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 recent publications, as well as the main recent or upcoming events of the EHS Programme. This newsletter is mainly intended for participants in OECD activities associated with the EHS Programme. At the same time, the OECD secretariat hopes that it is also of value to a broader audience with an interest in human health and environmental safety issues connected with the use of chemicals, pesticides and biotechnology.

50TH ANNIVERSARY OF OECD

This year, 2011, marks the 50th anniversary of OECD. The 50th anniversary Ministerial Council Meeting 2011 will bring together world leaders and ministers, sharing better policies to build a resilient and balanced world economy, supported by new sources of growth and jobs in developed and developing countries. On the afternoon of 25 May, the Chair of the Ministerial Meeting, US Secretary of State Hillary Rodham Clinton, and the Vice-Chair, German Chancellor Angela Merkel, will meet with world leaders in a commemoration of the OECD’s 50th anniversary.

40TH ANNIVERSARY OF CHEMICAL SAFETY AT OECD: SPECIAL EVENT, 15TH JUNE 2011

2011 is also the 40th anniversary of work on chemical safety at OECD. Since the establishment of the first chemicals safety work in 1971 the work has grown into the Environment, Health and Safety programme, which today includes work on chemicals, pesticides and biotechnology. OECD will hold a special event to mark this occasion on 15th June. It will be an opportunity to look back and reflect on those aspects of the work which have been a success over the years and on which the programme can build in the years to come. At the same time, it will be more than an opportunity to look back. It will also provide a context in which to address those opportunities and challenges which have yet to be met within the EHS programme of work and within the context of the wider directions and priorities of the OECD as a whole as well. With this in mind,
the event will cover two specific themes: i) **New Approaches to Testing and Assessment - ensuring safety and efficiency**; and ii) **Challenges to the Substitution of Harmful Chemicals**. More information is available on this event at the OECD web site at: [www.oecd.org/environment/40yearschemicals](http://www.oecd.org/environment/40yearschemicals).

### CHEMICALS PROGRAMME

#### 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 3 March, 2011 and 29 March, 2011, India and Brazil respectively fulfilled all the conditions to adhere to the OECD system for MAD in the assessment of chemicals. They join Singapore and South Africa 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 Argentina, Malaysia and Thailand. The Secretariat continues to work with China and Chinese Taipei, and several other countries, in view of their provisional adherence to the MAD Council Acts as well.

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### TEST GUIDELINES

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

#### Draft New or Updated Test Guidelines

The following new, updated or corrected Test Guidelines, approved by the Working Group of National Coordinators of the Test Guidelines Programme (WNT), have been adopted on 22 July 2010 and are available on the public website.
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
487 In vitro Mammalian Cell Micronucleus Test

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 current activities under the Test Guidelines Programme

Draft Test Guideline for an Extended One-Generation Reproductive Toxicity Study (EOGRTS)

An expert meeting (held on 14 September 2010 in the Netherlands) and a combined WNT/expert meeting (held on 19-21 October 2010 in the United States) discussed a third retrospective analysis led jointly by the Netherlands and the United States, on the basis of a wider 2-generation reproductive toxicity study database, and solved most remaining issues related to the draft Test Guideline. The Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology agreed on the final text and endorsed the draft Test Guideline. This draft Test Guideline will be submitted to the OECD Council with other Test Guidelines that were approved by the WNT at its recent meeting (12-14 April 2011). A draft Guidance Document related to this Test Guideline was also approved.

Several Test Guideline-related documents that had been approved at the 2010 WNT meeting have been published in the Series on Testing and Assessment (see recent publications in the Series on Testing and Assessment below). An updated work plan for the Test Guidelines Programme was posted on the public website. Information on some important current issues/projects follows.
**Endocrine disrupters**

A validation management group for non-animal testing met on 30 November-2 December 2010, in Paris. It addressed comments from the WNT on the draft Test Guideline for the H295R Cell-Based Assay for Steroidogenesis. It also continued discussing issues related to a Performance-Based Test Guideline (PBTG) for an Oestrogen Receptor α Transcriptional Activation Assay for endocrine disrupters, taking into account the outcome of a meeting on the concept of PBTG that was held on 29 November 2010.

A Fish Drafting Group met on 16-17 June 2010 in Paris and on 9-10 February 2011 in Tokyo. It discussed the validation and a draft Guidance Document for the Androgenised Female Stickleback Screening Assay, the validation and a draft Test Guideline for the Fish Sexual Development Test, and progress on fish long term testing.

A draft Guidance Document for the Assessment of Chemicals for Endocrine Disruption has been developed and revised on the basis of the comments received from an Advisory Group on Endocrine Disrupter Testing and Assessment (EDTA AG) and from the WNT. Remaining issues were discussed at the April EDTA AG meeting on 18-19 April 2011.

A draft Detailed Review Paper (DRP) on new endocrine endpoints/methods that could be included in Test Guidelines is under development; a detailed outline of the DRP and a chapter on epigenetic effects of endocrine disrupters were presented at the April meeting of the EDTA AG. The first draft DRP is expected to be available in June 2011.

Two draft new Test Guidelines were submitted and approved at the 23rd meeting of the WNT (12-14 April 2011): the Test Guideline for the H295R Cell-Based Steroidogenesis Assay, and the Test Guideline for the Fish Sexual Development Test. The draft Guidance Document for the 21-Day Androgenised Female Stickleback Screening Assay was also approved.

**Genotoxicity**

An expert group meeting on genotoxicity was held on 1-2 March 2011 to discuss the need for updating the set of existing Test Guidelines for assessing genotoxicity, i.e. updating or deleting existing Test Guidelines, and developing new Test Guidelines. This meeting was followed on 3-4 March by a meeting of experts that discussed remaining issues on the draft Test Guideline for a Transgenic Rodent in vivo Gene Mutation Assay, which was approved at the recent meeting of the WNT (12-14 April 2011).

**Skin Irritation**

An expert group meeting on skin irritation/corrosion was held on 19-21 October 2010 in Germany. It discussed a new project for developing a Guidance Document on Skin Irritation/Corrosion and related Test Guidelines and reviewed the different types of tools that can be used in a testing strategy, and their applicability.

**Fish Toxicity Testing Framework**

A Workshop on a Fish Toxicity Testing Framework was held on 28-30 September 2010 in the United Kingdom. A draft document, prepared by a group of experts before the workshop, was discussed and revised during the Workshop. A revised version was prepared on the basis of the comments from the WNT. More work is needed to finalise the document.

**Design and Conduct of Chronic Toxicity and Carcinogenicity Studies**

An Expert group met in Paris on 23-24 November 2010 to discuss the development of an updated version of the Guidance Document 116 on the design and conduct of chronic toxicity and carcinogenicity studies supporting TG 451, 452 and 453. This draft updated version includes other sections on the study design, the mode of action and statistics. The draft document was approved at the April WNT meeting.
Molecular Screening and Toxicogenomic

An extended advisory group on molecular screening and toxicogenomics met on 6-7 December 2010, in the United States. This group is exploring new scientific approaches for assessing chemicals in the future. The aim of the meeting was essentially to share information on scientific progress in the area of High Throughput Systems, in particular the US ToxCast Program, and toxicogenomics. ToxCast is screening hundreds of chemicals with hundreds of in vitro test methods. Some concrete results from the US ToxCast Program were presented for 26 chemicals nominated by the OECD on the basis of their specific mode of action.

Recent and Forthcoming events:

- Meeting of a small expert group on the Fish Toxicity Testing Framework: 6-8 June 2011
- Meeting of a validation management group for non animal testing: 30 November-2 December 2011, Budapest, Hungary
- Meeting of a validation management group for ecotoxicity testing: autumn 2011
- Meeting of the expert group on the review of OECD Test Guidelines on genotoxicity: autumn 2011

Recent publications in the Series on Testing and Assessment:

- No. 131 Report of the Validation of the Avian Acute Oral Toxicity Assay
- No. 124 Guidance Document for the Derivation of an Acute Reference Dose
- No. 130 Guidance Document on Using Cytotoxicity Tests to Estimate Starting Doses for Acute Oral Systemic Toxicity Tests
- No. 132 Report of the Multi-Laboratory Validation of the H295R Steroidogenesis Assay to Identify Modulators of Testosterone and Estradiol Production
- No. 133 Report of the Peer Review for the H295R Cell Based Assay for Steroidogenesis
- No. 134 Report of the Validation of a Soil Bioaccumulation Test with Terrestrial Oligochaetes by an International Ring Test
- No. 137 Explanatory Background Document to the Test Guideline on in vitro skin Irritation Testing

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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 third meeting of the Clearing House on New Chemicals (CHNC), led by Australia, was held from 3-4 March, 2011 in Washington, DC. The meeting, chaired by Dr. Marion Healy (Australian Government National Industrial Chemicals Notifications and Assessment Scheme), focused on on-going
work to support the Parallel Process, activities related to definitions/exemptions/exclusions, and a communication strategy. (The “Parallel Process” refers to a company notifying in multiple jurisdictions and authorising participating governments to share information when conducting their reviews.) With respect to work on the Parallel Process, members discussed the standard operating procedures (SOP) document for work sharing arrangements and agreed on possible guidance for the development of predetermined information set to include in a new substance notification. It is expected that the new guidance material will be made available in June. Members also agreed on next steps on an approach for identifying polymers of low regulatory concern (e.g., expansion of the polyester approved reactant list) as well as a work plan for perfluorinated polymers and low volume exemptions. To further the understanding of, and opportunities available from the participation in, the Parallel Process, work is underway to redesign the current OECD public website on new chemicals. Finally, work continues on the development of the electronic notification software.

On 2 March, 2011, prior to the Clearing House meeting, a workshop was held with representatives from industry. The aim of the workshop was to raise awareness and understanding of the Parallel Process, to present the various projects under the Clearing House, and to gauge interest from industry in participating in the work on polymers.

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**HAZARD ASSESSMENT**

*The Hazard Assessment Programme has evolved from the Existing Chemicals Programme and is concerned with the hazard assessment of industrial chemicals and mainly existing chemicals, i.e. 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 industrial chemicals is gathered or generated and co-operative assessments are carried out to agree on their hazards. eChemPortal offers free public access to information on properties of chemicals, allowing for a simultaneous search of multiple databases on the Internet, giving access to data submitted to government chemical review programmes at national, regional, and international levels.*

The Task Force on Hazard Assessment met for the third time on 29-30 June 2010. 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 third meeting, the Task Force:

- endorsed guidance for submitting assessments elaborated in national/regional and industry programmes to OECD as well as guidance for elaborating targeted assessments;
- endorsed the proposal to hold a workshop on metal specificities in environmental hazard assessment;
- endorsed a proposal for the new Cooperative Chemicals Assessment Programme which is to replace the HPV Chemicals Programme.

The 46th Joint Meeting endorsed the proposal for the new Cooperative Chemicals Assessment Programme in November 2010.

A joint workshop with WHO and ILSI/HESI was held in February 2011 at OECD Headquarters in Paris, on the risk assessment for exposure to multiple chemicals. The workshop report will be published in the second quarter of 2011.
The 31st SIDS Initial Assessment Meeting (SIAM 31, OECD Paris) was held in October 2010 in Oxford, United Kingdom. Full SIDS assessments and targeted assessments for 28 chemicals were agreed at SIAM 31. The agreed conclusions for chemicals discussed at SIAM 31 were endorsed by the Joint Meeting. On 15 April 2011. A special session on the identification of hydrocarbon solvents was organised to allow member countries and regional organisation to express their regulatory requirements and to agree on a set of identifiers for this type of chemicals of variable composition. A joint session between the SIAM and the (Q)SAR Application Toolbox Management Group was held to promote the use of non-testing information to fill data gaps and address issues identified by SIAM in the use of non-test data.

Since UNEP suspended publication of SIDS documents, initial assessments for 379 chemicals are publicly available on the OECD website [http://www.oecd.org/env/existingchemicals/data]. Assessments for 398 chemicals are publicly available on the UNEP website [http://www.chem.unep.ch/irptc/sids/OECDSDSIDSSidspub.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 268 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: http://www.oecd.org/env/existingchemicals/data.

A new version of eChemPortal, the Global Portal to Information on Chemical Substances, was publicly launched in December 2010 [http://www.oecd.org/ehs/eChemPortal]. This second version provides new searches based on certain properties or effects, such as physical chemical properties, environmental fate and behaviour, ecotoxicity and toxicity in the participating databases that can offer direct searching of assessment endpoint data. Since the last newsletter five additional databases / report collections have been added as participants: U.S. EPA Aggregated Computational Toxicology Resource (ACToR), AGRITOX - Base de données sur les substances actives phytopharmaceutiques, and Canadian Categorization Results (CCR). The European Chemicals Agency’s Dissemination portal with information on chemical substances registered under REACH (ECHA CHEM) and the OECD Existing Chemicals Screening Information Data Sets (SIDS) Database (OECD SIDS IUCLID) were added as participants in the search by chemical property functionality.

A new version of the IUCLID software [see http://iuclid.eu], IUCLID 5.3, was published on 24 February 2011 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 February 2010. An on-line public consultation was held from 18 January to 7 March 2011 to identify needs for future versions of IUCLID.

**Forthcoming events:**

- Workshop on metal specificities in environmental hazard assessment, 7-8 September 2011, Paris France.
- SIAM 33, 19-21 October 2011, Paris, France.

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(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 QSAR 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 2.1) released in February 2011 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 QSAR Toolbox to develop chemical categories according to the OECD Guidance on Grouping Chemicals, QSAR 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 Binding, DNA Binding, and Protein Binding)

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 3 of the Toolbox in 2012. The work is overseen by the QSAR Toolbox Management Group.

The following achievements have been made so far during the phase 2, and are incorporated in version 2:

- 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).

A public discussion forum has been set up on the following web page: [https://community.oecd.org/community/toolbox_forum]. On this site, the users of the QSAR 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.

A workshop on using mechanistic information for forming categories was held in Washington DC on 8-10 December 2010, hosted by the US-EPA. The outcome of this workshop will be used to further shape the work of the OECD (Q)SAR Project. The full report of the workshop will be published during the second quarter of 2011.
Recent publications:

- Strategies for grouping chemicals to fill data gaps to assess genetic toxicity and genotoxic carcinogenicity

Forthcoming events:

- 6th Meeting of the QSAR Toolbox Management Group, October 2011

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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 held its second meeting on 29-30 September 2010. The Task Force discussed progress of on-going projects on environmental exposure assessment taken over from the former Task Force on Environmental Exposure Assessment and also several new activities 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. Two new ESDs on Chemicals used in the Electronics Industry and on Blending of Fragrance Oils into Commercial and Consumer Products were published in September 2010. A number of projects to develop new ESDs, to revise existing ESDs and to assist the development and use of ESDs are on-going. Three new draft ESDs and one revised ESD 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 encouraged improvement of collaboration between the Task Force on Exposure Assessment and the Task Force on PRTRs on this issue. These two Task Forces agreed to have a joint session to discuss progress made by each Task Force as well as possible cooperation regarding releases from products.

Forthcoming event:

- A joint session between the Task Force on Exposure Assessment and the Task Force on PRTRs, 5 October 2011, Paris
- 3rd Meeting of the Task Force on Exposure Assessment, 5 – 6 October 2011, Paris
**Recent publications:**

- New ESD on Chemicals used in the Electronics Industry
- New ESD on Blending Fragrance Oils into Commercial and Consumer Products

**Forthcoming publications:**

- New ESD on the Use of Metalworking Fluids
- New ESD on Chemicals used in Water-based Washing Operations in Industrial and Institutional Laundries
- New ESD on the Application of Radiation Curable Coatings, Inks and Adhesives
- Revised ESD on Coating Application via Spray-painting in the Automotive Refinishing Industry

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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 result of the 2009 survey on “The production, use, and release of PFOS, PFAS, PFOA, PFCA and their related substances and products/mixtures containing these substances” has just been released and is available at:


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 PFC survey; 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:


As a first action item a PFC web portal has been established to disseminate information on perfluorinated chemicals, focusing on efforts by governments and intergovernmental organisations on managing PFCs as well as information on alternatives. The web portal can be accessed at [www.oecd.org/ehs/pfc](http://www.oecd.org/ehs/pfc). In addition to this a series of webinars and side-events are being organised in order
to disseminate and share information on PFCs. Side-events are planned at the occasion of POPs COP on 28 April 2011 and at the meeting of the Open-ended Working Group at the end of August 2011.

**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](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 available at:

[http://www.oecd.org/document/6/0,3746,en_2649_34375_1909638_1_1_1_1,00.html](http://www.oecd.org/document/6/0,3746,en_2649_34375_1909638_1_1_1_1,00.html)

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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.

An important recent element has been OECD’s response to the financial and economic crisis. A key element of this response is to foster “green” and innovation-led growth\(^1\). For its part, the WPMN has aligned its programme of work to support the overall mission and commitment of the organisation and its members. As such, it works closely with other international efforts.

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The WPMN work is a science and procedure-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 in OECD to create, maintain and improve the various scientific underpinnings of the national regulatory processes to guarantee protection of health and environment by addressing issues associated with chemicals production and use, while avoiding inefficiencies caused by duplicative work and 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) comprised of 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, UNITAR, ISO (TC 229), BIAC 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 website.

As of March 2011, there were 804 projects in the database either from OECD member delegations or from non-member economies or organisations.

In addition, the WPMN has conducted a further development of the database. This development included: i) improvement of the functionality to maintain a record of visits to the database that can be used as an indicator of the use of database; ii) creation of a new feature in the database to specifically identify the projects of the OECD’s Sponsorship Programme; and iii) installation of new guidance function (pop-up window) for easier data entries.

**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 endpoints relevant to human health and environmental safety. Since that time, delegations have been “signing up” to this work. As of March 2011, nearly 20 member countries, as well as some non-member economies and other stakeholders have committed to this programme in various capacities.

As part of the sponsorship program, a Guidance Manual for the Testing of Manufactured Nanomaterials has been published with an annex on Alternative Methods. This document will be updated as new information becomes available through the sponsorship programme.

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4 The European Commission, the Nordic Council of Ministers, China, South Africa and BIAC.

5 Detailed information about the sponsorship program can be available at: [www.oecd.org/env/nanosafety](http://www.oecd.org/env/nanosafety).
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, the Project has 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, the WPMN developed Preliminary Guidance Notes on Sample Preparation and Dosimetry and it was published in May 2010, 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 is compiling and analysing national information gathering schemes and regulatory programmes to assess the safety of manufactured nanomaterials. To date, major outputs of this project include: i) Analysis of Information Gathering Initiatives on Manufactured Nanomaterials along with a Table of Comparison of Information Gathering Schemes; and ii) the Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials. To identify trends of commercial activities and the regulatory landscapes of manufactured nanomaterials, follow-up reports are underway, including: i) Analysis of Information Gathering Schemes focusing on summary of lessons learned and summary of data collected; and ii) Regulated Nanomaterials: 2006-2009. As agreed at the 8th WPMN meeting, both of the documents will be finalized and then be made publicly available late 2011.

In addition, this Project piloted a collaborative workspace in October 2010 to share information and discuss issues on national voluntary or regulatory programmes between a few selected governments. Following the 8th WPMN meeting, this workspace will be expanded to involve all of the governments involved in the Project.

Co-operation on Risk Assessment

This project is evaluating risk assessment approaches for manufactured nanomaterials through information exchange and identifying opportunities to strengthen and enhance risk assessment methodologies. The outcome of the OECD Workshop on Risk Assessment of Manufactured Nanomaterials in Regulatory Context, which took place in Washington D.C., United States in September 2009 fostered work on the Risk Assessment of Manufactured Nanomaterials: Critical Issues document. This document was endorsed by the WPMN at its 8th meeting in March 2011, and will be publicly available later on in 2011.

The Role of Alternative Methods in Nanotoxicology

This project aims at addressing the use of alternative methods and testing strategies for manufactured nanomaterials. Accordingly, the work of this project is implemented in parallel with the Sponsorship Programme for Testing Manufactured Nanomaterials. A text on alternative methods was prepared included in the Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme6. Recent work from the 2nd Expert Consultation Meeting and compilation of case studies, including information gathering around in vitro dispersion protocols and particle size distribution characterization, is feeding directly into the Sponsorship Programme and simultaneously informing the ongoing efforts on development of Test Guidelines for Manufacture Nanomaterials.

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6 Guidance Manual for the Testing of Manufactured Nanomaterials: OECD’s Sponsorship Programme
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 manufactured nanomaterials sponsored are being developed.

The Project recently developed a Compilation and Comparison of Guidelines related to Exposure to Nanomaterials in Laboratories.

Co-operation on the Environmentally Sustainable Use of Manufactured Nanomaterials

This is the newest project established by the WPMN based on the 2009 OECD Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth. The aim is to enhance the knowledge base about life cycle aspects of manufactured nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development (from research to end-of-life). Through this project, the WPMN seeks to complement other ongoing WPMN work by considering potential positive contributions and unwished negative impacts on environment and health beyond just toxicological endpoints such as greenhouse gas effects, acidification, smog, ozone layer depletion, eutrophication, eco- and human-health toxicity, habitat destruction, desertification, land use as well as depletion of rare minerals and fossil fuels.

This Project is currently finalizing a report on National Activities Related to Life Cycle Assessment and Nanotechnology and planning a workshop on the Lifecycle Assessments of Nanomaterials for September 2011.

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.

Forthcoming events:

- Workshop on the Environmentally Sustainable Use of Manufactured Nanomaterials planned September, 2011.
- The Second International Symposium on the Risk Assessment of Manufactured nanomaterials, 29-30 September 2011, Tokyo, Japan
- Expert Meeting on Inhalation Toxicity, planned for September or October 2011
- Review Meeting of the Sponsorship Programme, 5-6 December 2011, OECD Conference Centre, Paris
- 9th Working Party on Nanotechnology, 7-9 December 2011, OECD Conference Centre, Paris

Recent Publications on Manufactured Nanomaterials:

- Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories (December 2010)
- List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision (December 2010)
- Current Developments/ Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (September 2010)

Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (May 2010)

Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (April 2010)


Upcoming Publications:

- Current Developments/ Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 8th Meeting of the Working Party on Manufactured Nanomaterials
- Risk Assessment of Manufactured Nanomaterials: Critical Issues
- Analysis of Information Gathering Schemes
- Regulated Nanomaterials: 2006-2009

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OTHER EHS PROGRAMMES

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

In October 2010 the 20th WGCA Meeting approved a draft addendum to the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response. It is based on 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. In early April 2011, the draft addendum was submitted to the Joint Meeting for declassification with the request that it be published as an EHS publication, in the series on Chemical Accidents, No. 22.

Safety Performance Indicators (SPI)

The second edition of the OECD Guidance on Developing Safety Performance Indicators was published in September 2008. The October 2010 WGCA Meeting took note of the report analysing the responses received to a questionnaire for a survey – conducted in 2010 – on how industry, public authorities and communities in member countries use and implement safety performance indicators and the OECD Guidance on SPI.

Natural hazard induced chemical accidents (Natech)

The Germany led steering group on natural hazard induced chemical accidents (SG-Natech) continues its activities – initiated in 2009 – on the development of best practices for the control of the impact of natural hazards on chemical installations. A second interim report was presented at the 20th WGCA Meeting in October 2010. The steering group is currently preparing a workshop on Natech planned to take place in the first half of 2012, hosted by Germany.

Corporate governance: the role of leadership in preventing chemical accidents

A steering group on corporate leadership (SG-CL) was established late in 2010; it is composed of representatives of the Czech Republic, Germany, Korea, the Netherlands, Sweden, the United Kingdom, the United States, the EC Joint Research Centre, the Chemistry Industry Association of Canada, and the European Process Safety Centre. Germany chairs the SG-CL and the UK is the project lead. The group is developing background documents intended to support the preparation of an OECD 'high level' event on the role of corporate leadership in chemical accident prevention, preparedness and response, planned to take place in 2012.

Risk and regulation of carbon capture and storage

The UK led steering group on the risk and regulation of carbon capture and storage (SG-CCS) was established in 2009. The October 2010 WGCA Meeting took note of the responses received to a questionnaire for a survey – conducted in 2010 – on carbon capture and long term storage. It was noted that not enough responses have been received, probably due to the fact that the CCS topic is not a big concern in member countries. However it was agreed that responses from the (major) countries concerned with the
CCS problem should be awaited before developing/finalising the survey report. A draft report will be submitted to the WGCA by mid-2011.

**Forthcoming Events:**

- 21st Meeting of the Working Group on Chemical Accidents, 5-7 October 2011, OECD, Paris

**Forthcoming publications:**

- Addendum to OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response*, EHS publication, series on Chemical Accidents, No. 22 (May 2011)

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**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 report on the implementation of the Council Recommendation on PRTRs [C(96)41/Final, as amended by C(2003)87] was submitted to the OECD Council in June 2010. The Council noted that the Recommendation is fully implemented in OECD member countries and agreed that there is no need for further report in future.

The detailed work plan on PRTRs for 2011-2012 was discussed and agreed upon by the Joint Meeting in November 2010. The work plan includes several activities with the aim of advancing and improving the use of PRTR data, such as: i) review or update of published Resource Compendium for PRTR Release Estimation Techniques for point source, diffuse source, and releases from products; ii) development of guidance or recommendation on the elements of PRTR scheme; and iii) maintenance and updates of web-based portal and databases.

*The Resource Compendium of PRTR Release Estimation Techniques, Part 4: Summary of Techniques for Products, Version 1.0* was published in April 2011. This document will be updated in next two years based on the latest information on available release estimation techniques and under the collaboration with the Task Force on Exposure Assessment and other relevant groups as recommended by the Joint Meeting. The Task Force on PRTRs will hold a joint session with the Task Force on Exposure Assessment on releases from products in October 2011 (See also the section on “Exposure Assessment”).

**Forthcoming events:**

- 14th Meeting of the OECD Task Force on PRTRs in 3-5 October 2011, Paris.
- A joint session between the Task Force on Exposure Assessment and the Task Force on PRTRs, 5 October 2011, Paris
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 nine Test Guidelines and four Guidance Documents. With the goal of harmonizing the calculation of MRLs across the OECD, a statistical calculation instrument – “MRL calculator” – of expected maximum residues from crop field trials was published last March. A Guidance Document for Crop Field Trials (to complement TG 509 published in September 2009) which deals with proportionality, zoning (i.e. equivalency of geographic or climatic regions in OECD countries) and crop grouping/ representative commodities/ extrapolation is nearing completion.

Biological Pesticides

The BioPesticides Steering Group (B PSG) organized its third Seminar on the “Characterisation and Analyses of Botanicals for the use in Plant Protection Products” on 30 March 2011, at OECD, Paris. This topic was selected considering its significance for the registration of biopesticides to take the first steps to resolve sciences issues associated with registering botanicals. The term “botanical” is used to describe active substances made from plants. This is however an extremely heterogeneous group of substances. On the longer term the aim is to develop a comprehensive Guidance Document on botanicals covering issues like extraction methods; identification and analytical methods; methods of manufacture; groupings or lead substances; low risk/concern; efficacy.

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 (comparison of existing guidance documents for dissipation/degradation and harmonisation of studies, etc.), and two, the development of a crosswalk for North American and European ecoregions, i.e. guidance on where to conduct such studies to maximise their utility (which will include a computerised map and a guidance document). In order to advance the project and to get expert input on technical and regulatory issues related to these two topics, Canada hosted an OECD expert workshop on 9-11 March 2011 in Ottawa.
Pollinators: Survey on testing, research, mitigation and information management

This project, led jointly by Canada, France and the US 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. The report on the survey results was published in May 2010. Based on the results of the survey, a work programme has been established. This project has four components that relate to understanding and potentially mitigating the potential effects of plant protection products (pesticides) on insect pollinators, i.e., honey bees (Apis mellifera) and non-Apis species. The components include 1) timely and accurate communication of pollinator-related incidents between OECD member states; 2) identifying and improving pesticide exposure and toxicity study methods toward enhancing insect pollinator risk assessment methodologies; 3) identify and enhance current risk mitigation measures based on sound science; 4) identify global research efforts on examining and potentially mitigating the effects of pesticides on insect pollinators.

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. Based on the recommendations from the Seminar, the OECD Pesticide Programme has agreed that a first step in fighting illegal international trade of pesticides should be the establishment of a network of experts and inspectors knowledgeable and active in this fight that could be used for rapid exchange of information on suspicious or rejected shipments.

Risk Reduction

The OECD is organising a Workshop entitled “Strategies for the adoption and implementation of Integrated Pest management (IPM) in agriculture contributing to the sustainable use of pesticides and to pesticide risk reduction” on 17-19 October 2011 in Berlin (Germany). The scope of the workshop will focus on IPM in agriculture; however, consideration of other IPM sectors may be given through case-studies (e.g. IPM in schools) and posters when successful elements and lessons learned could be identified and transferred. It will not be a scientific neither a technical event where detailed IPM research strategies would be presented and discussed. It will focus on practical measures, tools, mechanisms and structures, which help governments and stakeholders support the adoption and implementation of IPM and ultimately help them reduce pesticide risks.

The OECD is launching a new project on stocks of obsolete pesticides in OECD countries. It is envisaged that the outcomes will benefit participating countries in (i) documenting the known levels and estimates of obsolete pesticides in OECD member countries and the arrangements for the management of these products; (ii) documenting the methods being employed to assess the risks arising from obsolete pesticides and the activities being undertaken to mitigate these risks; (iii) bringing together best practice activities for the management of obsolete pesticides and associated wastes and; (iv) identifying areas for international co-operation between OECD member countries and others that will prevent accumulation of obsolete stocks (e.g. joint collections, funding mechanisms).
Registration and work sharing

OECD countries invest significant resources in evaluating agricultural pesticides before they are marketed (or re-evaluating pesticides that have been in use for many years) to ensure that they do not pose unacceptable risks to human health and the environment. Since many pesticides used in OECD countries are the same, governments have recognised the substantial benefits that can be gained if the task of pesticide evaluations for registration and re-registration is shared, rather than duplicating each others’ work. The OECD Pesticides Programme is working to establish the infrastructure that will facilitate such work sharing. In this context “work sharing” means, for example, dividing the work required to review a pesticide data submission among two or more countries, or one country using another’s evaluation to help it with its own national review. While respecting the rights of each country to make its own regulatory decision, work sharing should result in the same or a higher quality of assessment and should not delay decision-making. Greater international harmonisation of pesticide registration approaches could also reduce the need for duplicative testing by industry, thereby saving resources and preventing unnecessary loss of animal life, and could help ease barriers to trade. In this context, the OECD is developing a Guidance Document on the planning and implementation of joint reviews. The document will include a background on the joint review process together with guidance for applicants and guidance for regulatory authorities.

Forthcoming events:

- Registration Steering Group and meetings: 15 September 2011, Ottawa, Canada
- Risk Reduction Steering Group meeting: 20 October 2011, Berlin, Germany
- OECD Workshop on Integrated Pest Management: 17-19 October 2011, Berlin, Germany

Recent publications:

- Report of the OECD Seminar on Risk Reduction through Prevention, Detection and Control of the Illegal International Trade in Agricultural Pesticides, Series on Pesticides No. 59
- Report of the OECD Seminar on Pesticide Risk Reduction Strategies near/in Residential Areas, Series on Pesticides No. 58
- Results of OECD Survey on Education, Training and Certification of Agricultural Pesticide Users, Trainers and Advisors, and Other Pesticide Communicators, Series on Pesticides No. 54
- Results of OECD Survey on How Pesticide Ingredients other than the Stated Pesticide Active Ingredient(s) are Reviewed and Regulated, Series on Pesticides No. 55

Forthcoming publications:

- Report of the 2010 BPSG Seminar on the fate in the environment of microbial control agents and their effect on non-target organisms
- Report of the IPM workshop
- Guidance notes for the estimation of dermal absorption values
- Guidance document on crop field trials
- Guidance document on the planning and implementation of joint reviews

Contact: Sylvie Poret and Beatrice Grenier

Website:  [http://www.oecd.org/env/pesticides](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

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. A Guidance Document explaining how to conduct these methods for other product forms such as wipes or sprays might be developed.

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).

A Guidance Document on testing the efficacy of baits against cockroaches is being developed as no internationally accepted testing protocol is currently available. Existing efficacy guidelines for public health insecticides do not include bait products against cockroaches or are of a more general nature. The draft Guidance Document is aimed at providing an example of methodologies for the conduct of relevant tests and their evaluation alike.

Physical/chemistry studies

OECD Test Guidelines 114 (Viscosity of liquids) and 109 (Density of liquids and solids) will be updated to promote harmonisation and ensure that results from these studies are acceptable to governments in the various regions of the OECD regulating biocides. With the same purpose, a draft Test Guideline will be developed for pH. Although these methods are intended to be used for biocides, they may have utility beyond biocides.

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, is being revised.

Antifoulants

A document describing the different existing approaches to determine leaching rates of biocidal active substances from antifouling coatings is nearing completion. 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:

- 9th Meeting of the Task Force on Biocides, 1-2 December 2011, Vienna, Austria

Forthcoming publications:

- Possible Approach for Developing Data to Determine Leaching Rates of Biocidal Active Substances from Antifouling Coating Films
- Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field Testing

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

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 and other organisms. 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.

An OECD Workshop on "Regulatory Harmonisation and Decision Making in Environmental Risk Assessment" was held in conjunction with the 11th International Symposium on the Biosafety of Genetically Organisms (ISBGMO) in Buenos Aires, Argentina, on 15 November 2010. The preparation and implementation of the Workshop was ensured by delegates from 8 countries closely involved in the OECD biosafety work and the Secretariat. Key activities were presented to an international audience which provided useful feedbacks and suggestions for future work.
The Global Forum on Biotechnology (GFB) was formally established in December 2010 (replacing, for biotechnology-related activities, the previous Global Forum on the Knowledge-Based Economy). The GFB is co-managed by the ENV/EHS biosafety team, and the STI Biotechnology Unit (Working Party on Biotechnology). The GFB will allow to develop the participation of non-OECD countries in the two ENV/EHS programmes on Environmental Safety (= biosafety) and Food/Feed safety for products derived from modern biotechnology.

Three Consensus Documents prepared by the Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WG-HROB) were declassified in September 2010: 1) Biology of black spruce; 2) Horizontal gene transfer between bacteria; and 3) Molecular characterisation of transgenic plants. The publication of the latter document was an important step and constituted the conclusive output of a project jointly undertaken with the Task Force for the Safety of Novel Foods and Feeds since 2003.

Further documents, which are close to completion, will be considered by the WG-HROB for possible declassification in 2011/2012: Biology of Brassica species; of Biology of Cucurbita species; and Pathogenicity factors regarding potential health effects of micro-organisms (bacteria). The development of other Biology documents is contemplated by the WG-HROB, including on Sugarcane, Eucalyptus, and Grain sorghum. Work is also continuing on Tomato and on Fusarium oxysporum. Two key projects: Low Level Presence in Seed and Commodities in the Context of Environmental Safety; and Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants; have prepared their first complete draft documents for discussion at the next WG-HROB meeting in May 2011.

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. The document on GM Herbicide-tolerant resistant plants (Module III - agronomic and environmental aspects) and the Summary of the WG-HROB activities on tree species will be revised in the coming months.

The OECD Product Database (publicly available on Biotrack), which includes information on transgenic plants (unique identifiers, common and scientific names of host organisms, events and introduced genes etc.) is under reassessment by both the WG-HROB and the Food Safety Task Force in order to check the elements it contains and decide on further developments. The review includes aspects of interoperability with other databases, the CBD-Biosafety Clearing House and the FAO International Portal on Food Safety, Animal and Plant Health, for strengthening the existing collaboration and the mutual benefits.

The issue No. 21 of the "Biotechnology Update" (Newsletter of the OECD Internal Co-ordination Group for Biotechnology prepared by the EHS biosafety team), was finalised in January 2011. This newsletter, primarily used for internal update and information exchange, is also received by 35,000 people outside of the Organisation having registered through the public website.

**Forthcoming events:**

- 26th meeting of the Working Group, March 2012 (date to be confirmed)

**Recent Publications:**

- Consensus Doc. on Molecular Characterisation of Plants Derived from Modern Biotechnology
- Consensus Document on the Biology of *Picea mariana* (Mill.) spp. (Black Spruce)
- Guidance Document on Horizontal Gene Transfer Between Bacteria

**Forthcoming Publications:**

- Consensus Document on the Biology of the Brassica Crops (*Brassica* spp.)
- Consensus Doc. on the Biology of *Cucurbita* spp. (Squashes, Pumpkins, Zucchinis or Gourds)
SAFETY OF NOVEL FOODS AND FEEDS

The programme on the Safety of Novel Foods and Feeds addresses risk/safety assessment issues 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 of the Task Force for the Safety of Novel Food and Feeds. 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 20 Consensus Documents have been published by the Task Force, and the latest one on Molecular Characterisation of Plants Derived from Modern Biotechnology was issued in September 2010. This project was jointly undertaken with the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology (see description in the corresponding section).

The revision of the two earliest consensus documents on Low Erucic Acid Rapeseed (Canola) and Soybean, published by the Task Force in 2001, are close to completion and should be submitted for declassification in the coming months. The work is continuing on Sugarcane which might be proposed for declassification in 2011. Projects are contemplated on Common Bean (Phaseolus vulgaris) and Oyster mushroom (Pleurotus ostreatus) for development in 2011/2012.

Other subjects will be studied at the next meeting of the Task Force in May 2011 for possible future development of activities on the use of allergenicity data in comparative analysis, and on animal products.

Outreach and engagement with non member economies

Strengthening the involvement of non-member economies in the OECD Food Safety activities through the Global Forum on Biotechnology: see section "Harmonisation of Regulatory Oversight in Biotechnology" of the present EHS Newsletter.

Other activities on the risk/safety assessment of modern biotechnology

A document, “Instructions for Authors”, is used by the Task Force experts when preparing Consensus Documents on compositional considerations. This document is being updated, to take into account some aspects of the quality of the data that constitute the core of the Consensus Documents. Delegates might endorse a revised version of the "Instructions for Authors" at the 18th meeting of the Task Force in May 2011.
**Future events:**

- 19th Meeting of the Task Force, March 2012 *(date to be confirmed)*

**Recent Publication:**

📖 Consensus Doc. on Molecular Characterisation of Plants Derived from Modern Biotechnology

**Forthcoming Publications:**

📖 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
📖 Consensus Document on Compositional Considerations for New Varieties of Sugarcane (*Saccharum* spp. hybrids): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

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

**Contacts:** Bertrand Dagallier, Peter Kearns, Kazuyuki Suwabe

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**WORK WITH NON-MEMBERS**

**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 (including chemicals) of the relevant policies in these countries, Chile became a member of the Organisation on 7 May 2010, Slovenia became a member on 21 July 2010, Israel became a member on 7 September 2010, and Estonia became a member on December 9 2010. 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 full adherents. Discussions are underway with China and Indonesia regarding their participation in the MAD system.

**Contact:** Richard Sigman

**Website:** [http://www.oecd.org/document/42/0,3343,en_2649_34487_38598698_1_1_1_1,00.html](http://www.oecd.org/document/42/0,3343,en_2649_34487_38598698_1_1_1_1,00.html)
CROSS-CUTTING ISSUES

Environmental Outlook

Work continues on the development of a new OECD Environmental Outlook to 2050, which will focus on four areas identified as priorities by the 2008 Environmental Ministerial: climate change, biodiversity loss, water scarcity, and environment and health. The final publication will be completed in time for the next Environment Ministers meeting in 2012. The Environment and Health chapter will focus on current and projected health impacts associated with outdoor air pollution, unsafe water supply and sanitation, climate change and hazardous chemicals. The chemicals portion of this chapter will describe past, current and long-term trends in production, the assessment of chemicals, and policy implications of and the international framework for chemical safety.

Contact: Richard Sigman and Nathalie Delrue

Templates for Reporting Chemical Test Summaries

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, new and existing industrial chemicals). These OECD Harmonised Templates (OHTs) provide standard data format for reporting the studies done on chemicals to determine their properties or effects on human health and the environment. The OHTs 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 the OHTs, governments and industry will easily be able to electronically exchange test study summary information.

At present, 99 OHTs have been developed for reporting chemical test results for toxicology, ecotoxicology and physical/chemical properties. 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 OHTs, which can generate data files that can be imported into other database systems.

The templates, XML schema and schematron are available on OECD’s public website. The webpage was improved in October 2010 to be more user-friendly. The new webpage provides OHT users with a better approach for identifying and accessing the relevant documentation when reporting summaries of chemical studies. The OHTs are now classified along seven categories (Physico-chemical properties, Degradation and accumulation, Effects on biotic systems, Health effects, Analytical methods, Pesticide residue chemistry, and Efficacy) with all related documents displayed; latest version number and date is visible for each template, and updates made are easily traceable.

Templates are regularly updated or new ones developed, to include new or updated OECD Test Guidelines recently adopted by the OECD Council. For avoiding dispersed work and limiting the frequency of adaptation needed for OHT users, the updates and additions will be made on the website once a year approximatively. Recent updates were made in March 2011 to 37 OHTs in coordination with the upgrading of IUCLID 5.3 (the IUCLID system is currently one of the main users of the OHTs).

Contact: Bob Diderich and Bertrand Dagallier

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

Green Growth

The first draft of the Green Growth Synthesis Report was presented at the Green Growth Strategy Workshop held from 10-11 February 2011 at OECD headquarters. The workshop, which included
policymakers and experts from across OECD and partner countries, was organised to review the draft Report and ensure that it will be a useful tool to support countries' transition to greener economies.

The Green Growth Strategy will lay out the tools needed to shift to a more sustainable growth path, while identifying the benefits and economic opportunities that come from heading in that direction. A first step of this work will be the Synthesis Report which will be submitted to Ministers at the OECD Ministerial Council Meeting in May 2011. The Environment, Health and Safety Division is providing input to Green Growth initiative.

**Contact:** Richard Sigman

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**OECD Environmental Risk Assessment Toolkit**

The first version of the OECD Environmental Risk Assessment Toolkit was published in June 2010. 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.

The Joint Meeting agreed to undertake follow-up projects in 2011 with the aim to improve the usefulness of the Toolkit by including “non-OECD” tools developed by member countries and other international organisations as well as by developing a few case studies and road maps to illustrate how this Toolkit can be used in specific cases and objectives of environmental risk assessment.

**Contact:** Michihiro Oi

**Website:** [http://www.oecd.org/env/riskassessment/toolkit](http://www.oecd.org/env/riskassessment/toolkit)
WEB SITES

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<table>
<thead>
<tr>
<th>Topic</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHS Homepage</td>
<td><a href="http://www.oecd.org/ehs/">http://www.oecd.org/ehs/</a></td>
</tr>
<tr>
<td>Biocides</td>
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</tr>
<tr>
<td>Biosafety</td>
<td><a href="http://www.oecd.org/biotrack">http://www.oecd.org/biotrack</a></td>
</tr>
<tr>
<td>Chemical Accidents</td>
<td><a href="http://www.oecd.org/env/accidents">http://www.oecd.org/env/accidents</a></td>
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<td>Existing Chemicals</td>
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<tr>
<td>Good Laboratory Practice</td>
<td><a href="http://www.oecd.org/env/glp">http://www.oecd.org/env/glp</a></td>
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<tr>
<td>Harmonised Templates</td>
<td><a href="http://www.oecd.org/ehs/templates">http://www.oecd.org/ehs/templates</a></td>
</tr>
<tr>
<td>Harmonisation and Classification of Labelling</td>
<td><a href="http://www.oecd.org/env/classify">http://www.oecd.org/env/classify</a></td>
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<td>Mutual Acceptance of Data (MAD)</td>
<td><a href="http://www.oecd.org/ehs/mad">http://www.oecd.org/ehs/mad</a></td>
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<tr>
<td>Pollutant Release and Transfer Registers</td>
<td><a href="http://www.oecd.org/env/prtr">http://www.oecd.org/env/prtr</a></td>
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<tr>
<td>Test Guidelines</td>
<td><a href="http://www.oecd.org/env/testguidelines">http://www.oecd.org/env/testguidelines</a></td>
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</table>

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→ Email: [ehscont@oecd.org](mailto:ehscont@oecd.org)
→ Fax: +33 (0)1 44 30 61 80
STAFF IN THE EHS DIVISION

Since the last Environment, Health and Safety News (No. 25, issued in July 2010), the EHS Division has seen the following changes in staffing:

**Test Guidelines:** Shirlee Tan is working with us on secondment from the US EPA. Camilla Francis is providing administrative support to this programme.

**GLP/MAD and Test Guidelines:** Wakako Horiki has replaced Hitoshi Someya for these programmes.

**PRTR:** Michi Oi is responsible for this work, taking over from Peter Borkey.

**Hazard Assessment, (Q)SARS, Exposure Assessment and PRTR:** Sarah Jukes is providing administrative support to these programmes and Valérie Frison Beau has joined the team as a part-time Electronic Information Manager.

**Outreach:** Alastair Wood is supporting Richard Sigman in working with non-member countries.

**Harmonised Templates:** Bertrand Dagallier has now undertaken this programme

**Nanosafety and Biotechnology:** Kristan Markey is temporarily replacing Mar Gonzalez in the Nano team. Kazuyuki Suwabe has joined to help the work on Biotechnology after the departure of Yukihiki Fukase. Yidan Shen-Gress has returned to replace Charis Feeney-Orchard in providing administrative support for these areas.

Patric Amcoff left the secretariat at the end of April after working with us for eight years.
<table>
<thead>
<tr>
<th>NAME</th>
<th>PROGRAMME</th>
<th>PHONE</th>
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</tr>
</thead>
<tbody>
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