

Environment, Health & Safety News

No. 20, March 2007

Introduction

The Environment, Health and Safety News is issued approximately every eight months, between the meetings of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. It aims 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. 19, issued in July 2006), the EHS Division has seen the following changes in staffing:

Administration: *Lisa Eveleigh* is on maternity leave until 01 June 2007 and is being replaced by *Barbara Ladeuille*.

Front Office: *Katherine Perkins* is currently replacing *Barbara Ladeuille* as Assistant to the Head of Division and is also working on administration issues.

Chemical Accidents, Communication and IT issues: During *Jill Gibb's* maternity leave until June 2007, *Jannah Huxley* is working on communication and IT issues as well as providing assistance to the Chemical Accidents Programme.

Existing Chemicals: *Wendy Cormier* returned to EHS and provides secretarial support to the Existing Chemicals Programme as well as PRTR, (Q)SAR and Exposure Assessment.

Outlook: *Nicolas Gagnon* left the OECD at the end of December 2006.

Pesticides, Biocides, New Chemicals and GLP: *Laurel Sanderson* is providing secretarial support to these programmes during *Katherine Perkins'* temporary assignment. *Judith Corcoran* left the Division at the end of February to take up a post in the Nuclear Energy Agency.

Test Guidelines, HCL: *Jacy McGaw* has rejoined EHS on temporary assignment replacing *Jannah Huxley* as Assistant to the Test Guidelines and HCL Programmes.

CHEMICALS PROGRAMME

TEST GUIDELINES

The Test Guidelines Programme develops Test Guidelines and related documents needed to undertake the first step in chemical regulation – testing for health and environmental hazards.

Test Guidelines

As of January 2007 all OECD Guidelines for the Testing of Chemicals are available free of charge from SourceOECD or from the OECD Online Bookshop:

[http://www.oecd.org/document/40/0/0%2C2340%2Cen_2649_34377_37051368_1_1_1_1%2C00.html].

The 17th Addendum was adopted by the OECD Council on 19 July 2006. It encompasses:

New Test Guidelines

- 227 Vegetative Vigour Test
- 435 In Vitro Membrane Barrier Test Method for Skin Corrosion

Updated Test Guidelines

- 208 Seedling Emergence and Seedling Growth Test

The 18th Addendum was adopted by the OECD Council on 10 January 2007. It encompasses:

New Test Guidelines

- 224 Determination of the inhibition of the activity of anaerobic bacteria – reduction of gas production from anaerobically digesting (sewage) sludge
- 501 Metabolism in Crops
- 502 Metabolism in Rotational Crops
- 503 Metabolism in Livestock
- 504 Residues in Rotational Crops (Limited Field Studies)
- 505 Residues in Livestock

Test Guidelines 501-505 are included in a new section of the OECD Guidelines for the Testing of Chemicals (Section 5: Other Test Guidelines).

Acute inhalation Toxicity

Work on acute inhalation toxicity is progressing. Two expert meetings were held in 2006; one in Berlin on 11-12 July and the other in Washington on 28-30 November.

Cell Transformation Assays

An expert meeting was held in Washington on 3-5 October 2006 to prepare the final draft of the Detailed Review Paper on Cell Transformation Assays which will be submitted for approval at the next meeting of the Working Group of National Coordinators of the Test Guidelines Programme (WNT).

Endocrine Disrupters

The Validation Management Group for Non Animal Testing was held on 12-14 December 2006 in Tokyo; the Validation Management Group for Mammalian Effects Testing was held on 17-18 January 2007 in Ljubljana; the Validation Management Group for Ecotoxicity Testing was held on 23-24 January 2007 in Madrid. The outcome of these meetings will be submitted to the Task Force on Endocrine Disrupters Testing and Assessment (EDTA) and to the Working Group of National Coordinators of the Test Guidelines Programme (WNT) in March 2007.

The summary report of the validation peer review of the Uterotrophic Bioassay has been published. The validation reports of the Hershberger Assay, of the updated TG 407: Repeated Dose 28-day Oral Toxicity Study in Rodents, and of the Stably Transfected Transformation Assay are under peer review.

Toxicogenomics

A questionnaire on available “omics” methods was sent to member countries in July 2006 and a report will be prepared in 2007. The OECD/IPCS Advisory Group on Toxicogenomics prepared the extended Advisory Group Meeting on the project “Molecular Screening for Characterizing Individual Chemicals and Chemical Categories”, which will be held in May 2007.













Preparation of the 19th WNT Meeting



Several draft Test Guidelines (TG) are being finalized for submission to the next WNT meeting in March [TG for the Uterotrophic Bioassay, TG on Sediment-Water *Lumbriculus* Toxicity, TG on Developmental Neurotoxicity, TG on Estimation of emissions from preservative-treated woods to the environment, TGs on Pesticide Residue Chemistry]. In addition, several draft Guidance Documents, Detailed Review Papers and Validation Reports are being finalised.

Forthcoming events:

- EDTA Task Force Meeting, 27-28 March 2007, Paris, France
- 19th Meeting of the Working Group of National Coordinators of the Test Guidelines Programme (WNT19), 28-30 March 2007, Paris, France
- Extended OECD/IPCS Advisory Group on Toxicogenomics, 24 May 2007, Research Triangle Park, United States

Recent publications:

-  17th Addendum to the OECD Guidelines for the Testing of Chemicals
-  18th Addendum to the OECD Guidelines for the Testing of Chemicals
-  Detailed Review Paper on Aquatic Arthropods in Life Cycle Toxicity Tests with an Emphasis on Developmental, Reproductive and Endocrine Disruptive Effects
-  Guidance Document on the Breakdown of Organic Matter in Litter Bags
-  Detailed Review Paper on Thyroid Hormone Disruption Assays
-  Report of the Validation of the Updated Test Guideline 407: Repeat Dose 28-Day Oral Toxicity Study in Laboratory Rats
-  Report of the Initial Work Towards the Validation of the 21-Day Fish Screening Assay for the Detection of Endocrine Active Substances (Phase 1A)
-  Report of the Validation of the 21-Day Fish Screening Assay for the Detection of Endocrine Active Substances (Phase 1B)
-  Final OECD Report of the Initial Work Towards the Validation of the Rat Hershberger Assay : Phase-1, Androgenic Response to Testosterone Propionate, and Anti-Androgenic Effects of Flutamide
-  Guidance Document on the Definition of Residue
-  Guidance Document on Overview of Residue Chemistry Studies
-  OECD Report of the Initial Work Towards the Validation of the Rodent Uterotrophic Assay - Phase 1

-  OECD Report of the Validation of the Rodent Uterotrophic Bioassay: Phase 2. Testing of Potent and Weak Oestrogen Agonists by Multiple Laboratories
-  Summary Report of the Uterotrophic Bioassay Peer Review Panel, including Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the follow up of this report

Contact: Laurence Musset

Website: <http://www.oecd.org/env/testguidelines>

GOOD LABORATORY PRACTICE

The primary objective of the OECD Principles of GLP is to ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations in the framework of the Mutual Acceptance of Data (MAD).


The Working Group on GLP met for the 21st time 27 February – 1 March 2007, in Auckland, New Zealand. Chinese Taipei and Singapore took part as ad hoc observers. Now that the Joint Meeting has established a continuing programme of on-site evaluations on GLP compliance monitoring programmes in member and adhering non-member countries, the Working Group dealt with aspects of scheduling and administration of the programme as well as reporting; the first ten-year cycle of on-site evaluations will begin in 2008. The Working Group also endorsed a draft Advisory Document on Establishment and Control of Archives that operate in compliance with the Principles of GLP. It will be submitted to the Joint Meeting for declassification in March.

Turkey presented its GLP compliance monitoring programme and the report of the Mutual Joint Visit to the Polish GLP compliance monitoring programme was discussed. The 9th OECD Training Course for GLP Inspectors, a basic training course, will take place in Tel Aviv in September 2008. Planning also began for an event to be held with industry in Rome in April 2008.

Forthcoming events:

- 22nd Meeting of the Working Group on Good Laboratory Practice, 8-9 April 2008, Rome, Italy
- Meeting with Industry, 10-11 April 2008, Rome, Italy

Recent Publications:

-  A volume comprising all of the documents in the series on GLP and Compliance Monitoring: Good Laboratory Practice: OECD Principles and Guidance for Compliance Monitoring, 28€ paperback, 19€ E-book

Contact: Dian Turnheim

Website: <http://www.oecd.org/env/glp>

MUTUAL ACCEPTANCE OF DATA AND NON-MEMBER COUNTRIES

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and Good Laboratory Principles (GLP). It requires OECD governments to accept chemical test data developed for regulatory purposes in another country if these data were developed in accordance with the Test Guidelines and GLP Principles, thus increasing efficiency and effectiveness of chemical notification and registration procedures for governments and industry. A 1989 Council Decision-Recommendation on Compliance with GLP sets the framework for recognition of compliance assurance among governments. The MAD system has been open to non-OECD countries since 1997.

Argentina and Singapore have been invited by the Council to become provisional adherents to the Council Acts related to MAD; and Council will deal with a request by Brazil soon. India is a provisional adherent, while South Africa, Slovenia and Israel are full adherents to the system. The Secretariat continues to work with China, Chinese Taipei and several other countries in view of their provisional adherence to the MAD Council Acts as well.

Contact: Dian Turnheim

Website: <http://www.oecd.org/env/glp>
<http://www.oecd.org/env/testguidelines>

OUTREACH

The Joint Meeting has adopted a Statement of support of the objectives of the Strategic Approach to International Chemicals Management (SAICM) as contained in the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global Plan of Action. The Joint Meeting has also agreed to review its Programme of Work in light of the SAICM objectives. The Statement can be found at http://www.oecd.org/document/52/0%2C2340%2Cen_2649_34365_37999156_1_1_1_1%2C00.html.

NEW CHEMICALS

The New Chemicals Programme carries out a variety of activities which aim to reduce the time and resources governments spend evaluating new chemicals that companies wish to introduce to the market. It also helps reduce the resources that companies spend submitting information about these chemicals to governments.

Six substances have been submitted under the pilot phase of the parallel notification process aimed at simplifying and streamlining access to multiple markets for new chemicals. The Parallel Process refers to a company notifying in multiple jurisdictions and authorizing participating governments to share information when conducting their reviews. Jurisdictions participating in the Parallel Process utilise current evaluation processes to conduct their notification reviews. In addition, throughout this process, jurisdictions retain the sovereign right to make their own risk-based decisions. Efforts are being made to increase industry participation and involvement in the Parallel Process and companies interested in participating are encouraged to inform their national authorities. Information describing the Parallel Process Pilot Phase is available on the OECD website.

The two-year public review period to evaluate the applicability of draft definitions of key terms (i.e. articles, intermediates, hydrates, substances occurring in nature, incidental reaction products, impurities, mixtures and research and development) has now been completed. A publication with the final agreed terms expected to be available in mid-2007. Once published, OECD member countries will be encouraged to incorporate these definitions into existing legislation or regulations when amended. Harmonisation of such elements will facilitate the exchange of information and work sharing amongst countries.

An expert group meeting on polymers was held in Tokyo, Japan, 6-8 March 2007. The purpose of the meeting was to share information on national legislative schemes and investigate the potential for a common approach regarding polymer notification and possible reduced requirements. Participants agreed on a definition of a polymer of low concern but criteria used to identify such a polymer appeared to be different from one jurisdiction to another. Thus, participants will share data and provide scientific evidence and rationales for the use of the criteria. As a next step, it is envisaged to reach agreement on a harmonized approach regarding the identification of polymers of low concern.

In addition, work continues on the development of an electronic notification system which will allow companies to enter/maintain data at their location and then choose a specific authority notification format into which the data is inserted.

Recent event:

- Expert group meeting on polymers, 6-8 March, Tokyo, Japan

Forthcoming publication:

- 📖 Guidance on definitions of key terms

Contact: Richard Sigman and Nathalie Delrue

Website: <http://www.oecd.org/env/newchemicals>

EXISTING CHEMICALS

The Existing Chemicals Programme is concerned with the thousands of chemicals used world-wide that were put on the market before new chemical notification systems were established and whose hazards were not thoroughly evaluated by governments. Data on High Productive Volume (HPV) chemicals is gathered or generated and co-operative initial assessments are carried out to determine the need for further testing or risk management. The EXICHEM database regroups information on who is doing what on which chemicals in relation to safety.

The 23rd SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Jeju, Korea, on 17-20 October 2006. Assessments for 51 chemicals were agreed including the first assessment prepared under the procedure for direct submission by industry. Approximately 50 representatives from member countries and industry attended the meeting. The conclusions and recommendations for these chemicals were endorsed by the Task Force on Existing Chemicals and the Joint Meeting through written procedures. The SIDS Initial Assessment Profiles of these chemicals are available on the publicly accessible OECD HPV Database [<http://cs3-hq.oecd.org/scripts/hpv/>].

UNEP Chemicals has published initial assessments for 73 chemicals since July 2006. A batch of assessments for 57 chemicals was sent to UNEP Chemicals in December 2006 and the assessments are currently under preparation for publication. Final drafts for these chemicals are publicly available [<http://www.oecd.org/env/existingchemicals/siars>]. Altogether, assessments for 342 chemicals have been published by UNEP [<http://www.chem.unep.ch/irptc/sids/OECDSID/sidspub.html>] and 66, of which the hazard assessment parts have been agreed upon at OECD level, have been published by the European

Commission [<http://ecb.jrc.it/existing-chemicals/>]. Furthermore, the Secretariat has published 110 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: http://www.oecd.org/document/55/0%2C2340%2Cen_2649_34379_31743223_1_1_1_1%2C00.html.

Progress is being made on the development of a Global Portal to Information on Chemical Substances (Global Portal). The Steering Group for the development of the Global Portal met on 9-10 November 2006 and 31 January-1 February 2007. It reviewed the beta version of the first version of the Global Portal made available in December 2006 and elaborated a strategy to engage users. The Task Force on Existing Chemicals endorsed the modifications of the beta version in March 2007. The Global Portal should be publicly launched in mid-2007. A feasibility study is underway to investigate the feasibility of building and hosting the second phase of the Global Portal.

An update of EXICHEM, limited to new entries, is foreseen in early 2007.

Recent event:

- Task Force on Existing Chemicals, 1-2 March 2007, Paris, France

Forthcoming events:

- SIAM 24, 17-20 April 2007, Paris, France
- Meeting of the Steering Group for the Development of a Global Portal to Information on Chemical Substances, 7-8 June 2007
- SIAM 25, 16-19 October 2007, Helsinki, Finland

Contact: Bob Diderich

Website: <http://www.oecd.org/env/existingchemicals>
<http://www.oecd.org/env/existingchemicals/siars>
<http://www.oecd.org/env/hpvchemicals/globalportal>

(QUANTITATIVE) STRUCTURE-ACTIVITY RELATIONSHIP [(Q)SAR]

(Q)SARs are methods for estimating properties of a chemical from its molecular structure and have the potential to provide information on hazards of chemicals, while reducing time, monetary cost and animal testing currently needed. The OECD (Q)SAR Project is developing guidance material and a "Toolbox" for practical applications of (Q)SARs in specific regulatory contexts by governments and industry.

In August 2006, the OECD published a Report on the Regulatory Uses and Applications in OECD Member Countries of (Q)SAR Models in the Assessment of New and Existing Chemicals:

http://www.oecd.org/document/30/0%2C2340%2Cen_2649_34365_1916638_1_1_1_1%2C00.html

(Series on Testing and Assessment No. 58). This report compiles case studies received from 11 member countries with the aim of information exchange to increase understanding of the way (Q)SAR models are selected for use in regulatory applications and how their fitness for purpose has been established. The report will assist member countries in identifying (Q)SAR models which can be useful for their specific regulatory needs.

In February 2007, the OECD published a Guidance Document on the Validation of (Q)SAR Models:

http://www.oecd.org/document/30/0%2C2340%2Cen_2649_34365_1916638_1_1_1_1%2C00.html

(Series on Testing and Assessment No. 69). The purpose of this document is to provide detailed but non-prescriptive guidance that explains and illustrates how the OECD Principles for the Validation, for Regulatory Purposes, of (Q)SAR Models (approved by the 37th Joint Meeting in November 2004) can be interpreted for different types of (Q)SAR models. This document provides a harmonised framework which can be used for (Q)SAR validation studies undertaken in member countries.

As part of the OECD activities to increase the regulatory acceptance of (Q)SAR methods, a (Q)SAR *Application Toolbox* has been developed as a means of making (Q)SAR technology readily accessible, transparent, and less demanding in terms of infrastructure costs. The Toolbox will be created in two phases. As the first phase, the development of a "proof-of-concept" version started in 2006. With this proof-of-concept version, a user will be able to:

- Make estimations for single chemicals, linked to the CAS number or the structure of a chemical (e.g. SMILES notation), and receive the results of all the (Q)SAR estimates for all the models submitted by member countries and covering the appropriate domain, for the relevant endpoints that the user wishes to estimate;
- Receive summary information on the validation processes and results of the model so that the user can decide for which regulatory purpose the estimate can be used;
- Receive a list of analogues of the chemical, together with their (Q)SAR estimates;
- Receive estimates for metabolite activation/detoxification information for the chemical.



The aim of the proof-of-concept version is to prove that the above described functionalities can be integrated into a single stand-alone computer application. It is foreseen that the beta testing will be conducted in September 2007 and the proof-of-concept version will be made publicly available during the first half of 2008. Based on the experience with the proof-of-concept version, a project for the development of a second version with extended functionalities could be launched.

The Steering Group for (Q)SARs, the members of which are drawn from the Ad Hoc Group on (Q)SARs, met at the OECD on 26-27 October 2006 and 26 January 2007 to review the progress of the proof-of-concept version and to prepare it for discussion by the Ad Hoc Group. The Ad Hoc Group will meet in Madrid, Spain, on 17-18 April 2007 to review the progress of the project and to have an initial discussion for the second phase of the Toolbox development.

Forthcoming events:

- Meeting of the Ad Hoc Group on (Q)SARs, 17-18 April 2007, Madrid, Spain
- Beta testing of the proof-of-concept version of the (Q)SAR Application Toolbox, September 2007 (*details to be decided*)

Recent publications:

-  Report on the Regulatory Uses and Applications in OECD Member Countries of (Q)SAR Models in the Assessment of New and Existing Chemicals
-  Guidance Document on the Validation of (Q)SAR Models

Contact: Take Fukushima

Website: <http://www.oecd.org/env/existingchemicals/qsar>

RISK ASSESSMENT

Risk to human health and the environment posed by chemicals is determined by chemical-specific hazard properties and the extent of exposure to chemicals. OECD assists member countries in developing and harmonising methods for assessing such risk.



Emission Scenario Documents (ESDs) describe the sources, production processes, pathways and use patterns of chemicals with the aim of quantifying their emissions from production, formulation, use, service life and recovery/disposal into water, air, soil and/or solid waste. A number of projects to develop new ESDs and to enhance the use of ESDs are underway. The Task Force on Environmental Exposure Assessment met in

September 2006 in Ottawa and reviewed the progress of projects. The Task Force approved proposals for the development of three new ESDs and the following projects were launched: Radiation Curable Coatings (Formulation and End-Use); Use of Additives in Oil Well Stimulation; Application or End-Use of Adhesives.

Forthcoming event:

- 15th meeting of the Task Force on Environmental Exposure Assessment, October 2007, OECD

Forthcoming publications:

-  Report on the Development of Emission Scenario Documents on the Chemical Industry
-  P_{OV} (overall environmental persistence) and LRTP (long-range transport potential) Screening Tool Software

Contact: Take Fukushima

Website: <http://www.oecd.org/env/riskassessment>

HARMONIZATION OF CLASSIFICATION AND LABELLING

The Programme on Harmonisation of Classification and Labelling aims to harmonise the international classification of hazardous chemicals. Classification divides chemical substances and mixtures into different categories, based on their physical properties and health and environmental hazards. Chemicals are then labelled according to category requirements, the label indicating how the chemicals must be handled during transport, storage, use and in case of accident.

A scientific issue paper on Strong versus Weak Sensitizers, a scientific issue paper on Chronic Aquatic Hazards, and a draft issue paper on Toxic Gas Mixtures were submitted to the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS) in July 2006. In December 2006, the UN SCEGHS adopted the Programme of Work for the biennium 2007-2008.

A proposal for classification and labelling of chemicals for chronic aquatic hazards and a proposal for classification and labelling of ozone depleting chemicals have been submitted to the OECD Task Force on Harmonization of Classification and Labelling (TF HCL).

A meeting of the extended Validation Management Group on the Transformation/Dissolution Protocol was held in Brussels on 28-29 September 2006; it met to develop a validation report of the GHS Test Guidance on the Transformation/Dissolution Protocol (Phase 1). The draft report was sent to the TF HCL for approval in February 2007.

A report on the preparation of GHS Implementation in OECD countries is under development.

Recent event:

- Meeting of the Expert Group on Sensitization, 21-22 February 2007, Bethesda, United States

Forthcoming event:

- Meeting of the Task Force on Harmonization of Classification and Labelling, 4-5 July 2007, Bern, Switzerland

Contact: Laurence Musset

Website: <http://www.oecd.org/env/classify>

RISK MANAGEMENT AND CHEMICAL PRODUCT POLICY


The Risk Management Programme is concerned with the final step in chemical oversight: how to manage the use of chemical products so that society can take advantage of their benefits while minimising risks. It develops tools for OECD governments and facilitates information exchange about successful risk management approaches.

Preliminary Lists of PFOS, PFAS, PFOA, PFCA and Related Substances (developed in 2005 by Australia to facilitate data collection for the 2006 survey on production, import and use of these substances were published in April 2006 [ENV/JM/MONO(2006)15].

The second survey on “Production and Use of PFOS, PFAS, PFOA, PFCA and their Related Substances and Products/Mixtures Containing these Substances” was undertaken in 2006. Among others, the survey identified substances which are not yet listed in “Preliminary Lists”. Consequently, the Lists will be updated in 2007. The Joint Meeting reviewed and declassified the outcome of the survey in November 2006 and it was published in December 2006 [ENV/JM/MONO(2006)36].

In addition, Sweden hosted an OECD Workshop on PFCAs and Precursors on 20-22 November 2006 in Stockholm. The Workshop Report and its recommendations will be reviewed by the Joint Meeting in June 2007.

Recent publication:

-  Results of the 2006 Survey on Production and Use of PFOS, PFAS, PFOA, PFCA, and Their Related Substances and Products/Mixtures Containing these Substances, Risk Management Series No. 22 [ENV/JM/MONO(2006)36].

Contact: Henrik Harjula

Website: <http://www.oecd.org/env/riskmanagement>

OTHER EHS PROGRAMMES

POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRS)

PRTRs are databases of selected pollutant releases to air, water and soil, and of wastes transferred off-site for treatment or disposal. The programme aims to help individual countries in developing PRTRs, improving release estimation techniques and wide sharing of data between countries.

Meetings of the Task Force

The Task Force on Pollutant Release and Transfer Registers (TF on PRTRs) met on 27 February-1 March 2007. Participants agreed to take forward the following work areas: i) Releases from products; ii) Scoping study on SMEs; iii) Establishment of a global portal to PRTR information; and iv) A guidance document on Considerations for Ensuring Quality PRTR Data.

In November 2006, the Joint Meeting reviewed the “Scoping Study on Releases from Products” and expressed support for the continuation of the work. However, the scope of the study was considered too narrow, therefore, the next steps should focus on compiling existing information, in particular on product-related Release Estimation Techniques (RETs), and their application to sample pollutants from selected products. Future work, led by the Nordic PRTR group, will focus on the end-use of products that are not yet fully covered by any inventories. The output of the project will be a “Resource Compendium of PRTR RETs, Part 4: Summary of Techniques for Products”. The Scoping Study on SMEs began in November 2006 and is expected to be completed in June 2007. In March 2006, a working group, led by Canada, was set up to further the development of the global portal to PRTR information (www.prtr.net). The first task of the working group was to establish a prototype of the portal, which is being reviewed by the Task Force. The Task Force also reviewed a first draft of the document on Considerations for Ensuring Quality PRTR Data. Australia and the US will continue the work and aim to complete the document by the end of 2007.

Forthcoming event:

- 11th Meeting of the OECD Task Force on PRTRs, 12-14 March 2008, Paris, France.

Recent publication:

- 📖 Centre for PRTR Data (<http://www.oecd.org/env/prtr/data>)

Forthcoming publications:

- 📖 Considerations for Ensuring Quality PRTR data
- 📖 Global Portal to PRTR Information (www.prtr.net)

Contact: Henrik Harjula

Web site: <http://www.oecd.org/env/prtr>

PESTICIDES

The Pesticide Programme aims to harmonise the testing and assessment of agricultural pesticides, to promote work sharing and risk reduction. It achieves this by helping OECD countries to co-operate in the review of both chemical and biological pesticides used in Agriculture.

Development of Test Guidelines and Guidance Documents on Residue Chemistry

The US-led Expert Group on Pesticide Residue Chemistry has developed five Test Guidelines (Metabolism in Crops; Metabolism in Rotational Crops; Metabolism in Livestock; Residues in Rotational Crops; and Residues in Livestock) and two Guidance Documents (Definition of Residue; and Overview of Residue Chemistry Studies). The two Guidance Documents were published in October 2006 in the Series on Pesticides and the Series on Testing and Assessment. The five Test Guidelines were published in December 2006 as part of the 18th Addendum to the OECD Guidelines for the Testing of Chemicals. The Expert Group met in January 2007 to finalise several documents for the second phase of work: one Test Guideline on Stability of Pesticide Residues in Stored Analytical Samples; one Test Guideline on the Nature of Residues in Processed Commodities; and one Guidance Document on Residue Analytical Methods. The three documents will be submitted for approval to the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) at its 19th Meeting in March 2007.

Biological Pesticides

The BioPesticides Steering Group (BPSG), led by the Netherlands, met in June 2006 to continue its work to develop guidance on the evaluation of microbials for pest control. The document will cover such topics as: the taxonomic identification of micro-organisms in microbial pest control products; genetic toxicity assessment of microbial pesticides: needs and recommended approaches; occupational, bystander and consumer exposure and risk assessments for microbial pest control products; microbial metabolite residues in treated food crops; how to evaluate the environmental safety of microbial pest control products; and efficacy evaluation of microbials. A first draft Working Document was reviewed by the Working Group on Pesticides at their 20th Meeting in November 2006. The BPSG will hold a meeting on 24-25 April 2007 in Braunschweig, Germany. It is expected that the document will be finalised in 2008.

High Level Seminar on Registration Work Sharing

On 31 May 2006, Ireland's Pesticide Control Service hosted a seminar for senior managers in research-based pesticide companies. The objective of the seminar was to familiarise participants with the opportunities afforded through OECD joint reviews by governments of data submissions (dossiers) to achieve 'simultaneous' and early access to key global markets for new products, and to encourage companies to adjust development programmes to facilitate simultaneous data submissions to multiple markets. Based on these discussions, a document has been published which provides responses to questions that are frequently asked by governments and industry about the concept of work sharing between governments on pesticide registration reviews. Another document has also been published which provides an overview of country and regional review procedures to help government regulators gain a better understanding of the processes followed, and documents used, in other governments in which they may share the work on pesticide registration and re-registration.






OECD/EC Seminar on Harmonised Environmental Indicators for Pesticide Risk

A seminar jointly organised by OECD's Risk Reduction Steering Group and the EC HAIR Steering Committee and hosted by the German Ministry of Food, Agriculture and Consumer Protection, was held on 13 November 2006 in Bonn. The aims of this seminar were to present the indicators developed in the framework of the EC-funded HAIR project (HARmonised environmental Indicators for pesticide Risk); discuss issues related to further developments; and considered ways of broadening the use of these indicators across OECD member countries. The seminar report is scheduled to be declassified by the end of the year.





Forthcoming events:

- Risk Reduction Steering Group, 20 March 2007, Brno, Czech Republic
- Risk Reduction Seminar on Worker Safety and Training, 21 March 2007, Brno, Czech Republic
- Registration Steering Group, 22-23 March 2007, Brno, Czech Republic
- BioPesticide Steering Group Meeting, 24-25 April 2007, Braunschweig, Germany
- 21st meeting of the Working Group on Pesticides, 12-13 June 2007, Paris, France
- Risk Reduction Seminar on Training the Trainers, November 2007, Mexico City, Mexico
- Risk Reduction Steering Group, November 2007, Mexico City, Mexico
- Registration Steering Group, November 2007, Mexico City, Mexico

Recent publications:

-  3rd Revision of OECD Guidance for Country Data Review Reports on Plant Protection Products (Monographs)
-  Overview of Country and Regional Review Procedures for Agricultural Pesticides and Relevant Documents
-  Frequently Asked Questions about Work Sharing on Pesticide Registration Reviews
-  Five Test Guidelines:
 - 501 Metabolism in Crops
 - 502 Metabolism in Rotational Crops
 - 503 Metabolism in Livestock
 - 504 Residues in Rotational Crops (Limited Field Studies)
 - 505 Residues in Livestock
-  Two Guidance Documents:
 - Overview of Residue Chemistry Studies
 - Definition of Residue

Forthcoming publications:

-  Report of the Minor Use Survey Results
-  Report of the Seminar on Risk Reduction through Better Application Technology
-  Report of the Workshop on User Compliance Issues
-  Report of the OECD/EC Seminar on Harmonised Environmental Indicators for Pesticide Risk

Contact: Richard Sigman, Sylvie Poret and Marie-Chantal Huet

Website: <http://www.oecd.org/env/pesticides>

BIOCIDES

Work on Biocides (non-agricultural Pesticides) closely parallels the work on agricultural pesticides: harmonisation of testing of product efficacy to ensure the validity of label claims, producing emission scenarios and promoting sharing of information about risk reduction approaches.

Emission Scenario Documents (ESDs)

Work, funded and led by France, continues on the development of an ESD for insecticides used in households and for professional uses. This ESD addresses the distribution and concentration of insecticides in environmental compartments. The second draft, including revised scenarios covering other application methods than spraying applications, was discussed during the fourth expert meeting on 11 September 2006 in Vienna. The final ESD is expected to be published in early 2008.

Test Guideline for Wood Preservatives

A Test Guideline for measuring leaching of biocides from wood not covered, and in contact with, fresh water or sea water has been developed. Validation work was conducted by Germany with funding from the EC. The draft document will be submitted for approval to the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) at their 19th Meeting in March 2007.

Efficacy

The first meeting of the OECD Validation Management Group for Hard Surface Efficacy Testing was held in Berlin from 5-6 May 2006. This VMG is charged with validating five different draft Test Guidelines that will be used to determine if new biocide products, that will be used on hard surfaces (e.g., hospital tables), actually kill a significant number of bacteria, viruses, fungi, spores and mycobacteria (i.e., if they are effective). The objective of the first meeting was to design the validation study that will be comprised of round-robin testing amongst over 20 laboratories. The ring trials are scheduled to begin in the second quarter of 2007, and conclude in the fourth quarter.

A document which analyses current protocols for testing treated articles will be published in the second quarter of 2007.

Forthcoming event:

- Fifth Meeting of the Task Force on Biocides, September 2007; Paris, France

Recent publication:

- 📖 Analysis and Assessment of Current Protocols to Develop Harmonised Test Methods and Relevant Performance Standards for the Efficacy Testing of Treated Articles/Treated Materials

Forthcoming publication:

- 📖 Emission Scenario Document (ESD) for Insecticides Used in Households and for Professional Use

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CHEMICAL ACCIDENTS

The Chemical Accidents Programme works to develop guidance on prevention of and response to chemical accidents. It facilitates the sharing of information and experiences of both OECD and non-member countries.

Council Recommendation Concerning Chemical Accident Prevention, Preparedness and Response [C(2003)221]

Following a survey on evaluation of implementation of this Council Recommendation (undertaken in May-September 2006), the US lead has analysed the responses received and, based on this, will prepare a first draft of the survey report for review by an *ad hoc* group of experts. The final report will be discussed at the 17th Meeting of the Working Group on Chemical Accidents (WGCA) in October 2007.

Revision of Guidance on Safety Performance Indicators

The US-led Expert Group charged with revising the OECD Guidance on Safety Performance Indicators (published in 2003) met for the second time in Washington in November 2006. The proposed revision of the SPI Guidance will be submitted for review to the 17th WGCA Meeting in October 2007.

The Use of Safety Documents in the Control of Major Accident Hazards

Following a survey (March-July 2006) on the use of safety documents in the control of major accident hazards, the UK lead prepared a preliminary report for the 16th WGCA Meeting. The final report of the survey, including a proposal for possible future work, will be discussed at the 17th WGCA Meeting in October 2007.

Development of Guidance for Implementation of Integrated Management of SHE&Q

A Korean-led Expert Group is developing guidance to facilitate the implementation of the integrated management of safety, health, environment and quality in enterprises (and public authorities). A (December 2005) draft document was discussed at an Expert Meeting in September 2006 in Prague, Czech Republic. The revised draft will be circulated for comments in March 2007 to be further discussed, together with the comments received, at a third Expert Meeting that will take place in September 2007 in Seoul, Korea.

Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases

A Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases sponsored by Environment Canada and the EC Major Accident Hazards Bureau took place in Varese, Italy in October 2006. The objective was to share information and experiences on approaches used by OECD countries/regions to identify and select hazardous substances with respect to preventing and managing accidental releases. The report will include the conclusions and observations from the workshop and recommendations for further work. It will be published in April 2007.

Preparation of a Workshop on Human Factors in Chemical Accidents and Incidents

A Workshop on Human Factors in Chemical Accidents and Incidents, sponsored by the Federal Ministry for the Environment of Germany and the Government of Brandenburg, will take place on 8-9 May 2007 in Potsdam, Germany. The workshop will be held back-to-back with the 17th Meeting of the EC Committee of Competent Authorities responsible for the Seveso II Directive. The objective is to explore human factors related to the management and operation of a hazardous installation, and to share information on assessment tools for analysis and reduction of human error in the chemical industry, including small and medium enterprises. A Planning Committee, led by Germany, was established in April 2006 to help prepare the workshop. A letter of invitation to nominate workshop participants was sent to member countries in January 2007.

Preparation of a Workshop on Marshalling Yards

A Workshop on Marshalling Yards, sponsored by the Netherlands, will take place on 15-16 October 2007 at OECD headquarters in Paris. The objective is to exchange views on chemical safety issues connected with railroad marshalling yards; identify solutions in the areas of policy, technical measures, organisation and spatial planning; and make recommendations for best practices. A Planning Committee, led by the Netherlands, was established in January 2007 to help prepare the workshop. A letter of invitation to nominate participants will be sent to member countries in April-May 2007.

Forthcoming Events:

- Workshop on Human Factors in Chemical Accidents and Incidents, 8-9 May 2007, Germany
- Third Meeting of the Expert Group on Safety, Health, Environment and Quality Guidance, 3rd week of September 2007 [date TBA], Seoul, Korea
- Workshop on Marshalling Yards, 15-16 October 2007, OECD, Paris, France

- 17th Meeting of the OECD Working Group on Chemical Accidents (WGCA), 17-18 October 2007, OECD, Paris, France

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HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The main focus of OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology is on environmental risk/safety assessment of transgenic (genetically modified) crops. The work aims to ensure that the information used in risk/safety assessment, as well as the methods used to collect such information, is as similar as possible. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort, while reducing barriers to trade.

Strengthening the participation of non-member economies in the activities of the Working Group has remained a high priority. For this reason, a number of activities organised in 2006 involved the participation of non-members. Amongst other things, a workshop on the risk/safety assessment of transgenic plants was held on 29 September in Jeju Island, Korea.

The 19th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology met in Paris, 21-23 February 2007. The meeting agreed to a draft operational plan for the project on *Environmental Considerations*, which is intended to provide a comprehensive package of information elements used for risk/safety assessment of transgenic plants. The lead country (Canada) has started drafting the document.

A potential new project on adventitious presence (*or* low level, unavoidable presence) of transgenic seeds in conventional bulk shipments, which is an important issue for some sectors of industry and governments was also discussed. A parallel project on adventitious presence of transgenic crops is being undertaken by FAO/WHO Codex Alimentarius Committee – from a food safety point of view. This issue will be revisited at the next meeting of the Working Group to be held in October 2007.

The 19th meeting also made progress on various other projects, including: the Unique Identifier for transgenic micro-organisms; Consensus Document on Bt trait; Consensus Document on Lodgepole pine; Consensus Document on North American Larches; Guidance Document on Horizontal Gene Transfer between Bacteria; and Guidance Document on Potential Health Effects of Bacteria. It was reported at the meeting that considerable progress has been made on the project on Molecular Characterisation and on Consensus Document on Atlantic Salmon since the 18th meeting of the Working Group.



Forthcoming events:

- A workshop of the sub-working group on micro-organisms, June 2007, Russia
- OECD Seminar on Biotechnology in BioJapan 2007, September 2007, Yokohama, Japan
- 20th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, 24-26 October 2007, OECD Headquarters, Paris, France

Recent Publications:

-  Consensus Document on the Biology of Jack Pine
-  Revised 2006: OECD Guidance for the designation of a Unique identifier for Transgenic Plants

Forthcoming Publications:

-  Consensus Document on Safety information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Proteins
-  Consensus Document on the Biology of Native American Larches

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SAFETY OF NOVEL FOODS AND FEEDS

The programme for the safety of novel foods and feeds addresses risk/safety assessment issues, mainly related to the products of modern biotechnology. For the most part, therefore, the work is focused on the safety of foods and feeds derived from transgenic crops.

The work of the Task Force for the Safety of Novel Foods and Feeds is focused on promoting international harmonisation in the regulation of modern biotechnology in terms of human and animal health. The main outputs of the programme are consensus documents, which are mainly for use in regulatory assessment. The main advantages of these documents are that they: a) increase mutual understanding among countries; b) save on resources; and c) increase the efficiency of risk/safety assessment, while reducing non tariff barriers to trade.

To date, 11 consensus documents have been published on major crops such as maize, soy bean and rapeseed oil. In addition, three documents are under preparation on tomato, papaya, and cassava. The Task Force is currently revising the earliest consensus documents it published, *Low Erucic Acid Rapeseed* and *Soybean*, with a view to updating them.



The work of the Task Force benefits from input provided by participants from the Secretariat of the Convention on Biological Diversity (SCBD), the European Commission; Food and Agriculture Organization (FAO); the World Health Organisation (WHO); the Codex Alimentarius Commission; and the Business and Industry Advisory Committee to OECD (BIAC), in addition to the invited observers from non-member countries.

Finally, the Task Force is carrying out jointly with the Working Group on Harmonisation of Regulatory Oversight in Biotechnology a project on *Molecular Characterisation for Transgenic Plants*. It is expected that the first draft of the document will be completed in 2007.

Forthcoming Event:

- 13th Meeting of the Task Force for the Safety of Novel Foods and Feeds, 28-29 June 2007, OECD Headquarters Paris, France

Forthcoming Publications:

-  Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom *Agaricus bisporus*: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants
-  Consensus Document on Compositional Considerations for New Varieties of Sunflower: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

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SAFETY OF MANUFACTURED NANOMATERIALS

Nanotechnology involves materials and working devices or machines that are engineered at the scale of atoms and molecules. The main objective of on-going work in this area is to assist countries in developing tools to allow them to better address the safety aspects of manufactured nanomaterials.

In September 2006, the OECD Council approved the establishment of a Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the Chemicals Committee. This newly established Working Party met for the first time in London, 26-27 October 2006 and delegations exchanged information on current or planned activities related to the safety of manufactured nanomaterials in their countries or organisations. The information is available through the recent publication indicated below.

The WPMN discussed and agreed a draft Programme of Work, 2006-2008, which was approved by the 40th Joint Meeting.

The Working Party also considered implementation of this work and decided that this could best be achieved initially through six specific projects listed as follows:

- Development of an OECD Database on Human Health and Environmental Safety (EHS) Research.
- EHS Research Strategies on Manufactured Nanomaterials.
- Safety Testing of a Representative Set of Manufactured Nanomaterials.
- Manufactured Nanomaterials and Test Guidelines.
- Co-operation on Voluntary Schemes and Regulatory Programmes.
- Co-operation on Risk Assessments and Exposure Measurements.


Each of these projects is being managed through steering groups, which have begun their work by preparing draft operational plans in order to develop appropriate methods and strategies to help ensure human health and environmental safety. There are several linkages amongst these projects, therefore the steering groups for projects 2, 3 and 4 will meet jointly in Dortmund, Germany (22-23 March) in order to discuss their respective draft operational plans. They will also focus on the linkages between them in order to avoid overlaps and facilitate synergies.

The draft operational plans together with progress achieved within each project will be presented and discussed at the 2nd meeting of the WPMN, which will take place in Berlin, from 25-27 April.

Forthcoming events:

- Meeting of Steering Groups 2, 3 and 4 of the Working Party on Manufactured Nanomaterials, 21-23 March 2007, Dortmund, Germany
- 2nd Meeting of the Working Party on Manufactured Nanomaterials, 25-27 April 2007, Berlin, Germany
- 3rd Meeting of the Working Party on Manufactured Nanomaterials, 28-30 November 2007, Paris, France

Recent Publication:

-  Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 1st Meeting of the Working Party on Manufactured Nanomaterials, London, United Kingdom, 26-27 October 2006

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CROSS-CUTTING ISSUES

Templates for New and Existing Industrial Chemicals, Pesticides and Biocides

In March, 2006, OECD adopted 86 harmonised templates for reporting summary information on the results from chemical testing. The templates prescribe the format by which results should be entered into and maintained in databases so that data can easily be exchanged electronically. Electronic exchange formats, "XML schema" based on XML (Extensible Mark-up Language), are being developed for each template (e.g., one template for hydrolysis and one XML schema for hydrolysis), and should be available by the end of March 2007.

Contact: Richard Sigman and Nathalie Delrue

Integrated Approaches to fulfill Information Requirements for Testing and Assessment

Based on recommendations from the 39th Joint Meeting, an activity on Integrated approaches to fulfill information requirements for testing and assessment was launched in 2006. As a first step it is foreseen to organise a workshop at the end of 2007 to share experience on integrated approaches to fulfill information requirements by reviewing case studies for a few regulatory hazard endpoints. The workshop will review case studies using currently available tools and methods to fulfill the requirements for the endpoint [testing (*in vivo* and *in vitro*), (Q)SARs, read-across, chemical categories], how these tools and methods are used in different regulatory frameworks (new and existing industrial chemicals, biocides, pesticides) and how these tools and methods can be used in an integrated approach to fulfill the endpoint.

The expected outcome from the workshop will be recommendations to the Joint Meeting on future work to support member countries in using integrated approaches to fulfill information requirements for testing and assessment.

Contact: Bob Diderich and Anne Gourmelon

Website: http://www.oecd.org/document/13/0,2340%2Cen_2649_34365_36206733_1_1_1_1%2C00.html

Workshop on Experience in Applying the GHS Criteria for Classification and Labelling

An OECD workshop on experience in applying the GHS criteria to chemicals will be held on 5-6 July 2007 in Bern, hosted by Switzerland. The main objectives of the workshop are to: 1) share national experiences and identify possible problems in the application of the GHS criteria for classification; 2) evaluate the suitability of the SIAR as a basis for the derivation of the classification through a pilot exercise; 3) identify needs for further guidance in the application of the GHS criteria; and 4) identify the needs for developing further guidance for the Manual for the Investigation of HPV Chemicals.

The workshop will be divided in three parts: 1) national experience; 2) experience from the OECD HPV Chemicals Programme; and 3) break-out sessions to develop recommendations.

Contact: Anne Gourmelon, Bob Diderich

INTERNET

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EHS Homepage	http://www.oecd.org/ehs/
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Chemical Accidents	http://www.oecd.org/env/accidents
Existing Chemicals	http://www.oecd.org/env/existingchemicals
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Risk Assessment	http://www.oecd.org/env/riskassessment
Risk Management	http://www.oecd.org/env/riskmanagement
Safety of Manufactured Nanomaterials	http://www.oecd.org/env/nanosafety
Strategic Approach to International Chemicals Management	http://www.oecd.org/env/saicm
Test Guidelines	http://www.oecd.org/env/testguidelines

Most EHS Publications can be downloaded directly from OLIS or our website:

http://www.oecd.org/findDocument/0%2C2350%2Cen_2649_34365_1_1_1_1_1%2C00.html

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VEITH , Gilman	Test Guidelines [(Q)SAR]	14.81
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