Government/Research Councils Initiative on Risk Assessment and Toxicology

DEVELOPING NEW APPROACHES TO ASSESSING RISK TO HUMAN HEALTH FROM CHEMICALS

Report prepared by the Risk Assessment and Toxicology Steering Committee

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The Risk Assessment and Toxicology Steering Committee aims to stimulate the development of new, improved approaches to the assessment of risks to human health from chemicals.

The Committee takes forward the work of the Government/Research Councils Initiative on Risk Assessment and Toxicology. The Initiative was established in response to a statement in the 1995 UK Government *'Forward Look of Government Funded Science, Engineering and Technology'*, which recognised the inherent limitations of current procedures and committed the Government to pursuing opportunities presented by scientific advances.

The Steering Committee 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 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 Risk Assessment and Toxicology Steering Committee 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 Risk Assessment and Toxicology Steering Committee. The opinions expressed do not necessarily represent the policies of the participating Departments, Agencies and Research Councils.

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Contents

1 General introduction

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 all of us in our daily lives. But chemicals can harm human health and risks from their use therefore have to be assessed to ensure that exposures are properly controlled. Annex 1 lists the main exposures to chemicals and the UK Government departments or agencies responsible for assessing their risks.

The current methods for assessing risks to human health from chemicals rely heavily on data from tests carried out on animals. There are inherent limitations in these methods arising from the need to extrapolate results obtained from exposing experimental animals to the chemical, often in large amounts, to the human population, normally exposed to much lower amounts. Although the use of these methods has contributed to a reduction in risks, it is clearly desirable to reduce the limitations to ensure that the controls placed on the use of chemicals are appropriate.

There are no simple solutions to these limitations. However, recent advances in scientific techniques, employing novel biomarkers, molecular modelling and computer simulations, and *in vitro* toxicology may offer new possibilities. In addition to improving risk assessments, such techniques could contribute to a reduction in the number of animals used in testing, a principle to which Government departments and agencies are committed.

Government departments, recognising the limitations of current methods, articulated the need to develop improved methods in a statement in the 1995 UK Government *'Forward Look of Government Funded Science, Engineering and Technology'* (HMSO, 1995; Annex 2). The *Forward Look* committed Government departments, together with the relevant Research Councils, to making a co-ordinated drive to pursue the important opportunities presented by recent scientific advances.

This led to the establishment in 1996 of the Government/Research Councils Initiative on Risk Assessment and Toxicology. The work of the Initiative has been taken forward by the Risk Assessment and Toxicology Steering Committee, an informal committee of officials from Government and the Research Councils. The Steering Committee has followed up the proposals in the *Forward Look* by:

- reviewing current practice for managing risks to health from chemicals, taking into account both UK and overseas experience;
- starting to explore, with the Research Councils, how a joint research strategy might focus on these policy needs;
- holding workshops as a first step to the development and validation of innovative approaches to risk assessment; and
- promoting improved risk assessment decision-making.

Contribution of the Initiative to Government's work on risk

The principles underlying the methods used to assess risks to human health from chemicals are the same as those for other risks which the Government has responsibility for assessing and managing. Thus the same policy issues apply, including the use of expert judgement, openness and transparency. Operating as a subgroup of the Interdepartmental

Liaison Group on Risk Assessment (ILGRA), the Risk Assessment and Toxicology Steering Committee contributes to the priorities identified in ILGRA's work programme in the area of the assessment of risk to human health from chemicals (ILGRA 1996, 1998).

Working procedures

Since its establishment, the Risk Assessment and Toxicology Steering Committee has developed a programme of work for the Initiative, planned a series of workshops and managed the production of reports. Funding for the provision of secretariat services has been made available to the Medical Research Council's Institute for Environment and Health (IEH) by participating departments and Research Councils. These services have included the organisation of the workshops and Steering Committee meetings and the editorial work involved in the production of reports. The first phase of the Initiative has run from March 1996 to September 1999. From March 1996 until July 1998 the secretariat was headed by a member of the Health and Safety Executive's (HSE) staff seconded to the IEH. Since July 1998 it has been led, on a part-time basis, from HSE headquarters in London. The Steering Committee is chaired by Dr David Shannon, Chief Scientist of the Ministry of Agriculture, Fisheries and Food. Membership is listed in Annex 3.

The long-term aim of the Initiative is to stimulate research that will lead to the development of innovative approaches to chemical risk assessment in respect of human health by providing a focus, co-ordination and positive encouragement for research financed by individual Government departments or Research Councils (or consortia of these bodies). Workshops therefore looked at different aspects of risk assessment. They brought together regulatory toxicologists, policy advisors from Government and experts from academic institutions and industry to consider in depth a specific area of the risk assessment process and to make recommendations, including research needs.

Broadening the scope

The original remit of the Initiative as set out in the *Forward Look* statement focused on the scientific methods used in risk assessment, particularly the toxicological evaluation of chemicals. The 1998 ILGRA report to ministers indicates how recent developments connected with the public appreciation of risks (e.g., BSE) have raised the profile of, and had enormous implications for, the way Government and its agencies approach risk.

The Steering Committee has reacted to these influences by broadening its work to include policy issues relating to chemical risk assessment. Of particular interest to the Initiative are issues relating to consistency and transparency of approach.

2 The risk assessment process

The work of the Steering Committee is concerned with the assessment of risks to human health from exposure to chemicals. It also encompasses the interaction between risk assessment and the management of the risks*.

Risk assessment consists of:

- identifying the properties of a chemical that can lead to adverse (toxic) health effects (hazard identification);
- obtaining quantitative information about the hazard including, where possible, information on dose–response relationships (hazard characterisation);
- assessing exposure to the chemical (exposure assessment); and
- comparing exposure and hazard information (risk characterisation).

This basic process can be implemented and used in a variety of different ways, depending on the purpose of the assessment.

Hazard identification and characterisation are generally based on data from animal studies, although on occasions human data may be available. Chemicals requiring regulatory approval normally require a predetermined set of toxicological data designed to cover the health effects of concern. Data will normally be generated using internationally accepted procedures.

Lack of good exposure data is frequently a limitation in risk assessment. Rarely, except in the workplace and for human medicines, is the exposure of the individual measured directly. More often, population exposures are estimated using data on amounts in, for example, air, food or water, coupled with assumptions about how much enters the human body. In some circumstances modelling techniques are used to estimate exposures.

Finally risk characterisation compares information from hazard characterisation with exposure estimates. For chemicals for which it is considered a threshold exists for the toxic effects, a comparison of amounts considered to be of no concern to human health with estimates of exposure is used to inform risk management decisions. For chemicals for which a threshold for the toxic effects cannot be identified with any confidence, it is recognised that the risk assessment cannot determine a dose of no concern to human health. The risk management options normally exercised in such cases are aimed at eliminating exposure or reducing it to as low a level as is reasonably practicable.

*Risk management may also include ethical, social, economic and political considerations.

3 Results of the work undertaken

Outputs

At the outset, the Steering Committee realised that there are some variations between the risk assessment schemes used by Government departments and agencies. Risk assessments are carried out and used in different ways to inform specific risk management decisions (e.g., granting permission to market a pesticide for a specific use, setting an air quality standard). The procedures often reflect requirements of European Union (EU) directives or other international agreements, and each scheme has been developed independently, although on the basis of the same underlying fundamental principles. The Steering Committee has provided, for the first time, a forum for an interchange of views between departmental representatives involved in the operation of the different schemes.

Review of risk assessment approaches

In order to articulate the approaches used across Government, the Steering Committee commissioned a review '*Risk assessment approaches used by UK Government for evaluating human health effects of chemicals*' (Risk Assessment and Toxicology Steering Committee, 1999a) to:

- describe current risk assessment practices used in different Government departments and agencies;
- look for a common framework for and any necessary diversities in the procedures used;
- identify major areas of uncertainty and weakness in current risk assessment procedures; and
- make recommendations on areas in which the risk assessment process might benefit from harmonisation across departments, and areas that might be improved by targeted research or other means or benefit from innovative approaches.

The review looked at the risk assessment process, the type of information required and how it is collected, who evaluates the data and the framework for data evaluation. It was concluded that there is wide agreement across Government departments and agencies on the philosophies and methodologies used in chemical risk assessment. Nevertheless, there are diversities of approach in dealing with the difficult areas of:

- uncertainties
  - in extrapolating data from animal tests to humans in respect of health effects
  - in the estimation of exposure;
- variability
  - within the human population
  - in estimates of exposure; and
- gaps in the data on hazard identification
  - for example, many chemicals have not been tested for effects on reproduction.

The review led to a series of recommendations aimed at addressing the diversities of approach and improving the risk assessment process. These were divided into three groups:

- harmonisation
- development of improved methods and new approaches to risk assessment and
- improved transparency.

Workshops

On the basis of emerging priorities identified during the preparation of the review, the Steering Committee sponsored workshops on four important aspects of risk assessment. The first three workshops followed a common format of presentations from policy advisors and experts from academic institutions and industry followed by discussions of key issues, leading to a series of recommendations. The fourth comprised a discussion by Government risk assessors of how uncertainty is handled in four specific risk assessment schemes, using a series of case studies.

Population subgroups

The first workshop considered risk assessment strategies for dealing with variability within the human population (Risk Assessment and Toxicology Steering Committee, 1999b). Risk assessment frequently involves extrapolating from data obtained in a genetically defined strain of healthy animals to the human population, which will show variability as a result of age, sex, pregnancy status, disease state, lifestyle and genetic factors. The workshop considered the scientific basis of the current extrapolation procedures, whether special provision should be made for certain population subgroups, and the need for research to obtain better information to underpin extrapolation procedures.

Physiologically-based pharmacokinetic modelling

The second workshop considered the application to risk assessment of physiologically-based pharmacokinetic (PBPK) modelling (Risk Assessment and Toxicology Steering Committee, 1999c), which uses mathematical models based on biological principles to describe the way in which chemicals enter, are handled by and leave the body. This technique can help to highlight and reduce the uncertainties of estimating the dose of chemical the body or parts of the body may receive after exposure. PBPK modelling has already undergone significant development, particularly in the USA where it has made a valuable contribution to the risk assessment process, but its application to regulatory activity has been relatively limited. It is also widely used in the development of pharmaceutical preparations. The workshop participants concluded that PBPK modelling could improve the risk assessment process but that there was a need to develop research expertise within the UK. This would provide a resource on which departments could draw for a contribution to risk assessments on particular chemicals and for further development of the technique.

Exposure issues

The third workshop considered exposure assessment (Risk Assessment and Toxicology Steering Committee, 1999d), comparing current approaches to exposure estimation, exploring key issues of concern, and identifying areas of research that could lead to improved assessment. Background papers considered the current approaches for exposure assessment of chemicals in food and consumer products, water, soil, air and the occupational environment. The workshop participants concluded that there is a need for a more harmonised approach to exposure assessment, better pooling of expertise, and improved transparency in the choice of procedures used. It was recommended that Government departments and agencies should establish a specific forum to address common issues.

Uncertainty factors

The final workshop considered consistency and transparency in extrapolating from data generated in animals to humans (Risk Assessment and Toxicology Steering Committee, 1999e). The aim was to tease out the different influences on uncertainty factors by examining how four major risk assessment schemes (occupational exposure limits; air quality standards; pesticides approvals and food contaminants) would deal with four databases, each constructed to highlight a different situation, likely to be encountered in the risk assessment process. The particular issues considered were:

- the toxicological considerations applied to the database (discussion of scientific issues was not included)
- the allowance made for uncertainty in the database
- the influence of societal factors on the uncertainty factor
- the influence of the risk management scheme.

Copies of the review of risk assessment approaches and the four workshop reports and additional copies of this review can be obtained from the IEH. The Government/Research Councils Initiative on Risk Assessment and Toxicology has a web site linked to that of ILGRA (http://www.open.gov.uk/hse/dst/ilgra.htm), which provides access to the executive summary of each report.

Issues and challenges

By addressing key aspects of risk assessment, the four workshops furthered debate on the issues identified in the review of risk assessment approaches. The workshops on population subgroups and PBPK modelling provided a valuable contribution to the recommendations for the development of improved methods and new approaches to risk assessment. The workshop on exposure assessment made recommendations relating to harmonisation, to the development of improved methods and new approaches to risk assessment research, and to improved transparency. The final workshop on handling uncertainty focused on issues of harmonisation and improved transparency. Some of the key recommendations set out in the review and workshop reports are discussed below.

Harmonisation

Harmonisation means the use of approaches that are compatible and consistent; in terms of risk assessment methodology, it does not mean uniformity. The review of risk assessment approaches showed that the chemical risk assessment schemes used by the UK Government fit into a common framework, but some variations occur in the way the framework is applied. These differences reflect the fact that schemes have developed independently, often within an EU context. Despite the constraints in modifying schemes agreed within EU fora there may be opportunities for improving harmonisation.

Considerable progress has been made in harmonisation of standard protocols for the most widely used toxicity tests, by the agreement, through the Organisation for Economic Co-operation and Development (OECD). It is expected that a further drive towards harmonisation of testing requirements between different risk assessment schemes, for example pesticides and new chemicals, may reduce burdens on business and may contribute to a reduction in animal usage; nonetheless, the effectiveness of such harmonisation should be assessed. Such initiatives need to be pursued within the EU and within the context of global harmonisation.

An issue which concerns both harmonisation and transparency is the way uncertainty is handled in the risk assessment process. This is strikingly influenced by the risk management considerations. For example, in the occupational setting allowance is made for the fact that the workforce is generally only exposed for 40 hours per week, that it does not include the most vulnerable members of the population, and that exposures can be monitored and timely remedial steps taken to further control exposure, as necessary. A smaller allowance can therefore be made for uncertainties when setting a standard for occupational exposure than when setting one designed to protect the general public. However, such considerations are not always apparent in the information published on risk assessments. A clearer articulation of the uncertainties and how they are addressed within the different risk assessment schemes – key recommendations in the review – would help to increase the transparency of the process across the schemes. It would also demonstrate that, while the approaches used are not uniform, they are broadly consistent.

Development of improved methods and new approaches for risk assessments

A two-pronged approach is needed to the development of improved methods and approaches to risk assessment. In the short- to medium-term, work to refine test protocols and new approaches to analysing data may deliver improved procedures. The review makes a number of recommendations in this area.

The development of new alternatives to animal testing is a long-term objective. If it proves possible to develop a new technique for hazard identification, for example, using *in vitro* techniques, then the ultimate goal will be the validation and international acceptance of the method. This can be a slow process; even after a method has been developed it can take 10–20 years to complete the process leading to international acceptance. For example, the Ames test (a short-term test conducted in bacteria for mutagenic effects of chemicals) was first published in 1973, but was only accepted by the OECD in 1983. These time-scales indicate the magnitude of the challenge of moving away from conventional test methods, and highlight the need to continue, simultaneously, to try to improve existing methods.

The limitations inherent in the reliance on data generated in animal tests can only be overcome by the development of new risk assessment tools. A number of techniques have the potential to provide information additional to that obtained using currently agreed procedures. PBPK modelling, as indicated above, and also molecular modelling are two examples. The former was the topic of a workshop (Risk Assessment and Toxicology Steering Committee, 1999c). The latter

has the potential to use information from the 3-dimensional structure of a chemical to predict ways in which it could interact with proteins or genetic material. For the reasons given above there is no realistic prospect at present of either of these techniques replacing current procedures. As development continues, and they provide comparable or additional information to that provided by animal tests, it may ultimately be possible to consider them as alternatives. The realisation of this long-term goal will only be met by collaborative research involving Government departments and agencies, Research Councils, industry and international organisations.

The international acceptance of non-animal tests would, of course, have the effect of reducing animal use, although it may increase for a time during the development and validation of tests.

The total amount of chemical absorbed by a person's body influences the risk to his or her health, irrespective of whether exposure is from food, the workplace, outdoor air or a combination of these and other sources. Thus there is a need to move away from the present methods of situation-by-situation exposure assessment and to develop integrated approaches that assess total exposure and consider the health effects of mixtures of chemicals.

Improved transparency

Information on risk assessments is normally made available, within any necessary commercial constraints. There are opportunities for departments to improve transparency by considering how the thinking behind the risk assessment is presented, including:

- discussing inherent uncertainties in the data; and

- distinguishing between those elements of the risk assessment that have a clear scientific basis and those which are influenced by risk management considerations.

4 Future directions

The work undertaken so far has laid a firm foundation from which further progress can be made in the three key areas identified: harmonisation; development of improved methods and new approaches for risk assessments; and improved transparency.

The Steering Committee will continue to take forward the work of the Government/Research Councils Initiative on Risk Assessment and Toxicology but, to reflect the broader remit, will be known as the Interdepartmental Group on Health Risks from Chemicals. The remit and draft objectives of the Group are set out in Annex 4.

One important achievement has been improved communication between risk assessors involved in different risk assessment schemes. The review of risk assessment approaches has made a major contribution by articulating the similarities and differences between the various schemes in operation across departments. Thus the Steering Committee has played a valuable role in providing a forum for an interchange of views between departmental representatives involved in the operation of the different schemes. This will continue to be a key feature. It makes a significant contribution to joined-up working in the management of health risks from chemicals.

The review exercise and workshops have made a series of recommendations and identified a range of research needs. One of the Interdepartmental Group's first tasks will be to examine the recommendations and develop a research strategy. This will be discussed with the research community, Research Councils and other stakeholders, with a view to engaging them in the implementation of the strategy. In addition, Government departments propose to collaborate in funding a number of 'pump priming' projects to stimulate the development of new techniques.

Finally, a number of the recommendations arising from the Steering Committee's work relate to risk assessment policy, reflecting the broadened remit of the Initiative. To promote progress in these areas, activities will be developed which will reflect the international nature of chemical risk assessment work and determine where attempts should be made to influence UK and EU policy or OECD activities.

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

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

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

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

Annex 1: Main exposures* to chemicals and departments/agencies primarily responsible for assessing risks

Source of exposure	Department/Agency
Food contaminants and additives	MAFF/DH
Agricultural pesticides	PSD
Non-agricultural pesticides (biocides)	PSD/HSE
Veterinary products	VMD
Occupational Exposures	HSE
Consumer products	DTI/DH
Air quality	DETR/EA/DH/SEPA
Water quality	DETR/EA/DH/SEPA
Land quality	DETR/EA/SEPA
Human medicines	MCA

DETR, Department of the Environment, Transport and the Regions; DH, Department of Health; DTI, Department of Trade and Industry; EA, Environment Agency; HSE, Health and Safety Executive; MAFF, Ministry of Agriculture, Fisheries and Food; MCA, Medicines Control Agency; PSD, Pesticide Safety Directorate; SEPA, Scottish Environmental Protection Agency; VMD, Veterinary Medicines Directorate

*Exposures include manufactured chemicals and other chemicals in the environment.

Annex 2: Extract from the 1995 UK Government 'Forward Look of Government Funded Science, Engineering and Technology'*

The problem

Government Departments have a responsibility for assessing and managing risks to health from substances in food, household products, the workplace and the environment. Risk management and standard setting based on traditional risk assessment procedures usually provide a large margin of safety to take account of uncertainties in the risk assessment process. These procedures frequently do not provide meaningful estimates of risk. This has made it difficult to balance risks against benefits and to ensure an optimal use of resources.

Limitations of current methods

There are inherent limitations in the use of epidemiology and animal-based experiments to predict risks to humans. To detect effects in small numbers of animals it is generally necessary to use high doses; this may distort the effect of the substance. There are unavoidable problems in extrapolating from animals to man and from high to low doses. For example, there may be significant differences in ways humans and animals metabolise exogenous substances and also substantial differences in metabolic processes within the human population. Some individuals may also exhibit idiosyncratic reactions which are not predictable from traditional animal testing. The role of substances in the causation of allergies is such an example.

New options

Modern scientific techniques offer new approaches to risk assessment, for instance *in vitro* toxicology using human tissues, molecular modelling, computer simulation and the use of human biomarkers. There is a need to build on these approaches, together with the opportunities now being presented by advances in molecular biology, to allow Government in the UK to develop a better risk strategy.

The proposal

The policy needs have been identified by appropriate departments. They will explore with the Research Councils how a joint research strategy can be focused on these policy needs. Some preliminary joint-funded research by MAFF and DoE into low dose exposures to carcinogens is already proceeding at the MRC Institute for Environment and Health.

The intention is to review current practice for managing risks to health from toxic substances, taking into account both UK and overseas experience. The long-term aim is to develop and validate innovative approaches to generate better estimates of risk and improved assessment procedures. A further aim must be to press for new regulations to be risk-based, founded on agreed standards, and facilitated through multi-national collaboration in the research programme.

*HMSO, 1995 Forward Look of Government-funded Science, Engineering and Technology (Volume 1), London, UK, HMSO

Annex 3: Members of the Risk Assessment and Toxicology Steering Committee, 1996–June, 1999

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Annex 4: The remit and draft objectives of the Interdepartmental Group on Health Risks from Chemicals

Remit

To secure improvements in chemical risk assessment for human health by:

- promoting the development of improved methodologies;
- promoting improved approaches to risk assessment;
- promoting coherence and consistency in the practice of risk assessment;
- disseminating and advancing best practice.

Draft objectives to meet this remit are given below.

Draft objectives

- secure the development of innovative methods and improved approaches;
- provide a forum for discussing how greater coherence and consistency of approach can be achieved, nationally and internationally;
- identify and disseminate best practice in collaboration with stakeholders and other national and international organisations;
- publish a biannual research strategy for discussion with Research Councils industry and international organisations;
- report annually to ILGRA and funding bodies; and
- arrange for an independent evaluation of the Group's achievements at three-year intervals.

The Group will develop specific objectives as one of its first tasks.

Risk Assessment and Toxicology Steering Committee publications

cr 1 Developing New Approaches to Assessing Risk to Human Health from Chemicals

cr 2 Risk Assessment Approaches used by UK Government for Evaluating Human Health Effects of Chemicals

cr 3 Risk Assessment Strategies in Relation to Population Subgroups

cr 4 Physiologically-Based Pharmacokinetic Modelling: A Potential Tool for Use in Risk Assessment

cr 5 Exposure Assessment in the Evaluation of Risk to Human Health

cr 6 From Risk Assessment to Risk Management: Dealing with Uncertainty

Published by the Institute for Environment and Health, Leicester, 1999

Executive summaries of these reports are available at the ILGRA website:
http://www.open.gov.uk/hse/dst/ilgra.htm

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