

Introduction

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.

This edition is now available on the Internet as a “live-link” version.

☺ STAFF IN THE EHS DIVISION ☺

Since the last Environment, Health and Safety News (No. 15, issued in November 2003), the EHS Division has seen the following changes in staffing:

- In the *Test Guidelines* area, Drew Wagner took up duty as principal administrator in February 2004. Jennah Huxley, who provided secretarial support to the team, left in May when Keri Aspegren returned from maternity leave. Pilar Prieto joined in May on secondment from ECVAM and will work with us until September 2004. Hans-Christian Stolzenberg, who replaced Anne Gourmelon during her maternity leave, left at the end of June.
- Mar Gonzalez joined the *Biosafety* team in May 2004, as did Wendy Cormier who came from the Test Guidelines team as secretarial support when Alexia O’Hare left in May. Wendy also works on Chemical Accidents.
- Fanny Blanchet de la Lande arrived in June and is working with Bob Diderich on HPV until the end of August.
- Administrative assistant Bonnie Schaefer left EHS in February 2004 and has been replaced by Lisa Eveleigh.



TEST GUIDELINES

The 36th Joint Meeting endorsed an approach whereby wide-ranging discussions would be conducted within the OECD, including with the members of the Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT), the EDTA, and other stakeholders, on the desired focus and priorities of the Test Guidelines Programme, and the processes involved in the development and revision of Test Guidelines. The issues relating to the process of developing Test Guidelines include the impact of validation and peer review processes on the timely development of Test Guidelines, and the capacity of the Secretariat and member countries to continue to deliver practical end products in the TG Programme. The Chairman asked the Secretariat to develop a policy paper for the Joint Meeting in June 2005, following consultation with the appropriate OECD Working Groups and Task Forces. This issue was discussed at WNT16, and an Expert Consultation meeting will be organised in early 2005 to draft a report to the 38th Joint Meeting.

The draft OECD Guidance Document No. 34 on the ‘Validation and International Acceptance of New and Updated Test Methods for Hazard Assessment’ is currently under revision. Following the submission of

considerable comments on this draft document by member countries, the WNT agreed to conduct an Expert Consultation meeting to revise the draft. The USA has offered to host the meeting in October 2004. On a related note, Germany hosted an OECD Workshop on Data Interpretation Procedures (DIP) in early July 2004, based on the recommendations from the 2002 Stockholm Conference on Validation and Regulatory Acceptance of New and Updated Methods in Hazard Assessment. The outcomes of this conference will be considered in the revision of Guidance Document 34.

In April 2004, Council approved 14 new and updated Test Guidelines, which are being prepared for publication as the 15th Addendum.

New Test Guidelines:

- TG 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment;
- TG 219: Sediment-Water Chironomid Toxicity Using Spiked Water;
- TG 220: Enchytraeid Reproduction Test;
- TG 222: Earth Worm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*);
- TG 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test;
- TG 312: Leaching in Soil Columns;
- TG 427: Skin Absorption: In Vivo Method;
- TG 428: Skin Absorption: In Vitro Method;
- TG 430: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER);
- TG 431: In Vitro Skin Corrosion: Human Skin Model Test;
- TG 432: In Vitro 3T3 NRU Phototoxicity Test.

Updated Test Guidelines:

- TG 111: Hydrolysis as a Function of pH;
- TG 117: Partition Co-efficient (n-Octanol/Water): High performance Liquid Chromatography; (HPLC) Method;
- TG 202: *Daphnia* sp.: Acute immobilisation Test.

At WNT16 a number of new and revised Test Guidelines and Guidance Documents were finalised (some requiring some further minor technical amendments), and these will be provided to the Joint Meeting for endorsement. The Test Guidelines and Guidance Documents agreed by the WNT were:

- TG 104: Vapour Pressure;
- TG 123: Partition Co-efficient (1-Octanol/Water): Slow-Stirring Method;
- TG 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test;
- TG 221: Lemna Sp. Growth Inhibition Test;
- TG 425: Acute Oral Toxicity: Up and Down Procedure;
- TG 310: Ready Biodegradability – CO₂ in Sealed Vessels (Headspace Test);
- TG 311: Anaerobic Biodegradation of Organic Compounds in Digested Sludge – By Measurement of Gas Production;
- Guidance Document: Part 1 of the revised introduction to the OECD Guidelines for the Testing of Chemicals Section 3 “Degradation and Accumulation”: “Principles and Strategies Related to the Testing of Degradation Organic Chemicals”;
- Guidance Document No. 20 on Neurotoxicity Testing.

WNT16 also considered the priorities assigned by member countries on a number of new project proposals and agreed to add several proposals to the Rolling Workplan of the Test Guidelines Programme. These are: Project 2004/2.18 (New Guideline for the Determination of the Inhibition of the Activity of Anaerobic Bacteria - Reduction of Gas Production from Anaerobic Sewage Sludge), led by the UK, Medium (M) priority; Project 2004/2.19 (Fish Embryo Toxicity Test), led by Germany, Medium/High (M/H) priority; Project 2004/2.20 (Enhanced Test Guideline 211: *Daphnia Magna* Reproduction Test), led by Japan, Medium (M) priority; Project 2004/3.11 (New Guideline for a Litter Bag Test (Soil organic matter breakdown)), led by Germany, Medium (M) priority.

The WNT Chair, Dr. Maurice Zeeman of the USA, stepped down from that position following WNT 16. Members elected Dr. Otto Meyer from Denmark as the interim Chair until WNT 17, at which time there will be a call for nominations for a chair and vice-chair for the next three-year period.

Forthcoming events:

- Meeting of the Expert Group on Avian Avoidance and Dietary Toxicity, 9-10 September 2004, York, UK;
- Ad-hoc Expert Meeting on Terrestrial Plant Testing, 4-5 October 2004, Paris;
- 17th Meeting of the Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT17) proposed for 12-14 April 2005;
- Expert Consultation for the revision of Guidance Document 34, Validation and International Acceptance for New or Updated Test Methods for Hazard Assessment, 13-15 October 2004, Bethesda, USA.



ENDOCRINE DISRUPTERS TESTING AND ASSESSMENT

The validation of the Fish Screening Assay is proceeding (Phase 1B) in 14 laboratories from 7 OECD member countries. The objectives of this phase are to establish the sensitivity and reproducibility of the assay using weak chemicals with different modes of action (estrogen, androgen, aromatase inhibition), and applying the protocol in various laboratories. The results will be discussed at the Third Meeting of the Validation Management Group for Ecotoxicity Testing (VMG-eco 3) on 21-22 October in Paris.

The *Ad hoc* Expert Group on Amphibian Testing met in Paris on 28-29 June and reviewed the outcome of Phase 1 of the validation of the Amphibian Metamorphosis Assay for thyroid disruption. A common approach for the protocol has been agreed and will be applied in Phase 2, using three substances. The Expert Group will make a proposal to the VMG-eco for approval for the next validation step in September. This proposal will be accompanied by a call for possible additional participating laboratories. Phase 2 of the experimental work will be launched in November 2004.

Activities on Invertebrate Testing are on-going for the validation of a Copepod Test, that could be used (but not specifically) for the detection of endocrine disruption in aquatic arthropods; other assays are also considered and the progress made will be reviewed at a next meeting of the Ad hoc Expert Group on Invertebrate Testing (date to be agreed).

The validation program for the uterotrophic bioassay covering oestrogen and antiestrogen screening has been conducted. All reports and publications are finalised, and an independent peer review of the programme has been carried out. The peer review report has been discussed by the Peer Review Panel (PRP) and will be finalised and forwarded to the EDTA for consideration. A draft test guideline will be prepared and distributed for comment, subject to comments from the WNT.

The validation for the Hershberger bioassay covering androgen and antiandrogen screening has entered the final phase, using coded positive and negative substances. Completion is expected in September 2004. To address possible animal welfare concerns and avoid surgery, preliminary work on an alternative version has begun with completion of the initial work anticipated in October 2004. Reports for these projects will be drafted and submitted to the VMG-mammalian in December 2004.

The Validation Management Group for Non-Animal Testing (VMG-NA), previously agreed that four Detailed Review Plans (DRP) should be developed. The DRPs are anticipated to be available to the

Secretariat before the next VMG-NA meeting, which has been tentatively scheduled for the first week of November 2004.

Forthcoming events:

- Third Meeting of the Validation Management Group for Ecotoxicity Testing (VMG-eco 3), 21-22 October 2004, Paris;
- Meeting of Expert Group on Avian Reproduction Testing, 13-14 November 2004, Portland, Oregon, USA.



(Q)SARS ([Quantitative] Structure-Activity Relationships)

The Expert Group on (Q)SARs ([Quantitative] Structure-Activity Relationships) will hold its second meeting in Paris in September 2004, back to back with the joint session of the New and Existing Chemicals Task Forces. The Expert Group is expected to finalise the report of the pilot validation exercise which was proposed at the international workshop in Setubal, Portugal in 2002 and which aims to refine the validation principles for (Q)SARs. After these principles are agreed, the meeting will discuss the plan for coordinating member countries' efforts to validate individual (Q)SARs.

The Expert Group will also review the draft guidance documents on the use of (Q)SARs in regulatory assessments, and consider the plan for developing a guidance document on the validation of (Q)SARs.

Forthcoming events:

- Meeting of the Expert Group on (Q)SARs, 20-21 September 2004, Paris.



TOXICOGENOMICS

After the Special Session on Toxicogenomics at the 33rd Joint Meeting in February 2002, the International Programme on Chemical Safety (IPCS) and OECD agreed to hold twin workshops to explore the use of genomic methods in hazard/risk assessment of chemicals and to discuss possible international activities related to this topic. The first workshop was organised by IPCS in co-operation with OECD in November 2003 in Berlin and focused on human health effects. The workshop identified the opportunities for genomic methods to refine the toxicological tests with additional endpoints and improved understanding of mechanisms of action, and recommended case studies using chemicals with sufficient data in both toxicogenomics and conventional toxicology. The second workshop is to be organised by OECD in co-operation with IPCS and will be held in Kyoto, Japan, on 13-15 October 2004. Its focus will be environmental effects.

Forthcoming events:

- OECD/IPCS Workshop on Toxicogenomics, 13-15 October 2004, Kyoto.



GOOD LABORATORY PRACTICE

The 7th OECD Training Course for GLP Inspectors was held in Brussels, 26-30 April 2004. This course, which was organised by the Belgian GLP Compliance Monitoring Authority and devoted to auditing field studies, was attended by 80 participants from OECD countries and non-member countries (Brazil, China, Israel, Latvia, Romania).

The Working Group on GLP met for the 18th time on 3-4 May 2004. The major items dealt with were the report on the on-site evaluation to Israel in the framework of its provisional adherence to the OECD Council Decisions on Mutual Acceptance of Data, the endorsement of an Advisory Document on the Application of the Principles of GLP to in vitro Studies, and the work of the Steering Group on the development of a continuing programme of on-site evaluation visits. The next meeting of the Working Group will be hosted by the United States in Orlando, Florida in February 2005.

Recent and Forthcoming events:

- 7th OECD Training Course for GLP Inspectors, 26-30 April 2004, Brussels;
- 18th Working Group on GLP, 3-4 May 2004, Paris;
- 19th Working Group on GLP, February 2005, Florida, USA



MUTUAL ACCEPTANCE OF DATA AND NON-MEMBER COUNTRIES

Slovenia fulfilled all the conditions to adhere to the OECD system for the Mutual Acceptance of Data in the Assessment of Chemicals in May 2004, making it the second non-member country after South Africa to join this multi-lateral agreement related to non-clinical safety studies required for regulatory purposes.

The Joint Meeting in November will consider the recommendations of the Working Group on GLP regarding the full adherence of Israel to the MAD Council Decisions. A workshop on MAD will be held in Shenyang, China in September with participation of several members of the Working Group on GLP.

Forthcoming events:

- MAD Workshop, 14-15 September 2004, Shenyang, China.



RISK ASSESSMENT

Seven emission scenario documents (ESDs) were published in June 2004. ESDs describe the sources, production processes, pathways and use patterns of chemicals with the aim of quantifying their emissions (or releases) from production, formulation, use (industrial use, professional use, private use of chemical substances/preparations), service life (use in articles) and recovery/disposal into water, air, soil and/or solid waste. The OECD Task Force on Environmental Exposure Assessment works on the development of ESDs for various industry and use categories. Updated information is invited from the users of the ESDs, and the Task Force periodically reviews such information.

The Expert Group on Multimedia Models finalised the Guidance Document on the Use of Multimedia Models Estimating Overall Environmental Persistence and Long-Range Transport. This document will also

be used for the identification of new POP substances under the UNEP Stockholm Convention. The Expert Group continues to work on a project to compare the estimates from different multimedia models.

The Expert Group on Reporting Summary Exposure Information finalised the Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure. This document will be used in reporting of the post-SIDS (Screening Information Data Set) activity to collect exposure information, and can be used in other international or national chemical assessment programmes.

Forthcoming events:

- Meeting of the Task Force on Environmental Exposure Assessment, 13-15 September 2004, Vienna.

Recent publications:

- 📖 Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure;
- 📖 Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-Range Transport;
- 📖 Emission Scenario Documents on Plastic Additives, Water Treatment Chemicals, Photographic Industry, Rubber Additives, Textile Finishing, Leather Processing, and Photoresist Use in Semiconductor Manufacturing.



EXISTING CHEMICALS

Two SIDS Initial Assessment Meetings were held: SIAM 17 (11-14 November 2003, Arona, Italy) and SIAM 18 (20-23 April 2004, Paris, France). Approximately 90 representatives from member countries, industry, environmental NGOs and IPCS attended both meetings. Assessments for 39 and 78 chemicals were agreed on at SIAM 17 and SIAM 18 respectively. The conclusions and recommendations for these chemicals have been or are being endorsed by the Task Force on Existing Chemicals and the Joint Meeting through written procedure. The SIDS Initial Assessment Profiles of these chemicals are available on the publicly accessible OECD HPV Database [<http://cs3-hq.oecd.org/scripts/hpv/>].

The OECD Workshop on the Development and Use of Chemical Categories in the HPV Chemicals Programme was held in Brussels, Belgium, hosted by BIAC, on 29-30 January 2004. The conclusions and recommendations will be used to revise and improve the current guidance on the development and use of chemical categories as outlined in the *Manual for Investigation of HPV Chemicals*.

UNEP Chemicals published initial assessments for 27 chemicals in February 2004 and for 29 chemicals in April 2004 on their website: [<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>]. Since February 2004 assessment reports are published on the internet and paper copies are no longer produced. UNEP Chemicals also distributes CD-ROMs with all the published assessments which are available free of charge from UNEP Chemicals and from the OECD Secretariat. A further batch of assessments for 70 chemicals has been sent to UNEP Chemicals and is currently in preparation for publication.

Following the discussions at previous SIAMs and at the meeting of the Task Force on Existing Chemicals in October 2003, several chapters of the *Manual for Investigation of HPV Chemicals* have been updated and the revised chapters are available on the public OECD internet site:

[http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_37465,00.html]

The functions of the OECD HPV database have been modified as follows:

- The line for the recommendation has been removed from "SIDS Relevant Information" to avoid using the recommendation without the rationale, which may lead to misunderstanding;
- Direct links to each reference which is shown in "Existing Report" are now ready for use, allowing users to go to relevant websites directly from the HPV database without additional searches.

EXICHEM 2003 has been publicly accessible since mid 2004. The 2003 OECD HPV List is being developed and will be available by the end of 2004.

Development of a globally accessible data repository for HPV Chemicals (HPV Global Portal)

IFCS IV in Bangkok in November 2003 invited OECD to establish a detailed programme for an international repository on hazard information that would be available free of charge. Following the meeting of a Steering Group under the Task Force on Existing Chemicals for the development of such a data repository, the Joint Meeting agreed in February 2004 that OECD should consider this project. The United States and the European Commission are currently drafting governance rules, a project management plan and a requirements document. These will be presented and discussed in detail in September 2004 at the meeting of the Task Force on Existing Chemicals.

As currently envisaged, the data repository would consist of a single OECD internet site (HPV Global Portal). Data on HPV chemicals from different databases which share the same data structure would be linked to the portal and would therefore become accessible via a single query. The US-EPA and the European Commission databases for their national/regional chemicals programmes will be linked to the portal in a pilot phase. There are plans to extend this to other countries at a later stage.

Forthcoming events:

- 5th meeting of the IUCLID User Group Expert Panel, 7-8 July 2004, Paris, France;
- 13th Meeting of the Task Force on Existing Chemicals, 21-22 September 2004, Paris, France; (Combined Meeting of the Task Force on Existing Chemicals and the Task Force on New Industrial Chemicals Notification and Assessment will be held on 22 September 2004);
- SIAM 19, 19-22 October 2004, Berlin, Germany.



NEW CHEMICALS

In view of achieving Mutual Acceptance of Notification, the Task Force on New Industrial Chemicals Notification and Assessment is refining the concepts of Parallel process, Equivalence Framework and Predetermined set of Information. Work continues on revising its proposal on "working definitions" for key terms, and on notification exemptions and exclusions. A report on comparison of new Chemicals hazard/risk assessments, submitted at the May Task Force Meeting, is being revised for submission to the September Task Force Meeting. While work continues on hazard/risk assessment formats, specifications are being developed for notification forms and the flexible new system for new chemicals notification using a web browser.

Recent and Forthcoming Events

- 7th Task Force Meeting on New Industrial Chemicals Notification and Assessment, Paris, 24-25 May 2004;
- Meeting of the Expert Group on Work Element 1 (information sharing), Washington, 1-3 March 2004;
- 8th Task Force Meeting on New Industrial Chemicals Notification and Assessment, Paris, 21-23 September (combined meeting with the Task Force on Existing Chemicals on 22 September);

- Focus Session on New Chemicals at the 37th Joint Meeting, November 2004.



HARMONISATION OF CLASSIFICATION AND LABELLING SYSTEMS FOR CHEMICALS

The UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) requested that the OECD work on several proposals for addition to and revision of the GHS.

Three proposals have been agreed by the Task Force on HCL and declassified by the Joint Meeting. They will be officially submitted to the UN Sub-Committee of experts on the GHS at its July meeting. They are: (i) revising the terminology used in the GHS chapter on Reproductive Toxicity; (ii) Aspiration Hazards; and (iii) Respiratory Tract Irritation / Narcotic Effects. Two other proposals on (i) Reproductive Toxicity / Lactation; and (ii) revision of GHS Chapter 3.1 on Acute Toxicity and an issue paper on Environmental Terrestrial Hazards have been agreed at the Task Force Meeting held on 3-5 May 2004 and declassified by the Joint Meeting. They will be submitted to the UN SCE GHS at its July meeting for information and then to the December meeting for adoption.

Recent and Forthcoming Events:

- 13th Meeting of the Task Force on Harmonization of Classification and Labelling, Paris, 3–5 May 2004;
- Meeting of the Expert Group on Aquatic Environmental Hazards, Madrid, 25-26 March 2004;
- Meeting of the Expert Group on Sensitization Hazards, Paris, 5-6 May 2004;
- 14th Meeting of the Task Force on Harmonization of Classification and Labelling, Paris, 15-17 February 2005.

Recent Publications

- 📖 OECD Proposal for Classification and Labelling for Aspiration Hazards;
- 📖 OECD Proposal for Inclusion of Classification Criteria and Labelling for Respiratory Tract Irritation and Narcotic Effects;
- 📖 OECD Proposal for revision of GHS Chapter 3.7 with respect to terminology;
- 📖 OECD Proposal for inclusion of Classification Criteria and Labelling for mixtures with respect to lactation;
- 📖 OECD Proposal for revision of GHS Chapter 3.1 on Acute Toxicity (definitions for dust, mist and vapour; toxicity range estimates to point estimates; Respiratory Tract Corrosivity);
- 📖 Issues to be addressed to develop the Classification and Labelling for Terrestrial Environmental Hazards.



RISK MANAGEMENT

Hazard/Risk Information Sheets on Brominated Flame Retardants have been posted on the OECD public website for Pentabromodiphenylether, Octabromodiphenylether, Decabromodiphenylether, Hexabromocyclododecane and Tetrabromobisphenol A. These Information Sheets are to be updated regularly.

A questionnaire on the production and use of Perfluorooctane sulfonate (PFOS), Perfluoroalkyl sulfonate (PFAS), Perfluorooctanoic acid (PFOA), related substances and products/mixtures containing these

substances has been circulated to countries. Replies are requested by the end of July and a report compiling these will be submitted to the November Joint Meeting.

A brochure on Sustainable Chemistry has been posted on the public website. The Issue Team met in Berlin on 26 January and started work on the compilation of Sustainable Chemistry Assessment models. Countries are asked to provide updates to the list of Sustainable Chemistry R&D contacts by the end of August. The conclusions from the *Integrated Management of Chemicals, Products and Processes* workshop, held in Dessau, Germany in cooperation with OECD on 27-29 January, will be submitted to the November Joint Meeting.

The report of the OECD Workshop *Experiences and Perspectives of Service-Oriented Strategies in the Chemical Industry and Related Areas*, 13-14 November 2003 in Vienna (Austria), including conclusions from its Steering Group, will also be submitted to the November Joint Meeting.



CHEMICAL PRODUCT POLICY

Five participating countries carried out country surveys on *Identifying Problems associated with Exchanging Information across a Chemical Product Chain*. The results were presented at a workshop hosted by Sweden in Stockholm on 15-16 June 2004. Recommendations for improving information exchange across a chemical product chain and proposals for further work will be submitted to the November Joint Meeting.

Recent Events:

- CPP Workshop, Stockholm on 15-16 June 2004.



BIOCIDES

Work on the second ESD for biocides – on anti-fouling products – is nearing completion. This work, which is funded by the European Commission, focuses on products used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water. The OECD Steering Group on Anti-Fouling Products met in Ispra, Italy on 25 February 2004 to review the latest draft ESD. Following acceptance of the text by the European Commission, the draft ESD will be sent to experts in all OECD member countries for their comments, and then distributed, under written procedure, to Joint Meeting Heads of Delegation for declassification.

Test Guideline for Leaching of Wood Preservatives from Treated Wood

The ad hoc Expert Group under the then Biocides Steering Group which developed the wood preservatives Emission Scenario Document, identified the need to develop Test Guidelines to estimate the amount of biocides leaching from treated wood. Draft Test Guidelines have been prepared by drafting group WG 27 of the European Committee for Standardisation (CEN) and the OECD Secretariat for leaching of active ingredients from treated wood (both in and not in contact with water/soil). In response to the comments raised on these drafts, Germany has agreed to take the lead for “pre-validation” work to address the main issues. Once this work has been completed, the text will be revised and the guidelines will be submitted to experts in OECD countries for final comment followed by Joint Meeting review and adoption in 2005.

Efficacy

In April 2002, the USA hosted a workshop in Washington to exchange information on label claims, performance standards and efficacy testing parameters for biocidal products bearing public health claims that are used to control micro-organisms pathogenic to man. As follow-up to the workshop, work has begun which focuses on two types of biocidal products that have public health claims: (1) those used on hard surfaces; and (2) treated articles used as biocides. Funding for this work has been provided by the EC and the USA. This work will involve the collection and harmonisation of available test methods for these two product types together with the drafting of new methodology, if required. The contractors and Task Force on Biocides' subgroups responsible for these projects held a "kick-off" meeting on 30 January 2004 in Paris. A meeting has been scheduled for early November 2005 to discuss the interim report from the contractors. The final report will be completed in mid-2005.

Forthcoming publications:

- Emission Scenario Document (ESD) for Anti-fouling products.

Forthcoming meetings:

- Task Force on Biocides, 15-16 September 2004 (Vienna).
- Antimicrobial Efficacy Steering Group on Hard Surfaces/Efficacy Microbial Steering Group on Treated Articles, 3-4 November 2004, Brussels.



PESTICIDES

Development of Test Guidelines and Guidance Documents on Residue Chemistry

In 2003, the Working Group on Pesticides (WGP) initiated a new project on pesticide residue chemistry to develop a guidance document on the definition of the residue and four test guidelines: *plant metabolism*; *animal metabolism*; *animal feeding*; and *rotational crop studies*. Data derived from these guidelines will not only be used for regulatory purposes, but would also support FAO recommendations on Maximum Residue Levels (MRLs). An Expert Group has been established, composed of experts from Australia, Canada, Germany, Italy, Japan, the Netherlands, UK, USA (lead country), the EC, FAO, BIAC/CropLife International and OECD. The Group met for the first time in March 2004 in Washington and discussed the issues related to pesticide residue, i.e. how to identify and quantify pesticide residues/metabolites in crops and edible animal products (metabolism studies), how to measure residues which can be transferred to farm animals via feed (feeding studies), and how to measure possible residues in succeeding crops (rotational crops studies). The Group also discussed triggers and waivers on when or when not to conduct a specific study, crop grouping and selection of crops in plant studies and dosing in feeding studies. Five writing groups have started to prepare draft text for the four test guidelines and the guidance document. It is expected that the first drafts will be completed by October 2004. A second Expert Group meeting is tentatively planned for early 2005.

Study on Persistent and Bioaccumulative Pesticides

Following the publication of the report *Persistent, Bioaccumulative, and Toxic Pesticides in OECD Member Countries - Results of Survey on Data Requirements and Risk Assessment Approaches [ENV/JM/MONO(2002)22]*, the Netherlands agreed to take the lead in carrying out an examination of member country case studies to: (1) establish the capacity of different member country risk assessment and decision schemes to identify persistent and bioaccumulating substances; (2) establish the capacity of the decision making process to take persistence and bioaccumulation into account; and (3) establish the influence of the assessors' subjectivity to raw data interpretation and data selection. The Netherlands' analysis has now been completed, and the OECD report will be published in 2004.

A Vision for the Future: A Global Approach to the Regulation of Agricultural Pesticides

In February 2004, the Working Group on Pesticides and the Joint Meeting agreed to a ten-year vision for the harmonisation of regulatory approaches for agricultural pesticides (chemical and biological) to facilitate and promote the sharing of work between regulatory authorities. The highlight of this "Vision" is that by 2014, OECD countries will routinely accept dossiers prepared by stakeholders in the OECD format; will routinely exchange "monographs" containing reviews of the data submitted; and will use OECD "monographs" as a basis for independent risk assessments and regulatory decisions for new and existing pesticides.

Work-Sharing: Identifying Problems and Approaches for Overcoming these Problems

Under the auspices of the Registration Steering Group, in 2003 and 2004 various OECD member countries exchanged assessment reviews (human health, environmental health and environmental fate) to identify, through real examples, the similarities and differences between the government regulatory processes, study acceptability criteria, endpoint selection and study review documentation. Analyses of these joint reviews are currently underway to identify technical issues which are potential constraints to full "work-sharing". Since many pesticides used in OECD countries are the same, governments have recognised the substantial benefits that can be gained if the task of pesticide evaluations for registration and re-registration is shared. The current examination of parallel reviews is one of many activities OECD is undertaking to harmonise regulatory approaches to pesticide registration and to co-operate in sharing the work of pesticide review.

The Second Risk Reduction Survey

The year 2004 marks the 10th year of OECD's Working Group on Pesticides' work on risk reduction. The Risk Reduction Project surveyed the pesticide risk reduction activities being implemented in OECD and selected FAO countries with the aim of informing countries of other work underway and to initiate dialogue about approaches to risk reduction. The survey report was used as a starting point for the Workshop on Risk Reduction held in Uppsala, Sweden in 1995 which launched the Pesticide Risk Reduction Project. Almost a decade after the Uppsala workshop, the WGP has decided that to determine what has happened since and to identify gaps that could be filled by OECD activities. The WGP is therefore carrying out a Second Risk Reduction Survey to identify policies introduced, what worked, and what didn't, and their costs and benefit during the decade since the first survey. The members of the WGP are to send the survey responses by late September, and the findings will be discussed at the next meeting in November 2004.

Pesticide Risk Indicators

The Terrestrial Risk Indicator (TERI) Project was completed in early 2004. Terrestrial risk indicators help governments track trends in pesticide risk over time to terrestrial organisms and thereby measure progress in risk reduction. The TERI final report summarises the findings of pilot tests with four selected TERI indicators carried out by six participating countries (Belgium, Denmark, Germany, Italy, Norway, Switzerland) using national data. The project concluded that simple indicators are sufficient to track trends at a highly aggregated (e.g. national) level, as long as it is understood that indicators are "crude" tools to begin with. It was also noted that a more complex indicator is not necessarily a more accurate one. More reliable pesticides sales and use data are needed to improve the accuracy of these indicators. The Risk Reduction Steering Group approved the report, which will be considered at the next meeting of the WGP in November 2004 and then posted on the OECD web site.

The WGP participates in the EU-financed "HAIR" project (HARmonised environmental Indicators for pesticide Risk), which builds on earlier OECD work on aquatic risk and terrestrial risk indicators (ARI and TERI) projects. HAIR will develop, over the next three years, a set of harmonised environmental and human health risk indicators implemented by a computer software package. Some members of the Working Group on Pesticides participated in the HAIR project kick-off workshop held on 24-26 May 2004 in the Netherlands. Under the HAIR project, a proposal will be made for a joint workshop with the WGP to disseminate results at a later stage.

Risk Reduction Seminar Series

On 4 November 2003, the RRSg held a seminar on the issue of minor uses of pesticides in Canberra, Australia. "Minor use" pesticides are those used for pest control in a minor crop or for a small pest problem in a major crop. Minor uses can present registration issues because it is not always economically attractive for a pesticide registrant to maintain a small pesticide use that produces low revenue. This was the second in a series of seminars planned by the OECD Pesticide Risk Reduction Steering Group. The third seminar, held on 22 June 2004 in Bonn, Germany, focused on pesticide risk reduction through container management. These seminars provide an opportunity for OECD governments to discuss key issues related to pesticide risk reduction together with non-governmental stakeholders including farmers. The next seminars will be on labelling (Spring 2005) and application technology (Fall 2005).

Recent publications:

- 📖 Guidance for Registration Requirements for Invertebrates as Biological Control Agents (IBCA) – OECD Environment, Health and Safety Publication, Series on Pesticides, No. 21. [ENV/JM/MONO(2004)1];
- 📖 OECD Guidance for Country Data Review Reports on Microbial Pest Control Products and their Microbial Pest Control Agents (Monograph Guidance for Microbials) – OECD Environment, Health and Safety Publication, Series on Pesticides, No. 22;
- 📖 OECD Guidance for Industry Data submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials) – OECD Environment, Health and Safety Publication, Series on Pesticides, No. 23;
- 📖 Report of the Risk Reduction Seminar on Compliance, Environment, Health and Safety Publication, Series on Pesticides, No. 24. [ENV/JM/MONO(2004)6].

Forthcoming publications:

- Brochure: *A Global Approach to the Regulation of Agricultural Pesticides: A Vision for the Future*
- Case Study on the Assessment of Persistency and Bioaccumulation in the Pesticide Registration Frameworks in OECD Countries;
- Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Compliance and Risk Reduction, March 2003, Paris;
- Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Minor Use, November 2003, Canberra;
- Report of the OECD Project on Pesticide Terrestrial Risk Indicators (TERI).

Forthcoming Events:

- Registration Steering Group, 15 November 2004, Paris;
- Working Group on Pesticides, 16-17 November 2004, Paris;
- Workshop to Advance Work-savings, 26-28 January 2005, Washington DC.



CROSS-CUTTING ISSUES: NEW AND EXISTING INDUSTRIAL CHEMICALS, PESTICIDES AND BIOCIDES

The February 2004 Joint Meeting agreed that an Expert Group meeting should be held to: (i) examine existing templates used in member countries; (ii) determine the degree to which governments might be interested in pursuing work on harmonising specific templates (with electronic technologies), and, if

appropriate; (iii) prepare a proposal for further work which would be considered by the November 2004 Joint Meeting. (A “template” is a standard format or consistent approach used to summarise data contained in a test study report.)

The Expert Group met from 14-16 June 2004 in Paris to consider four draft harmonised templates covering four endpoints (varying in degree of complexity) which are fairly representative of the major areas of testing. These endpoint-templates are: skin irritation, repeat dose toxicity, acute toxicity to fish and hydrolysis. The Group also considered whether, and if so how, to develop harmonised templates for other endpoints beyond these four, and how electronic technologies could facilitate the sharing and archiving of data. The results of this meeting will be considered by the 37th Joint Meeting in November, 2004.



CHEMICAL ACCIDENTS

Guidance on Safety Performance Indicators

The *OECD Guidance on Safety Performance Indicators* was published in November 2003 as an interim document. It has been distributed widely via hard copy and is now available on the internet (http://www.oecd.org/document/45/0,2340,en_2649_34365_32425389_1_1_1_1,00.html). It will be tested in order to be sure that it is complete, and sets out an approach that can easily be applied by the various target audiences. To obtain the necessary feedback, an 18-month pilot study is being launched. About twenty volunteers belonging to the three main target groups (industry, public authorities and communities) agreed to try to implement the *Guidance on SPI* and provide feedback in a structured way. For this purpose, a feedback sheet is included in the web-based version of the SPI Guidance (<http://www2.oecd.org/safetyindicators/>), which allows users to send comments directly to OECD.

Chemical Accident Risk Assessment Thesaurus (CARAT)

CARAT (www.oecd.org/ehs/carat), an Internet data base of analyses of laws, regulations, guidance documents and definitions of terms related to the risk assessment of accidental releases of chemicals from fixed installations, was initiated by the Working Group on Chemical Accidents (WGCA) in recognition that it was difficult to communicate among countries about risk assessments.

The primary audience for CARAT is risk practitioners in government agencies, industry and consulting. The promotion and outreach efforts have been mainly targeted at members of the WGCA. The WGCA delegates have been requested (in preparation for a discussion at the 14th WGCA Meeting in November 2004 on the future of CARAT) to speak with various stakeholders in their countries in order to obtain additional information from the users outside of government on its utility and how it might be improved in the future or whether it should be eliminated.

Forthcoming Events:

- Workshop on *Lessons Learned from Chemical Accidents and Incidents*, 21-23 September 2004, Karlskoga, Sweden
- 14th Meeting of the Working Group on Chemical Accidents, OECD, Paris, 3-5 November 2004.

Recent publications:

-  *OECD Guidance on Safety Performance Indicators* – A companion to the *OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response*, 2nd edition published in June 2003. EHS publication, Series on Chemical Accidents, No. 11 (November 2003).

- 📖 Report of the Workshop on *Communication related to Chemical Releases Caused by Deliberate Acts* (25-27 June 2003, Rome, Italy). EHS publication, Series on Chemical Accidents, No. 12 (March 2004).
- 📖 Report of the Workshop on *Sharing Experience in the Training of Engineers in Risk Management* (21-24 October 2003, Montreal, Canada). EHS publication, Series on Chemical Accidents, No. 13 (March 2004).



POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRs)

New work areas

A Focus Session was held at the 36th Joint Meeting on possible future directions of OECD work on PRTRs. Five new working areas were proposed; 1) Products; 2) Small and Medium Size Enterprises (SMEs); 3) Environmental indicators; 4) Crosswalk between the waste specific and the chemical specific reporting of transfers; and 5) Socio-economic factors linked to PRTR data. The Task Force on PRTRs will report back to the Joint Meeting in June 2005 on the status and outcome of the scoping studies on these five new work areas.

Meetings of the Task Force

The Task Force on Pollutant Release and Transfer Registers (TF on PRTRs) met in Bath, United Kingdom on 21-23 June 2004. The new work plan for 2005-2008 was debated based on the outcome of the PRTR Focus Session at the 36th JM. The work plan will be presented to the 37th JM in November 2004.

Transfers

A special session on terms frequently used in relation to transfers was held at the Task Force meeting in Bath. The need to clarify certain terms arose in the context of finalising the “Resource Compendium of PRTR Release Estimation Techniques, Part 3: Transfers”. The meeting agreed to the “working definition” of certain terms that will be used in OECD PRTR publications.

Resource Centre for RETs

Canada had the lead on the development of a database to make PRTR release estimation techniques (RETs) widely available to the public. The database is called “Resource Centre for Release Estimation Techniques (RETs)” and is expected to be accessible via Internet by 1 October 2004. A link to the Resource Centre for RETs will be found on (<http://www.oecd.org/env/prtr>). The database is presently available only in English, but a French version will follow shortly.

Forthcoming Events:

- 8th Meeting of the Task Force on PRTRs, late April 2005, USA.

Forthcoming Publications:

- 📖 Resource Compendium of PRTR Release Estimation Techniques, Part 3: Summary of Techniques for Off-site Transfers;
- 📖 Evaluation framework for PRTR Release Estimation Techniques;
- 📖 Uses of PRTR Data; and
- 📖 Quality Assurance and Quality Control of PRTR data.



BIOSAFETY/BIOTECHNOLOGY

Harmonisation of Regulatory Oversight in Biotechnology

The 15th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held on 16-18 June 2004 in Paris and was attended by 60 participants from OECD member countries and 7 observers from non-member countries, the CBD Secretariat and BIAC.

The main objectives of the meeting were: i) follow up to the Washington Workshop on Review of Consensus Documents and Future Work in Harmonisation (October 2003); ii) identification of the next steps for the implementation of the unique identifier for transgenic organisms; and iii) the use of information on molecular characterisation for safety assessment.

Three main points emerged from discussion on the follow up to the Washington Workshop. A pilot scheme for priority-setting among consensus documents and other projects was finalised and delegates have agreed to participate in this before the next meeting of the Working Group (23-25 February 2005). The document “*Introduction to Consensus Documents*”, which describes the purpose of biosafety consensus documents and their drafting process will be forwarded to the Joint Meeting for declassification.

Significant progress was made on the “points to consider” document, which is intended for use by lead countries in drafting consensus documents. It outlines and explains the issues to include and will be completed at the next Working Group meeting.

The Working Group also considered a number of issues related to BioTrack. The draft Memorandum of Co-operation (MOC) with the Secretariat of the Convention of Biological Diversity (SCBD), which will replace an existing MOC, was discussed. This will define the information that OECD sends to the Biosafety Clearing House and will strengthen co-operation between the OECD and CBD Secretariats. This relates particularly to OECD’s Product Database (<http://www2.oecd.org/biotech/>).

Ninety-seven transgenic plant products have been assigned unique identifiers based on OECD’s guidance for designating unique identifiers. The issue of unique identifiers for micro-organisms was discussed and a document on options for advancing this issue is with member countries for their consideration before the next meeting.

The Working Group also considered a number of other harmonisation-related projects including: i) Molecular Characterisation; ii) Parameters for Environmental Risk/ Safety Assessment; and iii) Transgenic Fish. A draft operational plan for the project on molecular characterisation was agreed in co-operation with the Task Force for the Safety of Novel Foods and Feeds. A Steering Group, consisting of Canada (lead), Finland, France, Germany, Mexico, the Netherlands and the United States, will discuss the development of an operational plan and a project on “Parameters for Environmental Risk/ Safety Assessment”. Additionally, a Steering Group, consisting of Canada, Germany (lead), Norway, Sweden and the United States are currently finalising a detailed programme for a Workshop on “Transgenic Fish” that will take place in November in Moscow, Russia.

Finally, it was agreed that the 16th meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology will be held in Paris 23-25 February 2005.

Forthcoming Events

- Transgenic Fish Workshop. Moscow, Russia, November 2004.
- 16th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, Paris, February 2004.

Recent publications:

 Guidance Document on Methods for Detection of Micro-organisms into the Environment

Copies of the *Proceedings of the International Conference on LMOs and the Environment* which was held in the United States in November 2001 are available from the Secretariat on request.



SAFETY OF NOVEL FOODS AND FEEDS

During the recent months, the Task Force has completed its work on the safety assessment of animal feedstuffs derived from genetically engineered plants. It has also finalised a number of consensus documents, including those on cotton, rice, and barley. The cotton and rice documents were subsequently forwarded to the Joint Meeting for declassification. The barley document will be forwarded shortly.

The Task Force has also made progress on a number of other documents, including those on forage legumes, *Agaricus bisporus* (an edible mushroom), tomato, and sunflower. The project on molecular characterisation is being developed in collaboration with the Working Group for Harmonisation in Biotechnology.

At its next meeting in October 2004 the Task Force will also be considering how best to incorporate the needs of non-member countries in its work.

Forthcoming events:

- 9th Meeting of the Task Force for the Safety of Novel Foods and Feeds, October 2004, Paris.

Recent publications:

 Considerations of the Safety Assessment of Animal Feedstuffs derived from Genetically Engineered Plants.

INTERNET

You can find 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/>
- Chemical Accidents
<http://www.oecd.org/env/accidents>
- Harmonisation and Classification
<http://www.oecd.org/env/classify>
- Risk Assessment
<http://www.oecd.org/env/riskassessment>
- New Chemicals
<http://www.oecd.org/env/newchemicals>
- Risk Management
<http://www.oecd.org/env/riskmanagement>
- Test Guidelines
<http://www.oecd.org/env/testguidelines>
- Existing Chemicals
<http://www.oecd.org/env/existingchemicals>
- Good Laboratory Practice
<http://www.oecd.org/env/glp>
- Pesticides
<http://www.oecd.org/env/pesticides>
- Biocides
<http://www.oecd.org/env/biocides>
- Pollutant Release and Transfer Registers
<http://www.oecd.org/env/prtr>
- Biosafety
<http://www.oecd.org/biotrack>

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

http://www.oecd.org/findDocument/0,2350,en_2649_34365_1_1_1_1_1,00.html

 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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