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Introduction

The Environment, Health and Safety News is issued approximately every eight months, between Joint Meetings. 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. 17, issued in April 2005), the EHS Division has seen the following changes in staffing:

Front Office: *Barbara Ladeuille* has returned from her temporary assignment. In addition to her usual tasks, she is also working on administrative issues.

Biotechnology, Food Safety*: Jill Gibb* (on temporary assignment) is replaced by *Diana Morales* (part-time).

GLP, Existing Chemicals: *Valerie Darling* left OECD at the end of June 2005.

New Chemicals, Risk Management, PRTRs:: *Jacy McGaw* left OECD at the end of October. *Jenny Griffin* is providing secretarial support to these work areas and to Existing Chemicals. However, Jenny is currently absent on a temporary assignment, and during this time *Judith Corcoran* replaces her.

Pesticides and Biocides**:** *Kumi Kitamori* is on temporary assignment in the General Secretariat until May 2006. *Jeong-Won Park* is replacing her. *Katherine Perkins* is providing secretarial support to both programmes and to the GLP Programme.

Test Guidelines*: Jukka Ahtiainen* is seconded to the Test Guidelines Programme from the Finnish Environment Institute for November and December 2005. He is specifically working on the preparation of meetings in relation to Endocrine Disrupters and Ecotoxicity.

IT and Publications: during Sally Demarcellus' absence on temporary assignment, Jill Gibb is replacing her.

TEST GUIDELINES

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

General

The following draft new and updated Test Guidelines and draft guidance documents for the testing of chemicals, which were approved by the 17th Meeting of the National Co-ordinators of the Test Guidelines Programme (WNT) in April 2005, are in the process of endorsement, by written procedure, by the Joint Meeting. The draft Test Guidelines will be translated into French and will undergo final editing in both English and French to ensure consistency, prior to being sent via EPOC to Council in early 2006. Joint Meeting Approval will also be sought for the declassification of the OECD Document 'Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application'.

Draft New Test Guidelines:

- 227 Vegetative Vigour Test
- 435 In Vitro Membrane Barrier Test Method for Skin Corrosion

Draft Updated Test Guidelines:

- 208 Seedling Emergence and Seedling Growth test

Draft New Guidance Documents:

- GD34 on Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
- Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms)
- Draft Document
- Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application.

Deletion of Test Guidelines:

- TG302D: Inherent Biodegradability – CONCAWE Test

Effects on Biotic Systems

Member countries have been invited to participate in a ring-test, organised by Sweden and Denmark, on the copepod development and reproduction test, which is planned for between December 2005 and June 2006. Similarly, Japan is planning a ring-test on an enhanced version of the Daphnia reproduction test (TG 211) for the detection of endocrine active substances. Member countries will be invited to participate following discussions on this project at the Invertebrate Expert Meeting, held in OECD in Paris on 3-4 November. A draft Test Guideline on the breakdown of organic matter in litterbags was circulated for comments in September; the deadline for comment is the end of December. The scope of testing is mainly for pesticides, thus the Working Group on Pesticides is also involved in the commenting process.

Health Effects

An Expert consultation meeting will be held in Germany in February 2006 to progress the development of the acute toxic class and fixed-dose procedure inhalation toxicity Test Guidelines, which are being developed as alternatives to the existing LD50 acute inhalation Test Guideline 403.

An Expert Consultation was held in Japan in May 2005 to progress Test Guideline 426 on developmental neurotoxicity. In a related activity, an Expert Consultation was held in Paris in October 2005 to finalise the Guidance Document on reproductive toxicity testing and assessment (GD43). It is anticipated that these documents will be finalised in 2006.

Toxicokinetics

Activity on the revision of TG417 on Toxicokinetics has recommenced, under the lead of the USA. An Expert Group is being formed to proceed with the revision of this Test Guideline.

Special Activity on Endocrine Disrupters

The Validation Management Group – Non Animal (VMG-NA), which identifies or proposes validated or promising non-animal assays for endocrine chemicals testing and provides tools necessary for Level 1 and 2 activities of the EDTA Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals, will meet in Paris on 14-15 December 2005. The VMG-NA has established an Endocrine Disrupter Task Group on (Quantitative) Structure Activity Relationships [(Q)SAR] to provide expert input relating to non-animal and alternative test methods to the projects that are being conducted under the auspices of the Ad Hoc Group on (Q)SARs.

The Validation Management Group – Ecotoxicology (VMG-eco) meets in Paris on 12-13 December 2005. The main issue for discussion at the meeting is the validation status and scope of the 21-day fish screening assay. Negative substances have been tested; the results will be discussed at the meeting. Based on existing information, the objective of the meeting is a common understanding on the status of gonad histopathology and fecundity in this assay. A status report will be presented for other tests currently under validation.

The ninth meeting of the OECD Taskforce on Endocrine Disrupters Testing and Assessment (EDTA-9) is being planned, tentatively for late March or early April 2006. Issues expected to be discussed at the EDTA-9 include progress with the Hershberger assay, uterotrophic assay and enhanced test Guideline 407, along with the 21-day fish screening assay and the amphibian metamorphosis assay. A revised draft Peer Review Panel (PRP) report for the validation of the uterotrophic assay was circulated to Panel members in October 2005 and the report should be finalised before the end of the 2005 calendar year. The validation for the Hershberger bioassay covering androgen and anti-androgen screening, using coded positive and negative substances, has been delayed and is awaiting data from some of the participating laboratories. Completion is expected in mid-2006. The preparation of the report on the validation of the enhanced 28-day repeat dose assay for endocrine active substances in rodents (enhanced Test Guideline 407) is also underway.

Refocus of the Test Guidelines Programme

The 17th meeting of the Working Group of the National Coordinators of the Test Guideline Programme (WNT) in April 2005 discussed the desired focus and priorities of the Test Guidelines Programme (TGP), including the impact of validation and peer review on some areas of Test Guideline development, the prioritization and management of projects on the TGP rolling workplan, and the processes involved in the production and revision of Test Guidelines. A number of recommendations were made by the WNT and were considered, in the form of a policy paper on the future direction of the Test Guidelines Programme, at the 38th Joint Meeting in June 2005. As a consequence of those Joint Meeting considerations, the Guidance Document for the Development of OECD Guidelines for Testing of Chemicals (Guidance Document 1) and the Standard Project Submission Form (SPSF) have been substantially redrafted, and will be the subject of a Special Meeting of the WNT in late November 2005. The rolling workplan for the TGP for 2006-08 will also be finalised at this meeting. The changes proposed in GD1 are intended to simplify and streamline the process for new project proposals and assist National Coordinators in defining the scope of new projects for efficiency purposes. It is expected that the proposed changes will facilitate the development of harmonised OECD Test Guidelines. The revised GD1 is expected to be completed in time for the WNT18 in May 2006 in Berne, Switzerland.

Forthcoming events:

- Special Meeting of the Working Group of the National Coordinators of the Test Guidelines
- Programme (WNT), Paris, 28-29 November 2005
- 4th Meeting of the Validation Management Group for Ecotoxicity Testing, OECD, Paris, 12-13 December 2005
- 3rd Meeting of the Validation Management Group for Non Animal Tests, OECD, Paris, 14-15 December 2005

- 18th Meeting of the Working Group of the National Coordinators of the Test Guidelines
- Programme (WNT18), Berne, Switzerland, 16-18 May 2006

(Quantitative) Structure-Activity Relationships

The OECD Principles for the Validation, for Regulatory Purposes, of (Quantitative) Structure Activity Relationship [(Q)SAR] Models were approved in November 2004. Since that time the Ad Hoc Group on (Q)SAR has been established to oversee work in the following areas:

- Development of a Guidance Document on (Q)SAR validation, which is intended to be used in conjunction with, and explain and illustrate the application of, the OECD Principles.

- Development of a document on the current status of regulatory use and application of (Q)SAR models in member countries, which will assist in the identification and use of (Q)SAR models in regulation.

- Development of a (Q)SAR Application Toolbox to assist member countries to use (Q)SAR models to assist regulatory application and decision-making.

A small (Q)SAR Steering Group has been formed to assist the Secretariat in the planning and management of the work on (Q)SAR, and this group will meet on 1-2 December to progress the projects mentioned above and prepare them for discussion by the Ad Hoc Group during 2006.

Forthcoming events:

- Meeting of the (Q)SAR Steering Group, 1-2 December 2005, Paris
- Meeting of the Ad Hoc Group on (Q)SARs, 2006 (date and venue to be decided)

Forthcoming publications:

- 🕮 Report on the regulatory uses and applications in OECD member countries of (Q)SAR models in the assessment of new and existing chemicals

Toxicogenomics

The OECD, in close cooperation with the International Programme on Chemical Safety (IPCS), is developing a plan of action to explore and evaluate regulatory application of genomic methods in chemical assessment in order to meet the practical needs of the member countries. A small Advisory Group of experts, nominated by the IPCS and the OECD, has been established and has worked to identify areas for potential future work on toxicogenomics. Some of these areas, which will be further developed during 2006, include molecular screening for characterizing individual chemicals and chemical categories, and new biomarkers.

RISK ASSESSMENT

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

The Task Force on Environmental Exposure Assessment met on 13-14 October 2005 and agreed to finalise three Emission Scenario Documents (ESDs). Emission scenario documents 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. New projects for developing ESDs on blending of flagrance oils into products, formulation of adhesives, transport and storage of chemicals, and electronic industry have also begun.

Switzerland and Germany hosted a training workshop on application of multimedia models in assessing chemicals for persistence and potential for long range transport on 30-31 August in Zurich. A number of member countries have developed plans for workshops with similar topics in 2006.

A Policy Dialogue on Exposure Assessment was held on 6-7 June at OECD. This was a useful initial exchange of information on policy issues relating to exposure assessment for industrial chemicals. The 38th Joint Meeting agreed to hold a second policy dialogue back to back with the next Joint Meeting on 14 February 2006. Suggested topics for the second dialogue include "biomonitoring", "burden estimation approaches" and "inventory comparison".

Forthcoming events:

- Policy Dialogue on Exposure Assessment, 14 February 2006, Paris

Forthcoming publications:

- 🕮 Emission Scenario Document on Kraft pulp mills
- 🕮 Emission Scenario Document on Recovered paper mills
- 🕮 Emission Scenario Document on Non-integrated paper mills
- 🕮 Report on comparison of emission estimation methods used in Pollutant Release and Transfer Registers (PRTRs) and Emission Scenario Documents: Case study of Pulp and paper and Textile sectors

MUTUAL ACCEPTANCE OF DATA AND NON-MEMBER COUNTRIES

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and Good Laboratory Principles (GLP). It requires OECD governments to accept chemical test data developed for regulatory purposes in another country if these data were developed in accordance with the Test Guidelines and GLP Principles, thus increasing efficiency and effectiveness of chemical notification and registration procedures for governments and industry. The MAD system has been open to non-OECD countries since 1997.

A workshop on Mutual Acceptance of Data, GLP and compliance monitoring was held in Chinese Taipei on 4-5 October 2005. Several members of the Working Group on GLP took part in this information meeting for government and industry in Taipei. The Secretariat continues to work with China and Brazil in view of their provisional adherence to the MAD Council Acts as well, and has had preliminary discussions with several other non-members.

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. The EXICHEM database regroups information on who is doing what on which chemicals in relation to safety.

The 20th SIDS (Screening Information Data Set) Initial Assessment Meeting was held in Paris, 19-21 April 2005. Approximately 80 representatives from member countries and industry attended the meeting.

Assessments for 43 chemicals were agreed. The conclusions and recommendations for these chemicals were endorsed by the Task Force on Existing Chemicals and the Joint Meeting through written procedures. The SIDS Initial Assessment Profiles of these chemicals are available on the publicly accessible OECD HPV Database [http://cs3-hq.oecd.org/scripts/hpv/]. The 21st SIDS Initial Assessment Meeting was held in Washington, DC, hosted by the US-EPA on 18-20 October 2005. Assessments for 37 chemicals were agreed at this meeting.

UNEP Chemicals published initial assessments for 79 chemicals since April 2005. Altogether assessments for 105 substances will have been published in 2005 on their website: [http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html]. Furthermore, the Secretariat has published 110 IUCLID export files of previously agreed SIDS Dossiers on the OECD public website: http://www.oecd.org/document/55/0,2340,en_2649_34379_31743223_1_1_1_1,00.html.

EXICHEM 2003 has been publicity accessible since mid 2004 and EXICHEM 2004 will be available by the end of 2005.

Progress is being made on the development of a globally accessible data repository for hazard data on HPV chemicals (Global HPV Portal). The Steering Group for the development of the Global HPV Portal met on 28-29 April and 26-27 September 2005 and elaborated details of the building of the Portal as well as on its architecture and query functionalities.

The Task Force on Existing Chemicals will meet on 15-16 December 2005 in Tokyo, Japan. It will discuss a first proposal of a detailed outline of the Global HPV Portal. It will also discuss a proposal for a pilot exercise on the use of (Q)SAR models within the OECD HPV Chemicals Programme with the aim to improve the experience of hazard assessors with the use of these models. Furthermore, the Task Force will discuss a proposal for an informal exercise to apply the GHS criteria to chemicals assessed in the OECD HPV Chemicals Programme with the aim to gain hands-on experience and to identify potential problems in applying the GHS criteria.

Forthcoming events:

- 14th Meeting of the Task Force on Existing Chemicals, 15-16 December 2005, Tokyo, Japan
- Meeting of the Steering Group for the development of the Global HPV Portal, February 2006
- SIAM 22, 18-21 April 2006, Paris, France
- SIAM 23, 17-20 October 2006, Jeju, Korea

RISK MANAGEMENT AND CHEMICAL PRODUCT POLICY

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 data. It develops tools for OECD governments, and facilitates information exchange about successful risk management approaches.

Two questionnaires on consideration of chemical safety in green procurement have been respectively sent to governments and to companies that produce chemicals, mixtures, articles and components for articles. The responses to the questionnaires will be used to support the discussions at the Workshop that will be held in Seoul on 8-10 November 2005.

The Hazard/Risk Information Sheets on five brominated flame retardants are being updated by Switzerland to include new information on hazard and risk assessment and management.

Draft Lists containing PFOS, PFAS, PFOA and related substances have been developed by Australia to facilitate data collection for the 2006 survey. These lists are under revision by the end of 2005.

Forthcoming event:

- Workshop on Chemical Safety in Green Procurement, Seoul (Korea), November 2005

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 2005, the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) agreed on the OECD proposal for guidance on how to consider important factors in classification of carcinogenicity. The Sub-Committee also took note of the OECD paper on reproductive toxicity potency and its conclusion: the available scientific knowledge on this issue does not allow a general revision of the existing classification criteria.

In October 2005, The Joint Meeting endorsed the declassification of a proposal on sensitization elicitation, which will be submitted at the December 2005 UN Sub-Committee. A draft scientific issue paper on strong versus weak sensitizers and a draft scientific issue paper on chronic aquatic toxicity will be submitted for approval at the next Task Force Meeting. The expert groups continue work related to (i) the development of criteria for chronic aquatic toxicity and (ii) criteria for Toxic Gas mixtures.

The report of the validation test programme for the Transformation/Dissolution Protocol was recently sent to an independent statistician and to the validation management group for comments. The detailed comparison of classification systems for ozone depleting chemicals was sent to the Task Force for approval.

Forthcoming event

- Meeting of the Task Force on Harmonization of Classification and Labelling, Rome, 15-16 March 2006

Recent publications

- 🕮 Guidance on consideration of important factors in classification for carcinogenicity
- 🕮 Scientific issue paper on reproductive toxicity potency
- 🕮 Proposal for revision of GHS Chapter 3.4 on Respiratory and Skin Sensitization

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.

Work re-organization to facilitate the implementation of the Parallel Process was consolidated at the last Task Force Meeting in April 2005. Detailed procedures for implementing the pilot phase of the Parallel

Process were discussed and agreed at the meeting. These procedures cover the pre-notification phase, the notification phase and the assessment phase. The Task Force also agreed on (i) a Work Plan for engaging more countries and companies in the pilot phase, and (ii) the development of a Manual for New Chemicals.

Discussion papers on exemption/reduced notification requirements for R&D, polymers and site isolated intermediates are under preparation and will be submitted at the next Task Force Meeting. Work is progressing with respect to the development of a web based notification system.

Forthcoming events

- 10th Task Force Meeting, April 2006

PESTICIDES

The Pesticide Programme aims to harmonise the testing and assessment of agricultural pesticides, 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

A US-led Expert Group on Pesticide Residue Chemistry, established in October 2003, is developing two Guidance Documents (Definition of the Residue and Overview for Residue Chemistry Studies) and five Test Guidelines (Metabolism in Crops; Metabolism in Rotational Crops; Metabolism in Livestock; Residues in Rotational Crops; and Residues in Livestock) and templates for reporting test study summary data. The Expert Group held its second meeting in May 2005 at the US Environmental Protection Agency. Following the meeting, the draft Test Guidelines and Guidance Documents were circulated to members of the Working Group on Pesticides in August 2005 for a three-month commenting round. Adoption of the Guidelines and Guidance Documents by the Joint Meeting is anticipated in 2006. In addition to the US, the Expert Group is composed of experts from Australia, Canada, Germany, Italy, Japan, the Netherlands, the United States, the European Commission, FAO and CropLife International/BIAC. The Expert Group is also developing new Test Guidelines on processing studies and crop field trials.

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

An Australia led Expert Group on Dermal Absorption, established in January 2005, is developing guidance on the analysis and evaluation of dermal absorption studies for use in the risk assessment of pesticides. A meeting of the Expert Group was held in conjunction with the Joint FAO-WHO Meeting on Pesticides Residues in Geneva in September 2005 (providing the opportunity for participation of experts from Australia and North-America in addition to Europe). Participants reviewed the August 2005 version of the draft guidance, agreed to the objective and content of the guidance document, and made suggestions for its revision. They also agreed on actions to be undertaken for this revision and the completion of the guidance document.

Biological Pesticides

OECD is developing a Guidance Document which will address issues that are barriers to work sharing, across governments, on reviews of biological pesticide. Issue papers, which will form the basis of the Document, have been prepared on: (i) evaluation and interpretation of toxicology data – operator and consumer exposure; (ii) evaluation and interpretation of ecotoxicity and environmental fate data; (iii) waivers for persistence, competition, residues in soil and water; (iv) species/strains and indigenous vs exotic micro-organisms related issues; and (v) evaluation of efficacy of pesticides.

Changes to the OECD Dossier and Monograph Guidance

The OECD Dossier and Monograph Guidance documents have been revised, and the latest versions were posted on the OECD public web site in May 2005 [see http://www.oecd.org/env/pesticides]. The changes include new wording for existing OECD data points, new OECD data points, and an allocation of EU data points to different OECD points. The revisions appear in Dossier Guidance Appendix 6, Parts 4 and 5, the cover pages for Appendices 7 and 8, and Chapter 3 of the Monograph Guidance as well as Appendices 4, 6, 7 and 8.

Recent publications:

- 🕮 Summary Report of the OECD Project on Pesticide Terrestrial Risk Indicators
- 🕮 Report of the OECD Seminar on Pesticide Risk Reduction through Good Container Management [ENV/JM/MONO(2005)12]
- 🕮 OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances - Revision 2
- 🕮 OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances – Revision 2

Forthcoming publications:

- 🕮 Report of the Seminar on Risk Reduction through Better Labelling
- 🕮 Report of the Second Survey on Activities to Reduce Pesticide Risks in OECD Countries

Forthcoming events:

- Risk Reduction Steering Group 29 November 2005, Wellington, New Zealand
- Risk Reduction Seminar on Application Technologies, 30 November 2005, Wellington, New Zealand
- Registration Steering Group, 1-2 December 2005, Wellington, New Zealand
- Workshop on Compliance Issues, June, 2006, Ottawa, Canada

BIOCIDES

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

Emission Scenario Documents (ESDs)

The Emission Scenario Document on insecticides used in stables and manure will be published in the fourth quarter of 2005. This ESD examines ways to determine the distribution and concentrations of an insecticide in environmental compartments due to the use of that insecticide in stables and manure storage system. Insecticides which are applied in animal housing (e.g., stables) and manure storage areas can end up in manure which is used for land application. The ESD only focuses on releases to the environment, and not human exposure (e.g., through residues in crops). Austria provided funding for this project.

Work has begun on a parallel project, funded and lead by France, to develop an ESD for insecticides used in households, to determine the distribution and concentration of these products in environmental compartments. As the releases through waste treatment of such products might be an important contribution for local concentrations in the environment, the ESD will also integrate this life-cycle stage in the project.

Test Guidelines for Wood Preservatives

Pre-validation work has been carried out by Germany, funded by the European Commission, on two draft OECD Test Guidelines for measuring leaching of active ingredients from wood both in and not in contact with water/soil. The results of this exercise were discussed at the October, 2005 meeting of the Task Force on Biocides, and work is underway to resolve outstanding issues.

Efficacy

Delegates at the October 2005 meeting of the Task Force on Biocides agreed two draft reports which investigated the potential for harmonisation of efficacy test methods for antimicrobials that have public health claims, specifically: (1) those used for disinfection of hard surfaces; and (2) those used in treated articles/materials. The Task Force agreed to begin work to develop and validate a Test Guideline for hard surfaces and to develop a Technical Guidance Document for treated articles.

Forthcoming publication:

- 🕮 Emission Scenario Document (ESD) for Insecticides Used in Stables and on Manure

CROSS-CUTTING ISSUES: NEW AND EXISTING INDUSTRIAL CHEMICALS, PESTICIDES AND BIOCIDES

OECD is currently reviewing final drafts of approximately 85 "templates" which can be used to document an individual test study report summary or study evaluation report. Separate templates have been developed for toxicology, eco-toxicology and physical/chemical property study types. (A "template" is a standard format used to summarise data contained in a study report, but it is not a data entry screen.) It is anticipated that all of these templates will be adopted by the end of 2005. In addition, electronic exchange formats, "XML schema" based on XML (Extensible Mark-up Language) are being developed for each template (e.g., one template for hydrolysis and one XML schema for hydrolysis). Once adopted, the templates and XML schema will be added to the OECD public web site. At that point, each government will need to determine when to begin using the templates and XML schema, and which elements in the template are relevant to their programmes.

In parallel to this work, and in order to ensure that OECD governments and industry do not adopt divergent approaches for using the templates and XML schema, an ad hoc Steering Group has been created to co-ordinate work across relevant OECD programmes (i.e., new chemicals, existing chemicals, pesticides and biocides).

CHEMICAL ACCIDENTS

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

Guidance on Safety Performance Indicators

The Guidance on SPI was published as an interim document with the view that it be revised based on feedback from users. A pilot programme, launched in May 2004, was completed in September 2005. There were about twenty participating organisations from the three main target groups, i.e. industry, public authorities and communities, and from eight member countries (Canada, Czech Republic, Finland, Italy, the Netherlands, Switzerland, the United Kingdom and the United States. The information provided through the pilot programme and any additional feedback received will be analysed with a view to refining and updating the SPI Guidance. A navigable version is available through the Chemical Accidents web page or at: http://www2.oecd.org/safetyindicators/.

New Projects

A project led by Germany concerns the investigation of those issues which are not traditionally considered within the context of chemical accidents but which pose similar risks, are not addressed by legislation, in international fora or in guidance materials, entail risks that communities are not aware of, and for which there is no duplication of effort with other organisations. A questionnaire was circulated to member countries early 2005 and a small Evaluation Group (composed of experts from Germany, Italy, Norway, the Netherlands and Sweden) met in July 2005 to identify subjects of concern, i.e. new areas of work that could be included in the Chemical Accidents Programme. In October 2005, the 15th Meeting of the Working Group on Chemical Accidents agreed to include two new projects in the 2006-2008 Work Programme: marshalling yards and impact of natural disasters on industrial installations.

Guidance for Implementation of Integrated Management of Safety, Health, Environment and Quality

A Korea-led Expert Group is developing guidance based on examples/case studies and shared experience, in order to facilitate the implementation of integrated management of safety, health, environment and quality in enterprises (and public authorities). A meeting of the Expert Group (involving experts from Canada, the Czech Republic, Italy, Korea, and the Netherlands) hosted by the KOSHA took place in Seoul in September 2005 to review the first draft guidance. Further revision of the draft guidance document is planned, along with a pilot programme.

Chemical Accident Risk Assessment Thesaurus (CARAT)

After substantial initial interest in the CARAT data base, it has become increasingly difficult for countries to actively support it by increasing the number of entries. Consequently, there are not enough new and updated entries for it to be useful and viable. Therefore, as agreed by the WGCA members, a procedure to phase out CARAT has been implemented and the data base was definitively removed from the OECD web site in May 2005.

Forthcoming events:

- 16th Meeting of the OECD Working Group on Chemical Accidents, EC JRC, Ispra, Italy, 16-17 October 2006 (to be confirmed)
- OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances involved in Accidental Releases, EC JRC, Ispra, Italy, 18-20 October 2006, co-hosted by Environment Canada and the EC Major Accident Hazards Bureau (to be confirmed)

Recent publication:

- 🕮 Report on Integrated Management Systems – Potential Benefits Achievable from Integrated Management of SHE&Q. EHS publication, Series on Chemical Accidents, No. 15 (August 2005).

POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRS)

PRTRs are databases of selected pollution emissions to air, water and soil, and of wastes transferred for treatment or disposal. The programme aims to help individual countries develop PRTRs, to improve techniques for gathering data, and encourages the sharing and comparing of data between countries.

Meetings of the Task Force

The Task Force on Pollutant Release and Transfer Registers (TF on PRTRs) met in San Francisco, USA, 25-27 April 2005. The discussion focused on the following 2005-08 work areas: i) publication of the Sharing and Comparing database; ii) Framework for Selecting and Applying RETs; iii) Scoping studies on the "Releases from Products" and the "Crosswalk" (between release and waste); and iv) outline of the paper "Considerations for Ensuring Quality PRTR data".

Sharing and Comparing of PRTR data is a key task of the Task Force on PRTRs, and Japan has taken the lead in the development of this database to enable international sharing and comparing of PRTR data. In April 2005 the TF decided to continue work on the sharing of PRTR data, but terminate, for the time being, the work on the comparing of PRTR data. The final decisions on this issue, before publication, will be made at the next meeting of the TF in March 2006.

Efforts are underway to find resources for undertaking all the scoping studies. The Nordic PRTR Group has already committed to carry out the scoping study on the releases from products and UK will carry out the scoping study on the crosswalk. These scoping studies will be completed by the end of 2005. Resources have yet to be found for the scoping study on SMEs. The Joint Meeting's endorsement for the continuation of these work areas will be sought in February 2006.

The TF has developed an extended outline of the document "Considerations for Ensuring Quality PRTR data". In the next phase, TF members will be asked to provide paragraphs on best practices (and unsuccessful practices as well) for each of the outlined sections. Australia and the US will compile and edit the received input, and present the first draft document at the next TF meeting in March 2006.

Forthcoming event:

- 9th Meeting of the OECD Task Force on PRTRs, 21-23 March 2006, Ghent, Belgium

Recent publications:

- 🕮 Resource Compendium of PRTR Release Estimation Techniques, Part 3: Summary of Techniques for Off-site Transfers, Series on PRTRs, No. 8, ENV/JM/MONO(2005)9.
- 🕮 Framework for Selecting and Applying PRTR Release Estimation Techniques, Series on PRTRs, No. 9, ENV/JM/MONO(2005)18.

Forthcoming publications:

- 🕮 Considerations for Ensuring Quality PRTR data.

HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The Programme focuses on the use of modern biotechnology to create genetically modified organisms (GMOs), and environmental safety. With the programme on food and feed safety (see below) it aims to help OECD countries evaluate the potential risks of GMOs and ensure a higher standard of safety, to foster communication and mutual understanding of the regulatory process in different countries, and to reduce non-tariff trade barriers.

Consensus documents on the biology of Papaya and Oyster mushroom were recently published, bringing the total number of consensus documents to 29.

The Working Group has progressed on two other important projects: i) the role of information from molecular characterisation in safety assessment; and ii) parameters for environmental safety/ risk assessment. The molecular characterisation project is being carried out in cooperation with the Task Force for the Safety on Novel Foods and Feeds. The lead countries for this project have made the first draft, which is currently under consideration by the Steering Group of this project. As to the project on parameters for environmental safety/ risk assessment, a discussion paper which reviewed the criteria employed by different regulatory authorities for the environmental risk/ safety assessment of transgenic plants has been considered by the Working Group. Based on this, an operational plan for this project will be provided for the discussion at the next meeting.

Two expert workshops on the biology of Atlantic salmon took place in Moscow (November 2004) and Trondheim (October 2005). These concluded that a similar approach to that used for environmental risk/

safety assessment for transgenic plants could be used for transgenic fish, and a draft operational plan for a consensus document on the biology of Atlantic salmon was agreed. At its most recent meeting, the Working Group decided to begin work on this consensus document, thus addressing environmental risk/ safety issues associated with an animal species for the first time.

One of the major recent achievements related to BioTrack Online is the development of guidance for the designation of a unique identifier for transgenic plants. The Working Group is currently considering how the unique identifier will be applied to products other than transgenic plants – especially micro-organisms. As the conference of the parties to the Cartagena Protocol has requested the OECD to continue work in developing unique identifiers, progress will be reported at COP-MOP/ 3.

At the 17th meeting held 24-26 October 2005, the Working Group finalised a draft Programme of Work on Harmonisation of Regulatory Oversight in Biotechnology for 2006-2008. It will be considered by the 39th Joint Meeting in February 2006. During the last couple of years, there has been increased participation of other non-members such as Brazil, Cameroon, Chile, China, Egypt, India and Philippines, mostly under the auspices of OECD's Global Forum on the Knowledge-based Economy.

Forthcoming events:

- A side-event of COP-MOP/ 3 to celebrate the 20th anniversary of Blue Book
- 18th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Berne, 7-9 June 2006.

Recent publications:

- 🕮 *Consensus Document on the Biology of Papaya*
- 🕮 *Consensus Document on the Biology of Oyster mushroom*

SAFETY OF NOVEL FOODS AND FEEDS

The work of the Task Force for the Safety of Novel Foods and Feeds is complementary to that of the Working Group for Harmonisation in Biotechnology.

There has been an increasing participation from other key non-member economies such as: Argentina, Brazil, Chile, China, India, Latvia, Russia, Slovenia, South Africa, and Thailand. This has been achieved under the auspices of OECD's Centre for Co-operation with non-members.

Building on a Special Session (held during the 9th meeting in October 2004) on the use of consensus documents, the Task Force addressed at its 10th meeting (held in June 2005) how to involve more actively the expertise and interests of non member economies. One practical outcome is that Thailand and South Africa have now started to work on two consensus documents in co-operation with member countries. These documents are on papaya (Thailand) and cassava (South Africa). This will broaden the expertise that is available to the Task Force, while addressing a wider range of food and feed products that are of global interest.

During the 10th meeting of the Task Force, held in June 2005, it was agreed that the programme of work will be renewed during 2006-2008. Although the development of consensus documents will remain as the highest priority, a number of issues emerged during the discussion. For example, it was recognized that it will be important to be complementary to the activities of FAO/WHO/ Codex Alimentarius Commission. It was also considered important to consider safety issues related to novel foods (non-transgenic in origin) with "no history of safe use". Finally, it was agreed that there is a need to continue to strengthen the input of key non members. The draft Programme of Work will be considered at the next Joint Meeting (February 2006).

Forthcoming event:

- 11th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Berlin, Germany, 6-8 March 2006.

Recent publications:

- 🕮 Consensus Document on Compositional Considerations for New Varieties of Barley (Hordeum vulgare L.): Key Food and Feed Nutrients and Anti-Nutrients
- 🕮 Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites

Upcoming publication:

- 🕮 An Introduction to the Food/Feed Safety Consensus Documents of the Task force

Web site: Safety of Novel Foods and Feeds available through BioTrack Online:
http://www.oecd.org/biotrack

SAFETY OF MANUFACTURED NANOMATERIALS

Nanotechnology involves materials and working devices or machines that are engineered at the scale of atoms and molecules. The main objective of on-going work in this area is to assist countries in developing its tools to allow them to better address the safety aspects of manufactured nanomaterials.

The Joint Meeting held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety on 7 June 2005. This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environment safety issues associated with manufactured nanomaterials.

This session was followed by a discussion at the 38th Joint Meeting (8-10 June) to consider the next steps. The Joint Meeting recognized that nanotechnology offers a wide range of potential benefits which will impact on a large number of sectors. At the same time, it was noted that there should be a responsible and co-coordinated approach to the safety of the technology.

The Joint Meeting noted the wide range of issues that emerged during the session, but recognised a convergence of views around the need for: i) international coordination on regulatory schemes; ii) development of assessment methodologies and testing schemes; and iii) sharing and exchanging information amongst delegations. There was a strong consensus on the need for harmonisation in baseline information.

It was agreed that countries shall begin to work together in a proactive way. This should ensure human health and environmental safety while economic advantages may be taken of the opportunities the technology can provide.

The Joint Meeting was identified as an appropriate forum for ensuring co-operation, coordination, and communication between member countries, non-members economies, IGOs, industry and NGOs. Specifically, the Joint Meeting decided that the steering group for nanotechnology begins work to organize a first OECD Workshop on the Safety of Manufactured Nanomaterials.

Accordingly, the OECD Workshop on the Safety of Manufactured Nanomaterials will take place on 7-9th December 2005, in Washington, D.C. This event is being hosted by the United States and held under the auspices of the Joint Meeting.

Objectives and scope of the Workshop

The scope of the Workshop – as identified by the Joint Meeting - will include a consideration of information that is relevant to the human health and environmental safety concerns from a regulatory point of view (i.e.: definitions, nomenclature, characterisation; hazard identification; hazard and exposure assessment methods; and regulatory frameworks).

Thus, the workshop's objective is to determine the "state-of–the–art" for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

This is the first step to identify: i) work that is underway or has already been accomplished within each of these themes; and ii) any future research and policy work that needs to be undertaken.

Output of the Workshop

The output of the Workshop will include conclusions and recommendations, which will be presented in a report for consideration at the 39th Joint Meeting. The Joint Meeting will then decide on how best to address any recommendations in the future.

Forthcoming event:

- OECD Workshop on the Safety of Manufactured Nanomaterials, 7th- 9th December 2005, Washington, D.C., United States.

More information available at:

- Workshop on the Safety of Manufactured Nanomaterials: http://www.oecd.org/document/35/0,2340,en_2649_34365_35406051_1_1_1_1,00.html
- Special Session on the "potential implications of manufactured nanomaterials for human health and environmental safety" http://www.oecd.org/document/24/0,2340,en_2649_34365_35406872_1_1_1_1,00.html

INTERNET

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

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