

Environment, Health & Safety News

No. 22, July 2008

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. 21, issued in November 2007), the EHS Division has seen the following changes in staffing:

Front Office: As of 1 September, *Patricia Carlson* will replace *Barbara Ladeuille* as Assistant to the Head of Division and working on administration issues while Ms. Ladeuille is on temporary assignment.

Chemical Accidents: *Davina Till* has replaced *Jill Gibb* as assistant to this programme.

Existing Chemicals: *James Kim* has replaced *Amanda Sudic* providing secretarial support to the Existing Chemicals Programme as well as PRTR, Risk Management/Sustainable Chemistry, (Q)SAR and Exposure Assessment. *Sally de Marcellus* is now working full-time on Existing Chemicals.

Pesticides, Biocides, New Chemicals and GLP: *Davina Till* has replaced *Patricia Nilsson* providing secretarial support to these programmes.

Biosafety and Food Safety: *Yukihiko Fukase* has succeeded *Masatoshi Kobayashi* working on Biotechnology. *Bertrand Dagallier* is replacing *Mar Gonzalez* on Food Safety issues while she is on maternity leave.

Nanosafety: *Michelle Lee* is replacing *Mar Gonzalez* while she is on maternity leave.

(Q)SARS, Test Guidelines and HCL: *Takehiko Fukushima* has returned to Japan and has been succeeded by *Michihiro Oi*.

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.

The following draft new, updated or corrected Test Guidelines were endorsed by the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (Joint Meeting), by written procedure, on 13 June 2008. It is expected that they will be published in the third quarter of 2008 once they have been endorsed by the Environment Policy Committee (EPOC) and adopted by Council. Test Guidelines are available free of charge from SourceOECD or from the OECD Online Bookshop: [http://www.oecd.org/document/40/0/0%2C2340%2Cen_2649_34377_37051368_1_1_1_1%2C00.html].

Draft New Test Guidelines:

Section 2: Effects on Biotic Systems

- 226 Predatory Mite (*Hypoaspis (Geolaelaps) Aculeifer*) Reproduction Test in Soil
- 228 Determination of Developmental Toxicity of a Test Chemical to Dipteran Dung Flies (*Scathophaga Stercoraria* L. (Scathophagidae) and *Musca autumnalis* De Geer (Muscidae)

Section 3: Degradation and accumulation

- 314 Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater
- 315 Bioaccumulation in Sediment-dwelling Benthic Oligochaetes
- 316 Phototransformation of Chemicals in Water – Direct Photolysis

Section 5: Other Test Guidelines

- 508 Magnitude of Pesticide Residues in Processed Commodities

Draft Updated Test Guidelines:

Section 2: Effects on Biotic Systems

- 211 *Daphnia magna* Reproduction Test

Section 4: Health Effects

- 407 Repeated Dose 28-Day Oral Toxicity Study in Rodents

Draft Corrected Test Guideline:

Section 4: Health Effects

- 425 Acute oral toxicity: Up-and-Down Procedure

WNT

The last meeting of the National Coordinators of the Test Guidelines Programme (WNT), 2-4 April 2008, provisionally approved two Test Guidelines pending resolution of a few specific issues: the draft Test Guideline 487 for the *in vitro* mammalian Cell Micronucleus Test, and the draft Test Guideline for the Stably Transfected Human Estrogen Receptor- α Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals.

Endocrine disrupters

Several of the above Test Guidelines and supporting documents have been developed for the detection of endocrine disrupters. Technical issues related to these Test Guidelines were discussed by the validation management group for non animal testing (13-15 November 2007), the validation management group for mammalian testing (5-6 December 2007), the validation management group on ecotoxicity testing (16-17 January 2008), and the group on endocrine disrupter testing and assessment (1-2 April 2008). The WNT also started discussing issues related to performance-based Test Guidelines and “me too” tests.

Acute Inhalation Toxicity

An expert meeting was held on 15-17 April 2008 in Washington (United States) to finalize the work on the draft updated TG 403 including the “Concentration x Time” protocol, the new draft TG 436 that is an alternative to TG 403 for specific purposes, and the draft Guidance Document 39 on acute inhalation toxicity.

Revision of Test Guidelines 451, 452 and 453

A workshop was held on 26-28 February 2008 in Washington (United States). It agreed on policy issues related to the revision of the Test Guidelines on chronic toxicity and carcinogenicity and to the guidance document that will be developed to support the use of these Test Guidelines.

Fish Embryo Toxicity Testing

A second expert meeting was held on 14-15 May 2008 in Berlin (Germany). It discussed and resolved a number of technical issues related to the draft Test Guideline and developed a strategy for the development of the test method.

Amphibian Metamorphosis Assay

An expert group meeting was held on 21-22 May 2008. It addressed a number of technical issues related to the draft new Test Guideline for the Amphibian Metamorphosis Assay. The draft Test Guideline is open for comments until 15 September 2008.

Toxicokinetics

An expert group meeting was held on 9-10 June 2008 in Washington (United States). It discussed and agreed on the structure of the updated TG 417 on toxicokinetics, and on technical issues related to the draft Test Guideline.

Molecular screening

A meeting of the extended OECD/IPCS Advisory Group on Toxicogenomics was held on 19-20 June 2008 in Utrecht (Netherlands). Reports were presented on significant progress of the US ToxCast program, and on other member countries and stakeholders’ advances in high throughput screening and high content screening for prioritizing chemicals.

Forthcoming events:

- Expert group meeting on the extended 1 Generation Reproductive Toxicity Study, October 2008
- Meeting of the fish drafting group of the validation management group for ecotoxicity testing, October 2008
- Meeting of the validation management group for non-animal testing, November 2008
- 21th Meeting of the Working Group of National Coordinators of the Test Guidelines Programme (WNT21), April 2009

Recent publications:

- 📖 Retrospective Performance assessment of the Test Guideline 426 on Developmental Neurotoxicity (2008)
- 📖 Report of the Validation of the Rodent Hershberger Assay: Phase 2: Testing of Androgen Agonist, Androgen Antagonists and a 5 α -Reductase Inhibitor in Dose Response studies by Multiple Laboratories (2008)
- 📖 Report of the Validation Peer Review for the Hershberger Bioassay, and Agreement of the Working Group of National Coordinators of the Test Guidelines Programme on the follow-up of this report (2007)
- 📖 Summary Report of the Peer Review Panel on the Stably Transfected Transcriptional Activation Assay for Detecting Estrogenic Activity of Chemicals, and Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the Follow-up of this Report (2007)
- 📖 Report of the Validation of the Amphibian Metamorphosis Assay (Phase 3)
- 📖 Report of the Validation Peer Review for the Amphibian Metamorphosis Assay and Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the Follow-up of this Report
- 📖 Report of the Validation of an Enhancement of OECD TG 211: *Daphnia Magna* Reproduction Test
- 📖 Report of the Validation Peer Review for the 21-Day Fish Endocrine Screening Assay and Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the Follow-up of this Report
- 📖 Detailed Review Paper on Fish Life-Cycle Tests
- 📖 Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment
- 📖 Background Review Document on the Hershberger Assay
- 📖 Detailed Review Paper on the Use of Metabolising Systems for *In Vitro* Testing of Endocrine Disrupters

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 22nd time 8 and 9 April 2008, in Frascati, Italy. China, Chinese Taipei, Russia, Malaysia, and Thailand took part as ad hoc observers. The Working Group dealt with issues related to reporting for the new programme of on-site evaluations on GLP compliance monitoring programmes; the first on-site visits begin in the third quarter of 2008. The report of the Mutual Joint Visit to the Austrian GLP compliance monitoring programme for medical products was discussed. The Working

Group also began several projects related to exchange of information among compliance monitoring programmes and with regulatory authorities.



The 9th OECD Training Course for GLP Inspectors, which was to have taken place in Tel Aviv in September 2008 has been postponed. The Working Group is currently considering alternative arrangements for a basic training course in mid 2009.

An OECD event with Industry, hosted by Italy, took place in Frascati on 10 and 11 April back to back with the 22nd Working Group Meeting. This Symposium aimed at providing an open forum where the public sector (monitoring/regulatory authorities and relevant agencies) and the private sector (test facilities and relevant industrial organisations) could informally meet and discuss current GLP issues of interest to all partners involved. Eighteen presentations were given from various viewpoints of both public and industrial sectors and over 210 participants from 38 countries including ad hoc observers had active discussions (see the OECD public website: http://www.oecd.org/department/0,3355,en_2649_34381_1_1_1_1,00.html). It is expected that this event will be the first of a series of conferences with a similar approach to be held regularly.

Forthcoming event:

- 23rd Meeting of the Working Group on Good Laboratory Practice, May 2009, Paris

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 that Operate in Compliance with the Principles of GLP, No. 15 in the OECD Series on GLP and Compliance Monitoring.

Contact: Dian Turnheim

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

MUTUAL ACCEPTANCE OF DATA AND NON-MEMBER COUNTRIES

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and Good Laboratory Principles (GLP). It requires OECD governments to accept test data on chemicals 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.

Thailand and Malaysia have recently been invited by the Council to become provisional adherents to the Council Acts related to MAD. Current provisional adherents are India, Brazil, Singapore and Argentina, while South Africa, Slovenia and Israel are full adherents to the system. The Secretariat continues to work with China, Chinese Taipei and several other countries in view of their provisional adherence to the MAD Council Acts as well.

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

OUTREACH

The OECD Council adopted a Resolution on Implementation of the Strategic Approach to International Chemicals Management (SAICM) as contained in the Dubai Declaration on International Chemicals Management, with its the Overarching Policy Strategy and the Global Plan of Action [C(2008)32]. A four-year Programme of Work on Chemicals, which reflects the SAICM objectives, was also endorsed by Council in follow-up to the Resolution. The Resolution, which was welcomed by OECD Environment Ministers at their April meeting, can be found at <http://www.oecd.org/dataoecd/15/5/40573587.pdf>.

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.

As a follow-up to the expert group meeting on polymers that was held in Tokyo, in March 2007, participating governments have exchanged scientific data and descriptions of each country's rationale for the criteria they use for identifying polymers of low concern (PLC). Australia has now conducted an analysis of information obtained on over 200 polymers. The objective of this analysis is to identify correlations between the PLC criteria, various polymer characteristics and the potential for health or ecotoxicological concern. The final objective is to work toward the harmonisation of the PLC criteria across countries.

In addition, work continues on the development of an electronic notification system which will allow companies to enter/maintain data at their location and then choose a specific authority notification format into which the data is inserted. It is expected that this system will be available in the first half of 2009.

Recent event:

- New Chemicals Task Force meeting, 17-18 June, San Diego, USA

Forthcoming publication:

- 📖 Polymers of Low Concern: Initial Data Analysis

Contact: Richard Sigman

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 26th SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Paris, France on 16-18 April 2008. Assessments for 23 chemicals were agreed, including the second assessment prepared under the procedure for direct submission by industry. Over 60 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 have been submitted to the Joint Meeting for endorsement through written procedure. Initial assessments for 129 chemicals under preparation for publication by UNEP are publicly available on the OECD web site [<http://www.oecd.org/env/existingchemicals/siars>]. Altogether, assessments for 398 chemicals have been published by UNEP [<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>] and 72, for which the hazard assessment parts have been agreed upon at OECD level, have been published by the European Commission [<http://ecb.irc.it/existing-chemicals/>]. Furthermore, the Secretariat has published 198 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: http://www.oecd.org/document/55/0%2C2340%2Cen_2649_34379_31743223_1_1_1_1%2C00.html.

eChemPortal, the Global Portal to Information on Chemical Substances, was publicly launched in June 2007 [<http://www.oecd.org/ehs/eChemPortal>]. Since the launch two additional databases and one report collection have been added as participants:

- Hazardous Substances and New Organisms Chemical Classification Information Database (HSNO CCID), maintained by New Zealand's Environmental Risk Management Authority
- Data Bank of Environmental Properties of Chemicals (EnviChem), maintained by the Finnish Environment Institute (SYKE)
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS), maintained by Australia's NICNAS

Recent event:

- SIAM 26, 16-18 April 2008, Paris, France

Forthcoming events:

- SIAM 27, 14-16 October 2008, Ottawa, Canada
- Meeting of the IUCLID User Group Expert Panel, September 2008, Paris, France
- Meeting of the Task Force on Existing Chemicals, April 2009, Paris, France

Contact: Anne Gourmelon and 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 is being created in two phases. A proof-of-concept version was released in March 2008 and can be downloaded free of charge from the public OECD web site [<http://www.oecd.org/env/existingchemicals/qsar>]. With this proof-of-concept version, a user can:

- 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; and
- 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. Together with the first version of the Toolbox, guidance documents and training material have been published. Additional material will be published before the end of 2008.

A project for the development of a second version with extended functionalities was launched in 2008 and a call for tender has been published.



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* was held on 15-16 May 2008 in Utrecht, hosted by the Netherlands. The aim of the workshop was 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; and
- make recommendations (or set priorities) as to which structural alerts should be implemented into the (Q)SAR Application Toolbox.

The workshop was attended by 40 participants from member countries, NGOs and industry. Structural alerts for the following properties were discussed: mutagenicity and carcinogenicity, skin irritation, eye irritation, aquatic toxicity, biotic and abiotic degradation, acute oral toxicity, receptor binding affinity, and protein binding potency.

A number of recommendations were made at the workshop. The report from the workshop is to be published in September 2008.

Recent publications:

-  Proof-of-concept version of the (Q)SAR Application Toolbox
-  Training material for the use of the Toolbox

Contact: Mishihiko Oi and Bob Diderich

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

EXPOSURE 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 October 2008 in Dessau, Germany, and review the progress of projects.




Forthcoming event:

- 16th meeting of the Task Force on Environmental Exposure Assessment, October 2008, Dessau, Germany

Recent publications:

-  P_{OV} (overall environmental persistence) and LRTP (long-range transport potential) Screening Tool Software

Forthcoming publications:

-  Report on the Development of Emission Scenario Documents in the Chemical Industry
-  New ESD on Transportation and Storage of Chemicals
-  Revised ESD on Photolithography Use in Semiconductor Manufacturing

Contact: Michihiko Oi

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.



Two OECD proposals have been adopted by the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS):

- 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 (adopted in December 2007)
- Proposal for classification and labelling of ozone depleting chemicals (adopted in July 2008)

The Task Force on Harmonization of Classification and Labelling (HCL) met on 24-25 April 2008, following an expert group meeting on terrestrial environmental hazards and a meeting of the extended validation management group for the validation of the Transformation/Dissolution Protocol. The Task Force agreed on the following documents that have since been declassified by the Joint Meeting:

- Proposal for revising GHS Chapter 3.4 concerning strong versus weak sensitizers. This proposal was finalized at an expert meeting held on March 2008 in Bethesda (MA, United States);
- Progress report on the work related to terrestrial environmental hazards;
- Report of the Ring Test and Statistical Analysis of Performance of the Guidance on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media; and
- Considerations Regarding Applicability of the Guidance on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (Transformation/Dissolution Protocol).

Recent publications:

-  Report of the Ring Test and Statistical Analysis of Performance of the Guidance on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (Transformation/Dissolution Protocol), 2008
-  Report on the Workshop on the Application of the GHS Classification Criteria to HPV Chemicals, (5-6 July 2007, Bern), 2007

Contact: Laurence Musset

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

RISK MANAGEMENT AND SUSTAINABLE CHEMISTRY

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.

Risk Management

The most recent update of the Hazard/Risk Information Sheets, which are on the OECD public website for Risk Management (<http://www.oecd.org/env/riskmanagement>), was completed during the second quarter of 2008.

The 42nd Joint Meeting noted in February 2008 that progress has been made with most of the recommendations from the Workshop on PFCAs and Precursors on 20-22 November 2006 in Stockholm {see Workshop Report [ENV/JM/MONO(2007)11]}. The discussion revealed that considerable reductions have already been achieved in the framework of the US global voluntary Stewardship Programme on PFOA

(up to 90% emission reductions by the end of 2007). Japan informed of its industrial risk reduction programme. No information has yet been received regarding the situation in Italy and Korea, where PFC producers and/or users have been identified. Finally, the Joint Meeting emphasised the global nature of this problem (major PFC producers have been identified in China, India and Russian Federation). The Joint Meeting also encouraged countries and BIAC to use their networks and contacts to promote and establish risk reduction programmes in OECD and non-OECD countries where major PFC producers and/or users have been identified. Further progress will be reported to the next Joint Meeting in November 2008.

The 42nd Joint Meeting also addressed progress made with the revised survey scope on PFCs (recommendation 2 from the Workshop on PFCAs and Precursors). The results of two earlier surveys had demonstrated that the current survey mechanism is not capable of producing reliable data on production, import and use of PFCs. The Joint Meeting agreed that the survey scope should be revised to focus on the production of perfluorinated compounds (PFCs) and emissions from point sources. It was also recognised that, although information on uses would be of interest, there were procedural limitations to gathering such information at this time. The Steering Group on PFCs has agreed on the direction of a revised survey. The revised lists of chemicals and the survey questionnaire are currently under preparation, and will be presented to the 43rd Joint Meeting in November 2008. The survey will be carried out in 2009.

Sustainable Chemistry

The Issue Team on Sustainable Chemistry has developed an Internet Platform for information exchange, review of new developments and further elaboration of incentives for Sustainable Chemistry according to the agreement by the 41st Joint Meeting in June 2007. The Platform will be published in early 2009. The Secretariat has also started new work on the role of environmental legislation and innovation in promoting Sustainable Chemistry, as agreed by the 42nd Joint Meeting. A progress report will be submitted to the 43rd Joint Meeting in November 2008 and the first results will be reported to the 44th Joint Meeting in June 2009. This work has a close link with the OECD Innovation Strategy.

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.

The Task Force on Pollutant Release and Transfer Registers (TF on PRTRs) met on 12-14 March 2008. It agreed to continue the project on releases from products. This project is funded by the OECD and Nordic Council of Ministers, and carried out by the Finnish Environment Institute. The Nordic PRTR Group is overseeing the work and the final product will be *The Resource Compendium of PRTR Release Estimation Techniques, Part 4: Summary of Techniques for Products*. The work started in early 2008 with a literature survey and will continue in 2008 with a survey among the OECD countries to collect information from national programmes and existing inventories on releases from products. A draft report will be presented at the next TF meeting in March 2009. The project will also benefit from contacts with the industry as well as exposure assessment experts.

When the 42nd Joint Meeting declassified the Scoping Study on SMEs and agreed that the proposed studies could be undertaken and the missing release estimation techniques developed, it emphasised that countries will decide which releases, if any, would be included in PRTRs and in which form (as point or diffuse sources). The Task Force agreed that it would be desirable to make available information on releases from diffuse sources in PRTRs, but did not support any further studies to be undertaken at this stage.

The Task Force also agreed to develop a Geographic Information System (GIS) for the global portal to PRTR information (www.PRTR.net).

Forthcoming event:

- 12th Meeting of the OECD Task Force on PRTRs, March 2009, Paris

Recent publications:

- 📖 Scoping Study on the Inclusion of Releases and Transfers from Small and Medium-Sized Enterprises (SMEs) in PRTRs [ENV/JM/MONO(2008)5]
- 📖 PRTR Brochure
- 📖 Global Portal to PRTR information (www.PRTR.net)
- 📖 Considerations for Ensuring Quality PRTR Data [ENV/JM/MONO(2008)11]

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 work of the US-led Expert Group on Pesticide Residue Chemistry, established in 2004, consists of three phases. *Phase 1* – completed – in which five Test Guidelines (TG 501 to 505) and two Guidance documents (No. 31 and 32 in the series on Pesticides, 2006) have been developed. *Phase 2* – underway and close to completion – includes the development of three Test Guidelines and two Guidance Documents: two Test Guidelines (TG 506 and 507) and one Guidance Document (series on Pesticides, No. 39, 2007) have been published, and a third Test Guideline and associated guidance were approved by the Working Group of National Co-ordinators on Test Guidelines (WNT) at their 20th Meeting in April 2008. After approval, the Test Guideline will be published, by the end of 2008, under number 508 as part of the 20th Addendum of the OECD Guidelines for the Testing of Chemicals. *Phase 3* – initiated in 2007 – involves the development of one Test Guideline on Crop Field Trials and associated guidance. It is anticipated that these documents will be completed in 2009.

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. A new version of the *Guidance Notes for the Estimation of Dermal Absorption Values* has been circulated for a broad review to member countries' experts through the WGP and WNT. It is anticipated that the Guidance Notes will be finalised in 2009.

Biological Pesticides

The BioPesticides Steering Group (BPSG), led by the Netherlands, held its annual meeting at the US EPA, in Arlington on 17-18 April 2008. The BPSG meeting was preceded by a *Workshop on the Regulation of Biopesticides: Registration and Communication* (15-17 April 2008, US EPA). Forty-seven participants from twelve OECD countries, the European Food and Safety Authority (EFSA) and the International Biocontrol Agent Manufacturers Association (IBMA) attended the workshop. The main objective of the workshop was to resolve sciences issues and harmonise approaches for risk assessment/evaluation associated with the registration of biopesticides.

Minor Uses of Pesticides

As announced in the previous edition of this Newsletter, the OECD Pesticides Programme has set up an Expert Group on Minor Uses. (The term Minor Uses is meant to refer to small-scale pesticide use, i.e. pest control in a minor crop or a small pest problem in a major crop.). This new project should facilitate mechanisms that enable international cooperation on minor use issues, including work-sharing, technical guidance on the preparation of data submissions for minor uses, and minimising barriers to approval of safe minor uses. The first meeting of the group took place in June 2008 in Paris. Australia is chairing this Expert Group. The group is carrying out its work programme which deals with *cooperation activities* (such as collecting and maintaining baseline information on minor uses, issues concerning data sharing and joint reviews); *technical activities* (e.g. guidance on efficacy and crop safety and on residues); and *policy activities* (e.g. defining minor uses, developing incentives to enhance registration of minor uses). The Expert Group is ensuring good coordination with other international initiatives on minor uses, such as those under Codex.

Seminar on Spray Drift Risk Reduction Strategies

The Risk Reduction Steering Group is continuing to organise Seminars on issues of interest and concern to OECD governments. A recent Seminar took place in Paris in June 2008 to discuss reducing pesticide risks through spray drift reduction strategies. This one-day Seminar offered a good opportunity for stakeholders to share information about, and experience with their programmes to reduce spray drift (for example, establishing buffer zones, improving nozzle technology, developing farmer-friendly labels, working on education & training aspects). Participants showed great interest in following up the recommendations made at the seminar. As a start, a network of experts will soon be established to implement those recommendations, where possible.

Revision of OECD Monograph Guidance Document

The OECD Monograph Guidance Document has been revised to include text which specifies that Regulatory Authorities should not use the contents of a Monograph from another country as a basis for their regulatory decisions unless the data package upon which a particular Monograph was based has been provided to the Authority, or the owner of the data has granted permission for use of the summary evaluation in a Monograph in lieu of the data.




Promotion and Support of Joint Reviews/Work Sharing

Over the last few years, the OECD Pesticides Programme has been working to harmonise approaches and establish the infrastructure that will facilitate work sharing. Work sharing can be done by dividing up the review of each individual pesticide, with two or more governments reviewing different parts of the registration package. Work sharing can also be done by dividing up pesticides among two or more governments, with each government conducting the entire review of its assigned pesticide. A Guidance Document is being developed to assist governments who wish to work together on a common review. It will include, among other things, a detailed project plan which could serve as a model for future reviews. A workshop will be held in December 2008, to discuss the lessons learned by governments and companies who have participated in joint reviews, and to develop guidance on how to plan and conduct such reviews more successfully in the future. Finally, work is underway to develop a report which describes the qualitative and quantitative benefits of work sharing.

Forthcoming events:

- Working Group on Pesticides, November, 2008, Paris
- Lessons Learned Workshop, December, 2008 (Bonn, Germany)
- Registration Steering Group, February-March 2009, US
- Risk Reduction Seminar on Aerial Application, February-March 2009, US
- Risk Reduction Steering Group, February-March 2009, US

Recent publications:

-  The "Business Case" for the Joint Evaluation of Dossiers (Data Submissions) Using Work Sharing Arrangements (No. 41 in the Series on Pesticides)
-  Report of the Seminar on Risk Reduction through Better Worker Safety and Training (Monograph No. 42 in the Series on Pesticides)
-  Guidance Document on Magnitude of Pesticide Residues in Processed Commodities (Monograph No. 96 in the Series on Testing and Assessment)

Forthcoming publications:

- Report of the Seminar on Risk Reduction through Education/Training the Trainers
- Guidance Document on the planning and implementation of joint reviews
- Guidance Document on Magnitude of Pesticide Residues in Processed Commodities
- Working Document on the Evaluation of Microbials for Pest Control
- Report of the Workshop on the Regulation of Biopesticides: Registration and Communication

Contact: Richard Sigman, Beatrice Grenier 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.

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 mycobacteria. 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 mid 2008 and the validation report at the end of 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.

A Guidance Document for demonstrating the efficacy of pool and spa disinfectants is under development. It will recommend a test method for disinfectants to determine if they are effective against suitable indicator species of pathogens in the major classes of human pathogenic microorganisms commonly found in swimming pool and spa pool water (bacteria, protozoa and viruses).

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.

Human exposure

Work on a Guidance Document which describes ways to design a study for human exposure to biocides that will yield statistically valid data, is nearing completion. This document will describe a statistical design used in combination with a probabilistic approach that will require fewer experiments and hence lower costs.

Forthcoming event:

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

Recent publication:

- 📖 Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses

Forthcoming publications:

- 📖 Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects
- 📖 Human Exposure Study Design – Factors, Orthogonal Experiments and Probabilistic Modelling

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 42nd Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in February 2008, and by EPOC in June 2008. It will be forwarded to the Council in October 2008.

Revision of Guidance on Safety Performance Indicators (SPI)

The US led project on the revision of the 2003 OECD *Guidance on Safety Performance Indicators* is now at its final stage. There are currently two documents on developing safety performance indicators: one for Industry and one for Public Authorities and Communities/Public. The revised draft was submitted to the Joint Meeting for declassification on 30 June 2008, with a deadline for response of 11 August 2008. It will be published in September 2008 as EHS publications in the series on Chemical Accidents.

Integrated Management of Safety, Health, Environment and Quality (SHE&Q)

Korea leads a project on development of guidance to facilitate the implementation of integrated management of safety, health, environment and quality in enterprises (and public authorities). On 27th June 2008, a new draft was circulated to the Working Group on Chemical Accidents (WGCA) for review, with a deadline for comments of 1st September 2008.

Accident Reporting

The Joint OECD-EC Accident Reporting – Major Accident Reporting system (MARS): The European Commission has developed a new reporting form based on free-text fields and taxonomies for search, and an internet-based tool (e-MARS) for dissemination of information from MARS reports. The internet tool is currently being tested; it is anticipated that the technical work and testing will be completed by end of 2008.

Forthcoming events:

- 18th Meeting of the Working Group on Chemical Accidents (WGCA), October 2008, Bordeaux, France
- EU-OECD Seminar on Safety Performance Indicators, 8 October 2008, Bordeaux, France

Recent publications:

- 📖 Report of Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases (series on Chemical Accidents, No. 16)
- 📖 Report of Survey on the Use of Safety Documents in the Control of Major Accident Hazards (series on Chemical Accidents, No. 17)
- 📖 Report of Workshop on Human Factors in Chemical Accidents and Incidents (series on Chemical Accidents, No. 20)

Forthcoming publications:

- 📖 Guidance on Developing Safety Performance Indicators – Guidance for Public Authorities
- 📖 Guidance on Developing Safety Performance Indicators – Guidance for Industry
- 📖 Report of Workshop on Safety in Marshalling Yards

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, are as similar as possible among countries. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort. It also reduces barriers to trade.

The 21st meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held in Paris, 25-26 June 2008. Participants included, as usual, delegates from non-member countries (Argentina, Chile, Philippines, the Russian Federation and Slovenia).

Major progress was seen in the project on *Low Level Presence (LLP)* of transgenic seeds in conventional bulk shipments of crops. At the 20th meeting, the potential project was discussed as a follow-up to a proposal made at the 19th meeting by BIAC. The Working Group decided to hold a special meeting to discuss the feasibility of the Working Group undertaking a project on LLP. At the special meeting (14-15 April 2008) agreement was not reached on the feasibility of a project but a number of potential approaches were refined for consideration by the Working Group. At the 21st meeting, although an approach to the potential project was not decided, it was agreed that this issue should be considered further and the Bureau of the Working Group will prepare a proposal for the 22nd meeting.

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](http://appli1.oecd.org/olis/2002doc.nsf/linkto/env-jm-mono(2002)7-rev1)). To this end, the Sub-working Group on Micro-organisms developed a draft questionnaire for stakeholders to gather their views on the

development of a unique identifier for transgenic bacteria. At the 21st meeting, it was agreed that the questionnaire would be distributed to stakeholders in mid 2008. As a result, it is expected that this project will be moved forward substantially.

The first draft of a consensus document on the biology of *Atlantic salmon (Salmo salar)* was presented at the 21st meeting. This is the first example of a draft consensus document on the biology of an animal. Although there is a missing section that still needs to be addressed, the steering group believes that the document is now comprehensive and that it is important to invite the Working Group to review the document and to identify any substantive gaps from the point of view of a risk/safety assessment. Further refinement of the draft is expected for consideration at the 22nd meeting.

To date, none of the published consensus documents have been updated, and this is something which should be considered, especially in the case of some of the earlier documents. However, the Working Group has started a project on the biology of *Brassica* spp., which will substantially update the consensus document on the biology of *Brassica napus* L. published in 1997. An informal draft *Brassica* spp. document was presented at the 21st meeting by the lead country, Canada. As a result of the review of this draft by the Working Group and subsequent revision by the lead country, it is expected that the first official draft will be presented to the 22nd meeting.



At the 21st meeting, a draft *Guide for Preparation of Biological Consensus Documents* was presented. The draft was compiled by the Bureau and Secretariat as “Guide for Authors” which provides guidance not only on editorial style but also on how to incorporate internal scientific and technical review to improve the quality of drafts. The draft will be reviewed by the Working Group and forwarded for declassification if there is no major comment. It is expected to streamline the process of reviewing and finalising consensus documents.

The 21st meeting also made progress on various other projects. Especially, it was agreed that draft Consensus Documents on *Lodgepole Pine* and *Western White Pine* as well as a Draft Guidance Document on *Horizontal Gene Transfer between Bacteria* will be forwarded for declassification. It was also agreed that Draft Consensus Documents on *Cotton spp.* and *Acinetobacter* will be forwarded for declassification if there are no major comments after the Working Group has finished its final review of the current drafts.





Forthcoming events:

- 22nd meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, February 2009, 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 the Biology of Lodgepole Pine
-  Consensus Document on the Biology of Western White Pine
-  Guidance Document on Horizontal Gene Transfer between Bacteria

Contact: Yukihiro Fukase, Peter Kearns, Bertrand Dagallier

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

SAFETY OF NOVEL FOODS AND FEEDS

The Task Force for the Safety of Novel Foods and Feeds addresses risk/safety assessment issues, mainly related to the products of modern biotechnology, i.e. 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.

Consensus Documents

The main output of the programme is its **consensus documents on compositional considerations of specific food/feed crops**. These documents compile a common base of 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 new (genetically engineered) varieties with respect to human food and animal feed safety. These documents are not legally binding, but are highly valued because agreed upon through consensus by member countries.

Detailed information can be found in the 2006 publication *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force*, which explains the purpose for developing such tools, their practical contribution to the risk/safety assessment of products derived from transgenic organisms, and the process by which they are prepared.

To date, 14 consensus documents have been published: i) on major crops: Low Erucic Acid Rapeseed (Canola); Soybean; Sugar Beet; Potatoes; Maize; Bread Wheat; Rice; Cotton; Barley; Alfalfa and other Temperate Forage Legumes; Sunflower; ii) on a mushroom (*Agaricus bisporus*); and iii) on “Considerations for the Safety Assessment of Animal Feedstuffs Derived from GM Plants”. One document on Tomato is about to be issued and should be followed soon by three other publications on Papaya, Cassava, and Sweet Potato, while the work has started on Grain Sorghum and Sugarcane.

In addition, the Task Force established a process for revising published consensus documents; the two earliest ones, Low Erucic Acid Rapeseed (Canola) and Soybean, are being updated.

Outreach and non member economies engagement

Modern biotechnology being an increasingly global issue, the Task Force continues to involve more actively the non member economies. The work is developed in collaboration with Argentina, Brazil, China, Latvia, the Russian Federation, Slovenia, South Africa, Thailand and international agricultural research organisations such as CIAT Columbia and IITA Nigeria. This broadens the available expertise while addressing a wider range of food/feed products that are of global interest, including for tropical areas.

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 FAO; the 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. A common Brochure on the **OECD work on the risk/safety assessment of modern biotechnology** was published recently. A joint project on “Molecular Characterisation for Transgenic Plants” is being developed.


Recently, FAO and OECD agreed to make their databases interoperable regarding the information related to food safety assessment. By this arrangement, the OECD Product Database can exchange data with the FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH). This includes information such as

unique identifiers, event names, common/scientific names of the host organism and the names of introduced genes. This project was developed in response to a request from the Codex ad hoc Task Force on Food Derived from Biotechnology.


Future events:

- 15th Meeting of the Meeting of the Task Force for the Safety of Novel Foods and Feeds, February 2009, Paris

Recent publication:

 Brochure on the OECD work on the risk/safety assessment of modern biotechnology

Upcoming publication:

 Consensus Document on Compositional Considerations for New Varieties of Tomato (*Lycopersicon esculentum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

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

Contact: Bertrand Dagallier

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 of materials 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 OECD’s WPMN is to assist countries in developing tools to allow them to better address the safety testing and assessment of manufactured nanomaterials.

The Working Party on Manufactured Nanomaterials (WPMN) made significant progress on its 8 specific 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

The aim of this project is to develop an on-line database system which holds details of completed, current and planned research on the safety of manufactured nanomaterials. The database is intended to support all the activities of the WPMN by identifying research projects relevant to each of its activities. Delegations will edit existing information in the database or add new information over the summer of 2008. The database is expected to be launched publicly in November 2008.

Project 2: Research Strategies on Manufactured Nanomaterials

This project aims at developing a research strategy(ies) for manufactured nanomaterials. It has reviewed the current research programmes and identified research themes which already have wide coverage (“hot spots”) and those which are less covered (“gaps”). Recently, the WPMN decided that a report on this work will be declassified.

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

This project has identified 14 manufactured nanomaterials and list of endpoints for which they will be tested. 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.

As a result, a “sponsorship programme” was launched in November 2007, delegations agreed to fund and manage the testing of nanomaterials. As of July 2008, each nanomaterial had at least one delegation who had confirmed that they will be a lead sponsor, co-sponsor or contributor to this testing programme. To assist those sponsors, the WPMN is preparing a guidance manual. The Sponsors have started co-ordinating amongst themselves for the arrangement with a view to presenting the draft dossier development plans for specific nanomaterials at the 5th meeting of the WPMN. To support their activities, a workshop is scheduled to be held in Korea in November 2008.

Project 4: Manufactured Nanomaterials and Test Guidelines

This project finalised a preliminary review of 115 OECD Test Guidelines related to physical chemical properties, effects on biotic system, degradation and accumulation, as well as health effects. The review will be circulated to the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) for their comments. In addition, at the 4th meeting of the WPMN, it was agreed that this project will revise existing Test Guidelines or develop new Test Guidelines and/or guidance documents, as needed. They will be forwarded to the WNT for their consideration.

For example, work has been initiated on the development of guidance document on “sample preparation and dosimetry”, because nanomaterials tend to change their properties depending on the way in which they are prepared for testing as well as the test media in which they are used. This guidance will be important in ensuring the efficient use of existing Test Guidelines.

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

This project has analysed national information gathering programmes, whether voluntary or not, to assess the safety of manufactured nanomaterials. This project has: i) identified common elements to these initiatives; ii) prepared recommendations on approaches and elements to consider for information gathering initiatives; iii) identified current and proposed regulatory regimes and how they address information requirements; and iv) prepared a Questionnaire on Regulatory Regimes for Manufactured Nanomaterials, to identify various components of regulatory regimes which are or may be applicable to nanomaterials.

Project 6: Co-operation on Risk Assessment

This project is identifying existing risk assessment schemes and is reviewing them to establish if they are suitable for the assessment of nanomaterials.

Project 7: The Role of Alternative Methods in Nanotoxicology

This project was initiated relatively recently. It is looking into alternative test methods and will analyse how they might be used in an overall assessment plan for hazard testing of manufactured nanomaterials. This activity is closely related to the “sponsorship programme” of project 3.

Project 8: Exposure Measurement and Exposure Mitigation

The objective of this project is to exchange information on guidance documents for exposure measurement and exposure mitigation, and it will develop recommendations on future work that needs to be undertaken. The WPMN has been considering how best to address the measurement of exposure to nanomaterials in the work place, to consumers and the environment. For example, work is underway to provide recommendations on measurement techniques and sampling protocols for inhalational and dermal exposures in the workplace.

Forthcoming events:

- Meeting of Steering Group 7 -The Role of Alternative Methods in Nano Toxicology, September 2008, Paris, France
- Workshop on Exposure Assessment and Exposure Mitigation, October 2008, Frankfurt, Germany
- Meeting of Steering Group 8 - Co-operation on Exposure Measurement and Exposure Mitigation, October 2008, Frankfurt, Germany
- Workshop on Testing and Assessment of Manufactured Nanomaterials, November 2008, Korea
- Meeting of Sponsorship Programme for the Testing of Manufactured Nanomaterials, March 2009, Paris, France
- 5th Meeting of the Working Party on Manufactured Nanomaterials, March 2009, Paris, France
- 6th Meeting of the Working Party on Manufactured Nanomaterials, October 2009, Paris, France

Recent publications:

- 📖 Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)
[\[http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono\(2008\)2\]](http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)2)
- 📖 Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials (2008)
[\[http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono\(2008\)7\]](http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)7)
- 📖 List of Manufactured Nanomaterials and list of Endpoints for Phase One of the OECD Testing Programme (2008) [[http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono\(2008\)13-rev](http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)13-rev)]

Contact: Peter Kearns, Mar Gonzalez, Noriko Oki, Kyungyong Lee, Michelle Lee.

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. Thereafter seven additional templates have been developed. 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). The OECD harmonised templates and XML schema are available on the public web page [see http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html]. The web site was recently upgraded to include additional background information on templates, as well as to modify the templates to make them more user-friendly.

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

A workshop on Integrated Approaches to Testing and Assessment was held on 11-13 December 2007 in Washington. About 70 participants from member countries, industry and NGOs attended the event. The workshop was organised as the final phase of a case study exercise reviewing current and possible new approaches to address regulatory endpoints in various contexts (i.e. classification and labelling, priority setting, and risk assessment). The workshop developed recommendations for further work, in particular on ways to improve the use of (Q)SARs for information gathering and assessment, and on the grouping of chemicals for assessment. The workshop report has been declassified and is now available in the OECD Series on Testing and Assessment, No.88 [<http://www.oecd.org/dataoecd/19/7/40888238.pdf>]

Contact: Bob Diderich and Anne Gourmelon

Assessing the Scale and Drivers of Innovation within Sustainable Chemistry

Increased attention is being given to the role of environmental management and technological innovation in addressing environmental challenges, such as air emissions, waste water discharges, solid waste generation and climate change. Recent work in the OECD Environment Directorate indicates that the drivers of proactive corporate environmental strategies may vary by sector. In order to explore these issues in depth, new work has been launched on technological innovation for Sustainable Chemistry. This work will have three elements: i) analysis of the drivers of environmental management and performance within industrial sectors involved in the manufacture of chemicals and chemical products; ii) development of indicators of eco-innovation (representative areas) for Sustainable Chemistry; and iii) assessment of the relative importance of public policy and other factors in encouraging eco-innovation with respect to Sustainable Chemistry. This work will contribute to the development of the OECD Innovation Strategy, which will be discussed by the Ministerial Council Meeting (MCM) in 2010.

Contact: Nick Johnstone (National Policies Division) and Henrik Harjula

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/
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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

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

http://www.oecd.org/findDocument/0%2C2350%2Cen_2649_34365_1_1_1_1%2C00.html

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DE MARCELLUS , Sally	Existing Chemicals	19.42
DIDERICH , Bob	Existing Chemicals	14.85
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GOURMELON , Anne	Test Guidelines, Endocrine Disrupters	98.49
HARJULA , Henrik	PRTR, Risk Management	98.18
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LEE , Michelle	Nanotechnologies	16.00
RODRIGUEZ , Felicia	Biotechnology, Nanotechnologies	97.43
MUSSET , Laurence	Test Guidelines, HCL	16.76
MULLER , Ciara	Test Guidelines, HCL	16.74
OI , Michihiro	HCL, Risk Assessment (Environmental), Test Guidelines	79.07
OKI , Noriko	Nanotechnologies	14.63
PORET , Sylvie	Pesticides, Biocides	89.45
SCHULTZ , Terry	Test Guidelines [(Q)SAR]	14.81
SIGMAN , Richard	Pesticides, Biocides, New Chemicals	16.80
TAKENAKA-YAGI , Mio	GLP, Test Guidelines	76.98
TILL , Davina	Pesticides, Biocides, GLP, New Chemicals, Chemical Accidents	85.25
TURNHEIM , Dian	Deputy Head of Division, GLP	93.15
VISSER , Rob	Deputy Director of ENV, Head of EHS Division	93.10