999
(HMSO 1999 ISBN 1-851123-33-4)
- 10). **Chemicals Stakeholder Forum Annual Report 2000-2001**
November 2001
(HMSO 2001 ISBN 1-85112-700-3)

2. Issues considered by the Committee—published sources

- 11). **Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances**
Official Journal of the EC
L84 Volume 36, 5 April 1993
(available from HMSO)
- 12). **European Inventory of New and Existing Commercial Chemical Substances (EINECS)**
Official Journal of the EC
C1460 Volume 33, 15 June 1990
(available from HMSO)
NB. Only substances on EINECS are covered by the Regulation
- 13). **SI 1996 No. 506, The Environmental Protection (Controls on Substances that Deplete the Ozone Layer) Regulations 1996**
(HMSO ISBN 0 11 054183 9)

3. Issues considered by the Committee—Defra papers

Inventory of papers list 1

Title	Paper reference
1. An Overview of the Government's Chemicals Strategy	ACHS/00/1
2. Draft Terms of Reference	ACHS/00/2
3. Working Methods	ACHS/00/3
4. Conflicts of Interests/Register of Interests	ACHS/00/4
5. Draft Work Programme	ACHS/00/5
6. Identifying Chemicals of Concern: Second Tier Criteria	ACHS/00/6
7. Environmental Indicators	ACHS/00/7
8. Develop toxicity criterion and 'flesh-out' safety net	ACHS/01/8
9. Scrutinize draft list of substances that meet the Chemicals takeholder Forum Criteria	ACHS/01/9
10. New CFC Regulation SI—note line to take / conclusions to take from old annual report	ACHS/01/10
11. Lead Shot	ACHS/01/11
12. Development of Indicators of Hazardous Chemicals	ACHS/01/12
13. Identification of the critical tests for a substance from the base-set tests for the purposes of registration and authorisation	ACHS/01/13
14. Guiding principles for criteria for inorganic substances for the Safety Net	ACHS/01/14
15. Screen of the IUCLID database for substances that meet the Forum's criteria of for substances of greatest concern	ACHS/01/15

Inventory of papers list 2 – information papers

Title	Paper reference
1. Access to Advice from Departmental Advisory Committees	ACHS/INF/00/1
2. ICCA and OECD Initiative on High Production Volume Chemicals	ACHS/INF/00/2
3. European Commission's White Paper on a Future Chemicals Strategy	ACHS/INF/00/3
4. Conflicts of Interest and Consistency ACHS Website	ACHS/INF/01/4
5. Update on the European Commission's White Paper on a Future Chemicals Strategy	ACHS/INF/01/5
6. Progress in Screening Chemicals	ACHS/INF/01/6
7. Update on the European Commission's White Paper on a Future Chemicals Strategy—outcomes of technical work groups	ACHS/INF/01/7
8. Proteomics and Genomics—report and conclusions from the CoT symposium	ACHS/INF/01/8
9. Briefing on in vitro test methods	ACHS/INF/01/9
10. Briefing on Biomarkers	ACHS/INF/01/10

Index

Subject	page
Advisory Committee on Dangerous Substances	4
Advisory Committee on Hazardous Substances: assessors	2
declaration of interests	3
members	1,2,3
terms of office	2
terms of reference	1
work	5
Advisory Committee on Toxic Substances	4
Alkenes C10-13 chloro, (see Chlorinated paraffins)	7,8,9
Carcinogens	25, 26
Chemicals Stakeholder Forum	iii, iv, 1,5,7,8,9,13,20
Chemicals Strategy (UK)	4,12,17,18, 32
Chlorinated paraffins (alkenes C10-13 chloro)	4,7,10,11,12, 18,20,26,32
Committee on Carcinogenicity	4
Committee on Mutagenicity	4
Committee on Toxicology	4
Department for Environment, Food and Rural Affairs (Defra)	4
Department of Environment, Transport and the Regions (DETR)	4
Department of Health (DH)	4
Department of Trade and Industry (DTI)	4
European Commission (EC)	5,37,38
European Union	5,7,8
Environmental Protection Act 1990	1,12,16
Existing Substances Regulation	8,32
Health and Safety Executive (HSE)	4,29
International Uniform Chemical Information Database (IUCLID)	7
Lead	6,9,10,26
Montreal Protocol	6,9
Mutagens	11,25,40
Northern Ireland	1,4,17
Ozone depleting substances	6,9,36,37
Quantitative structure activity relationship (QSAR)	11,26,40
Risk: assessment	iii,1,2,8,32
management	17,8,20,22,23, 27,32,39,40
reduction	7

Annex A

Sections 140, 142 Of The Environmental Protection Act 1990

Part VIII Miscellaneous

Other controls on substances, articles or waste

Section 140. Power to prohibit or restrict the importation, use, supply or storage of injurious substances or articles.

- (1) The Secretary of State may by regulations prohibit or restrict-
 - (a) the importation into and the landing and unloading in the United Kingdom,
 - (b) the use for any purpose,
 - (c) the supply for any purpose, and
 - (d) the storage,of any specified substance or article if he considers it appropriate to do so for the purposes of preventing the substance or article from causing pollution of the environment or harm to human health or to the health of animals or plants.
- (2) Any such prohibition or restriction may apply-
 - (a) in all, or only in specified, areas;
 - (b) in all, or only in specified, circumstances or if conditions imposed by the regulations are not complied with; and
 - (c) to all, or only to specified descriptions of, persons.
- (3) Regulations under this section may-
 - (a) confer on the Secretary of State power to direct that any substance or article whose use, supply or storage is prohibited or restricted is to be treated as waste or controlled waste of any description and in relation to any such substance or article-
 - (i) to apply, with or without modification, specified provisions of part II; or
 - (ii) to direct that it be disposed of or treated in accordance with the direction;
 - (b) confer on the Secretary of State power, where a substance or article has been imported, landed or unloaded in contravention of a prohibition or restriction imposed under subsection (1)(a) above, to require that the substance or article be disposed of or treated in or removed from the United Kingdom;
 - (c) confer powers corresponding to those conferred by section 17 above on persons authorised for any purpose of the regulations by the Secretary of State or any local or other authority; and
 - (d) include such other incidental and supplemental, and such transitional provisions, as the Secretary of State considers appropriate.

- (4) The Secretary of State may, by regulations under this section, direct that, for the purposes of any conferred on him under subsection (3)(b) above, any prohibition or restriction on the importation into or the landing and unloading in the United Kingdom imposed-
- (a) by or under any Community instrument, or
 - (b) by or under any enactment,
- shall be treated as imposed under subsection (1)(a) above and any power conferred on him under subsection (3)(b) above shall be exercised accordingly.
- (5) The Secretary of State may by order establish a committee to give him advice in relation to the exercise of the power to make regulations under this section and Schedule 12 to this Act shall have effect in relation to it.
- (6) Subject to subsection (7) below, it shall be the duty of the Secretary of State before he makes any regulations under this section other than regulations under subsection (4) above-
- (a) to consult the committee constituted under subsection (5) above about the proposed regulations;
 - (b) having consulted the committee, to publish in the London Gazette and, if the regulations apply in Scotland or Northern Ireland, the Edinburgh Gazette or, as the case may be, Belfast Gazette and in any other publication which he considers appropriate, a notice indicating the effect of the proposed regulations and specifying-
 - (i) the date on which it is proposed that the regulations will come into force;
 - (ii) a place where a draft of the proposed regulations may be inspected free of charge by members of the public during office hours; and
 - (iii) a period of not less than fourteen days, beginning with the date on which the notice is first published, during which representations in writing may be made to the Secretary of State about the proposed regulations; and
 - (c) to consider any representations which are made to him in accordance with the notice.
- (7) The Secretary of State may make regulations under this section in relation to any substance or article without observing the requirements of subsection (6) above where it appears to him that there is an imminent risk, if those requirements are observed, that serious pollution of the environment will be caused.
- (8) The Secretary of State may, after performing the duty imposed on him by subsection (6) above with respect to any proposed regulations, make the regulations either-
- (a) in the form of the draft mentioned in subsection (6)(b) above, or
 - (b) in that form with such modifications as he considers appropriate;
- but the Secretary of State shall not make any regulations incorporating modifications unless he is of the opinion that it is appropriate for the requirements of subsection (6) above to be disregarded.
- (9) Regulations under this section may provide that a person who contravenes or fails to comply with a specified provision of the regulations or causes or permits another person to contravene or fail to comply with a specified provision of the regulation commits an offence and may prescribe the maximum penalty for the offence.
- (10) No offence under the regulations shall be made punishable with imprisonment for more than two years or punishable on summary conviction with a fine exceeding level 5 on the

standard scale (if not calculated on a daily basis) or, in the case of a continuing offence, exceeding one-tenth of the level on the standard scale specified as the maximum penalty for the original offence.

(11) In this section-

“the environment” means the air, water and land, or any of those media, and the medium of air includes the air within buildings and the air within other natural or man-made structures above or below ground;

“specified” means specified in the regulations; and

“substance” means any natural or artificial substance, whether in solid or liquid form in the form of a gas or vapour and it includes mixtures of substances.

Section 142. Powers to obtain information about potentially hazardous substances.

- (1) The Secretary of State may, for the purpose of assessing their potential for causing pollution of the environment or harm to human health, by regulations make provision for and in connection with the obtaining of relevant information relating to substances which may be specified by him by order for the purposes of this section.
- (2) The Secretary of State shall not make an order under subsection (1) above specifying any substance –
 - (a) which was first supplied in any member State on or after 18th September 1981; or
 - (b) in so far as it is a regulated substance for the purposes of any relevant enactment.
- (3) The Secretary of State shall not make an order under subsection (1) above specifying any substance without consulting the committee established under section 145 (5) except where it appears to him that information about the substance needs to be obtained urgently under this section.
- (4) Regulations under this section may –
 - (a) prescribe the descriptions of relevant information which are to be furnished under this section in relation to specified substances;
 - (b) impose requirements on manufacturers, importers or suppliers generally to furnish information prescribed under paragraph (a) above;
 - (c) provide for the imposition of requirements on manufacturers, importers or suppliers generally to furnish relevant information relating to products or articles containing specified substances in relation to which information has been furnished in pursuance of paragraph (b) above;
 - (d) provide for the imposition of requirements on particular manufacturers, importers or suppliers to furnish further information relating to specified substances in relation to which information has been furnished in pursuance of paragraph (b) above;
 - (e) provide for the imposition of requirements on particular manufacturers or importers to carry out tests of specified substances and to furnish information of the results of tests;
 - (f) authorise persons to comply with requirements to furnish information imposed on them by or under the regulations by means of representative persons or bodies;

- (g) impose restrictions on the disclosure of information obtained under this section and provide for determining what information is, and what information is not, to be treated as furnished in confidence.
- (h) create offences, subject to the limitation that no offence shall be punishable with imprisonment or punishable on summary conviction with a fine exceeding level 5 on the standard scale.
- (i) make any public authority designated by the regulations responsible for the enforcement of the regulations to such extent as may be specified in the regulations;
- (j) include such other incidental and supplemental, and such transitional, provisions as the Secretary of State considers appropriate.
- (5) The Secretary of State shall have regard, in imposing or providing for the imposition of any requirement under subsection (4)(b), (c), (d) or (e) above, to the cost likely to be involved in complying with the requirement.
- (6) In this section-
- “the environment” means the air, water and land or any part of them;
- “relevant information” in relation to substances, products or articles, means information relating to their properties, production, distribution, importation or use or intended use and, in relation to products or articles, to their disposal as waste;
- “substance” means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour and it includes mixtures of substances.
- (7) The enactments which are relevant for the purposes of subsection (2)(b) above are the following_
- | | |
|------------|---|
| 1875 c.17. | the Explosive Substances Act 1875; |
| 1960 c.34. | the Radioactive Substances Act 1960; |
| 1968 c.67. | Parts II, III and VIII of the Medicines Act 1968 |
| 1970 c.40. | Part IV of the Agriculture Act 1970; |
| 1971 c.38. | the Misuse of Drugs Act 1971; |
| 1985 c.48. | Part III of the Food and Environment Protection Act 1985; |
| 1990 c.16. | the Food Safety Act 1990; |
- and a substance is a regulated substance for the purposes of any such enactment in so far as any prohibition, restriction or requirement is imposed in relation to it by or under the enactment for the purposes of that enactment.

Annex B

Declaration of Members' Interests			
Member	Research Grants/Contracts	Company/Organisation	Interests Declared
Dr Stuart Dobson			None
Dr Gev Eduljee		Sita Environmental Trust	Director
Professor Roy Harrison	RESEARCH GRANTS: NERC; EPSRC. RESEARCH CONTRACTS: 3M healthcare; Ireland EPA; Stanger Science and Environment; Environmental Resources Management; DERA; Warwickshire Health Authority; Environment Agency; Birmingham City Council	Halifax Building Society Oak Property (1996) Ltd Bradford & Bingley Friends Provident Irwin Mitchell Environment Agency Minosus Limited Environmental Resources Management	Shareholder Shareholder Shareholder Shareholder Shareholder Consultant Consultant Consultant
Dr Paul Harrison	RESEARCH GRANTS: Defra; British Aerosol Manufacturers Association; Department of Health; Environment Agency; CEFIC.	None	None
Professor Gabrielle Hawksworth	RESEARCH GRANTS: GlaxoSmithKline; Pfizer Global R&D; Servier R&D; GW Pharmaceuticals	British Toxicology Society	Commissioner for the Medicines Commission, IUTOX 89 (holding company for running the toxicology conferences IUTOX 89 and EUROTOX 2000)
Ms Gwynne Lyons	None	Pesticides Action Network	Board of Directors
Dr Lorraine Maltby	RESEARCH GRANTS: Defra, EU	None	None
Professor Jane Plant	RESEARCH GRANTS/ CONTRACTS: British Geological Society, held.	Breast Cancer Understanding and Prevention	Director
Professor James Readman	RESEARCH GRANTS: NERC; CEC (MAST), Defence Research Agency; MAFF	None	None
Professor David Williams		None	None

Annex C

ACHS advice on the development of the safety net criteria for chemicals of greatest concern

1. Introduction

- 1.1 The Chemicals Stakeholder Forum has requested the ACHS to provide advice on the development of a safety net of criteria to identify chemicals of concern. In November 2000 the Chemicals Stakeholder Forum agreed a set of criteria to identify those chemicals that are of greatest concern (hereafter referred to as first tier criteria; Annex G). The ACHS subsequently held an initial discussion on the development of guidance for the safety net.
- 1.2 It was decided that the so-called 'safety net' (for the first tier criteria) needed more structure, in order that guidance can be given as to whether a substance is of high concern, and hence its use should be considered for risk management by the Chemicals Stakeholder Forum. However, it is important that the safety net does not become too rigid and thus lose its function to 'capture' substances of concern not meeting the standard PBT/CMR criteria. The safety net should be developed with the precautionary principle in mind, in a way that allows a flexible but consistent application to chemicals of concern.
- 1.3 Substances that may be identified by the safety criteria would require case by case expert consideration by the ACHS prior to the Chemicals Stakeholder Forum's consideration for risk management.

2. Safety net considerations

- 2.1 The application of the safety net to metals/elements and inorganic chemical substances was discussed, and it was agreed that there are particular complexities in identifying those of concern. Many occur naturally and are distributed in the environment in different ways governed by local geology and other factors. Many of these substances may be beneficial or essential to health, and not necessarily harmful in all use scenarios. Case by case examination is often required and it is not possible to broadly apply the Forum's criteria. Guidance on the application of the safety net to these substances requires further specific development, and the ACHS will advise further in due course.
- 2.2 The ACHS considers that the following types of organic substances or scenarios could be subject to the safety net criterion at this time. As a general principle, the following advice applies to substances including those that break down or are transformed (either abiotically or biotically) 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 $L(E)C_{50} < 0.1 \text{ mg/L}$, $NOEC < 0.01 \text{ mg/L}$, $L(E)D_{50} < 0.1 \text{ mg/Kg}$, $NOED < 0.01 \text{ mg/Kg}$. 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 continuously 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 adsorb 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 rate of degradation).

- 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 organisms². The ACHS will continue to examine this issue and will advise further.
- 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.

Secretariat
September 2001

² 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.

Annex D

Guidance on criteria for selecting inorganic substances for the chemicals stakeholder forum's safety Net

1. Introduction

- 1.1 The Chemicals Stakeholder Forum requested that the ACHS provide advice on guidance for their safety net, to select substances of high concern, so that the Stakeholder Forum may consider such substances for risk management. The ACHS subsequently held discussions at their first and second meetings and provided the Stakeholder Forum with guidance advice (Annex A). However, the ACHS felt that further work was required to develop guidance criteria for inorganic substances selected by the safety net. This paper outlines the ACHS guidance on criteria for inorganic substances and also some of the important considerations with respect to inorganic substances.
- 1.2 Developing criteria for inorganic substances and particularly metals and metalloids is more difficult than for organic substances because some are essential for human, wildlife, and ecosystem health and they are often naturally occurring. In addition, the natural background concentrations of these substances vary considerably.
- 1.3 The purpose of the criteria is to prioritise substances of high concern for 'fast-track' risk management consideration by the Stakeholder Forum. Therefore, hazard rather than risk-based criteria are required. However, traditional criteria such as persistence are inappropriate for such substances. 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. Inorganic species of arsenic tend to be far more toxic than organo-arsenic compounds while the reverse is the case for mercury substances. Bioaccumulation has difficulties too; whilst metals can accumulate (e.g. in bone) they are not lipophilic *per se* and hence, the standard log K_{ow} partition tests are inappropriate. However, metals ions associated with organic moieties can be lipophilic. The labile nature of some metal compounds and their ability to exchange functional groups in natural environments and in biota is a further important consideration with respect to the bioavailability and toxicity of such compounds.
- 1.4 A further complication with inorganic substances is that their toxicity is often dependent on their chemical speciation and/or the chemical into which it is incorporated. For example some minerals e.g. baryte containing potential harmful substances (barium), are resistant to weathering and therefore are of limited bioavailability. Likewise, some inorganic substances released into the environment in an inert form may be transformed to a more toxic form. Therefore, the toxicity guidance for inorganic substances will need to be applied to specific metal species, taking into consideration subsequent likely changes in speciation if the released chemical is susceptible to environmental influences such as the presence of redox agents, pH, biotic and abiotic processes, etc. In order for the guidance to accommodate these issues the ACHS may restrict the toxicity advice to 'comparatively stable' inorganic substances. This term would require definition; for example, metal species that persist in their released form in the relevant media for at least 10 years or have a half life greater than 10 years.
- 1.5 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 affects to the environment or human health *via* the environment.

2. Guidance statements for inorganic substances selected by the safety net

- 2.1 It is important to restate that the purpose of the Chemicals Stakeholder Forum's criteria is to prioritise substances of high concern for fast-track risk management consideration. Therefore, issues relating to exposure (e.g. natural background concentrations) should not be part of the safety net guidance. If a substance meets the Forum's criteria (based on intrinsic hazard properties) then issues of risk (e.g. tonnage and use etc.) will then be considered. The Forum may seek further advice from the ACHS on this point, for inorganic substances to clarify issues such as naturally varying background concentrations.
- 2.2 Inorganic substances that should be included in the safety net are those that:
- a) are very toxic to organisms in either the aquatic or terrestrial compartments. Toxicity thresholds for inorganic substances could be those with acute toxicity of $L(E)C_{50} < 0.1 \text{ mg/L(Kg)}$, or point estimate (or $NOEC/D < 0.01 \text{ mg/L(Kg)}$); and/or
 - b) 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.

For the reasons stated above, all inorganic substances selected by these guidelines will be considered by the ACHS on a case-by-case basis.

Annex E

ACHS advice on the development of the second tier criteria for chemicals of concern

1. Introduction

- 1.1 The Chemicals Stakeholder Forum has requested the ACHS to provide advice on the development of a Second Tier of criteria to identify chemicals of concern. In November 2000 the Chemicals Stakeholder Forum agreed a set of criteria to identify those chemicals that are of greatest concern (hereafter referred to as first tier criteria). The ACHS subsequently held an initial discussion on the development of a Second Tier set of criteria at its first meeting (27th March 2001), and presented interim advice to the Chemicals Stakeholder Forum at its fourth meeting (CSF/01/INF/10).

2. Persistence

Substances that are persistent are not significantly degraded in the environment within a given time. For most substances, however, there are no measured data on persistence. In addition, substances measured in experimental systems often have shorter half-lives than those same substances in the natural environment.

- 2.1 Most data are derived from ready biodegradation tests (Organisation for Economic Co-operation and Development (OECD) standardised), which have a pass or fail criterion. The ready biodegradation test is, therefore, a surrogate for environmental half-lives in many fora. The ready biodegradation test would be failed by an estimated 80-90% of new substances.
- 2.2 The only practical assessment of persistence is, therefore, the ready biodegradation test. Including environmental half-lives in the criterion, however, provides an incentive to industry to carry out environmental half-life tests. Furthermore, environmental half-lives should be stated with a view to a standardised test being developed in the future.

ACHS advises that possible second tier criteria for persistence are:

Persistence—not readily degradable (failure of the ready biodegradation test) unless environmental half-life < 30 days in water and < 60 days in soil or sediment.

3. Bioaccumulation

- 3.1 Bioaccumulation is the process by which a substance accumulates in a living organism, either from surrounding media or from food or water. $\log K_{ow}$ is a measure of the likely tendency of a substance to partition from water to organic media. A higher $\log K_{ow}$ value usually indicates a greater tendency to bioaccumulate.
- 3.2 Bioconcentration Factor (BCF) and Bioaccumulation Factor (BAF) are terms used to describe bioaccumulation.
- BCF refers to accumulation of a chemical into an organism through the aquatic environment.
- BAF refers to accumulation of a chemical into an organism via food and through the ambient environment.

- 3.3 For most substances BCF and BAF data are not available, therefore, $\log K_{ow}$ is the most pragmatic approach for the bioaccumulation criterion. Reducing the $\log K_{ow}$ from >5 to >4 would include many more chemicals.
- 3.4 $\log K_{ow}$ is a measure of the tendency to partition from water to organic media, such as lipids, which are present in living organisms. $\log K_{ow}$, therefore, gives an indication of the potential of a chemical to bioaccumulate. This may be different from the reality, however, as substances with a relatively low $\log K_{ow}$ might also bioaccumulate. Alternatively, degradation in the environment or metabolism in the organism may occur readily, or substances may adsorb so strongly to environmental media that they are not bioavailable to organisms. In addition, the rate of loss of a chemical from an organism may be very rapid.
- 3.5 Therefore, BCF and BAF should be included in the criterion in addition to $\log K_{ow}$. ACHS advises that possible second tier criteria for Bioaccumulation are therefore:

BAF (bioaccumulation factor) or BCF (bioconcentration factor) greater than or equal to 500, or $\log K_{ow}$ greater than or equal to 4, unless there are measured data to show the BCF is less than 500.

4. Toxicity

- 4.1 The toxicity of a chemical is assessed using organisms (usually algae, daphnia or fish), and determining the dose or concentration that is fatal to (or produces an adverse effect in) a certain percentage of the organisms. The highest concentration of a test substance that results in no adverse effect, is called the No Observed Effect Concentration (NOEC).
- 4.2 There is a general shift away from NOECs towards point estimates (i.e. EC_x ; concentration that elicits a response in $x\%$ of the organisms exposed), and therefore, the criterion should state either NOEC data or point estimate data. Point estimates rather than standard NOECs should be used wherever possible. Point estimates are derived from the same experimental data, but use a different statistical model to calculate the percentage of organisms affected at a specific concentration. This approach was considered by the ACHS to be more robust.
- 4.3 Changing the toxicity criterion from $L(E)C_{50} \leq 1 \text{ mg/L}$ to $L(E)C_{50} \leq 10 \text{ mg/L}$ might increase the number of new chemicals selected by approximately 40%. Toxicologists, however, work in orders of magnitude and, therefore, any toxicity threshold in between would be arbitrary.
- 4.4 The criteria agreed for the first tier included:
- 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.
- 4.6 The rationale for excluding Category 3 carcinogens and reproductive toxins from the first tier criteria was that they included substances for which there are suspicions, but not sufficient evidence for more definitive classification. It is likely to include a significant number of substances (possibly thousands). Thus, inclusion of substances that are Category 3 toxins may result in the selection of too many substances to be prioritised effectively.
- 4.7 Further, Category 3 carcinogens or reproductive toxins are ones where the mechanism involved is unlikely to be applicable to humans, or the effects were only noted at high dose levels associated with other (non-reproductive) toxic effects, or which were far in excess of any likely environmental exposure.

- 4.8 This rationale would equally apply to second set of criteria and it is proposed, therefore, that the CMR criteria used for the 1st tier criteria should remain unaltered.

5. Toxicity – additional considerations

- 5.1 The toxicity criterion should include toxicity data derived for all relevant media, not just the aquatic environment. This issue will require further development, in particular for atmospheric exposure.
- 5.2 Modelling techniques such as QSAR could be considered providing they are derived from accepted models appropriate for the chemical under scrutiny. In addition, supporting evidence (e.g. toxicity data) for related chemicals should be considered. Evidence of toxicity from QSAR models could lead to inclusion of the substance into the safety net – this approach is accepted by prioritisation schemes such as OSPAR.
- 5.3 The ACHS will keep a watching brief on novel toxicity endpoints/processes and detection methods, such as endocrine disruption and the use of biomarkers and proteomics, for possible future inclusion in the toxicity criterion.

ACHS conclusions on criteria for Toxicity are:

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 an order of magnitude higher than the first tier criteria i.e. $L(E)C_{50} \leq 10$ mg/L and long-term NOEC ≤ 1 mg/L respectively. No change is proposed to the toxicity criterion as defined in the first tier with reference to the thresholds and provisions set out in EC Directive 67/548/EEC.

Annex F

Advice from the ACHS on medium chain-length chlorinated paraffins (MCCPs)

1. Introduction

The Chemicals Stakeholder Forum is considering the medium chain-length chlorinated paraffins (MCCPs) with a view to agreeing risk management strategies ahead of the three to four year time scale of the European process. The Forum has requested advice from the Advisory Committee on Hazardous Substances (ACHS) on:

- whether MCCPs meet the Forum's first tier criteria for substances of greatest or high concern;
- the evidence and likelihood that MCCPs are present in human breast milk; and, if so, the likely risk to infants exposed to MCCPs through breast milk; and
- whether or not naturally occurring organohalogens could be mistaken for MCCPs, and whether or not MCCPs are naturally occurring.

2. Forum first tier criteria for substances of greatest or high concern

The Stakeholder Forum first tier criteria for chemicals of greatest or high concern are summarised in the table below:

Criterion:	First tier thresholds:
Persistence	$T_{1/2}$ water > 2 months OR soil/sediment > 6 months
Bioaccumulation	Log K_{ow} > 5 unless BCF < 5000 (greatest concern); Log K_{ow} > 4 unless BCF < 500 (high concern)
Toxicity vP and vB	L(E)C ₅₀ < 1 mg/L OR NOEC < 0.1 mg/L (No T). Substance of concern but less so than PBTs.
Safety net	Expert judgement from the ACHS on a case-by-case basis for substances of equivalent concern.

Persistence

The Committee noted that data on the persistence of MCCPs was not based on measured half-life data; however, based on the available information and the physico-chemical properties of MCCPs, there was no evidence to suggest that MCCPs would biodegrade.

After consideration of all the available evidence, the ACHS concluded that MCCPs meet the persistence criterion for substances of greatest concern.

Bioaccumulation

With respect to bioaccumulation potential, the log K_{ow} of MCCPs varies from 5.5 to 8.3 (MCCPs comprise a suite of chemicals and hence a range of values apply). Therefore MCCPs meet the Forum's criteria for substances of greatest concern (i.e. log K_{ow} > 5).

The Committee concluded that most of the measured data on actual bioaccumulation was of questionable quality. However, one bioconcentration study was considered to be sufficiently

robust, with a measured bioconcentration factor of 1087 in fish. This value was calculated using radio-labelled MCCPs. Since this technique measures both MCCPs and their metabolites in fish, it represents an upper limit for the true bioconcentration factor. However, the radio-labelled compounds in the fish were analysed and found to be mostly the parent MCCPs. The true bioconcentration factor (BCF) is thus likely to be close to 1087. A BCF of approximately 1000 would in any event be expected with MCCPs based on their lipophilicity (represented by $\log K_{ow}$)—bioconcentration tends to increase with increased lipophilicity until the $\log K_{ow}$ becomes so high that it limits the bioavailability of the substance.

Comparing the measured bioconcentration factor with the Forum's criteria, MCCPs meet the lower tier criterion ($BCF > 500$) for other substances of high concern.

After consideration of all the available evidence, the ACHS concluded that MCCPs meet the bioaccumulation criterion for substances of greatest concern.

Toxicity

Many of the toxicity tests were considered to be of questionable value or relevance, as the concentrations used exceeded the water solubility of MCCPs. However, the 21day *Daphnia* reproduction test demonstrated toxicity at 0.01mg/L, which is below the water solubility, and meets the Forum's criteria for substances of greatest concern by an order of magnitude (10 fold).

Samples of MCCPs are frequently contaminated with SCCPs, which could contribute a significant proportion of the overall toxicity. However, it remained the expert judgement of the ACHS that MCCPs meet the toxicity criterion for substances of greatest concern.

After consideration of all the available evidence, the ACHS concluded that MCCPs meet the toxicity criterion for substances of greatest concern.

In summary, based on the available data and the expert judgement of the ACHS, MCCPs meet the Forum's criteria for substance of greatest concern.

3. MCCPs in human breast milk

3.1 Evidence that MCCPs are found in human breast milk

The ACHS were presented with one study, that of Greenpeace, conducted in Germany in 1995, which purported to show that MCCPs were present in human breast milk. The ACHS were unable to endorse or refute the findings presented in the Greenpeace study due to the lack of specific details (methodology, quality assurance, good laboratory practice, etc.). In the absence of these essential quality assurance details, the ACHS concluded that the Greenpeace findings were acceptable as an initial, scoping study, but not as a definitive study.

Several other pieces of evidence were considered by the Committee:

- the presence of MCCPs in the breast milk of rodents exposed to MCCPs³ (study peer reviewed by WATCH advisory committee);
- the bioaccumulation potential of MCCPs, and evidence from bioaccumulation studies; and

³ Rodent study as reported in the draft human health risk assessment and as validated and peer reviewed by the Health and Safety Executive and their independent health advisory committee (WATCH).

- the physico-chemical properties of MCCPs.

After careful consideration of the Greenpeace study, and taking into account the likely behaviour of MCCPs in relation to its properties and bioaccumulation potential, the ACHS concluded that despite the uncertainty regarding the quality of the Greenpeace investigation, it was likely that MCCPs were present in human breast milk.

The ACHS concluded that MCCPs are likely to be present in human breast milk.

3.2 The likely risk to infants exposed to MCCPs through breast milk

Based on the Greenpeace study, the concentration of MCCPs in human breast milk was estimated to be $7\mu\text{g}/\text{kg}^4$ on a fat basis, or $0.25\mu\text{g}/\text{kg}^4$ on a whole milk basis, assuming a fat content of 3.6%. The Committee noted that the concentration of MCCPs in human breast milk as measured in the Greenpeace study ($0.25\mu\text{g}/\text{kg}$ whole milk) was approximately 5 million times lower than the concentration of MCCPs present in the milk of lactating dam rats that was lethal to the pups. Due to the considerable uncertainties associated with extrapolating between the rodent study and the presence of MCCPs in human breast milk, no advice can be made on the likely risk of effects on human infants.

Based on the available evidence, the ACHS, while noting the significantly lower levels of MCCPs measured in human breast milk relative to those reported to cause lethal effects in rat offspring, nevertheless recommended that a precautionary approach should be adopted with respect to the likely presence of MCCPs in human breast milk.

4. Consideration of the issue of naturally occurring organohalogens

Many organohalogen substances occur naturally. In a comprehensive study conducted by G W Gribble (Dartmouth College, Hanover, USA) and published in 1996, it was stated that the total number of natural organohalogens identified is about 2,570. Many simple naturally occurring halogenated alkanes (for example, halomethanes) are released in quantities that exceed those produced by man.

With regard to MCCPs, a number of straight (medium) chain C_{14} – C_{20} compounds were identified in the study, but none were paraffinic, all terminated in one or more functional groups such as (COOH) or (COOR), and none contained more than one halogen atom, attached to the other extremity of the chain.

Further, the MCCPs are a homologous series and such series are not formed in biological systems.

Therefore, MCCPs have not been identified as occurring naturally.

Summary

Based on the data placed before the Committee, the expert judgement of the ACHS was that:

- 1) *MCCPs meet the Forum's first tier criteria for substances of greatest concern.*
- 2) *MCCPs are likely to be present in human breast milk.*

⁴ $7\mu\text{g}/\text{kg} = 0.007\text{mg}/\text{kg}$; $0.25\mu\text{g}/\text{kg} = 0.00025\text{mg}/\text{kg}$.

- 3) *No comment can be made on the likelihood of effects on human infants, based on the data available to the Committee on the rodent study. There is approximately a 5 million-fold difference between rodent effect concentrations and measured levels in human breast milk, and considerable uncertainties.*
- 4) *MCCPs have not been identified as naturally occurring organohalogenes.*

Annex G

Specification for a Research Project to Develop Indicators of Hazardous Substances

I. Introduction

The Government's Chemicals Strategy, '*Sustainable Production and Use of Chemicals – A strategic approach*', was published in December 1999. The Chemicals Strategy sets out Government policies to avoid harm to the environment or to human health via environmental exposure to chemicals. It covers chemicals entering the environment through commercial production and use. The strategy sets out to achieve the following goals:

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

The Government's Chemicals Strategy states that, '*indicators of environmental exposure to hazardous substances, including targets for reducing overall exposure of the environment*', should be developed in order to help achieve the strategy's aims. Indicators will assist in monitoring progress with the UK Chemicals Strategy and identify areas where activity needs to be focussed to reduce the impacts of chemicals on human health and the environment. Indicators will also contribute to the implementation of the EU chemicals policy which is currently being developed.

The Government sought advice from the UK Chemicals Stakeholder Forum, the Advisory Committee on Hazardous Substances, the Environment Agency and other Government experts, on the development of environmental indicators of hazardous substances. This contract specification is based on these consultations.

Defra is also letting a consultancy to create a list of chemical monitoring programmes across the UK. This will be very useful in the development of indicators for hazardous chemicals.

II. Objectives

The key objective is to develop an operationally robust suite of indicators of environmental exposure to hazardous substances, including targets for reducing overall exposure of the environment. It is envisaged that a suite of indicators (not exceeding 20) will be necessary, having an overarching aim of measuring progress in reducing emissions of chemicals into the environment and thus, reducing exposure to humans and other biota. However, the minimum number of indicators should be used to make up the suite of indicators to provide the required information.

The suite of indicators should include:

- Indicators of production and emissions to environment;
- Indicators of progress with legislative and voluntary commitments in chemicals control and of our state of knowledge about the hazards and risks of chemicals; and
- Indicators of environmental exposure, both abiotic and biotic exposure, such indicators should, where appropriate, be developed to utilise information generated by existing monitoring programmes.

As a general principle, it will be important to link indicators with existing Government policy objectives, and determine what the indicators will be used for, and how they will be interpreted. The indicators must be as simple as possible and accessible to the public, allowing straightforward interpretation. Furthermore, the minimum data required for each individual indicator should be used.

III. Tasks

TASK I Development of a pragmatic conceptual framework

After an initial meeting, the research contractor will familiarise themselves with progress on the development of hazardous chemicals indicators in various key fora (e.g. Eurostat, European Environment Agency). In addition, the contractors will also familiarise themselves with the papers and outcomes of the discussions of the UK Chemicals Stakeholder Forum and Advisory Committee on Hazardous Substances (as supplied by Defra).

The research contractor will then carry out a review of the requirements of the UK Chemicals Strategy. Based on the review, the contractor will identify and set out a pragmatic conceptual framework for a proposed set of indicators. The contractor will propose level one headings (A, B, C, etc) which depict the main subjects and issues that need to be considered. Under each level one heading the contractor will propose level two headings (A1, A2, B1, B2, etc) which detail the specific issues that need to be considered to ensure adequate coverage of each headline subject. For each level two heading the contractor will recommend an indicator or suite of indicators, using the DPSIR (Driving forces, Pressures, State, Impact, Responses) framework, together with a justification and rationale for their selection.

The types of indicators that might be considered by the contractor could include those presented below, (note these suggestions are illustrative only):

- Indicators of our state of knowledge about chemicals, for example the percentage of chemicals used in the UK for which we have basic or more advanced hazard or risk assessments. This should take into account all initiatives, including ICCA (International Council of Chemical Associations), OECD, OSPAR, EU, IPCS etc.
- Indicators of the production and use of chemicals that meet the Forum's criteria for chemicals of most concern on the UK market per annum. It is intended that this should decrease with time as such chemicals are identified and risk management action taken. It is noted that production tonnages cannot be used as a proxy for exposure, as it does not include imported chemicals in products etc. It is, however, very important to measure production. The contractor should explore the practical possibilities of achieving this.
- A suite of indicators based on categories of use (e.g. the 40 Existing Substances Regulation categories), where the categories of use that have potential significance to environmental exposure are identified and monitored. This would refine and target activity on uses of

chemicals of concern, rather than simply using high production volume as a surrogate for overall exposure, regardless of use patterns.

- Indicators of performance in relation to UK Government meeting legislative commitments and targets, for example, UK POPs commitments, OSPAR compliance by 2020, reduction of chemicals that meet the Forum's criteria, and reduction of emissions of chemicals of concern.
- Indicators that track trends in the number and severity of chemical incidents (e.g. transport and factory spills and firewater runoff events) that result in environmental contamination, and record the impact of such incidents on the environment.
- Indicators of the presence of chemicals in biota (e.g. breast milk) and abiotic environments (e.g. rivers), using the most relevant and hence, potentially useful existing monitoring regimes, if appropriate.
- Indicators of environmental quality e.g. river quality. Environmental quality indicators need not be directly linked to measurements of hazardous chemicals. As long as the quality of the environment is increasing, the demonstration of cause and effect relationships is not necessary; (indeed, demonstration of such relationships is very difficult because environmental quality is a function of many different factors). Exceptions are chemicals that cause very specific and unusual effects, where causal links can be established. Consideration should be given to the terrestrial environment as well as aquatic systems. There is current development work being funded by the Environment Agency and you should take this into account.
- In addition to indicators of adverse effects, consideration should be given to indicators of the positive benefits of chemicals (e.g. improved life expectancy).

The contractor will submit a report on task (I) and the conceptual framework to Defra for discussion and comment.

TASK II Development of indicators

Under task (II), the research contractor will further develop the indicators identified in the conceptual framework.

IIa Review of existing indicators

The contractor should review existing indicators, including the Government's Sustainable Development Indicators and those developed by the Environment Agency. The contractor should also take into account information on existing monitoring programmes in the UK (e.g. monitoring programmes collated by the separate Defra consultancy). A separate research contract has been let to undertake such a review and the results of this work could be utilised in this study. An exploration of whether the banks of tissue and water, soil and sediment samples (that are known to exist) could be used to provide historical baseline data for indicators should be undertaken, (indicators should have temporal data, to allow trends to be observed). The contractor will take into account any ethical considerations with respect to the use of human tissue samples.

IIb Gap analysis

Based on the review of existing indicators, the research contractor will undertake a gap analysis to identify indicators in the conceptual framework which: (a) can be operationalised

using existing indicators or monitoring programmes in their present form; (b) are broadly based on existing indicators or monitoring programmes which will need to be modified in some way to make them applicable to the present study; and (c) will require the procurement of new data. The means by which the proposed indicators in categories (b) and (c) should be developed will be detailed by the contractor.

IIc Finalisation of indicators

The contractor will finalise and justify the selection of each indicator. If specific chemicals or groups of chemicals are included within one or other of the DPSIR categories, the contractor will justify each individual selection in terms of the theme(s) and issue(s) that they address. The contractor will research and confirm that none of the proposed indicators are impractical or unjustifiably costly to develop and maintain in the long term.

TASK III Logistics

The contractor will develop the logistics of setting up, operating and regularly updating each indicator, including compiling the necessary data and statistics. For each indicator, the contractor will indicate:

- whether historical statistics or monitoring data are available to develop a trend analysis, or whether other types of data are available to benchmark the indicator;
- how proposed indicators that form part of other programmes (e.g. the Government's, 'Quality of Life Counts' national indicators programme) can be incorporated into the proposed framework;
- how data for new proposed indicators should be measured and/or compiled, and the likely operational and administrative mechanisms and costs for collecting and maintaining such data in the long term;
- the proposed frequency of data collection for each indicator; and
- other issues considered to be of importance by the contractor in order to operationalise and thereafter maintain each indicator.

TASK IV Reporting and Communication of Information

The contractor will determine how the indicators can individually and collectively be effectively communicated and presented to the public, Stakeholder, and Government. The issues that might be considered could include, for example:

- the appropriate reporting and communication format(s) (annual reports, web site etc.);
- whether raw data should be reported;
- how the data should be benchmarked;
- whether trends should be reported, and if so, in what format;
- whether expectations or commitments in trends or exposure should be included;
- the type of commentary that might accompany the reporting of indicators;
- how diverging trends between two or more indicators should be interpreted and reported;
- etc.

V. Milestones/timetable

- Milestone: 1 Scoping meeting with Defra within 1 week of the contract start.
- 2 Progress report, reviewing indicator requirements of the Chemicals Strategy and identifying a pragmatic conceptual framework for a proposed set of indicators by Monday 18th May 2002 (task I)
- Milestone: 3 Progress report on the development of indicators (review of existing chemicals indicators, gap analysis, finalisation of development) by Friday 29th May 2002 (task II)
- Milestone: 4 Development of the logistics for the indicators by Monday 6th June 2002 (task III)
- Milestone: 5 Development of the reporting and communication strategies for the indicators by Friday 17th June 2002 (task IV)
- Milestone: 6 A draft final report by Friday 31st July 2002
- Milestone: 7 A final report by Friday 28th August 2002

V. Outputs / Deliverables

The contractor should produce the following outputs at specified stages in the agreed programme:

- A report on Task (I). This will be taken to the indicators steering group (made up members of the Chemicals Stakeholder Forum and ACHS) for advice and suggested amendments;
- A report on Task (II). This will be taken to the indicators steering group for advice and suggested amendments;
- A draft final report of the findings of the research by one month before the end of the contract; and
- A final report concisely presenting the proposed indicators and methodology for their application and use. Detailed appendices should be included where appropriate. It will be of a publishable standard and must be agreed with the Department. It will contain an executive summary; a factual statement of aims and methodology; the main findings; a discussion of the findings; and conclusions. The final report should be supplied in both electronic (Word/Excel) and 12 hard copy forms.

Annex H: Highlights of the new EC regulation on ozone depleting substances

The new EC Regulation repealed EC Regulation 3093/94 when it entered into force, 1 October 2000. Highlights of the Regulation include:

- ✓ New bans on the supply and use of Chlorofluorocarbons (CFCs), used in refrigeration, foam blowing, as a solvent and as an aerosol propellant, halons and bromochloromethane (CBM), used mainly in fire suppression and 1,1,1 trichloroethane, carbon tetrachloride, and hydrobromofluorocarbons (HBFCs), used mainly as solvents. These bans apply to both virgin and recycled material from 1st October 2000 for most applications, although certain delays and exemptions apply.
- ✓ Significant revisions to the use controls placed on Hydrochlorofluorocarbons (HCFCs) implemented through EC Regulation 3093/94. HCFCs were mainly used in refrigeration, foam blowing, and as solvents, all of these sectors have been affected by the Regulation.
- ✓ A revised timetable for the supply of HCFCs in line with the new use controls. From 2010 placing virgin HCFCs on the market will be prohibited, this will reduce their availability however recycled and reclaimed substances will still be accessible. Placing any HCFCs on the market will be prohibited from 2015; this includes recycled and reclaimed material.
- ✓ An immediate ban on the import of products containing ozone-depleting substances (excluding HCFCs). Import prohibitions relating to products containing HCFCs are to be introduced in line with the use prohibitions applicable to those same products.
- ✓ Tougher requirements regarding emissions reduction and the recovery of ozone depleting substances from products and equipment.

Refrigeration and air conditioning

The refrigeration and air conditioning market were immediately effected by EC Regulation 2037/2000. Placing CFCs on the market was prohibited from 1 October 2000. The use of CFCs was subsequently prohibited from 1 January 2001. As systems are decommissioned, any CFCs removed must be sent for destruction. Provision for exemption to this ban is available, for use in certain military applications, until December 2008.

Although the use of HCFCs was already prohibited in the manufacture of certain equipment under EC Regulation 3093/94, EC Regulation 2037/2000 extends these restrictions even further. The use of HCFCs in the manufacture of most new equipment is now prohibited from 1 January 2001. There are two exceptions however. The ban is deferred until 1 July 2002 for fixed air-conditioning equipment with a cooling capacity of less than 100 kW and 1 January 2004 for reversible air-conditioning/heat pump systems.

In an effort to control leakages, equipment containing a fluid refrigerating charge greater than 3 kg must be checked on an annual basis. In addition, the Regulation introduces minimum qualification requirements for all personnel handling ozone-depleting refrigerants. All CFCs used in refrigeration and air conditioning equipment recovered must be destroyed by an environmentally acceptable technology. This mandatory recovery is further extended to domestic appliances from 1 January 2002. Recovered HCFCs may be recycled for use until 2015.

Solvents

The use of CFCs, 1,1,1 trichloroethane, CBM, and carbon tetrachloride in any solvent application is prohibited from 1 October 2001. HCFC solvent applications previously prohibited under 3093/94 remain (i.e. use in non-contained applications) with a total ban on all other solvent applications from 1 January 2002. A temporary exemption exists for precision cleaning of electrical and other components in aerospace and aeronautics applications until 31 December 2008.

Aerosols

EC Regulation 3093/94 prohibited the use of HCFCs as an aerosol propellant from 1995. UK industry (non-medical) has voluntarily been CFC-free since 1989 however EC Regulation now makes this mandatory also, prohibiting the import of CFC propelled aerosols from third countries.

Fire protection systems

EC Regulation 2037/2000 prohibits the use of virgin halon in all systems and recycled and reclaimed in any system that did not exist prior to the Regulation entering into force. Owner/operators can continue to 'top up' systems manufactured prior to 1 October 2000 until 31 December 2002. All non-critical systems (as defined in Annex VII of the Regulation) must be decommissioned by 31 December 2003.

CBM, although technically a halon, is defined as a 'new substance' for the purpose of this Regulation. As such the rules differ to those that apply to halon. An immediate use ban became effective from 1 October 2000 prohibiting any existing systems from being topped up. EC Regulation 2037/2000 does not, however, require these systems to be decommissioned. Therefore, the CBM may stay in the system until for whatever reason (ie use or accidental discharge) they require 'topping up' or refilling. Once the system is no longer functional the substance must be recovered and destroyed by an environmentally acceptable technology.

Foams

The only ozone depleting substance used in foam blowing applications prior to EC Regulation 2037/2000 entering into force was HCFCs. This regulation now prohibits the use of HCFCs in the manufacture of most foam immediately. It further prohibits the use of HCFCs in the production of extruded polystyrene rigid insulating foams from 1 January 2002, Polyurethane foam for appliances from 1 January 2003, all other foams to include polyurethane spray and block foams from 1 January 2004. Ozone depleting substances must be recovered, where practicable, and destruction must be done by an environmentally acceptable technology.

Import controls

The import of CFCs, halons, carbon tetrachloride, and 1,1,1 trichloroethane is prohibited apart from those substances needed to satisfy applications identified as an essential⁵ or feedstock⁶ use, or

⁵ A use qualifies as essential only if it is necessary for the health, safety, or is critical for the functioning of society and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

⁶ Any controlled substance or new substance that undergoes chemical transformation in a process in which it is entirely converted from its original composition and whose emissions are insignificant.

processing agent⁷ application. HCFCs may be imported within the strict quantitative limits defined by the Regulation but only after the European Commission has granted the relevant import licence. The import of products and equipment:

1. Manufactured before the use ban applicable to the particular product and equipment or;
2. designed for an essential or critical use is not prohibited. EC Regulation 2037/2000 does prohibit the import of any other products or equipment however.

Export

The export of CFCs, carbon tetrachloride, 1,1,1 trichloroethane, and halon is prohibited from 1 October 2000 apart from those substances produced for basic domestic needs, essential uses, or those used in feedstock or process agent applications. The export of products or equipment containing these substances is also prohibited from 1 October 2000. However, there is a derogation for products and equipment containing halon where their export is required to satisfy any of the critical uses listed in Annex VII of the Regulation.

EC Regulation 2037/2000 does allow the use of CFCs in the manufacture of products or equipment destined for export to States Party to the Protocol, where the use of CFCs is still permitted, until 31 December 2001. It does, however, prohibit the export of HCFCs to any state not party to the Protocol from 1 January 2004.

Before any ozone depleting substance can be exported an export authorisation number must be obtained from the European Commission.

⁷ Controlled substances used as chemical processing agents in those applications listed in Annex VI, in installations existing at 1 September 1997, and where emissions are insignificant.

Annex I: UK chemicals stakeholder forum's first tier criteria for identifying chemicals of greatest 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 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

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

$\text{Log Kow} \geq 4$ 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 Log Kow.

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 criteria 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.

Safety net procedure

A safety net procedure would apply where chemicals did not meet the PBT criteria but there were reasons to believe that the chemicals raised equivalent concerns. It was anticipated that chemicals giving rise to concerns related to endocrine disrupting effects could be considered under this procedure. The Forum would receive expert advice in such cases.

Next steps

Following agreement by members, the Forum's criteria will be applied – with advice from the Advisory Committee on Hazardous Substances and other relevant advisory committees – to data from the ICCA programme and other relevant data. Chemicals which fulfil the criteria will then be fast tracked for consideration of risk management as set out in section 3.4.2 of the Government Chemicals Strategy.

The Stakeholder Forum also agreed on 30 November 2000 to consider proposals from the Secretariat for second tier criteria at its third meeting in March 2001 with a view to finalising such criteria at its fourth meeting in June 2001.

DEFRA Publications, Admail 6000, London SW1A 2XX
Tel: 08459 556000
<http://www.defra.gov.uk>
PB7826