

Environment, Health & Safety News

No. 19, July 2006

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. 18, issued in November 2005), the EHS Division has seen the following changes in staffing:

Nanomaterials: *Noriko Oki* has joined the Nanomaterials team. *Diana Morales* has taken over the secretarial support for this programme from *Jill Gibb*, who is now working on communication and IT issues and providing the secretarial support for Chemical Accidents.

Test Guidelines: *Drew Wagner* left the OECD at the end of December. *Laurence Musset* replaced Drew as the Principal Administrator of the Test Guidelines Programme. *Kotaro Yoshida* left the OECD at the end of March. *Nathalie Delrue* joined the Test Guidelines team on 1 May. Nathalie also works on New Chemicals. *Miriam Jacobs* left the OECD in July.

GLP: *Nobu Nakashima* is now working on GLP and Mutual Acceptance of Data issues.

Existing Chemicals: *Anne Gourmelon* is now working on Existing Chemicals as well as Test Guidelines. *Sally de Marcellus* has returned from temporary assignment and has taken over duties in the Existing Chemicals team.

Risk Management, New Chemicals, Chemicals Outlook: *Heung-Jin Choi* left the OECD in February.

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.

Refocus of the Test Guidelines Programme

A Special Meeting of the Working Group of the National Coordinators for the Test Guidelines Programme (WNT) was held on 28-29 November 2005. The WNT prepared the revision of the Guidance Document on the Development of Test Guidelines (GD N°1) and of the Terms of Reference for the WNT; it agreed on a revised Standard Project Submission Form (SPSF) and on the rolling work plan for 2006-2008.

Test Guidelines

The 16th Addendum was adopted by the OECD Council on 23 March 2006 and sent to the publication service; it encompasses:

New Test Guidelines

- 123 Partition Coefficient (1-Octanol/Water): Slow-Stirring Method
- 221 Lemna sp. Growth Inhibition Test
- 310 Ready Biodegradability –CO₂ in Sealed Vessels (Headspace Test)
- 311 Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production

Updated Test Guidelines

- 104 Vapour Pressure
- 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test
- 425 Acute Oral Toxicity – Up-and-Down-Procedure (UDP)

Revised introduction to Section 3 of the OECD Guidelines for the Testing of Chemicals

- Part 1 Principles and Strategy related to the Testing of Degradation of Organic Chemicals
- Part 2 Bioaccumulation and Behaviour in Soils and Sediments

The 17th Addendum was declassified by the Joint Meeting on 22 February 2006 and is expected to be adopted by Council at the end of August. 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

Acute inhalation Toxicity

An expert consultation meeting on acute inhalation toxicity was held in Berlin (Germany) on 22-24 February 2006; it discussed two alternative draft Test Guidelines: the acute toxic class and fixed-dose procedure inhalation toxicity Test Guidelines, and developed a strategy how to finalize the draft Test Guidelines and a related Guidance Document. It also discussed the revision of TG 403: Acute Inhalation Toxicity.

Call for nominations of laboratories for a validation study

The Secretariat has asked for nominations of participating laboratories for the validation of the Fish Sexual Development Test. The project is an initiative of the Nordic Countries. It is led by Denmark. The study will start in autumn 2006.

New Test Guideline on “Fish Embryo Toxicity Test”

The new draft Test Guideline was circulated for comments in May 2006. The deadline for comments is 1 September 2006.

Endocrine Disrupters

The Validation Management Group on Ecotoxicity Tests (VMG-eco) and the Validation Management Group on Non Animal Testing (VMG-NA) were held on 12-13 December 2005 and 14-15 December 2005 respectively, at the OECD. The Validation Management Group on Mammalian Effects Testing was held on

4-5 April 2006, in Washington (United States), and the Endocrine Disrupter Testing and Assessment (EDTA) Task Force was held on 26-27 April 2006 in Sundryberg (Sweden).

The respective roles of the EDTA Task Force and Validation Management Groups (VMGs) have been clarified by the WNT. The Draft Test Guideline on the Uterotrophic Assay was circulated in May 2006 for comments/approval. The peer review of the validation of the 21-day Fish Screening Assay, of the Hershberger Assay and of the updated TG 407: Repeated Dose 28-day Oral Toxicity Study in Rodents will start in the coming months. Different approaches will be used for the peer review process of these test methods validation.

All VMG validation reports and the summary report of the Uterotrophic Assay peer review panel, which have been endorsed by the WNT, will be submitted to the Joint Meeting with a view to their declassification; the WNT conclusions will be attached to the summary report of the peer review panel. The Detailed Review Paper (DRP) on the Use of Metabolism Systems for in vitro Testing of Endocrine Disrupters is being finalized.

18th WNT Meeting

At its 18th meeting (16-18 May 2006), the WNT agreed on:

- 5 new Test Guidelines and 2 Guidance documents on Pesticides Residue Chemistry
- A new Test Guideline “Determination of the inhibition of the activity of Anaerobic Bacteria”
- A Detailed Review Paper on Thyroid Hormone Disruption Assays
- A Detailed Review Paper on Aquatic Arthropods
- A Guidance Document for a Litter Bag Test on Organic Matter Breakdown.

After finalization, the above mentioned documents will be submitted to the Joint Meeting by written procedure as the 18th Addendum. Initial discussions took place at the 18th meeting of the WNT on the need to revise existing Test Guidelines to reflect scientific progress, address animal welfare concerns and improve cost effectiveness of test methods. A number of policy issues need to be addressed in relation to the revision of the Test Guidelines.

Toxicogenomics

The OECD, in close cooperation with the International Programme on Chemical Safety (IPCS), has developed a plan of action to explore and evaluate regulatory application of genomic methods in chemical assessment in order to meet the practical needs of the member countries. In February 2006, the 39th Joint Meeting endorsed three project proposals developed by a small Advisory Group of experts nominated by the IPCS and the OECD:

- Molecular Screening for Characterising Individual Chemicals and Chemical Categories;
- New Biomarkers; and
- Survey on Available Omics Tools.

The OECD/IPCS Advisory Group on Toxicogenomics will review the progress of each project and report back to the Joint Meeting on a regular basis.

Forthcoming events:

- Meeting of the Guidance Document Drafting Group for Acute Inhalation Toxicity Testing, Berlin (Germany), 11-12 July 2006
- Expert Meeting on the DRP on Cell Transformation Assays, Washington (United States), 3-5 October 2006
- Expert Consultation Meeting on Acute Inhalation Toxicity Testing, Washington (United States), 28-30 November 2006
- Meeting of the Validation Management Group for Non Animal Tests, Tokyo (Japan), 12-14 December 2006
- Meeting of the Validation Management Group for Ecotoxicity Testing, Madrid (Spain), 23-24 January 2007

- Meeting of the Validation Management Group for Mammalian Tests, Slovenia, January 2007
- EDTA Task Force Meeting, Paris, 27-28 March 2007
- 19th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT19), Paris 28-30 March 2007

Recent publications:

- 📖 Guidance Document on Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment (GD N°34)
- 📖 Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms) (GD N°53)
- 📖 Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application (N°54)
- 📖 Guidance Document for the Development of OECD Guidelines for the Testing of Chemicals (GD N°1 revised).

Contact: Laurence Musset

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

(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.

Three work items are currently underway by the Ad Hoc Group on (Q)SARs:

- Finalisation of a Guidance Document on the validation of (Q)SAR models, which is intended to be used in conjunction with, and explain and illustrate the application of the "OECD Principles for the Validation for Regulatory Purposes, of (Q)SAR models" approved in November 2004.
- Development of a case study report on the current status of regulatory use and application of (Q)SAR models in member countries, which will assist in the identification and use of (Q)SAR models in regulatory contexts.
- Development of a (Q)SAR Application Toolbox to assist member countries in the use of (Q)SAR models in regulatory application and decision-making.

The Steering Group for (Q)SARs, the members of which are drawn from the Ad Hoc Group, met at the OECD on 1-2 December 2005 to advance the projects mentioned above and prepare them for discussion by the Ad Hoc Group. Based on the outcome of the meeting of the Steering Group, a two-year project to develop a Toolbox Prototype began in April 2006. The Ad Hoc Group has developed drafts for the Guidance Document on the validation of (Q)SAR models as well as for the case study report. The final draft of the case study report was sent to the Heads of Delegations to the Joint Meeting in June 2006 seeking approval for declassification.

The Ad Hoc Group met in Stresa, Italy, on 8-9 June 2006 to review the progress of the projects and to discuss the future direction. The Ad Hoc Group agreed on a course of revision and early completion of the Guidance Document on the validation of (Q)SAR models and discussed design features of the (Q)SAR Application Toolbox Prototype such as modules and components. The Steering Group will meet in late October or early November 2006 to prepare the next meeting of the Ad Hoc Group, scheduled to take place in 2007.

Forthcoming events:

- Meeting of the Steering Group for (Q)SARs, October/November 2006 (*date and venue to be decided*)
- Meeting of the Ad Hoc Group on (Q)SARs, second quarter of 2007 (*date and venue to be decided*)

Forthcoming 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

Web site: http://www.oecd.org/document/23/0,2340,en_2649_34379_33957015_1_1_1_1,00.html

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.

Three Emission Scenario Documents (ESDs) and a case study report on comparison of methods used in PRTRs and ESDs were published in February 2006:

http://www.oecd.org/document/46/0,2340,en_2649_34365_2412462_1_1_1_1,00.html.

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 September 2006 in Ottawa and review the progress of each project.

Canada and the United States hosted a hands-on training workshop on application of multimedia models in assessing chemicals for persistence and potential for long range transport from 31 May to 2 June 2006 in Ottawa. Japan held a workshop with similar topics for East Asian countries in Tsukuba on 27-28 June 2006 in co-operation with the OECD.

The report of the first Policy Dialogue on Exposure Assessment was published in February 2006:

http://www.oecd.org/document/30/0,2340,en_2649_34365_1916638_1_1_1_1,00.html (see No. 51).

A second dialogue was held on 14 February 2006 at the OECD back to back with the 39th Joint Meeting. The Joint Meeting concluded that the dialogue had been useful for information exchange and supported its proposals on follow-up activities. The Joint Meeting recognised that the dialogue had completed its role at this stage and agreed to conclude it.

Forthcoming events:

- 14th meeting of the Task Force on Environmental Exposure Assessment, 20-21 September, Ottawa

Recent publications:

- 📖 Emission Scenario Document on Kraft Pulp Mills
- 📖 Emission Scenario Document on Recovered Paper Mills
- 📖 Emission Scenario Document on Non-integrated Paper Mills
- 📖 Report on comparison of emission estimation methods used in Pollutant Release and Transfer Registers (PRTRs) and Emission Scenario Documents: Case study of Pulp and paper and Textile sectors

Contact: Take Fukushima

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


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 20th time 4-6 April 2006. Chinese Taipei took part as an ad hoc observer. The main issue on the agenda was the finalisation of the proposal to the Joint Meeting on the establishment of a continuing programme of on-site evaluations on GLP compliance monitoring programmes in member and adhering non-member countries. If the Joint Meeting agrees to this proposal, the next round of on-site evaluations will begin in 2008. The Working Group also endorsed a position paper on "outsourcing of inspection functions by GLP Compliance Monitoring Authorities", subsequently declassified by the Joint Meeting http://www.oecd.org/department/0,2688,en_2649_34381_1_1_1_1_1,00.html and commented on a draft document on archiving in a GLP environment.

The Austrian GLP compliance monitoring programme for medical products presented its programme and the report of the Mutual Joint Visit to the Canadian GLP compliance monitoring programme for pesticides was discussed. The 8th OECD Training Course for GLP Inspectors, a basic training course, will take place in Edinburgh from 17-22 September. Organised by the UK, trainees from OECD and the following non-OECD countries were invited to take part: India, China, Chinese Taipei, Singapore, Cyprus, Malta, Latvia, Lithuania, Estonia, Bulgaria, Roumania, Argentina and Brazil.

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

Web site: <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 has been invited by the Council to become a provisional adherent to the Council Acts related to MAD. India is a provisional adherent, while South Africa, Slovenia and Israel are full adherents to the system. A workshop on Mutual Acceptance of Data, GLP and compliance monitoring was held in Singapore on 20-22 June 2006. Several members of the Working Group on GLP took part in this information meeting for government and industry in Singapore. The Secretariat continues to work with China, Chinese Taipei and Brazil in view of their provisional adherence to the MAD Council Acts as well, and has had preliminary discussions with several other non-members.

Contact: Dian Turnheim

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

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 22nd SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Paris on 18-21 April 2006. More than 100 representatives from member countries and industry attended the meeting. Assessments for 90 chemicals were agreed. The conclusions and recommendations for these chemicals were endorsed by the Task Force on Existing Chemicals and will be submitted to the Joint Meeting for adoption through written procedure in the course of July 2006.

Batches of assessments for 33 and 35 chemicals were sent to UNEP Chemicals in November 2005 and May 2006 and are currently under preparation for publication. [<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>]. Altogether assessments for 327 chemicals have been published and final drafts are publicly available for another 68 chemicals. Furthermore the Secretariat has published an additional 50 IUCLID export files of previously agreed SIDS Dossiers on the public OECD website:
http://www.oecd.org/document/55/0,2340,en_2649_34379_31743223_1_1_1_1,00.html.

Progress is being made on the development of a globally accessible data repository for hazard data on HPV chemicals (Global HPV Portal). The Steering Group for the development of the Global HPV Portal met on 7-8 March 2006 and 18-19 May 2006 and developed criteria for participating in a first version of the Global Portal and defined the roles and responsibilities in the management and for participating databases. Programming will take place in the summer and a beta version should be available by the end of 2006, followed by a review by the Steering Group and Task Force on Existing Chemicals. Discussions have also started in the Steering Group on the building of the second version of the Global Portal. A strategy to engage users is being elaborated.

The Task Force on Existing Chemicals met in Tokyo on 15-16 December 2006. It endorsed a proposal for an informal exercise to apply GHS criteria to chemicals assessed in the OECD HPV Chemicals Programme; this exercise will be implemented as from SIAM 23. The Task Force also endorsed revised guidance for various chapters of the Manual for Investigation of HPV Chemicals and these revisions are posted on the public OECD web site:
http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

An update of EXICHEM, limited to new entries, is foreseen in 2006. EXICHEM 2006 is expected to be published early 2007.

Forthcoming events:

- Meeting of the Steering Group for the development of the Global HPV Portal, 12-13 October 2006
- SIAM 23, 17-20 October 2006, Jeju, Korea
- SIAM 24, 17-20 April 2007, Paris, France

Contact: Bob Diderich

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

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.

The Korean Workshop on “Consideration of Chemical Safety in Green Procurement” proposed a number of new work areas, although time at the workshop was too limited to further develop these proposals [ENV/JM/MONO(2006)11]. Many proposed work areas require member country activities, rather than OECD involvement. Therefore, no new OECD work on CPP has been put forward, although there might be a need for a follow-up workshop at a later stage.

The Hazard/Risk Information Sheets of five brominated flame retardants have been updated by Switzerland to include new information on hazard and risk assessment and management (http://www.oecd.org/document/22/0,2340,en_2649_34375_1935254_1_1_1,00.html).



Draft Lists containing PFOS, PFAs, PFOA and related substances have been developed by Australia to facilitate data collection for the 2006 survey on production, import and use of these substances (published in April 2006, see below). In addition, Sweden will host an OECD Workshop on PFCA and Precursors in November 2006 in Stockholm.

A Sustainable Chemistry Network has been established for information exchange, review of new developments and further elaboration of incentives for sustainable chemistry.

Forthcoming event:

- OECD Workshop on PFCA and Precursors, 20-22 November 2006, Stockholm, Sweden

Recent publications:

-  Workshop Report on Consideration of Chemical Safety in Green Procurement, Risk Management Series No. 20 [ENV/JM/MONO(2006)11]
-  Preliminary Lists of PFOS, PFAS, PFOA and related Compounds and Chemicals that may degrade to PFCA, Risk Management Series No. 21 [ENV/JM/MONO(2006)15]

Contact: Henrik Harjula

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

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.

In December 2005, the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS) adopted the proposal on sensitization elicitation. The Sub-Committee also took note of the conclusion of the OECD Task Force on Harmonization of Classification and Labelling with respect to the work on carcinogenicity potency estimation methods (i.e. that the work should be discontinued for the time being and a decision on whether or not to restart it should be taken later).





The Task Force on Harmonization of Classification and Labelling was held in Rome on 15-16 March 2006. The Task Force agreed on a draft scientific issue paper on strong versus weak sensitizers, a draft scientific issue paper on chronic aquatic hazards, and a draft issue paper on Toxic Gas Mixtures. The declassification of these documents was agreed by the Joint Meeting, and they will be submitted at the July meeting of the UN SCEGHS. The Task Force also agreed on a scheme for classification of substances for chronic aquatic hazards; the expert group on chronic aquatic hazards is now finalising a proposal for classification of substances and mixtures for chronic hazards.

A meeting of the Validation Management Group and of the expert group on the Transformation/Dissolution Protocol was held on 13-14 March 2006; it prepared a proposal on next steps for the validation of the protocol; this proposal was agreed by the Task Force. An expert meeting on Toxic Gas Mixtures was held 17 March 2006; it agreed on further work to develop a proposal on Toxic Gas Mixtures. In cooperation with UNITAR, the Secretariat is developing a questionnaire on the status of GHS implementation to be circulated to OECD countries and non member economies.

Forthcoming events (to be confirmed)

- Meeting of the Validation Management Group and expert group on the Transformation/ Dissolution Protocol, Brussels, 28-29 September 2006
- Meeting of the Task Force on Harmonization of Classification and Labelling, Washington, 15-16 February 2006

Recent publications

-  Detailed Comparison of Classification Systems for Ozone Depleting Chemicals
-  Scientific Issue Paper on Strong versus weak Sensitizers
-  Scientific Issue Paper on Chronic Aquatic Toxicity
-  Issue Paper on Toxic Gas Mixtures

Contact: Laurence Musset

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

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.

A document describing the OECD New Chemicals Task Force's two year pilot project testing a parallel notification process aimed at simplifying and streamlining access to multiple markets for new chemicals, has been published. The Parallel Process refers to a company notifying multiple jurisdictions and authorizing participating governments to share information when conducting their reviews. Jurisdictions participating in the Parallel Process utilize 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. Companies interested in participating are encouraged to inform their national authorities.

Discussion papers on exemption/reduced notification requirements for R&D, polymers and site isolated intermediates are being developed for eventual adoption by OECD. Harmonisation of such elements will facilitate the exchange of information and work amongst countries. In addition, work continues on the development of an electronic notification system, which will allow companies to enter information for all possible notifications for a particular new chemical

Recent publications:

 Pilot Phase of the OECD Parallel Process for the Notification of New Chemicals

Contact: Richard Sigman

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

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 draft Test Guidelines (*Metabolism in Crops; Metabolism in Rotational Crops; Metabolism in Livestock; Residues in Rotational Crops; and Residues in Livestock*) and two draft Guidance Documents (*Definition of the Residue; and Overview of Residue Chemistry Studies*). The Expert Group met in February 2006 in Rome to revise the seven draft documents following a commenting round that took place in the second half of 2005. The revised documents were approved by the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) in May 2006. The five Test Guidelines have been submitted to the Joint Meeting for approval, and the two Guidance Documents will be submitted at the end of August. The Expert Group has also started a second phase of work consisting of developing three additional Test Guidelines: *Storage Stability; Processing Studies: Nature of the Residue; and Processing Studies: Magnitude of the Residue*; and one Guidance Document on *Analytical Methods*. A meeting is planned to take place early 2007 in Washington, D.C.

Biological Pesticides

The BioPesticides Steering Group (BPSG) led by the Netherlands is developing guidance for microbial pesticides evaluations, on issues that are barriers to work sharing across governments. The group has prepared issue papers on the following: evaluation and interpretation of toxicology data; evaluation and interpretation of environmental toxicology and fate data; waivers; species/strains related issues; and efficacy of pesticides. The BPSG met in Paris on 13-14 June 2006 to review all of the issue papers and to consolidate them into one document with the view to developing a Guidance Document on science issues related to microbial pesticides assessments.

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.

Risk Reduction Seminar Series

This seminar on Application Technology, the fifth in the OECD risk reduction seminar series, was held on 30 November 2005 in Wellington and co-hosted by the New Zealand Food Safety Agency and the Environmental Risk Management Agency. The main purpose of this seminar was to identify key approaches to achieving risk reduction through innovative and more practical and economical use of application technologies. The seminar was preceded by a field-trip to the Wairarapa, which provided delegates an opportunity to see and compare actual practices of spraying equipments including aerial and boom spraying, air blast spraying, and over-row spraying. Seminar discussions were focused on the major areas such as standardisation of equipment, labelling, promoting innovation, and certification. The seminar report is scheduled to be declassified and published in 2006.

Risk Reduction Workshop on Pesticides User Compliance

A workshop on user compliance, organised by OECD's Risk Reduction Steering Group and hosted by the Pest Management Regulatory Agency, Health Canada, was held from 6-8 June 2006 in Ottawa. The workshop provided a useful forum for pesticides users, regulators and compliance officers to exchange practical information on national programs and to suggest ways of promoting interactive regulatory compliance. A workshop report, which will be published in 2007, will contain the results from a survey conducted in early 2006, prior to the workshop, to examine how pesticide users perceive the current mechanisms of compliance and what regulators do to promote user compliance.




Forthcoming events:

- EU/OECD Risk Reduction Seminar on HAIR (Harmonised Environmental Indicators for Pesticide Risk), 13 November 2006, Bonn, Germany
- Registration Steering Group, 13 November, 2006; Bonn, Germany
- 20th meeting of the Working Group on Pesticides, 14-15 November; Bonn, Germany
- Risk Reduction Seminar on Worker Safety and Training, 20 March 2007, Brno, Czech Republic
- Risk Reduction Steering Group, 21 March 2007, Brno, Czech Republic
- Registration Steering Group, 22-23 March, 2007 Brno, Czech Republic

Recent publications:

- 📖 Report of the Seminar on Risk Reduction through Better Labelling
- 📖 Report of the Second Survey on Activities to Reduce Pesticide Risks in OECD Countries

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

Contact: Richard Sigman

Web site: <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 is to determine the distribution and concentration of insecticides in environmental compartments. The first draft focusing on spray application was discussed during the third expert meeting on 10 February 2005, and revised scenarios covering other application methods will be submitted for discussion at the next expert group meeting in Vienna (11 September, 2006). As releases through waste treatment of such products might be an important contribution for local concentrations in the environment, the ESD will also integrate this life-cycle stage in the project.

The Emission Scenario Document on insecticides used in stables and manure, funded by Austria and led by Ireland, was published in January 2006. This ESD examines ways to determine the distribution and concentrations of active substances in insecticides, acaricides and products to control other arthropods, used in animal housing and manure storage systems. This document presents realistic worst case emission scenarios that are applicable throughout OECD countries.

Test Guidelines for Wood Preservatives

The US EPA hosted a technical meeting from 8-9 June, 2006, to discuss the scientific issues associated with draft Test Guidelines for measuring leaching of biocide active ingredients from wood both in and not in contact with water and/or soil. Pre-validation work has been carried out by Germany, funded by the European Commission, on two draft OECD Test Guidelines and the results from this and other sources were used to prepare revised drafts of the Guidelines which will be considered by the next meeting of the Task Force on Biocides.

Efficacy

This 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.


Forthcoming events:

- Fourth Meeting of the Expert Group on ESDs for Insecticides, 11 September 2006; Vienna, Austria
- Fourth Meeting of the Task Force on Biocides, 12-13 September, 2006; Vienna, Austria

Recent publication:

 Emission Scenario Document (ESD) No. 14 for Insecticides Used in Stables and on Manure

Forthcoming publication:

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

Contact: Richard Sigman

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

CROSS-CUTTING ISSUES

Templates for New and Existing Industrial Chemicals, Pesticides and Biocides

On 1 March, 2006, OECD adopted 86 harmonised templates for reporting summary information of the results from chemical testing. These templates, which have been prepared for database developers, prescribe the format by which results should be entered into and maintained in databases so that the data can easily be exchanged electronically. Separate templates have been developed for toxicology, eco-toxicology and physical/chemical property study types. (A “template” is a standard format used to summarise data contained in a study report, but it is not a data entry screen.) In addition, 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).

The European Commission hosted an OECD expert meeting, from 26-28 June in Ispra, Italy, on the information technology issues associated with the OECD templates. Participants discussed relevant approaches that are being used to implement the templates (or experiences with such approaches), which could help governments as they begin to design new (or modify an existing) systems. The objectives of the meeting were for Delegates to: (1) learn about which governments or programmes have an IT system, are designing a system, or are planning to design a system that uses or could use the new OECD templates and XML schema; (2) get technical briefings, at a minimum, on relevant systems under development; and (3) discuss possible next steps, if any, with respect to inter-governmental or OECD work (e.g., if one government wants to use part or all of another government's system).

Integrated approaches to fulfill information requirements for testing and assessment

Based on the recommendations from the 39th Joint Meeting, an activity on Integrated approaches to fulfill information requirements for testing and assessment has been launched in 2006. As a first step it is foreseen to organise a workshop in 2007 with the objective to share experience on integrated approaches to fulfill information requirements by reviewing case studies for one regulatory hazard endpoint (aquatic toxicity). The workshop could 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 would be recommendations to the Joint Meeting on future work to support member countries in using integrated approaches to fulfil information requirements for testing and assessment.

Contact: Richard Sigman, Bob Diderich

Web site: http://www.oecd.org/document/13/0,2340,en_2649_34365_36206733_1_1_1_1,00.html

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]

The Recommendation C(2003)221 adopted on 15th January 2004, requires that the Working Group on Chemical Accidents (WGCA) pursue a programme of work designated to facilitate the implementation of the OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response and Guidance on Safety Performance Indicators*; and evaluate the implementation of this Recommendation. The EPOC and Joint Meeting must review the implementation of the Council Act within the three years of its adoption. To accomplish this task, the US, with participation of experts from Canada and Germany, developed a questionnaire to collect information on implementation of the Council Act in OECD countries. The questionnaire was circulated to the WGCA on May 26, 2006 with a deadline for response of 13th September 2006.

Guidance on Safety Performance Indicators

Following the May 2004 – September 2005 pilot programme to test the Guidance on SPI (published as an interim document in 2003), an Expert Meeting led by the US met in London on 9-11 May 2006 to revise the guidance. The expert meeting decided to divide the SPI Guidance into two documents: one for industry; and one for the other stakeholders (incorporating the public authorities and communities section of the current document). A second expert meeting is planned to take place in Washington on 26-29 September 2006.

Use of Safety Documents in the Control of Major Accident Hazards

In the EU the Seveso II Directive requires operators of certain hazardous sites to produce a document known as a 'safety report'. Likewise the US EPA has developed, for industry operators, guidance on risk management programs that contain all the elements related to prevention and safety. Equivalent documents on prevention programmes and the safety information are generally produced in other OECD countries. The WGCA decided to explore the purposes of such documents and look at how they are used in OECD countries. In this regard, a Project Committee led by the UK developed a questionnaire to collect the information. The questionnaire was circulated to member countries on March 20, 2006 with a deadline for response of 1st July 2006.

Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases

An OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases sponsored by Environment Canada and the EC MAHB (Major Accident Hazards Bureau) will take place in Varese, Italy on 16-18 October 2006. The overall objective of the workshop is to share information and experiences on approaches used by member countries to establish lists of hazardous substances and threshold quantities regulated under chemical accidents policies. A Planning Committee, lead by Canada, was established in November 2005 to help prepare the workshop. A letter of invitation to nominate workshop participants was sent to member countries on March 6, 2006 with a deadline for response of 15th September 2006.

Guidance for Implementation of Integrated Management of SHE&Q

A Korean-led Expert Group is developing guidance to facilitate the implementation of integrated management of safety, health, environment and quality in enterprises (and public authorities). A draft document dated December 2005 was circulated for review to the WGCA with a deadline for response of 1st May 2006. An Expert Meeting will take place in Prague, Czech Republic, on 20-22 September 2006 to revise the draft SHE&Q guidance based on the comments received.

Forthcoming Events:

- Expert Meeting for Review of the draft Guidance for Implementation of Integrated Management of SHE&Q, 20-22 September 2006, Prague, Czech Republic
- Expert Meeting for Revision of the OECD Guidance on Safety Performance Indicators, 26-29 September 2006, Washington, USA
- OECD-EC Workshop on *Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases*, 16-18 October 2006, Varese, Italy
- 16th Meeting of the OECD Working Group on Chemical Accidents (WGCA), 19-20 October 2006, Varese, Italy

Contact: Marie-Chantal Huet

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

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 in Ghent, Belgium, 21-23 March 2006. The discussion focused on the following 2005-08 work areas: i) publication of the Sharing database; ii) Scoping studies on the “Releases from Products”, the “Crosswalk” (between releases in chemicals and waste) and SMEs; iii) establishment of a global portal to PRTR information; and iv) A guidance document on “Considerations for Ensuring Quality PRTR Data”.

The Task Force agreed that the Sharing database would be published as: “Centre for PRTR Data” (Published in July 2006, see below). Although the database is physically located in and will be maintained by Japan, the access is provided through the OECD public website, as already applied to the Resource Centre. The Terms of Reference for the maintenance and update of the database will be provided at the next meeting of the Task Force for discussion and adoption.

The Task Force reviewed in March 2006 the draft scoping studies on the “Releases from Products” and the “Crosswalk”. Both scoping studies will be completed during the third quarter of 2006 and submitted to the 40th Joint Meeting for review and approval of the next steps in these work areas. The European Commission will provide funding for the scoping study on SMEs which will be commenced in October 2006.

The Task Force agreed to establish a small working group, led by Canada, to further the development of the global portal to PRTR information (www.prtr.net). The first task of the small working group would be to undertake a feasibility study on this project that will be reviewed at the next meeting of the Task Force.

Forthcoming event:

- 10th Meeting of the OECD Task Force on PRTRs, 27 February-1 March 2007, Copenhagen, Denmark

Recent publications:

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

Forthcoming publications:

- 📖 Considerations for Ensuring Quality PRTR data

Contact: Henrik Harjula

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

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 39th Joint Meeting agreed a new Programme of Work for 2006-2008. As in the past, the publication of consensus documents continues to be a major output of the work. Consensus documents are intended to be a snapshot of current information for use during the regulatory assessment of products of modern biotechnology, addressing the core set of issues that member countries believe are relevant to risk/safety assessment. They are intended to be used by applicants for regulatory reviews of products, regulators and government for information sharing, research reference and public communication.

To date, 28 Consensus Documents have been published including those for the biology of crops, trees and micro-organisms, and for selected traits that may be introduced into crop species. A number of others are in preparation. Recently, the OECD published two volumes of those consensus documents which have been published so far.

During 2006, the OECD is organising a series of events to celebrate the 20th anniversary of the publication of the Blue Book, *Recombinant DNA Safety Considerations*, OECD (1986), which was the first intergovernmental activity on the environmental safety of transgenic organisms. For example, there was a side-event at COP/MOP-3 (the Cartagena Protocol on Biosafety) which was held on 13 March. It took the form of a workshop in which the past work of the OECD was described, emphasising its relevance to risk assessment. There was also a summary of current activities. Finally, there were presentations from two non-member economies (Brazil and Cameroon) which discussed the value of OECD's work to their countries. By way of follow-up, there will also be a workshop in September, held in conjunction with the 9th International Symposium on the Biosafety of Genetically Modified Organisms. This workshop, entitled *Beyond the Blue Book*, will be held in Jeju Island, Korea, 29 September 2006.

The 18th meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology was hosted by the Swiss Federal Office for the Environment, in Bern, Switzerland, 7-9 June 2006. As in the past, the 18th meeting benefited from the participation of key non-member economies including Argentina, Brazil, Cameroon, Chile, China, India, Philippines the Russian Federation and Slovenia.

The 18th meeting was an opportunity to make progress on a number of draft consensus documents, such as those on banana, tomato, squashes, herbicide tolerance, *Bt* trait, lodgepole pine, larches, *Fusarium*, *Acinetobacter* and *Brassica* species. There was also progress on two guidance documents related to micro-organisms: i) a document on horizontal gene transfer; and ii) a document on pathogenicity. There was also a progress report on the drafting of a consensus document on the biology of Atlantic salmon, which will be the first consensus document on an animal biology.

Another important initiative for the 18th meeting of the Working Group was a project on *parameters for environmental risk/safety assessment*. Although this project is still in the early stage, the output could be significant because it has intended to provide a comprehensive package of information elements used for assessment. The Working Group agreed on the steps needed to finalise an operational plan for this project. As this is related to some topics which have been discussed under the Cartagena Protocol, close links with the Secretariat of the Convention of Biological Diversity have been maintained.

In recent years, one of the major recent achievements related to BioTrack Online has been the development of guidance for the designation of a unique identifier for transgenic plants. At the 18th meeting of the Working Group, text was agreed on how to designate “unique identifiers” for stacked events. That is, plants which contain two or more transformation events. Progress was also made on developing unique identifiers for micro-organisms.

Forthcoming events:

- OECD Workshop: *Beyond the Blue Book*, Jeju Island, Korea, 29 September 2006
- 19th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, OECD Headquarters, Paris, 21-23 February 2007

Recent Publications:

- 📖 *Safety Assessment of Transgenic Organisms: A Compilation of OECD Consensus Documents Volumes 1 and 2*
- 📖 *Points to Consider for Consensus Document on the Biology of Cultivated Plants*
- 📖 *Consensus Document on the Biology of Capsicum annum complex*
- 📖 *Consensus Document on Information Used in the Assessment of Environmental Applications involving Acidithiobacillus*
- 📖 *Abstracts of the OECD Expert Workshop on the Biology of Atlantic salmon (Salmo salar), Moscow 29 November-1 December 2004.*
- 📖 *Consensus Document on the Biology of Western White Pine*

Forthcoming Publications:

- 📖 *Consensus Document on the Biology of Banana and Plantain.*
- 📖 *Consensus Document on the Biology of Fusarium.*

Contact: Masatoshi Kobayashi

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

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 main output of the Task Force for the Safety of Novel Foods and Feeds is its consensus documents. These documents compile information on the major components of specific crop plants, such as key

nutrients, toxicants, anti-nutrients and allergens. This information is of value in the risk/safety assessment of new (transgenic) varieties, because typically, such risk/safety assessment involves a comparison of these components between the new variety, and existing traditional varieties. To date 12 consensus documents have been published on major crops such as maize, soy bean and rapeseed oil. Others are being drafted.

As modern biotechnology has become an increasingly global issue, the Task Force has progressively invited observers from non-member countries – Argentina; Russia; Slovenia; Brazil; Chile; China; India; Latvia; South Africa; and Thailand – to participate in its work. Their 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.

The Task Force continues to involve more actively the expertise and interests of non member economies. As a consequence, Thailand and South Africa have now started to work on two consensus documents on the compositional considerations on papaya and cassava, respectively. These consensus documents are being drafted in co-operation with delegations from member countries. This will broaden the expertise that is available to the Task Force, while addressing a wider range of food and feed products that are of global interest.

The Programme of Work for the Safety of Novel Foods and Feeds for 2006-2008 was agreed by the 39th Joint Meeting February 2006. At its 11th meeting (6th-8th March 2006), the Task Force decided the next steps in carrying forward the projects areas during the period 2006-2008, while strengthening the input of key non members.

Forthcoming Event:

- 12th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Athens, Greece, 13-15th September 2006.

Recent Publications:

 *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force*

Forthcoming Publication:

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

Contact: Mar Gonzalez

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

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 December 2005, the Joint Meeting held the OECD Workshop on the Safety of Manufactured Nanomaterials to identify potential safety issues in detail. The Workshop was held 7 - 9 December 2005 in Washington D.C. and was hosted by US EPA. There were 120 delegates from OECD member countries, Argentina, China and India, and stakeholders.

The workshop produced a report around the four themes: 1) definitions, nomenclature and characterisation (related to a regulatory context); 2) environmental fate and effects (hazard identification and assessment methods); 3) human exposure and health effects (hazard identification and assessment methods); and 4)

exchange of information on regulatory frameworks (limited mainly to the industrial chemicals sector). The conclusions and recommendations are described in detail in the Workshop Report.


The 39th Joint Meeting discussed the conclusions and recommendations of the Workshop and decided that work should be undertaken to address the human health and environmental safety aspects of nanomaterials. The aim of the programme will be to ensure that all stakeholders work together in order to promote efficiencies in national testing and assessment efforts while avoiding non-tariff barriers to trade in the products of these technologies.

To develop a programme of work based on the conclusions and recommendations of the Washington Workshop, the Joint Meeting recommended the establishment of a Working Party on Manufactured Nanomaterials (WPMN). This group will focus on the implications of the use of nanomaterials for human health and environment safety, focussing on testing and assessment methods and cover the focus areas discussed by the Washington Workshop. The exact terms for the establishment of the WPMN are still being discussed within the OECD.

Internal coordination related to nanotechnologies at OECD

OECD's Committee for Scientific and Technological Policy (CSTP) is currently exploring possible activities related to applications of nanotechnologies. The secretariats of the Joint Meeting and the CSTP have been working closely together to ensure that their respective activities are complementary. In order to foster co-ordination by the Directorates concerned, the Secretariat agreed that OECD's Internal Co-ordination Group for Biotechnology (ICGB) (which currently co-ordinates biotechnology issues) will provisionally deal with issues related to the applications of nanotechnologies and the implications of nanomaterials.

Recent Publications:

-  The Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication, 7-9 December 2005

Contact: Peter Kearns, Mar Gonzalez and Noriko Oki

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


INTERNET

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

- EHS Homepage
<http://www.oecd.org/ehs/>
- Chemical Accidents
<http://www.oecd.org/env/accidents>
- Harmonisation and Classification
<http://www.oecd.org/env/classify>
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- Biocides
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- Pollutant Release and Transfer Registers
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- Safety of Manufactured Nanomaterials
<http://www.oecd.org/env/nanosafety>
- Biosafety
<http://www.oecd.org/biotrack>

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

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

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- Fax: 33 1 44 30 61 80
- OLIS, or
- <mailto:ehscont@oecd.org>

Staff in the ENV/EHS Division		
[☎ all phone numbers (33 1) 45 24 xx xx] ; [✉ all email addresses firstname.lastname@oecd.org]		
NAME	PROGRAMME	PHONE
AMCOFF, Patric	Test Guidelines/Animal Welfare	16.19
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CORCORAN, Judith	Risk Management, PRTRs, Existing Chemicals	84.51
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