Environment, **H**ealth & **S**afety **N**ews

No. 21, November 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. 20, issued in March 2007), the EHS Division has seen the following changes in staffing:

Administration: *Lisa Eveleigh* has returned from maternity leave.

Front Office: *Barbara Ladeuille* has returned to her position as Assistant to the Head of Division and working on administration issues.

Good Laboratory Practice and Test Guidelines: *Mio Takenaka-Yagi* has replaced *Nobu Nakashima* as administrator to these programmes.

Chemical Accidents, Communication and IT issues: *Jill Gibb* returned from maternity leave.

Existing Chemicals: *Wendy Cormier* has left the OECD. *Amanda Sudic* has replaced her providing secretarial support to the Existing Chemicals Programme as well as PRTR, (Q)SAR and Exposure Assessment.

Pesticides, Biocides, New Chemicals and GLP: *Patricia Nilsson* is providing secretarial support to these programmes during *Katherine Perkins'* temporary assignment.

Test Guidelines, HCL: *Ciara Muller* is replacing *Jennah Huxley*, while she is on temporary assignment, as Assistant to the Test Guidelines and HCL Programmes.

(Q)SARs: *Gil Veith* has left the OECD. *Terry Schultz* is replacing him on the (Q)SAR programme.

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.

A new set of Test Guidelines was adopted on 16 October 2007. They are available free of charge from SourceOECD or from the OECD Online Bookshop:
[**http://www.oecd.org/document/40/0%2C2340%2Cen_2649_34377_37051368_1_1_1_1%2C00.html**].

New Test Guidelines:

Section 2: Effects on Biotic Systems

225 Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment

Section 3: Degradation and accumulation

313 Estimation of Emissions from Preservative – Treated Wood to the Environment: Laboratory Method for Wooden Commodities that are not covered and are in Contact with Fresh Water or Seawater.

Section 4: Health Effects

426 Developmental Neurotoxicity Study

440 Uterotrophic Bioassay in Rodents: a short-term screening test for oestrogenic properties

Section 5: Other Test Guidelines

506 Stability of Pesticide Residues in Stored Commodities

507 Nature of Pesticide Residues in Processed Commodities – High Temperature Hydrolysis

The above Test Guidelines and the recent publications listed below were submitted for approval at the last meeting of the National Coordinators of the Test Guidelines Programme (WNT), 28-30 March 2007. The new Detailed Review Papers, Guidance Documents and Validation Reports are published in the Series on Testing and Assessment. They are available on the public website.

Inhalation Toxicity

An expert meeting was held on 18-19 June 2007 in De Bilt (Netherlands) for the revision of several Test Guidelines on inhalation acute and repeated dose toxicity (TG 403, 412 and 413). The group agreed on the work plan for the performance assessment of the "Concentration x Time" protocol that is proposed to be added to TG 403.

Development and reproduction test on invertebrates

A meeting of the invertebrate Expert Group took place on 18-19 June 2007 in Columbia, South Carolina (United States) to discuss several development and reproduction tests on invertebrates.

Fish Embryo Toxicity Testing

An expert meeting was held on 9-11 October 2007 in Berlin (Germany). It discussed issues related to the performance assessment of the assay.

In vitro Miconucleus Test

An expert consultation meeting was held in Atlanta, Georgia (United States) to solve remaining issues. The draft Test Guideline is expected to be submitted to the next WNT meeting for approval.

Extended F1 Generation Study

The lead countries for this new project (Germany, Netherlands and the United States) met on 25 October 2007 in Berlin (Germany) and discussed the status of retrospective analyses and a work plan for developing a draft Test Guideline.

Toxicogenomics

A meeting of the Extended OECD/IPCS Advisory Group on Toxicogenomics was held on 23 May 2007 in Durham, North Carolina, United States to assess the overall feasibility of the project titled "Molecular Screening for Characterizing Individual Chemicals and Chemical Categories". The group will develop an agreement on the Molecular Screening Project, such as target chemicals, assays, endpoints of concern and the way of data sharing, and partnerships for the project, including a plan of the next meeting in 2008. A U.S. EPA White Paper foreseen in February 2008 will provide further information for partnering countries/stakeholders.

Forthcoming events:

- EDTA Task Force Meeting, 1-2 April 2008, Paris, France
- 20th Meeting of the Working Group of National Coordinators of the Test Guidelines Programme (WNT20), 2-4 April 2008, Paris, France
- Meeting of the Validation Management Group for non-animal testing: 13-15 November 2007, Ispra, Italy
- Meeting of the Validation Management Group for mammalian testing: 5-6 December 2007, Paris, France
- Meeting of the validation Management Group for ecotoxicity testing, 16-17 January 2008, Paris, France:
- Workshop on the revision of Test Guidelines 450, 451 and 452: 26-28 February 2008, Washington DC (United States)

Recent publications:

- 🕮 Six new Test Guidelines (225, 313, 426, 440, 506, 507)
- 🕮 Detailed Review Paper on Non-Genotoxic Carcinogens Detection: the performance of In Vitro Cell Transformation Assay
- 🕮 Detailed Review Paper for Avian Two-generation Toxicity Testing
- 🕮 Guidance Document on the Uterotrophic Bioassay – Procedure to test for Antioestrogenicity
- 🕮 Guidance Document on the Honey Bee (Apis Mellifera L.) Brood Test under semi-field conditions
- 🕮 Guidance Document on Amphibian Thyroid Histology
- 🕮 Additional data supporting the Test Guideline on the Uterotrophic Bioassay in rodents
- 🕮 Report of the Validation of the Rat Hershberger Assay: Phase 3: Coded Testing of Androgen Agonist, Androgen Antagonists and Negative Reference Chemicals by multiple laboratories. Surgical Castrate Model Protocol.
- 🕮 Final Report of the Validation of the Amphibian Metamorphosis Assay for the detection of Thyroid Active Substances: Phase 1 – Optimisation of the Test Protocol.
- 🕮 Final Report of the Validation of the Amphibian Metamorphosis Assay: Phase 2 – Multi-chemical Inter-laboratory Study

- 🕮 Final Report of the Validation of the 21-day Fish Screening Assay for the Detection of Endocrine Active Substances. Phase 2: Testing Negative Substances
- 🕮 Validation Report of the Full Life Cycle Test with the Harpacticoid Copepods Nitocra Spinides and Amphiascus Tenuiremis and the Calanoid Copepod Acartia Tonsa – Phase 1
- 🕮 Summary Report of the Validation Peer Review for the updated Test Guideline 407, and Agreement of the Working Group of 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. A report was included in the last issue of the EHS newsletter.

Forthcoming events:

- 22nd Meeting of the Working Group on Good Laboratory Practice, 8-9 April 2008, Frascati, Italy
- Event with Industry, 10-11 April 2008, Frascati, Italy
- The 9th OECD Training Course for GLP Inspectors, 8-11 September 2008, Tel Aviv, Israel

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
- 🕮 Advisory Document on Establishment and Control of Archives

Contact: Dian Turnheim and Mio Takenaka-Yagi

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.

Singapore, Brazil and Argentina all became provisional adherents to the Council Acts related to Mutual Acceptance of Data in the Assessment of Chemicals. India is a provisional adherent but has made substantial progress toward establishing a GLP compliance monitoring programme which is harmonised with those in OECD countries. South Africa, Slovenia and Israel are full adherents to the MAD systems. The Secretariat and the Working Group on GLP continue to work with China, Chinese Taipei, Malaysia and Thailand in view of their provisional adherence as well.

Contact: Dian Turnheim

Website: **http://www.oecd.org/env/glp**
http://www.oecd.org/env/testguidelines

OUTREACH

The Joint Meeting 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 is also currently developing a new Programme of Work which will reflect 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.

Eight 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 and additional explanatory material will be posted shortly.

A guidance document on definitions of key terms on New Chemicals Notification was published on the OECD public website in June. OECD member countries are now encouraged to incorporate these definitions into existing legislation or when amending regulations. Harmonisation of such elements will facilitate the exchange of information and work sharing amongst countries.

As a follow-up to the expert group meeting on polymers that was held in Tokyo, Japan, 6-8 March 2007, participating governments have exchanged scientific data and descriptions of each country's rationale for the criteria used for identifying polymers of low concern. Australia is now conducting an analysis of information obtained on approximately 150 to 200 polymers. The objective of this analysis is to analyse and compare the criteria for PLCs across countries, and to work toward the harmonisation of these criteria.

In addition, work has resumed 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. It is expected that this system will be available in the first half of 2008.

Recent event:

- New Chemicals Task Force meeting, 12-13 September, Ispra, Italy

Recent publication:

- 🕮 Guidance on Definitions of Key Terms for New Chemical Notification

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. eChemPortal offers free public access to information on properties of chemicals, allowing for a simultaneous search of multiple databases on the Internet, giving access to data submitted to government chemical review programmes at national, regional, and international levels.

The Task Force on Existing Chemicals met on 1-2 March 2007 as well as on 19 October 2007. The Task Force agreed that further efficiency could be gained in the HPV Chemicals Programme by streamlining the SIDS Documents and by encouraging direct submissions by industry. Furthermore, the Task Force specifically reviewed the synergies between the OECD HPV Chemicals Programme and several national/regional chemical review programmes (such as REACH, the US HPV Challenge Program, the Canadian CEPA 1999 Program, the Japan HPV Challenge Program). Based on those discussions the Task Force recommended that the Secretariat investigate the possibility to

- investigate more systematically non-HPV chemicals;
- produce targeted hazard assessments;
- improve the use of (Q)SAR methodologies;
- use priority setting tools to identify and provisionally set aside low-hazard chemicals.

The 24th SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Paris on 17-20 April 2007. Assessments for 35 chemicals were agreed. 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. The 25th SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Helsinki, Finland, hosted by the Finnish Environment Institute on 17-18 October 2007. Assessments for more than 100 chemicals were agreed. The conclusions and recommendations for these chemicals are being submitted to the Task Force on Existing Chemicals and the Joint Meeting for endorsement through written procedures.

UNEP Chemicals has published initial assessments for 57 chemicals since March 2007. A batch of assessments for 71 chemicals was sent to UNEP Chemicals in July 2007 and the assessments are currently under preparation for publication. Final drafts for these chemicals are publicly available. Altogether, assessments for 398 chemicals have been published by UNEP [**http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html**] and 68, 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 198 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website.

eChemPortal, the Global Portal to Information on Chemical Substanceswas publicly launched in June 2007 [http://www.oecd.org/ehs/eChemPortal]. A study is underway to investigate the feasibility of building and hosting the second phase of the Global Portal.

In March 2007, "EXICHEM 2004 addition 1", new entries for 2005, was published [http://www.oecd.org/ehs/exichem]. In the future, information on who is doing what on which chemical will be available through eChemPortal.

Recent event:

- SIAM 24, 17-20 April 2007, Paris, France
- SIAM 25, 16-19 October 2007, Helsinki, Finland
- Task Force on Existing Chemicals, 19 October 2007, Helsinki, Finland

Forthcoming events:

- SIAM 26, 15-18 April 2008, Paris, France

Recent publications:

- 🕮 Guidance on Grouping of Chemicals (Chemical Categories) [http://appli1.oecd.org/olis/2007doc.nsf/linkto/env-jm-mono(2007)28].
- 🕮 SIDS Initial Assessment Profiles are available on the publicly accessible OECD HPV Database [http://cs3-hq.oecd.org/scripts/hpv/]
- 🕮 Final drafts of the initial assessments of 71 chemicals are publicly available [http://www.oecd.org/env/existingchemicals/siars]
- 🕮 198 IUCLID export files of previously-agreed SIDS Dossiers http://www.oecd.org/document/55/0%2C2340%2Cen_2649_34379_31743223_1_1_1_1%2C00.html.

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.

As part of the OECD activities to increase the regulatory acceptance of (Q)SAR methods, a *(Q)SAR Application Toolbox* is being 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);
- Receive information on the mechanisms of action of the chemicals;

- Receive estimates for metabolite activation/detoxification information for the chemicals;
- Access experimental results for those chemicals;
- Build chemical categories and fill data gaps by read-across and trend analysis.

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. The beta version was reviewed by member countries, industry and NGOs at the on-site beta test session which was held on 3-4 September 2007 in Bourgas, Bulgaria, as well as the off-site commenting round in September-October 2007 using the software downloaded from a password protected website. The beta-version is available from the Secretariat on a request basis. The final version of the proof-of-concept version will be publicly released during the first half of 2008. It will be available free of charge. Based on the experience with the proof-of-concept version, a project for the development of a second version with extended functionalities will be launched in 2008.

The proof-of-concept version of the Toolbox already contains, among other tools, a number of structural alerts relevant for potentially identifying specific hazards or for grouping (categorising) chemicals. During the second phase of the development of the Toolbox, a more extensive set of structural alerts will be integrated. As a kickoff of this work, a *Workshop on Structural Alerts for the (Q)SAR Application Toolbox* will be held in the second quarter of 2008. The aim of the workshop will be to:

- identify structural alerts that governments and industry already use in their day-to-day assessment work to potentially identify specific hazards or to categorise chemicals;
- exchange information on how those structural alerts are used;
- exchange background information on those structural alerts;
- make recommendations (or set priorities) as to which structural alerts should be implemented into the (Q)SAR Application Toolbox.

The Task Force on Existing Chemicals at its meeting in Paris on 1-2 March 2007 and the Ad Hoc Group on (Q)SARs at its meeting in Madrid, Spain, on 17-18 April 2007 reviewed the progress of the OECD (Q)SAR Project and made recommendations for the further work. The Steering Group for (Q)SARs, the members of which are drawn from the Ad Hoc Group on (Q)SARs, will meet in Paris on 28-29 November 2007 to discuss a plan for the second phase of the Toolbox development.

Forthcoming events:

- Meeting of the Steering Group for (Q)SARs, 28-29 November 2007, Paris
- Release of the proof-of-concept version of the (Q)SAR Application Toolbox, first half of 2008
- Workshop on Structural Alerts for the (Q)SAR Application Toolbox, second quarter of 2008

Recent publications:

📖 Proof-of-concept version of the (Q)SAR Application Toolbox

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 will meet in December 2007 in Paris and review the progress of projects.

Forthcoming event:

- 15th meeting of the Task Force on Environmental Exposure Assessment, 18-19 December 2007, Paris

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.

The Task Force on Harmonization of Classification and Labelling (HCL) met in Bern (Switzerland) on 4-5 July 2007. It agreed on a proposal for the revision of GHS Chapter 4.1 *Hazardous to the Aquatic Environment* and Annex 9 (sections A9.1 to A9.3), in order to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category. This proposal was declassified by the Joint Meeting and will be submitted to the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS) in December 2007.

A proposal for classification and labelling of ozone depleting chemicals is under final review by the OECD Task Force on Task Force on HCL. This proposal is expected to be submitted to the UN SCEGHS in July 2008.

The expert group on Sensitization continues working on the development of a proposal for revising GHS Chapter 3.4 concerning strong versus weak sensitizers. An expert meeting is planned beginning of March 2008 in the United States.

A meeting of the expert group on terrestrial hazards was held on 23-24 October 2007 in Arlington, Virginia (United States); it addressed the items of the mandate given by the UN SCEGHS and agreed on the structure of the report that will be submitted to the Sub-committee in December 2008. This meeting was followed, on 25-26 October, by a meeting of the extended Validation Management Group (VMG) on the Transformation/Dissolution Protocol. The extended VMG agreed on the content of the Report of the Ring Test and Statistical Analysis of Performance of the Test Guidance on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media. It also exchanged views on the work that needs to be completed for developing the following report.

Forthcoming event:

- Meeting of the Task Force on Harmonization of Classification and Labelling, 24-25 April 2007, Paris, France

- Expert group meetings on Terrestrial Hazards, 23 April 2007, Paris France

Recent publications:

- 🕮 Report on the preparation of GHS Implementation by the OECD Countries

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.

Sweden hosted an OECD Workshop on PFCAs and Precursors on 20-22 November 2006 in Stockholm. The Workshop Report was published in June 2007, and the 41st Joint Meeting reviewed its recommendations in June 2007. Implementation of these recommendations is currently underway.

The 39th Joint Meeting agreed on the Hazard/Risk Information Sheets, which are on the OECD public website for Risk Management (**http://www.oecd.org/env/riskmanagement**), and that they should be updated in 2007. To this end, a letter has been sent to member countries in early October requesting new information. This update will be completed during the first quarter of 2008.

The 41st Joint Meeting noted in June 2007 that the OECD work on Sustainable Chemistry contributes to the SAICM implementation and supported the development of an Internet-based platform for facilitating the information exchange, review of new developments and further elaboration of incentives for Sustainable Chemistry. Several Delegations encouraged the Issue Team to engage multiple stakeholders to the network and collect positive examples of progress. It was also emphasised that it would be valuable to measure the progress in implementation both in OECD member countries and non-OECD economies. To this end, the Issue Team has started to develop the platform for collecting the above indicated information, including information on the implementation of Sustainable Chemistry and on tools for its further promotion. Some new work areas will also be explored to encourage eco-innovation towards Sustainable Chemistry.

Recent publication:

- 🕮 Report of an OECD Workshop on Perfluorocarboxylic Acids (PFCAs) and Precursors, Risk Management Series No. 23 [ENV/JM/MONO(2007)11].
- 🕮 Revised Lists of PFOS, PFAS, PFOA, PFCA and Related Substances (developed by Australia to facilitate future data collection on production, import and use of these substances) [ENV/JM/MONO(2006)15]

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

In November 2006, the 40th Joint Meeting reviewed the "Scoping Study on Releases from Products" and expressed support for the continuation of the work. The next steps will focus on compiling existing information, in particular on product-related Release Estimation Techniques (RETs), and their application to sample pollutants from selected products. This work, led by the Nordic PRTR group, will focus on the end-use of products that are not yet fully covered by any inventory, and will start in early 2008. The final output of the project will be a "Resource Compendium of PRTR RETs, Part 4: Summary of Techniques for Products".

The Scoping Study on releases by SMEs began in November 2006 and is now in its final stages. It will be presented to 42nd Joint Meeting for review and approval of the next steps. The global portal to PRTR information (**www.prtr.net**), a project led by Canada, is expected to be published in early 2008 and will be presented to the 42nd Joint Meeting in February 2008. The Guidance Document on Considerations for Ensuring Quality PRTR Data will be completed by the end of 2007 and be published in early 2008.

Forthcoming event:

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

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 and 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, established in 2004, has already developed two Guidance Documents and five Test Guidelines which were published respectively in October and December

2006 (Phase 1). The second phase of the work began in 2006 and consists of developing three Test Guidelines and one Guidance Document. The Guidance Document, "Pesticide Residue Analytical Methods" was published as an EHS publication both in the series on Pesticides (No. 39) and the series on Testing and Assessment (No. 72). Two of the three Test Guidelines were approved by the Environment Policy Committee and they are currently being reviewed by the OECD Council. These Test Guidelines cover "Stability of Pesticides Residues in Stored Commodities" and "Nature of the Pesticide Residues in Processed Commodities – High Temperature Hydrolysis." After approval, the two Test Guidelines will be published, by the end of 2007, under numbers 506 and 507 as part of the 19th Addendum of the OECD Guidelines for the Testing of Chemicals. The third Test Guideline of Phase 2 is still under development; it will be submitted to the Working Group of National Co-ordinators of the Test Guidelines Programme for consideration at their 20th Meeting in April 2008.

Development of Guidance Notes on the Analysis and Evaluation of Dermal Absorption Studies

An Australian led Expert Group, established in 2005, is developing guidance on the analysis and evaluation of dermal absorption studies for use in the risk assessment of pesticides as well as industrial chemicals, biocides and agricultural veterinary products. The Group met at the OECD in Paris on 1-2 October 2007 to revise and complete the draft document. A new version of the "Guidance Notes on Determination of Dermal Absorption" will be circulated to member countries for review in early 2008, with publication expected by the third quarter of 2008.

Biological Pesticides

The BioPesticides Steering Group (BPSG), led by the Netherlands, met in April 2007 in Braunschweig, Germany to finalise its work to develop guidance on the evaluation of microbials for pest control. The document covers the following topics: 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; evaluation of the environmental safety of microbial pest control products; and efficacy evaluation of microbials. The draft "Working Document on the Evaluation of Microbials for Pest Control" will be submitted to the 22nd Working Group on Pesticides Meeting in February 2008 for their review, prior to submitting to the Joint Meeting for final approval.

Minor Uses of Pesticides

Minor use, or small-scale pesticide use, most frequently involves 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 register or maintain a small pesticide use that produces low revenue and does not cover the cost of testing and registration. It is important, however, for farmers to have access to user-friendly, environmentally sound and economically viable minor use solutions because without such pesticides, they may resort to unauthorised or inappropriate pesticides to protect their crops and yields.

OECD, working with other international organisations, particularly FAO, has launched a new initiative to support the most cost-effective development and review of the necessary data for minor use registration. OECD will facilitate mechanisms that enable international cooperation on minor use issues including work-sharing, technical guidance on the preparation of data submissions for minor use, and minimising barriers to approval of safe minor uses. An Expert Group on Minor Uses was established in June, 2007 to carry out the work, and co-ordinate within the Pesticides Programme.

Business Case

OECD countries invest significant resources in evaluating agricultural pesticides before they are marketed (or re-evaluating pesticides that have been in use for many years) to ensure that they do not pose unacceptable risks to human health and the environment. 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, rather than duplicating each others' work. The OECD Pesticides Programme is working to establish the infrastructure that will facilitate such work sharing. The adoption of an OECD-wide future "vision," with specific deadlines for work sharing, should lead to additional (and more routine) work sharing arrangements between governments and industry. A document is currently being developed, with publication expected in the first quarter of 2008, which describes the qualitative and quantitative benefits of work sharing.

Seminar on Risk Reduction through Education / Training the Trainers

A seminar organised by OECD's Risk Reduction Steering Group and hosted by Mexico's Research on Chemicals and Ecotoxicological Risks National Institute of Ecology, will be held on 15 November 2007 in Mexico City. The aims of this seminar are to identify key issues concerning pesticide risk reduction through better training of the trainers, to describe national and international legislative and non-legislative activities for training the trainers to reduce risks from handling and using agricultural pesticides, and to suggest options or further steps for OECD countries and key stakeholders in OECD and non-OECD countries which could address the identified issues.

Forthcoming events:

- 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
- Working Group on Pesticides, February, 2008, Paris

Recent publications:

- 🕮 Guidance Documents *Pesticide Residue Analytical Methods*
- 🕮 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

Forthcoming publications:

- Report of the Seminar on Risk Reduction through Education/Training the Trainers
- The "Business Case" for the Joint Evaluation of Dossiers (Data Submissions) Using Work Sharing Arrangements
- Working Document on the Evaluation of Microbials for Pest Control
- Guidance Document on the planning and implementation of joint reviews

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 release rates to the environment and efficacy to ensure the validity of label claims, producing emission scenarios and promoting sharing of information about risk reduction approaches.

Wood Preservatives

The emissions from preservative (i.e., biocide) treated wood to the environment need to be quantified to enable an environmental risk assessment of the treated wood. A new Test Guideline that describes a laboratory method for the estimation of emissions from preservative treated wood in contact with fresh water or sea water was published in October, 2007. A separate Guidance Document for measuring leaching of biocides from wood not covered and not in contact with the ground is under development.

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 fourth draft was discussed during the fifth meeting of the Task Force on Biocides on 20 September 2007 in Paris. The final ESD is expected to be published in early 2008.

Efficacy

OECD's Biocides Programme is currently developing test methods for the generation of efficacy data for public health antimicrobial biocides (i.e. disinfectants) used on hard surfaces as there are currently no universally accepted test methods for assessing efficacy of these public health-related antimicrobials. A Validation Management Group (VMG) has been formed to validate five different draft test methods that could be used to determine if new biocide products that will be used on hard surfaces (e.g., hospital tables), are effective against a significant number of bacteria, viruses, fungi, spores and mycobateria (i.e., if they are effective). The VMG met for the first time in 2006 to design the validation study that will be comprised of round-robin testing amongst over 20 laboratories. The ring trials are scheduled to be completed in spring 2008.

A Guidance Document on the evaluation of the efficacy of antimicrobial treated articles is nearing completion. This will address treated articles/materials (i.e., plastic, textiles or pre-formed articles pre-treated with biocidal products before first use). Work to develop a series of Test Guidelines to determine the efficacy of biocides used to treat articles is under consideration, as is development of a Guidance Document for establishing the efficacy of biocides used in swimming pools and spas.

Forthcoming event:

- Sixth Meeting of the Task Force on Biocides, September 2008

Recent publication:

- 🕮 Test Guideline 313: Estimation of Emissions from Preservative-Treated Wood to the Environment: Laboratory method for Wooden Commodities that are not Covered and are in Contact with Fresh Water or Sea Water
- 🕮 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

- 🕮 Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects

Contact: Richard Sigman and Sylvie Poret

Website: **http://www.oecd.org/env/biocides**

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.

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

The report on the review of implementation of the Council Recommendation was approved by the Working Group on Chemical Accidents at its 17th Meeting on 17-18 October 2007. It is based on responses to an extensive survey questionnaire circulated to member countries in 2006. This survey requested information on national laws and policies related to chemical accidents as well as on the use of the *OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response*, and the *OECD Guidance on Safety Performance Indicators*. The report will be forwarded to the 42nd Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (February 2008).

Value of OECD Projects to Delegations – Overview of Survey Results

A survey of member countries to assess the value of OECD projects to delegations was conducted in 2006. A short questionnaire was circulated to delegations, asking for views about specific projects and requesting additional suggestions to improve the Chemical Accidents Programme. This was prepared as a companion to the review of the Implementation of the OECD Council Recommendation concerning Chemical Accident Prevention, Preparedness and Response. The survey results were discussed at the 17th WGCA Meeting in October 2007.

Revision of Guidance on Safety Performance Indicators (SPI)

Following a second SPI Expert Group Meeting in November 2006, the SPI Guidance has undergone extensive revisions. There are currently two documents: one for Industry; one for Public Authorities (including federal, state, and local public authorities as well as elected officials and emergency responders). The main changes concern the SPI Guidance for Industry; Chapter 2 is new and is based on the UK's HSE (Health and Safety Executive) document "Developing Process Safety Indicators" as well as lessons learned from the OECD SPI Pilot Programme. This chapter provides a seven-step approach for designing, implementing, and revising an SPI Programme. The draft SPI Guidance for Industry was approved by the 17th WGCA Meeting in October 2007. The whole SPI Guidance, that for Industry and that for Public authorities, will be reviewed by the Working Group by the end of 2007.

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

The report on the use of safety reports or equivalent documents in the control of major accident hazards was approved by the 17th WGCA Meeting. This report is based on responses to a survey questionnaire circulated to member countries. The report includes conclusions and suggests undertaking further work in this area.

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

The report of the Workshop on "Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases" that took place in Varese, Italy in October 2006 has been published as an Environment, Health and Safety publication, in the series on Chemical Accidents, No. 16.

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, took place on 8-9 May 2007 in Potsdam, Germany. The workshop was held back-to-back with the 17th Meeting of the EC Committee of Competent Authorities responsible for the Seveso II Directive. The objective was 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. The draft conclusions and recommendations of this workshop were approved by the 17th WGCA Meeting in October 2007. The full report will be available early 2008.

Workshop on Safety in Marshalling Yards

A Workshop on "Safety in Marshalling Yards", sponsored by the Dutch Ministry of Housing, Spatial Planning and the Environment, took place on 15-16 October 2007 at the OECD headquarters in Paris. The objective was to: exchange views on chemical safety issues connected with railroad marshalling yards; identify solutions in the areas of policy, civil design and technical measures, organisational measures and spatial planning; and, make recommendations for good practices. The conclusions and recommendations from the workshop will be available for review by the WGCA by end of 2007.

Forthcoming Events:

- 18th Meeting of the OECD Working Group on Chemical Accidents (WGCA), 8-9 October 2008, OECD, Paris, France [To be confirmed]

Recent Publications:

- Report of the Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases, Varese, Italy, October 2006 [ENV/JM/MONO(2007)29)

Contact: Marie-Chantal Huet

Website: **http://www.oecd.org/env/accidents**

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.

The 20th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology met in Paris, 24-26 October 2007. Participants included, as usual, many delegates from non-member countries (Argentina, Brazil, Cameroon, Chile, Estonia, India, Philippines, Russian Federation and Slovenia).

Major progress was seen in the project on *Environmental Consideration of Risk/ Safety Assessment of the Release of Transgenic Plants*. This project intends to provide a comprehensive package of information elements to be used in considerations during risk/ safety assessment of transgenic plants. The Working Group considers that this document could be the third milestone of OECD's work on biosafety, following the well-known publications, *Recombinant DNA Safety Considerations* (the so-called Blue Book) and *Safety Considerations for biotechnology: Scale-up for Crops*. A steering group on this project held a second meeting at the Finnish Environment Institute in Helsinki at the end of August. The key components and structure of the document were deliberated there. The second draft is expected to be completed in May 2008.

Major progress has also been made on the project of *Unique Identifier for Transgenic Micro-organisms*. This is a project to develop a unique identification system for transgenic micro-organisms (bacteria) that have gone through the regulatory process leading to commercial application for release into the environment. This builds on existing guidance for the unique identifier for transgenic plants (**http://appli1.oecd.org/olis/2002doc.nsf/linkto/env-jm-mono(2002)7-rev1**). In June 2007, the Sub-working Group on Micro-organisms of the Working Group held a workshop at Moscow State University, where it developed a draft questionnaire for stakeholders to gather their views and input on the development of a unique identifier for transgenic bacteria. This workshop was hosted by the Ministry for Education and Science of the Russian Federation, the Russian Academy of Science (RAS) and Scientific Council of RAS on Biotechnology. The draft questionnaire was discussed at the 20th meeting of the Working Group. It is expected the questionnaire will be distributed to stakeholders in early 2008.

The second round of discussion on the potential new project on low level presence of transgenic crops in conventional bulk shipments, which is an important issue for some sectors of industry and governments, was made during the meeting. As there still were diverse opinions/ expectations on the objectives and scope of this potential project, it was agreed to organise a workshop to intensively discuss this topic. This workshop will be held in April 2008. It is worthwhile noting that a parallel project on adventitious presence of transgenic crops has been undertaken by FAO/WHO Codex Alimentarius Committee – from a food safety point of view.

The 20th meeting also made progress on various other projects, including: the project on molecular characterisation; some consensus documents on tree species (Douglas fir, Lodgepole pine, Western White Pine and Black spruce); a Consensus Document on *Cucurbita* spp.; a Consensus Document on *Fusarium*; a Consensus Document on Acinetobacter; a Guidance Document on Horizontal Gene Transfer between Bacteria; and a Guidance Document on Potential Health Effects of Bacteria.

Forthcoming events:

- 21st Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, 25-27 June 2008, OECD Headquarters, Paris

Recent Publications:

- 🕮 Consensus Document on Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Proteins
- 🕮 Consensus Document on the Biology of the native North American Larches

Forthcoming Publications:

- 🕮 Consensus Document on the Biology of Douglas Fir
- 🕮 Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Acinetobacter*

Contact: Peter Kearns and Masatoshi Kobayashi

Website: *BioTrack Online* (**http://www.oecd.org/biotrack**)

SAFETY OF NOVEL FOODS AND FEEDS

The main focus of OECD's Task Force 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. 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.

Since 1999, the Task Force for the Safety of Novel Foods and Feeds (Task Force) has been addressing aspects of the safety assessment of foods and feeds derived from genetically engineered crops. The aim of the work is to ensure that the types of information used in risk/ safety assessment, as well as the methods used to collect such information, are as similar as possible amongst countries.

Consensus Documents on compositional considerations of specific food/feed crops.

The main output of the food and feeds programme are ***consensus documents*** on compositional considerations of specific food/feed crops. These documents compile scientific information on the major components of specific crop plants, such as key nutrients, toxicants, anti-nutrients and allergens that may be useful in assessing the safety of specific crops with respect to human food and animal feed safety. This information is of value in the safety assessment of new (genetically engineered) varieties because, typically, safety assessment involves a comparison of these components between the new variety, and existing traditional varieties. These documents are not legally binding, but because they are agreed upon through consensus by member countries, they are highly valued during the risk/ safety assessment process.

To date, eleven consensus documents addressing major crops have been completed and published on: low Erucic Acid Rapeseed (Canola); Soybean; Sugar Beet; Potatoes; Maize; Bread Wheat; Rice; Cotton; Barley; Alfalfa and other Temperate Forage Legumes; and Sunflower. In addition, the Task Force recently published the first consensus document on a mushroom (*Agaricus bisporus*), using the same structure as in the crop plant documents. The Task Force also develops documents on other important topics in safety assessment. For example, it published a document on 'Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants', which is complementary to the other consensus documents. In addition, a consensus document on Tomato will soon be completed; and three documents are being prepared on Papaya, Cassava, and Sweet Potato.

The Task Force has recognised the need for keeping the information included in the consensus documents as updated as possible in order to reflect the latest data and information available on the levels of key constituents in the crops. With this in mind, the Task Force established a process for revising published consensus documents. At the present time, the two earliest documents are being updated: low Erucic Acid Rapeseed (Canola); and Soybean.

A useful background document for understating the scope and development of the Task Force consensus document is *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force*. This document was published in 2006 and it explains, amongst other things, i) why the Task Force decided to prepare consensus documents as part of its programme of work; ii) the purpose and use as a practical contribution to the risk/safety assessment of foods and feeds derived from transgenic organisms; and iii) the process by which consensus documents are drafted and brought to final publication.

Outreach and non member economies engagement

One of the main features of the Task Force has been the creation and maintenance of stable networks with non member economies, as well as invited experts to its work. The Task Force recognised that modern biotechnology is an increasingly global issue, and thus the need to meet standards goes beyond OECD member countries. The Task Force benefits from the participation of delegations from: Argentina, Brazil, China, Latvia, the Russian Federation, Slovenia, South Africa and Thailand. These countries are active in

food safety assessment and have expertise to bring to bear on the topic. They have made active contributions to the consensus documents which have been published and the substance of the texts has been strengthened as a result.

The Task Force involves more actively the expertise and interests of non member economies, not only to broaden the expertise available to the Task Force, but also for addressing a wider range of food and feed products that are of global interest. For example, Thailand and South Africa are currently preparing three consensus documents on compositional considerations for papaya, cassava, and sweet potato. These crops are of high importance for their respective countries, as well as for many other OECD members countries and non-members economies. These three consensus documents are being drafted in co-operation with delegations from OECD member countries.

To date, non members participation has been possible through the Global Forum on the Knowledge-based Economy (GFKE) under the auspices of OECD's Centre for Co-operation with non-members.

Finally, the Task Force also involves the Codex Alimentarius Commission, the United Nations (U.N.) Food and Agriculture Organization (FAO); the U.N. World Health Organization (WHO); and the Business and Industry Advisory Committee to OECD (BIAC).

OECD work on the risk/safety assessment of modern biotechnology

The Task Force complements the activities of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, which addresses environmental safety issues associated with genetically modified crops.

At the present time, the Task Force is carrying out jointly with the Working Group a project on Molecular Characterisation for Transgenic Plants. The first draft has recently being completed and it is currently under discussion by both the Working Group and the Task Force.

In addition, a Brochure on the ***OECD work on the risk/safety assessment of modern biotechnology***, which aims to capture activities of both the Task Force and Working Group, has been finalised and will soon be publicly available.

Finally, the OECD work also complements other international activities. Recently, the OECD (Task Force) and the FAO Secretariats prepared a joint proposal for contributing to the Codex Information Sharing Mechanism, which was agreed by the Codex *ad hoc* Task Force on Food Derived from Biotechnology.

Future events:

- 14th Meeting of the Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 8-10 April 2008.

Recent 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 the Sunflower: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*

Upcoming Publications:

- 🕮 *Consensus Document on Compositional Considerations for New Varieties of Tomato (Lycopersicon esculentum): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*
- 🕮 *Brochure on the OECD work on the risk/safety assessment of modern biotechnology*

Web site: *BioTrack Online* (**http://www.oecd.org/biotrack**)

Contacts: Mar Gonzalez

SAFETY OF MANUFACTURED NANOMATERIALS

The term "manufactured nanomaterials" covers a diverse range of materials that are developed to exploit the changes in behavior and properties that occur at the nanoscale. The number of products and the diversity of nanomaterials are predicted to increase rapidly in the coming decade as a result of the high levels of investment that is driving innovation across many sectors. The main objective of the OECD work in this area is to assist countries in developing tools to allow them to better address the safety aspects of manufactured nanomaterials.

The Working Party on Manufactured Nanomaterials (WPMN), which is a subsidiary body of OECD's Chemicals Committee, was established in 2006. The aim of its programme of work is to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials, in order to assist in their safe development.

In order to implement its programme of work, there are six main projects underway. There are also several parallel activities to address specific issues identified by the projects. The current status of these projects and activities are summarised below.

Project 1: Development of an OECD Database on Human Health and Environmental Safety Research

Phase 1 of this project is developing a resource for delegations to identify past, current and planned research related to human health and environmental safety. The information derived from this database will be useful in implementing each of the other projects. A prototype of the database (Phase 1) will be presented at the 3rd meeting of the WPMN (28-30 November 2007). The next steps for phase 2 of the database development will also be agreed at the meeting.

Project 2: Research Strategies on Manufactured Nanomaterials

This project aims at developing a research strategy(ies) for manufactured nanomaterials. A questionnaire has recently been completed by delegations concerning past, current, and planned research on the safety of manufactured nanomaterials. Based on the results from the questionnaire, this project will identify a list of research themes, which should be undertaken to address human health and environmental safety, as well as those areas that have not yet been addressed. A preliminary analysis on research priorities will be discussed at the 3rd WPMN. Recommendations and the possibilities for international co-operation on the prioritised research projects will be developed by mid 2008.

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

This project has developed a list of representative manufactured nanomaterials and a minimal required set of endpoints to support a testing programme for nanomaterials. It is expected that this will provide an understanding of the kind of information on the intrinsic properties of nanomaterials relevant to exposure and effects assessment for human health and environmental effects for a specified set of endpoints.

The 3rd WPMN will discuss the next steps for implementing a "sponsorship programme" for testing manufactured nanomaterials, which is proposed to be developed in two phases. The 1st Phase will include the testing of specific manufactured nanomaterials for identified endpoints. This will allow the development of data of the type that would indicate (or contra-indicate) further testing (i.e.: on characterization, fate and

environmental and mammalian toxicity endpoints) that could be considered by the WPMN for the second phase in completing testing dossiers for specific nanomaterials. There will also be a consideration of Alternative (test) Methods.

Project 4: Manufactured Nanomaterials and Test Guidelines

This project aims at reviewing the published OECD Test Guidelines (while taking into account other internationally accepted testing methods) to identify whether or not they are suitable for use when considering nanomaterials. Four small drafting groups have been established to review Testing Guidelines for: i) Physical Chemical Properties; ii) Effects on Biotic Systems; iii) Degradation and Accumulation; and iv) Health Effects. The 3rd WPMN will consider preliminary conclusions and recommendations from a review of Test Guidelines related to physical chemical properties, which has been recognised as the first priority of this project.

Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

A number of countries have put "voluntary schemes" or "stewardship programmes" in place to assess the safety of nanomaterials. As part of this project, an *Analysis of Information Gathering Initiatives* has been completed. It includes the similarities and differences identified in these national initiatives. This analysis also includes a number of considerations and recommendations on approaches and elements to consider by those countries wishing to launch similar initiatives. In addition, a *Comparison of Regulatory Regimes for Manufactured Nanomaterials* has also been completed. This exercise identifies how current and proposed regulatory regimes address the risk assessment of manufactured nanomaterials, and suggests a "template" form to identify the various components of regulatory regimes which are or may be applicable to nanomaterials.

Project 6: Co-operation on Risk Assessment

This project aims at identifying existing risk assessment schemes and is reviewing them to establish if they are suitable for the assessment of nanomaterials. This project is currently compiling current risk assessment strategies and methodologies for chemicals that are being currently used - or may be extended to include - manufactured nanomaterials. At the same time, supporting tools will be identified that are currently available which offer the potential to strengthen and enhance risk assessment of manufactured nanomaterials.

Additional work to be considered

At its next meeting, the WPMN will discuss how to move forward with future work on: i) alternative (test) methods; and on ii) exposure measurement and mitigation methods. Draft operational plans have been prepared for both these areas for consideration at the 3rd WPMN.

Co-ordination and Outreach

The WPMN is currently developing a "Vision Statement of the OECD Work on Manufactured Nanomaterials", which will explain the programme to a broader audience of stakeholders. The WPMN also publishes, periodically, compilation documents on current developments/ activities on the safety of manufactured nanomaterials in countries and organisations. The WPMN has also agreed on the need for ensuring the outputs of the WPMN be disseminated as widely as possible. With this in mind, the WPMN is developing a communication strategy for ensuring that the products of the WPMN be available and accessible to a broad audience.

Engagement with non members

Nanotechnologies are a global issue and consequently the need to meet environmental and health safety standards goes beyond OECD member countries. For this reason, the WPMN is increasingly involving the participation of key non-member economies (to date, Brazil, China, the Russian Federation, and Thailand), as well as receiving the inputs of BIAC (the Business and Industry Advisory Committee to

OECD) and environmental NGO's. The WPMN also co-ordinates with other activities addressing nanotechnologies such as: i) internal (the activities of OECD's Working Party on Nanotechnology); and ii) external (with other international and /or national initiatives). As a result, there is strong communication with other international organisations such as the IOMC participating organisations, UNESCO, and ISO.

Forthcoming events:

- 3rd Meeting of the Working Party on Manufactured Nanomaterials, 28-30 November 2007, Paris, France
- 4th Meeting of the Working Party on Manufactured Nanomaterials, 11-13 June 2008, Paris, France

Recent Publication:

- 🕮 Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials, Berlin, Germany, 24-26 April 2007

Contact: Peter Kearns, Mar Gonzalez and Noriko Oki

Website: **http://www.oecd.org/env/nanosafety**

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. In order for information technology developers to build data entry screens and/or database systems based on the OECD templates which can generate data files that can be imported into other database systems, each template has to have a corresponding "XML schema" (i.e., a common electronic data export/import format). These XML schema were posted on the public web page in June, 2007. [*see* http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html]

Work has now shifted to the development of new templates and XML schema for recently adopted Test Guidelines.

Contact: Richard Sigman and Nathalie Delrue

Website: **http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.htm**

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 a workshop will be held on 11-13 December 2007 in Washington D.C., hosted by the US-EPA 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 the Application of the GHS Classification Criteria to HPV Chemicals

The OECD workshop on the application of the GHS classification criteria to HPV chemicals was held on 5-6 July in Bern (Switzerland). The report of the workshop has been declassified by the Joint Meeting and will be soon available on the public website. It will be submitted to the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals in December 2007, for information.

Contact: Anne Gourmelon, Bob Diderich, Laurence Musset

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/**
Biocides	**http://www.oecd.org/env/biocides**
Biosafety	**http://www.oecd.org/biotrack**
Chemical Accidents	**http://www.oecd.org/env/accidents**
Existing Chemicals	**http://www.oecd.org/env/existingchemicals**
Existing Chemicals Pointer Database	**http://www.oecd.org/ehs/exichem**
Global Portal to Information on Chemical Substances	**http://www.oecd.org/ehs/eChemPortal**
Good Laboratory Practice	**http://www.oecd.org/env/glp**
Harmonisation and Classification of Labelling	**http://www.oecd.org/env/classify**
New Chemicals	**http://www.oecd.org/env/newchemicals**
Pesticides	**http://www.oecd.org/env/pesticides**
Pollutant Release and Transfer Registers	**http://www.oecd.org/env/prtr**
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**

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

If you are unable to find what you are looking for, please contact the Secretariat:
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GOURMELON, Anne	Test Guidelines, Endocrine Disrupters	**98.49**
HARJULA, Henrik	PRTR, Risk Management	**98.18**
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