ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Environment, **H**ealth & **S**afety **N**ews

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Introduction

The Environment, Health and Safety News is issued approximately every eight months, between the meetings of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. It aims to provide an update on the main events and activities of the EHS Programme. Information on new publications arising from the Programme as well as dates and venues of upcoming events and meetings are given.

This edition is now available on the Internet as a "live-link" version.

STAFF IN THE EHS DIVISION

Since the last Environment, Health and Safety News (No. 22, issued in July 2008), the EHS Division has seen the following changes in staffing:

Head of Division: *Rob Visser* has become full-time Deputy Director of the Environment Directorate and is no longer the Head of the EHS division. *Dian Turnheim* is currently the Acting Head of Division**.**

GLP: *Bertrand Dagallier* is now working on Good Laboratory Practice, in addition to his work on Food Safety. *Mio Takenaka-Yagi* has returned to Japan and has been succeeded by *Hitoshi Someya*, who also works on Test Guidelines.

Test Guidelines: *Agnieszka Kinsner-Ovaskainen* has joined the Test Guidelines Programme.

Nanosafety: *Mathieu Moslonka-Lefebvre* worked as an intern from September 2008 to March 2009 on the Nanosafety Programme. *Mar Gonzalez* is now working full-time on Nanosafety.

CHEMICALS PROGRAMME

TEST GUIDELINES

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

The following new, updated or corrected Test Guidelines were adopted by the Council on 3 October 2008 and are available free of charge from SourceOECD or from the OECD Online Bookshop: [http://www.oecd.org/document/40/0%2C2340%2Cen_2649_34377_37051368_1_1_1_1%2C00.html].

New Test Guidelines:

Section 2: Effects on Biotic Systems

226 Predatory Mite (*Hypoaspis* (*Geolaelaps*) *Aculeifer*) Reproduction Test in Soil

228 Determination of Developmental Toxicity of a Test Chemical to Dipteran Dung Flies (*Scathophaga Stercoraria* L. (Scathophagidae) and *Musca automnalis* De Geer (Muscidae)

Section 3: Degradation and accumulation

314 Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater

315 Bioaccumulation in Sediment-dwelling Benthic Oligochaetes

316 Phototransformation of Chemicals in Water – Direct Photolysis

Section 5: Other Test Guidelines

508 Magnitude of Pesticide Residues in Processed Commodities

Updated Test Guidelines:

Section 2: Effects on Biotic Systems

211 *Daphnia magna* Reproduction Test

Section 4: Health Effects

407 Repeated Dose 28-Day Oral Toxicity Study in Rodents

Corrected Test Guideline:

Section 4: Health Effects

425 Acute oral toxicity: Up-and-Down Procedure

In addition to the draft, new or updated Test Guidelines mentioned later in this section, the following draft Test Guidelines will be submitted to the next meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT), 31 March - 2 April 2009, for approval:

- New and updated Test Guidelines for acute, sub-acute and sub-chronic inhalation toxicity studies
- Updated Test Guidelines for carcinogenicity and chronic toxicity studies
- New Test Guideline for a Collembolan reproduction test
- New Test Guideline on Crop Field Trial (for pesticide residue)

Two draft Test Guidelines were approved provisionally at the last WNT meeting, pending resolution of a few specific issues.The draft Test Guideline for a Stably Transfected Human Estrogen Receptor-α Transcriptional Activation Assay (STTA) for Detection of Estrogenic Agonist-Activity of Chemicals, will be submitted for approval at the next WNT meeting.The draft Test Guideline for an *in vitro* mammalian Cell Micronucleus Test, which comprises experiments in several laboratories and on several chemicals to evaluate the performance of the cytotoxicity measurements are nearly completed. After completion of these experiments, the draft Test Guideline will be submitted to the WNT for final approval, revised as appropriate.

Two draft Test Guideline-related documents will be submitted to the next WNT meeting for approval: (i) Guidance Document for Histologic Evaluation of Endocrine and Reproductive Tests in rodents, (ii) Detailed Review Paper on Transgenic Rodent Mutation Assays,

Endocrine disrupters

The validation management group for non-animal testing (VMG NA) met on 19-21 November 2008), and continued discussing issues related to performance-based Test Guidelines and "me too" tests. In addition to the draft Test Guidelines for the 21-day Fish Assay, mentioned below, and the STTA assay, mentioned above, new draft Test Guidelines for the Hershberger bioassay and for an amphibian metamorphosis assay will be submitted to the next WNT meeting for approval. A workshop on OECD countries activities regarding Endocrine Disrupter testing and assessment, which will be held in Denmark on 22-24 September 2009, is under preparation.

21-day Fish Assay: a short-term screening for endocrine or reproductive activity

A drafting group met in October 2008 to address comments from the validation peer review and comments from the WNT on the draft Test Guideline. The draft Test Guideline will be submitted to the 2009 WNT meeting for approval.

Skin Irritation

An expert group meeting was held in Berlin (Germany) in October 2008 to discuss a draft Test Guideline proposed by the European Commission for an *in vitro* assay for skin irritation, using a human skin model test. A second meeting will be held in the United States on 15-17 June 2009.

Eye Corrosion/Severe Irritation

An expert group met in Washington D.C. on 4-5 December 2008 to discuss two draft Test Guidelines proposed by the United States for two *in vitro* methods: the Bovine Corneal Opacity and Permeability test method and the Isolated Chicken Eye test method. Both will be submitted to the 2009 WNT meeting for approval.

Extended One-Generation Reproductive Toxicity Study

An expert group met in October 2008 in Paris. It discussed a draft Test Guideline for an Extended One-Generation Reproductive Toxicity Study. A request for data on multi-generation reproductive toxicity studies was posted on the OECD public website. A data analysis of available databases will support refinement of the triggers for a second generation study.

Acute Reference Dose

A small drafting group met in October 2008 in Berlin (Germany) to discuss a draft Guidance Document for the Derivation of an Acute Reference Dose.

Forthcoming events:

- 21st Meeting of the Working Group of National Coordinators of the Test Guidelines Programme, 31 March - 2 April 2009, Paris
- Expert Group meeting on skin irritation, Washington D.C., 15-17 June 2009
- Workshop on OECD countries' activities regarding Endocrine Disrupter Testing and Assessment, Denmark, 22-24 September 2009
- WHO/OECD Training Workshop on Risk Assessment Methodology, 5-6 October 2009
- Expert Group meeting for the development of a Guidance Document on the design and conduct of chronic toxicity and carcinogenicity studies, 7-8 October 2009, Paris
- Expert group meeting on the extended one – (see previous page)-Generation Reproductive Toxicity Study: 22-23 October 2009, Paris
- Meeting of the validation management group for non-animal testing: November 2009, Paris

Recent publications:

- 🕮 Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment (2008)
- 🕮 Background Review Document on the Rodent Hershberger Bioassay (2008)
- 🕮 Report of the Validation of the Amphibian Metamorphosis Assay (Phase 3)(2008)
- 🕮 Report of the Validation Peer Review for the Amphibian Metamorphosis Assay and Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the Follow-Up of this Report (2008)
- 🕮 Report of the Validation of an Enhancement of OECD TG 211: Daphnia Magna Reproduction Test (2008)
- 🕮 Report of the Validation Peer Review for the 21-Day Fish Endocrine Screening Assay and Agreement of the Working Group of the National Coordinators of the Test Guidelines Programme on the Follow-Up of this Report(2008)
- 🕮 Detailed Review Paper on Fish Life-Cycle Tests (2008)
- 🕮 Detailed Review Paper on the Use of Metabolising Systems for *in vitro* testing of Endocrine Disruptors (2008)
- 🕮 Comparison between OECD Test Guidelines and ISO Standards in the areas of Ecotoxicology and Health Effects (2008)
- 🕮 Report of the Second Survey on Available Omics Tools (2008)

Contact: Laurence Musset

Website: **http://www.oecd.org/env/testguidelines**

MUTUAL ACCEPTANCE OF DATA AND NON-MEMBER COUNTRIES

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and 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.

In July 2008, Malaysia became the eighth non-member to adhere to the Council Decisions related to Mutual Acceptance of Date in the Assessment of Chemicals. Malaysia joins the other provisional adherents: India, Brazil, Singapore and Argentina. South Africa, Slovenia and Israel are full adherents to the MAD system, which means that non-clinical health and environmental safety data generated in these three countries must be accepted for regulatory purposes in OECD and other adhering countries. The Secretariat continues to work with Thailand, China, Chinese Taipei, Estonia, and several other countries in view of their provisional adherence to the MAD Council Acts as well.

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

OUTREACH

In May 2007, OECD countries agreed to invite Chile, Estonia, Israel, Russia and Slovenia to open discussions for membership of the Organisation. The approval of so-called "road maps" marked the start of accession talks with the applicant countries. In contrast to many other international organisations, becoming a member of OECD is not something that is automatically open to countries. Each applicant country must have demonstrated its attachment to the basic values shared by all OECD members: an open market economy, democratic pluralism and respect for human rights. It must also state its position vis-à-vis the OECD "legal instruments" (meaning the Decisions, Recommendations and Declarations adopted within the framework of the Organisation) in the various fields of activity of the OECD. In other words, it has to show both its willingness and ability to adopt the main principles of the Organisation, as well as the legal and political obligations that result therefrom. In the field of chemicals management, the Chemicals Committee will review the position of the five applicant countries and present its recommendations to the Council for decision.

In May 2007, OECD countries also offered enhanced engagement, with a view to possible membership, to Brazil, China, India, Indonesia and South Africa. Enhanced engagement was offered to those countries whose engagement in the work of the OECD is particularly important for the fulfilment of the Organisation's mandate to promote policy convergence and global economic development. Partners should be willing and able to engage with the OECD and contribute to its work in a sustained and comprehensive manner. Each Enhanced Engagement programme will contain a mix of several elements, notably Committee participation, economic surveys, adherence to instruments, integration into the statistical reporting and information systems, sector-specific peer reviews and other policy dialogue initiatives. In the field of chemicals management, adherence to the OECD Acts on Mutual Acceptance of Data (see above) is a key factor of success of the enhanced engagement process. Enhanced engagement countries also have in 2009 the opportunity to directly and actively participate in the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology and its subsidiary bodies.

Several other non-members from Africa, America, Asia and Europe also participated recently as ad hoc observers in some of these meetings.

Contact: Sylvie Poret

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

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.

To date, nine substances have gone through or are in the pilot phase of the parallel notification process aimed at simplifying and streamlining access to multiple markets for new chemicals. The parallel process refers to a company notifying in multiple jurisdictions and authorising participating governments to share information when conducting their reviews. Jurisdictions participating in the parallel process utilise current evaluation processes to conduct their notification reviews. In addition, throughout this process, jurisdictions retain the sovereign right to make their own risk-based decisions. In 2006 a document was published [ENV/JM/MONO(2006)12)] which described the three phases of the parallel process (Pre-notification, Notification and Assessment), as well as the roles of the lead, secondary and observer countries. Based on the experience to date, work is underway to develop another document on the Standard Operating Procedures with respect to the Pre-Notification phase. Analysis continues of the experience of those who participated in the parallel process and ways to make this process more efficient. Efforts also continue on ways to increase industry participation and involvement in the parallel process, and companies interested in participating are encouraged to inform their national authorities. Information describing the parallel process pilot phase is available on the OECD website.

Following an expert group meeting on polymers that was held in Tokyo in March 2007, participating governments began exchanging scientific data and descriptions of each country's rationale for the criteria they use for identifying polymers of low concern (PLC). In January 2009, a report was published [ENV/JM/MONO(2009)1] which contains an analysis of data on 205 polymers and identifies correlations between polymer characteristics and the potential for health or ecotoxicological concern.

Work continues on the development of an electronic notification software programme. The objective of this project is to create an electronic notification system that could be used to generate new substance notifications for all OECD jurisdictions. Beta testing of the software program began in late 2008.

The 43rd Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology agreed to a new structure for managing the work on new chemicals. The Task Force on New Chemicals which was had been responsible for the management of work since 1999, will be replaced by a Clearing House of interested countries, chaired by Australia.

Recent publications:

- 🕮 Data Analysis of the Identification of Correlations Between Polymer Characteristics and Potential for Health or Ecotoxicological Concern

Contact: Richard Sigman

Website: **http://www.oecd.org/env/newchemicals**

EXISTING CHEMICALS

The Existing Chemicals Programme is concerned with the thousands of chemicals used world-wide that were put on the market before new chemical notification systems were established and whose hazards were not thoroughly evaluated by governments. Data on High Productive Volume (HPV) chemicals is gathered or generated and co-operative initial assessments are carried out to determine the need for further testing or risk management. eChemPortal offers free public access to information on properties of chemicals, allowing for a simultaneous search of multiple databases on the Internet, giving access to data submitted to government chemical review programmes at national, regional, and international levels.

The 27th SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Ottawa, Canada in October 2008. Assessments for 41 chemicals were agreed. 58 Representatives from member countries and industry attended the meeting. The conclusions and recommendations for these chemicals were submitted for the Task Force on Existing Chemicals and to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for endorsement through written procedure, and are now publicly available from the HPV database [http://cs3-hq.oecd.org/scripts/hpv/]. Initial assessments for 147 chemicals under preparation for publication by UNEP are publicly available on the OECD web site [**http://www.oecd.org/env/existingchemicals/siars**]. Altogether, assessments for 398 chemicals have been published by UNEP [**http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html**], of which, 85 of the hazard assessment parts 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 198 IUCLID export files of previously-agreed SIDS Dossiers on the OECD public website: **http://www.oecd.org/document/55/0%2C2340%2Cen_2649_34379_31743223_1_1_1_1%2C00.html**.

eChemPortal, the Global Portal to Information on Chemical Substances was publicly launched in June 2007 [**http://www.oecd.org/ehs/eChemPortal**]. Since the last newsletter two additional databases / report collections have been added as participants: Canada's Existing Substances Assessment Repository (CESAR), maintained by Environment Canada in collaboration with Health Canada, and the Japan Existing Chemical Database (JECDB), managed by the Japanese Ministry of Health, Labour and Welfare.

The IUCLID User Group Expert Panel met in September 2008 at OECD headquarters in Paris. The meeting set priorities and discussed actions for moving forward the proposals submitted regarding the needs of users of IUCLID 5 software [see **http://iuclid.eu**], i.e. user interface and functionalities, additional training course materials and guidance documents. Stakeholders were particularly interested in developments which would facilitate the use of ICULID 5 as a tool to gather and submit data on properties of biocidal and pesticidal substances and products. The European Chemicals Agency, the owner the IUCLID 5 software, will consider the needs expressed by the Panel.

The Task Force on Existing Chemicals has been replaced by a Task Force on Hazard Assessment, whose mandate has a broader scope, including generic issues on all industrial chemicals, new and existing.

Forthcoming events:

- SIAM 28, 15-17 April 2009, Paris, France
- Ad hoc expert group meeting on OECD cooperation on the assessment of chemicals after 2010, 24-26 March 2009, Paris, France
- Task Force on Hazard Assessment, 26-27 March 2009, Paris, France

Contact: Bob Diderich, Anne Gourmelon, and Sally de Marcellus

Website: **http://www.oecd.org/env/existingchemicals**
http://www.oecd.org/env/existingchemicals/siars
http://www.oecd.org/env/hpvchemicals/globalportal

(QUANTITATIVE) STRUCTURE-ACTIVITY RELATIONSHIPS [(Q)SAR]

(Q)SARs are methods for estimating properties of a chemical from its molecular structure and have the potential to provide information on hazards of chemicals, while reducing time, monetary cost and animal testing currently needed. The OECD (Q)SAR Project is developing guidance material and a "Toolbox" for practical applications of (Q)SARs by governments and industry in specific regulatory contexts.

As part of the OECD activities to increase the regulatory acceptance of (Q)SAR methods, a *(Q)SAR Application Toolbox* is being developed as a means of making (Q)SAR technology readily accessible, transparent, and less demanding in terms of infrastructure costs. The Toolbox is being created in two phases. A first version was released in March 2008 and can be downloaded free of charge from the public OECD web site [**http://www.oecd.org/env/existingchemicals/qsar**]. With this proof-of-concept version, a user will be able to:

- Describe the structure of a chemical;
- Find out if a chemical is included in national/regional regulatory inventories or existing chemical categories;
- Search for available experimental results;
- Explore a chemical list for possible analogues;
- Group chemicals based on mechanism or mode of action or structural similarity;
- Group chemicals based on a common metabolite;
- Identify chemicals with anomalous metabolic pathways or toxicity mechanisms;
- Fill data gaps for chemicals in a category using read-across, trend analysis or (Q)SAR models; and
- Design a data matrix of a chemical category for printing/exporting results.

Furthermore, in September 2008, a set of training materials (slide shows and videos) was released which can be freely used for training users of the Toolbox. Among others, the material covers the following subjects:

- How to fill a data gap by qualitative read-across from an analogue based on similarity of mechanism of action;
- How to fill a data gap by qualitative read-across from an analogue based on similarity of structure;
- How to define a category by mechanistic properties, retrieve experimental data available for identified analogues, prune the analogues within the category belonging to different subcategories and fill data gaps by trend-analysis;
- How to build a chemical category and how to perform a preliminary evaluation of the category;
- How to evaluate an ad-hoc analogue approach;
- How to evaluate an ad-hoc category.

Furthermore, a guidance document on how to import additional experimental results into the Toolbox was published.

In December 2008, an improved version (1.1) was released. It contains additional databases with experimental results as well as additional sets of structural alerts to categorise chemicals.

A project for the development of a second version with extended functionalities has been launched in 2008, financed by the European Chemicals Agency. The actual work began in November 2008.

Recent publications:

- 🕮 Version 1.1 of the (Q)SAR Application Toolbox

- 🕮 Training materials for the use of the Toolbox

Contact: Michihiro Oi and Bob Diderich

Website: **http://www.oecd.org/env/existingchemicals/qsar**

EXPOSURE ASSESSMENT

Risk to human health and the environment posed by chemicals is determined by chemical-specific hazard properties and the extent of exposure to chemicals. OECD assists member countries in developing and harmonising methods for assessing such risk.

Emission Scenario Documents (ESDs) describe the sources, production processes, pathways and use patterns of chemicals with the aim of quantifying their emissions from production, formulation, use, service life and recovery/disposal into water, air, soil and/or solid waste. A number of projects to develop new ESDs and to enhance the use of ESDs are underway. The Task Force on Environmental Exposure Assessment met in October 2008 in Dessau, Germany. As an outcome of the work of the Task Force, a guidance document for writing ESDs was published in December 2008, and three ESDs are being processed for publication.

At the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, held in November, it was agreed to broaden the scope of the Task Force to include work on human exposure and to rename it a Task Force on Exposure Assessment. The new Task Force will meet in Paris in late 2009.

Forthcoming event:

- Meeting of the Task Force on Exposure Assessment, in the 4th quarter of 2009, Paris

Recent publications:

- 🕮 Complimenting Guideline for Writing Emission Scenarios Documents: The Life Cycle Step "Service Life"

Forthcoming publications:

- 🕮 New ESD on Adhesive Formulation
- 🕮 New ESD on the Formulation of Radiation Curable Coatings, Inks, and Adhesives
- 🕮 Revised ESD on Photo-resist Use in Semiconductor Manufacturing

Contact: Michihiro Oi

Website: **http://www.oecd.org/env/riskassessment**

HARMONIZATION OF CLASSIFICATION AND LABELLING

The Programme on Harmonisation of Classification and Labelling aims to harmonise the international classification of hazardous chemicals. Classification divides chemical substances and mixtures into different categories, based on their physical properties and health and environmental hazards. Chemicals are then labelled according to category requirements, the label indicating how the chemicals must be handled during transport, storage, use and in case of accident.

In July 2008, the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCEGHS) took note of an OECD Progress report on the work related to terrestrial environmental hazards, and of two OECD reports related to the validation of the Transformation/Dissolution Protocol for metals and metal compounds in aqueous media.

The UN SCEGHS also adopted the following OECD proposals with minor editorial changes, in December 2008:

- Proposal for revising GHS Chapter 3.4, *Respiratory or Skin Sensitization* concerning strong versus weak sensitizers
- Proposal for revising GHS Chapter 4.1, *Hazardous to the Aquatic Environment* with regard to the completion of the validation of the Transformation/Dissolution Protocol, and proposal for revising GHS Annex 10 related to the Transformation/Dissolution Protocol
- Proposal for revising GHS Annex 3 to insert a precautionary statement and codes for Ozone Depleting Chemicals

Recent publication:

- 🕮 Considerations regarding Applicability of the Guidance on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (Transformation/Dissolution Protocol), 2008

Contact: Laurence Musset

Website: **http://www.oecd.org/env/classify**

RISK MANAGEMENT AND SUSTAINABLE CHEMISTRY

The Risk Management Programme is concerned with the final step in chemical oversight: how to manage the use of chemical products so that society can take advantage of their benefits while minimising risks. It develops tools for OECD governments and facilitates information exchange about successful risk management approaches.

The latest update of the Hazard/Risk Information Sheets, which are on the OECD public website, was completed during the fourth quarter of 2008, and the updated Information Sheets were uploaded on the website in January 2009.

At the 42nd Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, the Secretariat outlined the progress made on Recommendation 2 from the 2006 Workshop on PFCAs and Precursors: "*the OECD and BIAC need to define a co-operative process of how to collect*

more reliable data in the OECD survey on PFCs" [ENV/JM/MONO(2007)11]. The results of two earlier surveys had demonstrated that the current survey mechanism is not capable of producing reliable data on production, import and use of perfluorinated chemicals (PFCs). The Joint Meeting agreed that the survey's scope should be revised to focus on the production of PFCs and emissions from point sources. A draft of a new survey questionnaire, including the substances to be surveyed, will be reviewed by the Joint Meeting during the second quarter of 2009. Australia will have the lead on this survey which is scheduled to be undertaken in mid-2009.

A Sustainable Chemistry Network was established in 2006 for information exchange, review of 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 an Internet Platform for information exchange, review of new developments and further elaboration of incentives for Sustainable Chemistry. The Platform was placed on the Sustainable Chemistry password protected website in January 2009 for test use purposes by the Joint Meeting (and its subsidiaries) and will be made public later in 2009.

The Secretariat (staff of the National Policies Division of the Environment Directorate) has started new work on the role of environmental legislation and innovation in promoting Sustainable Chemistry, as agreed by the 42nd Joint Meeting. The work started in November 2008 by exploiting a database of patents to find those related to Sustainable Chemistry. The aim is to submit to the 44th Joint Meeting 3-4 indicative areas of innovation within Sustainable Chemistry (*e.g.* bio-based polymers, solvents, fuel cells, nanotechnology, etc.) which can be used for the development of indicators. This work will contribute to the OECD Innovation Strategy.

Contact: Henrik Harjula

Website: **http://www.oecd.org/env/riskmanagement**

OTHER EHS PROGRAMMES

POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRS)

PRTRs are databases of selected pollutant releases to air, water and soil, and of wastes transferred off-site for treatment or disposal. The programme aims to help individual countries in developing PRTRs, improving release estimation techniques and wide sharing of data between countries.

Meetings of the Task Force

The Task Force on Pollutant Release and Transfer Registers (TF on PRTRs) met in March 2009. The following major work areas were discussed: i) Releases from products; ii) Establishment of a GIS application for the global portal to PRTR information; iii) Improving comparability of PRTR Data; and iv) Survey on the implementation of Recommendation C(96)41/Final.

The Task Force agreed in March 2008 on the continuation of the project on releases from products. This project is funded by the OECD and Nordic Council of Ministers, and carried out by the Finnish Environment Institute. The Nordic PRTR Group is overseeing the work and the final product *The Resource Compendium of PRTR Release Estimation Techniques, Part 4: Summary of Techniques for Products* will be completed by the end of 2009

The Task Force agreed to continue initiatives towards the development of a geographic application (GIS) for the PRTR.net. The first phase of the application is expected to be available by the end of 2009.

The TF agreed to undertake in 2009-2010 a feasibility study on "Improving Comparability of PRTR Data". A work programme of this work area was discussed at the TF meeting in March 2009. The study will be carried out in 2009-2010.

The previous report to Council on the implementation of the Recommendation [C(96)41/Final], as amended by [C(2003)87], was transmitted in 2007, based on a survey undertaken in 2006 [C(2007)21]. The TF agreed that the next survey will be carried out in 2009 and a report to Council be prepared in 2010.

Forthcoming event:

- 13th Meeting of the OECD Task Force on PRTRs, May 2010, Paris, France.

Contact: Henrik Harjula

Web site: **http://www.oecd.org/env/prtr**

PESTICIDES

The Pesticide Programme aims to harmonise the testing and assessment of agricultural pesticides and to promote work sharing and risk reduction. It achieves this by helping OECD countries to co-operate in the review of both chemical and biological pesticides used in Agriculture.

Development of Test Guidelines and Guidance Documents on Residue Chemistry

The US led pesticide residue project consists of three phases: Phase 1 – completed – in which five Test Guidelines (TG 501 to 505) and two Guidance Documents have been developed (*Guidance on the Definition of the Residue*; and *Guidance on Overview of Residue Chemistry Studies*); Phase 2 – completed - in which three Test Guidelines (TG 506 to 508) and two Guidance Documents (*Guidance on Pesticide Residue Analytical Methods* and *Guidance Document on Magnitude of Pesticide Residues in Processed Commodities)* have been published; and Phase 3 – initiated in 2007 – which focuses on the development of a Test Guideline, Guidance Document and Template for crop field trials, revisions of two existing GDs on definition of residue and overview of residue studies, as well as: (i) technical work to harmonise data development practices; (ii) consideration of crop extrapolation/representative crops; (iii) development of an approach for a statistical calculation of expected maximum residues from crop field trials; (iv) analysis of zoning; (v) identification of adequate residue data set; and (vi) critical Good Agricultural Practices (cGAP).

Development of Guidance Notes on the Analysis and Evaluation of Dermal Absorption Studies

An Australian-led Expert Group established in 2005 is developing guidance on the analysis and evaluation of dermal absorption studies for use in the risk assessment of pesticides as well as industrial chemicals, biocides and agricultural veterinary products. In May 2008, a new version of the *Guidance Notes for the Estimation of Dermal Absorption Values* was circulated for a broad review to member countries' experts through the WGP (Working Group on Pesticides) and WNT (Working Group of National Co-ordinators on Test Guidelines). The document is currently being revised, and a draft will be provided to the Working Group on Pesticides for consideration during its June 2009 meeting.

Biological Pesticides

The *Working Document on the Evaluation of Microbials for Pest Control* was published on in December, 2008 [ENV/JM/MONO(2008)36]. The document describes the views of different OECD countries on how they address certain scientific issues in the safety evaluation of microbial pest control products. These areas include: taxonomy; genetic toxicity; operator and consumer exposure; residues in treated food crops; and efficacy evaluation. The publication is intended to be used as guidance in the safety assessment of microbials, and the preparation and evaluation of the dossiers and monographs for microbial pest control products.

A workshop on the Regulation of Biopesticides: Registration and Communication was held in Washington, DC in April 2008. The objectives of the workshop were to: (i) resolve science issues and harmonise approaches for risk assessment/evaluations associated with the registration of biopesticides; (ii) improve communication and information exchange between regulators and industry; and (iii) consider and prepare a follow-up to some of the conclusions and recommendations of the European REBECA project (Regulation of Biological Control Agents). The report of the workshop will be published in mid-2009.

Development of guidance on the evaluation of persistent, bioaccumulative and toxic (PBT) pesticides

Work has begun on a new project to develop (i) guidance on key definitions and environmental risk assessment issues (Phase 1); and (ii) guidance for assessing environmental risk of PBT pesticides (Phase 2). An Expert Group (PBTEG) has been established to conduct the work; it is composed of experts from: Australia, Canada, Germany, the Netherlands, the United Kingdom, the United States (project lead), and UNEP. The PBTEG met in November 2008, at OECD in Paris to define the elements of the Phase 1 document, and identify additional background material needed.

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

A new project has been initiated to develop: (i) guidance for terrestrial field dissipation studies (US lead); and (ii) a crosswalk for North American and European ecoregions (Canada lead). The development of terrestrial field dissipation study guidance involves: a collection of North American and European field dissipation studies guidance documents; establishment of criteria for determining similarity, and comparison of existing guidance; and development of a first draft comparison document. The development of a crosswalk between North American and European ecoregions will consist of a pilot analysis of two case studies and construction of an ecoregion crosswalk, including identification of European ecoregion, determination of similarity to North American ecoregion, and development of an ecoregion crosswalk guidance document.

Minor Uses of Pesticides

Following its first meeting in June 2008, the new Expert Group on Minor Uses (EGMU) that reports to the Registration Steering Group (RSG), has started to implement the activities in its work plan. All activities are linked to the ultimate goal of assisting countries/registrants/growers solve their minor use problems through activities associated with baseline information, collaborative data generation, joint reviews and data sharing. The long-term objective is the development of a guidance document for solving minor use data gaps. Another activity, which might become part of an overall guidance document, is the preparation of guidance on "defining minor uses". The goal is not to have one OECD definition, but rather to help countries set their own on the basis of current practices and provided that some critical elements are included. In the first half of 2009, the EGMU will also be carrying out a two-part survey, on both "efficacy and crop safety data requirements for minor use registration" and "regulatory incentives for the registration of minor uses". Finally, the EGMU is ensuring good coordination with the recently established Codex Electronic Working Group on Minor Uses. Australia, chair of the EGMU, and also vice-Chair of the Codex EWG, as well as other countries are active in both international fora. The EGMU will review all these issues at its second face-to-face meeting, on 26 June, 2009 in Paris.

Risk Reduction

The Risk Reduction Steering Group is continuing to organise seminars on issues of interest and concern to OECD governments. Following the June 2008 Seminar on Reducing Pesticide Risks through Spray Drift Reduction Strategies, a new Network of Experts on Spray Drift, chaired by US EPA, was established. One of its first activities will be to set up a public website to share information about, and experience with, spray drift technical and regulatory aspects. In late February 2009, another Risk Reduction Seminar on Aerial Application was held in San Francisco, preceded by a one-day field trip that will illustrate issues associated with aerial application.

Other Risk Reduction activities include:

- A survey on education, training and certification of pesticide users and trainers will be carried out in the first half of 2009. This is a follow-up activity to two previous Risk Reduction Seminars on "better worker safety and training" and on "education and training the trainers".

- A new activity to address pesticide counterfeiting and illegal trade might start in 2009, with a short survey initiated by the pesticide industry, CropLife International, to assess understanding, determine issues and identify stakeholders.

Support of Joint Reviews/Work Sharing

A workshop on *Lessons Learned with the Planning and Implementation of Joint Reviews of Pesticides Dossiers*, was held in Bonn, Germany in December, 2008, hosted by the German Ministry of Food, Agriculture and Consumer Protection. Approximately 85 participants from 13 countries (including Brazil and Kenya), UNEP and BIAC attended the workshop. The objectives of the workshop were to review the processes followed by, and outcomes from, joint reviews – in which two or more governments share the work to review a pesticide dossier – that have been carried out to date. In particular, it focused on assessing what went according to plan, what did not, and identifying hurdles that hindered the efficient completion of the joint reviews. The workshop participants made a number of recommendations, which were considered at the meeting of the Registration Steering Group in February, 2009 in San Francisco, US.

Expert Group on the Electronic Exchange of Pesticides Data

One of the main recommendations from the Expert Group Meeting on the Electronic Exchange of Pesticides Data that was held in the US, in April, 2008, was the establishment of an *ad hoc* Expert Group which would implement the recommendations from the meeting, as well as initiate new work which would facilitate the electronic exchange of pesticides data. A "transport" subgroup has been formed to manage the development of a universal "overall" XML schema for the organization of all data files in a pesticide dossier and monograph. "Transport" systems, for pesticides, are IT tools for submitting all the required dossier information for registering a pesticide in an electronic format and for archiving and managing such information. These systems are designed for handling large numbers of documents and for exchanging such documents. Transport-systems are already in use in some countries (e.g., CADDY XML in the EU and e-PRS in Canada) or currently under development (e.g., PRISM in the US). To complement this work, and ensure a common understanding of terminology, the subgroup is developing a data dictionary. The subgroup is also developing an "XML converter" which would render an XML file, submitted in compliance with OECD templates/schema and schematron, into a Word document.

Forthcoming events:

- Expert Group Meeting on Minor Uses meeting, 26 June, 2009, Paris
- Working Group on Pesticides, 29-30 June, 2009, Paris
- BioPesticides Steering Group Meeting (and Seminar), Paris, France 1-3 July, 2009
- Registration Steering Group and Risk Reduction Steering Group meetings; 16-20 November, 2009 Japan

Recent publications:

- 🕮 Working Document on the Evaluation of Microbials for Pest Control (No 43 in the Series on Pesticides)
- 🕮 Test Guideline No. 508, and related Guidance Document, on the Magnitude of the Pesticide Residues in Processed Commodities

Forthcoming publications:

- 🕮 Report of the Seminar on Risk Reduction through Spray Drift Reduction Strategies as part of National Risk Management
- 🕮 Report of the Seminar on Risk Reduction through Education/Training the Trainers
- 🕮 Guidance Document on the Planning and Implementation of Joint Reviews
- 🕮 Report of the Workshop on the Regulation of Biopesticides: Registration and Communication

Contact: Richard Sigman and Marie-Chantal Huet

Website: **http://www.oecd.org/env/pesticides**

BIOCIDES

Work on Biocides (non-agricultural pesticides) closely parallels the work on agricultural pesticides: harmonisation of testing of product release rates to the environment and efficacy to ensure the validity of label claims, producing emission scenarios and promoting sharing of information about risk reduction approaches.

Efficacy

OECD's Biocides Programme is currently developing test methods for the generation of efficacy data for public health antimicrobial biocides (i.e. disinfectants) used on hard surfaces as there are currently no universally accepted test methods for assessing efficacy of these public health-related antimicrobials. A Validation Management Group (VMG) has been formed to validate five different draft test methods that could be used to determine if new biocide products that will be used on hard surfaces (e.g., hospital tables), are effective against a significant number of bacteria, viruses, fungi, spores and mycobateria. The VMG met for the first time in 2006 to design the validation study comprised of round-robin testing amongst over 20 laboratories. The ring trials are scheduled to be completed in the first part of 2009 and the validation report in late 2009.

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 is about to begin.

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

Wood Preservatives

The emissions from preservative (i.e., biocide) treated wood to the environment need to be quantified to enable an environmental risk assessment of the treated wood. A new Test Guideline that describes a laboratory method for the estimation of emissions from preservative treated wood in contact with fresh water or sea water was published in October 2007. A separate Guidance Document for measuring leaching of biocides from wood not covered and not in contact with the ground is nearing completion.

Human exposure

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

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 will begin soon.

Forthcoming event:

- Seventh Meeting of the Task Force on Biocides, 19-21 October 2009

Recent publications:

- 🕮 Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses
- 🕮 Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects

Forthcoming publications:

- 🕮 Human Exposure Study Design – Factors, Orthogonal Experiments and Probabilistic Modelling
- 🕮 Guidance Document for Demonstrating Efficacy of Pool and Spas Disinfectants

Contact: Richard Sigman and Sylvie Poret

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

CHEMICAL ACCIDENTS

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

Review of Implementation of the Council Recommendation Concerning Chemical Accident Prevention, Preparedness and Response [C(2003)221]

The report on the review of implementation of the Council Recommendation approved by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology and the Environment Policy Committee (EPOC), was declassified by the Council in October 2008.

Safety Performance Indicators (SPI)

The US-led project on the revision of the 2003 OECD *Guidance on Safety Performance Indicators* is completed. There are two Guidance Documents on Developing Safety Performance Indicators: one for Industry and one for Public Authorities and Communities/Public. They were published in September 2008.

A joint EU-OECD Seminar on Safety Performance Indicators took place in October 2008 in Bordeaux, France. This event was sponsored and hosted by the French Ministry for Ecology, Energy, Sustainable Development and Spatial Planning (MEEDDAT). The Seminar followed the 18th Meeting of the OECD Working Group on Chemical Accidents (WGCA), and preceded the 20th Meeting of the Seveso-Committee of Competent Authorities (CCA), in the context of the French presidency of the European Union.

New Projects

The Working Grouop on Chemical Accidents (WGCA) will begin the following new projects: (a) development of addenda to the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (started); (b) development of safety practices related to the storage of fireworks in the context of land use planning; (c) the role of corporate leadership in preventing chemical accidents; (d) control of the impact of natural hazards on chemical installations (started); (e) safety and security related to explosives and precursors for explosives; (f) risk and regulation of carbon capture and storage (to be initiated mid-2009); (g) review of siting policies and sites for new import/export/storage for liquefied natural gas; and (h) analysis of H_2S-poisonning incidents.

Forthcoming Events:

- 19th Meeting of the Working Group on Chemical Accidents (WGCA), 7-8 October 2009, OECD, Paris

Recent publications:

- 🕮 Report of Survey on the Use of Safety Documents in the Control of Major Accident Hazards (series on Chemical Accidents, No. 17, 2008)
- 🕮 Guidance on Developing Safety Performance Indicators for Public Authorities and Communities/ Public (series on Chemical Accidents, No. 18, 2008)
- 🕮 Guidance on Developing Safety Performance Indicators for Industry (series on Chemical Accidents, No. 19, 2008)
- 🕮 Report of Workshop on Human Factors in Chemical Accidents and Incidents (series on Chemical Accidents, No. 20, 2008)
- 🕮 Report of Workshop on Safety in Marshalling Yards (series on Chemical Accidents, No. 21, 2008)

Forthcoming publications:

- 🕮 Addendum to OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (end of 2009)

Contact: Marie-Chantal Huet

Website: **http://www.oecd.org/env/accidents**

HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The main focus of the programme on Harmonisation of Regulatory Oversight in Biotechnology is on environmental risk/safety assessment of transgenic (genetically modified) crops. The work aims to ensure that the information used in risk/safety assessment, as well as the methods used to collect such information, is as similar as possible among countries. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort. It also reduces barriers to trade.

The 22nd meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held in Paris in February 2009. Participants included, as usual, delegates from non-member countries (Argentina, Brazil, Chile, China, India, Philippines, and the Russian Federation).

Major progress was seen in the project on *Low Level Presence (LLP)* of transgenic seeds in conventional bulk shipments of crops. This topic was first proposed as a potential project at the 19th meeting by BIAC and has been discussed in the subsequent regular meetings and a special meeting held in April 2008. At the special meeting, no agreement was reached on the feasibility of a project, but a number of potential

approaches were refined for consideration by the Working Group. At the 21st meeting, although an approach to the potential project was not decided, it was agreed that this issue should be considered further. At the 22nd meeting, the Working Group discussed a draft project outline proposal prepared by its Bureau. Among other things, the format for future information sharing on LLP was intensively discussed. The Working Group will consider how to annotate questionnaires for collecting experiences related to LLP and the proposed project outline at its next meeting.

Important progress was also made in the project on *Molecular Characterisation of Plants Derived from Modern Biotechnology*, developed jointly with the Task Force for the Safety of Novel Foods and Feeds. A revised draft Consensus Document, prepared by a Steering Group, was discussed in a joint session with the Task Force in February 2009. Some delegations proposed that the text could be more comprehensive by covering also other techniques and topics. A new version based on comments from delegations will be prepared for discussion by the next meetings of the Working Group and Task Force.

The project on *Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants* took a significant step. A face-to-face meeting of the Steering Group was held in February 2009 to discuss coverage and language of a new annotated outline to make the document more useful and less ambiguous for users involved in environmental risk/safety assessment. The lead country, Canada, will revise the draft based on comments by the Steering Group for future discussions.

The 22nd meeting also agreed to forward the *Consensus Document on the Biology of Banana and Plantain* for declassification, pending no major adverse comments after final review of the current draft. In addition, it was agreed that the draft *Consensus Document on the Biology of Cucurbita spp.* will be considered for declassification at the next meeting.

Forthcoming events:

- 23rd meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, 19-21 October 2009, OECD Headquarters, Paris

Recent Publications:

- 🕮 Consensus Document on the Biology of Douglas-Fir
- 🕮 Consensus Document on the Biology of Western White Pine *(revises/replaces the 2006 issue)*
- 🕮 Consensus Document on the Biology of Lodgepole Pine
- 🕮 Consensus Document on the Biology of Cotton
- 🕮 Consensus Document on Information Used in the Assessment of Environmental Applications involving *Acinetobacter*
- 🕮 Guide for Preparation of Biology Consensus Documents

Forthcoming Publications:

- 🕮 Guidance Document on Horizontal Gene Transfer between Bacteria

Contact: Yukihiko Fukase, Peter Kearns, Bertrand Dagallier

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

SAFETY OF NOVEL FOODS AND FEEDS

The programme on the Safety of Novel Foods and Feeds addresses risk/safety assessment issues, mainly related to the products of modern biotechnology, that is, foods and feeds derived from transgenic crops. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort, while reducing barriers to trade.

Consensus Documents

The Consensus Documents on compositional considerations of specific food/feed crops constitute the main outputs of the programme. They compile a common base of scientific information on the major components of crop plants, such as key nutrients, toxicants, anti-nutrients and allergens that may be useful in assessing the safety of new (genetically engineered) varieties with respect to human food and animal feed safety. These documents are highly valued because they are agreed through consensus by member countries and other stakeholders.

To date 15 Consensus Documents have been published, the latest one on *Tomato* issued in October 2008. As agreed at the 15th meeting of the Task Force for the Safety of Novel Foods and Feeds held in February 2009, publications on *Cassava* and *Sweet Potato* will follow during the coming months, while work is continuing on Papaya, Grain Sorghum and Sugarcane. In addition, the process for revising consensus documents which have been previously published was launched for the two earliest ones, Low Erucic Acid Rapeseed (Canola) (2001) and Soybean (2001).

Outreach and engagement with non member economies

The Task Force continues to involve actively key non member economies because modern biotechnology is an increasingly global issue, including in tropical areas. For example Argentina, Brazil, Chile, China, Latvia, Russian Federation and Thailand participated in the 15th meeting of the Task Force (February 2009).

The participation of non members' has been possible, up until now, through the Global Forum on the Knowledge-based Economy, under the auspices of OECD's Centre for Co-operation with Non-Member Economies. The future framework for this participation is expected to be a *Global Forum on Biotechnology*, which will be undertaken in co-operation with the Working Group on Harmonisation in Biotechnology.

In order to broaden the available expertise, the Task Force activities are developed in collaboration with international agricultural research organisations such as CIAT Columbia, IITA Nigeria, as well as more recently, the International Life Sciences Institute (ILSI). The Codex Alimentarius Commission, the FAO; the World Health Organization (WHO); and the Business and Industry Advisory Committee to OECD (BIAC) are also involved in the Task Force.

Other activities on the risk/safety assessment of modern biotechnology

The Task Force complements the activities of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, which addresses environmental safety issues associated with genetically modified crops. A joint project on *Molecular Characterisation of Plants derived from Modern Biotechnology* is being developed (see the section above).

The interoperability of FAO and OECD databases regarding the information related to food safety assessment will be reassessed in the coming months for possible improvement. By this arrangement, the OECD Product Database can exchange data with the FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH). This includes information such as unique identifiers, common and scientific names of host organisms, events and introduced genes. The project was developed in response to a request from the Codex ad hoc Task Force on Food Derived from Biotechnology.

At its 15th meeting, the Task Force opened discussions on a proposal for revising or adapting the OECD Test Guideline 408 (90-day toxicity study) to apply to whole foods, and on improvements of the quality of data used for the Consensus Documents.

Future events:

- 16th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 17-19 November 2009.

Recent Publication:

- 🕮 Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Anti-Nutrients and Allergens

Upcoming Publications:

- 🕮 Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-Nutrients, Toxicants and Allergens
- 🕮 Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [*Ipomoea batatas* (L.) Lam.]: Key Food and Feed Nutrients, Anti-Nutrients, Toxicants and Allergens

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

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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 work on the safety of manufactured nanomaterials is to assist countries in developing tools to allow them to better address the human health and environmental safety implications of these materials.

The 5th meeting of the Working Party on Manufactured Nanomaterials (WPMN) was held on in March 2009. The 5th WPMN followed a two-day meeting of its "Sponsorship Programme" where those delegations who are testing manufactured nanomaterials (see project 3 below) reviewed their dossier development plans (DDPs) for the testing programme. As a result of the 5th WPMN, significant progress was made on the eight projects included in its programme of work. The current status of each of these projects is summarised below.

Project 1: Development of an OECD Database on Human Health and Environmental Safety Research

This database holds details of completed, current and planned research on the safety of manufactured nanomaterials. During the last few months, delegations have been populating the database with information from national research programmes. It was agreed that the database will be made publicly available on 1st April 2009. The link to access the database will be provided through the OECD website (www.oecd.org/env/nanosafety).

Project 2: Research Strategies on Manufactured Nanomaterials

This project aims at developing a research strategy(ies) for safety issues related to manufactured nanomaterials. To date, it has reviewed current national research programmes and identified research themes

which already have wide coverage ("hot spots") and those which are less well covered ("gaps"). This project will move forward in close collaboration with Project 1 when the database is publicly available.

Project 3: The "Sponsorship Programme" - Safety Testing of a Representative Set of Manufactured Nanomaterials

This project was launched in November 2007 when delegations agreed to fund and manage the testing of 14 nanomaterials for 59 endpoints relevant to human health and environmental safety. Since that time, delegations have been "signing up" to this work. By the end of WPMN5, 15 member countries, the EC, the Nordic Council of Ministers, China and BIAC have committed to this programme as either "sponsors", "co-sponsors" or "contributors". A summary of the latest arrangements is found on the OECD web site.

During the meeting, it was possible to review and comment on "Dossier Development Plans (DDPs)" for ten of these nanomaterials. Amongst other things, these DDPs identify for each nanomaterial, who is doing the testing as well as when and where. They also explain which test methods will be used for specific endpoints. It was noted that work has already begun on the testing of some of these nanomaterials, notably, fullerenes, single-wall carbon nanotubes and multi-wall carbon nanotubes.

As part of the "sponsorship" programme, a drafting group had prepared a "*Guidance Manual for Sponsors*" which is intended to assist sponsors in their testing work. (It is also intended to be of more general value for other stakeholders who are working on the testing of nanomaterials but not necessarily engaged in the OECD work). The WPMN recommended that this "*Guidance Manual*" be declassified. At the same time, it noted that subsequent versions of this *Manual* may be needed in light of the experience gained with the sponsorship programme.

The work on the "sponsorship programme" was facilitated by a Workshop hosted by the Korean delegation in Busan, Korea, in November, 2008.

Project 4: Manufactured Nanomaterials and Test Guidelines

The WPMN has undertaken a *Preliminary Review* of 115 OECD test guidelines (designed for the safety assessment of chemicals) to assess whether or not they are suitable for nanomaterials. This review also benefited from input from the WNT (Working Group of National Coordinators of the Test Guidelines Programme). It addresses Guidelines related to: i) physical chemical properties; ii) effects on biotic systems; iii) degradation and accumulation; and iv) health effects. It was agreed that this review will be forwarded to the Chemicals Committee for declassification.

A key finding of the work done during this *Review* was the need, as a high priority, to prepare *Guidance on Sample Preparation and Dosimetry* This is because nanomaterials have distinct properties which may be affected by the test medium in which they are used. WPMN5 reviewed the first draft of such a *Guidance* document and recommended that it be forwarded to the WNT for input from that body.

The WPMN also reviewed the first draft of a document on *Non-inhalation Exposure Methods for Studies on the Pulmonary Toxicology of Nanoparticles*. It was agreed that this document be subject to a further round of comments.

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

This project has analysed national information gathering programmes, whether voluntary or part of an existing regulatory framework, to assess the safety of manufactured nanomaterials. This project has: i) identified common elements to these initiatives; ii) prepared recommendations on approaches and elements to consider for information gathering initiatives; iii) identified current and proposed regulatory regimes and how they address information requirements; and iv) prepared a Questionnaire on Regulatory Regimes for Manufactured Nanomaterials, to identify various components of regulatory regimes which are or may be applicable to nanomaterials.

Project 6: Co-operation on Risk Assessment

The 5th WPMN agreed to hold a workshop on risk assessment of manufactured nanomaterials in a regulatory context in September/ October 2009. The Steering Group for this project will organise this workshop in co-ordination with BIAC. The workshop is expected to provide substantial inputs to a report drafted as a result of this project in 2008, entitled *Critical Issues in the Risk Assessment of Manufactured Nanomaterials* which is expected to be declassified as a result of input from the workshop.

Project 7: The Role of Alternative Methods in Nanotoxicology

This project was initiated relatively recently. It is looking into alternative test methods and will analyse how they might be used in an overall assessment plan for hazard testing of manufactured nanomaterials. This activity is closely related to that of project 3. A meeting of Steering Group 7 was held in September 2008, in Paris.

Project 8: Exposure Measurement and Exposure Mitigation

In the early stages of this work, the focus has been on the analysis of national guidance documents for exposure measurement and exposure mitigation. The aim has been to consider the merit of such documentation when considering nanomaterials in occupational settings. For example, work has been underway to consider recommendations on measurement techniques and sampling protocols for inhalation and dermal exposures in the workplace. A "face-to-face" meeting of Steering Group 8 was held in Frankfurt, Germany in October 2008, back-to-back with an OECD Workshop on Exposure Assessment and Exposure Mitigation.

- 🕮 The WPMN5 recommended the declassification of four documents resulting from this work (see below). It also agreed that this activity should be extended to consumer and environmental exposure.

OECD Conference on Potential Environmental Benefits of Nanotechnology

- 🕮 An OECD Conference on the Potential Environmental Benefits of Nanotechnology is being organised jointly with OECD's Directorate for Science Technology and Industry and delegates to the Working Party on Nanotechnology (WPN), a subsidiary body of OECD's Committee for Science and Technology Policy. This event will take place 15-17 July 2009 in OECD's Conference Centre. Amongst other things, the Conference will address applications of nanotechnology with the potential to reduce pollution, contribute to cleaner production and remediation.

Programme on the Safety of Manufactured Nanomaterials: A Road Map

- 🕮 The Programme on the Safety of Manufactured Nanomaterials has multiple activities and events associated with it. For this reason, the 5th meeting of the WPMN began work on a "road map" which will identify the expected outputs and events during (primarily) the coming two years. This document will be finalised for the next meeting of the Chemicals Committee (June 2009).

Forthcoming events:

- Nano Safety Conference, 22-24 April, 2009, Ljubljana, Slovenia
- Conference on the Potential Environmental Benefits of Nanotechnology, 15-17 July, 2009, OECD Headquarters, Paris
- 6th Meeting of the Working Party on Manufactured Nanomaterials, 28-30 October 2009, OECD Headquarters, Paris

Recent Publications:

- Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 4th Meeting of the Working Party on Manufactured Nanomaterials (2008) [**http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)7**]

Upcoming Publications:

- Preliminary Review of OECD Test Guidelines for Applicability to Nanomaterials
- Analysis of Information Gathering Initiatives: Manufactured Nanomaterials
- EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs
- Table of Comparison on Information Gathering Schemes: Manufactured Nanomaterials
- Report of the Workshop on Exposure Assessment and Exposure Mitigation
- Identification and Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation
- Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance
- Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Nanotechnology Workplace
- Sponsorship Programme for Testing Manufactured Nanomaterials: Guidance Manual for Sponsors
- Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 5th Meeting of the Working Party on Manufactured Nanomaterials (2009)

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CROSS-CUTTING ISSUES

Assessing the Scale and Drivers of Innovation within Sustainable Chemistry

Increased attention is being given to the role of environmental management and technological innovation in addressing environmental challenges, such as air emissions, waste water discharges, solid waste generation and climate change. Recent work in the OECD Environment Directorate indicates that the drivers of pro-active corporate environmental strategies may vary by sector. In order to explore these issues in depth, new work has been launched on technological innovation for Sustainable Chemistry (2008-2010). This work will have three elements: i) analysis of the drivers of environmental management and performance within industrial sectors involved in the manufacture of chemicals and chemical products; ii) development of indicators of eco-innovation (representative areas) for Sustainable Chemistry; and iii) assessment of the relative importance of public policy and other factors in encouraging eco-innovation with respect to Sustainable Chemistry. This work will contribute to the development of the OECD Innovation Strategy, which will be discussed by the ministerial Council Meeting (MCM) in 2010.

Templates for New and Existing Industrial Chemicals, Pesticides and Biocides

OECD initiated a project in 2005 to develop harmonised "templates," or standard formats for reporting summaries of the results of tests on all types of chemicals (e.g., pesticides, biocides, and industrial chemicals). The templates are aimed at developers of database systems as they prescribe the formats by which such information can be entered into and maintained in databases. By using these templates, governments and industry will easily be able to electronically exchange test study summary information. In 2006, OECD adopted 87 templates for reporting summary information of the results from tests on chemicals for toxicology, eco-toxicology and physical/chemical properties. The templates were posted on OECD's

public website. In 2008, five new templates associated with Test Guidelines for residue chemistry were adopted.

In order for information technology developers to build data entry screens and/or database systems based on the OECD templates which can generate data files that can be imported into other database systems, each template has to have a corresponding XML schema. (i.e., a common electronic data export/import format). In 2007, XML schemas for the original 87 templates were posted on the public web site, and drafts schema have now been prepared for the latest five templates. A guidance document has also been developed to assist lead countries prepare new, or revise existing templates.

Contact: Richard Sigman and Nathalie Delrue

Website: **http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.htm**

INTERNET

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

EHS Homepage	**http://www.oecd.org/ehs/**
Biocides	**http://www.oecd.org/env/biocides**
Biosafety	**http://www.oecd.org/biotrack**
Chemical Accidents	**http://www.oecd.org/env/accidents**
Existing Chemicals	**http://www.oecd.org/env/existingchemicals**
Existing Chemicals Pointer Database	**http://www.oecd.org/ehs/exichem**
Global Portal to Information on Chemical Substances	**http://www.oecd.org/ehs/eChemPortal**
Good Laboratory Practice	**http://www.oecd.org/env/glp**
Harmonisation and Classification of Labelling	**http://www.oecd.org/env/classify**
New Chemicals	**http://www.oecd.org/env/newchemicals**
Pesticides	**http://www.oecd.org/env/pesticides**
Pollutant Release and Transfer Registers	**http://www.oecd.org/env/prtr**
Risk Assessment	**http://www.oecd.org/env/riskassessment**
Risk Management	**http://www.oecd.org/env/riskmanagement**
Safety of Manufactured Nanomaterials	**http://www.oecd.org/env/nanosafety**
Strategic Approach to International Chemicals Management	**http://www.oecd.org/env/saicm**
Test Guidelines	**http://www.oecd.org/env/testguidelines**

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

http://www.oecd.org/findDocument/0%2C2350%2Cen_2649_34365_1_1_1_1_1%2C00.html

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