General Distribution OCDE/GD(95)134

OECD ENVIRONMENT MONOGRAPHS No. 105

REPORT OF
THE OECD WORKSHOP ON
ENVIRONMENTAL HAZARD/RISK
ASSESSMENT

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1995

26811

OECD
ENVIRONMENT
MONOGRAPHS

No. 105

REPORT OF THE OECD WORKSHOP ON ENVIRONMENTAL HAZARD/RISK ASSESSMENT

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1995

Also published in the Environment Monograph series:

Environment Monograph No. 92, *Guidance Document for Aquatic Effects Assessment* (1995)

(For a complete list of OECD Environmental Health and Safety publications, see page 89)

ENVIRONMENT MONOGRAPHS

The Environment Monograph series makes technical documents prepared by the OECD Environment Directorate available to the public. For a complimentary copy of this publication, contact the Environmental Health and Safety Division, OECD Environment Directorate, 2 rue André-Pascal, 75775 Paris Cedex 16, France.

Fax: (33-1) 45 24 16 75

Foreword

This Environment Monograph contains the report of the OECD Workshop on Environmental Hazard/Risk Assessment, which took place in London in May 1994. The Workshop was hosted by the Department of the Environment (DoE) of the United Kingdom.

Work on hazard assessment in the OECD's Chemicals Programme is closely related to the work on Test Guidelines, co-operative investigation of existing chemicals, and the Pesticide Programme. The objectives of hazard assessment activities are to promote awareness, improvement, and, to the extent possible, harmonization of hazard assessment procedures for chemicals (including pesticides) and to encourage mutual use and acceptance of hazard assessments in OECD and other countries. These activities include the development and compilation of practical methods and procedures; promotion of their application in conjunction with co-operative investigations of chemicals; and promotion of harmonization of assessment reports. In recent years, workshops have been held (and documents produced) on aquatic exposure assessment, initial assessment of occupational and consumer exposure, and data estimation methods.

The Joint Meeting of the Chemicals Group and Management Committee recommended that this document be derestricted. It is being published on the responsibility of the Secretary-General of the OECD.

Table of Contents

Executive Summary 11

Résumé 15

Introduction 19

Objectives 19
Focus 20
A Comparison of Ecological Hazard/Risk Assessment Schemes 20
Workshop Structure 21
Definitions of Key Terms 21

Workshop Discussion Topics 23

Summary of Working Group and Plenary Session Discussions 25

Assessment of Different Chemical Types 25
Tiered Assessment 25
Data and Tests 25
Data and Emissions 25
Extrapolation and Uncertainty 25
Models 27
Predicted Environmental Concentrations 27
Monitoring and Field Data 27
Significance of Effects 28
Expert Judgement 28
Validation 28
Points from the Final Plenary Session 29

Recommendations for Further Work 31

Annex 1 - List of Participants 37

Annex 2 - Composition of the Working Groups 43

Annex 3 - Working Definitions of Key Terms for the Workshop 45

Annex 4 - Comparison of Ecological Hazard/Risk Assessment Schemes 49

Annex 5 - Report of the Working Group on Environmental Fate and Exposure 65

Annex 6 - Report of the Working Group on Aquatic Effects 71

Annex 7 - Report of the Working Group on Terrestrial Effects 79

OECD Environmental Health and Safety Publications 89

Executive Summary

As part of OECD's Hazard Assessment Programme, a Workshop on Environmental Hazard/Risk Assessment was held in London on 24th-25th May 1994. It was hosted by the UK Department of the Environment (DoE) and chaired by Dr Norman King of the DoE. The Workshop objectives were to:

(i) improve awareness and understanding in OECD Member countries of the various environmental hazard/risk assessment schemes in use, or in advanced stages of development;

(ii) identify similarities and differences in the various approaches and the reasons for these differences;

(iii) recommend further work for OECD in building consensus on environmental hazard/risk assessment procedures, whilst at the same time avoiding duplication of work done in other fora.

These objectives were designed to contribute to the longer-term goal of encouraging the mutual use and eventually the mutual acceptance of hazard/risk assessments of chemicals among OECD Member countries and others. The Workshop focused on environmental hazard/risk assessment for the regulation of chemicals, i.e. new and existing chemicals (including detergents) and pesticides. Hazard/risk assessments of effluents, accidents, etc. were not addressed.

The Workshop was organised around a series of Plenary Sessions and three Working Groups, on Environmental Fate and Exposure, Aquatic Effects, and Terrestrial Effects. The Working Groups were asked to address a set of questions on topics which covered important aspects of the hazard/risk assessment process. The topics included such areas as whether different chemical types needed to be treated differently, the structure of schemes (e.g. are tiers used?), data required, tests to be used, the use of models, approaches to extrapolation, identification of uncertainties, and the use of expert judgement. From their discussions of these areas, the Working Groups were asked to identify where further work by OECD is needed.

To provide information to Workshop participants and to facilitate discussions and the identification of further work required, a document summarising thirteen environmental hazard/risk assessment schemes used by various OECD Member countries or international organisations to support current regulatory requirements was developed. This document, "A Comparison of Ecological Hazard/Risk Assessment Schemes" will be made available as a separate OECD Environment Monograph.

Summary of Discussions

A particularly important outcome of the Workshop was the agreement that the scientific principles involved in risk characterisation and risk assessment of general chemicals and of pesticides are fundamentally the same. Any differences in assessment for these two types of chemicals will relate to details in the application of the assessment process rather than in the principles applied.

It was recognised that most hazard/risk assessment schemes have a tiered structure, enabling a progressive refinement of exposure/effects ratios. The Workshop agreed that this structure is highly desirable. It also agreed with the concept of having harmonized sets of base tests for initial risk assessments for the aquatic and the terrestrial environments, but felt that further testing at higher tiers should be done on the basis of potential exposure. A distinction was made between terrestrial effects testing for the initial assessment of pesticides and of general chemicals. It was recognised that, because of the nature and use of pesticides, some terrestrial effects data will always be needed at a base set level. However, for general chemicals, it cannot automatically be assumed that there will be exposure in the terrestrial environment. Effects data should therefore only be required after an initial comparison of information on fate and potential toxicity.

The Environmental Fate and Exposure Group agreed that *reliable* monitoring data, when available, should take precedence over predictions from models in the risk assessment of chemicals (with the exception of new chemicals on which monitoring data cannot be available). However, exposure models were viewed by the Workshop as being essential tools that play an important role in the exposure assessment process. The Workshop agreed that the estimation of Predicted Environmental Concentrations (PEC) using models will, in general, be the most cost-effective approach. It was recognised that work is needed on the harmonization of model selection and application, whilst allowing for geographic specifications.

The Workshop recognised that there are difficulties and uncertainties involved in the various extrapolations made during risk characterisation and assessment, and in the application of expert judgement. Clear, transparent reporting of risk characterisations and assessments was therefore viewed as being essential in order that the assessments can be understood and possibly used by others.

Summary of Recommendations for Further Work

The Workshop identified work needed on the development of Test Guidelines, in addition to that needed on risk assessment procedures. High priority was given to the development of: (1) guidance for the testing of difficult substances (e.g. poorly soluble substances, mixtures) in aquatic tests; (2) guidelines for assessing the effects of chemicals in aquatic sediments; and (3) a set of standard terrestrial effects tests.

A number of recommendations were made in relation to work on assessment procedures for environmental fate and exposure and aquatic and terrestrial effects. These included:

> *Environmental fate and exposure* – the development of practical instruments such as an emission database and emission scenarios to estimate releases, guidance for determining rate constants and other parameters derived from laboratory tests for incorporation into models, and harmonized models for predicting environmental concentrations.

> *Aquatic and terrestrial effects* – work on extrapolation techniques and assessment factors, e.g. (1) harmonization of assessment factors used in aquatic effects

assessment; (2) development of guidance on the extrapolation of data obtained on single substances to preparations and mixtures; and (3) derivation of assessment factors for terrestrial effects assessment.

General – All Working Groups recommended the development of guidance on: (1) criteria for assessing the suitability of non-standard data; (2) the quantification and reporting of uncertainty in risk assessment; and (3) the consistent, transparent reporting of a risk assessment such that it can be understood and used by others.

Finally the Workshop recognised the need for the efficient use of resources and the importance of transparency in risk assessment procedures. Risk assessment can easily become so information-hungry that higher tiers become difficult and disproportionate in terms of resource use. It was recognised that cost-benefit and animal welfare are factors that should be considered when requesting additional tests, and that the setting of criteria for ending the risk assessment process may be required. With regard to transparency, the importance of communicating risk assessment results to the public, who ultimately determine the acceptability of risks, was highlighted. In addition, the importance of providing readily understood (and hence more useable) results to those involved in risk management and risk reduction was stressed.

Résumé

Dans le cadre du Programme de l'OCDE sur l'évaluation des dangers, un atelier consacré à l'évaluation des dangers et risques environnementaux s'est tenu à Londres les 24 et 25 mai 1994. Cet atelier, accueilli par le Ministère de l'Environnement (DoE) du Royaume-Uni, était placé sous la présidence du Dr Norman King (DoE). Les objectifs de l'atelier étaient les suivants :

(i) améliorer, dans les pays Membres de l'OCDE, la connaissance et la compréhension des différentes méthodes d'évaluation des dangers et risques environnementaux, actuellement utilisées ou en cours de développement ;

(ii) identifier les différences et les similitudes des diverses approches ainsi que les raisons de ces différences ;

(iii) recommander à l'OCDE de procéder à des travaux complémentaires pour développer, de manière consensuelle, des procédures d'évaluation des dangers et risques environnementaux, en évitant en même temps de répéter des travaux déjà en cours ailleurs.

Ces objectifs doivent permettre, à long terme, d'encourager l'utilisation réciproque et, en définitive, l'acceptation mutuelle des évaluations des dangers et des risques liés aux produits chimiques entre les pays Membres de l'OCDE et les autres pays. L'atelier s'est intéressé principalement à l'évaluation des dangers et des risques environnementaux dans le contexte de la réglementation des produits chimiques nouveaux et existants (y compris les détergents) et des pesticides. Les évaluations des dangers et des risques concernant les effluents, les accidents, etc. n'ont pas été examinées.

L'atelier comprenait une série de sessions plénières et trois groupes de travail, notamment sur le devenir dans l'environnement et l'exposition, les effets aquatiques et les effets terrestres. Il a été demandé aux groupes de travail de répondre à une série de questions portant sur des aspects importants du processus d'évaluation des dangers et des risques. Les questions abordaient les sujets suivants: les types de produits chimiques qui nécessiteraient ou non d'être traités différemment, la structure des schémas (des essais séquentiels par exemple), les données requises, les essais à utiliser, l'utilisation de modèles, les méthodes d'extrapolation, les incertitudes, le recours à l'expertise, etc. Sur la base de leurs discussions, les groupes de travail devaient identifier les domaines dans lesquels l'OCDE devait engager des travaux complémentaires.

Un document de travail avait été préparé afin d'apporter des informations aux participants et de faciliter les discussions et l'identification des travaux complémentaires requis. Ce document résume treize méthodes d'évaluation des dangers et des risques environnementaux, utilisées dans les pays Membres de l'OCDE ou par des organisations internationales, qui sont à la base des réglementations actuelles. Ce document, intitulé «A Comparison of Ecological Hazard/Risk Assessment Schemes» (Comparaison des méthodes d'évaluation des dangers et des risques écologiques), sera disponible en tant que Monographie de l'OCDE sur l'environnement.

Résumé des discussions

Les participants sont convenus de reconnaître que les principes scientifiques utilisés pour caractériser et évaluer les risques des produits chimiques industriels et des pesticides sont fondamentalement les mêmes. Les différences entre les évaluations de ces deux types de produits chimiques concernent des détails dans l'application du processus d'évaluation plutôt que les principes appliqués.

Il a été reconnu que la plupart des méthodes d'évaluation des dangers et des risques ont une structure séquentielle, permettant de préciser progressivement le rapport exposition/effets. L'atelier a estimé que cette structure était fortement souhaitable. La réunion a également accepté le concept d'ensembles harmonisés d'essais de base pour les évaluations initiales des risques concernant les milieux aquatique et terrestre ; cependant des essais complémentaires à des niveaux supérieurs devraient être effectués seulement lorsqu'ils sont nécessaires pour tenir compte d'une exposition potentiellement élevée. Pour l'évaluation initiale des effets terrestres, une distinction a été faite entre, d'une part, les essais de pesticides et d'autre part les essais de produits chimiques industriels. S'agissant des pesticides, il a été reconnu que, à cause de leur nature et de leur utilisation, certaines données sur les effets terrestres sont toujours nécessaires au niveau de l'ensemble de base. Pour les produits chimiques industriels, il ne peut être automatiquement admis qu'une exposition aura lieu dans l'environnement terrestre ; par conséquent des données sur les effets terrestres ne doivent être requises qu'après comparaison initiale des informations sur le devenir dans l'environnement et sur la toxicité potentielle.

Le groupe de travail sur le devenir dans l'environnement et l'exposition a reconnu que des données de suivi *fiables*, quand elles sont disponibles, sont préférables aux prédictions issues de modèles d'évaluation (à l'exception des produits chimiques nouveaux pour lesquels des données de suivi ne sont jamais disponibles). Cependant, les modèles d'exposition ont été considérés par l'atelier comme des outils essentiels, ayant un rôle important dans le processus d'évaluation de l'exposition ; l'estimation des Concentrations Environnementales Prévues qui fait appel à des modèles sera, en général, l'approche la plus rentable. Il a été reconnu que des travaux sur l'harmonisation de la sélection et de l'application des modèles qui tiennent compte des spécifications géographiques sont nécessaires.

L'atelier a reconnu l'existence de difficultés et d'incertitudes dues d'une part aux diverses extrapolations utilisées au cours de l'évaluation et de la caractérisation des risques, et d'autre part à l'application de jugements basés sur l'expertise. Des lors, des rapports d'évaluation et de caractérisation des risques, clairs et transparents, sont essentiels pour que les évaluations puissent être largement comprises et utilisées.

Résumé des recommandations pour des travaux complémentaires

L'atelier a conclu qu'en plus des travaux sur les procédures d'évaluation des risques d'autres travaux sont nécessaires pour élaborer des lignes directrices pour les essais. L'atelier a accordé une grande priorité à la mise au point de : (1) conseils pour les essais aquatiques de substances difficiles (les substances peu solubles et les mélanges, par exemple) ; (2) lignes directrices pour évaluer les effets des produits chimiques dans les sédiments aquatiques ; et (3) un ensemble d'essais standard pour les effets terrestres.

Parmi les recommandations qui ont été faites concernant les travaux à effectuer sur les procédures d'évaluation dans les domaines du devenir dans l'environnement et de l'exposition il y a :

Devenir dans l'environnement et exposition – développement d'instruments pratiques tels qu'une base de données sur les émissions et des scénarios d'émission pour estimer les rejets; conseils sur la façon d'incorporer des constantes cinétiques et autres paramètres déterminés en laboratoire dans des modèles et harmonisation des modèles de prévision de concentrations environnementales.

Effets aquatiques et terrestres – travaux sur les techniques d'extrapolation et facteurs d'évaluation, incluant par exemple (1) l'harmonisation des facteurs d'évaluation utilisés pour les effets aquatiques (2) mise au point de conseils sur la façon d'extrapoler des données obtenues sur des substances individuelles aux préparations et mélanges (3) mise au point de facteurs d'évaluation pour les effets terrestres.

Général – Tous les groupes de travail ont recommandé le développement d'orientations sur : (1) les critères permettant d'évaluer la qualité de données peu courantes (2) la quantification de l'incertitude dans l'évaluation de risques et la façon de la signaler et (3) les rapports d'évaluation de risques, logiques et transparents, afin qu'ils soient largement compris et utilisés.

Finalement, l'atelier a reconnu le besoin d'utiliser efficacement les ressources et de rendre transparentes les procédures d'évaluation de risques. L'évaluation de risques peut facilement exiger tellement d'informations que des essais complémentaires deviennent difficiles et disproportionnés en termes d'utilisation des ressources. Il a été reconnu que le rapport coût/bénéfice et le bien-être des animaux sont des facteurs devant être pris en compte lors de la demande d'essais complémentaires, et que des critères d'arrêt du processus de l'évaluation des risques doivent être mis en place. L'importance de communiquer les résultats de l'évaluation des risques au public, qui détermine en définitive l'acceptation des risques, a été soulignée. L'importance de fournir des résultats facilement compréhensibles (et, partant de là, davantage utilisables) à ceux et celles qui sont impliqué(e)s dans la gestion et la réduction des risques a également été soulignée.

Introduction

Within the OECD countries, a variety of hazard/risk assessment schemes are used to evaluate chemicals. Whilst there are a number of similarities between these schemes, there are also a number of differences which may lead to different hazard/risk assessment conclusions in different countries for the same substance in similar circumstances. As part of its Hazard Assessment Programme, OECD held a Workshop on Environmental Hazard/Risk Assessment to evaluate the potential for consensus building and harmonization of the schemes, and to propose future activities for OECD in this area.

The Workshop was hosted by the UK Department of the Environment (DoE) at Church House Conference Centre, Westminster, London, on 24th-27th May 1994 and chaired by Dr Norman King of the DoE. There were 61 participants from 16 Member countries, the Czech Republic, the European Commission, the International Programme on Chemical Safety (IPCS), the United Nations Environment Programme (UNEP), the World Wide Fund for Nature (WWF) and several industry groups (see the List of Participants in Annex 1).

Mr Derek Osborn, Head of the UK Environmental Protection Command, opened the Workshop. In his address, Mr Osborn stressed the need for the Workshop to identify areas for harmonization in order to encourage the acceptance of risk assessments for individual chemicals across many countries, thus reducing inconsistencies, duplication of effort, costs to industry, and the need for animal testing, and thereby increase the opportunities for free trade in chemicals. Mr Osborn also pointed out that the Workshop results would contribute to meeting the objectives for the environmentally sound management of chemicals established by the UN Conference on Environment and Development (i.e. in Chapter 19 of Agenda 21).

Objectives

The Workshop objectives were to:

(i) improve awareness and understanding in OECD Member countries of the various environmental hazard/risk assessment schemes in use, or in advanced stages of development;

(ii) identify similarities and differences in the various approaches any reasons for these differences;

(iii) recommend further work for OECD in building consensus on environmental hazard/risk assessment procedures, whilst at the same time avoiding duplication of work done by other fora.

These objectives were designed to contribute to the longer-term goal of encouraging the mutual use and eventually the mutual acceptance of hazard/risk assessments of chemicals between OECD Member countries and others.

Focus

The focus of the Workshop was on environmental hazard/risk assessment for the regulation of chemicals, i.e. new and existing "general" chemicals (including detergents) and pesticides. It addressed the areas of environmental fate and exposure and aquatic and terrestrial effects, and covered both initial (screening) and comprehensive assessments. Hazard/risk assessments of effluents, landuse, accidents, etc. were not addressed.

A Comparison of Ecological Hazard/Risk Assessment Schemes

To provide information to Workshop participants and to facilitate discussions at the Workshop, the document "A Comparison of Ecological Hazard/Risk Assessment Schemes" (hereafter referred to as the Summary Document) was prepared. This document presents a review of the following thirteen schemes used by various OECD Member countries or international organisations to support current regulatory requirements:

* OECD - Draft SIDS Manual, Provisional Guidance for the Initial Assessment of Environmental Exposure and Aquatic Effects

* OECD - Guidance Document for Aquatic Effects Assessment

* EC - Risk Assessment of Notified New Substances, Technical Guidance Document

* EC - Draft Technical Guidance on Environmental Risk Assessment of Existing Substances

* Japan - Outline of Policies for the Safety Management of Chemicals

* Japan - Pesticide Safety Evaluation

* US EPA - Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act

* US EPA - Ecological Risk Assessment under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

* Canada - Draft Guidelines for Conducting Environmental Assessments for Priority Substances under the Canadian Environmental Protection Act

* Netherlands - Uniform System for the Evaluation of Substances (USES)

* Sweden - Principles for Identifying Unacceptable Pesticides

* European and Mediterranean Plant Protection Organisation/Council of Europe (EPPO/CoE) - Decision-Making Scheme for the Environmental Risk Assessment of Plant Protection Products

* European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) - Environmental Hazard Assessment of Substances

The above schemes were developed to address a variety of needs (e.g. initial screening, approval for use, labelling, etc.) and a range of chemicals (general chemicals, agricultural pesticides, etc.). They were selected to illustrate the types of hazard/risk assessment procedures in use throughout the OECD region rather than because of any evaluation of their particular merits. For general chemicals, national hazard/risk assessment schemes within the European Union were not included since there are EU schemes available. With respect to the assessment of plant protection products within the EU, it was not possible to include the EC scheme in the Summary Document since, at the time of the Workshop, Annex VI of Directive 91/414/EEC, the "Uniform Principles for the Evaluation of Plant Protection Products," had not been finalised.

The Summary Document will be made available as a separate OECD Monograph.

Workshop Structure

The Workshop was organised around a series of Plenary Sessions and three Working Groups: Environmental Fate and Exposure, Aquatic Effects, and Terrestrial Effects. The membership of each Working Group is given in Annex 2.

Each Working Group reported on progress during Plenary Sessions. The Plenary Sessions provided the opportunity for feedback to the Working Group from all participants, the pursuit of some more general issues towards the end of the Workshop, and the opportunity to reach agreement on recommendations for further work for OECD in hazard/risk assessment.

Definitions of Key Terms

A number of words and phrases used widely in hazard/risk assessment do not have consistent, agreed meanings. For this reason, a set of working definitions were developed for use at the workshop to avoid misunderstandings and to clarify concepts (see Annex 3). These definitions are also used in this report. The most important terms with respect to this report are *risk characterisation, risk estimation and risk assessment:*

Risk characterisation is the estimation of the incidence and severity of the adverse effects likely to occur in an environmental compartment due to actual or predicted exposure to a substance, i.e. integration of the effects and exposure assessments.

Risk estimation is the quantification of the likelihood (i.e. probability) that adverse effects will occur in an environmental compartment due to actual or predicted exposure to a substance.

Risk assessment is the determination of the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation.

Workshop Discussion Topics

In order to focus the Workshop discussions and to help achieve the objectives outlined above, each Working Group addressed a predetermined set of topics covering important aspects of the risk characterisation and assessment process. Some of the discussion topics were common to all three Working Groups, whilst others were specific to either the Working Group on Environmental Fate and Exposure or to those on Aquatic and Terrestrial Effects. The topics addressed are listed below, with an indication of the types of questions discussed.

All Working Groups:

Assessment of Different Chemical Types	–	Are the scientific principles for risk assessment the same for different chemical types (e.g.general chemicals and pesticides)?
Tiered Assessment	–	How are schemes structured? Are tiers used? What triggers are used to move from tier to tier? Are cut-off criteria used (i.e. can schemes be exited based solely on intrinsic properties of chemicals)?
Extrapolation	–	What extrapolation approaches are used, and at what level (e.g. acute to chronic, laboratory to field, few species to many, local, short-term fate and effects to wider, longer-term scales, typical to worst-case conditions)?
Uncertainty	–	Where are the uncertainties in the risk characterisation/ assessment process? How are they handled at present? How should they be expressed?
Expert Judgement	–	Where is expert judgment used? How can consistency be maintained?
Validation	–	Are schemes validated? How should this be done?

Environmental Fate and Exposure Group only:

Data and Emissions	–	What data are required? Are data requirements fixed or flexible? What is the role of (Q)SARs? Are field data used? How are emissions/release estimates made? Are intermittent releases taken into consideration? Should emissions be based on a "worst-case" or "typical case"?

Models	–	What types of models are used (e.g. steady-state multi-media, non-steady-state mono-compartment)? Is harmonization necessary?
Monitoring and field data	–	To what extent do schemes require or use monitoring or field data?
Predicted Environmental Concentrations (PECs)	–	For which environmental compartments are PECs determined, and on what scales (e.g. local, regional, global)?

Aquatic and Terrestrial Effects Groups only:

Data and Tests	–	What data are required? Are data requirements fixed or flexible? What is the role of (Q)SARs? Are internationally harmonized testing methods available? Can non-standard data be used? Are field data used? Are additional tests/endpoints desirable?
Exposure	–	Are all potential routes of exposure considered adequately?
Significance of Effects	–	What criteria are used to determine whether an effect is ecologically important? What are the criteria to determine, for example, high, medium and low risk?

In addition, the Working Groups were asked to identify elements of the risk characterisation/assessment process which would benefit from improved harmonization, and to make specific recommendations for further work which could be done by OECD.

The initial intention was that the Working Groups would address these topics from the perspective of their own particular areas of expertise (i.e. fate and exposure, aquatic or terrestrial effects), using the schemes reviewed in the Summary Document as a basis for discussions, and in doing so produce a more detailed comparison of these schemes. Each Group did this to some extent, but there was insufficient time for them to examine all the schemes in detail. A comparison of the schemes was therefore prepared after the Workshop and is presented in Annex 4.

Summary of Working Group and Plenary Session Discussions

This section summarises and collates the outcome of the discussions of the three Working Groups. It focuses on the major issues raised and areas of agreement reached in the Working Group and Plenary Sessions. The reports from the individual Working Groups are presented in Annexes 5 to 7.

Assessment of Different Chemical Types

The meeting agreed that the scientific principles involved in risk characterisation and assessment of general chemicals and of pesticides are fundamentally the same. Any differences in assessment for these two types of chemicals will relate to details in the application of the assessment process rather than in the principles applied, e.g. differences in use pattern and the understanding of releases to the environment, and the effects of high biological activity and selectivity of action of pesticides.

Tiered Assessment

Most risk characterisation/assessment schemes are tiered (either explicitly or implicitly), enabling a progressive refinement of exposure/effects ratios. The meeting felt that a tiered structure is highly desirable but that it is not possible, or necessary, to specify the number of tiers that would be generally required; the number of tiers required depends on a particular situation. Trigger values to move from tier to tier should generally be based on exposure/effects ratios, but the use of production volumes, usage criteria, the results of earlier studies, or the use of effects data only (e.g. where exposure/effects ratios are uncertain or unknown) should not be precluded.

Data and Tests

The meeting agreed that before complex effects data are required, consideration must be given to a chemical's fate and distribution. The Aquatic and Terrestrial Effects Working Groups agreed with the concept of a harmonized set of base tests for initial risk assessments, but felt that further testing should be required on the basis of potential exposure (i.e. tests would be focused on the environmental compartment of concern based on knowledge of the likely fate of the chemical). Both groups therefore advocated a flexible testing strategy beyond the 'base set'. It was recognised that the base set tests for the aquatic environment (e.g. green algae, daphnids and fish) are well established, with widely accepted procedures.[1]

---

[1] *However, some harmonization of these tests is needed, particularly with respect to test duration (e.g. some green algal tests are run for 72 hours and others for 96 hours; some daphnid acute tests are run for 24 hours, and others for 48 hours).*

The situation with regard to the inclusion of terrestrial tests in a base set is rather different. The meeting agreed that, in principle, requests for any terrestrial effects data should be dependent on the likelihood of exposure and on whether the substance is potentially toxic. Because of the nature and use of pesticides, some terrestrial effects data will probably always be needed at a base set level, although it is not possible to define a single common set of requirements (these should depend on the fate and distribution of the chemical in the various terrestrial compartments). For general chemicals, it cannot automatically be assumed that there will be exposure in the terrestrial environment. Terrestrial data should therefore only be required at a base set level after an initial comparison of information on fate and potential toxicity.

Both Effects Groups agreed on the need for harmonized test methods and GLP, but appreciated the need to develop criteria for assessing the acceptability of non-standard data. A set of standard terrestrial tests, including representatives from soil organisms, plants, terrestrial invertebrates (above ground) and terrestrial vertebrates, was proposed by the Terrestrial Effects Working Group. Tests would be selected from this standard set on the basis of predicted exposure.

The Aquatic Effects Group recognised that testing strategies were more fully developed for pesticides, where experience with the use of higher tier tests is greater, than for general chemicals. It identified the need to further develop strategies for the latter.

Data and Emissions

The Environmental Fate and Exposure Working Group agreed that the estimation of releases should follow the principles of the life-cycle approach (i.e. identifying releases during production, formulation, use, transport and disposal). They acknowledged that release estimation is difficult and associated with considerable uncertainty, but that a tiered approach, generally going from reasonable worst-case to more realistic scenarios, is appropriate. They recommended the development of an emission data base and emission scenarios for estimating releases.

Extrapolation and Uncertainty

All the Working Groups recognised that there are difficulties and uncertainties involved in the various extrapolations made during risk characterisation and assessment. The Environmental Fate and Exposure Group agreed that extrapolation of laboratory-generated data to field situations depends on the test type and endpoints considered. They suggested that extrapolation of data from aquatic biodegradation tests to what happens during sewage treatment is more uncertain than extrapolation of laboratory pesticide degradation data to the field.

The Effects Groups indicated that the derivation and use of assessment factors as a means of extrapolation needs particular attention. The Aquatic Group questioned the use of assessment factors based on the lowest NOEC or LC_{50} values for substances with large data bases. It felt that all acceptable data should be incorporated into the risk characterisation in order to minimise uncertainty and maximise the use of available data. Both Effects Groups had reservations about the use of effects data for pelagic aquatic organisms to predict effects to aquatic sediment- or soil-dwelling organisms (e.g. the equilibrium partitioning approach), whilst recognising that this approach may be useful in the absence of other data.

The Environmental Fate and Exposure Group felt that it would be useful to quantify uncertainty (e.g. by expressing risk in probabilistic terms), but recognised that this would be extremely difficult as one tries to assess propagation of error from one source to another. The Fate and Exposure Group and the Terrestrial Group recommended that uncertainties identified in testing results and in risk characterisations and assessments should be reported clearly for the benefit of risk managers and decision makers.

The Environmental Fate and Exposure Group concluded that experience in the pesticides area could provide useful information for the application of extrapolation techniques to general chemicals for fate and exposure.

Models

The use of models in risk characterisation was addressed by the Environmental Fate and Exposure Group. This Group agreed that models are essential tools that play an important role at various points in the exposure assessment process, but that work is needed on the harmonization of model selection and application, whilst allowing for geographic specifications.

Predicted Environmental Concentrations

The Fate and Exposure Group agreed that although it may be desirable to determine PECs for all environmental compartments, in practice risk assessors would derive them initially for a few compartments and successively add more if thought necessary. The Group supported the proposal from the SETAC Task Force on Multimedia Modelling for the identification of *primary compartments* into which substances are released directly (air, water, soil), *secondary compartments* to which substances are transferred from another medium (e.g. groundwater), and *tertiary compartments* where substances undergo multimedia transfer (food chain). The Group felt that the selection of compartments for which PECs should be determined is dependent on the aim and type of assessment (initial vs. comprehensive) and data availability.

Monitoring and Field Data

The Environmental Fate and Exposure Group agreed that *reliable* monitoring data, when available, should take precedence over predictions from models in the risk assessment of chemicals (with the exception of new chemicals for which monitoring data cannot be available). It was stressed, however, that the monitoring method and the monitoring programme need to be validated. The Fate and Exposure Group also concluded that the estimation of PECs from models will, in general, be the most cost-effective approach but that, on occasion, monitoring programmes may have to be implemented.

Significance of Effects

In reviewing the schemes in the Summary Document, the Terrestrial Effects Working Group concluded that although most schemes claim to address risks to populations, or ecosystems, none of them in fact generates data which will allow a proper ecological evaluation of population-level effects (with the exception of the assessment on soil micro-organism function). The Group felt that work should be initiated to develop a better understanding of the significance of ecological effects seen in the field on populations and ecosystems.

The Aquatic Effects Group recognised that monitoring data, particularly in relation to existing chemicals, can play a significant role in risk characterisation.

Expert Judgement

All the Working Groups recognised that expert judgement is essential and is currently used at various decision points in all hazard/risk assessment schemes, including:

- collection and appraisal of data (including validation of test methods);
- selection and use of models;
- selection of appropriate testing strategies;
- interpretation of test results;
- extrapolation;
- applying the data available to risk characterisation.

The Terrestrial Effects Working Group agreed that expert judgement for terrestrial effects is particularly important for pesticides. In view of the variability in routes and patterns of exposure, and consequently in the diversity of tests required, it would be difficult to apply automatic criteria in the interpretation of results. For general chemicals, the Group felt that expert judgement is required principally in selecting the appropriate testing strategy and in applying the data to the risk characterisation and risk management decisions.

All Groups thought it essential that expert judgement be applied according to consistent standards in a well-documented way in order to provide transparent risk assessments which can be understood and possibly used by others.

Validation

The Working Groups identified two types of validation important in risk assessment:[2]

- internal validation, i.e. checking that the scheme, and its component models, are capable of giving reproducible results when used with the same input data by different people;

[2] *The use of valid input data is also obviously important. For example, results from SAR/(Q)SAR calculations can be compared to actual test data and vice versa. The US EPA has established specific criteria for assessing the validity of toxicity tests themselves.*

- external validation, i.e. checking that the predicted effects or exposure concentrations are correct.

Internal validation can be achieved by exercises such as ring testing (round robins), checks for internal consistency, and sensitivity analyses. Sensitivity analysis can be used to indicate the principal "drivers" of a scheme. External validation can be achieved through comparing predicted with observed effects/fate/distribution by means of monitoring.

Six of the schemes reviewed in the Summary Document (in preparation) and summarised in Annex 4 attempt some form of validation: OECD aquatic general chemicals, EC existing general chemicals, USES, ECETOC, US FIFRA and EPPO.

Points from the Final Plenary Session

Three additional issues were raised and discussed briefly during the final Plenary Session: the efficient use of resources in risk assessments; the transparency of risk assessments; and risk management.

The efficient use of resources in risk assessments was seen as being very important. It was acknowledged that risk assessments can easily become so information-hungry that higher tiers become difficult and disproportionate in terms of resource use. Consequently, the need for additional tests should be carefully considered, taking into account cost-benefit and animal welfare.

With respect to transparency, participants recognised the need to make risk assessment procedures and the results derived from them more readily understood and hence more useable by those concerned with risk management/risk reduction. In addition, it was considered important not to overlook the importance of communicating the results to the public, who ultimately determine the acceptability of risks.

Finally, the Chairman mentioned the related subjects of risk-benefit and the application of cost-benefit to the results of risk assessment. These subjects were intentionally omitted from the scope of the Workshop, since they lie more within the remit of risk management than risk assessment, but it was generally acknowledged that they would receive increasing attention in future. The Workshop was informed that the UK has been doing some work on these issues and intends to develop this work further with the help of Dutch and German colleagues. The output will be a paper which could be the basis for a discussion of the subject within OECD.

Recommendations for Further Work

The recommendations for further work proposed by the Environmental Fate and Exposure, Aquatic Effects, and Terrestrial Effects Working Groups are listed in Tables 1 to 3 respectively and a number are described below. For many of the recommendations, activities are already in progress or planned either by OECD or by other international organisations and groups. These activities, where known, are also indicated in the tables.

Test Guidelines

The Workshop agreed that work is needed on the development of Test Guidelines in addition to risk assessment procedures. Recommendations on Test Guidelines work were made for aquatic and terrestrial effects, but not for environmental fate and exposure. High priority was given by the Aquatic Effects Working Group to the development of guidance on testing difficult substances (including complex mixtures) and the development of OECD Test Guidelines for assessing the effects of chemicals in sediment. The Terrestrial Effects Working Group gave high priority to the development of a set of standard terrestrial effects tests. Their proposal for this set of tests is included in the Report of the Working Group in Annex 7.

Risk Assessment Procedures

The Environmental Fate and Exposure Working Group agreed on the need for transparent exposure assessment schemes. The Group felt these could be realised through the development of a number of practical instruments such as an emission database and emission scenarios for estimating releases, guidance for determining rate constants and other parameters derived from laboratory tests for incorporation into models, and harmonized models for estimating environmental concentrations. This Group also emphasized the importance of developing guidance associated with exposure assessment; the gathering, appraisal and extrapolation of chemical and environmental data; and the use of models. It recommended that this be incorporated into existing OECD initiatives to develop guidance for risk characterisation.

Both Effects Working Groups recommended that work be carried out on extrapolation techniques and assessment factors. The Aquatic Effects Working Group felt the harmonization of assessment factors throughout OECD countries was very important, but recognised it would be very difficult to achieve. The Aquatic Effects Group also recommended that guidance be developed on the extrapolation to preparations and mixtures of data obtained for single substances. The Terrestrial Effects Working Group agreed on the need to improve extrapolation methods, including assessment factors, for the terrestrial environment and recommended a number of steps which could be taken (see Table 3).

All the Working Groups recommended the development of guidance for: (1) criteria to assess the suitability of non-standard data for use in risk characterisation; (2) the quantification and reporting of uncertainty in risk assessment; and (3) the transparent use and reporting of expert judgement.

Reporting

The Terrestrial Effects Working Group was the only group to specifically recommend work on the development of consistent transparent assessment reports, although all Groups, in their discussions, recognised the importance of fully documenting a risk characterisation.

Risk Assessors/Risk Managers

The Environmental Fate and Exposure Group recommended that a forum be established for risk assessors and risk managers, to ensure mutual understanding of their respective capabilities and needs.

Table 1. Recommendations for further work from the Environmental Fate and Exposure Working Group

Recommendations for further work	Activity ongoing in OECD or elsewhere
1. Develop transparent exposure assessment schemes through the development of the following "tools": • emission database and emission scenarios for estimating releases • harmonized models for estimating environmental concentrations (regional and global) • guidance for determining rate constants and other parameters derived from OECD tests for incorporation into models • procedures for quantifying and reporting uncertainties in exposure assessment	• OECD work on product release transfer registry (PRTR) • OECD workshops on emission factors and new developments with models under consideration • use of product registers (Nordic countries, France, Switzerland) • SETAC workshops (April and November 1994) on harmonization of environmental fate models for regulatory applications • OECD, EU working on harmonization of assessment reports
2. Develop guidance for understanding/interpretation of the use of models/risk assessment schemes	• OECD existing chemicals guidance documents • EU guidance documents for new and existing chemicals, etc.
3. Establish forum to: • provide dialogue between risk assessors and risk managers • identify and resolve practical difficulties arising from exposure assessment	• US EPA

Table 2. Recommendations for further work from the Aquatic Effects Working Group

Recommendations for further work		Activity ongoing in OECD or elsewhere
Firm recommendations:		
1.	Develop guidance on how to test "difficult substances", including complex mixtures	Canada, UK, US EPA, ECETOC, OECD, ISO, CONCAWE
2.	Develop harmonized sediment test guidelines, triggers for testing and testing strategies	OECD, US EPA, Canada, Paris Commission
3.	Develop criteria for assessing the acceptability of non-standard data for inclusion in risk characterisation	UK, EU, IPCS, UNEP/IRPTC
4.	Improve implementation of OECD Council Act on the Mutual Acceptance of Data	OECD
5.	Harmonize assessment factors and other related issues • Which approach? • Assessment factors applicable to (Q)SAR data	No known activity
6.	Develop guidance on extrapolation of data obtained on single substances (e.g. active ingredients) to preparations and mixtures	No known activity
7.	Promote use of sensitivity analysis within risk assessment	EPPO/CoE
Possibly also:		
8.	Develop guidance for long-term, micro/mesocosm and other "special" tests and extend testing strategies to include them	SETAC, US EPA and OECD for micro/mesocosms, OECD work on testing strategies planned
9.	Develop guidance on assessment of indirect effects	No known activity
10.	Develop guidance on risk assessment for intermittent exposure	May be included in EU guidance documents
11.	Develop methods to quantify uncertainty in risk assessments and to estimate probability of adverse effects occurring	No known activity
Co-ordinate with others on:		
12.	Development of guidance on the use of expert judgement	OECD, EU, ECETOC
13.	Validation of risk assessment schemes	EPPO/CoE
14.	Further development and use of (Q)SARs	EU, US EPA, OECD

Table 3. Recommendations for further work from the Terrestrial Effects Working Group

Recommendations for further work	Activity ongoing in OECD or elsewhere
General:	
1. Co-operate with other international organisations involved in development of risk assessment and test guidelines	OECD liaises with ISO, EU, EPPO/CoE, IPCS, UNEP, FAO
2. Encourage consistent transparent assessment reports and provide technical guidance to promote expert judgement	OECD, EU working on harmonization of assessment reports. Canadian/US Trade Agreement, German/US Bilateral Agreement of the Environment
Specific:	
3. Develop set of standard terrestrial effects tests	OECD, EU, EPPO/CoE, IOBC
4. Promote improvement of extrapolation methods and uncertainty analysis, including assessment factors. Could involve the following steps: • Review approaches taken in aquatic assessment and other types of risk assessment to identify suitable principles and approaches • Construct database containing relevant published toxicity data for a wide range of terrestrial species • Research project to derive new data for database using standard laboratory toxicity tests on plants and invertebrates • Establish OECD working group to evaluate and make recommendations on how extrapolations should be handled for terrestrial effects	IRPTC has database including terrestrial data OECD Discussion Paper Regarding Terrestrial Effects Assessment The US EPA Office of Research and Development has a database (ECOTOX) which includes test data.
5. Advance development of improved methods for assessing no-effect levels and other end-points (review range of parameters used as end-points and statistical methods for generating robust measures of toxicity)	OECD for statistical analysis
6. Develop better understanding of ecological significance of effects seen in the field on populations and ecosystems (organise workshop to discuss and make recommendations for further work for OECD and other bodies?)	No known activity
7. Provide criteria to judge validity of non-standard data	UK, EU, IPCS, UNEP/IRPTC

Annex 1

List of Participants

AUSTRALIA

Mr. Jack HOLLAND
Manager, Chemical Section
Commonwealth Environment
Protection Agency

BELGIUM

Mme C. VAN DER WIELEN
I.S.Se.P.
Liège

CANADA

Mr. David MCBAIN
Chief, Chemicals Evaluation Division
Commercial Chemicals Evaluation Branch
Environment Canada
Ottawa

Mr. Caje RODRIGUES
Section Head, Pesticides Division
Commercial Chemicals Evaluation Branch
Environment Canada
Ottawa

DENMARK

Mr. Henrik TYLE
Chemicals Division
Danish E.P.A.
Copenhagen

Mr. Claus HANSEN
Pesticides Division
Danish E.P.A.
Copenhagen

Mr. Finn BRO-RASMUSSEN
Danish Technical University
Lyngby

Mrs. Lise SAMSØE-PETERSEN
Danish Water Quality Institute
Hørsholm

FINLAND

Mr. Jukka MALM
Senior Officer
National Board of Waters and Environment
Helsinki

Ms. Kaija KALLIO-MANNILA
Senior Officer
National Board of Waters and Environment
Helsinki

FRANCE

Mlle Frédérique BRIENS
Ministère de l'Environnement
Direction de la Prévention de pollutions et des risques
Sous-direction des Produits et des déchets
Bureau des Substances et Préparations chimiques
Paris

Mr. Kees ROMIJN
Rhône-Poulenc Agro
Lyon

Mlle Paule VASSEUR
Laboratoire de Toxicologie
Centre des Sciences de l'Environnement
Metz

GERMANY

Mr. Gerd WELTER
Umweltbundesamt
Federal Environment Agency
Berlin

Mr. Michael HERRMANN
Umweltbundesamt
Federal Environment Agency
Berlin

Mr. Volker KOCH
Hoechst AG-UCV, D787
Frankfurt/M

ITALY

Mr. Alessandro DI DOMENICO
Istituto Superiore di Sanita
Laboratorio di Tossicologia Comparata
ed Ecotossicologia
Rome

JAPAN

Mr. Masayuki YASUNO
National Institute for Environmental Studies
Japan Environment Agency
Tsukuba

Mr. Kazumi KAWAHARA
Chemical Biotesting Center
Chemical Inspection and Testing Institute
Kurume

NETHERLANDS

Mr. Peter T.J. VAN DER ZANDT
Ministry VROM
The Hague

Ms. Trudie CROMMENTUIJN
RIVM/ACT (Toxicology Advisory Centre)
Bilthoven

Mr. Jan LINDERS
RIVM/ACT
Bilthoven

NEW ZEALAND

Ms. Sue THOMAS
Ministry of Agriculture and Fisheries
Agricultural Compounds Unit
Upper Hutt

NORWAY

Ms. Inger Grethe ENGLAND
Norwegian Pollution Control Authority
Oslo

Mr. Torsten KÄLLQVIST
Norwegian Institute of Water Research
Oslo

Ms. Heidi MORKA
National Agricultural Inspection Service
Ås

SWEDEN

Mr. Ivar LUNDBERGH
National Chemicals Inspectorate
Solna

Mr. Stefan GABRING
National Chemicals Inspectorate
Solna

Mr. Lars ANDERSON
National Chemicals Inspectorate
Solna

SWITZERLAND

Mr. Christof STUDER
Federal Office of Environment, Forests
and Landscape
Bern

Mr. A. DE MORSIER
Ciba Geigy AG
Basel

Mr. A. RIGGENBACH
Federal Research Station for Fruit Growing,
Viticulture and Horticulture,
Wädenswil

UNITED KINGDOM

Mr. Norman J. KING
(Chairman of Plenary Sessions)
Department of the Environment
London

Mr. Steve ROBERTSON
Department of the Environment
London

Mr. David BROOKE
Building Research Establishment
Environment Section
Garston, Watford

Mr. Peter CAMPBELL
Ministry of Agriculture, Fisheries and Food
Rothampsted Experimental Station
Harpenden, Herts.

Mrs. Margaret DAVIES
Department of the Environment
London

Miss Melissa THOMAS
Department of the Environment
London

UNITED STATES

Mr. Tony MACIOROWSKI
US EPA
Washington, DC

CEC

Ms. Kornelia GREIN
DG XI.A-2
Brussels
Belgium

Mr. Louis SMEETS
DG Agriculture
DG VI.BII-1
Brussels
Belgium

CZECH REPUBLIC

Ms. Eva TYLOVÁ
Department of Environmental Risks and
Monitoring
Ministry of Environment
Prague

BIAC

Mr. Hugo WAETERSCHOOT
Expert, Department Environmental Affairs
Union Minière
Belgium

Mr. Klaas H. den HAAN
Environmental Adviser
Health, Safety and Environment Division
Shell International Petroleum Maatschappij
B.V.
The Hague
Netherlands

Mr. George M. GRAY
Research Associate
Harvard Center for Risk Analysis
Harvard School for Public Health
Boston,
Massachusetts,
USA

ECETOC

Mr. John SOLBÉ
Port Sunlight Laboratory
Bebington, Wirral
UK

Mr. Tom FEIJTEL
Procter & Gamble ETC
Strombeck-Bever
Belgium

GIFAP

Mr. Johann GUTH
Staff Ecology & Public Relations
Ciba Ltd
Plant Protection Division
Product Safety
Switzerland

Mr. David RILEY
Ecology Section Manager
Zeneca Agrochemicals
Jealott's Hill Research Station
Bracknell, Berkshire
UK

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY (IPCS)

Mr. M. YOUNES
Chief, Assessment of Risk
and Methodologies
Programme for the Promotion of Chemical Safety
World Health Organization
Geneva
Switzerland

Mr. Paul HOWE
IPCS/WHO Temporary Advisor
The Institute of Terrestrial Ecology
Monks Wood
Huntingdon, Abbots Ripton
Cambridgeshire
UK

UNEP/IRPTC

Ms. Agneta SUNDÉN-BYLÉHN
IRPTC/UNEP
Geneva
Switzerland

Mr. John JACKSON
GEMS/MARC/UNEP
London

Ms. Raquel DUARTE-DAVIDSON
GEMS/MARC/UNEP
London
UK

WORLD WIDE FUND FOR NATURE (WWF)

Mr. J.M. WEEKS
c/o I.T.E., Monks Wood
Abbots Ripton
Huntingdon, Cambridge
UK

OECD CONSULTANTS

Mr. Andrew Hart
Central Science Laboratory, MAFF
Worplesdon
Guildford, Surrey
UK

Mr. Peter Smith
(Rapporteur of Plenary Sessions)
Central Science Laboratory, MAFF
Worplesdon
Guildford, Surrey
UK

ORGANISING COMMITTEE

Mr. Peter GREIG-SMITH
MAFF
Fisheries Laboratory
Lowestoft,
Suffolk,
UK

Ms. Jane HOPKINS
(Rapporteur of Plenary Sessions)
Office of Pesticide Programs (H7501-C)
US Environmental Protection Agency
Washington, DC
USA

Ms Anne BARTON
Office of Pesticide Programs (H7501-C)
US Environmental Protection Agency
Washington, D.C.
USA

Mr. Herbert KOEPP
Biologische Bundesanstalt für Land -
und Forstwirtschaft (BBA)
Braunschweig
Germany

Mr. Richard STEPHENSON
Environmental Dept.
Shell Research Ltd
Sittingbourne Research Centre
Sittingbourne, Kent
UK

Mr. Roger TREGUNNO
Department of the Environment
London
UK

Mr Cees VAN LEEUWEN
Risk Assessment and Environmental Quality
Division
Directorate-General for Environmental
Protection
Ministry of Housing, Physical Planning and
Environment
The Hague
Netherlands

Ms. Nicky GRANDY
Environmental Health and Safety Division
OECD
2, rue André-Pascal
75775 Paris Cédex 16
France
Fax: +33 1 4524 1675

Mr. Teruyoshi HAYAMIZU
Environmental Health and Safety Division
OECD
2, rue André-Pascal
75775 Paris Cédex 16
France
Fax: +33 1 4524 1675

Annex 2

Composition of the Working Groups

Environmental Fate and Exposure

Chairman
Mr. Jan LINDERS, Netherlands
Rapporteurs
Mr. Tom FEIJTEL, ECETOC
Mr. David MCBAIN, Canada

Mlle Frédérique BRIENS, France
Mr. Finn BRO-RASMUSSEN, Denmark
Mr. David BROOKE, United Kingdom
Ms. Raquel DUARTE-DAVIDSON, UNEP
Ms. Inger Grethe ENGLAND, Norway
Mr. M. GILBERT, IPCS/WHO
Mr. Johann GUTH, GIFAP
Mr. Klaas H. den HAAN, BIAC
Mr. Michael HERRMANN, Germany
Mr. Kazumi KAWAHARA, Japan
Mr. Volker KOCH, Germany
Mr. Ivar LUNDBERGH, Sweden
Mr. Louis SMEETS, CEC
Mr. Christof STUDER, Switzerland
Ms. Eva TYLOVÁ, Czech Republic

Aquatic Effects

Chairman
Mr. Herbert KOEPP, Germany
Rapporteurs
Mr. Tony MACIOROWSKI, United States
Mr. Richard STEPHENSON, GIFAP

Mr. Alessandro DI DOMENICO, Italy
Mr. Stefan GABRING, Sweden
Ms. Kornelia GREIN, CEC
Mr. John JACKSON, GEMS/MARC/UNEP
Mr. Torsten KÄLLQVIST, Norway
Mr. Jukka MALM, Finland
Mr. A. DE MORSIER, Switzerland
Mr. Steve ROBERTSON, United Kingdom
Mr.J. SOLBÉ, Unilever Research, ECETOC
Ms. Sue THOMAS, New Zealand
Mr. Henrik TYLE, Denmark
Mme. C. VAN DER WIELEN, Belgium
Mr. Peter T.J. VAN DER ZANDT, Netherlands
Mlle Paule VASSEUR, France
Mr. Hugo WAETERSCHOOT, BIAC
Mr. J.M. WEEKS, WWF
Mr. Gerd WELTER, Germany
Mr. Masayuki YASUNO, Japan

Terrestrial Effects

Chairman
Mr. Peter GREIG-SMITH, United Kingdom
Rapporteurs
Mr. Lars ANDERSON, Sweden
Mr. Kees ROMIJN, France

Mr. Peter CAMPBELL, United Kingdom
Ms. Trudie CROMMENTUIJN, Netherlands
Ms. Margaret DAVIES, United Kingdom
Mr. George M. GRAY, BIAC
Mr. Claus HANSEN, Denmark
Mr. Jack HOLLAND, Australia
Mr. Paul HOWE, IPCS/WHO
Ms. Kaija KALLIO-MANNILA, Finland
Ms. Heidi MORKA, Norway
Mr. A. RIGGENBACH, Switzerland
Mr. David RILEY, GIFAP
Mr. Caje RODRIGUES, Canada
Mr. Steve ROBERTSON, United Kingdom
Mrs. Lise SAMSØE-PETERSEN, Denmark
Ms. Agneta SUNDÉN-BYLÉHN, IRPTC/UNEP
Miss Melissa THOMAS, United Kingdom

Annex 3

Working Definitions of Key Terms for the Workshop

Preamble

There is potentially some confusion in the use of words and phrases that occur regularly in hazard/risk assessment schemes, because these technical terms do not have consistent, agreed meanings. The following working definitions were used during the Workshop and in the preparation of this report, in order to avoid misunderstandings and to clarify the concepts.

The definitions of the key terms given below may differ from those used in the Summary Document prepared for the Workshop. The reason for this is that, in the Summary Document, the terms used to describe the various assessment schemes are those which have been used in the original schemes themselves, i.e. there has not been any attempt to harmonize the terms. Therefore the following definitions should be applied with care in interpretations of the information in the Summary Document.

Definitions of Key Terms

Assessment factors are numerical adjustments that can be used as tools to extrapolate from experimentally-determined effects endpoints to estimate an environmental concern level, i.e. that concentration of a substance at and above which ecosystems could be adversely affected. They can be used to extrapolate from acute to chronic effects, from laboratory to field conditions, from a few species to many, etc. (It should be noted that concern levels are not "safe" levels. They merely indicate that further assessment or information may be required.)

Bioaccumulation/bioconcentration is the increase in concentration of a substance in or on an organism (or specified tissues thereof) relative to the concentration of the substance in the environmental media to which it is exposed.

Cut-off criteria are values indicating properties of a substance which are considered totally unacceptable and thus no further testing would take place. (Cut-off criteria can apply to properties of both fate and effects. For example, a pesticide may not be granted registration if its toxicity is greater than a specified value (e.g. 1 mg/l) regardless of the estimated exposure, or if its half-life is longer than a certain time period, or if it is likely to contaminate groundwater).

Dose-response assessment* is the estimation of the relationship between dose or concentration and the incidence and/or severity of an effect.

Effects assessment is the identification and quantification of the potential adverse effects of a substance and therefore includes **hazard identification** and **dose-response assessment.**

Exposure is the process by which an organism comes into contact with a substance resulting in a dose (the amount of a chemical either in the organism as a whole or in a target tissue). Exposure is determined by the concentration and form of a substance in the environment, coupled with the presence of the organism.

Exposure assessment* is the determination of the emissions, pathways and rates of movement of a substance in the environment, and its transformation or degradation, in order to estimate the concentrations/doses to which ecological systems and populations are or may be exposed.

Fate is the pattern of distribution of a substance in the environment, or in organisms, and its changes with time (in concentration, chemical form, etc).

Hazard identification* is the identification of the adverse effects which a substance has an inherent capacity to cause.

LOEC/Lowest Observed Effect Concentration is the lowest tested concentration of a substance at which the substance is observed to have a significant effect when compared with the control.

MATC/Maximum Allowable Toxicant Concentration is a hypothetical toxic threshold concentration lying between the LOEC and the NOEC. (It is usually calculated as the geometric mean of the LOEC and NOEC.)

MTC/Maximum Tolerable Concentration in water indicates the maximum concentration of a substance where no unacceptable adverse effects on the system are expected.

NOEC/No Observed Effect Concentration is the highest tested concentration of a substance which causes no significant effects compared with the control and is the test concentration immediately below the LOEC. It has the same meaning as the **No Observed Effect Level (NOEL)**.

PEC is the Predicted Environmental Concentration and is synonymous with the **EEC**, the Estimated Environmental Concentration.

PNEC is the Predicted No Effect Concentration.

QSARs are Quantitative Structure Activity Relationships.

Quotient method is the calculation of the ratio of an exposure parameter to a toxicity parameter or vice versa (e.g. PEC/PNEC).

Risk assessment is the determination of the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation

Risk characterisation or hazard assessment* is the estimation of the incidence and severity of the adverse effects likely to occur in an environmental compartment due to actual or predicted exposure to a substance, i.e. integration of the effects and exposure assessments.

Risk estimation* is the quantification of the likelihood (i.e. probability) that adverse effects will occur in an environmental compartment due to actual or predicted exposure to a substance.

Safety factors account for the uncertainty or variability in an estimate of a no effect level by adding an extra margin of safety and therefore differ from assessment or application factors.

SARSs are Structure Activity Relationships.

Tier testing sets out a structured approach to assessing the fate and effects of substances, where tests in higher tiers may be required depending upon the results of tests at earlier stages (i.e. lower tiers). (Under a tiered structure, for example, data requirements for effects testing might progress from acute to chronic laboratory studies to field studies.)

Triggers/trigger values are criteria applied to results from tests (for fate or effects) which would prompt further studies, e.g. moving to the next tier.

Uncertainty can result from lack of knowledge, inherent variability (stochasticity), confounding effects, or imprecise measurements. It obliges data to be interpreted as a distribution of values rather than a single value. It causes decision-makers either to consider the possibility that effects may be greater or less than predicted, or to conduct additional research and testing in order to reduce uncertainty.

Validation is the process of assessing whether the predictions or conclusions reached in a risk assessment are correct.

----

* ***These definitions are in agreement with those developed by UNEP, ILO and IPCS for use in discussions concerning an Intergovernmental Mechanism for Chemical Risk Assessment and Management at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992.***

Annex 4

Comparison of Ecological Hazard/Risk Assessment Schemes

In this Annex, a very general comparison is made between the schemes reviewed in the Summary Document prepared for the Workshop:

* OECD – Draft SIDS Manual, Provisional Guidance for the Initial Assessment of Environmental Exposure and Aquatic Effects

* OECD – Guidance Document for Aquatic Effects Assessment

* EC – Risk Assessment of Notified New Substances, Technical Guidance Document

* EC – Draft Technical Guidance on Environmental Risk Assessment of Existing Substances

* Japan – Outline of Policies for the Safety Management of Chemicals

* Japan – Pesticide Safety Evaluation

* US EPA – Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act

* US EPA – Ecological Risk Assessment under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

* Canada – Draft Guidelines for Conduction Environmental Assessments for Priority Substances under the Canadian Environmental Protection Act

* Netherlands – Uniform System for the Evaluation of Substances (USES)

* Sweden – Principles for Identifying Unacceptable Pesticides

* EPPO/CoE – Decision-Making Scheme for the Environmental Risk Assessment of Plant Protection Products

* ECETOC – Environmental Hazard Assessment of Substances

The comparison is not exhaustive; instead it is intended to deal with some of the main topics discussed at the Workshop that may be important when considering the potential for harmonization. Further, it does not attempt to judge the relative merits of different approaches; it aims simply to provide a factual comparison. Where appropriate, the possible reasons for any differences between the schemes are given.

This comparison is divided into sections broadly following the format of topics addressed by each of the Working Groups at the Workshop. Where possible, topics discussed separately by the Fate/Exposure and Effects Groups are incorporated under these general topic headings. An extra section is included at the beginning to examine the different purposes for which the schemes were developed. These schemes' intended uses will to some extent explain any differences between them, and any comparison should be made in the light of these differences.

The following areas are discussed:

a) Purpose and scope of the schemes
b) Tier testing
c) Data
d) Extrapolation
e) Uncertainty
f) Expert judgement
g) Validation
h) Summary of comparison of the schemes

a) Purpose and scope of the schemes

The purpose and use of the schemes differs widely (see Summary Table 1). Six are intended predominantly for registration, two for notification, two for priority-setting, one for making decisions on the need for risk reduction, one for establishing sound principles based on empirical assessment of existing published data (ECETOC), and one for a specific national legislative purpose (Canada).

One scheme deals only with effects data (OECD Aquatic scheme), one deals solely with human health and safety (Japanese General Chemicals), and one deals mainly with human health and safety (Japanese Agricultural Chemicals).

It is clear that the schemes were designed to answer a variety of very different questions, and that the legislative framework within which the schemes were developed and are used has had a significant effect on them. As will be seen in the following sections, variations due to the different purposes of the schemes are greater than those resulting from whether the schemes assess general chemicals or pesticides.

b) Tier testing

A tiered approach is generally used. In nine of the thirteen schemes, tiering is explicit (see Summary Table 3).

Of the four schemes that are not overtly tiered, one, the OECD SIDS scheme, is intended for priority setting for further activity and, in this sense, the entire scheme may be viewed as the first tier of a more comprehensive risk assessment.

Another scheme which is not overtly tiered is the Canadian Existing General Chemicals Scheme. This reflects the different purpose of the scheme. Under the Canadian Environmental Protection Act (CEPA) of 1988, any substance on the CEPA Priority

Substances List has to be assessed and a decision must be made as to whether or not that substance is toxic, as defined by the act. In order to reach this decision, a weight of evidence approach is used, drawing on as many sources of data as possible. For this reason, all data are considered concurrently.

The other two schemes that are not overtly tiered are the Japanese General Chemicals and Agricultural Chemicals Schemes. In practice, however, some tiering of data requirements does occur in these schemes.

Some form of tiering, then, is present in all but one of the schemes. This reflects the efficiency of tiered systems. In tiered systems, further data is required only when shown to be necessary by analysis of data collected at lower tiers. For most purposes, tiering has been adopted as a means of efficiently establishing well-targeted data requirements, which in turn serves to minimise costs and animal suffering.

The comparison of Predicted Environmental Concentration (PEC) with the Predicted No Effect Concentration (PNEC) is the most commonly used trigger to move between tiers and is a key measure of risk (see Summary Tables 4, part 2 and 6).

Of the eleven schemes which consider both exposure and effects, all except the two Japanese schemes explicitly use exposure : toxicity ratios as an index of risk. Of the nine that use exposure : toxicity ratios, eight use PEC/PNEC ratio or a similar measure. The EPPO/CoE Pesticides scheme uses a variety of measures (including PEC/PNEC) but, like PEC/PNEC, all are exposure : toxicity ratios. In the majority of schemes, exposure : toxicity ratios are not only used to move between tiers in tiered schemes, but can also be used in final risk classification in combination with other factors such as significant effects in field trials.

The OECD Aquatic scheme considers effects only, but is balanced by another document on exposure to provide an exposure : effects ratio.

The use and choice of cut-off values varies a great deal between schemes (see Summary Table 3). Cut-off criteria range from those based on mobility (Swedish Pesticides), bioaccumulation potential (Swedish Pesticides) and persistence (Swedish Pesticides, Japanese Agricultural Chemicals) to those based on acute toxicity (US Pesticides). The cut-off thresholds vary between different schemes.

c) Data

The use of some kind of acute and chronic toxicity measure is common to all schemes (see Summary Table 4, part 2). All use LD50 or L(E)C50 measures of acute toxicity (mortality), and the majority also use NOECs. Effects assessment is similar for general chemicals and pesticides schemes.

The main difference between general chemicals and pesticides schemes is in the estimation of emissions/releases, and of fate and distribution. Pesticides are applied deliberately in specific locations at specific times, whereas most general chemicals may be released from many point or diffuse sources at many different stages during the life-cycle of the chemical. A further difference occurs among general chemicals schemes since monitoring data may be available for existing chemicals whilst for new chemicals, emissions can be estimated only from release scenarios and use patterns.[1]

Consequently, for pesticides, environmental fate and distribution are measured or calculated at a very local scale, and high quality data (a known quantity applied) are usually available to make a reliable estimate. For existing general chemicals, however, monitoring data are more frequently used alongside local and regional fate/distribution models, whilst, only modelled estimates are possible for new general chemicals.

Consideration is given to multiple exposures (continuous release is considered one case of multiple exposure for the purposes of this comparison) in twelve of the thirteen schemes, though this is not always explicitly stated (see Summary Table 2). Multiple exposures are considered routinely by most of the general chemicals schemes, since emission/release scenarios often incorporate continuous release for many categories of chemicals (e.g. OECD, EC, US schemes, ECETOC, USES, Canadian scheme). Among the pesticides schemes, however, where release is usually at a specific time in a specific location, multiple exposures need to be considered explicitly.

Breakdown products of the chemicals examined are considered in nine of the thirteen schemes. The OECD schemes, the ECETOC scheme and the Japanese Agricultural Chemicals schemes do not explicitly mention the consideration of breakdown products. Among the schemes that do consider breakdown products, few (e.g. the Swedish Pesticides scheme, the EPPO/CoE Pesticides scheme) explicitly state the requirement at some stage to examine breakdown products.

Virtually all schemes recommend that priority be given to data from tests performed to Good Laboratory Practice (GLP) standards (see Summary Table 4, part 1). Only the ECETOC scheme does not provide guidance on the use of quality assurance schemes, but it recognises that data quality is important. Most schemes do consider other data, and many recommend that expert judgement be used to assess the suitability of non-standard data.

Ten of the thirteen schemes recommend the use of standard tests conforming to guidelines produced by one or more of OECD, EC, EPA, ASTM. The choice of the various preferred test guidelines, however, differs between schemes (see Summary Table 4, part 1). Eight prefer OECD guidelines among others, whilst five specify EC guidelines, five specify EPA test guidelines, and one specifies ASTM guidelines. Wherever EC guidelines are specified, OECD guidelines, are given as an alternative. The EC has in the main adopted OECD guidelines and there is little difference between the two. The choice of preferred guidelines reflects to some extent the country/region of origin of the scheme.

Of the three schemes that do not specify standard tests, neither the ECETOC not Canadian Existing General Chemicals schemes specifies guidelines since they are intended for use with all available data; the Japanese Agricultural Chemicals scheme makes no reference to standard tests.

Laboratory studies provide an important and cost-effective source of data and play a central role in the hazard/risk assessment process. All schemes attempt to assess

[1] *During the review of this report by Workshop participants, it was pointed out that, in practice, a risk assessment for a new chemical is often made by comparison with an existing chemical with similar characteristics and use pattern.*

environmental hazard/risk in the field, but they all rely to a large extent on laboratory studies. Laboratory tests are used to obtain effects data (e.g. lethal and non-lethal toxic effects; all schemes) and to provide data used in fate and distribution models (e.g. the properties of the substance; all except the OECD effects-only scheme).

Field studies are considered important in all schemes, but these data are not required by any of the schemes until the last tier (e.g. US Pesticides scheme, EPPO/CoE, ECETOC). Monitoring/residue data are also considered important (except for new chemicals schemes where such data do not exist), but for the majority of substances such data are not available (existing chemicals in Japan are an exception), and fate/distribution has to be modelled using laboratory data. One scheme uses only laboratory data (USES) because it covers preliminary/refined and not the comprehensive stage of risk assessment.

The range of chosen test species varies from few to many (see Summary Table 4, part 2), and the actual chosen test species also varies widely between schemes.

Most schemes request data from at least an aquatic "green" algal plant, a Daphnid and a fish (e.g. OECD SIDS scheme, EC new and existing chemicals schemes, ECETOC scheme), but others require many more test species (e.g. EPPO/CoE, US Pesticides scheme). Furthermore, the preferred test species often differ between schemes (e.g. the preferred fish species differ between the United States, Europe and Japan).

The range and choice of test species represent the different species present, and their differing ecological/economic importance, within different OECD countries (e.g. silkworms are considered only by the Japanese Agricultural Chemical scheme). For an initial assessment, standard species from set taxonomic groups from different trophic levels are used, but for more refined assessments, different, more representative species may be needed for a particular area.

The use of mortality as an endpoint is common to all schemes examining effects, but the schemes differ widely in the range of non-lethal endpoints that are suggested and recognised (see Summary Table 4, part 2). The use of biochemical, behavioural, reproductive and growth-rate effects endpoints varies between schemes. For example, all US, EC and OECD schemes, and the ECETOC scheme, use growth and reproduction as non-lethal effects endpoints but do not use changes in behaviour or biochemistry, whereas the EPPO/CoE scheme also explicitly considers behavioural and biochemical effects. Schemes also use different measures and interpretations of significant effects on growth and reproduction. For example, the EC new and existing general chemicals schemes specify a range of reproductive and growth tests that differ from those specified in the US Pesticides scheme.

d) Extrapolation

Extrapolation is an intrinsic feature of environmental risk assessment and is consequently found in many forms in all schemes (see Summary Table 5). Laboratory measures of toxicity on a single species are extrapolated, not only to the field but also across species (to other related species; all schemes), from acute to chronic toxicity (i.e. from short-term toxicity data to long-term risk; all schemes) and often from lethal to sublethal toxicity (i.e. extrapolation of lethal toxicity measures to Predicted No Effect Concentrations [PNECs]; five of the twelve schemes for which there are details). Extrapolation from laboratory data to real situations is common to all schemes for which there are details (see Summary Tables 1 and 1 and 5).

For fate/distribution estimation, extensive extrapolation also occurs. Local PECs are often extrapolated to regional PECs (seven of the twelve schemes for which there are details) and there is also some extrapolation of initial PECs across time to PECs some time after emission/release (assumptions within the individual schemes, e.g. US General Chemicals Scheme, EPPO/CoE).

Many schemes use application/assessment/safety factors in the process of extrapolation. Their use varies a great deal between schemes (see Summary Table 5). Some assessment factors are broadly similar across schemes. For example, factors applied to acute toxicity measures are broadly similar across schemes. A factor of 1000 is generally applied to a single-species acute toxicity measure (where only one is available, or the lowest of three; e.g. EC, US, OECD schemes and USES). A factor of 100 is often applied if acute toxicity data are available for three species (e.g. US and OECD schemes, USES; not EC schemes) and a factor of 10 is often used for NOECs from at least three species (EC, OECD schemes and USES; not US schemes). Other assessment factors, however, differ considerably between schemes. For example, factors applied to various chronic toxicity measures and to NOECs differ, e.g. EC schemes apply a factor of 50 if only two NOECs are available, but the US General Chemicals scheme uses a factor of ten for any available chronic toxicity data. Another scheme (ECETOC) applies empirically derived assessment factors that differ from those used in all other schemes.

e) Uncertainty

Worst-case assumptions are the most commonly used method of dealing with uncertainty (see Summary Table 4, part 1).

Ten of the thirteen schemes use worst-case assumptions/scenarios as a tool for dealing with uncertainty. In most cases other methods are used as well, including statistical procedures (such as the HC_5 method aimed at providing protection for 95 per cent of species in an ecosystem), iterative assessment (i.e. conducting a preliminary risk assessment with a high degree of uncertainty and then refining the exposure or toxicity measure with more realistic data), and assessment factors (see previous section). Of the three that differ, two, the Japanese schemes, provide no details of the use of worst-case assumptions and the other, the Swedish scheme, uses only cut-off values based on the intrinsic properties of a substance. In the Swedish scheme, "unacceptability" is in itself a worst-case assumption since a chemical determined as having certain properties can be designated as unacceptable if there is any possibility of exposure.

f) Expert judgement

In all but one of the schemes, scope is provided for the use of expert judgement (see Summary Table 3), and in many its importance is stressed. The only scheme not explicitly providing for expert judgement is the Swedish Pesticides scheme. This reflects the different purpose of the Swedish scheme, since it is used for identifying unacceptable chemicals before a full risk assessment is conducted. Expert judgement may be used for a variety of reasons, for example to assess the suitability of data or to make specific decisions within the scheme such as on the likelihood of exposure of an organism to a particular chemical. The provision for expert judgement in nearly all of the schemes reflects a general recognition of the complexity of the issues involved in environmental hazard/risk assessment.

g) Validation

Many forms of validation are attempted within the schemes. Some schemes use a range of chemicals for which there is much empirical data to check that the scheme is producing reasonable risk assessment decisions (e.g. USES, ECETOC). For such schemes, details of a validation exercise usually form part of the scheme's documentation. Some schemes examine individual risk assessment decisions against other sources of data such as monitoring, poisoning incidents, long-term field experiments, etc. (e.g. US FIFRA, EPPO/CoE). Others examine the scheme itself by comparing its performance with regulatory decisions that have already been made (e.g. EPPO/CoE). Six of the twelve schemes for which there are details attempt some form of validation (see Summary Table 3).

Some of the schemes include explicit provisions for modification in the light of new or future developments, whereas others do not (see Summary Table 3). Of those that do provide scope for modification, some allow for extra compartments to be added at a later date (e.g. EPPO/CoE and ECETOC anticipate the addition of air compartments, and the US General Chemicals Scheme anticipates the addition of ecosystem tests) and others allow for new test guidelines to be incorporated (e.g. US, EC and OECD schemes and USES). Others, such as the EPPO/CoE, recognise that the science underpinning the risk assessment schemes may require more extensive revision in future.

Whilst modification to include new developments in a rapidly evolving area of science is desirable, it is possible that such modification will lead to further divergence of the schemes in the future. For this reason, it would be desirable for the purposes of harmonization for such changes to be incorporated in a co-ordinated way whenever possible.

h) Summary of comparison of the schemes

The schemes reviewed in this document were designed to answer a variety of very different questions, and were developed within diverse legislative frameworks. This has had a significant effect on them. Variations due to the different uses of the schemes are greater than those resulting from whether the schemes assess general chemicals or pesticides. Some of the schemes include scope for future modifications. It is important that such modifications are incorporated in a co-ordinated way to avoid further divergence of the schemes.

Most schemes are tiered. This reflects the efficiency of tiered systems. For most purposes, tiering has been adopted as a means of efficiently establishing well-targeted data requirements. In the majority of schemes, exposure : toxicity ratios are not only used as triggers to move between tiers but can also be used in final risk classification in combination with other factors such as significant effects in field trials.

There is far less variation between schemes in the way that effects are measured compared to the way exposure is measured/estimated. Effects assessments are similar for general chemicals and pesticides schemes. The main difference lies in the estimation of emissions/releases, and fate and distribution. Another difference between pesticides and general chemicals schemes relates to the scale at which risk is assessed. For pesticides schemes, risk is assessed on a very local scale (i.e. at the field level) whereas, for general chemicals, risk may be assessed either at point sources or, more commonly, at larger local or regional scales. A further difference occurs among general chemicals schemes since, for existing chemicals, monitoring data may be available, whilst for new chemicals emissions can be estimated only from release scenarios and use patterns.

Virtually all schemes recommend that priority be given to data from tests performed to Good Laboratory Practice (GLP) standards, and most schemes recommend the use of standard tests and guidelines. Extrapolation from simple data to complex situations is intrinsic in hazard/risk assessment and is included in all of the schemes. Worst-case assumptions are the most commonly used method of dealing with uncertainty. In all but one of the schemes, scope is provided for the use of expert judgement, reflecting a general recognition of the complexity of the issues involved in environmental hazard/risk assessment.

Differences in the thresholds for various risk criteria appear, to some extent, to reflect the different purposes of the various schemes. Some schemes attempt to determine high, medium and low risk, whilst others categorise risk according to closely-defined scheme-specific criteria (e.g. an "unacceptable" pesticide in the Swedish scheme, a "toxic" substance in the Canadian scheme).

Some of the differences in cut-offs, risk criteria, and application factors reflect differences in the political, economic and ecological circumstances in the different countries in which the schemes were developed and are applied. Others arise from technical differences of opinion. Whilst it is important for local differences to be reflected by the various schemes, it may be possible to harmonize the choice of cut-offs, risk criteria and application factors, and to reflect local considerations in the risk management decision based on the measure of risk, rather than in the measure of risk itself.

Summary Table 1: Overview of Intended Use of the Schemes

Scheme/ Question	OECD-SIDS General Chemicals	OECD-Aquatic General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
What type of chemical will be analysed in the scheme?	High Production Volume existing general chemicals	New & existing general chemicals	New general chemicals	Existing general chemicals	New & existing chemicals	New & existing general chemicals	Existing general chemicals	New & existing general chemicals, pesticides & biocides	New & existing general chemicals, pesticides & biocides	Pesticides	Pesticides	Pesticides	Pesticides
To what regulatory decision will the results be applied?	Priority setting for further activity	Priority setting & setting of environmental quality objectives	Notification	Decisions on need for risk reduction	Registration	Pre-notification	To designate a toxic under CEPA & for setting priorities	Priority setting & registration (for use by EU Member States)	No details	Registration & labelling	Registration	Registration	Registration
To which legislation does the scheme apply (e.g. within the EU, the US, OECD-wide)?	OECD Council Decision [C(90)163(Final)]	No details	Directive 93/32/EEC Directive 93/67/EEC	EC Regulation 793:93 Regulation 1488/94	Chemical Substances Control Law, Japan	US Toxic Substances Control Act (TSCA)	Priority Substances List of the Canadian Environment Protection Act CEPA	EC Regulation 763/93, Directives 67/548/EEC, 91/414/EEC, 93/67/EEC, & two Acts from the Netherlands	7th Amendment of EU Directive 67/548/ EEC in 1992.	Agricultural Chemicals Regulation Law of Japan	Swedish Ordinance (1985:836) on Pesticides	US Federal Insecticide, Fungicide & Rodenticide Act (FIFRA)	To influence implementa-tion of EU 91/414/EEC
What is the scheme intended to assess (e.g. risk to individuals etc)?	Risk to individuals, populations & ecosystems; mainly ecosystems	Risk to individuals, populations & ecosystems; mainly ecosystems	Risk to communities & ecosystems	Risk to communities & ecosystems	Potential to cause pollution that may affect human health	Risk to individuals, populations & ecosystems	Risk to population, community and ecosystem	Risk to populations and ecosystems	To protect populations, communities and ecosystems	Mainly human health but also environmental safety	Unaccept-ability of chemicals	Risk to species and populations	Risk to individual, population, community & ecosystem
Intended for initial or comprehensive risk assessment?	Initial	Initial, refined and comprehensive	Comprehensive for all 3 compartments & secondary poisoning	Comprehensive for all 3 compartments & secondary poisoning	Initial for designated chemicals, comprehen-sive for specified chemicals	Initial, refined & comprehensive	Comprehensive	Initial and refined; NOT comprehensive	Initial, refined and comprehen-sive	No details	Initial screening	Initial, refined & comprehen-sive	Initial, refined & comprehen-sive
Predictive or retrospective?	Predictive & retrospective	Predictive	Predictive	Predictive & retrospective	Predictive & retrospective	Predictive (mostly)	Retrospective & predictive	Predictive & retrospective	Predictive & retrospective	Predictive & retrospective	Predictive & retrospective	Predictive & retrospective	Predictive & retrospective

Summary Table 2: Overview of Scope of the Schemes

Scheme/Question	OECD-SIDS General Chemicals	OECD-Aquatic General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
Exposure and effects considered separately/ together?	Separately but combined to assess risk	Effects assessment only	Separately but combined to assess risk	Separately but combined to assess risk	Physical and chemical properties only	Separately but combined to assess risk	Separately but combined to assess risk	Separately but combined to assess risk	Separately but combined to assess risk	Exposure considered but effects assessment unclear	Mainly fate & distribution; little on effects	Separately but combined to assess risk	Separately but combined to assess risk
What are the compartments of concern addressed by the scheme?	Aquatic only	Aquatic only	Aquatic (mainly) but also soil & air, and terrestrial via secondary poisoning	Aquatic (mainly) but also soil & air, and terrestrial via secondary poisoning	Not specified – at least aquatic	Aquatic (mainly) but also terrestrial	Air, soil, water, sediment (global warming & ozone depletion in section 11b)	Aquatic, terrestrial and air	Aquatic only	Aquatic, marine and terrestrial	Aquatic, soil, terrestrial, ground and surface water	Aquatic, estuarine, marine, terrestrial (and surface water and terrestrial residues)	Aquatic, soil, terrestrial, ground and surface water
What are the temporal and spatial scales considered?	Local, regional, national and global	No spatial details; temporal: months and years	Local and regional	Local, regional and continental	National scale for human health	Local and regional; 1 year for new chemicals	Local and regional & global	Local and regional (mainly); continental also. Temporal: days to years	Local and regional	No details	Local only; temporal: months to years	Local and regional; temporal: immediate, and months to years	Local (mostly), regional and national also
Are multiple exposures considered?	Yes	Yes	Yes	Yes	Implicitly	Yes	Yes	Yes	Yes	Yes	Implicitly	Yes	Yes
Are breakdown products considered?	No	No	Yes	Yes	Yes	If known, yes	Yes, their dispersal	Yes	No	No	Yes	Yes	Yes

Summary Table 3: Overview of Strategies for Assessing Hazards and Risks

Scheme/ Question	OECD-SIDS General Chemicals	OECD-Aquatic General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
Tiered approach?	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Are the assessments qualitative or quantitative?	Quantitative	Quantitative	Quantitative (or qualitative if not possible)	Quantitative (or qualitative if not possible)	Qualitative	Quantitative	Quantitative & qualitative	Quantitative	Quantitative	Qualitative	Qualitative	Quantitative	Quantitative
Presumption of hazard or no hazard?	Neither	Neither	Neither	Neither	Neither	Neither	Neither	Neither	Neither	Neither	Presumption of hazard	Neither	Neither (except for honeybees: hazard)
Expert judgement required?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Implicit	Yes	Yes
External validation	No	Yes (internal)	No	Yes	No	No	No details	Yes (internal)	Yes (internal)	No	No	Yes	Yes
Is there scope for modification?	Yes, in line with new guidelines	No details	Technical guidance subject to review	Technical guidance subject to review	No	Yes, to incorporate new tests	Complete flexibility	Yes	Yes, the addition of extra compartments	No	No	Yes	Yes
Internal consistency between compartments?	One compartment only	One compartment only	Yes, but air only qualitatively	Yes, but air only qualitatively	No details	Yes, all compartments are 4-tiered	Yes, all compartments use same method to assess risk	Yes, all compartments use same method to assess risk	One compartment only	No details	No details	Yes, all compartments use same method to assess risk	Broadly yes, but many details differ
Approach to ensure environmental protection? Most sensitive species or other?	HC5 statistical approach or the most sensitive species method	HC5 (and other) statistical approaches, also most sensitive species method	Most sensitive species method	Most sensitive species method	No details	Most sensitive species method	Most sensitive species method (other approaches currently being examined)	HC5 statistical approach or the most sensitive species method	Empirically derived application factors from a statistical approach	No details	Most sensitive relevant nontarget species	Range of specified species or the most sensitive species method	Range of species in some parts: most sensitive species method in others
Are there cutoff criteria (i.e. those used to exit from scheme)?	No	No	Classification as "Dangerous to the environment" used as entry	No	Yes, for biodegrad-ability, bioaccum-ulation, and chronic toxicity	No	No	No	No	Yes, persistence & toxicity cutoff values are used	Yes	Yes (on the basis of toxicity)	No

Summary Table 4: Overview of Methods for Gathering Information – Part 1

Scheme/Question	OECD-SIDS. General Chemicals	OECD-Aquatic. General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan-General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
Are the tests used closely prescribed?	OECD guidelines to be followed	OECD, EC, EPA, ASTM guidelines followed	EC and OECD guidelines followed	EC and OECD guidelines; other data considred	OECD guidelines to be followed	EPA test guidelines followed	No	EC & OECD guidelines followed, other data considered	No	No	OECD or EPA guidelines recommended	EPA Guidelines & Standard Evaluation Procedures.	OECD, EC, EPA guidelines; others examined
Quality assurance?	GLP	GLP	GLP	GLP (preferred)	OECD-GLP	GLP	Only if available	GLP	No guidelines	GLP	GLP	GLP	GLP
How is uncertainty dealt with (e.g. confidence limits, sensitivity analysis)?	Iterative approach and worst-case assumptions	Worst-case assumptions used in places	Iterative approach. Worst-case assumptions and statistical methods	Iterative approach & worst-case assumptions; statistical methods considered	No details	Worst-case data and assumptions and assessment factors	Worst-case scenarios and uncertainty factors	Realistic worst-case scenarios used and uncertainty analysis included	Iterative approach, worst-case assumptions and a sensitivity analysis	No details	Cut-off values are set to minimise uncertainty	Realistic worst-case assumptions and worst-case data	Iterative approach, worst-case assumptions and data used
Does the scheme use model, experimental, monitoring data?	Laboratory and modelled data	Laboratory, modelled and field data	Laboratory and field data and models	Laboratory field and monitoring data and models	Physical and chemical properties only	Data and models	Laboratory field and monitoring data and models	Starting point is data; then models are used	Data and models	Field and laboratory data	Laboratory, field and monitoring data & models	Laboratory, field and monitoring data & models	Laboratory, field and monitoring data & models
How are emissions estimated?	Estimated from use categories and emission factors	Not estimated, effects only	Emission scenarios over lifecycle of the chemical with release fractions	Emission scenarios over lifecycle of the chemical with release fractions	No details	From all potential points, quantities and durations, life-cycle assessment	Any means available to prove entry; direct measurement & emission factors	From emission scenarios over life cycle, and volumes and properties of the substance	From use categories and emission scenarios	No details	Local pesticide applications & use and properties data	Local pesticide applications and use and properties data	Local pesticide applications and use and properties data
What type of PECs are estimated (e.g. for soil,water, sediment, biota)?	Water, air and soil	Not estimated, effects only	Aquatic and soil (& PEC oral for secondary poisoning)	Aquatic soil, air, sediment, & PEC oral for secondary poisoning, WWTP conc.	Aquatic (measured)	Aquatic (sediment & soil as needed)	Biota, soil, air, water & sediment (& upper atmosphere under section 11b)	Water, fish, soil, sewage, air and earthworms	Aquatic and soil	Water, soil and crops	Soil and biota	Soil, ground & surface water, crops, fish and nontarget aquatics	Soil, sediment, plants, water, insects, earthworm & vertebrates
Types of fate models used (local, regional etc)	Local and regional multimedia	None, effects only	Local & regional multimedia	Local, regional and continental multimedia	No details	Local and regional multimedia system models	Local and regional multimedia	Many multimedia, local regional models	Local and regional multimedia	No details	Simple, process oriented fate models	Local and regional multimedia	Local and regional multimedia

Summary Table 4: Overview of Methods for Gathering Information – Part 2

Scheme/ Question	OECD-SIDS General Chemicals	OECD Aquatic General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
Different routes of exposure considered? (Add all, one only?)	No details	Limited number of potential routes	Different routes are considered	Different routes are considered	No details	Yes, when needed	Primary route considered	Many potential routes considered; all added.	Many considered and summated	No details	Only main considered though others recognised	Main considered and others recognised	All considered and added; primary route recognised
Data required for limited or broad range of taxonomic groups/ species?	Algae, fish and Daphnid	Fish, Daphnid, algae, (mammals & birds for secondary poisoning)	Fish, algae Daphnid, plants, earthworms	Fish, algae Daphnid, plants, earthworms, vertebrates and soil organisms	No details	Algae, Daphnid, fish, rodent plant early growth data, and, earthworm and soil microbial toxicity	No rigid requirements	Fish, algae, Daphnid, microbes, earthworms, mammals and birds.	Fish, algae and Daphnid (will accept any aquatic species)	Fish, silkworm, bees, pest natural enemies and wild birds	All data required for pesticide registration)	Birds, amphibia, fish, mammals, plants, and aquatic and terrestrial invertebrates	Birds, mammals, fish, aquatic invertebrates, plants, soil arthropods, soil microbes & earthworms
What are the measured and predicted effects endpoints (e.g. mortality, sublethal effects, biochem., physiology)?	Estimated: maximum tolerable concentration for the ecosystem. Measured: mortality and sublethal effects	Mortality, growth, reproduction and biochemical effects	Mortality, growth, reproduction, absence of effects, and other sublethal effects; bioaccumulation	Mortality, growth, reproduction, absence of effects, and other sublethal effects; bioaccumulation	Human health and pollution only	Mortality, growth, reproduction and bioaccumulation potential	Individual mortality, growth, reproduction, population growth, ecosystem structure and nutrient cycling	Mortality, growth, reproduction sublethal effects, and fate/ degradabilty and bio-accumulation	Mortality, absence of sublethal effects	No details	Bio-accumulation potential, mobility and bio-degradability; toxicity also	Mortality, growth and development, reproduction and bio-concentration	Mortality, reproduction, behaviour, sublethal, population effects, bio-accumulation & environmental fate alone
What are the triggers to move from tier to tier?	MTC/PEC compared; consider further testing	Presence of better data	PEC/PNEC > 1 then refine either PEC or PNEC with more information including further testing or risk reduction	PEC/PNEC > 1 then refine either PEC or PNEC with more information including further testing or risk reduction	None	Toxicity only, PEC higher than concern level, significant field effects, bioaccumulation	None	Production volume and if PEC/NEC > 1 then it is refined	PEC/PNEC > 1 then refine either PEC or PNEC at the next tier	None	Cut-off values trigger the assessment of properties; if not unacceptable then full risk assessment done	EEC compared to a toxicity criterion (an effects measure)	Potential exposure is used but the ultimate triggers are exposure/effects ratios

Summary Table 5: Overview of Extrapolation in the Schemes

Scheme/ Question	OECD-SIDS General Chemicals	OECD-Aquatic General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
What types of extrapolation are used (e.g. from acute to chronic, lab. to field, few to many species, temporal & spatial scales, typical to worst-case)?	Local to regional; individual to ecosystem; laboratory to real; acute to chronic; few to many species; and across species	Individual to ecosystem; laboratory to real; acute to chronic; few to many species; across species; short- to long-term toxicity; and lethal to sublethal	Local to regional; laboratory to real; acute to chronic; few to many species; across species; short to long-term toxicity; and from lethal to sublethal	Local to regional; laboratory to real; acute to chronic; few to many species; across species; short- to long-term toxicity; and from lethal to sublethal	No details	Local to regional; individual to population; laboratory to real; acute to chronic; few to many species; across species; and across time	Individual to ecosystem; laboratory to real; acute to chronic; few to many species; across species; and short- to long-term toxicity	Local to regional; individual to population; laboratory to real; acute to chronic; few to many species; across species; and from lethal to sublethal	Local to regional; individual to population; laboratory to real; acute to chronic; few to many species; and across species	Laboratory to real; from few to many species; and across species	Laboratory to real; from few to many species; and across species	Local to regional; laboratory to real; acute to chronic; few to many species; across species; lethal to sublethal; and across taxa	Individual to population; laboratory to real; acute to chronic; few to many species; across species; from typical to worst-case; across time
Does the scheme apply assessment factors and how are they determined?	Ranging from 1000 for acute tests to 10 for NOECs with at least 3 species	Ranging from 1000 for acute tests to 10 for NOECs with at least 3 species; different sets of factors given for aquatic lives and for fish-eating vertebrates	Ranging from 1000 if only base set L(E)C50 data available to 10 for the lowest NOEC if there is no bioaccumulation; factors from 10 to 100 used for vertebrate secondary poisoning assessment	Ranging from 1000 if only base set L(E)C50 data available to 10 for the lowest NOEC; factors from 10 to 100 used for vertebrate secondary poisoning assessment	No details	Ranging from 1000 for single acute value (SAR is treated the same as test data) to 1 for field tests; extra safety factors for endangered species	Multiplication safety factors ranging from 0.01 to 0.1; many may be applied to the same data for different reasons	Ranging from 1000 to 1 depending on data; 3 different sets of factors are given, may also use EC-New General Chemicals Safety Factors	Empirically determined from toxicity studies using a range of general and agricultural chemicals	Human safety factors only	None	Factors range from 5 to 20 depending on restricted use or endangered species considerations	Many examples, e.g. earthworm; factor of 10 for species differences and 10 for the difference between lethal and safe levels, giving an overall factor of 100

Summary Table 6: Overview of Interpretation in the Schemes

Scheme/Question	OECD-SIDS. General Chemicals	OECD-Aquatic. General Chemicals	EC-New General Chemicals	EC-Exist General Chemicals	Japan General Chemicals	US-TSCA General Chemicals	Canada Existing General Chemicals	USES Pesticides & General Chemicals	ECETOC Pesticides & General Chemicals	Japan Pesticides	Sweden Pesticides	US-FIFRA Pesticides	EPPO Pesticides
What are the criteria used to identify the severity of risk and how are these derived? If cutoff values are applied, what are they?	Risk is determined by comparison of PEC with a "low risk level of the chemical"	Effects only are assessed	Risk is determined by comparing PEC with PNEC. Values over 1 show extra data are required or the risk needs to be reduced	Risk is determined by comparing PEC with PNEC. Values over 1 show extra data are required or the risk needs to be reduced	Chemicals are placed in 1 of 2 categories, "specified" or "designated"	Risk is determined by a quotient method whereby a PEC is compared with a "concern concentration"	Risk is determined by comparing an environmental concentration with an "estimated effects threshold"	Risk is determined by comparing PEC with NEC and a probabilty function is included. Upper and lower limits of risk are defined	Chemicals are designated as "hazard" or "no hazard" on the basis of an exposure/ effects comparison	Risk is classified into 4 categories on the basis of toxicity and use	Risk is classified on the basis of mobility, bio-degradability and bio-accumulation potential	Risk is determined by a quotient method whereby a PEC is compared with a "toxicological level of concern"	Risk is determined by means of exposure/ effects ratio though bio-accumulation potential is also used to define risk
Integration of different risks?	One compart-ment only	Effects and one compartment only	No details	No details	No details	No details	According to CEPAs	No integration	One compartment only	No details	No details	No details	Some guidance (a chapter)
Are chemicals assessed in isolation or compared to others?	In isolation	In isolation but data from other chemicals are used for QSARs	Structurally analogous chemicals may be considered, QSARS	Structurally analogous chemicals may be considered, QSARs	No details	In isolation but data from other chemicals are used for SARs	In isolation (though it may be part of a mixture or a broad group)	In isolation, though different chemicals may be ranked	Limited ranking against other chemicals possible	In isolation	Compared to other chemicals; use safer if available	In isolation but compared to alternatives for decision making	In isolation except one use of a toxic standard
Are differences in priority and perception accomodated?	Locally relevant models are used when available	No details	Different regional/ climatic factors & minimise vertebrate testing	Different regional/ climatic factors & minimise vertebrate testing	No details	Extra assessment factors are used for endangered species	Endangered species and parks are given special consideration	Different default values can be entered for different countries	Few examples only	No details	No details	Extra safety factors are used for endangered species	Local differences in agricultral practice, climate, etc. are given
How are the results used alongside other information such as human health and economics?	No details	No details	Environmental protection has equal status with human health	Environmental protection has equal status with human health	Human safety only	Economic factors are considered and environmental protection has equal status with human health	Under the CEPA, a chemical harmful either to health or the environment is classed as "toxic"	Human health and other factors are mentioned but details of how these factors are weighed are not given	No details	The scheme is mainly concerned with human safety	Assessed alongside human health and user safety	Risk is weighed against benefit	Some guidance (one chapter is provided)

Annex 5

Report of the Working Group on Environmental Fate and Exposure

Chairman: Jan Linders, RIVM/ACT, the Netherlands
Rapporteurs: Tom Feijtel, ECETOC and David McBain, Environment Canada

Introduction

In addition to the objectives identified by the Steering Committee, members of the Working Group suggested that guidance derived from the deliberations should provide advice to countries, including developing countries, who may not have risk characterisation and assessment expertise and schemes such as those reviewed in the Summary Document.

Discussion Topics

Tiered Assessment

In reviewing the application of tiered approaches to data gathering and decision making, the Working Group agreed that most schemes use a step-wise or tiered approach as well as an iterative approach primarily to reduce uncertainty in estimates. The Working Group did not feel it was possible to specify the number of tiers that would be generally applicable or necessary to evaluate exposure to new and existing substances and to pesticides. The iterative approach to assessing exposure scenarios for pesticides was cited as an example of a case where many iterations may be necessary. The reasoning behind the Working Group's position reflects the difficulty in anticipating the availability of relevant data required at each stage of the assessment scheme.

The tiered approaches discussed by the Working Group generally involve the initial estimation and subsequent refinement on the basis of available data and the results from simple models. Reference was made to previous work of the OECD Hazard Assessment Advisory Body.

The Working Group identified the need for better guidance for conducting exposure assessments so that consistency and transparency are achieved, both of which are important aspects associated with mutual acceptance of assessments.

The Working Group agreed that the scientific principles for exposure assessment of new and existing substances and pesticides are fundamentally the same. This includes fate and distribution of the substances. Identified differences relate mainly to use pattern and understanding of release to the environment (i.e. magnitude and associated uncertainties). The Working Group recognised that a variety of "tools" exist for assessing exposure to these substances; however, not all of these tools are necessarily applicable to all use categories.

Data and Emissions

The Working Group observed that the estimation of releases is a complex activity and is associated with considerable uncertainty. They emphasised the need for flexibility in the approach and refinement of input.

The Working Group agreed that the estimation of releases should follow the principles of the lifecycle approach (e.g. identifying releases during production, formulation, use, transport and disposal). Furthermore, consensus was reached that a tiered approach was appropriate for estimating emissions, generally going from worst-case scenarios to more realistic scenarios based on additional data (e.g. monitoring or similar data). An objective identified by the Working Group in this regard is to derive *realistic and relevant* estimates of release. The Working Group also acknowledged the role of worst-case scenarios. They noted that they depend on the decision points being addressed in the schemes, but that they are most suited to demonstrating a lack of concern for the substance. There is also a need to acknowledge non-typical situations which may not have been addressed in the assessment but are nevertheless relevant to decision making.

The Working Group felt that the impact of chemical categories on release estimates should be included in future work, particularly for naturally occurring substances like metals. Since there are no internationally agreed methods for emission estimation, the Working Group felt that further work in this area would be appropriate. The experience of some countries with product registries and release inventories may play a role.

Extrapolation

The Working Group agreed that extrapolation of laboratory-generated data to field situations is feasible but will strongly depend on test type and endpoints considered (e.g. aquatic biodegradation tests where it is difficult to extrapolate to sewage treatment, versus pesticide degradation tests where considerable correlations have been established). Chemical properties and environmental conditions were also viewed as critical to the extrapolation from medium to medium.

It was generally felt by the Working Group that experience in the pesticides area could provide useful information for the application of extrapolation techniques to general chemicals for fate and exposure.

Uncertainty

The Working Group acknowledged the different aspects of uncertainty which apply to both exposure and effects assessments. With regard to exposure, the Working Group noted various sources of uncertainty associated with input data, [model] assumptions and environmental parameters. Collectively, these introduce uncertainty in the determination of Predicted Environmental Concentrations (PECs). These uncertainties are further propagated in the risk characterisation and assessment (e.g. PEC/PNEC quotient).

An important aspect of uncertainty identified by the Working Group concerns the need to be transparent (i.e. documenting known uncertainties) and to communicate the uncertainties identified by the assessors. Expressing the risk in probabilistic terms was considered as an option to communicate uncertainties.

The Working Group felt that it would be useful to quantify uncertainty; however, this was considered extremely difficult as one tries to assess propagation of error from one source to another. Furthermore, there must be similar efforts to identify and quantify uncertainty associated with the effects assessment and the behavioural aspects of the target organism.

The Working Group recommended that exposure assessment approaches be kept simple and transparent. When dealing with a number of sources of uncertainty, assessors should use sensitivity analyses to understand the impact of each on the exposure estimates.

Models

The Working Group considered that models are essential tools that play an important role at various points in the exposure assessment process. These roles include:

- understanding environmental distribution and ultimate fate;
- providing insights into the influence of environmental external factors on distribution;
- use in intermediate [exposure or risk] assessment decision-making (e.g. screening, research, planning, etc.); and
- predicting environmental concentrations in the complete absence of monitoring data as may be experienced with new substances.

In certain circumstances, it was recognized that predicted concentrations from models may be more cost-effective than implementation of monitoring programmes.

The Working Group confirmed that model users must have an adequate level of expertise in order to run the models and properly interpret the results and their limitations.

The Working Group concluded that, at present, there is no harmonization in the selection and application of models to assess exposure. The differences lay in the choice of model (regional or local), the point in the scheme at which they are used (initial screening or comprehensive assessment), and the selection of "settings" (model input parameters, generic or site-specific).

In discussing the possibility of harmonization, the Working Group referred to the experience of the SETAC Task Force on Multimedia Modelling. This Task Force tested a variety of simple multimedia fugacity models and confirmed that given the same input values, model outputs are the same. The Working Group took this as confirmation that harmonization of model parameters and assumptions (e.g. intermedia transfer rates, advective rates, etc.) is feasible. However, the Working Group recognized that the models also rely on geographic specifications (i.e. model unit world) which can be generic or specific.

The Working Group noted differences between regional multimedia models and local [monocompartmental] models where the latter models are far more sensitive to local environmental specifications.

Monitoring and Field Data

To initiate its discussion, the Working Group defined the terms as follows:

Monitoring – regular collection of analytical or biological (e.g. environmental effects monitoring) data on the presence of the substance in one or more environmental compartments;

Field Data – a single set of observations on the presence of the substance in one or more environmental compartments that are collected for a particular purpose (e.g. pesticide registration).

The Working Group considered that reliable monitoring data, when available, take precidence over predictions from models in the final risk characterisation/assessment (exception noted above for new substances where monitoring data cannot be available). The group observed that as one progresses towards the final risk characterisation/assessment, monitoring data would probably have been collected using the tiered approach discussed earlier. They also noted that, for field data in particular, assessors should be cautious in the use of data since they may have built-in limitations (e.g. biases), thus limiting more general use.

The Working Group noted the interplay between models and monitoring programmes and acknowledged that model output may trigger monitoring activity.

Predicted Environmental Concentrations

In discussing the compartments for which PECs should be determined, the Working Group agreed that, in principle, all may possibly be important to the characterisation and assessment of risk. However, it was concluded in practice, that assessors have a choice to either start with few compartments and successively add more, or vice versa if fate information supports a more focused approach.

Based on discussions within the SETAC Task Force on Multimedia Modelling, the Working Group supported the idea of segregating compartments depending on the manner in which substances enter them. This results in the identification of: *primary compartments* into which substances are directly released (air, water, soil); *secondary compartments* into which substances are transferred from another medium (e.g. ground water); and *tertiary compartments* where substances undergo multimedia transfer (food chain).

The Working Group noted that the selection of compartments is dependent on the aim and type of assessment (initial vs. comprehensive) and data availability. In addition, the corresponding PNEC must be available for the target population (or sub-groups). It was also noted that effects levels expressed as environmental quality objectives (e.g. water use guidelines) may also be compared to the derived PEC.

In terms of the geographic scale to be covered by the PEC, use category and type of assessment were considered to be determining factors. Derived PECs should also match PNECs in both time (duration of exposure) and scale.

Expert Judgement

The Working Group considered "expert judgement" to be the application of the knowledge and experience of scientists to decision making in the various steps of the fate and exposure assessment. It is applied at the following steps considered part of the exposure assessment scheme: collection and appraisal of data; selection and use of models and interpretation of results; and determining the PEC.

It was noted that expert judgement involves individuals, but is most effective through interaction and communication among scientists with different but relevant backgrounds (e.g. peer review). In applying expert judgement, the weight of evidence approach plays a role in seeking consensus.

The Working Group emphasised the need for transparency (e.g. in the form of documentation) concerning the application of expert judgement, assumptions and criteria.

Validation

In discussing validation, the Working Group confirmed their understanding that it is a process for assessing whether PECs and conclusions derived from them in a risk characterisation/assessment are correct. It was generally agreed that follow-up monitoring activity, and/or the use of available monitoring data, is most suited to validating risk conclusions and may provide the additional benefit of validating the scheme for other related substances. A variety of methods were identified for internal validation of the various parts of the exposure assessment scheme listed above, in the first paragraph under "Expert Judgement". Examples include round robin comparisons, sensitivity analyses, etc.

Recommendations for Further Work

To address the need for transparent exposure assessment schemes, the Working Group recommended the development of the following "tools":

- emission database and emission scenarios for estimating releases;
- harmonized models for estimating environmental concentrations on regional and local scales (building upon existing experience acquired by OECD Member countries);
- guidance for determining rate constants and other parameters derived from standard OECD tests for incorporation into models; and
- procedures for quantifying and reporting uncertainties in exposure estimates.

The Working Group emphasised the importance of developing guidance associated with: exposure assessment; the gathering, appraisal and extrapolation of relevant chemical and environmental data; the use of models; and the communication of exposure assessments and their uncertainties. They recommended that the results of such work be incorporated into existing OECD initiatives to develop guidance for risk characterisation.

It was also recommended that OECD and other relevant bodies continue to provide fora for identification and resolution of practical difficulties that arise from the assessment of exposure, including the application of models and monitoring data. The Working Group recommended a forum for risk assessors and risk managers be established to ensure mutual understanding of their respective capabilities and needs.

Annex 6

Report of the Working Group on Aquatic Effects

Chairman: Herbert Koepp, BBA, Germany
Rapporteurs: Tony Maciorowski, US EPA, and Richard Stephenson, GIFAP

General Background

When risk characterisation and assessment schemes are to be used internationally rather than nationally, more detailed guidance may be required to increase mutual acceptance and to ensure harmonized approaches. It also needs to be recognised that a risk characterisation may be used within different risk assessment and risk management contexts. If risk characterisations and assessments are to be mutually accepted internationally, the process by which they are conducted must be sufficiently well defined and transparent to ensure reproducible outcomes. To achieve transparency, the Working Group concluded that assumptions, analyses, and scientific decision points need to be fully documented. However, it was also understood that risk characterisations and assessments may result in different risk management decisions in different countries due to different concerns and constraints (e.g. environmental, geographical, social, legal and political).

Discussion Topics

Tiered Assessment

Most of the schemes covered in the Summary Document prepared as background to the Workshop use a tiered approach for aquatic effects testing. There was agreement in the Working Group that tiered approaches are appropriate. However, in practice the conceptual framework presented in tiered approaches is not always followed in a rigid step-by-step fashion. On occasion, the availability of data at higher tiers may preclude the need for certain tests at lower tiers and some risk characterisations may not require data at all tiers. This situation was considered more likely for existing general chemicals, and currently registered pesticides, than for new general chemicals or new pesticides.

Trigger values to move to higher tiers should, in principle, be based on exposure/effects comparisons whenever possible, even if PEC or PNEC values are qualitative rather than quantitative. On occasion, production volume tonnage figures may provide a basis for triggering further effects testing, particularly when no other basis for determining a PEC is available.

Recognising that exposure and effects comparisons are a basic principle of risk assessment, the use of other relevant information (e.g. knowledge of mode of action, toxic properties, persistence and bioaccumulative properties) is not precluded when considering triggers for higher tier tests.

Data and Tests

The concept of a harmonized set of base tests for initial tier risk assessments was generally agreed. Short-term fish, daphnid and green algal tests are widely accepted as providing the initial or base set of tests for a preliminary risk characterisation. When available, the ready biodegradation test provides some information on toxicity to bacteria. It was recognized that significant difficulties exist in testing difficult test substances (e.g. low-solubility, volatile and oily compounds) and mixtures. Guidance is needed in this area. Some concern was expressed regarding difficulties in maintaining test substance concentrations in algal tests, leading to difficulties in data interpretation for some substances.

The Working Group agreed there was a need to maintain this widely accepted base set of tests to provide maximum international comparability of data and to allow utilisation of the extensive existing data base.

Testing beyond the base set can consist of several broad categories:

i) Additional short-term tests for specific situations or needs (e.g. marine and estuarine environments, sediments, key regional species, likely susceptible species, or geographical factors such as temperature). There are a number of tests potentially available to fulfil these requirements, some of which are already standardised, but few have been harmonized internationally. Care needs to be exercised in judging when there is a requirement for additional acute tests (e.g. data for freshwater species may be an adequate substitute for marine species where the substance is not modified in marine waters compared with freshwater environments).

ii) Longer-term tests designed to establish subchronic or chronic effects. There are a limited number of internationally harmonized tests available, but more are required (e.g. higher aquatic plant tests).

iii) Multi-species tests, and microcosm and mesocosm tests to examine ecological end points such as functional and indirect effects, are required by some risk characterisation schemes. Again, there has been some progress towards building scientific consensus for some tests, but these tests have not been subject to a formal harmonization process.

Testing strategies beyond the base set need to be flexible to allow for the selection of appropriate tests and suitable end points. The testing strategy employed will be determined by using previously collected effects data and evidence for potentially significant exposure. For pesticides, where experience of the use of higher tier tests is much greater, testing strategies are more fully developed than for general chemicals. There is a need to further develop harmonized testing strategies, particularly for general chemicals.

Concern was expressed that despite the existence of the OECD Council Decision on the Mutual Acceptance of Data (MAD), problems were still encountered in some areas in obtaining acceptance of data generated according to harmonized guidelines.

It was considered that (Q)SARs represent an important aid to priority setting and selection of testing strategies. It was recognised, however, that (Q)SARs require substantial expertise for proper application. There is a need for further development of (Q)SARs to incorporate a wider variety of end points, although the Group did not think that at present they were capable of replacing base set testing.

There was agreement that future testing should be carried out following accepted methods/guidelines and in compliance with GLP. However, it was recognised that data already available for existing substances may have been derived from tests, and using species, which differ from accepted guidelines, or from studies which are non-GLP compliant. Nevertheless, the Group agreed that these data should be accepted for risk characterisation provided "validity" criteria are met.

Validity criteria for non-standard data for classification and labelling purposes may be less stringent than those for risk characterisation. When using non-standard data or non-GLP compliant data, priority should be given to those with the highest scientific quality.

Throughout the process of data generation, due concern should be given to animal welfare and the minimisation of vertebrate testing.

Extrapolation and Uncertainty

Extrapolations from aquatic effects data occur in a variety of situations within risk characterisation and are subject to uncertainty from a variety of sources, e.g.:

- intra species;
- acute to chronic;
- laboratory to field;
- few species to many species.

Assessment factors are used to allow for uncertainty in most schemes. Several approaches have been used to develop assessment factors:

i) a combination of science (e.g. acute/chronic ratios) and regulatory convention;

ii) empirical derivation from analysis of existing data bases (e.g. ECETOC);

iii) Individual scientific consideration of the substance and scenario of concern;

iv) statistical approaches (e.g. HC5 method).

Assessment factors encompass a number of elements which are not easily separable (acute to chronic, chronic to field, species to species, and other aspects of uncertainty). It would be valuable to establish the contribution of each of the above elements to the final assessment factor.

For substances with large data bases, the use of assessment factors on the lowest NOEC values or lowest LC50 values makes no use of the additional information contained within these larger data bases. The Group questioned whether this made the most effective uuse of the available data.

The EC50 value from algal toxicity tests is utilised as an acute toxicity end point, equivalent to fish and daphnid LC/EC50 values when assessment factors are used, despite the fact that the green algal test is a chronic toxicity test. The desirability of this is questioned.

Where derived PNEC values are below natural background concentrations for naturally occurring substances, or below minimal nutritional requirements, they should be reassessed.

There are a number of issues related to the use of statistical extrapolation techniques:

i) The number and representativeness of available data. Care needs to be taken that adequate numbers of end points from a sufficiently broad range of taxonomic groups are used.

ii) The goodness of fit of the chosen distribution. Concern was expressed that the distributions typically used may not adequately reflect the underlying distribution of the end-point values.

iii) The effects of outliers. Particular concern was expressed that the inclusion of outliers with unusually low susceptibility leads to a decrease in the HC5.

In the schemes reviewed in the Summary Document (in preparation) and compared in Annex 4, the existence of data beyond the minimum requirements at the various tiers are dealt with differently or not allowed for. It is desirable that all acceptable data be appropriately incorporated into the risk characterisation in order to minimise uncertainty.

Exposure

Several routes of exposure are potentially important for aquatic organisms, including direct uptake through the body surface, direct ingestion, and magnification through the food web. The Group considered that direct uptake through the body surface is the most important route of exposure for aquatic organisms. Biomagnification through the aquatic food chain is not considered of major importance for aquatic effects assessment. However, bioconcentration can be important when considering the potential for the secondary poisoning of birds and mammals. Currently log P_{ow} is used as a trigger for bioconcentration tests with fish, and is likely to provide a conservative estimate of the BCF as it does not take account of metabolism. When radio-labelled materials are used for the determination of BCF values, care needs to be taken to ensure appropriate labelling and, where necessary, specific analysis of the test substance to confirm whether the label retained in the fish is parent or metabolite(s).

The Group was concerned about using data from pelagic species to characterise risk to benthic organisms because of the potential for multiple routes of exposure of the latter, compared with the former. Sediment test guidelines are being developed or are used in several countries and should be harmonized at an early stage. Regarding the exposure of sediment-dwelling species, the equilibrium partitioning approach was not considered wholly appropriate at the present time. However, it may be useful in the absence of any better data.

The Group agreed that intermittent exposure is not sufficiently dealt with in the existing schemes; the UK approach is to reduce the assessment factor instead of adjusting the PEC.[1]

Significance of Effects

There was agreement that risk characterisation should be based on a comparison of exposure and effects endpoints. It was also recognised that there is a need to understand, and if possible to quantify, the uncertainty in exposure and effect indices, thereby allowing an estimate of the possible effect on the risk quotient (i.e. sensitivity analysis to be promoted).

The Group recognised that biological monitoring data, particularly in relation to existing chemicals, can play a valuable role.

There is a need to be able to quantify and communicate the risk in a way that is appropriate for inclusion in risk management decisions.

Expert Judgement

Expert judgement can be considered to be the synthesis and interpretation of information by an individual or group. It is an essential element of the development of adequate risk assessment schemes. Those who exercise expert judgement should have appropriate experience, training, and knowledge of the process of risk characterisation and assessment. It is essential that expert judgement be applied to consistent standards in a transparent way to maximise the opportunities for sharing of the result. Expert judgement, when used, must be sufficiently consistent to provide proper support to regulatory/legal decisions. It is important that there is explicit recognition of instances where expert judgement has been used in risk assessment reports.

Expert judgement may be necessary to assess input data prior to their use in risk characterisation. This is particularly important where non-standard data are to be used. Also, when testing "difficult substances", there may be an increased need for expert interpretation. Where testing strategies are poorly established, expert judgement will be necessary to establish an appropriate strategy; this will be especially necessary where it is anticipated that the data sets will be extensive or complex. Risk characterisations which require weighting of scientific evidence rather than clear-cut decisions will also require expert judgement.

The development of guidance on the application of expert judgement in risk characterisation is required.

---

[1] *Research carried out by the US EPA research laboratory in Corvallis, Oregon, has shown that intermittent exposure can be more toxic to organisms than constant exposure. Reference: Seim, W.K., L.R. Curtis, S.W. Glenn, and G.A. Chapman. 1984. Growth and survival of developing steelhead trout (Salmo gairdneri) continuously or intermittently exposed to copper. USEPA, Office of Research and Development, Corvallis, Ore., Report EPA-600/J-84-055.*

Validation

Validation of risk assessment schemes can be divided into two elements:

i) *internal validation*, i.e. checking that the scheme is capable of giving reproducible results when used with the same input data by different "experts". Internal validation should examine the contributions of various parts of the process to any variability that is present; areas for consideration include use of assessment factors and use of expert judgement. Sensitivity analysis will provide a useful tool for internal validation and can be used to indicate the principal "drivers" of the scheme(s).

ii) *external validation*, i.e. checking that the predicted (lack of) effects or exposure concentrations are correct. This can be achieved by comparison of predicted with observed field effects. This approach is more easily applied to simple situations dealing with relatively well defined exposures and end points, e.g. application of pesticides and the determination of their effects on individual organisms such as honey bees or silk worms. Another approach to external validation is to compare the output from different schemes for the same or closely related substances.

Recommendations

Firm recommendations:

1. Develop guidance in support of Test Guidelines on how to test "difficult substances" (organic and inorganic) including complex mixtures.

2. Develop harmonized sediment Test Guidelines, triggers for testing and testing strategies.

3. Develop criteria[2] for assessing the acceptability of non-standard data for inclusion in risk characterisation.

4. Improve the implementation of the OECD Council Act on the Mutual Acceptance of Data (MAD).

5. Harmonize assessment factors (bearing in mind possible legal constraints) and other related issues.

   - Which approach (OECD/EC/EPA/ECETOC/statistical)?
   - What assessment factors should be used with data derived from (Q)SARs?

6. Develop guidance on the extrapolation of data obtained on single substances (e.g. active ingredients) to preparations and mixtures.

7. Promote the use of sensitivity analysis within risk assessment.

[2] *During the Member country review process for this workshop report, the US EPA indicated that criteria should also be developed to judge the validity of standard data.*

Possibly also:

1. Develop guidance for long-term, micro/mesocosm and other "special" tests and extend current testing strategies to include these types of tests.

2. Develop guidance on the assessment of indirect effects (not secondary toxicity/poisoning).

3. Develop guidance on the assessment of risk where there is intermittent exposure.

4. Develop methods to quantify uncertainty in risk assessments and to estimate the probability of adverse effects occurring.

Co-ordinate with others on:

1. Development of guidance on the use of expert judgement.

2. Validation of risk assessment schemes.

3. Further development and use of (Q)SARs.

Annex 7

Report of the Working Group on Terrestrial Effects

Chairman: Peter Greig-Smith, MAFF, UK
Rapporteurs: Lars Anderson, KemI, Sweden, and Kees Romijn, GIFAP

Introduction

The Terrestrial Effects Working Group comprised members from a wide variety of backgrounds, but included a large majority with experience in the risk assessment of pesticides. This was not considered to be a disadvantage in comparing approaches for pesticides and general chemicals, because there has historically been a greater need for detailed assessments of risk for pesticides than for general chemicals.

The discussion was restricted to risk characterisation and assessment of defined use patterns of chemicals, and did not include hazards arising from spillage and other accidents.

Discussion Topics

Tiered Assessment

The Summary Document prepared as background to the Workshop, which compared thirteen existing hazard/risk assessment schemes, revealed that all the schemes concerned with the terrestrial environment have a tiered structure, although some do not make this explicit. The Japanese schemes for general chemicals and pesticides rely only on human health criteria and therefore do not really address environmental risk assessment. The Group concluded that tiered assessment, whether formal or informal, is a universal and essential feature of risk assessment.

Tier 1 represents the first point in an assessment at which exposure and effects are compared. Beyond this level there may be several tiers. The differences in the number of tiers defined in the schemes are unimportant, and depend on the characteristics of a particular risk assessment context. It is important to recognise that assessment is an iterative procedure involving progressive refinement of exposure/effect ratios. Early comparisons of exposure and effects are based on standard tests. At later tiers of assessment, standard tests should be employed if available. In the case of general chemicals, this will usually be sufficient to satisfy data requirements; but for pesticides there may be advantages in flexibility, so as to allow test design to be matched to the particular circumstances of the chemical and its use. Information sought at later tiers may be aimed at refining estimates of exposure by quantifying exposure from the route initially identified or by considering additional routes. Similarly, refinement of effects may involve greater accuracy and precision for effects on a particular species or the addition of different endpoints or tests on other species.

Triggers/cut-off criteria

Triggers to move from lower to higher tiers can be based on (a) usage criteria that dictate the amount of data needed, or (b) the results of earlier studies that indicate a need for more data to clarify exposure or effects. The criteria used vary from scheme to scheme. In some cases this is justifiable due to their different purposes, but in others there is scope for harmonization.

In some cases, it may not be necessary to perform a terrestrial risk assessment, because of:

(a) the application of cut-off criteria – i.e. intrinsic properties such as bioaccumulation potential and persistence, which are regarded as totally unacceptable regardless of likely exposure to terrestrial organisms. However, the circumstances in which this might occur are rare. **Note:** It is not appropriate to employ terrestrial effects data as cut-off criteria, because specific effects are relevant only if there is exposure.

(b) exposure of organisms of concern is not possible (e.g. soil-incorporated pesticides should not require evaluation of toxicity to honey bees).

It is important that the use of cut-off criteria is not generalised to all pesticides or all general chemicals. These criteria must be applied cautiously on a case-by-case basis.

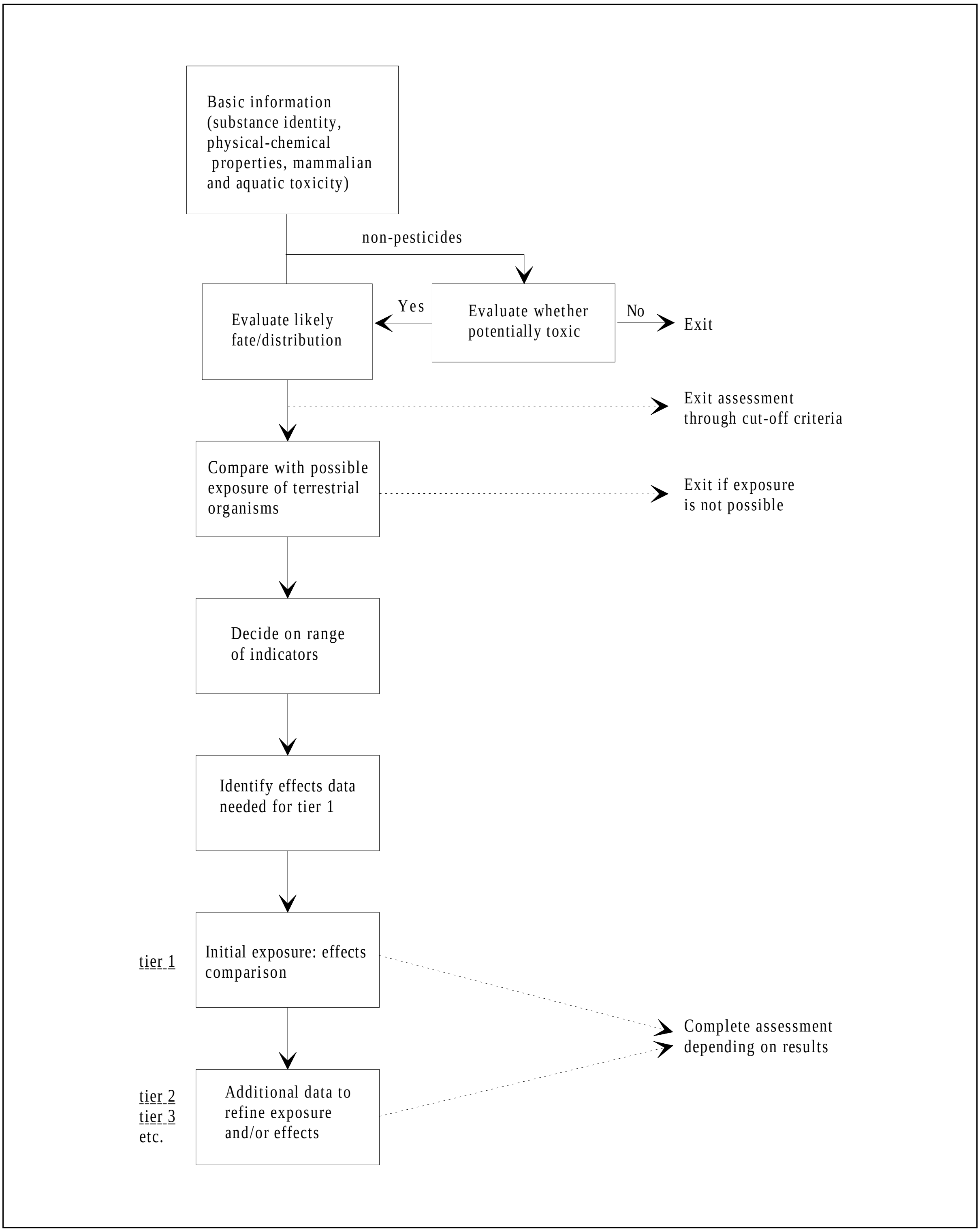
The sequence of actions in the early stages of assessment is summarised in Figure 1.

Data and Tests

Base-set data

The issue of how much, and what, terrestrial effects data to include at the outset of evaluations requires careful definition. In principle, requests for *any* such data should be dependent on first a preliminary assessment of the likelihood of exposure, followed by determination of whether the substance is potentially toxic. In practice, it is known from the nature of pesticides that they *are* potentially toxic, and *will* reach the environment, although not necessarily to compartments that are relevant to terrestrial animals and plants. Accordingly, it is certain that *some* terrestrial effect data will be needed for pesticides, though it is not possible to define a single common set of requirements. For general chemicals, neither assumption can be made automatically. Therefore, it is appropriate that in this case the "base-set" is defined to include *only* the "basic" aquatic data (in addition to the routine physical/chemical and human health data). Any terrestrial data required should be added after the initial comparison of information on fate and bio-activity, but before the initial tier of risk assessment (Figure 1).

Annex 7, Figure 1. Sequence of actions in the early stages of risk assessment for effects on the terrestrial environment



Evaluating potential exposure and choosing indicators

Knowledge of the use pattern and disposal of the chemical should be used to predict its distribution in the various compartments of the terrestrial environment. This will enable the selection of groups of organisms that are relevant for assessment, and hence the identification of suitable effects tests needed for tier 1 (see Table 2). For example, agricultural pesticides applied as sprays may expose terrestrial organisms via air, surfaces, soil or through the foodchain. Accordingly, the initial effects data for these pesticides should typically include all the groups identified in the matrix. In contrast, pesticides intended only for use in glasshouses are not expected to reach the terrestrial environment immediately, and therefore no tests on terrestrial organisms are required at the initial stage. Similarly, no terrestrial effects testing is typically required for general chemicals at this early stage. Table 1 indicates how this task can be approached.

Table 1. Organisms of concern in various terrestrial compartments

Distribution of the chemical in the environment	Organisms of concern			
	Soil organisms	Plants	Invertebrates (above ground)	Vertebrates
Air		X	X	X
Surfaces			X	X
Soil (water, particles, vapour)	X	X		
Food chain			X	X

N.B. Some organisms cannot be placed uniquely into one category.

The principles of this approach are common to general chemicals and pesticides. However, it is generally easier to achieve for substances that are released intentionally into the environment in a specific use pattern (pesticides) than those which enter the terrestrial environment in a less prescribed way.

Tests

To provide information for tier 1 assessment of the exposure/effects ratio, it is valuable to have a set of standard tests on representative terrestrial organisms.

The group proposed that an appropriate set of standard tests should include representatives of each of the four categories in Table 1. Table 2 summarises the types of species proposed.

For certain groups, it may be possible to substitute for these standard tests by making use of industry-generated screening data (i.e. for plants and for herbivorous invertebrates) or data from the scientific literature. In addition, the efficacy screening tests for plants and herbivorous invertebrates used by industry could be used as a starting point for the development of test guidelines.

Table 2. Proposal for a list of standard terrestrial tests

Soil organisms	- one soil arthropod - earthworm - micro-organism function
Plants	- one test for exposure through root uptake - one test for exposure through leaves
Terrestrial invertebrates (above ground)	- predatory mite - parasitic wasp - honey bee - herbivore
Terrestrial vertebrates[1]	- bird

The list is quite long compared to that for standard aquatic tests. This is necessary because potential patterns of exposure are more diverse in the terrestrial environment than in water. Also, it should be stressed again that not all of these tests will be used in any one case.

The group recognised that there are serious shortcomings in the current methods for the determination of NOECs. There is a need to address this by developing better approaches to experimental design and statistical calculation of no-effect levels and other endpoints.

---

[1] *Mammalian toxicity is covered by tests for human health assessment. Amphibians are omitted because their most sensitive life-stages are aquatic.*

There may be a trade-off between tests that simulate exposure in the real environment but are highly variable, and those which are more standardised and repeatable but are usually of less ecological relevance. The latter are more useful at early stages of risk assessment, and the former more appropriate in higher tiers.

If data on toxicity to soil-dwelling organisms are missing at an early stage, an approach that involves extrapolating from aquatic data may be accepted as a substitute. This approach includes three assumptions:

(i) equilibrium partitioning, which suggests that availability of a chemical can be predicted in one medium from another;

(ii) exposure of soil organisms is via pore water;

(iii) distributions of species' sensitivities are similar between aquatic organisms and soil-dwelling organisms.

The uncertainties in these assumptions mean that the potential of the approach is limited to generic early screening procedures. For more specific evaluations of risk to terrestrial species, missing toxicity data should trigger the need for tests on relevant terrestrial species.

For both pesticides and general chemicals, the group agreed that it is necessary to consider the principal breakdown products of substances. Current approaches (e.g. to evaluate the fate and toxicity of any breakdown products that represent more than 10 per cent of the original substance) were felt to be satisfactory.

Uncertainty and Extrapolation

The Group felt that there are many sources of error at all stages of the risk assessment procedure, and that conclusions are therefore subject to considerable uncertainty. Steps should be taken to encourage reporting of results and conclusions in ways that make clear the degree of uncertainty for the benefit of risk managers and decision makers.

One area that needs particular attention is the use of assessment factors. The current approach, which is based on assignment of assessment factors according to the number of test results that are available, should be regarded as provisional until it is possible to develop a better basis for logical factors that take into account knowledge about mechanisms, differences between species, etc. This is less well developed than in the aquatic environment, and it would be valuable to improve the information (e.g. industry screening test results) available for terrestrial effects. Improvement of information available could be done, for example, by constructing a database of existing information, initiating research studies to obtain new data, and seeking consensus on current approaches.[2]

---

[2] *The USA EPA Office of Research and Development (ORD) has the ECOTOX database that includes test data for terrestrial plants and animals and is a very useful source of information.*

Ecological Significance of Effects

There is little opportunity for comparing or harmonizing the classification of risks between schemes, because each scheme has its own purpose, specific to its aim (labelling, approval, etc.) and to priorities in the country concerned.

Most schemes claim to address risks to populations or ecosystems, but none of them generates data which allow a proper ecological evaluation of population-level effects. An exception is the assessment of impacts on soil micro-organism function, which is related to "natural" perturbations as a benchmark for what should be regarded as a "serious" effect. There is scope for a scientific initiative to pursue ways of improving this aspect of interpretation.

All schemes give importance to both local and regional scales of potential impact. However, between pesticides and general chemicals, there is a difference in the way risks are handled between in respect of information on expected volume of use. For new and existing substances, some schemes involve an initial trigger based on production volume, which dictates the amount of data required and the nature of the risk evaluation. If production changes, the evaluation must be renewed. For pesticides, information on the quantities to be used is required at the outset, but may not be included in the risk assessment until a late stage. Thus, local risk is evaluated first, regardless of how widely the product is to be used, but later tiers of assessment can be influenced by the knowledge that, for example, it will be widespread. In some cases, this aspect may not be integrated until the conclusions on risk are used in decision-making on acceptability.

Expert Judgement

Expert judgement is needed in all schemes for a variety of purposes which include deciding on the need for tests, assessing the validity of data, interpreting results, and contributing to risk management decisions. All efforts should be made to ensure that experts' decisions are clearly documented, in order to ensure that the risk assessment process is as transparent as possible.

Expert judgement in the context of terrestrial effects is particularly important for pesticides. Because of the variability in routes and patterns of exposure, and hence the diversity of tests, it would be difficult to apply automatic criteria in the interpretation of results.

For general chemicals, there is a greater requirement to use internationally agreed test guidelines to ensure the mutual acceptability of data and assessment in an international context than for pesticides. Expert judgement is therefore required principally to select the appropriate testing strategy and apply the data to risk characterisation and risk management decisions.

Expert judgement is also instrumental in the design of risk assessment schemes and in setting criteria that are then available for use by less expert assessors.

Validation

The Group considered that two types of validation are important in risk assessment. First, the overall efficiency of the scheme itself, and of component models, must be validated by exercises such as ring testing, external calibration, and checks for internal consistency. Second, it may be possible to validate individual predictions by carrying out monitoring or other independent checks on the level of risk.

Monitoring may also provide important data for risk assessment. The results of monitoring may confirm the validity of:

- the assumptions made in the risk assessment;
- the risk assessment process itself;
- the size and/or nature of the predicted effects and exposure.

Monitoring data also provide information on whether environmental quality targets are being met, the success of risk management strategies, the accumulation of chemicals in the environment, and the cause of environmental effects. In the past, environmental monitoring programmes have identified certain effects of chemicals that were not predicted by existing risk of assessment procedures, such as ozone depletion and bird eggshell thinning.

The power of monitoring to detect effects is often poor. This limits its utility for providing assurance of a lack of impact in the field. The Group was unable to reach a consensus on the value of monitoring as a validation tool and the direction of its future development for this purpose.

Conclusions

Overall, the group felt that both general chemicals and pesticides should be accommodated in a common concept and risk assessment framework. The apparent differences of approach that are observed in practice are due to the fact that these categories of chemicals differ in ways which determine how they are assessed within the common framework. It would therefore be useful to identify the range of factors which may be important in influencing environmental risk and hence dictate what approaches are suitable in risk assessment.

Recommendations

The Group felt that it is essential for OECD to be active in two ways that will help to advance scientifically-based hazard and risk assessment:

1. to co-operate with other international organisations involved in the development of risk assessment and test guidelines;

2. to encourage consistent, transparent assessment reports and provide technical guidance to promote expert judgement.

In addition, the following specific initiatives should be pursued:

3. In order to provide a set of standard terrestrial effects tests, a Working Group should be established to review current activities in a variety of organisations, leading to proposals for new terrestrial effects test guidelines;

4. Efforts should be made to promote the improvement of extrapolation methods and uncertainty analysis, including assessment factors. This could involve the following steps:

   - commissioning a review of approaches taken in aquatic assessment and other types of risk assessment, to identify suitable principles and approaches;

   - constructing a database containing relevant published, and high-quality unpublished, toxicity data for a wide range of terrestrial species;

   - setting up a research project to derive new data for the database on terrestrial effects, using standard laboratory toxicity tests on plants and invertebrates;

   - establishing an OECD Working Group to evaluate, and make recommendations about, how extrapolations should be handled for terrestrial effects.

5. Ways should be considered to advance the development of improved methods for assessing no-effect levels and other end-points. This would involve reviewing the range of parameters used as endpoints, and the experimental designs and statistical methods appropriate for generating robust measures of toxicity.

6. It is important to begin to develop a better understanding of the ecological significance of effects seen in the field on populations and ecosystems. This will require scientific progress in many areas. The best first step might be to organize a Workshop to discuss and make recommendations on further work by OECD and other bodies.

7. The quality and consistency of terrestrial risk assessments could be enhanced by providing criteria on which to judge the validity of non-standard data.[3] Such validity criteria would be useful for all parts of environmental risk assessments, but may be particularly relevant to terrestrial cases because of the need to employ flexible designs in higher tier field tests.

[3] *During the Member country review process for this workshop report, the US EPA indicated that criteria should also be developed to judge the quality of <u>standard</u> data.*

PUBLICATIONS LIST

ENVIRONMENTAL HEALTH AND SAFETY DIVISION,

OECD ENVIRONMENT DIRECTORATE

NOTE: [F] following a title indicates that the entire publication is available from the OECD in a separate French translation. The other publications listed are available in English only, but they often contain a French summary.

[GLP] following a title indicates that the publication is part of the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Translations of this series into Russian, Polish, Czech, Slovak, Hebrew, Spanish and Italian either exist or are planned. For more information, please contact the Environmental Health and Safety Division.

OECD Publications on Sale:

OECD Guidelines for Testing of Chemicals (December 1993)[F]
(OECD No. 97 93 50 1) ISBN 92-64-14018-2 992 pages
Price in France: FF 800
Price in other countries: FF 1040 US$ 178.00 DM 300

Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles (April 1993)[F]
(OECD No. 93 04 1) ISBN 92-64-13859-5 80 pages
Price in France: FF 80
Price in other countries: FF 100 US$ 19.00 DM 33

[Prepared in collaboration with the OECD Directorate for Science, Technology and Industry.]

Aquatic Biotechnology and Food Safety (January 1994)
(OECD No. 97 94 05 1)   ISBN 92-64-14063-8   100 pages
Price in France: FF 80
Price in other countries: FF 100   US$ 18.00   DM 30

[Prepared in collaboration with the OECD Directorate for Science, Technology and Industry.]

Environmental Impacts of Aquatic Biotechnology (in press: scheduled for publication in December 1995)

[Prepared in collaboration with the OECD Directorate for Science, Technology and Industry.]

The publications above may be ordered directly from: OECD Publications Service, 2 rue André-Pascal, 75775 Paris Cedex 16, France. Telex: 640 048. Fax: (33-1) 49 10 42 76.

OECD Environment Monographs:

Environment Monographs are available at no charge, in limited quantities, from the Environmental Health and Safety Division, OECD Environment Directorate, 2 rue André-Pascal, 75775 Paris Cedex 16, France. Fax: (33) (1) 45 24 16 75.

No. 14, *Final Report of the Expert Group on Model Forms of Agreement for the Exchange of Confidential Data on Chemicals* (1988)[F]

No. 15, *Final Report of the Working Group on Mutual Recognition of Compliance with Good Laboratory Practice* (1988)[F]

No. 17, *The Use of Industry Category Documents in Source Assessment of Chemicals* (1989)[F]

No. 24, *Accidents Involving Hazardous Substances* (1989)[F]

No. 25, *A Survey of Information Systems in OECD Member Countries Covering Accidents Involving Hazardous Substances* (1989)[F]

[superseded by the *Users Guide to Information Systems Useful to Emergency Planners and Responders Available in OECD Member Countries* (1991)]

No. 26, *Report of the OECD Workshop on Ecological Effects Assessment* (1989)[F]

No. 27, *Compendium of Environmental Exposure Assessment Methods for Chemicals* (1989)[F]

No. 28, *Workshop on Prevention of Accidents Involving Hazardous Substances: Good Management Practice* (1990)[F]

No. 29, *Workshop on the Provision of Information to the Public and on the Role of Workers in Accident Prevention and Response* (1990)[F]

No. 30, *Workshop on the Role of Public Authorities in Preventing Major Accidents and in Major Accident Land-Use Planning* (1990)[F]

No. 31, *Workshop on Emergency Preparedness and Response and on Research in Accident Prevention, Preparedness and Response* (1990)[F]

No. 35, *A Survey of New Chemicals Notification Procedures in OECD Member Countries* (1990)[F]

No. 36, *Scientific Criteria for Validation of In Vitro Toxicity Tests* (1990)[F]

No. 39, *International Survey on Biotechnology Use and Regulations* (1990)[F]

Users Guide to Hazardous Substance Data Banks Available in OECD Member Countries, OCDE/GD(91)102 (1991)[F]

[Also translated into Spanish by the United Nations Environment Programme's Industry and Environment Office (UNEP IE).]

Users Guide to Information Systems Useful to Emergency Planners and Responders Available in OECD Member Countries, OCDE/GD(91)103 (1991)[F]

[Also translated into Spanish by UNEP IE.]

No. 43, *International Directory of Emergency Response Centres* (1992)[F]

[The International Directory is a co-operative project of OECD and UNEP IE. Emergency response centres listed in this Directory are located in both OECD and non-OECD countries.]

No. 44, *Workshop on Prevention of Accidents Involving Hazardous Substances: The Role of the Human Factor in Plant Operations* (1992)

No. 45, *The OECD Principles of Good Laboratory Practice* (1992)[F, GLP]

No. 46, *Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1992)[F, GLP]

[superseded by Environment Monograph No. 110, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1995)]

No. 47, *Guidance for the Conduct of Laboratory Inspections and Study Audits* (1992)[F, GLP]

[superseded by Environment Monograph No. 111, *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits* (1995)]

No. 48, *Quality Assurance and GLP* (1992)[F, GLP]

No. 49, *Compliance of Laboratory Suppliers with GLP Principles* (1992)[F, GLP]

No. 50, *The Application of the GLP Principles to Field Studies* (1992)[F, GLP]

No. 51, *Guiding Principles for Chemical Accident Prevention, Preparedness and Response: Guidance for Public Authorities, Industry, Labour and Others for the Establishment of Programmes and Policies related to Prevention of, Preparedness for, and Response to Accidents Involving Hazardous Substances* (1992)[F]

[The Guiding Principles are **also available in Russian**. They are being translated into Spanish, and may also be translated into other languages. For more information, please contact the Environmental Health and Safety Division.]

No. 52, *Report of the OECD Workshop on Monitoring of Organisms Introduced into the Environment* (1992)

No. 58, *Report of the OECD Workshop on Quantitative Structure Activity Relationships (QSARS) in Aquatic Effects Assessment* (1992)

No. 59, *Report of the OECD Workshop on the Extrapolation of Laboratory Aquatic Toxicity Data to the Real Environment* (1992)

No. 60, *Report of the OECD Workshop on Effects Assessment of Chemicals in Sediment* (1992)

No. 65, *Risk Reduction Monograph No. 1: Lead* (1993)

No. 66, *Report of the OECD Workshop on Strategies for Transporting Dangerous Goods by Road: Safety and Environmental Protection* (1993)

[The OECD's Chemical Accidents Programme and Road Transport Research Programme co-operated in organising this workshop.]

No. 67, *Application of Structure-Activity Relationships to the Estimation of Properties Important in Exposure Assessment* (1993)

No. 68, *Structure-Activity Relationships for Biodegradation* (1993)

No. 69, *Report of the OECD Workshop on the Application of Simple Models for Exposure Assessment* (1993)

No. 70, *Occupational and Consumer Exposure Assessments* (1993)

No. 73, *The Application of the GLP Principles to Short-term Studies* (1993)[F, GLP]

No. 74, *The Role and Responsibilities of the Study Director in GLP Studies* (1993)[F, GLP]

No. 76, *OECD Series on the Test Guidelines Programme No. 1: Guidance Document for the Development of OECD Guidelines for Testing of Chemicals* (1993; reformatted 1995)[F]

No. 77, *Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results* (1993)

No. 81, *Health Aspects of Chemical Accidents: Guidance on Chemical Accident Awareness, Preparedness and Response for Health Professionals and Emergency Responders* (1994)[F]

[Four international organisations collaborated in the preparation of this publication: the International Programme on Chemical Safety (IPCS), OECD, UNEP IE, and the World Health Organization – European Centre for Environment and Health (WHO-ECEH).]

No. 88, *US EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships* (1994)

No. 90: *Ottawa '92: The OECD Workshop on Methods for Monitoring Organisms in the Environment* (1994)*****

No. 91: *Compendium of Methods for Monitoring Organisms in the Environment* (1994)*****

[*****Monographs No. 90 and 91 are companion documents.]

No. 92, *Guidance Document for Aquatic Effects Assessment* (1995)

No. 93, *Report of the OECD Workshop on Chemical Safety in Port Areas* (1994)

[This Workshop was co-sponsored by OECD, the International Maritime Organization (IMO) and UNEP.]

No. 94, *Report of the OECD Special Session on Chemical Accident Prevention, Preparedness and Response at Transport Interfaces* (1995)

No. 95, *Report of the OECD Workshop on Small and Medium-sized Enterprises in Relation to Chemical Accident Prevention, Preparedness and Response* (1995)

No. 98, *OECD Series on the Test Guidelines Programme No. 2: Detailed Review Paper on Biodegradability Testing* (1995)

No. 99, *Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results* (1995)

No. 100, *Comparative Analysis of Data Elements Used in the Assessment of Certain Products of Modern Biotechnology* (1995)

No. 101, *Risk Reduction Monograph No. 2: Methylene Chloride* (1994)

No. 102, *Risk Reduction Monograph No. 3: Selected Brominated Flame Retardants* (1994)

No. 103, *Risk Reduction Monograph No. 4: Mercury* (1994)

No. 104, *Risk Reduction Monograph No. 5: Cadmium* (1994)

No. 105, *Report of the OECD Workshop on Environmental Hazard/Risk Assessment* (1995)

No. 106, *Data Requirements for Biological Pesticides* (1995)

No. 107, *Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology* (1995)

No. 108, *Final Report on the OECD Pilot Project to Compare Pesticide Data Reviews* (1995)

No. 110, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1995)[F, GLP]

No. 111, *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits* (1995)[F, GLP]

No. 115, *Guidance for the Preparation of GLP Inspection Reports* (1995)[F, GLP]

No. 116, *The Application of the Principles of GLP to Computerised Systems* (1995)[F, GLP]

No. 117, *Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop* (1995)