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INTERDEPARTMENTAL LIAISON GROUP ON RISK ASSESSMENT

**INTERDEPARTMENTAL GROUP ON HEALTH RISKS
FROM CHEMICALS**

Annual Report to ILGRA

1 October 2000 to 31 September 2001

A Paper by Michael Topping, Chemical Risk Assessment Unit.

Background

The Interdepartmental Group on Health Risks from Chemicals (IGHRC), a sub-group of ILGRA, takes forward ILGRA's purpose and objectives in regard to the Government's activities on chemicals. Membership consists of relevant Departments, Agencies and Research Councils (see annex 1 for membership list). The IGHRC aims to reduce the uncertainties and limitations in the process of assessing risks to people's health by stimulating the development of new, improved approaches to the assessment of chemical risks. Its specific objectives are to:

- Promote the development of methods and techniques to improve the information used in the process of toxicological risk assessment;
- Promote improved approaches to the regulatory use of toxicological risk assessment;
- Promote coherence and consistency in the practice of toxicological risk assessment as used within different risk management and regulatory frameworks across government; and
- Disseminate and advance best practice within government.

IGHRC was established in October 1999. The Departments, Agencies and Research Councils listed in Annex 1 have provided funding to the MRC's Institute for Environment and Health to enable them to provide resource to carry forward IGHRC's work programme.

The paper to ILGRA in November 2000, set out the work of IGHRC during its first year and the programme for the remaining two years. This document was published in December 2000. This paper reports on progress up October 2001.

Issue

Report to ILGRA on the work of the IGHRC from October 2000 to October 2001.

Progress on delivering the work plan

Overview

IGHRC has made substantial progress on all areas of the workplan during the last 12 months. Details are described under six headings; research, reports, guidance documents, specific-issue working groups, sharing experience and initiating change, and future work.

Reports

The First Report and Forward Plan to 2002 and Annexes to the First Report and Forward Plan to 2002

This document was published and distributed for consultation in December 2000. A limited response to the consultation was received during March and April 2001. The Secretariat have responded to each letter and a short summary of the comments has been put on the IGHRC website.

Weight of Evidence Approach to Assessing Chemical Carcinogens in the UK

The aim of this document is to summarise, in one place, the available information on the weight of evidence approach as used in the UK for the hazard assessment of chemical carcinogens; currently such information is spread over several UK Government documents. This report is intended for people not familiar with current guidance and for officials involved in risk assessment. It is hoped that this compilation of the relevant information in one document will be of benefit to those involved in the risk assessment of chemical carcinogens in the UK.

The draft document is currently being reviewed by the IGHRC Executive Committee and following amendments will be circulated to the Steering Committee for their comment. It is expected that this document will be distributed to all relevant departments and agencies.

Guidance Documents

Guidance on Addressing Uncertainty in the Toxicological Aspects of Human Health Risk Assessment of Chemicals

As there is currently no single UK Government position or document on the derivation and use of uncertainty factors in chemical risk assessment, the aim of this document is to develop a framework setting out how UK Government departments, agencies and their advisory committees handle the uncertainties in toxicological aspects of risk assessment, including the derivation and application of uncertainty factors. The document is concerned with threshold related effects, and does not cover those toxic effects for which the assumption is made that there is no threshold, e.g. genotoxic carcinogens. This document will thus provide guidance to those both within and outside Government on the way in which toxicological uncertainty is addressed in

the regulatory setting, whilst helping to increase transparency, coherence and consistency.

A guidance document has been prepared and reviewed by an IGHRC working group and amendments have been made. The draft will be circulated for formal comment around departments and the expert committees outlined below will be consulted on the content of the document.

- Advisory Committee on Toxic Substances (ACTS)
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)
- Working group on Assessment of Toxic Chemicals (WATCH)
- Medical and Toxicology Panel of the Advisory Committee on Pesticides
- Committee on Carcinogenicity (COC)
- Expert Panel on Air Quality Standards (EPAQS)
- Veterinary Products Committee (VPC)

Human Exposure Assessment of Chemical Substances in the UK

The purpose of this planned guidance document is to provide a harmonised guidance document that will assist, but not constrain, those Government departments having to either undertake or evaluate exposure assessments. The document needs to be logical, understandable, contain all required underlying principles (and, where appropriate, supporting science), but not extensive detail, be applicable to all government departments which undertake or evaluate exposure assessments to chemical substances as part of their responsibility and be sufficiently robust for presentation to EU and international fora.

It is essential before the preparation of this document that the IGHRC Secretariat consults with the Scientific Secretariat of those UK medical and scientific committees concerned with chemical exposures to ensure that their views are sought and their needs are met. The committees to be consulted are outlined below.

- Advisory Committee on Pesticides
- Advisory Committee on Hazardous Substances
- Scientific Committee on Plants
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)
- Working Group on Risk Assessment of Mixtures of Pesticides and Veterinary Medicines (WiGRAMP)
- Working Party on Chemical Contaminants in Food
- Working group on Assessment of Toxic Chemicals (WATCH)
- Veterinary Products Committee (VPC)
- Committee on Products and Processes of Construction for use in Public Water Supply
- Committee on the Medical Effects of Air Pollution (COMEAP)
- Expert Panel on Air Quality Standards (EPAQS)

To facilitate consultation on the content of the guidance document, a two-day workshop will be held at the Institute for Environment and Health on 14 and 15 November 2001.

The programme for this workshop has been finalised and the speakers confirmed. Letters of invitation have been sent to the expert committees outlined above.

Specific-Issue Working Groups

Physiologically-Based Pharmacokinetic Modelling

A one day workshop, '*PBPK Modelling in Human Health Chemical Risk Assessment*' co-organised by the IGHRC and the British Toxicological Society (BTS) took place on 7 March 2001 at the Health and Safety Laboratory in Sheffield. This workshop was designed to increase knowledge and expertise in physiologically-based pharmacokinetic (PBPK) modelling as a tool for improving the predictive value of chemical risk assessment. Designed to appeal to individuals actively involved in risk assessment, it included presentations by key experts in the field and a 'hands-on' session with examples of data modelling using PBPK software.

All participant places were filled and the results of a questionnaire distributed on the day indicated that the meeting had been very successful and well received. The BTS, as a result of this meeting, are holding a session on PBPK modelling as part of their Continuing Education programme at the Annual Conference next April. It is hoped that a speciality section of the BTS will be established for computational methods that will include PBPK.

Probabilistic Modelling

Many Government scientists involved in chemical risk assessment have expressed an interest in probabilistic modelling but do not understand much about it or how it might be applied to their special field of interest or concern. With this in mind, the IGHRC are organising a workshop or rather an introductory session to 'Probabilistic Modelling in Human Chemical Risk Assessment' for March/April next year. The main speaker, Dr Wout Slob from RIVM, the Netherlands, has been confirmed. Numerous members of the BTS, in response to a letter circulated by Lewis Smith (Chairman of the BTS), have expressed their interest in attending or assisting in the workshop. The IGHRC is currently compiling the programme for this event.

Sharing Experience and Initiating Change

First Course – Presenting and Publishing Understandable and Transparent Risk Assessments from Chemical Exposures.

This course is aimed at people in government involved in risk assessment and comprises of presentations and case studies. The programme and speakers have been confirmed and the course will take place at IEH, on 24 and 25 October 2001.

Second Course – The Role of Risk Management in Risk Assessment

The content for this course is currently being developed.

Research

RAMRED database

A database was compiled of all Government-funded research in five areas of human health chemical risk assessment: uncertainty factors (toxicological), variability and

susceptibility, exposure models, probabilistic modelling and physiologically based pharmacokinetic modelling (pre October 2000). A questionnaire was sent to the Departments, agencies and research councils on 21 March for updates on relevant research projects they are funding. The database, called the Risk Assessment Methodology Research Database (RAMRED), was modified according to the information received, and launched on the World Wide Web in May 2001 at <http://wads.cfs.le.ac.uk/ieh/ramred/index.htm>. This database can now be searched by any member of the public for information such as, project titles, abstracts, funding organisation etc.

Continued maintenance of the RAMRED database will be decided by the Steering Committee when the site has been monitored for six months.

First pilot project 'A Study On Variation In Human Toxicodynamics'

Using the RAMRED database to identify research needs, a call for tenders was put out and the first pilot study was contracted to Professor Renwick at the University of Southampton in December 2000. Professor Renwick was asked to critically review the information available on variation in human toxicodynamic response to chemical exposure, to highlight the limitations in knowledge and to suggest research to meet the data gaps. To date the IGHRC has received two quarterly reports and the project is proceeding according to schedule and is due for completion December 2002.

The specification for a second pilot project on exposure models for use in the UK is currently under consideration.

Priority research topics for improving chemical risk assessment

The IGHRC document '*Priority research topics for improving chemical risk assessments*' outlines the five research areas the IGHRC has agreed will stimulate the development of methods and techniques that will improve information used in the toxicological risk assessment process. This document has been prepared and reviewed by the Executive Committee and Steering Committee and will be circulated to all the Departments, research councils and agencies, to be included in their calls for research proposals, where appropriate.

An 'Awareness Note' has been produced, drawing attention to the current and future activities of the IGHRC, including training courses, workshops and guidance documents. The aim of this note is to raise the profile of the IGHRC among those departments that are not yet aware of the IGHRC work programme. The Chairman of the IGHRC has circulated this 'Awareness Note' around the relevant Government departments. This note will also be attached as an annex to the document '*Priority research topics for improving chemical risk assessments*'.

Future Work

Terminology in risk assessment

The IGHRC have discussed the possibility of producing a document outlining and explaining the terminology used in risk assessment within the UK. A joint report on terminology by the Organisation for Economic Co-operation and Development (OECD) and the International Programme on Chemical Safety (IPCS) is due to be

published shortly. It was agreed that the IGHRC would await the report with a view to endorsing it and incorporate it into the IGHRC training courses and workshops.

Chemical Mixtures

The IGHRC have discussed the issue of chemical mixtures and believe that a position document on chemical mixtures might be very useful to Government Departments and their expert committees. The Working Group for the Risk Assessment of Mixtures of Pesticides (WiGRAMP), a subgroup of the COT, are currently drafting a report on chemical mixtures of pesticides and veterinary medicines. The report will be released early next year. In addition, the British Toxicological Society is hosting a half-day meeting in April on chemical mixtures. The IGHRC will await the outcome of this meeting and the WiGRAMP report before taking forward a document of general applicability on chemical mixtures next year.

Extension of Funding

In order to enable the IGHRC to carry out these additional items and complete the existing work programme, the Steering Committee have agreed funding for the IEH until October 2003.

Action.

ILGRA are invited to note this report from the IGHRC.

Contact

Michael.Topping, HSE, Room 605, Rose Court, 2 Southwark Bridge, London SE1 9HS;
Tel: 0207 717 6461; fax: 0207 717 6299; e-mail: michael.topping@hse.gsi.gov.uk>

Annex A

LIST OF IGHRC STEERING COMMITTEE MEMEBERS

Name	Department
Mr Andy Browning	Veterinary Medicines Directorate
Mrs Kathy Cameron	Department for Environment, Food, and Rural Affairs
Dr Ian Dewhurst	Pesticides Safety Directorate
Dr Raquel Duarte-Davidson	Environment Agency
Dr Steve Fairhurst	Health and Safety Executive
Dr Robin Fielder	Department of Health
Dr Declan Mulkeen	Medical Research Council
Dr Trevor Morris	Department of Trade and Industry
Professor Mike Moore	Natural Environment Research Council
Dr Vyra Navaratnam	Home Office
Dr Beverley Parsons	Biotechnology and Biological Sciences Research Council
Dr David Shannon (Chairman of Steering Committee)	Department for Environment, Food, and Rural Affairs
Dr Henry Stemplewski	Medicines Control Agency
Dr Andrew Wadge	Food Standards Agency
Professor Iain Purchase (Chairman of the Executive Committee)	University Of Manchester
Dr Michael Topping (Secretariat)	Health and Safety Executive
Dr Len Levy (Secretariat)	Institute for Environment and Health
Dr Carol Courage (Secretariat)	Institute for Environment and Health