

Environment, Health & Safety News

No. 25, July 2010

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.

STAFF IN THE EHS DIVISION

Since the last Environment, Health and Safety News (No. 24, issued in November 2009), the EHS Division has seen the following changes in staffing:

Main Office: *Alastair Wood* has replaced *Daniel Garley* as Division CI, Communications and Publications Co-ordinator.

Risk Management / Sustainable Chemistry and PRTR: *Henrik Harjula* has retired after more than 10 years of service with us. *Peter Borkey* is taking his place as of the 1st July 2010.

Existing Chemicals: *Melanie Guilhaumon* has joined as a consultant.

Biosafety: *Carina Arambula* will start on the 5th July for a 6-month internship.

Nanosafety: *Valérie Frison Beau* started in January as an intern and will be working with us until the 18th July. *Jeong Rim Lee* has also recently joined the Nano team as an intern.

Yidan Shen-Gress, who joined the team of EHS assistants to provide additional administrative support, has now left. *Sarah Jukes*, who has been with us over the last few months for administrative support, will also be leaving us in July.

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.

Draft New or Updated Test Guidelines

The following new, updated or corrected Test Guidelines were approved at the last meeting of the Working Group of National Coordinators of the Test Guidelines Programme (WNT) on 23-25 March 2010. They have been endorsed by the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, as well as by the Environment Policy Committee. It is expected that they will be adopted by the Council in July and then published.

Draft New Test Guidelines:

Section 2: Effects on Biotic Systems

- 223 Avian Acute Oral Toxicity Test
- 233 Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment

Section 3: Degradation and Bioaccumulation

- 317 Bioaccumulation in Terrestrial Oligochaetes

Section 4: Health Effects

- 439 In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method
- 442A Skin Sensitization: Local Lymph Node Assay: DA
- 442B Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA

Draft Updated Test Guidelines:

Section 2: Effects on Biotic Systems

- 209 Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)

Section 4: Health Effects

- 417 Toxicokinetics
- 429 Skin Sensitization: Local Lymph Node Assay

Draft Corrected Test Guideline:

Section 4: Health Effects

- 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Other activities under the Test Guidelines Programme

The WNT also approved a number of documents related to Test Guidelines. Some are already published (see *recent publications in the Series on Testing and Assessment* below). The following documents will be published in the coming weeks/months:

- Guidance Document on the Determination of the Toxicity of a Test Chemical to Dung Beetles
- Guidance Document on the Design and Conduct of Chronic Toxicity and Carcinogenicity Studies, supporting TG 451, 452, and 453 (First Edition)
- Report of the Validation of the Avian Acute Oral Toxicity Assay
- Guidance Document for the Derivation of an Acute Reference Dose
- Guidance Document on Using Cytotoxicity Tests to Estimate Starting Doses for Acute Oral Systemic Toxicity Tests
- Report of the Multi-Laboratory Validation of the H295R Steroidogenesis Assay to Identify Modulators of Testosterone and Estradiol Production
- Report of the Peer Review for the H295R Cell Based Assay for Steroidogenesis
- Example of Material Transfer Agreement Template
- Report of the Validation of a Soil Bioaccumulation Test with Terrestrial Oligochaetes by an International Ring Test
- Explanatory Background Document to the Test Guideline on *in vitro* skin Irritation Testing

The WNT also agreed to the inclusion of several new projects in the Test Guidelines work plan, the update of which is expected to be available on the public website in a few weeks. Information on some important current issues/projects follows.

In Vitro Mammalian Cell Micronucleus Test

The draft Test Guideline for an *in vitro* mammalian Cell Micronucleus Test, which was already provisionally approved by the WNT, was approved by written procedure on 27 November 2009, after completion of experiments in several laboratories and on several chemicals to evaluate the performance of the cytotoxicity measurements. It will be submitted to Council and published with other Test Guidelines approved at the last WNT meeting.

Endocrine disrupters

The first meeting of the Advisory Group on Testing and Assessment of Endocrine Disrupters (EDTA AG) was held on 17-18 May 2010. The EDTA AG agreed on recommendations to be included in a draft Detailed Review Paper on availability of *In Vitro* Receptor Assays in Fish for Screening of Endocrine Modulating Activities of Environmental Chemicals. It also agreed on the objectives, scope and draft outline of a Guidance Document for assessing endocrine disrupters, and on the scope of a future Detailed Review Paper on new endocrine endpoints.

A validation management group for non-animal testing met on 17-19 November 2009 in Washington D.C. It addressed issues related to the validation/peer review of the H295R Cell-Based Assay for Steroidogenesis. It also continued discussing issues related to a Performance-Based Test Guideline for an Estrogen Receptor α Transcriptional Activation Assay for endocrine disrupters, as well as Material Transfer Agreements (MTA) for *in vitro* assays. An example MTA was submitted to - and approved by - the WNT at its March meeting; it is expected to be available on the public website within two months.

A validation management group for ecotoxicity testing met on 8-9 December 2009 in Paris. It discussed an androgenised female stickleback screening assay, a chironomid full-life cycle test, a Detailed Review Paper on molluscs life-cycle toxicity testing, the phase 2 results of the fish sexual development test, progress on fish life cycle testing, a copepod development and reproduction test, a mysid 2-generation test,

and amphibian growth, development and reproduction assay. At its March 2010 meeting, the WNT approved the draft Test Guideline for a chironomid full-life cycle test (see *Draft New Test Guidelines - TG 233* above), and agreed that the stickleback screening assay should be developed as a Guidance Document. Several documents, agreed by the validation management group and endorsed by the WNT and the Joint Meeting, are already published (see *Recent publications in the Series on Testing and Assessment* below).

Skin Irritation

TG 439 was approved by the WNT at its last meeting (see above). The WNT also agreed to the inclusion of a new project in the work plan for developing a Guidance Document on Skin Irritation/Corrosion and related Test Guidelines. This project will start with an expert meeting (see *Forthcoming events* below) reviewing the different types of tools that can be used in a testing strategy, and their applicability.

Extended One-Generation Reproductive Toxicity Study (EOGRTS)

In February 2010, the Joint Meeting agreed that before taking a final decision on the EOGRTS Test Guideline, a third retrospective analysis on the 2-generation reproductive toxicity studies should be performed and should involve all interested countries. The work on the third retrospective analysis started after the February 2010 Joint Meeting, led jointly by the Netherlands and the US, on the basis of a wider 2-generation reproductive toxicity study database. There will be two meetings of the Expert Group (see *Forthcoming events* below) before the November 2010 Joint Meeting that is expected to reach a final agreement on the Test Guideline.

Fish Testing Framework

An expert group is developing a draft document that will present different issues aspects/issues related to fish testing (e.g. review of existing Test Guidelines, recommendations for updating Test Guidelines, examples of fish testing strategies). The draft document will be discussed at a workshop in September (see below).

Derivation of an Acute Reference Concentration (ARfC)

An expert group is developing a Guidance Document for the Derivation of an Acute Reference Concentration. The group met on 27-29 January 2010 at EPA in Arlington, USA. A first draft document will be circulated for review to member countries in July-August 2010.

Design and Conduct of Chronic Toxicity and Carcinogenicity Studies











An expert group is developing a second edition of the GD 116 on the Design and Conduct of Chronic Toxicity and Carcinogenicity Studies supporting TG 451, 452 and 453. This second edition will include other sections on the study design, the mode of action and statistics. The draft document will be sent for review to member countries in July 2010 and the expert group will meet in November 2010 (see *Forthcoming events* below).

Forthcoming events:

- Workshop on a fish testing framework, 28-30 September 2010, United Kingdom
- Expert group meeting on skin irritation/corrosion, 19-21 October 2010, Germany
- Expert group meeting on the draft extended one-generation reproductive toxicity study, 19-21 October 2010, United States
- Expert group meeting on the development of the 2nd edition of GD 116 on the design and conduct of chronic toxicity and carcinogenicity studies, 23-24 November 2010, Paris
- Meeting of the validation management group for non animal testing: 30 November-2 December 2010, Paris

- Meeting of the extended Advisory Group on Molecular Screening and Toxicogenomics, 6-7 December 2010, United States
- 23rd Meeting of the Working Group of National Coordinators of the Test Guidelines Programme, 12-14 April 2011, Paris

Recent publications in the Series on Testing and Assessment:

-  No. 113 Report of the Focus Session on Current and Forthcoming Approaches for Chemical Safety and Animal Welfare (2010)
-  No.114 Performance Assessment of Different Cytotoxic and Cytostatic Measures for the In Vitro Micronucleus Test (MNVIT): Summary of results in the collaborative trial (2010)
-  No. 115 Guidance Document on the Weanling Hershberger Bioassay in Rats: A short-term Screening Assay for (Anti)Androgenic Properties (2009)
-  No.118 Workshop Report on OECD Countries Activities Regarding Testing, Assessment and Management of Endocrine Disrupters Part 1 and II (2010)
-  No. 121 Detailed review paper (DRP) on Molluscs Life-Cycle Toxicity Testing (2010)
-  No. 123 Guidance Document on the Diagnosis of Endocrine-related Histopathology in Fish Gonads (2010)
-  No 125 Guidance Document on Histopathology for Inhalation Toxicity Studies, Supporting TG 412 (Subacute Inhalation Toxicity: 28-Day Study) and TG 413 (Subchronic Inhalation Toxicity: 90-Day Study) (2010)
-  No 126 Short Guidance on the Threshold Approach (2010)
-  No 127 Peer review report of the validation of the 21-day Androgenised Female Stickleback Screening Assay (2010)
-  No 128 Validation report of the 21-day Androgenised Female Stickleback Screening Assay (2010)

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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.

The second meeting of the *Clearing House on New Chemicals* (CHNC), led by Australia, was held from 24-26 February, 2010 in Tokyo, Japan. The main objectives of the meeting, chaired by Dr. Marion Healy (Australian Government National Industrial Chemicals Notifications and Assessment Scheme), were to refine the work sharing arrangements under the 'Parallel Process', develop a work plan for activities related to definitions/exemptions/exclusions, take stock of work on the development of the electronic notification software programme and identify next steps, and explore further outreach activities.

With respect to work on the Parallel Process, members reached agreement on a number of issues related to the draft Standard Operating Procedures (SOP) document which is intended to serve as a guide for participating countries and companies on the process and steps involved in the parallel process. (The "Parallel Process" refers to a company notifying in multiple jurisdictions and authorising participating governments to share information when conducting their reviews.) Progress was also made on revising the template for the Parallel Process Modus Operandi (MO) - a work sharing agreement signed by the individual jurisdictions which sets operational procedures and boundaries for sharing information on new industrial substances – and an 'Agreement to Participate' template which would be signed by the notifier and competent authority. Members also considered a thought starter, developed by industry, which outlines a possible approach for deciding what information elements to include in a new substance notification.

Work on definitions, exclusions and exemptions is underway, focusing on polymers and low volume exemption criteria. The new working group that was established to promote participation in the Parallel Process is developing promotional materials to encourage participation by countries that are either in the process of developing, or currently have, notification and assessment systems. Work has also begun on the development of new material for the OECD public website on new chemicals. Finally, with respect to the development of an electronic notification software programme, the US EPA, on behalf of the Clearing House, has issued a formal public Request for Information soliciting technical ideas to help in the development of the software programme.

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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.

An *Ad hoc* Expert Meeting on the OECD Cooperation on the assessment of chemicals after 2010 was held on 24-26 March at the OECD in Paris. The meeting recommended a number of new activities to be part of the programme in addition to those already underway. The recommendations were endorsed by the 44th Joint Meeting in June 2009; some activities are being implemented on an interim basis until the end of 2010.

The Task Force on Hazard Assessment met for the second time on 18-20 November 2009. The main tasks of the Task Force are to oversee the evolution of the HPV Chemicals Programme (including the improvement and harmonisation of hazard assessment methodologies), oversee the development and implementation of the Global Portal to Information on Chemical Substances (eChemPortal), and oversee the work on (Quantitative) Structure Activity Relationships [(Q)SARs]. At its second meeting, the Task Force:

- endorsed preliminary guidance for submitting assessments elaborated in national/regional and industry programmes to OECD as well as preliminary guidance for elaborating targeted assessments;
- agreed on a way forward to improve the acceptance of QSAR approaches and for developing guidance for elaborating extended targeted chemical categories;
- endorsed the proposal to hold a workshop on using mechanistic information in forming chemical categories for read-across for regulatory purposes;
- agreed on a way forward to avoid duplication.

The 30th SIDS Initial Assessment Meeting (SIAM 30, OECD Paris) was held in April 2010. Assessments for 30 chemicals were agreed at SIAM 30. The agreed conclusions for chemicals discussed at SIAM 30 were submitted to the Task Force on Hazard Assessment for endorsement and will then be submitted to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for endorsement through written procedure. The interim implementation of the new HPV Chemicals programme is on-going. Targeted assessments have been submitted for discussion and agreement by Canada, Germany and Japan. Case studies of targeted and extended chemical categories have been submitted for discussion.

Since UNEP suspended publication of SIDS documents, initial assessments for 271 chemicals are publicly available on the OECD web site [<http://www.oecd.org/env/existingchemicals/data>]. Altogether, assessments for 398 chemicals have been published by UNEP [<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>]. Assessments for 110 chemicals have been agreed upon at OECD level and have been published by the European Commission [<http://ecb.jrc.it/existing-chemicals/>]. Furthermore, the Secretariat has published 281 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: <http://www.oecd.org/env/existingchemicals/data>.

In January 2010, a new version of the OECD Existing Chemicals Database was launched: <http://www.oecd.org/env/existingchemicals/data>. This database tracks all High Production Volume (HPV) chemicals through the process of investigation in the OECD programme on the Investigation of Existing Chemicals. The new functionality offered to users includes the ability to view information on more than one assessment per chemical, to create public reports, and to download final assessments.

eChemPortal, the Global Portal to Information on Chemical Substances, was publicly launched in June 2007 [<http://www.oecd.org/ehs/eChemPortal>]. Since the last newsletter two additional databases / report collections have been added as participants: The Result of the GHS Classification by the Japanese Government (GHS-J) and the United Kingdom Coordinated Chemicals Risk Management Programme Publications (UK CCRMP Outputs). As well, Approximately 1000 Chinese chemical names have been added to the eChemPortal index of chemical names allowing a search by chemical name in Chinese.

A new version of the IUCLID software [see <http://iuclid.eu>], IUCLID 5.2, was published on 15 February 2010 by the European Chemicals Agency, the owner of the IUCLID 5 software. This new version incorporates improvements proposed at the meeting of the OECD IUCLID User Group Expert Panel in September 2008. The Expert Panel met again in February 2010 to discuss proposals for future developments of the IUCLID software, i.e. user interface and functionalities, additional training course materials and guidance documents, to be incorporated into version 5.3 in 2011.

Forthcoming events:

- Task Force on Hazard Assessment, 29-30 June 2010, OECD, Paris.
- Workshop on using mechanistic information in formic chemical categories for read-across for regulatory purposes, 8-10 December 2010, Washington DC, US
- SIAM 31, 19-22 October 2010, Oxford, United Kingdom.

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

(QUANTITATIVE) STRUCTURE-ACTIVITY RELATIONSHIPS [(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 by governments and industry in specific regulatory contexts.

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 latest version of the Toolbox (version 1.1.02) released in January 2010 can be downloaded free of charge from the public OECD web site [<http://www.oecd.org/env/existingchemicals/qsar>].

Furthermore, various materials to help the use of the Toolbox have been developed, which are also available on the public webpage above. They include:

- A set of training materials (slide shows and videos) on how to use the Toolbox
- FAQs on the Toolbox
- Guidance and Instruction for the use of the Toolbox (e.g. Guidance on Importing Databases, Guidance Document for using the (Q)SAR Application Toolbox to develop chemical categories according to the OECD Guidance on Grouping Chemicals, (Q)SAR Application Toolbox: Tips and Tricks)

- General guidance documents and reports on (Q)SAR approaches (e.g. A series of Reports of Expert Consultation on specific adverse effects such as Estrogen Receptor Bindings and DNA Bindings)

The phase 2 project for the development of an updated version with extended functionalities has been on-going since November 2008, financed by the European Chemicals Agency. It aims for the release of version 2 of the Toolbox in 2010, and version 3 in 2012. The work is overseen by the (Q)SAR Application Toolbox Management Group, and the Group held its third meeting on 21-22 April 2010 for the beta test of the Toolbox version 2.

The following achievements have been made so far during the phase 2, and will be incorporated in version 2, expected to be released in October 2010:



- the implementation of the OECD Harmonized Templates in the database structure of the Toolbox,
- a development of a module to exchange data between IUCLID 5 and the Toolbox,
- a function to automatically generate detailed reports for estimations made with the Toolbox,
- the quality assurance of the identity of chemicals in the databases of the Toolbox,
- the inclusion of additional databases (especially for mammalian toxicity), and
- the review and improvement of existing categorisation mechanisms (such as DNA-binding), and the addition of new categorisation mechanisms (such as for estrogen receptor binding affinity).

The beta of version 2.0 was tested by members of the (Q)SAR Application Toolbox Management Group in May 2010 and the final version 2.0 is scheduled to be released in October 2010.

A public discussion forum has been set up in May 2010 on the following web page: https://community.oecd.org/community/toolbox_forum. On this site, the users of the (Q)SAR Application Toolbox can:

- exchange experience with using the software (tips and tricks),
- seek guidance,
- exchange databases,
- exchange user defined profilers and QSARs, and
- make suggestions for improvements.

Recent publications:

-  [Strategies for grouping chemicals for data gap filling for acute aquatic toxicity endpoints](#)
-  Report of the Expert consultation on Scientific and Regulatory Evaluation of Organic Chemistry Mechanism-Based Structural Alerts for the identification of DNA-binding Chemicals [[part I](#), [part II](#)]

Forthcoming events:

- 4th Meeting of the (Q)SAR Application Toolbox Management Group, October 2010
- Workshop on using mechanistic information in formic chemical categories for read-across for regulatory purposes, 8-10 December 2010, Washington DC, US

Contact: Michihiro 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.

The Task Force on Exposure Assessment, restructured from the former Task Force on Environmental Exposure Assessment met for the first time on 30 November – 1 December 2009. The Task Force discussed progress of on-going projects on environmental exposure assessment taken over from the former Task Force and also possible new work regarding exposure assessment for humans.

One of the major activities of the Task Force is to develop Emission Scenario Documents (ESDs) which 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. A number of projects to develop new ESDs, to revise existing ESDs and to assist the development and use of ESDs are on-going. Two new draft ESDs were approved by the Task Force and they will be published soon.

The risk caused by chemicals in products was identified as one of emerging policy issues in the International Conference of Chemicals Management (ICCM2) held in May 2009. As a consequence, the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology reviewed and discussed relevant OECD work on chemicals in products in February 2010. The Joint Meeting agreed to improve collaboration between the Task Force on Exposure Assessment and the Task Force on PRTRs on developing release estimation techniques from products, and also encouraged to increase the development of ESDs related to releases from products.

Forthcoming event:

- 2nd Meeting of the Task Force on Exposure Assessment, 29 – 30 September 2010, Stockholm, Sweden

Recent publications:



[New ESD on Formulation of Radiation Curable Coatings, Inks and Adhesives](#)



[Revised ESD on Photoresist Use in Semiconductor Manufacturing](#)

Forthcoming publications:



New ESD on Chemicals Used in the Electronics Industry



New ESD on Blending Fragrance Oils into Commercial and Consumer Products

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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.

Perfluorinated chemicals

The OECD monitors the manufacture and use of PFOA and PFOA-related chemicals and other PFAS and PFAS-related chemicals, in addition to PFOS and PFOS-related chemicals through surveys conducted every 2-3 years. The 2009 survey questionnaire on “Product content and environmental release information on selected PFCs” was circulated to producers of basic chemistries and responses were received. The survey outcome report will be published in the third quarter of 2010.

The ICCM2 adopted a Resolution in May 2009 and the 44th Joint Meeting agreed in June 2009 that the OECD Steering Group on PFCs should work with the IOMC to encourage governments and other stakeholders to participate in PFC risk reduction programmes and to contribute to: a) the OECD survey of product content and environmental release information on PFOS, PFAS, PFCA, their related substances and products/mixtures containing them; and b) information exchange on alternatives currently in use, and report to the OEWG in 2011 and to ICCM 3 in 2012. The related discussion at the ICCM 2 can be found on page 13 and the Resolution on page 40 of the ICCM 2 report:

<http://www.saicm.org/documents/iccm/ICCM2/ICCM2%20Report/ICCM2%2015%20FINAL%20REPORT%20E.pdf>.

As a first action item a web portal will be developed to disseminate information on perfluorinated chemicals, focusing on efforts by governments and intergovernmental organisations on managing PFCs as well as information on alternatives. A first version of the web portal is scheduled to be released at the end of 2010.

Sustainable Chemistry

A Sustainable Chemistry Network was established in 2006 for information exchange, reviewing new developments and further elaboration of incentives for sustainable chemistry, engaging multiple stakeholders in the network and collecting positive examples of progress, as well as measuring the progress in implementation both in OECD member countries and non-OECD economies. To this end, the Issue Team on Sustainable Chemistry has developed, and continues to maintain, an Internet Platform for Sustainable Chemistry (<http://www.oecd.org/env/sustainablechemistry/platform>). The Platform was published in 2009.

A draft report has been prepared which uses patent data to investigate invention in selected Sustainable Chemistry fields, highlighting areas for further analysis of innovation. These fields include, for example, biochemical fuel cells, aqueous solvents and bleaching technologies. The draft report describes the major trends in patent applications, the level of international cooperation in the Sustainable Chemistry area, and who (i.e., companies, universities, research centres) is involved in Sustainable Chemistry invention. The final report is expected in late 2010 or early 2011.

Contact: Peter Borkey

Websites: <http://www.oecd.org/env/riskmanagement>
<http://www.oecd.org/env/sustainablechemistry>

WORK WITH NON-MEMBERS

Mutual Acceptance of Data

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and Principles of Good Laboratory Practice (GLP). It requires OECD governments to accept non-clinical environment and health safety data developed for regulatory purposes in another country if these data were generated in accordance with the Test Guidelines and GLP Principles, thus increasing efficiency and effectiveness of chemical notification and (re-)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.

On 12 January, 2010, Singapore fulfilled all the conditions to adhere to the OECD system for the Mutual Acceptance of Data in the Assessment of Chemicals. Singapore joins South Africa, Slovenia and Israel as non members who are full adherents which means that non-clinical health and environmental safety data generated in these countries must be accepted for regulatory purposes in OECD and other adhering countries. *Provisional* adherents to the Mutual Acceptance of Data system currently include India, Brazil, Argentina and Malaysia. The Secretariat continues to work with Thailand, China, Chinese Taipei, Estonia, and several other countries in view of their provisional adherence to the MAD Council Acts as well.

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

Accession

In May 2007, OECD countries agreed to invite Chile, Estonia, Israel, Russia and Slovenia to open discussions for membership of the Organisation. Following the evaluation by OECD committees of the chemicals management and other policies of Chile, Estonia, Israel, and Slovenia, on 15 December 2009, Chile was invited to become a member of the OECD. On 7 May, 2010 Estonia, Israel and Slovenia were invited to join the Organisation. Chile deposited its instrument of accession to the OECD Convention on 7 May 2010, and is now a member of OECD. Estonia, Israel and Slovenia are expected to join the OECD in the coming months. OECD committees continue to review the relevant policies of the Russian Federation.

Enhanced Engagement

The Chemicals Committee continues to develop relationships with the Enhanced Engagement countries. South Africa is a full adherent to the Council Decisions related to Mutual Acceptance of Data (MAD) in the Assessment of Chemicals – and currently co-chairs the Working Group on GLP - and Brazil and India are provisional adherents. Discussions are underway with China and Indonesia regarding their participation in the MAD system.

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Website: http://www.oecd.org/document/42/0,3343,en_2649_34487_38598698_1_1_1_1,00.html

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.

A survey on the implementation of the Council Recommendation on PRTRs [C(96)41/Final, as amended by C(2003)87] was conducted in August 2009 and the draft report of the survey was endorsed by the Joint Meeting in February 2010 as well as the Environmental Policy Committee (EPOC) in May 2010. The report concludes that the Recommendation is well implemented and that there is no need for further reports. The report will be submitted to the OECD Council.

The Task Force on PRTRs met on 19-21 May 2010 to discuss major work areas such as release estimation techniques from products, development and maintenance of the global portal to PRTR information, and the project for improving comparability of PRTR Data. The Task Force also discussed and agreed a detailed work plan for 2011-2012, which will be forwarded to the 46th Joint Meeting in November 2010 for approval.

Regarding the project on releases from products, the Task Force agreed on a schedule for publishing the first outcome of the project as *the Resource Compendium of PRTR Release Estimation Techniques, Part 4: Summary of Techniques for Products* in 2010. It was also agreed that the work on improving release estimation techniques should continue over the next two years and possibly beyond 2012 in collaboration with the Task Force on Exposure Assessment and any other relevant groups as recommended by the Joint Meeting (See also the section on “Exposure Assessment”).

Forthcoming event:

- 14th Meeting of the OECD Task Force on PRTRs in April 2011, Paris.

Forthcoming publications:

- 📖 Resource Compendium of PRTR Release Estimation Techniques, Part 4: Summary of Techniques for Products

Contact: Peter Borkey

Website: <http://www.oecd.org/env/prtr>
<http://www.oecd.org/env/prtr/rc>
<http://www.oecd.org/env/prtr/data>
<http://www.prtr.net>

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.

Residue Chemistry

Since it began to work on residue chemistry a few years ago, the OECD has published 9 Test Guidelines and several Guidance Documents. Phase 3 of this project, which is underway, focuses on the development of a Guidance Document for *Crop Field Trials*. Phase 3 activities also include: (i) technical work to harmonise data development practices; (ii) consideration of crop grouping/ extrapolation and representative crops; (iii) development of a statistical calculation instrument – “MRL calculator” – of expected maximum residues from crop field trials; (iv) analysis of zoning; (v) identification of adequate residue data sets; and (vi) critical Good Agricultural Practices (cGAP).

Biological Pesticides

The BioPesticides Steering Group (BPSG) organized its second Seminar on the “Fate in the environment of microbial control agents and their effect on non-target organisms” on 19 May 2010, at OECD, Paris. This topic was selected considering its significance for the registration of biopesticides. The importance of the fate in the environment of microbial control agents, natural background levels and their effect on non-target organisms will be a topic of a second Working Document currently under preparation by the BPSG. The report of the first Seminar held in 2009 that addressed “Identity and Characterisation of micro-organisms” is in preparation.

Development of guidance for terrestrial field dissipation studies and crosswalk between North American and European ecoregions

This project is composed of two parts: one, the development of harmonised guidance for conducting terrestrial field dissipation studies (led by the US), and two, the development of a crosswalk for North American and European ecoregions (led by Canada). In order to advance the project and solve some of the issues, Canada will be hosting an OECD expert workshop in March 2011 in Ottawa. The project expert group is currently developing the agenda of this 3-day event.

Pollinators: Survey on testing, research, mitigation and information management

This project, led jointly by the US and Canada, aims to explore issues related to pollinator declines – a topic of great concern to OECD member countries. In March 2009, countries were surveyed on: how incident information on bees is collected and managed, what pollinator testing requirements exist, what areas are the subject of research concerning pollinator declines, and what approaches are employed to mitigate potential risks to pollinators from pesticides. Responses were received from seventeen countries and organisations: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Japan, the Netherlands, Poland, Slovak Republic, Slovenia, United Kingdom, United States, and IBMA (International Biocontrol Manufacturers Association). The report on the survey results was published in May 2010. Based on the results of the survey, a work programme is being established and will be considered by the Registration Steering Group and Risk Reduction Steering Group in October 2010.

Illegal International Trade in Agricultural Pesticides

A seminar on *Risk Reduction through Prevention, Detection and Control of the Illegal International Trade in Agricultural Pesticides* took place on 19 May 2010, at the OECD in Paris. It addressed both trade in counterfeited pesticides and trade in pesticides that are not registered in the country of destination. The main objectives of the Seminar were to: collect information about the extent of the problem and possible future

trends; get a better overview of national current practices and activities for the control of imports/exports of agricultural pesticides; identify ways to improve information exchange and cooperation between regulators and customs within a country and among countries; identify ways to reduce risk through avoiding illegal trade of pesticides; and suggest and discuss options of further steps for the OECD, governments and key stakeholders in OECD and non-OECD countries in order to address the identified issues and implement solutions in an effective manner. Several speakers from OECD countries, non-OECD countries (Brazil and China) and the pesticide industry made insightful and illustrative presentations that described the problem and real cases. The Seminar participants made several recommendations that will be reviewed and discussed by the OECD Pesticide Programme at its meetings of October 2010.

Risk Reduction

In November 2009, in Tokyo, the Risk Reduction Steering Group (RRSG) organised a Seminar on *Pesticide Risk Reduction Strategies near / in Residential Areas*. The seminar explored issues and risk reduction strategies associated with professional pesticide uses in agricultural fields, residential areas and other settings (e.g. horticulture settings, golf courses, public/urban areas such as sport/leisure yards, streets, public gardens, schools, and railways).




In May 2010, a new OECD public website on “Managing Pesticide Spray Drift” was launched. It offers access to a variety of information on pesticide spray drift posted by regulatory authorities of OECD member countries. It provides a central point for quickly finding information about regulatory and technical approaches to reduce pesticide spray drift. This website includes information structured around five main themes of pesticide spray drift: Government laws, policies, and guidance; Best management practices; Application technologies; Studies and validation test methods; and Predictive models. This new website is available at: www.oecd.org/env/spraydrift

The OECD agreed to organise a Workshop on Integrated Pest Management (IPM) in October 2011. It will aim at examining how the implementation and adoption of IPM have changed in the last decade (since the previous OECD workshop on IPM in 1998) and making recommendations to identified stakeholders to lead to greater pesticide risk reduction.



Forthcoming events:




- Registration Steering Group and Risk Reduction Steering Group meetings; 11-15 October 2010; OECD, Paris
- Working Group on Pesticides Meeting, March 2011; OECD, Paris
- BioPesticides Steering Group Seminar and annual Meeting, March 2011; OECD, Paris
- OECD Workshop on Integrated Pest Management, October 2011

Recent publications:

-  Report of the OECD Seminar on Pesticide Risk Reduction through Better National Risk Management Strategies for Aerial Application, Series on Pesticides No. 50
-  OECD Survey on Pesticide Maximum Residue Limit (MRL) Policies: Survey Results Series on Pesticides No. 51
-  OECD Survey of Pollinator Testing, Research, Mitigation and Information Management: Survey Results, Series on Pesticides No. 52

Forthcoming publications:

-  Report of the 2009 BPSG Seminar on identity and characterisation of micro-organisms
-  Results of OECD Survey on Education, Training and Certification of Agricultural Pesticide Users, Trainers and Advisors, and Other Pesticide Communicators

-  Results of OECD Survey on How Pesticide Ingredients other than the Stated Pesticide Active Ingredient(s) are Reviewed and Regulated
-  Maximum Residue Limit Calculator
-  Guidance notes for the estimation of dermal absorption values

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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

The 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 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. A validation study comprised of round-robin testing amongst over 20 laboratories has been completed and the draft validation report is available on the OECD web site. Test Guidelines for testing the efficacy of liquid products have been developed and are being reviewed by experts. They will be accompanied by a Guidance Document explaining how to use these methods for other product forms such as wipes or sprays.

A Guidance Document on the evaluation of the efficacy of antimicrobial treated articles was published in November 2008. It covers efficacy testing of articles treated with antimicrobials in the manufacturing process with the intention of achieving an external effect. Also included are articles which have been modified in some way during service so as to exert an antimicrobial effect (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 has begun with the development of Test Guidelines demonstrating the proof of principle at laboratory level (i.e. demonstrating whether a treated article is efficacious) for two types of materials: porous and non porous.

A Guidance Document for demonstrating the efficacy of pool and spa disinfectants is nearing completion. 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).

Emission Scenario Documents (ESDs)

The *ESD for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses* was published in July 2008. It describes methods for estimating emissions of these products, excluding insecticide treatments for vector control. Users are encouraged to provide updated information for its continuous development. Work to develop an ESD for insecticides for vector control has begun.

The *ESD on Wood Preservatives*, published in 2003, will be updated.

Antifoulants

A document describing the different existing approaches to determine leaching rates of biocidal active substances from antifouling coatings is under development. Antifoulants are chemical agents added to paint applied to ship and boat hulls and other underwater structures to prevent encrustation by aquatic organisms such as algae or barnacles. Antifoulant paints contain biocides which are released slowly over a period of time minimising fouling. As they are by their very nature toxic to aquatic organisms, antifouling biocides could have an impact on non-target organisms.



Risk reduction

The Biocides Programme is beginning to work on risk reduction policies. The first step will consist of a survey to do a stocktaking of the situation in member countries with a view to defining a detailed work programme in this area. The ultimate objective is to identify effective risk reduction measures.






Forthcoming events:

-  8th Meeting of the Task Force on Biocides, 6-7 September 2010, Paris, France

Recent publications:

-  Series on Biocides, Number 2: Possible Approach for Developing Validated Data for Estimating Exposure of Users of Biocidal Products - Factors, Orthogonal Experiments and Probabilistic Modelling
-  Series on Testing and Assessment, Number 107: Preservative-Treated Wood to the Environment: For Wood Held in Storage after Treatment and for Wooden Commodities that are not Covered and are not in Contact with Ground

Forthcoming publications:

-  Guidance Document for Demonstrating Efficacy of Pool and Spas Disinfectants
-  Quantitative Method for Evaluating Bactericidal Activity of Microbicides Used on Hard, Non-Porous Surfaces
-  Quantitative Method for Evaluating Mycobactericidal Activity of Microbicides Used on Hard, Non-Porous Surfaces
-  Quantitative Method for Evaluating Fungicidal Activity of Microbicides Used on Hard, Non-Porous Surfaces
-  Quantitative Method for Evaluating Virucidal Activity of Microbicides Used on Hard, Non-Porous Surfaces

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CHEMICAL ACCIDENTS

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

Addendum to Guiding Principles for Chemical Accident Prevention, Preparedness and Response

The Working Group on Chemical Accidents (WGCA) established a Steering Group to develop an addendum to the second edition of the OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response*. This Steering Group, led by the Secretariat, met on 13-14 April 2010 at the OECD in Paris. It reviewed the conclusions and recommendations from six workshops that were sponsored by the WGCA since the publication of the second edition of the *Guiding Principles* in 2003. The Addendum is being drafted based on the outcome of the April meeting; it will be submitted for review and approval to the 20th Meeting of the WGCA.

Safety Performance Indicators (SPI)

The second edition of the OECD Guidance on Developing Safety Performance Indicators for Public Authorities and Community/Public and Guidance on Developing Safety Performance Indicators for Industry was published in September 2008. The 19th WGCA Meeting in October 2009 recommended surveying member countries to learn and gather information on how industry, public authorities and communities are using and implementing SPI programmes. A questionnaire was circulated on 4th May 2010 with a deadline for response of 30th July 2010.

Natural hazard induced chemical accidents (Natech)

The Germany led Steering Group on natural hazard induced chemical accidents (SG-Natech) continues its activities on the development of best practices for the control of the impact of natural hazards on chemical installations. The group works via e-mail and teleconferences. A first interim report (September 2009) is being revised and expanded to be used in the development of a discussion document for a future workshop on Natech (anticipated to take place in 2011 or 2012).


Risk and regulation of carbon capture and storage

A Steering Group, led by the U.K, was established to conduct work on the risk and regulation of carbon capture and storage. It has developed a questionnaire for a survey of member countries addressing CO₂ capture, transport and injection into storage. The questionnaire was circulated to member countries on 15th January 2010 with a deadline for completion of 15th April 2010. Responses were received from twelve countries: Belgium; Czech Republic; France; Germany; Korea; Netherlands; Norway; Slovak Republic; Sweden; Switzerland; Turkey and the United Kingdom. The survey results are being analysed; a preliminary report will be presented at the 20th WGCA meeting.

Forthcoming Events:

- 20th Meeting of the Working Group on Chemical Accidents (WGCA), 6-8 October 2010, OECD, Paris

Forthcoming publications:

-  Addendum to OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (2010-2011)

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HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The programme on Harmonisation of Regulatory Oversight in Biotechnology is mainly focused 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 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 24th meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held in Paris in June 2010. Participants included, as usual, delegates from non-member countries (Argentina, Brazil, India, South Africa, Philippines, Russian Federation and Slovenia). Their participation used to be through the Global Forum on the Knowledge-Based Economy but this arrangement has been replaced this year with a Global Forum on Biotechnology.

An important step was the agreement by the meeting to recommend declassification of the *Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology*. This project, jointly undertaken with the Task Force for the Safety of Novel Foods and Feeds, was initiated in 2003. The document had been developed by a Steering Group and its successive revisions were examined at Working Group and Task Force meetings. During a joint Working Group / Task Force session held on 9 June 2010, Canada (the lead country) presented the few outstanding issues which were remaining in the draft. Each point was examined and a solution agreed. The updated document will be submitted to the Joint Meeting for declassification in the coming weeks.

It was agreed that three other draft Consensus or Guidance Documents were ready for submission for declassification by the end of 2010, after final improvements: Biology of *Picea mariana* (Black Spruce), Biology of *Curcubita* species, Horizontal gene transfer between Bacteria. Further documents which are close to completion will be considered by delegates later in the year for their possible declassification in 2011: Biology of *Brassica* species, Pathogenicity Factors in Assessing the Potential Health Effects of Micro-organisms (Bacteria), Assessment of Environmental Applications involving *Fusarium oxysporum*.

The preparation of three new Biology Consensus Documents on *Cassava*, *Sugarcane*, and *Eucalyptus* are contemplated, and their ad hoc drafting groups are being constituted.

In regard to the project on *Low Level Presence (LLP) in Seed and Commodities in the Context of Environmental Safety*, last responses to the questionnaire are being collated. The Bureau will draft the first synthesis to be circulated at the end of 2010 for comments by the Working Group.

The project on *Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants* made progress with the preparation of a draft annotated outline. Canada (lead) will prepare a first draft in the coming months, for comments by the Working Group.

The draft document on the biology of *Atlantic Salmon*, the first one to be prepared on an animal species, is under reorganisation by the co-lead countries, Finland, Norway and the United States. A Steering Group was newly established to benefit from an enlarged expertise with the participation of Canada, Chile,

Germany and the Russian Federation. The document on *GM Herbicide-tolerant resistant plants* (Module III - agronomic and environmental aspects) also made progress and a new revision was circulated early June. A Steering Group will be set up for better focusing its content on the key elements. The *Summary of Activities of the Working Group on Tree Species* will be revised soon, for public release.

The interoperability of CBD-BCH, FAO and OECD Product databases was reassessed. By this arrangement, the OECD Product Database (publicly available on Biotrack) can exchange data with the Biosafety Clearing House developed by the Convention on Biodiversity along the Cartagena Protocol requirements (CBD-BCH). This includes information such as unique identifiers, common and scientific names of host organisms, events and introduced genes. Cooperation is also taking place with the FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH), which was developed in response to a request from the Codex ad hoc Task Force on Food Derived from Biotechnology. In early 2010, a set of key OECD Consensus Documents was identified, and each of them summarised to enable their insertion in IPFSAPH with direct linkages. A general examination of Biotrack by both the Working Group and the Task Force will start from mid 2010 in order to check the contained information, and decide on further developments (updates, improve its use, strengthen its relevance to concerned stakeholders, possible refocusing etc.).






Forthcoming events:

- OECD Workshop on the OECD biosafety activities, to be held in conjunction with the 11th International Symposium on the Biosafety of Genetically Organisms (ISBGMO), Buenos Aires, Argentina, 15-20 November 2010
- 25th meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, 9-11 May 2011, OECD Headquarters, Paris

Recent Publication:

-  Brochure “OECD and Risk/Safety Assessment in Modern Biotechnology” (updated June 2010)

Forthcoming Publications:

-  Consensus Doc. on Molecular Characterisation of Plants Derived from Modern Biotechnology
-  Consensus Doc. on the Biology of *Picea mariana* (Mill.) spp. (Black Spruce)
-  Consensus Doc. on the Biology of *Cucurbita* spp. (Squashes, Pumpkins, Zucchini or Gourds)
-  Guidance Document on Horizontal Gene Transfer Between Bacteria
-  Summary of Activities of the Working Group on Tree Species subject to Transgenic Improvements

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SAFETY OF NOVEL FOODS AND FEEDS

The programme on the Safety of Novel Foods and Feeds addresses risk/safety assessment issues, mainly related to the products of modern biotechnology, that is, 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 Consensus Documents on compositional considerations of specific food/feed crops constitute the main outputs of the programme. They compile a common base of scientific information on the major components of 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 highly valued because they are agreed through consensus by member countries and other stakeholders.

To date 19 Consensus Documents have been published, the latest ones on *Grain Sorghum*, *Sweet Potato* and *Papaya* issued in June 2010. The revision of the two earliest consensus documents on *Low Erucic Acid Rapeseed (Canola)* and *Soybean*, published in 2001, are now almost ready and will be submitted for declassification in the coming months after final improvements. The work is continuing on *Sugarcane*, and will start on *Common Bean (Phaseolus vulgaris)* in 2011.

Other subjects will be studied in the coming months for possible future development of Task Force activities: Pulse crops, Oyster mushroom, Animal products, and Allergenicity.

A major achievement was made at the 17th meeting of the Task Force held in June 2010, with the agreement on the *Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology*. This project, initiated in 2003, was jointly undertaken with the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology (see description in the Working Group section).

Outreach and engagement with non member economies

The Task Force continues to involve key non member economies because modern biotechnology is an increasingly global issue, including in tropical areas. Argentina, Brazil, India, Latvia, Philippines, the Russian Federation, Slovenia and South Africa participated in the 17th meeting of the Task Force.

The participation of non members' has been possible, up until now, through the Global Forum on the Knowledge-based Economy, under the auspices of OECD's Centre for Co-operation with Non-Member Economies. It will continue under the *Global Forum on Biotechnology* that was set up this year, to be undertaken in co-operation with the Working Group on Harmonisation in Biotechnology and the Biotechnology Unit of the Directorate for Science, Technology and Industry.

Other activities on the risk/safety assessment of modern biotechnology

A document, "Instructions for Authors", is used by the Task Force when preparing Consensus Documents. This document will be updated to take into account aspects of the *quality of the data* that constitute the core of the Consensus Documents. This relates to data relevance and good sources, traceability of the information, natural and methodological variations, and the facilitation of data interpretation.

The interoperability of FAO and OECD databases regarding the information related to food safety assessment was reassessed. By this arrangement, the OECD Product Database can exchange data with the FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH). The project was developed in response to a request from the Codex ad hoc Task Force on Food Derived from Biotechnology. A number of key OECD Consensus Documents were identified in early 2010 and will be included in IPFSAPH. A general examination of Biotrack was initiated mid 2010 by both the Working Group and the Task Force in

order to check the contained information, and decide on further developments (updates, improve its use, strengthen its relevance to concerned stakeholders, possible refocusing etc.)

Future events:

- 18th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 12-13 May 2011

Recent Publications:

- 📖 Brochure “OECD and Risk/Safety Assessment in Modern Biotechnology” (updated June 2010)
- 📖 Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [*Sorghum bicolor* (L) Moench]: Key Food and Feed Nutrients and Anti-Nutrients
- 📖 Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [*Ipomoea batatas* (L.) Lam.]: Key Food and Feed Nutrients, Anti-Nutrients, Toxicants and Allergens
- 📖 Consensus Document on Compositional Considerations for New Varieties of Papaya (*Carica papaya* L.): Key Food and Feed Nutrients, Anti-Nutrients, Toxicants and Allergens

Forthcoming Publications:

- 📖 Consensus Doc. on Molecular Characterisation of Plants Derived from Modern Biotechnology
- 📖 Revised Consensus Document on Compositional Considerations for New Varieties of Low Erucic Acid Rapeseed (Canola): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants
- 📖 Revised Consensus Document on Compositional Considerations for New Varieties of Soybean: [*Glycine max* (L.) Merr.]: Key Food and Feed Nutrients, Anti-Nutrients and Allergens

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SAFETY OF MANUFACTURED NANOMATERIALS

The term “manufactured nanomaterials” covers a diverse range of materials that are being 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 in nanotechnology across many sectors. The main objective of OECD’s WPMN is to assist countries in developing tools to allow them to better address the human health and environmental safety implications of manufactured nanomaterials.

The Working Party on Manufactured Nanomaterials (WPMN) was established in 2006 at a time when nanomaterials were becoming more common in products. Its work is intended to ensure that human health and environmental safety aspects of nanotechnology are adequately addressed. A major focus of its work is to ensure that existing instruments (for example, the OECD Test Guidelines) can be reliably applied to nanomaterials. Accordingly, it seeks to promote international co-operation in addressing the human health and environmental safety implications of manufactured nanomaterials.

As an important recent impact on the WPMN work, *the Interim Report of the Green Growth Strategy: Implementing our commitment for a sustainable future* was presented at the OECD Ministerial Council Meeting in June 2010. As mentioned in the Interim Report, nanotechnology for renewable energy production and storage as well as water management was recognized as one of the most promising

technologies, along with ICTs and biotechnology, to enable green growth in terms of green innovation. In addition, it is encouraged to address both the environmental and economic benefits that could be derived from the development and use of manufactured nanomaterials under the provision that potential safety issues are being addressed at the same time as the technology is developing. In conclusion, our work on manufactured nanomaterials can have significant potential to contribute to fostering green growth based on green technologies by addressing EHS risks that may discourage manufactured nanomaterials from being applied even in environmentally sustainable use.

The WPMN work is a science and rules-based approach which is based on information gathering, priority setting, testing and other methodologies to fill data gaps, to facilitate the assessment of hazards, potential exposure, risk assessment and, where needed, risk management measures. By developing the methodologies in OECD to implement this approach and by harmonising their policies and instruments, member countries can reap the benefits of sharing the work among themselves. For this reason, efforts continue to be made in OECD to create, maintain and improve the various parts of a process which guarantees protection of health and environment by addressing issues associated with chemicals production and use, while avoiding inefficiencies caused by duplicative work and the creation of non-tariff barriers to trade. This is implemented by the WPMN through a number of projects as outlined below. It should be noted that each of the eight projects is managed by a steering group (SG) comprising delegates to the WPMN.

In addition to delegates from OECD member countries and the European Commission, the WPMN work benefits from the participation of representatives from China, Thailand, South Africa, the Russian Federation, Singapore, as well as other organisations such as FAO, UNEP, WHO, UNITAR, ISO (TC 229), BIAC, TUAC and Environmental NGOs.

Significant progress in implementing the programme of work has been made to date. The current status of the implementation of each of the projects is summarised below.

OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities

The Database was publicly launched on 1st April 2009. It provides details of completed, current and planned research projects on the safety of manufactured nanomaterials. The research can be searched by the names of nanomaterials, OECD test guidelines and/or by specific endpoints. The link to access the database is provided through the OECD website¹. As of 1st May 2010, there were 762 projects in the database either from OECD member delegations or from non-member economies or organisations.

In addition, the WPMN has conducted a *preliminary evaluation of the database*. This evaluation included: i) examining the user friendliness of the database; ii) identifying gaps in database entries; and iii) conducting a preliminary examination of information in the database that will facilitate analysis of global research activities.

Safety Testing of a Representative Set of Manufactured Nanomaterials: The “Sponsorship Programme for Testing Manufactured Nanomaterials”

This project was launched in November 2007 when delegations agreed to fund and manage the testing of a number of nanomaterials for specific endpoints² relevant to human health and environmental safety. Since that time, delegations have been “signing up” to this work. As of June 2010, 14 member countries, as well as some non-member economies and other stakeholders³ have committed to this programme in various capacities⁴ in order to pool expertise and to fund the testing.

As part of the sponsorship program, a *Guidance Manual for the Testing of Manufactured Nanomaterials* had initially been published in 2009 and its *First Revision* was published in June 2010. This

¹ See: www.oecd.org/env/nanosafety.

² See *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD’s Sponsorship Programme* [ENV/JM/MONO(2009)20/REV]; and *List of Manufactured nanomaterials and List of Endpoints for Phase One of the OECD Testing programme* [ENV/JM/MONO(2008)13/REV].

³ The European Commission, the Nordic Council of Ministers, China and BIAC.

⁴ Detailed information about the sponsorship program can be available at: www.oecd.org/env/nanosafety.

document will continue to be updated and amended in an iterative manner based upon the accumulation of knowledge as the testing programme moves forward.

Manufactured Nanomaterials and Test Guidelines

The unique properties of manufactured nanomaterials have raised the question as to whether existing OECD test guidelines are adequate to address their characterisation and the assessment of their toxicological properties. A Preliminary Review of 115 OECD test guidelines has shown that most tests are suitable but that in some cases, modification will be needed.

In addition, it noted the importance of developing *Guidance on Sample Preparation and Dosimetry* because nanomaterials have distinct properties which may be affected by the test medium in which they are used. Accordingly, *Preliminary Guidance Notes on Sample Preparation and Dosimetry* have been published although it is expected that the document will be further developed and updated as new information becomes available.

Co-operation on Voluntary Schemes and Regulatory Programmes

This project has examined various national voluntary reporting schemes and regulatory programmes to assess the safety of manufactured nanomaterials. As major outputs of this project, the *Analysis of Information Gathering Initiatives on Manufactured Nanomaterials*, including a *Table of Comparison of information gathering schemes* has been published, as well as the *Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials*. In order to update global activities on manufactured nanomaterials as well as regulatory trends over time, follow-up surveys on information gathering schemes and regulated nanomaterials (2006-2009) are underway.

Co-operation on Risk Assessment

This project is to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity.

The OECD Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context took place on 16-18 September 2009 in Washington D.C, United States. This event was co-hosted by the Business and Industry Advisory Committee to OECD (BIAC) and the Society for Risk Analysis (SRA). The report of this workshop is now publicly available.

The outcomes of this workshop will allow the completion of the document, *Critical Issues in the Risk Assessment of Manufactured Nanomaterials*, which will aim to introduce the current practices and challenges on risk assessment of manufactured nanomaterials as well as strategies for assessing risk in circumstances where data is limited. This document will be developed and published in the near future.

The Role of Alternative Methods in Nanotoxicology

This project aims at addressing the use of alternative methods and integrated testing strategies (ITS) for manufactured nanomaterials. Accordingly, the work of this project is implemented in parallel with the *Sponsorship Programme for Testing Manufactured Nanomaterials*. As a parallel effort, a text on alternative methods was prepared for its inclusion in the *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme*.

A steering Group (SG7) leading this project convened in a first Expert Consultation Meeting on 28-30 April 2010 in Paris. The meeting comprised of experts from Austria, Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, UK, EC, BIAC and ICAPO. The meeting successfully addressed a number of topics and agreed on several areas for future work, most notably the following: i) proposal for continued discussions in a focused session at the next SG7 meeting on *in vitro* dispersion protocols [ENV/CHEM/NANO(2010)17]; ii) proposal for a draft 3-tiered ITS; iii) proposal for a draft discussion document on information exchange and DDPs; iv) proposal for a preliminary prioritised list of assays requiring further evaluations; and v) a proposal for high through-put screening testing of *in vitro* cytotoxicity

assays for potential development of a Performance-Based Test Guideline. A 2nd SG7 meeting is scheduled to be held in Paris 18-20 January 2011.

Exposure Measurement and Exposure Mitigation

Through this project the WPMN is exchanging information on guidance for exposure measurement and exposure mitigation for manufactured nanomaterials. The project covers exposure in occupational settings, consumer exposure, as well as environmental exposure. In addition, a number of case studies on the exposure assessment of sponsored manufactured nanomaterials will be developed.

Finally, through this project leadership, the WPMN will participate as an associated partner with the Aerosol Society Symposium, which will be held in 2010.

Co-operation on the Environmentally Sustainable Use of Nanotechnology

Following the OECD Conference on the Potential Environmental Benefits of Nanotechnology: Fostering Innovation-Led Growth which was held on 15-17 July 2009 in OECD's Conference Centre, a new project was recently established by the WPMN. The aim is to investigate potential benefits of applications based on the use of manufactured nanomaterials. As such, it will follow-up on environmental benefits, sustainability and life-cycle related issues. Through this project, the WPMN seeks to complement ongoing WPMN work regarding the potential positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development. The operational plan of this new project has recently been finalized.

Establishment of WPMN's IT collaborative Platform

WPMN's IT collaborative platform was set up in February 2010 as a replacement for Password Protected Sites (CWS). Using this new IT tool, delegations can share information, create documents as well as undertake interactive discussions.

Under the WPMN's new platform, a Community of Practice (COP) was also established as a sub-category addressed to a wider audience. COP refers to a global body of scientific experts who will convene via a website to discuss and resolve technical issues that impede the current research activities of the Sponsorship Programme. As of June 2010, four COPs are organized on the following issues: i) Ecological effects; ii) Human health, Environment Risk Management; iii) physical-chemical properties; and iv) fate.

Co-ordination and Outreach

Since its establishment, the WPMN has emphasised the importance of co-ordination with related bodies and organisations. OECD is a Participating Organisation (PO) of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), which also includes FAO, ILO, UNEP, UNIDO, UNITAR and WHO (UNDP and the World Bank are observers). OECD has kept these other organisations up to date with the work of the WPMN through the IOMC. In addition, communication has been maintained with the International Organisation for Standardization (ISO), in particular with its Technical Committee 229 on nanotechnologies.

Following the recommendation from the 2nd International Conference on Chemicals Management (ICCM2) which was held on 11-15 May 2009 in Geneva, Switzerland, OECD and UNITAR held a series of *IOMC/OECD/UNITAR Awareness-Raising Workshops for Developing and Transition Countries on Nanotechnology /Manufactured Nanomaterials* in association with SAICM regional meetings. These were as follows:

- 27 November 2009, in Beijing, China
- 11 December 2009, in Lodz, Poland
- 26-27 January 2010, in Abidjan, Cote d'Ivoire
- 12 March 2010, in Kingston, Jamaica
- 11-13 April 2010, in Alexandria, Egypt

Forthcoming events:

- Workshop on Workplace Aerosols, 28 June-1 July 2010, Karlsruhe Germany
- Sponsorship Programme meeting, 5-6 July 2010, OECD Conference Centre, Paris
- 7th meeting of the Working Party on Manufactured Nanomaterials, 7-9 July 2010, OECD Conference Centre, Paris
- 7th Working Party on Nanotechnology, 29 September – 1 October 2010, OECD Conference Centre, Paris

Recent Publications on Manufactured Nanomaterials (July 2009-June 2010):

- 📖 Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme; First Revision (2010)
- 📖 Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (2010)
- 📖 Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (2010)
- 📖 OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012 Operational Plans of the Projects (2010)
- 📖 Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a regulatory context, held on 16-18 September 2009, in Washington D.C., United States (2010)
- 📖 Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 6th Meeting of the Working Party on Manufactured Nanomaterials (2010)
- 📖 Analysis of Information Gathering Initiatives on Manufactured Nanomaterials (2009)
- 📖 Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010 (2009)
- 📖 Current Developments in Delegations and other International Organizations on the Safety of Manufactured Nanomaterials - Tour de Table (2009)
- 📖 Manufactured Nanomaterials: Work Programme 2009-2012 (2009)
- 📖 Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)
- 📖 Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)
- 📖 Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)

Forthcoming Publications:

- 📖 Comparison of Exposure Mitigation Guidances for Laboratories: Manufactured Nanomaterials

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CROSS-CUTTING ISSUES

Cost Savings associated with OECD's Environment, Health and Safety Programme

OECD has recently issued a report which documents over € 150 million in annual cost savings that accrue to governments and industry by working together through the Environment, Health and Safety Programme. Since many chemical substances are traded internationally, varying national requirements regarding their safety can mean duplication of efforts and significant costs for the chemicals industry, and can pose barriers to trade. By agreeing on test methods and data quality standards and sharing the workload of chemical safety testing and assessments, countries get good quality and cost-effective results. For non-clinical health and safety testing, for example, the results of such studies done in one OECD country must be accepted by the others as long as they follow the OECD Test Guidelines and Principles of Good Laboratory Practice. This saves the chemicals industry expensive duplicate tests and reduces the number of animals needed for testing. The report describes the quantifiable benefits that are derived as a result of the harmonisation of testing and assessment of new pesticides and industrial chemicals and the systematic investigation of high production volume chemicals. Non quantifiable benefits – such as ensuring the safety of manufactured nanomaterials, harmonising biotechnology assessments, harmonising chemical classification and labelling, etc. – which are just as real, likely and important as the quantifiable benefits, are also described in the report. The report, *Cutting Costs in Chemicals Management: How OECD Helps Governments and Industry*, is available at: www.oecd.org/ehs

Contact: Richard Sigman

Environmental Outlook

In 2008, OECD published an Environmental Outlook to 2030, which highlighted four priority areas where urgent action is needed: climate change, biodiversity loss, water scarcity, and *environment and health*. The 2008 Environment Ministerial requested that a new Environmental Outlook be developed focusing on these four priority areas, and completed in time for the next Environment Ministers meeting in 2012. As with the previous Environmental Outlooks, this one will be based on the projections of key economic drivers for environmental change utilising the OECD's ENV-Linkages model and projections of environmental impacts based on the IMAGE suite models run by the Dutch Environmental Assessment Institute (PBL). With respect to the *Health and Environment* chapter, while the major emphasis will be on current and projected health impacts associated with outdoor air pollution and unsafe water supply and sanitation, the chapter will also explore health impacts from exposure to chemicals and hazardous substances and indoor air pollution.

Contact: Richard Sigman

Templates for New and Existing Industrial Chemicals, Pesticides and Biocides

OECD initiated a project in 2005 to develop harmonised “templates,” or standard formats for reporting summaries of the results of tests on all types of chemicals (e.g., pesticides, biocides, and industrial chemicals). The templates are aimed at developers of database systems as they prescribe the formats by which such information can be entered into and maintained in databases. By using these templates, governments and industry will easily be able to electronically exchange test study summary information. At present, 99 templates for reporting summary information of the results from tests on chemicals for toxicology, eco-toxicology and physical/chemical properties have been developed. For each of them, a

corresponding XML schema and schematron has been developed (i.e. a common electronic data export/import format). They are used by 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.

Templates are regularly updated or new ones developed, to include new or updated OECD Test Guidelines recently adopted by the OECD Council.

The templates, XML schema and schematron are available on OECD's public website. A new website is being developed, more user friendly. For each endpoint all related documents will be displayed. In addition, version number and date of last update will be more visible. This new website should be available by the end of summer.

Contact: Bob Diderich and Nathalie Delrue

Website: <http://www.oecd.org/ehs/templates>

Green Growth

At the June 2009 OECD Ministerial Council Meeting (MCM), Ministers endorsed a Declaration which calls on OECD to develop a "Green Growth" Strategy. Green growth means promoting economic growth while reducing pollution and greenhouse gas emissions, minimising waste and inefficient use of natural resources, and maintaining biodiversity. The objective of the Green Growth Strategy is to help OECD and non-OECD governments identify policies that can achieve clean, low-carbon growth, and it will include a set of policy recommendations and analysis which can be used to develop national action plans, self-assessment and peer reviews at the OECD. The development of the Strategy will include most of the Directorates within OECD, although the Environment, Economics and Science Technology and Industry Directorates will form the core group. The *Interim Report* of the Green Growth Strategy was discussed at the meeting of the OECD Council at Ministerial Level, from 27 to 28 May, 2010. This Report provides an initial examination of the challenges and opportunities for policy makers who aim to transition to a greener economy. The Green Growth Strategy *Synthesis Report*, which will address the issues described in the Interim Report, will be presented to the 2011 Ministerial Council Meeting. The Environment, Health and Safety Division is providing input to Green Growth initiative.

Contact: Richard Sigman

OECD Environmental Risk Assessment Toolkit

The first version of the OECD Environmental Risk Assessment Toolkit was approved by the 45th Joint Meeting in February 2010 and has been published. This Toolkit describes the work flow of environmental risk assessment and management with links to relevant OECD products that can be used in each step of the work flow. The Toolkit could contribute to capacity building of relevant stakeholders by improving the access and use of various tools and guidance on risk assessment and management of chemicals developed under the OECD Environment, Health and Safety Programme.

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

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INTERNET

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Test Guidelines	http://www.oecd.org/env/testguidelines

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