

Environment, Health & Safety News

No. 11, March 2001

Introduction

The EHS Programme now has a slightly revised name: *Environment, Health and Safety*. The name of the Newsletter of the EHS Programme therefore is also revised. The *Environment, Health and Safety News* is a newsletter which comes out midway between Joint Meetings, approximately every eight months. Its purpose is to provide an update on the main events and activities of the EHS Programme. Information on new publications arising from the Programme as well as dates and venues of upcoming events and meetings are given.

Meetings related to the EHS Programme, which will take place between now and the end of the year are referred to under "Future events" at each topic.

STAFF IN THE EHS DIVISION

The Environment, Health and Safety Division has recently welcomed several new staff members. Libby Harrison is Principal Administrator, replacing Nicky Grandy and heading up the Pesticide Programme and Risk Assessment teams. Dorothy Canter is on secondment from the US EPA for an initial period of 6 months. Dorothy assists with the human health related work of the Test Guidelines Programme including endocrine disrupters. Suzanna Lynch is replacing Jenny Griffin, who left on a one-year personal leave. Suzanna will provide support for Chemical Accidents and Risk Management. Eisaku Toda is the successor of Satoru Morishita. Eisaku is from the Japanese Environment Ministry and has a background in ecotoxicology and exposure assessment (including exposure modelling). Geoff Wilson is seconded as a consultant from the UK Health and Safety Executive and is working on Existing Chemicals and Biocides.

Meredyth Desmond, Minna Kittilä, and Niels Schenk have left the Organisation. Wendy Woods has changed her name after her marriage to Wendy Cormier.

OTHER CHANGES

The Waste Management activity is no longer part of the Environment, Health and Safety Division. It is now incorporated in the new Environment Directorate "National Policies Division".



ENVIRONMENTAL OUTLOOK FOR THE CHEMICALS INDUSTRY

In 1998, OECD Environment Ministers asked the OECD to develop a forward-looking environmental strategy for consideration at their May 2001 meeting. To support such work, an Environmental Outlook report has been published which analyses trends and provides projections for the future. One chapter of this report deals with chemicals. As background for that chapter, a separate report, entitled "*Environmental Outlook for the Chemicals Industry*" has been developed. This report provides an analysis of past, current and projected trends up to 2020 for chemical products, consumption and trade; environmental and health impacts; and environmental, health and safety policies. The report will be published in late April, and will be available for downloading, free-of-charge, at:

<http://www.oecd.org/ehs>

Persons interested in obtaining a hard copy (also free of charge) should contact OECD, by e-mail, at:

ehscont@oecd.org.



TEST GUIDELINES

On 20th January 2001 Council adopted the following new and revised Test Guidelines:

- TG 121 (new Guideline): Estimation of the Adsorption Coefficient (Koc);

- TG 303 (updated Guideline): Simulation Test: Aerobic Sewage Treatment;
- TG 414 (updated Guideline): Prenatal Developmental Toxicity Study;
- TG 416 (updated Guideline): Two Generation Reproduction Toxicity Study.

They were published as the 12th addendum to the OECD Guidelines for the Testing of Chemicals in March.

Two new Guidelines are being considered by EPOC and will next be submitted to Council for adoption as part of the 13th Addendum: TG 307: Aerobic and Anaerobic Transformation in Soil; and TG 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems.

Other achievements of the Test Guideline Programme include the agreement reached by the 2nd Consultation Meeting of Experts on Acute Toxicity Testing on the revision of the three alternative tests to the conventional acute toxicity test (TG 401). The three Guideline proposals and a related Guidance Document will be submitted shortly to the Joint Meeting for approval.

The work on percutaneous absorption testing is also coming to a closure with the agreement reached by the Steering Committee of this exercise. Member countries' experts are currently reviewing the two proposals, together with an accompanying Guidance Document.

The following technical meetings related to the development of Test Guidelines and Guidance Documents have been held since July 2000:

- 2nd Consultation Meeting of experts on Acute Toxicity Testing, Paris, 28th-29th August, 2000;
- Joint OECD/ILSI Workshop on Developmental Neurotoxicity Testing, Washington, DC, USA, 23rd-24th October 2000;
- 2nd Meeting of the Expert Group on testing in Birds, Nashville, USA, 16th-17th November 2000.

More than 70 projects are included in the Workplan for 2000-2001, which was approved by the 31st Joint Meeting. An overview of the Programme, can be found on the following web address:

<http://www.oecd.org/ehs/test>

Future events:

- ◆ 3rd Meeting of the Validation Management Group for Mammalian Effects of Endocrine Disrupters [VMG(mammalian)3], Paris, 26th-28th March, 2001;
- ◆ 1st Meeting of the Validation Management Group for Ecotoxicity effects of Endocrine Disrupters [VMG(eco)1], Paris 29th-30th March, 2001;
- ◆ 5th Meeting of the Endocrine Disrupters Testing and Assessment (EDTA) Task Force, OECD, Paris, May 2001;
- ◆ 13th Meeting of Working Group of National Co-ordinators of the Test Guidelines Programme, OECD, Paris May 2001.

Recent and Forthcoming publications in the Series on Testing and Assessment:

- 📖 *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation (No.19)* (November 2000);
- 📖 *Guidance Document on Neurotoxicity Testing (No.20)* (available Spring 2001);
- 📖 *Detailed Review Paper on Appraisal of Test Methods for Sex-Hormone Disrupting Chemicals (No. 21), March 2001;*
- 📖 *Analysis of Responses from Member Countries to the OECD Questionnaire on the National Concern, Regulatory Activities and Priorities for Work on Endocrine Disrupting Substances (August, 2000, published on EHS endocrine disrupters Website);*
- 📖 *Guidance Document on Performance of Outdoor Monolith Lysimeter Studies (No. 22)* (September, 2000);
- 📖 *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (No. 23)* (November, 2000);
- 📖 *Guidance Document on Acute Oral Toxicity (No. 24);*
- 📖 *Revised Analysis of Responses Received from Member Countries on the Questionnaire on Regulatory Acute Toxicity Data Needs (No. 26)* (September 2000).



ENDOCRINE DISRUPTERS

Since the Validation Management Group (mammalian) 2 meeting in January and the EDTA 4 Meeting in May 2000, the work on phase 2 of the validation of the Uterotrophic Assay for oestrogen (ant)agonistic effects is progressing well. Participating laboratories have all finished and reported the studies they have conducted and the progress report will be discussed at the VMG 3 meeting in March.

The phase 2 work for the Enhanced TG 407 is well underway and approximately half the planned studies have been conducted. The 1st phase of the Hershberger Assay for androgen (ant)agonistic effects was slightly delayed. Progress will be reported at the VMG 3 meeting.

The ecotoxicity-related work has now started and a separate VMG for ecotoxicological effects of endocrine disrupters has been established. This Group will first focus on the validation of a fish screening test and a bird (two-generation) test. The development of tests for amphibian effect assessment of endocrine disrupters will be considered after a Consultation Meeting of Experts in this area in April 2001.

In addition to the validation projects, a start has been made with consideration of the activities aimed at a global strategy on endocrine disrupters assessment. Possibilities for a joint approach with respect to priority setting, tiered testing strategies and subsequent hazard and risk assessment approaches will be discussed at a Secretariat's Tripartite Consultation Meeting with the EC, Japan and the USA in March 2001.

Details of the Special Activity on Endocrine Disrupters can be found on the following webpage:

<http://www.oecd.org/ehs/endocrin>

Future Events:


- ◆ 3rd Meeting of the Validation Management Group (mammalian effects), Paris, France (26th-27th March, 2001);
- ◆ 1st Meeting of the Validation Management Group (ecotoxicity effects), Paris, 28th-29th March, 2001);
- ◆ Tripartite Consultation on Global Strategies, Paris, 30th March, 2001);

- ◆ Consultation Meeting on Amphibian Testing, Paris, 26th-27th April, 2001);
- ◆ Fifth meeting of the EDTA Task Force (Paris, France) May 2001.



GOOD LABORATORY PRACTICE

All 33 Mutual Joint Visits to national GLP compliance monitoring authorities in order to examine the programmes have now been completed. The evaluation phase of the pilot project will begin once the Working Group on GLP has reviewed the remaining MJV reports at its December 2001 meeting. A report will be prepared for the November 2002 Joint Meeting.



HARMONISATION OF CLASSIFICATION AND LABELLING SYSTEMS FOR CHEMICALS

In addition to more than 50 Teleconferences, the following Meetings related to the work on harmonisation of classification and labelling have been held since July 2000:

- 7th Meeting of the Extended Expert Group on Aquatic Environmental Hazards, Paris, 4th-5th September, 2000;
- 10th Meeting of the Task Force on Harmonisation of Classification and Labelling, Paris, 6th-8th September, 2000.

Hazardous to the Aquatic Environment

In November 2000, the 31st Joint Meeting approved Chapters 1-6 of the Guidance Document on Aquatic Environmental Hazard Classification. The only Chapter that needed further work was Chapter 7 on Metals and Metal Compounds. The Drafting Group for this Chapter continued its work after November and managed to reach full consensus on the Chapter in January 2001.

Closely related to the Chapter on Metals and Metal Compounds was the work on a highly technical test protocol for the dissolution/transformation of metal compounds in the environment. The Metals Group (merged in 2000 with the Expert Group on Aquatic Environmental Hazards to become the Extended Expert Group) had been working on this protocol since 1995 and

had, so far, been unable to reach consensus on the protocol. However, in March 2001, after numerous teleconferences, the group finally managed to reach a compromise solution. After its declassification, the protocol will be published in the Series on Testing and Assessment.

Classification of Mixtures

In September 2000 the Task Force on Harmonisation of Classification and Labelling reached agreement on the proposed harmonised classification systems for specific target organ systemic toxicity for substances. The Task Force also agreed on all but three Chapters of the Document on Harmonised Classification Criteria for Chemical Mixtures. The agreed endpoints are acute toxicity, sensitisation, mutagenicity, reproductive toxicity and carcinogenicity. Further work was needed on skin and eye irritation and on hazards to the aquatic environment.

The 31st Joint Meeting endorsed the agreed classification systems and urged the various groups to continue their work and complete all chapters before spring 2001. In early March 2001, the Drafting Group on Skin and Eye hazards indeed finished their work by reaching consensus on a harmonised system for corrosion and irritation hazards of mixtures.

The work on Chapter 9 on the aquatic environmental hazards of mixtures took more time and needed more teleconferences to solve all issues. In mid March 2001, however, the Drafting Group came sufficiently close to consensus to consider involvement of the Extended expert Group and the Task Force. It is expected that all work will be finished in May 2001.

New Endpoints

Work on four new endpoints has started and is lead by the following Member countries:

- Canada for: Water-activated corrosivity and toxicity;
- Canada for: Aspiration Hazards;
- Sweden for: Narcotic Effects; and
- UK for: Respiratory Irritation.

Questionnaires have been circulated to Member countries to obtain information on how these endpoints are currently handled.

Details of the Programme can be found at the following web address:

<http://www.oecd.org/ehs/class>

Future events:

- ◆ 11th Meeting of the Task Force on Harmonisation of Classification and Labelling, OECD, Paris, October 2001.

Recent and Forthcoming Publications in the Series on Testing and Assessment:

📖 *Detailed Review Document on Hazard Classification Systems for Specific Target Organ Systemic Toxicity after Single and/or repeated Exposure in OECD Member countries (No.25), January 2001;*

📖 *Guidance Document on the Use of the Harmonised System for the Classification of Chemicals which are Hazardous for the Aquatic Environment (No. 27);*

📖 *Guidance Document on Transformation and Dissolution of Metals and Metal Compounds in Aqueous Media (no.29);*

📖 *Detailed Review Document on Hazard Classification Systems for Chemical Mixtures (No.30), January 2001.*



RISK ASSESSMENT

The 31st Joint Meeting, November 2000, endorsed the extension of the mandate of the Task Force on Environmental Exposure Assessment for another two years. It also endorsed several new projects discussed at the seventh Task Force meeting held on 13th-14th September 2000 in Sweden.


One of the new projects is the OECD/UNEP Workshop on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-Range Transport in the Context of PBTs/POPs Assessment. This workshop will be attended by experts of multimedia models and their “users”, e.g. regulators and risk assessors, and discuss how multimedia models could be used in risk assessment, with particular focus on PBTs and POPs. The first meeting of the Steering

Group for this Workshop was held on 1st-2nd March 2001. A letter requesting nominations for participation in this Workshop will be sent to Heads of Delegations to the Joint Meeting in early April.

Another new activity is the development of harmonised templates to be used by industry for providing summary information on environmental, consumer and workplace exposure to industrial chemicals. Member countries have nominated experts to the Ad-hoc Expert Group on Reporting Exposure Information, and the Group will meet for the first time on 22nd-23rd March.

Development of Emission Scenario Documents (ESDs) is the core activity of the Task Force. Comments were collected on the draft ESD on Lubricants and Lubricant Additives, which will be further revised considering these comments. A draft ESD on Photographic Industry is under development, and will be circulated in mid-2001.

Recent Publications in the Series on Emission Scenario Documents:

 *Guidance Document on Emission Scenario Documents (No. 1) (August 2000).*

Future Events:

- ◆ OECD/UNEP Workshop on Multimedia Models (Ottawa, Canada; 29th-31st October 2001);
- ◆ 8th Meeting of the Task Force on Environmental Exposure Assessment (Ottawa, Canada; 1st-2nd November 2001).



NEW CHEMICALS

The Task Force on New Industrial Chemicals has continued to make progress implementing its Work Plan. A “modus operandi” document has been developed and agreed which provides for a transparent process for sharing information exchanged during a multilateral arrangement in which two or more countries exchange copies of their assessments of the same new chemical. In order to identify opportunities for multilaterals, and to develop case studies for comparing assessments across countries, chemical companies

have provided OECD Member countries with a list of chemicals that had been notified in more than one country. Governments are now invited to review the list and decide if they want to volunteer to participate in a multilateral. A document has been completed which itemises all of the data elements found in OECD Member country new chemical notification forms and work is underway to develop a standardised form--for use by all OECD countries--based on these elements. If agreed, such a form would simplify reporting, reduce costs and facilitate data sharing across countries. A consultant report that analyses new chemical notification exclusions and exemptions is nearing completion. The purpose of this report is to determine whether there are opportunities for harmonizing these requirements across OECD countries. Finally, the Task Force has made tentative plans to hold a workshop in the fall to discuss the results of the multilaterals, the draft notification form, and how to proceed with work on low concern/exempt chemicals.



EXISTING CHEMICALS

The 11th OECD Screening Information Data Set (SIDS) Initial Assessment Meeting (SIAM11) was held in Orlando, Florida on 23rd-26th January 2001. This was the largest SIAM meeting held to date; with approximately 80 participants and 31 HPV Chemicals being discussed. It was also the first meeting to consider the input of a voluntary industry initiative announced in 1998 to provide assessments of HPV chemicals on 1000 chemicals by 2004 – the ICCA initiative. Conclusions were drawn on the potential hazards and recommendations on whether or not the chemicals are candidates for further work at the national, regional or international level were finalised for 28 of the 31 chemicals; all 11 of the ICCA initiative chemicals were finalised. One of the positive outcomes of the meeting was that Member countries accepted the assessments made by industry, were able to reach conclusions on the hazards of the selected chemicals and could make recommendations on their priority for further work. CEFIC published a press release after SIAM 11, in which Fred Webber, President of the ICCA Board said, “We are delighted that these first dossiers have been accepted. This has created a very positive impetus to our programme.

We can now generate the initial hazard assessment reports on all the HPV chemicals, confident that after discussion with member states they will be accepted for review by the OECD.”

The OECD is to make an evaluation of how to best use of the voluntary industry initiative to significantly increase the number of assessments agreed in OECD. This evaluation will be completed by the Joint Meeting in February 2002. The next Task Force meeting, on 25th-26th April in Paris, will undertake the first interim evaluation of this initiative. Further ICCA initiative chemicals are expected to be discussed at upcoming SIAMs in 2001.

Future Events:

- ◆ SIAM 12, 27th-29th June 2001, OECD, Paris;
- ◆ SIAM 13, 6th-9th November 2001, Bern, Switzerland.

PERFLORO OCTANYL SULFONATE (PFOS) AND ITS DERIVATIVES

A number of OECD countries together with industry, are undertaking work on PFOS in order to fully assess its environmental impact. A meeting was held January 2000, in Florida, USA at the request of the 31st Joint Meeting in order to consolidate assessment work being undertaken in a number of Member countries and by industry, and to finalise an OECD hazard assessment on this group of chemicals. The meeting agreed that the US and UK would jointly lead the activity with the overall aim to complete an OECD initial hazard assessment on this group of chemicals by mid 2001.

INTEGRATION OF WORK ACROSS THE PESTICIDES, BIOCIDES, NEW AND EXISTING CHEMICALS PROGRAMMES

The 30th Joint Meeting requested the Secretariat to explore areas where co-ordination and co-operation might be needed across the Pesticides, Biocides, New and Existing Industrial Chemicals Programmes. In response, a “brainstorming” meeting of experts from each of the programmes was held on 26th May 2000 in Paris. The meeting focused on three possible areas of work: harmonizing formats for data submission;

harmonizing formats for assessment reports; and developing approaches for electronic submission of data. Participants at the brainstorming meeting felt that the most benefit could be derived from working toward greater compatibility of formats for robust study summaries. This would be a long-term goal that could be achieved through the normal course of modifying existing formats. The 31st Joint Meeting expressed great interest in all three concepts, with universal support for work on robust study summaries. Delegates also identified benefits to exchanging information/experiences on electronic data submissions.

RISK MANAGEMENT

As a follow up to the 1998 London Workshop on integrating socio-economic analysis (SEA) into chemical risk management decision-making, work is currently underway to develop a “Technical Guidance” document on the application of SEA. Following review by a group of external experts, publication is expected by the end of the year.

An ad hoc group under the Issue Team on Socio-Economic Analysis held a Workshop on the “Convergence of Risk Assessment and Socio-economic Analysis to Better Inform Chemical Risk Management Decisions” from 1st-2nd May 2000 in the U.S. The intent was to foster better understanding and collaboration between economists and risk assessors and to examine possible solutions to issues of common interest.. A copy of the final workshop report is available at the web site for “Risk WORLD”:

<http://www.riskworld.com/Nreports/2000/RA-EAWorkshopMay2000.pdf>

In 2000, a questionnaire was distributed to OECD Member countries to collect information on models (computerised or capable of being computerised) for predicting health or environmental effects, exposure potential and possible risks. Over 60 questionnaires were completed. A database is being developed to manage this information, and it will be available on the OECD web site later this year.

The German government hosted the OECD *Workshop on Risk Communication for Chemical Risk Management and Special Sessions on Communicating PRTR Data and the Results of HPV Chemicals Activities to the Public* in Berlin

from 18th-20th September 2000. The main objective of the workshop was to collect information - in addition to that developed for the workshop background report that was based on a survey of Member countries, NGOs and industry - which could serve as input into the preparation of a guidance document on risk communication. Eighty-six participants attended, representing 13 Member countries and the European Commission. In addition to government representatives, other stakeholders who attended included representatives from: BIAC; the European Environmental Bureau; Consumers International; Consumers Japan; the Consumers Union (US); the Japanese Consumers' Co-operative; Euro Coop; European Trade Union; the World Wide Fund for Nature International; and members of the media and academia. The workshop focused on the following key themes of and approaches to risk communication: Risk Perception; Risk Communication Tools and Approaches; Public Involvement; and Resourcing for and Evaluation of Risk Communication. Based on the results from the workshop, a concise guidance document will be developed which will include practical approaches and principles, considerations and tools for risk communication.

In the fall of 2000, a survey was sent to Member countries and industry to collect information on current and planned activities in the area of research and development and education related to Sustainable Chemistry. A total of 70 responses were received from 13 countries and one international organisation. Using these results as background information, a workshop was held in Tokyo (11th-12th October 2000) hosted by Japan's Ministry of International Trade and Industry, co-sponsored by the governments of Japan and the US and held in co-operation with the Japan Chemical Innovation Institute. Fifty-four participants from seven Member countries representing academia, government and industry attended the workshop. Workshop participants developed a draft mid/long-range work plan for OECD work in this area, and developed a draft document entitled *Foundation for the Establishment of Programmes for Research and Development in the Context of Sustainable Chemistry*. This document will support Member government efforts to establish national programmes on sustainable chemistry R&D.

Future publications:

- 📖 *Collection and Recycling of Nickel-Cadmium Batteries; Experiences of OECD Countries;*
- 📖 *Technical Guidance Document on Conducting Socio-Economic Analysis;*
- 📖 *Guidance Document on Risk Communication in the Context of Chemical Risk Management.*



POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRs)

Two key PRTR documents were published since the last EHS newsletter was issued. The first is a report on OECD Member country progress in implementing a PRTR [*PRTR Implementation: Member Country Progress*; ENV/EPOC (2000)8]. It describes the remarkable pace at which Member countries are implementing PRTRs. This report, which responds to an instruction in the PRTR Council Act for the Environment Policy Committee to review actions taken by Member countries to implement a PRTR and to report on progress of Member countries in implementing a PRTR, is available on the PRTR public web site:

<http://www.oecd.org/ehs/prtr/index.htm>

The second document, *Presentation and Dissemination of PRTR Data: Practices and Experiences*, provides information and examples of Member country activities to present and disseminate PRTR information. The dissemination of data to the public is an essential part of a PRTR. This document gives governments, industry reporters and non-governmental organisations an important tool to help them more effectively implement the public right-to-know aspect of a PRTR.

OECD work on PRTR release estimation techniques (RETs) has advanced at a good pace. Activities at the OECD level are intended to help countries reduce resources spent to find and adapt techniques used in other countries. The 30th Joint Meeting established a Task Force on PRTR release estimation techniques to co-ordinate and manage work in this area.

The first meeting of the Task Force on PRTR Release Estimation Techniques took place in

Stockholm on 15th September 2000. The primary objective of this meeting was to prepare a work plan for the Task Force. As a result of this meeting, a work plan containing eight projects was developed. Projects included in the work plan are based on recommendations from the 1999 Canberra Workshop on RETs. The project list includes:

- Create a resource compendium of release and transfer estimation techniques for point and diffuse sources;
- Establish a clearinghouse of release estimation techniques. (The US EPA will lead the first phase);
- Develop guidance on selecting and adapting release estimation techniques;
- Review emission factors;
- Establish an informal communication mechanism to enhance information sharing. (Environment Australia will lead this project.);
- Develop a guidance document on the development of RET communication tools. (Environment Australia will lead this project.);
- Conduct a study on potential uses of PRTR data;
- Review release estimation techniques. (US EPA will lead the initial stage.)

Prior to the meeting of the Task Force, a Joint Session of the PRTR Task Force and the Task Force on Environmental Exposure Assessment (EEA) took place. The purpose of this meeting was to explore potential links between the two work programmes. Several areas of work were identified for which continued co-ordination would be of value; in particular, the work on Emission Scenario Documents by the EEA Task Force and the work on Emission Factors and the work on the uses of PRTR data by the RET Task Force.

Forthcoming publications:

📖 *Resource Compendium of PRTR Release Estimation Techniques, Parts 1-3;*

📖 *Uses of PRTR Data;*

📖 *Selecting and Adapting PRTR Release Estimation Techniques;*

📖 *Release Estimation Techniques Communication Tools;*

📖 *PRTRs and Environmental Management Systems.*

Future events:

- *2nd Meeting of the Task Force on Release Estimation Techniques, 9th-11th April, 2001, Washington, D.C.;*
- *3rd Meeting of the Task Force on Release Estimation Techniques, 1st November, 2001, Ottawa.*

Website: <http://www.oecd.org/ehs/prtr>



PESTICIDES

Work Sharing

A successful OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews was co-hosted by the European Commission and the United States Environmental Protection Agency in Brussels 12th-14th February 2001. The Workshop was attended by over 90 participants representing 25 different countries, the European Commission, The Sahelian Pesticide Committee, FAO, WHO, Grower Groups and the Global Crop Protection Federation.

The purpose of the workshop was to explore ways to increase the efficiency of agricultural pesticide evaluations through improved international co-operation.

The main objectives of the workshop were to:

- share experiences;
- understand what governments, industry and other stakeholders expect to gain from work sharing;
- identify incentives and hurdles for work sharing;
- explore the ways in which these hurdles may be overcome;
- recommend practices and procedures for how work can be shared more routinely in the future; and
- identify ways in which the products from work sharing activities among OECD countries could be used by other countries and international organisations involved in pesticide assessment (e.g. IPCS/WHO, FAO).

Main conclusions

1. Work sharing works:
 - Work sharing is already happening and is supported.
 - More work sharing is possible and could be done more effectively.
 - Work sharing results are of higher quality and are more efficient.
2. Work sharing has wider international applications, for example it should be possible to share work with; JMPR and CODEX; the Rotterdam Convention on (Prior Informed Consent) PIC; and the forthcoming Stockholm convention on (Persistent Organic Pollutants) POPs. There are also increasing opportunities for sharing work between regions e.g. EU and NAFTA, and OECD and non-OECD countries etc.
3. Effective communications, planning and commitment are essential to establish good work sharing practices. In addition, good communications help to build confidence and trust between work sharing partners, e.g. between government and government, government and industry, small country and large country, exporting and importing country, government and growers, etc.

Main Recommendations

1. A commitment from all stakeholders is needed to improve the process of work sharing and satisfy the growing public demand for effective chemical pesticides with increased human and environmental safety.
2. Transparency is needed to establish good work sharing practices and to help build confidence between stakeholders and develop public confidence in the process.
3. Investment, both in people and financial, is needed if work sharing is going to progress further.
4. Work sharing should become the normal way of doing things, and should receive a high level of support and promotion from senior government officials.
5. Work sharing projects initially should be simple and focussed on success in the short-term, whilst not losing sight of the longer-term objectives.
6. Improved global communications are needed. Existing platforms for communication should be used and enhanced, e.g. OECD.

7. The harmonisation process should be accelerated where appropriate.
8. Strategic planning is required to ensure better co-ordination between governments, industry and grower groups. Better planning would help streamline the co-ordination of evaluations of new and existing substances.
9. An infrastructure should be developed to facilitate work sharing.
10. Flexibility is important, including a willingness to accept and agree that there are differences between different stakeholders. The final outcome can be a decision at the national level.

The OECD Working Group on Pesticides, at its June 2001 meeting, will prioritise these recommendations and develop a work plan for future projects on improving work sharing activities globally.

Future events:

The second meeting of the Joint OECD/FAO Zoning Steering Group (ZSG) will take place in Paris, March 29th–30th 2001. The 11th Meeting of the Working Group on Pesticides, held in November 2000, agreed with the pragmatic approach suggested by the ZSG on a series of steps for dividing the world into zones for residue trials designed to help set acceptable levels of pesticide residues in food. The purpose of this second meeting is to discuss the progress made to date and to agree a future work plan.

Obsolete Pesticides

The OECD-FAO-UNEP Workshop on Obsolete Pesticides (September 2000) warned that the problem of obsolete pesticides in developing countries is urgent, and that concerted action is needed to address it.

The workshop was intended to raise awareness about the problem of obsolete pesticides and to make recommendations and inspire commitments for action. This was the first time that people from all sides of the issue had come together in such a forum. And they did so in an extremely positive spirit of co-operation.

The workshop was hosted by the US Environmental Protection Agency and organised by the OECD Working Group on Pesticides,

OECD Development Assistance Committee Working Party on the Environment, FAO Obsolete Pesticide Programme, and UNEP Chemicals Programme. Seventy people attended, including representatives of obsolete pesticide projects and agencies for pesticide regulation, hazardous waste management, and aid and development from 15 OECD countries and 15 developing countries. Representatives from the European Commission, World Bank, Caribbean Environmental Health Institute, International HCH and Pesticide Association, Global Crop Protection Federation, Pesticide Action Network, and Secretariat of the Basel Convention also attended.

As described in the last issue of this newsletter, stocks of obsolete pesticides, often abandoned, unlabelled and improperly stored, are posing serious health and environmental risks in virtually all developing countries and countries with economies in transition. FAO and others have undertaken projects to dispose of the stocks and prevent new ones from accumulating. But the workshop participants agreed that much more is needed. Delay will make the problem more expensive and difficult to solve, as the pesticides spread farther into surrounding land and water.

The workshop made recommendations for those most involved in the obsolete pesticide issue - developing and transitional countries, pesticide donor countries and aid agencies, pesticide producers, non-governmental organisations, and international organisations - and gave examples of how they could work together. The new IOMC Co-ordinating Group on Stocks of Obsolete Pesticides and Industrial Chemicals has agreed to track progress in implementing the workshop's recommendations, and to report the results to the OECD Working Group on Pesticides.

The workshop report, including a description of the obsolete pesticide problem, as well as recommendations for action, is available in English and French at:

<http://www.oecd.org/ehs/pesticid.htm>.

Guidance Documents on Registration

The OECD Working Group on Pesticides has recently approved the revised versions of the two guidance documents:

- Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances (*Dossier Guidance*); and
- Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances (*Monograph Guidance*).

The first guidance document is used by pesticide companies when they apply for registration of a chemical pesticide (i.e. the companies submit a 'dossier'); the second one is used by governments when they review the data submitted by the pesticide companies (i.e. the governments write a 'monograph'). Both OECD documents provide guidance on the structure (format and presentation) of the dossiers and the monographs.

The Working Group on Pesticides first approved these two guidance documents in 1998 and slightly revised them in 1999. The new revised versions are not drastically different from the original ones but they now include more detailed examples of study summary reports (i.e. Tier-II summaries examples are given in Appendices 7 and 8 of the dossier guidance). No further revision of the two guidance documents is expected for several years, in order to allow industry and governments time to gain experience with using the new documents.

The two new revised guidance documents, dated March 2001, will be soon put on the Internet site at:

<http://www.oecd.org/ehs/PestGD01.htm>

Biocides

Programme Prioritisation

During the November 2000 meetings of the Working Group on Pesticides (WGP) and the Joint Meeting, the OECD Biocides Programme was refocused. The original programme of work as agreed by the June 1999 WGP meeting (Document ENV/JM/PEST(99)2) contained work in the following six areas.

- (i) harmonisation of data requirements;
- (ii) hazard/risk assessment - initial focus on developing guidance for exposure assessment;
- (iii) efficacy - guidance on testing and assessment, and acceptability criteria;

- (iv) development of test guidelines for fate and effects (human health and environmental);
- (v) co-operation among countries in biocide reviews;
- (vi) risk reduction - information exchange.

In the refocused programme work in the areas of exposure assessment and efficacy were given priority. Specifically, it was agreed that the objectives for the work in the priority areas should be:

Exposure Assessment

- the development of the environmental Emission Scenario Document (ESD) for wood preservatives building on the recommendations of the OECD Belgirate Workshop (see Section following);
- at a later stage, the development of such environmental ESDs for biocide product types other than wood preservatives.

Efficacy

- the development of guidance for efficacy testing and assessment, and
- work towards harmonisation of pass/fail criteria.

Exposure Assessment – Follow-up of two workshops

The September 2000 meeting of the Biocides Steering Group (BSG) and the November 2000 of the Working Group on Pesticides (WGP) reviewed the recommendations for further work from both OECD workshops on exposure assessment to wood preservatives, held the first half of 2000. Priority was given to developing an OECD Environmental Emission Scenario Document for wood preservatives based on the Belgirate Workshop conclusions. This document will cover emissions from 1) the application of wood preservative to wood, and storage of treated wood (before use); 2) treated wood in service. An expert group was nominated by the BSG to carry out this work. It consists of experts from Canada, France, Denmark, Germany, Netherlands, Switzerland and industry. The development of the ESD is jointly overseen by the BSG and the Task Force on Environmental Exposure Assessment. The Expert Group had its first meeting on 26th-28th February 2001 and will

have a second meeting on 28th-30th May 2001. It aims to submit the first draft ESD to the BSG and Task Force with the request to allow a wide circulation to all OECD Member Countries by June 2001.

Recent Publications:

- 📖 *Report of the OECD Workshop on Environmental Exposure Assessment to Wood Preservatives, 10-12 April 2000, Belgirate, Italy;*
- 📖 *Report of the OECD Workshop on Human Exposure Assessment to Wood Preservatives, 19-21 June 2000, Ottawa, Canada.*

Both workshop publications are available at:

<http://www.oecd.org/ehs/Biocides/index.htm>

Efficacy-Workshop on Biocide Issues

The efficacy of biocides products was given high priority in the refocused Biocides Programme. Therefore, the United States Environmental Protection Agency (USEPA) offered to host a Workshop on efficacy issues of certain biocides (those carrying public health claims). The tentative date for the Workshop is late 2001/early 2002 to be held in the USA. The Workshop objectives will be to:

- 1) exchange information on efficacy testing methods, product claims, and performance standards or acceptability criteria used by OECD Member countries to regulate specific biocides;
- 2) begin discussions on areas of critical scientific interest (e.g. impregnation of materials with biocides); and
- 3) determine those regulatory and scientific areas where harmonization has not occurred or could be achieved.

It is expected that this workshop will contribute considerably to achieving the objectives of the Biocides Programme in this area.

The Biocides Steering Group (BSG) agreed that a Workshop Organising Committee should be formed with members from OECD countries and from industry. Membership of this committee has now been agreed and a first meeting is planned for mid May.

Risk reduction

The OECD Working Group on Pesticides exchanges information on their national risk reduction activities from biocide use. Updates on countries' activities are available on the Biocide Programme web site:

<http://www.oecd.org/ehs/Biocides/BioRRupd.htm>

Future Events:

- ◆ 2nd meeting of the Expert Group for developing the Emission Scenario Document for wood preservatives, 28th-30th May 2001, OECD, Paris;
- ◆ 1st meeting of the Organising Committee for the OECD Workshop on Biocide Efficacy Issues, 14th-15th May 2001, OECD, Paris;
- ◆ 5th meeting of the Biocides Steering Group, September 2001, Washington, USA.

OECD Database on Pesticide and Biocide reviews

The internet version of the database is expected to be available by April 2001. At first only the OECD Member countries governments will have access to the database. However, to increase collaboration with the non-OECD countries, contact names of the OECD regulatory government officials will also be placed on the OECD pesticide public site.

Forthcoming publications in the Series on Pesticides:

📖 *Guidance Notes for Analysis and Evaluation of Repeat Dose Toxicity Studies (no. 10).*



CHEMICAL ACCIDENTS

Audits and Inspections

More than 100 experts attended the recent Workshop on Audits and Inspections (Madrid, 6th-9th March 2001). This workshop, co-sponsored by the European Commission, provided an excellent opportunity to hear about participants' experience of (industry) audits and (government) inspections. Speakers from OECD governments, industrial organisations, research

institutes and accreditation companies made very interesting presentations on:

- Audits and follow-up;
- Inspections and enforcement;
- Relationships between audits and inspections (and between industry and public authorities);
- Co-operation among inspection authorities (within a country);
- How audits and inspections may contribute to improvements.

These presentations generated a lot of ideas and led to lively discussions among the participants. In addition, the Workshop helped improve trust between public authorities and industry (as well as other stakeholders). Participants recognised that more events of this kind could contribute to improved levels of safety in hazardous installations.

Environmental Consequences of Chemical Accidents

The Working Group on Chemical Accidents held a one-day session on 28th November 2000 to look at the environmental aspects of chemical accidents. The session brought together 35 participants and examines the areas of:

- Prevention and Preparedness, with a focus on risk assessment methods and practices used to identify and evaluate environmental aspects of potential accidents; and
- Response and Post-Accident, with a focus on accident response, reporting and post-accident studies and their impact on the environmental aspects of risk assessments.

Conclusions and recommendations of these two events (the "workshop on audits and inspections" and the "session on environmental consequences of chemical accidents"), will be published and will provide input for the on-going revision of the OECD *Guiding Principles for Chemical Accident Prevention Preparedness and Response*.

Future Events:

- ◆ Fifth Meeting on the Revision of the Guiding Principles, Rome, 7th-8th May 2001;
- ◆ Fifth Meeting on Safety Performance Indicators, Rome, 9th-10th May 2001;

- ◆ Third CARAT training session for data entries, Bilthoven, 7th-10th May 2001;
- ◆ Workshop on Integrated Management Safety, Health, Environment and Quality, Seoul, 26th-29th June 2001;
- ◆ 11th Meeting of the Working Group on Chemical Accidents, OECD, Paris, 7th-9th November 2001.

Recent and Forthcoming publications in the Series on Chemical Accidents:

- 📖 *Report of the OECD Workshop on New Developments in Chemical Emergency Preparedness and Response, Lappeenranta, Finland, 3rd-6th November 1998, (No. 5);*
- 📖 *Report of the OECD Expert Meeting on Acute Exposure Guideline Levels (AEGs) (No. 6).*

BIOTECHNOLOGY

The OECD completed its response to the request of the G8 Heads of State and Government last year, to “undertake a study of the implications of biotechnology and other aspects of food safety...”. The results of this study fed into the G8 Summit held in Okinawa, Japan, in July 2000. These reports have been posted on OECD's web site at:

http://www.oecd.org/subject/biotech/g8_docs.htm

and the communiqué of the Okinawa Summit is available at the address:

<http://www.g8kyushu-okinawa.go.jp/e/documents/commu.html>.

The Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

The Working Group held a workshop in Charmey, Switzerland, 2nd-4th October, on Unique Identification Systems for Transgenic Crops. A major objective of the Workshop was to identify ways of improving the database of biotechnology products, which have been approved in OECD countries. This database is part of the OECD's information system, BioTrack Online. The Workshop also discussed methods of developing a unique identification system for transgenic plants that could be used within the product database. The conclusions and recommendations of the Workshop will be discussed further at the

10th meeting, to be held in June 2001. The Workshop report is being published.

The first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) was held in Montpellier, France, from 11th to 15th December 2000. The outcome of the discussions on the Biosafety Clearing House (BCH) were of particular interest to the Working Group. A key paragraph from the report on the BCH is as follows:

“The ICCP recommends to the Executive Secretary, that during the pilot phase use is made of existing information systems, such as the use of the ICGEB database and the OECD/UNIDO databases, including the product database, as models for implementing the obligations under Articles 10 and 11.1 of the Biosafety Protocol.”

The Working Group continues to develop its consensus documents that include technical information used in the regulatory review of biotechnology products. The information used in these documents is mutually acceptable among OECD Member countries. The most recent publications are indicated below.

In addition, the Working Group, along with the experts from non Member countries, is preparing for the international conference on the environmental impact on living modified organisms, proposed by the EPOC and encouraged by the OECD Council Ministerial.

Future events:

- ◆ 10th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 6th-8th June 2001;
- ◆ International Conference on the Environmental Impact of LMOs (November 2001 in the United States).

Recent publications: two consensus documents related to plant biosafety:

- 📖 *Consensus Document on Biology of Populus L. (Poplars);*
- 📖 *Consensus Document on the Biology of Glycine max (L.) Merr. (Soybean).*

Upcoming publications:

- 📖 *Consensus Document on the Biology of Sugar beet;*
- 📖 *Consensus Document on the Biology of European White Birch.*

The Task Force for the Safety of Novel Foods and Feeds

The most recent activity of the Task Force for the Safety of Novel Foods and Feeds was a Workshop on the Nutritional Assessment of Novel Foods and Feeds, which was hosted by Health Canada in Ottawa, Canada, 5th-7th February 2001. Participants were asked to review and make recommendations in the following key areas:

- Nutritional assessment as a tool to substantiate nutritional/efficacy claims and establishing safety;
- The challenges in assessing the nutritional value of future products for which compensatory changes are expected to occur in the plant;
- Whether there is a need to move to a total diet consideration in contrast to the current approach that focuses at the single food/feed product level; and
- The identification of novel livestock feed particularities compared to those of novel foods.

The results of the Workshop will be discussed at the next meeting of the Task Force to be held in May 2001.

The Task Force is continuing its work on consensus documents, which are complementary to those of the Working Group, and which identify the critical nutrients and critical toxicants associated with major crop plants. The first two consensus documents, one on soybean and the other on canola/ oilseed rape, is being published.

Future events:

- ◆ Fourth Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 21st-23rd May 2001.

Upcoming publications:

- 📖 *Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed;*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Antinutrients.*

Web site: BioTrack Online
<http://www.oecd.org/ehs/service.htm>

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INTERNET

The EHS web site continues to grow. A new addition is:

- New Industrial Chemicals Information Directory
<http://www.oecd.org/ehs/NewChem/index.htm>

You can find out more information about the work of the EHS Programme from our homepage and related linked pages on the Internet:

- EHS Homepage
<http://www.oecd.org/ehs/>
- Chemicals Programme
<http://www.oecd.org/ehs/chem2.htm>
- Pesticide Programme
<http://www.oecd.org/ehs/pesticid.htm>
- Chemical Accidents Programme
<http://www.oecd.org/ehs/accident.htm>
- BioTrack Online
<http://www.oecd.org/ehs/service.htm>

Most EHS Publications can be downloaded directly from the web site:

- <http://www.oecd.org/ehs/ehsmono/>

📖 Most publications can be obtained free-of-charge from the Secretariat:

- Fax: 33-1-45 24 16 75,
- OLIS, or
- <mailto:ehscont@oecd.org>



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CHEONG, Hoe-Seog	Environmental Outlook and Strategy (EOS)	17.37
CORMIER, Wendy	Test Guidelines	16.74
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