



## Environment, Health & Safety News

No. 27, December 2011

### *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.*

### **40<sup>TH</sup> ANNIVERSARY OF CHEMICAL SAFETY AT OECD:**

This year, 2011, is the **40th Anniversary of the OECD Chemicals Programme**. To mark the occasion, a special event was held on 15<sup>th</sup> June at OECD Headquarters, in conjunction with the 47<sup>th</sup> Joint Meeting. The theme of this event was *Planning for the Next Decade: Promoting Global Convergence of Chemicals Management Policies: Avoiding Divergence in a World of Growing Scientific Complexity*. In other words, it was forward looking and reflected on possible challenges for the coming decade based on the strengths and achievements of the Programme.

The event benefited from the participation of former delegates to the Joint Meeting and former members of the secretariat as well as current delegates and members. To support the discussions a document was prepared entitled **OECD Environment, Health and Safety Programme: Achievements, Strengths and Opportunities**. This document is a comprehensive description of the background to the Chemicals Programme and the wider Environment, Health and Safety Programme as it is today. It was subsequently declassified and is available on OECD's web site.

In considering the future, two challenges were considered in detail: i) *New Approaches to Testing and Assessment - Ensuring Safety and Efficiency*; and ii) *Challenges to the Substitution of Harmful Chemicals*. The aim of considering these two challenges was to identify whether or not they would be appropriate issues for the Joint Meeting to address in the future, especially within the context of the programme of work beyond 2012.

The issue of *New Approaches to Testing and Assessment* arises because scientific advances are accelerating the development of new testing and information gathering methods such as *in vitro* testing, toxicogenomics and (Q)SARs. There is the related issue of developing strategies for combining and using this type of information in assessment procedures. The meeting noted that it should be possible to develop science-based and transparent integrated approaches for testing and assessment that have global regulatory acceptance. Subsequently, the 47<sup>th</sup> Joint Meeting recommended taking stock and reviewing, in cooperation with other intergovernmental organisations, existing activities on integrated approaches for testing and assessment. The ultimate aim could be the elaboration of an agreed framework for developing and using such approaches to promote efficiency and reduce the potential for barriers to trade.

The issue of *Challenges to the Substitution of Harmful Chemicals* arose despite the fact that methods are well advanced for determining the direct risks to human health and the environment from exposure to chemical substances. However, it is known that the production and use of chemicals can also pose other less direct risks to humans and the environment throughout their life cycle, for example, through the depletion of natural resources, high energy consumption and the release of greenhouse gases. These indirect impacts are less well characterized. As governments are implementing new policies aimed at substituting existing substances with “greener” alternatives, new and more holistic methodologies will be needed to ensure that the substituted products and processes leave a smaller environmental footprint throughout their lifecycle. The 47<sup>th</sup> Joint Meeting subsequently concluded that this is an issue which could be addressed with an initial focus on exploring the different approaches to decision-making that could be taken in the substitution of harmful chemicals. This will be a necessary step in identifying whether there are sufficient methodologies in common to be able to move forward with work at the international level.

Despite the discussion on these future challenges, it was clear that there remains strong support for the existing core activities of the Joint Meeting in respect of the testing and assessment of chemicals. At several times during the event there was mention of the MAD Council Decisions and the savings that accrue to member countries and industry through the programme. A number of interventions stressed the need to continue to pay strong attention to the core activities.

## 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 31 August, Argentina fulfilled all the conditions to adhere to the OECD system for MAD in the assessment of chemicals. They join Brazil, India, 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. At the moment, full adherence for Argentina and Brazil only applies to industrial chemicals, pesticides and biocides. Provisional adherents to the Mutual Acceptance of Data system are currently 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 health and environmental hazards.*

#### **New or Corrected Test Guidelines**

The following new or corrected Test Guidelines, approved by the Working Group of National Coordinators of the Test Guidelines Programme (WNT), have been adopted on 28 July 2011 and are available on the public website.

#### **New Test Guidelines:**

##### **Section 2: Effects on Biotic Systems**

**234 [Fish Sexual Development Test](#)**

**235 [Chironomus sp., Acute Immobilisation Test](#)**

## Section 4: Health Effects

- 443 [Extended One-Generation Reproductive Toxicity Study](#)
- 456 [H295R Steroidogenesis Assay](#)
- 488 [Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays](#)

### Corrected Test Guideline:

#### Section 2: Effects on Biotic Systems

- 201 [Freshwater Alga and Cyanobacteria, Growth Inhibition Test](#)

### Other current activities under the Test Guidelines Programme

Several Test Guideline-related documents that had been approved at the April 2011 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 is outlined below.

#### *Eye irritation/corrosion*

An expert meeting (held on 29-30 September 2011 at ECVAM, Joint Research Centre, Italy), agreed on the added value, strength, weaknesses and applicability domain of existing and draft Test Guidelines for *in vitro* methods on eye irritation/corrosion and agreed on a draft updated TG 405 (Acute Eye Irritation/Corrosion), and on new draft Test Guidelines for the *in vitro* Fluorescein Leakage and the Cytosensor Microphysiometer Test Methods.

#### *Skin irritation/corrosion*

An expert group will meet in January 2012 to discuss the draft updated TG 430 (*In vitro* skin corrosion: transcutaneous Electrical Resistance Test (TER) and draft updated TG 431 (*In vitro* skin corrosion: Human Skin Model Test), to discuss an integrated Testing Strategy, to review available information on the *in vitro* LabCyte EPI-Model24 with a view to its addition to TG 439 (*In vitro* skin irritation: Reconstructed Human Epidermis Test Method) as a “me too” test, and to discuss the applicability of *in vitro* test methods to mixtures and the possible update of TG 404 (Acute Dermal Irritation/Corrosion).

#### *Genotoxicity*

The deletion of several Test Guidelines is expected to be submitted for adoption to the OECD Council in 2012. An expert group meeting on genotoxicity will meet on 31 January-2 February 2012 to discuss the update of several existing Test Guidelines for *in vitro* and *in vivo* test methods. The main issue currently being discussed is related to the top dose.

#### *Reproductive Toxicity*

An expert meeting will be held on 25-26 January 2012 in the United States to discuss a draft Guidance Document supporting TG 443 (Extended One Generation Reproductive Toxicity Study).

#### *Bioaccumulation in Fish: Aqueous and Dietary Exposure*

An expert group met on 7-8 November 2011 in Dessau (Germany) to discuss several issues related to the dietary study ring test and draft updated Test Guideline 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure) and agree on the draft ring test report and draft Test Guideline.

## ***Fish Toxicity Testing Framework***

An expert meeting was held on 1-2 September 2011 in Paris to discuss remaining issues related to the document *Fish Toxicity Testing Framework*, in particular a generic fish testing strategy. This document is expected to be finalised and published in 2012.

### ***Endocrine disrupters***

The validation management group for ecotoxicity testing met on 9-10 November 2011 to discuss a draft Test Guideline for a Medaka Multi-generation Test, possible amendments to TG 229 (Fish Short Term Reproduction Assay), progress on the development of an extended TG 229, a draft updated TG 211 (Daphnia magna Reproduction Test), a draft updated TG 210 (Fish, Early-Life Stage Toxicity Test), a Larval Amphibian Growth and Development Assay, a protocol for the validation of the Xenopus Embryonic Thyroid Signalling Assay, and progress with pre-validation of a Mollusc Partial Life Cycle Test.

A validation management group for non-animal testing will meet on 30 November-2 December 2011, in Budapest, Hungary. It is expected to discuss the validation progress of several *in vitro* test methods, discuss and agree on a draft new Test Guideline for a Stably Transfected Transcriptional Activation (STTA) Assay for the Detection of Estrogen Receptor Agonists and Antagonists and on a draft Performance-Based Test Guideline (PBTG) for STTA assays for the Detection of Estrogen Receptor Agonists. The validation management group will also discuss issues related to metabolic capacities of *in vitro* assays for the detection of endocrine disrupters, *in vitro* thyroid assays, species specific differences, and high throughput *in vitro* screening.

An advisory group on endocrine disrupters testing and assessment will meet on 12-13 December 2011 in Paris to discuss and agree on the following draft documents:

- A draft Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption: the draft document is being finalised and it is expected to be published in 2012. The objectives of this Guidance Document is to support regulatory authorities' decisions on the hazard of specific chemicals when they receive test results from a Test Guideline or other standardised assay and to provide guidance on how to increase evidence on whether or not a substance may be an endocrine disrupter.

- Three draft case studies: the draft case studies have been developed to evaluate whether the conclusions and next steps recommended in the draft Guidance Document are sensible and helpful when assessed in the light of comprehensive datasets.

- A draft Detailed Review Paper (DRP) on the State of Science on Novel *In Vitro* and *In Vivo* Screening and Testing Methods and Endpoints for Evaluating Endocrine Disrupters: the draft DRP is under development and expected to be published in 2012.

### ***Molecular Screening and Toxicogenomics***

The Extended Advisory Group on Molecular Screening and Toxicogenomics will meet in June 2012 in Paris. It will continue exploring new scientific approaches for assessing chemicals in the future, and sharing information on scientific progress in the area of High Throughput Screening, in particular the US ToxCast Program, and toxicogenomics. It is expected that the development of Adverse Outcome Pathways will be discussed.

### ***Recent and Forthcoming events:***

- Expert meeting on the update of TG 305 (Bioconcentration/ Flow-Through Fish Test) and new TG on Fish Dietary Bioaccumulation, 7-8 November 2011, Dessau, Germany
- Meeting of the validation management group for ecotoxicity testing: 9-10 November 2011, Paris
- Meeting of the validation management group for non animal testing: 30 November-2 December 2011, Budapest, Hungary
- 3<sup>rd</sup> Meeting of an Advisory Group on Endocrine Disrupter Testing and Assessment, 12-13 December 2011, Paris

- Expert meeting on cell transformation assays, 14-15 December 2011, Paris
- Expert meeting on skin irritation/corrosion, 18-19 January 2012, Helsinki
- Expert meeting on reproductive toxicity, 25-26 January 2012, Arlington, United States
- Expert group meeting on genotoxicity, 31 January-2 February 2012, Paris
- Expert group meeting on the Fish Embryo Toxicity Test, 16-17 February 2012, Berlin, Germany
- 24<sup>th</sup> Meeting of the Working Group of National Coordinators of the Test Guidelines Programme, 24-27 April 2012, Paris

***Recent publications in the Series on Testing and Assessment:***

-  [Detailed Review Paper on Environmental Endocrine Disruptor Screening: The use of Estrogen and Androgen Receptor Binding and Transactivation Assays in Fish](#) No. 135
-  [Validation Report of the Chironomid Full Life-Cycle Toxicity Test](#) No. 136
-  [Report of the Phase 1 of the Validation of the Fish Sexual Development Test for the Detection of Endocrine Active Substances](#) No. 141
-  [Report of the Phase 2 of the Validation of the Fish Sexual Development Test for the Detection of Endocrine Active Substances](#) No. 142
-  [Peer Review Report for the Validation of the Fish Sexual Development Test and Agreement of the Working Group of National Co-ordinators of the Test Guideline Programme on the Follow-up of the Peer Review](#) No. 143
-  [Validation Report for the Acute Chironomid Assay](#) No. 144
-  [Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay: Retrospective Performance Assessment](#) No. 145
-  [Guidance Document on the Androgenised Female Stickleback Screen](#) No. 148
-  [Guidance Document for the Derivation of an Acute Reference Concentration \(Arfc\)](#) No. 153
-  [Guidance Notes on Dermal Absorption](#) No. 156
-  [Validation Report Phase 1 for the Zebrafish Embryo Toxicity Test, Part 2](#) No. 157
-  [Report of Progress on the Interlaboratory Validation of the OECD Harpacticoid Copepod Development and Reproduction Test](#) No. 158
-  [Validation Report for the Skin Irritation Test Method using Labcyte Epi-Model24](#) No. 159
-  [Guidance Document on the Bovine Corneal Opacity and Permeability \(Bcop\) and Isolated Chicken Eye \(Ice\) Test Methods: Collection of Tissues For Histological Evaluation and Collection of Data on Non-Severe Irritants](#) No. 160
-  [Peer Review Report for the Validation of the Stably Transfected Transcriptional Activation Assay for the Detection Androgenic and Anti-Androgenic Activity of Chemicals](#) No. 161

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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.*

A workshop on polymers was held from 26-28 October, 2011 at the US EPA. The *Approved List of Monomers/Reactants for Polyesters* that was created, and amended once, by the USEPA for use in the administration of TSCA, has been adopted as well by the jurisdictions of Canada and Australia. The current list was last updated in the mid-1990's. The purpose of the workshop was to discuss: the scientific rationale of this list, the process for qualifying 46 candidate substances for addition to the current list, the concept of an equivalence principle to facilitate additions of substances similar to those already listed, whether inorganic polymers meet the OECD polymer definition, and a test protocol to distinguish between chemicals and polymers. Workshop participants included government and/or industry representatives from Australia, Canada, Japan, Republic of Korea, and the United States, as well as a representative from the European Chemicals Agency, ECHA.

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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 is an internet portal that 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 fourth time on 30-31 May 2011. The main tasks of the Task Force are to oversee the Cooperative Chemicals Assessment Programme (former HPV Chemicals Programme), 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 fourth meeting the Task Force:

- agreed that Adverse Outcome Pathways should be included in the QSAR Toolbox in the long-term, and recommended to develop a collaborative platform to gather scientific input, and to link with other OECD groups such as the Advisory Group on Molecular Screening and Toxicogenomics, and other organizations such as WHO;
- held a brainstorming session on categorization activities in member countries with a view to develop a common inventory of chemical structures and a common understanding of chemicals that can be assessed together in a category;

- established a correspondence group to develop further guidance for the characterisation of the identity of substances of unknown or variable composition or of biological origin (UVCBs);
- endorsed a report on the public availability of national/regional GHS classifications;
- agreed a long-term development plan for eChemPortal.

A workshop on metals specificities in environmental risk assessment took place on 7-8 September 2011 at the OECD Conference Centre in Paris. The [workshop material](#) is available on the public website and the workshop report, including concept papers on metals specificities, case examples and recommendations, will be published towards the end of 2011.

The thirty second SIDS Initial Assessment Meeting (SIAM 32) and the first Cooperative Chemicals Assessment Meeting (CoCAM 1, formerly SIAM) were held in Paris in April and October 2011 respectively. Full SIDS assessment and targeted assessments for 50 chemicals were agreed (25 chemicals at SIAM 32 and 25 chemicals at CoCAM 1). The agreed conclusions were endorsed by the Joint Meeting and published (SIAM 32) or will be endorsed later in 2011 (CoCAM 1). A joint session between SIAM 32 and the Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA) was held in April 2011 to review the applicability of the draft guidance document on EDTA and the illustrative case studies. At SIAM 32, participants were invited to a hands-on training session with the QSAR Toolbox. In September 2011, a survey questionnaire was circulated to the different OECD groups dealing with hazard assessment of chemicals to launch the revision of the guidance document on grouping chemicals.

Since UNEP suspended publication of SIDS documents, 422 initial assessments are publicly available on the OECD website [<http://www.oecd.org/env/hazard/data>]. Assessments for 398 chemicals are publicly available on the UNEP website [<http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html>]. Assessments for 110 chemicals have been agreed upon at OECD level and have been published by the European Commission [<http://esis.jrc.ec.europa.eu/index.php?PGM=ora>]. Furthermore, the Secretariat has published 268 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: <http://www.oecd.org/env/hazard/data>

Since the last newsletter the Japan CHEMicals Collaborative Knowledge database (J-CHECK) and the Canadian Categorization Results (CCR) database were added as participants in the search by chemical property functionality of eChemPortal, the Global Portal to Information on Chemical Substances [<http://www.oecd.org/ehs/eChemPortal>]. 1600 Korean chemical names and 1000 Chinese names have been added to the eChemPortal index of chemical names allowing a search by chemical name in Chinese and Korean.

A minor upgrade of the IUCLID software [see <http://iuclid.eu>], IUCLID 5.3.1, was published in August 2011 by the European Chemicals Agency, the owner of the IUCLID 5 software, including bug fixes and some new functionalities. Two Webinars of the OECD IUCLID User Group Expert Panel were held in April and in June 2011 to discuss the proposals received from the on-line public consultation (January - March 2011) on identifying needs for future versions of IUCLID and to prioritize those proposals. The Expert Panel met in September 2011 in Paris to discuss the development plans of IUCLID 5 and IUCLID 6.

#### ***Forthcoming events:***

- The Steering Group for the Development of a Global Portal to Information on Chemical Properties, 15-16 February 2012, Paris, France
- Task Force on Hazard Assessment, 13-14 June 2012, Paris, France
- CoCAM-2, 17-19 April 2012, Paris, France

#### ***Recent publications in the Series on Testing and Assessment:***



**[Case study: Assessment of an Extended Chemical Category, the Short-Chain Methacrylates, Targeted on Bioaccumulation](#)**, No. 152

 [WHO OECD ILSI/HESI International Workshop on Risk Assessment of Combined Exposures to Multiple Chemicals](#), No. 140

 [Report of the Workshop on Using Mechanistic Information in Forming Chemical Categories](#), No. 138

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<http://www.oecd.org/ehs/eChemPortal>

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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 2.2) released in July 2011 can be downloaded free of charge from the public OECD web site [<http://www.oecd.org/env/hazard/qsar>].

Furthermore, various materials to help the use of the Toolbox have been developed, which are also available on the public webpage above. A new set of [training material and video tutorials](#) was published in July 2011.

Title and main features	Slides	Video tutorial
Step-by-step example on how to predict the skin sensitisation potential approach of a chemical by read-across based on an analogue approach (for beginners).	<a href="#">PPT</a>	<a href="#">Video</a>
Step-by-step example of how to predict aquatic toxicity for an untested target chemical by the trend analysis approach (for beginners).	<a href="#">PPT</a>	
Step-by-step example of how to predict Ames mutagenicity for a chemical by a qualitative read-across approach (for beginners).	<a href="#">PPT</a>	
Step-by-step example of how to predict acute toxicity to <i>Tetrahymena pyriformis</i> by trend analysis using category pruning capabilities.	<a href="#">PPT</a>	<a href="#">Video</a>
Step-by-step example of how to build and evaluate a category based on mechanism of action with protein and DNA binding.	<a href="#">PPT</a>	<a href="#">Video</a>
Step-by-step example of how to build a category for more than one target chemicals and predict acute toxicity to fish.	<a href="#">PPT</a>	
Step-by-step example of how to evaluate an ad-hoc category of aliphatic amines and to predict an ecotoxicological endpoint.	<a href="#">PPT</a> <a href="#">Aliphatic amines.smi</a>	
Step-by-step example of how to build a user-defined profiling scheme.	<a href="#">PPT</a>	<a href="#">Video</a>
Step-by-step example of how to categorize an inventory by mechanistic behaviour of the chemicals which it consists.	<a href="#">PPT</a> <a href="#">OECD Mock Inventory.smi</a>	
Step-by-step example of how to build a user-defined QSAR.	<a href="#">PPT</a>	<a href="#">Video</a>

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 QSAR Toolbox Management Group met in October 2011 to review the progress made with the preparations of version 3. The focus of the development of version 3 compared with version 2 will be on:

- The ability to take into account the tautomerisation of chemicals.
- Enhanced capabilities to predict the formation of metabolites in different media.
- Enhanced capabilities of grouping chemicals according to modes or mechanisms of action.

The [public discussion forum](#) continues to be a popular site where 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.

***Recent publications in the Series on Testing and Assessment:***

 [Report of the Workshop on Using Mechanistic Information in Forming Chemical Categories](#),  
No. 138

***Forthcoming events:***

- 7<sup>th</sup> Meeting of the QSAR Toolbox Management Group, April 2012

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[https://community.oecd.org/community/toolbox\\_forum](https://community.oecd.org/community/toolbox_forum)

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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 the exposure of chemicals to human health and the environment.*

The Task Force on Exposure Assessment held its third meeting on 5-6 October 2011. The Task Force discussed progress of on-going projects on environmental exposure assessment and also several new activities regarding exposure assessment for humans. A joint session on releases of chemicals from products with the Task Force on PRTRs was held on 5<sup>th</sup> October 2011. These two Task Forces agreed to collaborate on two projects: further information exchange on the current activities on releases from products, and information exchange on the status of the current approaches, practices, methods and modelling tools used to assess exposure where wastes are disposed of in a sewage treatment plant.

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. Four new ESDs and one revised ESDs were published between May and November 2011. A number of projects to develop new ESDs, to revise existing ESDs and to assist the development and use of ESDs are on-going such as formulation and application of thermal and carbonless copy paper, chemical vapour deposition in the semiconductor industry, use of adhesives, textile dyeing, industrial use of industrial cleaners, case study on plastic additives, waste disposal of metals, and application of industrial coatings. The Task Force finalized one new ESD on use of chemicals in the oil well production industry. The Task Force also finalized a new guidance document for the exposure assessment of environmental media based on monitoring data. Both are expected to be published in early 2012.

***Forthcoming event:***

- 4<sup>th</sup> Meeting of the Task Force on Exposure Assessment, early Autumn (TDB) 2012, Budapest

***Recent publications:***

-  [New ESD on the Use of Metalworking Fluids](#), Series on Emission Scenario Documents No. 28
-  [New ESD on Chemicals used in Water-based Washing Operations in Industrial and Institutional Laundries](#), Series on Emission Scenario Documents No. 29
-  [New ESD on the Application of Radiation Curable Coatings, Inks and Adhesives](#), Series on Emission Scenario Documents No. 27
-  [New ESD on the Chemical Industry](#), Series on Emission Scenario Documents No. 30
-  [Revised ESD on Coating Application via Spray-painting in the Automotive Refinishing Industry](#) Series on Emission Scenario Documents No. 11

***Forthcoming publications:***

-  New Guidance document for the exposure assessment of environmental media based on monitoring data
-  New ESD on the Use of Chemicals in the Oil Well Production 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 Perfluorooctanoic Acid (PFOA) and PFOA-related chemicals and other Perfluoroalkyl sulfonate (PFAS) and PFAS-related chemicals, in addition to Perfluorooctane sulfonate (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

(Perfluorocarboxylic acid) and their related substances and products/mixtures containing these substances” has been published and is available [here](#).

The Second International Conference on Chemicals Management (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 ICCM’s Open-Ended Working Group (OEWG) in 2011 and to ICCM 3 in 2012. The progress report that was delivered to the OEWG is now available [here](#).

As one of the first actions a PFC web portal was 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 have been organised in order to disseminate and share information on PFCs (see a list of these on [www.oecd.org/ehs/pfc](http://www.oecd.org/ehs/pfc)).

In order to ensure a more complete geographical coverage of PFC related activities, and to take account of the fact that an increasing share of PFC production is now occurring outside of the OECD area, UNEP and OECD have set-up a partnership to establish a Global PFC Group with representatives from each of the SAICM regions, non-governmental organizations, and other international organizations, as well as current OECD participants on PFC activities. Terms of reference have been circulated by UNEP Chemicals to SAICM focal points and made available on the [SAICM website](#). Nominations and coordination of the members from each of the SAICM regions are taking place through SAICM regional focal points.

A workshop on perfluorinated chemicals and the transition to safer alternatives was organized by OECD and UNEP and took place in the framework of SAICM’s regional Asia-Pacific meeting in Beijing on 5 September 2011. It provided an opportunity to exchange information on recent PFC related regulatory and other activities as well as to brainstorm about possible activities that could be carried-out by the newly established Global PFC Group (i.e. to support developing countries in their efforts in this area) and to move the PFC agenda forward more broadly. A summary of these discussions is available [here](#).

### ***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 inventions related to Sustainable Chemistry. The final report is available [here](#).

An international Conference on Sustainable Chemistry was jointly organised by the German Federal Environment Agency (UBA), the Organization of Economic Co-operation and Development (OECD), the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) and die United Nations Industrial Development Organization (UNIDO). The event focused on the challenges and opportunities that exist to

move sustainable chemistry forward and suggested a number of ways in which OECD could help to do this. The summary record of the event is available [here](#).

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## SAFETY OF MANUFACTURED NANOMATERIALS

*On the nano-scale, typically within the range of 1-100 nm in at least one dimension, the properties of materials can be different from those on a larger scale. The novel properties of nanomaterials can be applied to diverse application areas, such as in medicine, environment and energy production. Manufactured nanomaterials are already used in a number of commercial applications; which raises questions regarding potential unintended hazards to humans and the environment and whether nanomaterials need special measures to deal with potential risks. There is a need for a responsible and co-ordinated approach to ensure that potential safety issues are being addressed at the same time as the technology is developing. Therefore, OECD's Working Party on Manufactured Nanomaterials (WPMN) was established to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials and its objective is to assist countries in their efforts to assess the safety implications of nanomaterials.*

The WPMN programme has focused in generating appropriate methods and strategies to address potential safety issues, through various projects led by Steering Groups. 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 in April 2009, and now includes data on more than 803 research projects. Currently, the database has been evaluated for: i) data quality; ii) user-usefulness in identifying research priorities; and iii) gap analysis.

Other features are currently under consideration, mainly to provide critical information and support for other projects of the WPMN. For example, work is underway to: i) develop keywords for use in analysis of the database; ii) include other types of information, such as uses and applications of nanomaterials that will assist in exposure and hazard assessment; and iii) include information on risk assessment approaches, risk mitigation and risk communication related to human health and environmental safety. The database can be found at: [www.oecd.org/env/nanosafety/database](http://www.oecd.org/env/nanosafety/database).

### ***Safety Testing of a Representative Set of Manufactured Nanomaterials: The "Sponsorship Programme for Testing Manufactured Nanomaterials"***

This project, through the launching of a "Sponsorship Programme for Testing Manufactured Nanomaterials" (November 2007), builds upon the concept that much valuable information on the safety of manufactured nanomaterials, as well as the methods to assess safety, can be derived by testing certain nanomaterials for human health and environmental safety effects.

The Sponsorship Programme involves OECD member countries, as well as some non-member economies and other stakeholders to pool expertise and to fund the safety testing of specific manufactured nanomaterials. Thirteen manufactured nanomaterials<sup>1</sup> are being tested (based on materials which are in, or

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<sup>1</sup> [List of Manufactured nanomaterials and List of Endpoints for Phase One of the OECD Testing programme: Revision](#)

close to, commerce) for a number of endpoints selected for their relevance in providing crucial information for human health and environmental safety.

For the moment, the Sponsorship Programme is in its first phase and Dossier Developments Plans (DDPs) for each sponsored nanomaterial are under preparation. These DDPs will include detailed information about the tests performed and the information gathered. The first phase is anticipated to be completed in June 2012.

As the second phase of the Programme is intended to address, amongst other things, additional endpoints that are necessary to gain an understanding of the hazard potential of the respective sponsored nanomaterials, a Task Group on Phase 2 was established and is considering those issues that might comprise the second phase of the Programme. In developing proposals for Phase 2, the Task Group is considering the work and needs across the WPMN as a whole. The evaluation and utilisation of the Phase 1 results will be important to build a firmer basis to start the discussion of Phase 2 and a clear outcome will be expected in developing the tools for harmonising national requirements regarding the safety of nanomaterials, including test methods and data quality.

A meeting to analyse progress and identify any cross cutting issues will be held in December 2011 at the OECD Headquarters in Paris.

### ***Manufactured Nanomaterials and Test Guidelines***

Through this project, OECD is carefully evaluating any concrete proposals for the development or revision of test guidelines and/or guidance documents, which need to take into account existing information and results coming from the scientific community. A Preliminary Review of 115 OECD test guidelines (TGs) has shown that most are suitable but that, in some cases, modification will be needed in order to apply them to manufactured nanomaterials.

One of its outcomes, a document [\*Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials\*](#) (GNSPD) has been published, as a “living document” and it is expected to be revised as new information becomes available. It was agreed to set up a task group to update/revise/finalise the GNSPD at the 8<sup>th</sup> meeting of the WPMN, held in Paris in March 2011. In addition, an Expert Meeting on Inhalation Toxicity Testing for Nanomaterials was held on 19-20 October in The Hague, the Netherlands. A part of the outcome of this meeting will be taken into account by the task group in their review on the GNSPD.

A meeting to revise and update this document, GNSPD, will be held on 5 December 2011 at the OECD Headquarters in Paris.

### ***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.

At the present time, two follow-up surveys have been carried out amongst national bodies which aim to: i) update trends relating commercial activities and the regulatory oversight; as well as ii) collect specific information on manufactured nanomaterials (such as types and volumes used). Finally, as agreed at the 8<sup>th</sup> meeting of the WPMN, two documents were agreed and will be published in early 2012: i) *Regulated Nanomaterials, 2006-2009*; and ii) *Information Gathering Schemes on Nanomaterials, Lessons Learned and Reported Information*.

### ***Co-operation on Risk Assessment***

The overall objectives of this project are to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and to identify opportunities to strengthen and enhance risk assessment capacity. Through this project, it is expected that the outcomes of the work of the other WPMN projects will be integrated into an overall framework within which risks of manufactured nanomaterials are assessed.

Currently, a document *Risk Assessment of Manufactured Nanomaterials – Critical Issues*, is being developed. This document aims at introducing the current practices and challenges on risk assessment of

manufactured nanomaterials as well as strategies for assessing risk in circumstances where data are limited. Furthermore, this document will make clear the necessity of direct research toward specific risk assessment issues in concert with current efforts to develop basic data sets.

### ***The Role of Alternative Methods in Nanotoxicology***

This project addresses the use of alternative methods and Integrated Testing Strategies (ITS) for manufactured nanomaterials. As such, it is focused on those *in vitro* or other alternative methods (for reduction, refinement or replacement of animals in tests) and ITS approaches that could be further explored in respect to manufactured nanomaterials.

A second Expert Consultation Meeting on Alternative Test Methods in Nanotoxicology of the WPMN took place on 18-20 January 2011 in Paris. Several steps were identified for implementing the work. These include: i) an update on particle size measurements for the characterisation of nanomaterials; ii) progress on storage/exchange of study results with the EC JRC NanoHUB; iii) a revision of [Guidance Document 34](#) and the need for nano-specific validation criteria; iv) a draft status report on *in vitro* dispersion protocols for ZnO; v) an integrated testing approach with a short-term inhalation study; vi) three test systems for *in vitro* testing regarding effects in the lung; and vii) considerations on integrated testing in ecotoxicology. A third Expert Consultation Meeting will be held in 2012.

### ***Exposure Measurement and Exposure Mitigation***

Through this project, the WPMN is exchanging information on guidance for exposure measurement and exposure mitigation for manufactured nanomaterials.

A number of specific projects on occupational, consumer and environmental exposure have been identified and prioritised by the WPMN. Currently three projects are underway: i) Techniques and Sampling Protocols for Determining Concentrations of Manufactured Nanomaterials in the Air; ii) Compilation of Available Methods and Models Used for Assessing Exposure to Manufactured Nanomaterials; and iii) Compilation of Available Information on Disposal and Treatment Technologies of Manufactured Nanomaterials. In addition, a project to Determine Degradation Half-lives of Nanomaterials is under development. Furthermore, several case studies on the exposure assessment of manufactured nanomaterials will be developed. Two case studies are underway on nano-silver and nano-gold.

The Steering Group, managing this work, held a “face-to-face” meeting on Exposure Measurement/Mitigation on 9 August 2011 in Boston, United States, a “back-to-back” with an event of the 5<sup>th</sup> International Conference on Nanotechnology – Occupational and Environmental Health. The Steering Group drafted a number of conclusions and recommendations for further work, for consideration by the WPMN in December 2011.

### ***Co-operation on the Environmentally Sustainable Use of Manufactured Nanomaterials***

The aim of this project is to investigate the potential benefits of applications based on the use of manufactured nanomaterials. Through this project, the WPMN seeks to complement current WPMN work regarding the potential positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development.

As part of this project, a document on *National Activities on Life Cycle Assessment of Nanomaterials* has been compiled. It is expected to be published in early 2012.

A workshop on the Environmentally Sustainable Use of Manufactured Nanomaterials and a “face-to-face” meeting of Steering Group 9, which is managing this work, were held 14-15 September 2011 in Rome, Italy. These meetings: i) established an international scientific dialogue on life-cycle aspects of manufactured nanomaterials, potential positive and negative impacts on the environment and health of nano-enabled applications at different stages of development; and ii) identified how case studies can be adapted to the needs of decision-makers.

### ***Forthcoming Events:***

- Meeting on Phase 2 of the OECD’s Sponsorship Programme and Further Testing Strategies, 1-2 December 2011, OECD Conference Centre in Paris.

- Meeting of Steering Group 4 - Manufactured Nanomaterials and Test Guidelines, 5 December 2011, OECD Conference Centre in Paris.
- Review Meeting of the Sponsorship Programme on the Testing of Manufactured Nanomaterials, 6 December 2011, OECD Conference Centre in Paris.
- 9<sup>th</sup> Meeting of the WPMN, 7-9 December 2011, OECD Conference Centre in Paris.
- 3<sup>rd</sup> Expert Consultation Meeting on Alternative Test Methods in Nanotoxicology, 2012

***Recent Publications on Manufactured Nanomaterials:***

-  [Current Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 8<sup>th</sup> Meeting of the Working Party on Manufactured Nanomaterials](#), No. 29
-  [Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories](#), No. 28
-  [Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials](#), No. 24

***Upcoming Publications:***

-  Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials
-  Current Developments/ Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 9<sup>th</sup> Meeting of the Working Party on Manufactured Nanomaterials
-  Regulated Nanomaterials: 2006-2009
-  Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information
-  National Activities on Lifecycle Assessment of Nanomaterials

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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. The Programme is managed by the Working Group on Chemical Accidents (WGCA).*

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

An Addendum has been developed as a supplement to the second edition of the OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response*, published in 2003. It takes into account the results of five workshops held under the auspices of the WGCA during the period from 2003-2007. The draft Addendum was published in June 2011 as an Environment, Health and Safety (EHS) publication in the series on Chemical Accidents, [No. 22](#).

#### ***Natural hazard induced chemical accidents (Natech)***

A Germany-led Steering Group on Natech accidents (SG-Natech) established in 2008 works on the development of best practices for the control of the impact of natural hazards on chemical installations (two interim reports were prepared in 2009 and 2010 respectively). The SG-Natech is organising a *Workshop on Natech Risk Management* that will be held on 23-25 May 2012, in Dresden, Germany. The event will be sponsored and hosted by the Federal Ministry for the Environment of Germany (BMU) and the Government of Saxony.

#### ***Corporate governance: the role of leadership in preventing chemical accidents***

A Steering Group on Corporate Leadership (SG-CL) led by the Netherlands and the United Kingdom was established in December 2010 to investigate the role of leadership in preventing accidents. The SG-CL is developing OECD *Guidelines on Corporate Governance for Process Safety* with the aim that they are launched at a high level Conference that will take place on 15 June 2012, at the OECD in Paris. The event will be sponsored by the Ministry of Social Affairs and Employment of the Netherlands.

#### ***Risk and regulation of carbon capture and storage***

The UK led Steering Group on Carbon Capture and Storage (SG-CCS) established in 2009, analysed the responses to a survey of member countries conducted to collect information in order to identify the major hazard implications of CO<sub>2</sub> sequestration. The SG-CCS recognised that data from the survey is not sufficient to define the full range of credible accident scenarios for CCS. Two interim reports were developed in 2010 and 2011 respectively. The final report is being completed to be submitted to the Working Group on Chemical Accidents (WGCA) for approval; it is anticipated that it will be published early in 2012, as an EHS publication, in the series on Chemical Accidents, No. 23.

#### ***Forthcoming Events:***

- Workshop on *Natech Risk Management*, 23-25 May 2012, Dresden, Germany
- Conference for the launching of *Guidelines on Corporate Governance for Process Safety*, 15<sup>th</sup> June 2012, OECD, Paris

- 22<sup>nd</sup> Meeting of the Working Group on Chemical Accidents, 17-19 October 2012, OECD, Paris

***Forthcoming publications:***

-  Report of *Survey on Risk and Regulation of Carbon Capture and Storage*, EHS publication, series on Chemical Accidents, No. 23 (first half of 2012)

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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.*

The work plan currently focuses on advancing and improving the use of PRTR data. Current projects are: i) review or update of the published Resource Compendium for PRTR Release Estimation Techniques for point sources, diffuse sources, and releases from products; ii) development of guidance or recommendation on the elements of a global PRTR; and iii) maintenance and updates of web-based portal and databases.

The 14<sup>th</sup> Task Force on PRTRs was held on 3-5 October in Paris with a joint session with the Task Force on Exposure Assessment on releases from products (See also the section on “Exposure Assessment”). The Task Force discussed the following topics: application, use and presentation of PRTR data; release estimation techniques for point sources; release estimation techniques for diffuse sources; releases from products; and current progress of the three web-based resources - Centre for PRTR Data, Resource Centre for Release Estimation Techniques, and PRTR.net (global portal to PRTR information). A special roundtable session was held to discuss specific topics: 1) PRTR and sustainable development and 2) experiences and practices in ensuring data quality for releases and transfers reported to PRTR registers. The Task Force agreed to update the Resource Compendium Part 1 on Point Sources. In addition, the report on “Global Pollutant Release and Transfer Register: Proposal for a Harmonised List of Pollutants” was finalized and is expected to be published in early 2012. As a next step, the Task Force agreed to investigate the common lists of sectors and thresholds.

***Forthcoming events:***

- 15<sup>th</sup> Meeting of the OECD Task Force on PRTRs: 24-26 September 2012, Paris.

***Upcoming Publications:***

-  Global Pollutant Release and Transfer Register: Proposal for a Harmonised List of Pollutants

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## 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.*

### **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 also reduces the need for duplicative testing by industry, thereby saving resources and preventing unnecessary loss of animal life, and helps ease barriers to trade.

The Registration Steering Group is considering updating the Guidance for Country Data Review Reports (Monograph) and Guidance for Industry Data Submissions (Dossier) for chemical pesticides.

### **Residue Chemistry**

Since it began to work on residue chemistry a few years ago, the OECD has published nine Test Guidelines, five Guidance Documents and the "MRL calculator", a statistical instrument for calculating maximum residue limits. The Residue Chemistry Expert Group will now begin the review of the use of proportionality of pesticide residue levels in crops for regulatory decisions.

### **Minor Uses**

The Expert Group on Minor Uses (EGMU) met for the third time on 9 September 2011, in Ottawa, Canada. The EGMU is now engaging in three new activities, i.e., Project 1 on developing a guidance document to address and solve minor uses; Project 2 on enhancing minor uses from global joint reviews; and Project 3 on developing a guidance document on the exchange and use of international efficacy and crop safety data for minor uses.

EGMU experts and the OECD Secretariat will be involved in the second Global Minor Uses Summit that will be held on 21-23 February 2012 at FAO, Rome.

### **Illegal International Trade in Agricultural Pesticides**

Following the 2010 one-day seminar on *Risk Reduction through Prevention, Detection and Control of the Illegal International Trade in Agricultural Pesticides*, the Pesticide Programme has recently established an OECD Network of Experts and Inspectors knowledgeable and active in fighting international illegal trade of agricultural pesticides. Currently the Network includes members in regulatory authorities from 16 countries/regions representing OECD member countries and OECD Enhanced Engagement countries.

## ***Integrated Pest management (IPM)***

The OECD organised a Workshop on IPM entitled “Strategies for the adoption and implementation of Integrated Pest management in agriculture contributing to the sustainable use of pesticides and to pesticide risk reduction” on 16-19 October 2011 in Berlin (Germany). The workshop addressed four main issues: # 1: Technology and Information; # 2: Economics and Market Access; # 3: Policies and Strategies; and # 4: Measurement and Impacts. At the end of the workshop, the participants developed key conclusions and a set of recommendations to the OECD that will be considered for future possible IPM activities by the Pesticide Programme and a report will be published towards the end of 2011.

## ***Risk Reduction***

In the area of pesticide spray drift, the Network of Experts on Spray Drift continues its activities and is currently expanding its website on “Managing Pesticide Spray Drift” ([www.oecd.org/env/spraydrift](http://www.oecd.org/env/spraydrift)) to include new information on existing and future research activities on spray drift and additional best practice documents on aerial application.

Additionally, the Pesticide Programme will be launching in early 2012 a survey on “risk management/mitigation approaches and options related to pesticide use near residential areas”, led by the UK. In particular, the aim of the survey is to provide an information source on the various approaches to spray drift risk mitigation adopted by countries (whether on a legal or voluntary basis).

In the area of compliance and enforcement, the OECD Expert on Compliance has developed the “OECD Best Practice Guidance on Pesticide Compliance and Enforcement”, under the active leadership of Canada. The Best Practice Guidance document provides general guidance for pesticide regulators, including those that may not have their own compliance requirements, guidance or policies. It provides guidance for promoting and monitoring compliance in five key areas of the pesticide life cycle i.e., Manufacturing; Distribution (including transportation and sale); Use; Storage; and Container Recycling & Disposal. It is due to be published in the spring of 2012. As a follow-up activity, the Canada and the US have offered to lead a project to establish a forum of national authorities active in pesticide compliance and enforcement.

## ***Forthcoming events:***

- Working Group on Pesticides: week of 11-15 June 2012, OECD, Paris
- BioPesticides Steering Group meeting and one-day Seminar: Week of 11-15 June 2012, OECD, Paris
- Risk Reduction Steering Group meeting and one-day Seminar: week of 26-30 November 2012, Queenstown, New Zealand
- Registration Steering Group meeting: week of 26-30 November 2012, Queenstown, New Zealand

## ***Recent publications:***

- 📖 [Guidance Notes for the Estimation of Dermal Absorption Values](#), Series on Testing and Assessment No. 156
- 📖 [Guidance Document on Crop Field Trials](#), Series on Pesticides No. 66 / Series on Testing and Assessment No. 164
- 📖 [OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products](#), Series on Pesticides No. 65
- 📖 [Report of the Second OECD Biopesticides Steering Group Seminar on the Fate in The Environment of Microbial Control Agents and Their Effects on Non-Target Organisms](#), Series on Pesticides No. 64
- 📖 [Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses](#), Series on Pesticides No. 63

-  [OECD Survey on Regulatory Incentives for the Registration of Pesticide Minor Uses: Survey Results](#), Series on Pesticides No. 62
-  [OECD Survey on Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses: Survey Results](#), Series on Pesticides No. 61
-  [Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides](#), Series on Pesticides No. 60

***Forthcoming publications:***

-  Guidance to the Environmental Safety Evaluation of Microbial Biocontrol Agents
-  OECD Best Practice Guidance on Pesticide Compliance and Enforcement
-  OECD Survey on the Integrity of Pesticides at the Manufacturing, Import and Distribution Stages: Survey Results
-  Report of the workshop on the “Development of harmonised international guidance for pesticide terrestrial field dissipation studies and crosswalk of North American and European eco-regions”, Ottawa, Canada, March 2011
-  Report of the third OECD Biopesticides Steering Group Seminar on the “Characterisation and Analyses of Botanicals for the use in Plant Protection Products”, OECD, Paris, March 2011
-  Report of the Integrated Pest Management workshop, Berlin, Germany, October 2011

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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***

Four draft *Test Guidelines for evaluating efficacy of microbicides used on hard non-porous surfaces* and a companion Guidance Document were circulated for a second commenting round in October 2010 until January 2011:

- Test Guideline on *Quantitative method for evaluating **bactericidal** activity of microbicides used on hard non-porous surfaces.*
- Test Guideline on *Quantitative method for evaluating **fungicidal** activity of microbicides used on hard non-porous surfaces.*
- Test Guideline on *Quantitative method for evaluating **mycobactericidal** activity of microbicides used on hard non-porous surfaces.*
- Test Guideline on *Quantitative method for evaluating **virucidal** activity of microbicides used on hard non-porous surfaces.*

- Guidance Document on the *Conduct of quantitative methods for evaluating the bactericidal, fungicidal, mycobactericidal and virucidal activities of microbicides used on hard non-porous surfaces*.

The revised draft Test Guidelines and Guidance Document were submitted to the 23rd Meeting of the WNT (Working Group of National Co-ordinators of the Test Guidelines Programme). Delegates raised a number of issues and recommended holding a meeting of experts and regulators to solve them, including some unsolved issues raised during the October 2010 review round. This meeting took place on 13-14 September 2011, at OECD in Paris, and agreed that the four Test Guidelines and the companion Guidance Document will be merged into one document as follows: the content of the Guidance Document will be an introductory part followed by the four Test Guidelines, i.e. the detailed description of the test procedures. In the meantime, the US EPA has launched a collaborative evaluation of the bactericidal test method which is expected to be completed in June 2012.

A draft Guidance Document for demonstrating the efficacy of pool and spa disinfectants in laboratory and field testing was submitted for approval to the 23rd WNT Meeting in April 2011. The document was provisionally approved waiting for the resolution of an issue related to the selection of species. The revised draft Guidance Document is under review.

A first draft Guidance Document on assays for testing the efficacy of baits against cockroaches was circulated for comments to the Task Force on Biocides and WNT from August to end of October 2011.

### ***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. These three draft Test Guidelines are being circulated for comments to the TFB and to the WNT.

### ***Emission Scenario Documents (ESDs)***

The update of the *ESD on Wood Preservatives*, published in 2003, is nearing completion.

### ***Forthcoming events:***

- 📖 9<sup>th</sup> 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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## HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

*The programme on the Harmonisation of Regulatory Oversight in Biotechnology is focused on environmental risk/safety assessment of transgenic (genetically modified) crops as well as other organisms of commercial interest. It aims to ensure that the information used in risk/safety assessment, as well as the methods used to collect this information, is as similar as possible among regulatory authorities. 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 25<sup>th</sup> meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology (WG-HROB) was held in Paris in May 2011. An important step was the agreement by the meeting to recommend declassification of the *Guidance Document on the Use of Information on Pathogenicity Factors in Assessing the Potential Adverse Health Effects of Micro-organisms: Bacteria*. The final document was published in September 2011. It was also agreed that two other draft Consensus Documents were almost ready for declassification, after final check and improvements: i) the Biology of the *Brassica* crops; and ii) the Biology of *Curcubita* species.

A document on the Biology of Tomato, close to completion, will be considered for possible declassification in 2012. The work started on drafting a document on Eucalyptus (lead country: Australia), and an *ad hoc* drafting group was constituted to prepare a document on Sorghum.

Concerning the project on *Low Level Presence (LLP) in Seed and Commodities in the Context of Environmental Safety*, the first comprehensive draft was presented at the 25<sup>th</sup> meeting of the WG-HROB. The Bureau will prepare the revised draft, based on the comments received from delegations.

The project on *Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants* made progress with the first full draft submitted by Canada (lead) at the 25<sup>th</sup> meeting of the WG-HROB. A "face-to-face" meeting of the Steering Group was hosted by Mexico in Guadalajara from 26-28 September 2011. This meeting allowed the revision of the draft document: the structure of each section was reviewed; introductory summaries were drafted for each consideration; key points to be taken into account in the general parts and in each section of the document were agreed. The specific importance of Biodiversity, overarching most of the protection goals, will be highlighted in the future text.

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.

In regard to the OECD Product Database (<http://www2.oecd.org/biotech/>), which includes information on transgenic plants (unique identifiers, common and scientific names of host organisms, events and introduced genes etc.), a call for new entries and updates was circulated prior to the 25<sup>th</sup> meeting of the WG-HROB. Delegations are invited to submit such information to the Secretariat at any time. It was agreed that the Secretariat would continue to explore the feasibility and ways to improve the database, and the WG will discuss further the matter at its 26<sup>th</sup> meeting in March 2012.

The issue **No. 22** of the "Biotechnology Update" (Newsletter of the OECD Internal Co-ordination Group for Biotechnology prepared by the EHS biosafety team), was finalised in July 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:***

- 26<sup>th</sup> meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 28-30 March 2012, OECD Headquarters, Paris

### ***Recent Publications:***



**[Guidance Document on the Use of Information on Pathogenicity Factors in Assessing the Potential Advers Health Effects of Micro-organisms: Bacteria](#), No. 52**

### ***Forthcoming Publications:***

-  Consensus Document on the Biology of the Brassica Crops (*Brassica* spp.)
-  Consensus Doc. on the Biology of *Cucurbita* spp. (Squashes, Pumpkins, Zucchini or Gourds)
-  Consensus Document on the Biology of Tomato (*Lycopersion* spp.)

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

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

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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 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 21 Consensus Documents have been published by the Task Force, including the latest one on [\*Compositional Considerations of New Varieties of Sugarcane\*](#) issued in October 2011. 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 published in the coming months. Projects are contemplated on *Common Bean (Phaseolus vulgaris)* and *Oyster mushroom (Pleurotus ostreatus)* for development in 2012.

Other emerging subjects, such as "compositional data of animal products", "new biotechnological techniques", "compositional considerations of pineapple", and other topics are considered by the Task Force for possible future activities.

### ***Outreach and engagement with non member economies***

An important aspect of the work has been to strengthen the involvement of non-member economies in the OECD Food Safety as well as Biosafety activities through the Global Forum on Biotechnology. Regular participants include Argentina, Brazil, India, Philippines, Russia and South Africa.

### ***Other activities on the risk/safety assessment of modern biotechnology***

The "Instructions for Authors", used by the Task Force experts when preparing Consensus Documents on compositional considerations, is being updated to take into account some aspects related to the *quality of the data*. Its publication is expected in December 2011.

### **Future events:**

- 19<sup>th</sup> Meeting of the Task Force for the Safety of Novel Foods and Feeds, 22-23 March 2012, OECD Headquarters, Paris

### **Recent Publication:**

- 📖 [Consensus Document on Compositional Considerations for New Varieties of Sugarcane \(\*Saccharum\* spp. hybrids\): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants](#), No. 23

### **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
- 📖 Safety Assessment of Novel Foods and Feeds derived from Transgenic Crops – OECD Consensus Documents– Volumes 1 and 2. *This compendium will collate the key documents produced by the Task Force between 2002 and 2011 – Issue expected in March/April 2012*

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

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

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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, Slovenia, Israel and Estonia all became members in 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, and agreed a new strategy at its meeting in June, 2011. 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:** [OECD Enlargement](#)

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## CROSS-CUTTING ISSUES

### *Environmental Outlook*

A Global Forum on Environment, which focused on a draft Environmental Outlook Report, was held from 3 to 4 October, 2011 at OECD headquarters. The objective of the meeting was to review the draft chapters of the *Environmental Outlook to 2050*. This report focuses 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 focuses 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 describes 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*

The OECD Harmonised Templates (OHTs) provide standard data formats for reporting the results of 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 test results for toxicology, eco-toxicology environmental fate and physical/chemical properties. For each of them, corresponding XML schema and schematron have been developed (*i.e.* a common electronic data export/import format).

The templates (and associated XML files) are available on OECD's public website. They are classified along seven categories (*Physico-chemical properties, Degradation and accumulation, Effects on biotic systems, Health effects, Analytical methods, Pesticide residue chemistry, and Efficacy*). Templates are regularly updated and new ones developed to include new and revised OECD Test Guidelines adopted by the OECD Council, or to bring improvements identified by template users. Updates made are easily traceable on the website (last series in March 2011 related to 37 OHTs).

The revision of OHT 49 on sediment toxicity, following the publication of Test Guideline 225 (Sediment-Water *Lumbriculus* Toxicity Test using Spiked Sediment), was endorsed by the Joint Meeting in November 2011 and is scheduled to be published in December 2011. On-going work that is expected to be completed in the coming months is: new template on leaching from preservative-treated wood, completion and update of the templates on pesticide residues. Other templates related to test results with endocrine disrupters and nanomaterials, as well as a generic template for *in vitro* results are currently under development.

Contact: Bertrand Dagallier

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

## ***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. The modified Toolkit, case studies and road maps are scheduled to be published in early 2012. It is expected that a list of existing exposure models will also be published on the OECD website together with the amended Toolkit.

**Contact:** Hirofumi Aizawa

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

## WEB SITES

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

EHS Homepage	<a href="http://www.oecd.org/ehs/">http://www.oecd.org/ehs/</a>
Biocides	<a href="http://www.oecd.org/env/biocides">http://www.oecd.org/env/biocides</a>
Biosafety and Food/Feed safety	<a href="http://www.oecd.org/biotrack">http://www.oecd.org/biotrack</a>
Chemical Accidents	<a href="http://www.oecd.org/env/accidents">http://www.oecd.org/env/accidents</a>
Exposure Assessment	<a href="http://www.oecd.org/env/exposure">http://www.oecd.org/env/exposure</a>
Global Portal to Information on Chemical Substances	<a href="http://www.oecd.org/ehs/eChemPortal">http://www.oecd.org/ehs/eChemPortal</a>
Good Laboratory Practice	<a href="http://www.oecd.org/env/glp">http://www.oecd.org/env/glp</a>
Harmonised Templates	<a href="http://www.oecd.org/ehs/templates">http://www.oecd.org/ehs/templates</a>
Harmonisation and Classification of Labelling	<a href="http://www.oecd.org/env/classify">http://www.oecd.org/env/classify</a>
Hazard Assessment	<a href="http://www.oecd.org/env/hazard">http://www.oecd.org/env/hazard</a>
Mutual Acceptance of Data (MAD)	<a href="http://www.oecd.org/ehs/mad">http://www.oecd.org/ehs/mad</a>
New Chemicals	<a href="http://www.oecd.org/env/newchemicals">http://www.oecd.org/env/newchemicals</a>
Pesticides	<a href="http://www.oecd.org/env/pesticides">http://www.oecd.org/env/pesticides</a>
Pollutant Release and Transfer Registers	<a href="http://www.oecd.org/env/prtr">http://www.oecd.org/env/prtr</a>
(Q)SARS	<a href="http://www.oecd.org/env/hazard/qsar">http://www.oecd.org/env/hazard/qsar</a>
Risk Assessment	<a href="http://www.oecd.org/env/riskassessment">http://www.oecd.org/env/riskassessment</a>
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Strategic Approach to International Chemicals Management	<a href="http://www.oecd.org/env/saicm">http://www.oecd.org/env/saicm</a>
Sustainable Chemistry	<a href="http://www.oecd.org/env/sustainablechemistry">http://www.oecd.org/env/sustainablechemistry</a>
Test Guidelines	<a href="http://www.oecd.org/env/testguidelines">http://www.oecd.org/env/testguidelines</a>

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If you are unable to find what you are looking for, please contact the Secretariat:

→ 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. 26, issued in May 2011), the EHS Division has seen the following changes in staffing:

*Head of EHS: Bob Diderich has been appointed the new Head of Division to replace Dian Turnheim who retires in January 2012.*

*Test Guidelines: Shirlee Tan has left the OECD secretariat.*

*Nanosafety and Biotechnology: Mar Gonzalez has returned to the Nano team while Kristan Markey has rejoined the US EPA. Yidan Shen-Gress has left and Christiana Oladini-James joined the team for providing administrative support in these areas.*

**ENV/EHS Staff Directory**  
**E-fax Number: +33 (0)1 44 30 61 80**

<b>NAME</b>	<b>PROGRAMME</b>	<b>PHONE</b>	<b>OFFICE</b>
<b>TURNHEIM, Dian</b>	Head of Division	<b>93.15</b>	0339
<b>AIZAWA, Hiro</b>	Risk Assessment, Test Guidelines, PRTRs	<b>79.07</b>	0240
<b>BORKEY, Peter</b>	Risk Management/Sustainable Chemistry	<b>13.85</b>	0159
<b>CHENEY, Milly</b>	Pesticides, Biocides, GLP/MAD, New Chemicals, Outlook	<b>85.25</b>	0263
<b>DAGALLIER, Bertrand</b>	Food Safety, Biosafety, Harmonised Templates, Metapath	<b>84.51</b>	0283
<b>DELRUE, Nathalie</b>	Test Guidelines	<b>98.44</b>	0319
<b>DE MARCELLUS, Sally</b>	Hazard Assessment	<b>19.42</b>	0240
<b>DIDERICH, Bob</b>	Hazard Assessment, (Q)SAR	<b>14.85</b>	0253
<b>EVELEIGH, Lisa</b>	Finance	<b>95.43</b>	0340
<b>FRANCIS, Camilla</b>	Test Guidelines, HCL	<b>16.74</b>	0263
<b>GIBB, Jill</b>	Administrative Assistant	<b>93.16</b>	0320
<b>GONZALEZ, Mar</b>	Nanotechnologies	<b>76.96</b>	0295
<b>GOURMELON, Anne</b>	Test Guidelines/Endocrine Disrupters, Hazard Assessment, HCL	<b>98.49</b>	0319
<b>HANAWA, Hiroyuki</b>	Nanotechnologies	<b>14.63</b>	0295
<b>HORIKI, Wakako</b>	Test Guidelines, GLP/MAD	<b>76.98</b>	0332
<b>HUET, Marie-Chantal</b>	Pesticides, Chemical Accidents, Test Guidelines	<b>79.03</b>	0283
<b>JUKES, Sarah</b>	Risk Assessment, PRTR, Existing Chemicals, (Q)SAR, Templates	<b>17.37</b>	0263
<b>KEARNS, Peter</b>	Biosafety, Food Safety, Nanotechnologies, Chemical Accidents	<b>16.77</b>	0285
<b>KIM, Bobby</b>	Nanotechnologies	<b>98.81</b>	0289
<b>LEE, Jeong Rim</b>	Nanotechnologies	<b>14.81</b>	0295
<b>MUSSET, Laurence</b>	Test Guidelines, HCL	<b>16.76</b>	0318
<b>OLADINI-JAMES, Christiana</b>	Biotechnology, Food Safety, Nanomaterials, Chemical Accidents	<b>17.08</b>	0263
<b>PORET, Sylvie</b>	Pesticides, Biocides	<b>89.45</b>	0238
<b>SCHULTZ, Terry</b>	(Q)SAR	<b>17 99</b>	0332
<b>SIGMAN, Richard</b>	GLP, Pesticides, Biocides, New Chemicals	<b>16.80</b>	0255
<b>SUWABE, Kazuyuki</b>	Biosafety/Food Safety	<b>76.19</b>	0289
<b>WOOD, Alastair</b>	Division CI, Communications, Publications	<b>79.05</b>	0320