



The Interdepartmental Group
on Health Risks from Chemicals:

First report and forward plan to 2002

The Interdepartmental Group on Health Risks from Chemicals aims to stimulate the development of new, improved approaches to the assessment of risks to human health from chemicals.

The Group contributes to the work of the Interdepartmental Liaison Group on Risk Assessment as outlined in its second report to Ministers in 1998, *'Risk Assessment and Risk Management: Improving Policy and Practice within Government Departments'*.

The Steering Committee of the Interdepartmental Group on Health Risks from Chemicals comprises participants from the Department of the Environment, Transport and the Regions, the Department of Health, the Department of Trade and Industry, the Home Office, the Ministry of Agriculture, Fisheries and Food, the Environment Agency, the Health and Safety Executive, the Food Standards Agency, the Medicines Control Agency, the Pesticides Safety Directorate, the Veterinary Medicines Directorate, the Biotechnology and Biological Sciences Research Council, the Medical Research Council, the Natural Environment Research Council and the Institute for Environment and Health.

The Secretariat is based at the Medical Research Council's Institute for Environment and Health.

The Interdepartmental Group on Health Risks from Chemicals operates as a subgroup of the Interdepartmental Liaison Group on Risk Assessment.

The Interdepartmental Liaison Group on Risk Assessment is an informal committee of officials responsible for policy development and practical application of risk assessment in UK Government departments. The group reports periodically to Ministers on a co-ordinated programme to promote consistency and coherence in risk assessment practices across Government.

This document has been prepared by the Interdepartmental Group on Health Risks from Chemicals. The opinions expressed do not necessarily represent the policies of the participating Departments, Agencies and Research Councils.

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Foreword

The Interdepartmental Group on Health Risks from Chemicals (IGHRC) is an informal Group of representatives from government departments, agencies and research councils with an interest in chemical risk assessment. Last year the group (previously called the Risk Assessment and Toxicology Steering Committee) published a series of six reports, the culmination of a three-year work programme, which made wide ranging recommendations for improving chemical risk assessment procedures.

The IGHRC operates as a subgroup of the Interdepartmental Liaison Group on Risk Assessment (ILGRA), an informal committee of officials responsible for policy development and practical application of risk assessment in UK Government departments. Ministers have endorsed the work of ILGRA, in particular work to encourage greater coherence and consistency among departments. The IGHRC contributes to this work. The overall aim of the IGHRC is to reduce uncertainties and limitations in the conduct of chemical risk assessment for human health as used by government, in order to increase the robustness of and confidence in the outputs that emerge from regulatory processes which rely on risk assessment.

This report explains how the group has prioritised the recommendations from the six reports, sets out an action plan and describes the progress we have made towards implementing it.

The IGHRC recognises that progress will only be possible with the support of, and collaborative partnerships with, stakeholders. When we published the six reports last year we received a lot of support for the work of the Group. We hope, in reading this report and its associated forward plan, you will feel we have made good progress. We would very much appreciate your views on the work programme we have set out. Please send your comments to Ms Jane Stevens at the MRC Institute for Environment and Health, University of Leicester, 94 Regent Road, Leicester LE1 7DD, UK. We look forward to hearing from you by 31 March 2001.

Responses to this consultation will be made available to the public on request after the close of the consultation unless the consultee specifically requests their views should be treated as confidential.

A handwritten signature in black ink that reads "David Shannon". The signature is written in a cursive, slightly informal style.

David Shannon
Chairman of the IGHRC
Chief Scientist of the Ministry of Agriculture, Fisheries and Food

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Executive summary

The purpose of this document is to outline the proposed strategy and programme of work of the Interdepartmental Group on Health Risks from Chemicals (IGHRC), up to September 2002.

The IGHRC has scrutinised the recommendations from the six reports produced by its forerunner, the Risk Assessment and Toxicology Steering Committee, and considered them under two headings, a) research and b) supporting integrated policy development and implementation. The Group's forward strategy focuses on these two areas.

Research

The IGHRC aims to co-ordinate and prioritise research recommendations from the Risk Assessment and Toxicology Steering Committee reports and to propose a research strategy, focusing on risk assessment, for the departments, agencies and research councils to fund as appropriate. In addition, the IGHRC intends to directly fund pilot studies in several key cross-cutting areas. To date the IGHRC has identified five areas of research of particular interest to take forward into the research strategy, as follows:

- toxicology and uncertainty factors
- human variation and susceptibility
- the role of probabilistic modelling
- exposure models
- physiologically-based pharmacokinetic models.

The IGHRC has established a research database in these five areas, which has been used to identify gaps in current government-sponsored research funding. Human variability in relation to toxicodynamics was identified as an area in which very little research is currently being supported. Therefore, the IGHRC will initially support a single

one-year project to produce a critical review of the information available on variation in human toxicodynamic response to chemicals.

Supporting integrated policy development and implementation

Recommendations from the Risk Assessment and Toxicology Steering Committee reports have been classified by the IGHRC under the headings *policy*, and *coherence and consistency*, and three specific types of activity have been identified to implement these recommendations:

- the production of guidance documents
- the formation of the IGHRC specific-issue working groups
- sharing of experience and initiating change.

Guidance documents

The IGHRC proposes to work with government departments to prepare guidance documents on various aspects of chemical risk, with the purpose of making risk assessments more coherent and consistent. Such documents would also be of value to support the UK negotiating position in international fora, particularly in Europe. The IGHRC proposes to produce guidance documents in the next two years, as summarised below.

- A guidance document on *the derivation and selection of uncertainty factors* in chemical risk assessment.
- A guidance document on *exposure assessment*, including the collection and analysis of data. This will provide a key contribution to improving current risk assessment practice and promote convergence of the methods currently

used. To inform the IGHRC of the precise nature of the guidance document required, an expert workshop will be convened, followed by production and publication of the exposure assessment guidance.

- The draft IPCS discussion document ‘*Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis*’* is currently available to government departments and expert committees carrying out chemical risk assessment. The need for additional guidance on using *the weight of evidence approach to evaluating carcinogens* will be considered in the light of feedback on the usefulness of the IPCS document in practice.

Specific-issue working groups

The Risk Assessment and Toxicology Steering Committee recommended the establishment of interdepartmental groups to develop and share expertise on a number of issues, including *physiologically-based pharmacokinetic (PBPK) models, exposure assessment and probabilistic modelling*. The IGHRC proposes to help establish such specific-issue working groups. Members with appropriate expertise will be drawn from government and from other (non-governmental) establishments. During the next two years the IGHRC proposes the following actions.

- To work with the British Toxicology Society (BTS) to set up a speciality section or club to address the issue of PBPK modelling. Stakeholders and other interested parties will be welcome to join this group. Discussions are ongoing with the BTS as to how this should proceed.
- Set up a specific-issue working group to discuss exposure assessment: decisions will await the outcome of the workshop to identify the scope and content of the guidance document on exposure assessment (see above).
- Convene a workshop on probabilistic modelling to define the scope of work to be conducted in this area. To facilitate discussions at the workshop, a consultant will be employed to produce a working document outlining the current state of the art and application of probabilistic modelling in the UK.

* Copies of the draft IPCS *Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogens* can be obtained from Dr Robin Fielder, Department of Health, Skipton House, 80 London Road, Elephant and Castle, London SE1 6LW

Sharing experience and initiating change

Sharing experiences across government departments on various issues will lead to a more consistent and coherent approach to risk assessment. Such sharing of experience may also initiate changes in procedure, or at least lead to a better understanding of why different processes occur in different departments. The IGHRC proposes to establish development opportunities in the form of courses, which it sees as the most appropriate vehicle for this activity. Four recommendations from the Risk Assessment and Toxicology Steering Committee that pertain to risk assessment will provide the topics for the proposed courses. The topics are:

- the impact of risk management on risk assessment
- reporting of risk assessment in a logical and transparent manner
- improved communication with the public
- risk management options explained.

New issues for consideration

It is important that the IGHRC is aware of emerging issues and that the group acts as a useful vehicle for identifying these issues and proposing actions to deal with them. For example, the *human genome project* could provide data of benefit for risk assessment, and thus ways in which these data might be usefully considered could be the subject of a workshop.

1 General introduction

1.1 Purpose of this report

The purpose of this document is to outline the proposed strategy and programme of work of the Interdepartmental Group on Health Risks from Chemicals (IGHRC) up to September 2002. The work programme has been developed to facilitate improvement of the risk assessment process with regard to human health; it includes research (Section 2.1), activities to support integrated policy development and implementation (Section 2.2) and emerging new issues (Section 2.3). A schedule of activities is outlined in Section 3. Further details are provided in the separately published annexes that accompany this report (IGHRC, 2000).

1.2 Background

Chemicals have brought society considerable economic and social benefits. They and their products and technologies are essential to most manufacturing and many service operations, and to the general population in daily life. However, chemicals can harm human health, and assessments have to be carried out to ensure that risks from the production, use and disposal of chemicals are properly managed. Chemical risk assessments are routinely conducted by government departments and agencies (Risk Assessment and Toxicology Steering Committee, 1999a,b). Recent government reports (DETR, 1999; HSE, 1999) indicate the government's commitment to prevent harm to the environment and people's health from exposure to chemicals.

The process of risk assessment is subject to a number of limitations and uncertainties (Risk Assessment and Toxicology Steering Committee, 1999b). For the vast majority of chemicals, assessment of risk relies on data from either experiments on animals or *in vitro* studies, owing to the difficulties and ethical considerations in

obtaining human data. Uncertainties lie in the extrapolation of experimental data to the human situation, in the potential variations in susceptibility between individuals and in estimates of exposure to chemicals. The precise methods used to deal with the uncertainties inherent in the process of risk assessment may vary depending on the use of the chemical (Risk Assessment and Toxicology Steering Committee, 1999b), and although the reasons for the use of different approaches may be justifiable, they may not always be clear.

The development of techniques to help reduce uncertainties in data, the interpretation of data and variations in risk assessment methodologies would result in increased confidence in the outputs of risk assessments, and in the risk management choices that flow from them. Improved scientific techniques might also help to reduce the need to rely on animal testing and/or help to bring about reductions in the number of animals needed for risk assessments, principles to which government departments and agencies are committed.

In the UK Government 'Forward Look of Government Funded Science, Engineering and Technology', Government departments recognised the limitations of current methods and the need to improve them (HMSO, 1995). The 'Forward Look' committed government departments and research councils to coordinate their efforts to use recent scientific advances to improve risk assessment. This led to the establishment, in 1996, of the government/research councils *Initiative on Risk Assessment and Toxicology*. The Risk Assessment and Toxicology Steering Committee, an informal committee of scientists from government and research councils and the forerunner of the IGHRC, then commissioned a review 'Risk Assessment Approaches used by UK Government for Evaluating Human Health Effects of Chemicals'

(Risk Assessment and Toxicology Steering Committee, 1999b). The Committee also sponsored four workshops on different aspects of risk assessment; these were population subgroups, physiologically-based pharmacokinetic modelling, exposure issues, and uncertainty factors. The workshop reports (Risk Assessment and Toxicology Steering Committee, 1999 c, d, e, f), published in June 1999, made a series of recommendations and identified a range of research and other needs. The IGHRC is charged with considering these recommendations.

1.3 The Interdepartmental Group on Health Risks from Chemicals

The IGHRC comprises two committees, a Steering Committee and an Executive Committee. Membership of the two committees is presented at the end of this report.

The main focus of the IGHRC's activities is to seek ways to improve the procedures underpinning risk assessment. In pursuit of this, the specific aims of the IGHRC are to:

- promote the development of methods and techniques that will improve information used in the toxicological risk assessment process;
- promote improved approaches to toxicological risk assessment for use in a regulatory context;
- promote coherence and consistency in the practice of toxicological risk assessment as used within the different risk management and regulatory frameworks used in government; and
- act to disseminate and advance best practice within government.

The remit of the IGHRC is outlined more fully in Annex 1.

The recommendations from the six reports produced by the Risk Assessment and Toxicology Steering Committee have been scrutinised by the IGHRC and considered under two headings, that is, research recommendations, and supporting integrated policy development and implementation, which includes policy recommendations and recommendations relating to coherence and consistency (Annex 2a–c). The process by which these recommendations have been prioritised is set out in Section 2.

2 The work programme

2.1 The research programme

The IGHRC aims to co-ordinate and prioritise research recommendations from the Risk Assessment and Toxicology Steering Committee reports and to propose a research strategy, focusing on risk assessment, for the departments, agencies and research councils to fund as appropriate. In addition, the IGHRC intends to directly fund pilot studies in several key cross-cutting areas.

The IGHRC has prioritised the research recommendations (Annex 3) and identified five areas of particular interest to the IGHRC, as follows:

- toxicology and uncertainty factors
- human variation and susceptibility
- the role of probabilistic modelling
- exposure models
- physiologically-based pharmacokinetic models.

For each of the five areas a brief specification has been prepared outlining research that the IGHRC considers would help improve chemical risk assessment (presented in Annex 4a–e). In addition the departments, agencies and research councils with an interest or involvement in human health risk assessment have drawn up lists of projects they are currently funding in each of the five areas. This information has now been entered into a searchable database on risk assessment methodology research (Annex 5). Brief summaries explaining which current research falls within each of the five areas, and identifying gaps in research, are presented in Annex 6a–d. These will form the basis of a research strategy to be proposed to the departments, agencies and research councils.

As noted above, the IGHRC has resources to fund some pilot studies up to the year 2002. Using the database described, human variability in relation to toxicodynamics was identified as an area in which very little research is currently being supported. Therefore the IGHRC will initially fund a single one-year project to produce a critical review of the information available on variation in human toxicodynamic response to chemicals. The call for tenders for ‘*A study on variation in human toxicodynamics*’ was published in *Nature* in April 2000 and put on the IGHRC Web site*. The successful tender has been selected and work will commence in December 2000. Based on the outcome of the review the IGHRC may propose that the departments, agencies and research councils fund more long-term projects in this area.

2.2 Supporting integrated policy development and implementation

The original remit of the Risk Assessment and Toxicology Steering Committee, as set out in the ‘Forward Look’ statement (HMSO, 1995), focused on the scientific methods used in risk assessment, particularly the toxicological evaluation of chemicals. The 1998 ILGRA report to ministers (ILGRA, 1998) indicates how developments in the public perception of risks (e.g., those connected with BSE) have raised the profile of, and had enormous implications for, the way government and its agencies assess and manage risk. Thus policy issues, in particular those relating to coherence and consistency, are now part of the remit of the IGHRC.

A number of recommendations from the Risk Assessment and Toxicology Steering Committee

*<http://www.le.ac.uk/ieh/ighrc/ighrc.html>

reports have been classified by the IGHRC under the headings policy, and coherence and consistency (Annex 2b,c) and actions have been proposed for each recommendation (Annex 7a,b). The IGHRC has identified three specific types of activities:

- the production of guidance documents
- the formation of the IGHRC specific-issue working groups
- sharing of experience and initiating change.

Topics proposed for each of these activities are outlined in Box 1.

Box 1 Proposed activities to implement the policy, coherence and consistency recommendations

1 Guidance documents

- uncertainty factors / dealing with uncertainty
- collection and analysis of exposure data
- weight of evidence for carcinogens

2 Specific-issue working groups

- physiologically-based pharmacokinetic modelling
- exposure assessment
- probabilistic modelling

3 Sharing experience and initiating change

- human variability
- human exposure
- impact of risk management on risk assessment
- reporting of risk assessment in a logical and transparent manner
- improved communication with the public
- risk management options explained
- justifying uncertainty factors

2.2.1 Guidance documents

The IGHRC proposes to work with government departments to prepare guidance documents on various aspects of chemical risks, with the purpose of making risk assessments more coherent and consistent. Such documents would also be of value in supporting the UK negotiating position in international fora, particularly in Europe.

Procedures for preparing guidance documents will emphasise the importance of having the involvement and full support of the relevant departments and UK expert committees and their scientific secretariats. Experts may assist in the drafting of these documents. It is planned that the draft documents should be approved by the departments and expert committees, thereby effectively producing a UK position on the topic in question. An outline procedure to produce such a document is summarised below.

- Confer with stakeholders and expert(s) on the content and structure of the document
- Draft the document with the aid of the expert(s)
- Circulate to stakeholders for comment
- Incorporate stakeholders comments and circulate to the expert committees for comment
- Produce agreed final document

Proposed topics for guidance documents are listed in Box 1 and outlined briefly below.

Uncertainty factors

There is no single UK Government position on *the derivation and selection of uncertainty factors* in chemical risk assessment. A guidance document that sets out the historical and scientific justifications, the reasons for using particular uncertainty factors and circumstances in which they are used would assist consistency and transparency. The IGHRC proposes to begin work on this document in the autumn of 2000 (see Section 3 for schedule of activities).

Collection and analysis of exposure data

A guidance document on *exposure assessment*, including collection and analysis of data, would provide a key contribution to improving current risk assessment practice and promote convergence of the methods currently used. To inform the

IGHRC of the precise nature of the guidance document required, an expert workshop will be convened in the first quarter of 2001 (Section 3). The aims of the workshop will be to:

- identify the critical issues to take forward
- identify the scope and shape of the guidance document
- outline the contents page for the guidance document.

Weight of evidence for carcinogens

A guidance document on *the weight of evidence approach to evaluating carcinogens*, as used by the UK expert committees, would be useful to government. A draft IPCS discussion document ‘*Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis*’* makes a key contribution in this area. The Framework document is currently available to government departments and expert committees carrying out chemical risk assessment. The need for additional guidance will be considered in the light of feedback on the usefulness of the IPCS document in practice.

2.2.2 The IGHRC specific-issue working groups

The Risk Assessment and Toxicology Steering Committee recommended the establishment of interdepartmental groups to develop and share expertise on a number of issues, including *physiologically-based pharmacokinetic (PBPK) models, exposure assessment and probabilistic modelling* (see Box 1).

The IGHRC proposes to help establish such specific-issue working groups, the functions of which, depending on the topic being considered, might include:

- provision of expertise to government departments on request;
- identification of co-ordinated interdepartmental research; and
- facilitating the development of guidance documents.

* Copies of the draft IPCS *Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogens* can be obtained from Dr Robin Fielder, Department of Health, Skipton House, 80 London Road, Elephant and Castle, London SE1 6LW

Members with appropriate expertise may be drawn from government and from other (non-governmental) establishments.

Physiologically-based pharmacokinetic models

The IGHRC has approached the British Toxicological Society (BTS) with a view to setting up a speciality section or club within the BTS to address the issue of PBPK modelling. Stakeholders and other interested parties will be welcome to join this group. Discussions are ongoing with the BTS as to how this should proceed.

Exposure assessment

The setting up of a specific-issue working group to discuss exposure assessment will await the outcome of the workshop (to identify the scope and content of the guidance document) to be held in the first quarter of 2001 (see Section 2.2.1).

Probabilistic modelling

Probabilistic modelling has many applications and the IGHRC proposes to convene a workshop during the summer of 2001 to define the scope of work to be conducted in this area. To facilitate discussions at the workshop, a consultant will be employed to produce a working document outlining the current state of the art and application of probabilistic modelling in the UK.

2.2.3 Sharing experience and initiating change

Sharing experiences across government departments on various issues will lead to a more consistent and coherent approach to risk assessment. Such sharing of experience may also initiate changes in procedure, or at least lead to a better understanding of why different processes occur in different departments. Sharing experience and initiating change may be achieved through interdepartmental training, specific-issue working groups, workshops or other means. Topics to be taken forward under this activity are outlined in Box 1.

The IGHRC proposes to establish development opportunities in the form of courses, which it sees as the most appropriate vehicle for this activity. For example, a course on development of communication skills may increase the clarity and transparency with which risk assessment documents are written. Such a forum would also provide an opportunity to exchange views and ideas.

Four recommendations (see Box 1) pertain to risk assessment, and course outlines will be established for at least three of these in the first instance:

- the impact of risk management on risk assessment
- reporting of risk assessment in a logical and transparent manner
- improved communication with the public
- risk management options explained.

The other topics, 'human variability', 'human exposure' and 'justifying uncertainty', may be considered at a later date. It is envisaged that the first course will be conducted in the summer of 2001, the second in the first quarter of 2002 and the third in the third quarter of 2002 (see Section 3).

2.3 New issues for consideration

As previously explained, the recommendations discussed by the IGHRC have come from the Risk Assessment and Toxicology Steering Committee reports. New topics and issues in risk assessment will become important in the future, and may also require interdepartmental action. The IGHRC will be a useful vehicle for identifying these issues and proposing actions to deal with them.

As an example, one issue that has become prominent recently is that of the impact of the human genome project. Complete mapping of the human genome will generate many exciting opportunities for innovative approaches to toxicological and mechanistic studies and will undoubtedly have an impact on the practice of human health chemical risk assessment. The IGHRC could consult experts through a workshop to explore the impact of this new resource. In addition, it will also be necessary in the future to consider the rapidly developing field of proteomics (the characterisation of gene expression at the protein level). Environmental chemicals and dietary constituents may well be among the most important factors influencing alterations in gene expression.

3 Schedule of activities for October 1999 to September 2002

The proposed IGHRC work programme up to 2002, with outline timings and milestones, has been described in detail in Section 2. Figure 1 presents a summary schedule of activities in diagrammatic form, indicating the approximate start and finish dates plus a brief description of each element and indicative costs.

In short, the IGHRC proposes:

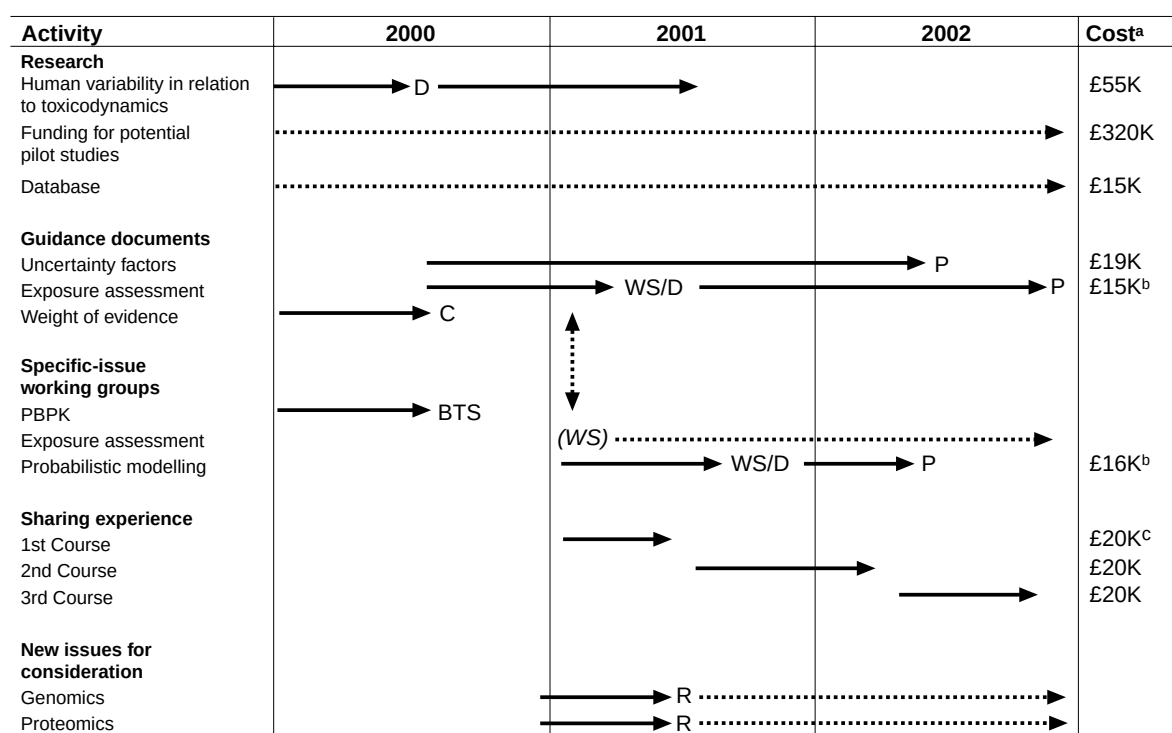
- to fund one pilot research project at present;
- to update and maintain the risk assessment methodology research database;
- to produce two guidance documents (uncertainty factors and exposure assessment);

- to work in tandem with the BTS to set up a PBPK specific-issue working group;
- to convene a workshop to take forward probabilistic modelling in the UK; and
- to establish courses to facilitate sharing experience and initiating change in the process of risk assessment.

Other possible activities include exploring the impact of genomics and proteomics on risk assessment.

The total cost of the activities outlined in Figure 1 can be accommodated within the programme budget for the three-year period.

Figure 1 Outline Schedule of activities, October 1999 to September 2002



D, Decision point; P, Publication; WS, Workshop; C, Consultation; BTS, British Toxicological Society; R, Review;

→ Activity;→ Possible activity; ^a Including T&S and accommodation for non government participants only;

^b Cost includes one-day workshop; for two-day increase by £2500; ^c Half of this cost may be recouped if participants pay for the course

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Risk Assessment and Toxicology Steering Committee, (1999c) *Risk Assessment Strategies in Relation to Population Subgroups* (cr3) Leicester, UK, Institute for Environment and Health

Risk Assessment and Toxicology Steering Committee (1999d) *Physiologically-Based Pharmacokinetic Modelling: A Potential Tool for use in Risk Assessment* (cr4) Leicester, UK, Institute for Environment and Health

Risk Assessment and Toxicology Steering Committee (1999e) *Exposure Assessment in the Evaluation of Risk to Human Health* (cr5) Leicester, UK, Institute for Environment and Health

Risk Assessment and Toxicology Steering Committee (1999f) *From Risk Assessment to Risk Management: Dealing with Uncertainty* (cr6) Leicester, UK, Institute for Environment and Health

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