Environment, Health & Safety News

No. 33
November 2015

OECD
BETTER POLICIES FOR BETTER LIVES

CHEMICALS PROGRAMME

HAZARD ASSESSMENT AND INTEGRATED APPROACHES TO TESTING AND ASSESSMENT

*The **Hazard Assessment Programme** has evolved from the Existing Chemicals Programme and is concerned with the hazard assessment of industrial chemicals and mainly existing chemicals, i.e. the thousands of chemicals used worldwide that were put on the market before new chemical notification systems were established and whose hazards were not thoroughly evaluated by governments. The current programme focuses on the development and application of **Integrated Approaches to Testing and Assessment (IATA)** and the exchange of experience on new hazard assessment methodologies. **IATA** are frameworks used for hazard identification, hazard characterisation and/or safety assessment of a chemical or group of chemicals, which integrate and weigh all relevant existing data and guide the targeted generation of new data where required to inform regulatory decision-making regarding potential hazard and/or risk.*

*The **OECD** is already actively working on the development of tools and approaches such as chemical categories and **(Q)SARs** which 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.*

Eight assessment reports for 19 chemicals have been published and 36 **IUCLID** dossiers have been uploaded to the OECD Existing Chemicals Database.

Developments on QSARs

In December 2014, a *new* version of the OECD QSAR Toolbox was released (v3.3). This contained:

- new functionalities
- usability improvements
- new databases and profilers

After that, in the process of continuous improvement a number of updates were released. At present, ***version 3.3.5*** is available for downloading.

In **May 2015**, all tutorials were updated and four *new* ones were implemented. The new tutorials illustrate new applications functionalities such as for e.g., calculating correlations between endpoints (with an example based on Toxcast data), or filtering / sub-categorizing data with biological data and not only with chemically-based profilers. One tutorial focuses on **DART** tools to predict developmental and reproductive toxicity (DART).

In ***June 2015***, a **QSAR Toolbox Management Group Meeting** was held in Paris. The main goal was to discuss the first set of deliverables relative to the ongoing development of the next (4.0) version of the Toolbox. The work performed so far has been approved by the Group. The next step will be the discussion of the second set of deliverables planned for ***January 2016***.

- **AOP developments**

As part of the AOP Knowledge Base (AOP KB,) the tool *Effectopedia* is currently under development to allow for a sophisticated and quantitative depiction of the relationships between molecular initiating events, key events, and the *in vivo* adverse outcomes in an **Adverse Outcome Pathway (AOP)**.

The semantic annotations, processable quantitative information in *Effectopedia* will ultimately allow for the development of quantitative AOPs and hence predictive tools for the adverse effects of chemicals. Multiple interface advancements have been introduced allowing for the description of various test methods (*in chemico, in vitro, in vivo*) along with easy to interpret summaries of the result of their application over different chemical substances.

New interfaces for in silico models have been also been developed allowing complete mathematical description of the models as well as used parameters and assumptions. Some of the current development efforts are also dedicated on facilitating the integration between the modules of the AOP-KB. A new *Effectopedia* feature is the ability to add and display relevant AOP-Wiki content in the Effectopedia interface of the corresponding element.

- **Task Force activities, new documents and case studies**

A project team under the **Task Force for Hazard Assessment** (TFHA) and the **Task Force on Exposure Assessment** (TFEA) continued to work on the topic of assessing risks from the **combined exposures to multiple chemicals**. Information gathering has been conducted on considerations for problem formulation and hazard assessment, and is underway for exposure assessment and will be launched for risk characterisation. Several web-discussions have been held on example case studies and approaches. The drafting of a guidance and considerations document has begun which will encompass the four areas.

A draft guidance document on the incorporation of bioavailability concepts for assessing the ecological risk and/or environmental quality standard setting of **inorganic metals and metal compounds** was discussed at the meeting of the Task Force on Hazard Assessment in **June 2015**. The guidance will be revised in Q4 2015 based on the comments received.

In May the **European Commission's *Joint Research Centre*** finalised two draft guidance documents that aim to contribute to a harmonized approach for the reporting of IATAs to facilitate a consistent application and evaluation. The first document introduced the overall concept of IATA, proposed a set of general principles for the evaluation of IATA and for the use of these principles as a basis for the development of templates aimed at the reporting of structured approaches to data integration. The second document provided an outline of how the AOPs for skin sensitisation can inform IATA.

In an annex the principles and templates presented in the first document have been used to document a number of structured approaches to data integration that have been developed for skin sensitisation. Based on the comments received from the TFHA, revised documents are scheduled to be discussed in Q4 2015 / Q1 2016.

The project regarding case studies on **Integrated Approaches to Testing and Assessment** (IATA), with a focus on assessment aspects, was successfully launched with a review of four case studies:

- In Vitro Mutagenicity of 3,3'-Dimethoxybenzidine Based Direct Dyes
- Repeated Dose Toxicity of Substituted Diphenylamines
- Hepatotoxicity of Allyl Esters
- Bioconcentration Potential of Biodegradation Products of 4,4'-Bis (chloromethyl)-1,1'-biphenyl

A guide to harmonise and support **reporting and justification of grouping/read-across** case studies was developed. These case studies and learnings from them will be discussed at a face to face meeting in ***November 2015***.

In ***August 2015*** the **Task Force on Hazard Assessment** and the **Working Group on Pesticides** endorsed a document on the *Fundamental and Guiding Principles for (Q)SAR analysis of chemical carcinogens with mechanistic considerations.* In this document, prepared by **US EPA** and **Health Canada**, the importance of mechanistic consideration in (Q)SAR analysis, the critical role of mechanistic consideration in improving various (Q)SAR approaches and possible integrative approaches of *combining chemoinformatics and bioinformatics* are discussed, mainly using carcinogenicity as an illustrative toxicity endpoint. The document is expected to be published by the end of 2015.

Launch of Pilot Classification exercise

In 2015 a joint **UNSCEGHS/OECD** Pilot Classification Exercise was started which should give further insight into the level of effort needed to create and maintain a global list of recommended harmonised classifications. The **US**, **ECHA** and the **Russian Federation** agreed to prepare C&L assessment reports for three selected chemicals. The draft assessments have been submitted for comments to the OECD in **August 2015**, which will be discussed in Q4 2015.

A draft guidance document for characterising the identity and composition of hydrocarbon solvents for assessment purposes has been developed. It is being revised to take into account the comments received from the **Task Force of Hazard Assessment** and will be sent in Q4 to the TFHA for endorsement.

Forthcoming events:

- 11th Meeting of the QSAR Toolbox Management Group, January 5, 2016, OECD, Paris
- Meeting of the project team for IATA case studies, 19-20 November 2015, OECD, Paris
- 9th Meeting of the Task Force on Hazard Assessment, June 20-21, 2016, OECD, Paris

Recent publication(s) in the Series on Testing and Assessment:

- 🕮 **No. 212**: Guidance on Selecting a Strategy for Assessing the Ecological risk of Organometallic and Organic Metal Salt Substances based on their Environmental Fate
- 🕮 **No. 215**: Report of the Workshop on a Framework for the Development and Use Of Integrated Approaches to Testing and Assessment

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Websites: **http://www.oecd.org/env/hazard**
http://www.oecd.org/env/hazard/qsar
https://community.oecd.org/community/toolbox_forum
https://aopkb.org
http://www.effectopedia.org

SAFETY OF MANUFACTURED NANOMATERIALS

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

Publishing of nanomaterial dossiers

At the ***14th meeting of the Working Party on Manufactured Nanomaterials*** (WPMN-14) held in February 2015, it was agreed that all of the finalised dossiers for eleven nanomaterials should be published. Subsequently, a dedicated public website was launched in ***June 2015*** to communicate the results from the Testing Programme. This **website** collates all the necessary information related to the Testing Programme and gives an overall view on the work.

At the time of writing, Dossiers are available on this site for the following materials: **cerium oxide; dendrimers; fullerenes** (C60); **gold nanoparticles; multi-walled carbon nanotubes** (MWCNTs); **nanoclays; silicon dioxide**; **silver nanoparticles**; **single-walled carbon nanotubes** (SWCNTs). In addition, **titanium dioxide** (NM100-NM105) has already been declassified and is progressively being posted on the public site. Similarly, the last dossier on **zinc oxide** has been declassified and will be made available on the web site before the end of the year.

Work has begun on the assessment of the data from the Testing Programme. The **Netherlands** has been leading an evaluation of the applicability of the test methods used to determine the physical-chemical properties of the various nanomaterials in the testing programme. The WPMN has considered the results of its work at its 15th meeting in ***November 2015***, and agreed on the declassification of the report.

The work of the WPMN on Test Guidelines continues to address whether existing Test Guidelines are adequate to address nanomaterials or whether it will be necessary to develop new or adapted nano-specific Test Guidelines. There are eight projects currently underway designed to address Test Guideline or guidance development.

The table below summarises the current status of progress on each project:

Title of the Activity	**Test Guideline and/ or Guidance Document under review / Workshops or meetings**	**Lead country(ies)**
Amendments to the Inhalation Test Guidelines and Guidance to Accommodate Nanomaterials	**Existing Test Guidelines under review:** **403** (Acute Inhalation) **436** (Acute Inhalation –Acute Toxic Class) **412** (Subacute Inhalation Toxicity) **413** (Subchronic Inhalation Toxicity A meeting was held on 21-22 September 2015 in Washington. D.C. to discuss the feasibility of an update of these TGs.	**U.S.**
Guidance Document on Aquatic (and Sediment) Toxicology Testing of Nanomaterials	New Guidance Document to be developed	**U.S.** **Canada**
Test Guideline for the Dissolution Rate of Nanomaterials in the Aquatic Environment	New Test Guideline to be developed	**U.S.**
Guidance Document for Dispersion and Dissolution of Nanomaterials in Aquatic Media – Decision Tree	New Guidance Document to be developed	**Germany**
Test Guideline for Agglomeration Behaviour of Nanomaterials in different Aquatic Media	New Test Guideline to be developed An expert meeting was held on 28th-29th January 2015 in Dessau-Roßlau, Germany and a second meeting on 28 September 2015, at the OECD Conference Centre in Paris	**Germany**
Guidance Document on Assessing the Apparent Accumulation Potential of Nanomaterials	**Existing Test Guideline 305** (Bioaccumulation in Fish) to be reviewed	**U.K.,** **Spain**
Test Guideline for Nanomaterial Removal from Wastewater	New Test Guideline to be developed	**U.S.**
Guidance Document on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity Test Guidelines for Testing of Manufactured Nanomaterials	New Guidance Document to be developed on the use of TGs: **487** (*In Vitro* Mammalian Cell Micronucleus Test) **473** (*In Vitro* Mammalian Chromosomal Aberration Test) **476** (*In Vitro* Mammalian Cell Gene Mutation Tests)	**E.U.**

Risk Assessment and Regulatory Programmes

This part of the programme aims at: i) identifying regulatory needs for the risk assessment and risk management of manufactured nanomaterials; and ii) developing risk assessment approaches to strengthen and enhance regulatory risk assessment capacity.

The following **three pilot projects** are currently on-going:

- Approaches on nano equivalence/ grouping/ read-across concepts based on physical-chemical properties for regulatory regimes: results from a survey. The final draft is under review by the WPMN and is expected to be published in ***early 2016***.
- Physical and Chemical Property Analysis for Read Across and Risk Assessment Guidance. The draft report is in preparation by lead countries.
- Different types of risk assessments and identifying different levels of uncertainties used to inform risk assessment outcomes and risk management measures in member countries. The draft survey report is under preparation by the lead country.

Exposure Measurement and Exposure Mitigation

The objective of this programme is to exchange information on (or develop) guidance for exposure measurement and mitigation. The following projects were finalised and published in **July 2015**:

- Analysis of the Survey on Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials; and
- Harmonised tiered approach to measure and assess the airborne exposure to engineered nano-objects in the workplace.

The following projects are in various stages of development:

- Exposure assessment: Case studies on **nano-silver** and **nano-gold**; and
- Biodurability of nanomaterials and their surface ligands; and

Furthermore, a **survey** has been conducted to identify available information and data on consumer and environmental exposure assessment and mitigation measures with the aim to prioritize future work and research needs. The final report on the analysis of the survey will be presented at **WPMN-16** in ***June 2016***.

Environmentally Sustainable Use of Manufactured Nanomaterials

This project addresses the potential of nano-based applications to address environmental challenges such as climate change, pollution of water/soil/air and natural resource depletion. It covers the potential negative impacts that new technologies may have on human health and the environment.

An **expert workshop** was held in Zurich, Switzerland, on 20 January 2015 to finalise the **draft *Guidance Manual on a life-cycle analysis case study of multi-walled carbon nanotubes***. The final report was published in ***July 2015***.

Forthcoming Events:

- 16th Meeting of the Working Party on Manufactured Nanomaterials, ***12-16 September 2016*** Paris, France

Recent publication(s) in the *Series on Manufactured Nanomaterials*:

- No. 61 - Developments on the safety of manufactured nanomaterials - 2014
- No. 60 - Developments on the safety of manufactured nanomaterials - 2012
- No. 59 - Developments on the safety of manufactured nanomaterials - 2013
- No. 58 - Preliminary guidance notes on Nanomaterials: Interspecies variability factors in human health risk assessment
- No. 57 - Guidance Manual towards the Integration of Risk Assessment into Life Cycle Assessment of Nano-Enabled Applications
- No. 56 - Analysis of the Survey on Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials
- No. 55 - Harmonized Tiered Approach to Measure and Assess the Potential Exposure to Airborne Emissions of Engineered Nano-Objects and their Agglomerates and Aggregates at Workplaces
- Nos. 44-54 - These items are the dossiers derived from the Testing Programme on Manufactured Nanomaterials which are located at: **http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm**

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EXPOSURE ASSESSMENT

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

New documents released

Three Emission Scenario Documents (ESDs) were published in 2015:

1) use of industrial cleaners
2) use of adhesives
3) chemical vapour deposition in the semiconductor industry

Currently, projects are on-going on the development or revision of the following documents:

1. ESD on textile dyeing,
2. Complementing document for the ESD on coating industry; application of paint solvent to industrial coatings,
3. Case study on the release of plastic additives,
4. ESD for metals released during waste disposal,
5. ESD for lube oil additives,
6. ESD for the use of aqueous firefighting foam,
7. Compilation of case studies of uses of fluorocarbon substitutes in refrigeration, air-conditioning, electronics, metal cleaning and foam blowing.
8. ESD for chemicals used in hydraulic fracturing, and
9. ESD for the use of vapor degreasers.

Activities of the Task Force

The **Task Force on Exposure Assessment (TFEA)** held its 7th meeting on ***17-18 June 2015*** in OECD, back-to-back with the meeting of the **Task Force on Hazard Assessment**.

The TFEA is developing a table on the *relationship between lifecycle stage and use descriptor*s to analyse similarity and differences between the **OECD ESDs** and the **EU Specific Environmental Release Categories (SpERCs)**. This project is scheduled to be finalized in 2016.

A project team under the **Task Force for Hazard Assessment** and the **Task Force on Exposure Assessment** continued to work on the topic of assessing risks from the combined exposures to multiple chemicals. Information gathering has been conducted on considerations for problem formulation and hazard assessment, and is underway for exposure assessment and will be launched for risk characterisation. Several **web-discussions** have been held on example case studies and approaches. The drafting of a ***guidance and considerations document*** has begun which will encompass the four areas.

Furthermore, the TFEA reviewed the progress of two projects;

(1) **Development of International Harmonized Use Codes** between the U.S, Canada and the EU. This project aims to facilitate the exchange of information and consistency in reporting of chemicals during their manufacture, processing, and use, and
(2) The **development of draft database with product release and exposure information**. The database is compiling existing data on releases from, and exposures to, chemicals in commercial and consumer end products.

These products are expected to be finalized in the course of 2015-2016.

New projects

The **TFEA** agreed to launch the following ***new*** activities:

(1) development of a **database on exposure to children** through mouthing to facilitate estimation of oral exposure to children,
(2) development of a **biomonitoring database** to compile information on publicly available biomonitoring data across countries to identify chemicals for assessment or to regulate the use of chemicals,
(3) **review of biodegradation removal prediction methods** in waste water treatment plants to improve release estimation from wastewater treatment plants.

The TFEA also decided to explore the possibility to develop guidance for measuring releases from products (e.g. chamber testing) in order to harmonise existing guidelines used in OECD member countries.

Forthcoming event:

- 8th Meeting of the Task Force on Exposure Assessment, in the week of 28 August 2016, Dortmund, Germany

Recent publication(s):

- Emission Scenario Document (ESD) on Industrial use of Industrial Cleaners
- Emission Scenario Document (ESD) on Chemicals Vapour Deposition in the Semiconductor Industry
- Emission Scenario Document (ESD) on Use of Adhesives

Contact: Takahiro Hasegawa

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

METHODOLOGIES FOR ASSESSING THE RISKS OF CHEMICALS TO CHILDREN

Children are more vulnerable than adults to environmental hazards, such as those presented by chemicals, owing to their different physiological, metabolic factors and activity levels. The OECD has initiated an activity to help support governments assess the risk of chemicals to children.

The **Task Force on Exposure Assessment** established two subgroups to discuss issues around children's health. The first subgroup will develop a decision tree to determine the need for specific exposure assessments for children, using relevant case studies.

Another subgroup was established in June 2015 to develop an *in silico* exposure tool that facilitates estimation of oral exposures of children via the mouthing of objects and to develop an associated guidance document.

✉ ***Contact:*** Eeva Leinala, Takahiro Hasegawa

Website: http://www.oecd.org/chemicalsafety/childrens-health.htm

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NOTIFICATION AND REPORTING TOOLS

The development of I.T. Tools at OECD focuses on the harmonization of electronic formats for exchanging information on chemicals. These formats can then be used for the development of databases or regulatory submission tools in countries, ensuring that data gathered in one country can be exchanged seamlessly with other countries without reformatting or that electronic dossiers developed for submission in one country can be submitted to multiple countries or jurisdictions.

New Chemicals

The main objectives of the **OECD Clearing House on New Chemicals** are to

(1) undertake and facilitate work aimed at streamlining the New Chemicals notification processes; (2) enhance the exchange of information and work sharing on new chemical notification and assessments; (3) facilitate greater mutual recognition of assessments; and (4) progress towards mutual acceptance of notifications.

The Clearing House held its latest annual meeting in Vancouver, Canada, on ***7-8 October 2015*** at which the mandate of the group was reviewed and a number of new project proposals were discussed, including projects to consider harmonised definitions and criteria. The meeting was preceded by a **technical workshop/webinar** on the ***'Utilisation of Analogues in New Chemical Programmes'*** which was attended by 40 government and industry representatives.

The workshop involved the sharing of current approaches by government and industry, as well as the discussion of case studies illustrating the approaches and challenges faced when utilising analogues for the purpose of new chemicals notification and assessment. One outcome from the workshop is the *proposal to develop harmonised guidance for industry on justifying an acceptable analogue for a new chemicals submission*.

The Clearing House is currently finalising a project aimed at increasing the scope of new polymers subject to reduced regulatory requirements in a harmonised way across the participating jurisdictions. As a result of this project an **additional 24 monomers** will be added to the

"*polyester approved reactant lists*" that delineate those polyesters qualifying as "polymers of low concern" under US TSCA, Canada CEPA and Australia NICNAS jurisdictions. The next step will be the preparation of a report providing the list of additional monomers, and outlining the criteria and process used.

The Clearing House has also been exploring the options for a computer program that will enable notifiers to input and store the information elements required for new chemical notifications and then generate the completed notification forms, both as a printed hard copy and as an electronic file. After the preparation of a systems requirement document the Clearing House is currently considering whether IUCLID can be utilised for this purpose.

Forthcoming Events: Meeting of the Clearing House on New Chemicals (2016; North America)

Contact: Eeva Leinala

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

Harmonised Templates for Reporting Chemical Test Summaries

The overall set of improvements to OHTs, approved in ***February 2015***, is being prepared for publication by the end of December. The changes affect all templates, and this general update provides an opportunity for renovating the public website by simplifying the html template files and associated welcome pages. The set will also include several new templates approved earlier this year: OHT 201 on intermediate effects, OHT 301 on chemical use and exposure information, and OHTs 23-2 to 23-5 added to the series on physico-chemical properties: Self-reactive substance; Organic peroxide; Corrosive to metals; and Gases under pressure.

Relating to Effects on Biotic Systems, two OHTs on Short- and Long-term toxicity to aquatic vertebrates are being modified for adapting them to revised Test Guidelines, while one new OHT on Endocrine disrupter testing in aquatic vertebrates – *in vivo* is developed to cover several Test Guidelines on fish and amphibian assays. From the Health Effects Series, the OHTs on Skin irritation/corrosion and Eye irritation are also in the process of revision. All these templates are aimed to be approved by the end of the year.

Collaboration continued with the Metapath project, focusing on a comparison of the data evaluation report (DER) composers and the existing OHTs. ***New composers on Livestock metabolism, Plant metabolism and Confined rotational crops metabolism*** *have been tested by the MetaPath Users Group* since ***July 2015***.

Contact: Bertrand Dagallier

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

IUCLID

IUCLID (International Uniform Chemical Information Database) is a software tool used to capture and store, submit, and exchange data on chemical substances stored according to the ***OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs).*** The objective of

the OECD IUCLID User Group Expert Panel is to collect and discuss user needs in terms of the User Interface of IUCLID.

The **IUCLID User Group Expert Panel** and other stakeholders were invited to take part in five phases of external testing exercises of IUCLID 6 in 2014 and 2015 covering specific functionalities and webinars introducing each phase.

- **Phase 1**: installation testing was held in ***March 2014***.
- **Phase 2**: functional testing and security management was held from ***19 May to 9 June 2014***.
- **Phase 3**: IUCLID 5 migration, import and export, and dossier creation was held from 30 September to ***15 November 2014***.
- **Phase 4**: correction of issues, document selection panel, other improvements, installation testing, regression tests) of IUCLID 6 was held ***31 March to 1 May 2015***).

A webinar was held on **13 March 2015** on how to prepare for the upgrade in 2016 to the IUCLID 6 distributed version (server version).

The beta-version of the upcoming IUCLID 6 was published on 9 July 2015. The beta-version does not contain all the data structures and functionalities of the final IUCLID 6 release but was published to allow IUCLID users to familiarise themselves with the new look-and-feel and for users of the IUCLID distributed version to test the installation process and prepare their IT environments for the transfer in 2016.

A full version of IUCLID 6 will be released in Q2 2016.

The **IUCLID User Group Expert Panel** met on ***29-30 September 2015*** and reviewed and discussed issues regarding the deployment of the beta-version, the scope of the official release and specifications for new functionalities to be included in that release, and the two external testing phases that will be held before the release. As well, the meeting reviewed and discussed Expert Panel members' plans on the use of IUCLID 6, customisation possibilities and needs to support the management of chemical information in different jurisdictions, and prioritisation of business requirements for future maintenance releases of IUCLID 6.

Forthcoming events:

- Meeting of the IUCLID User Group Expert Panel, 27-28 September 2016 (tentative), Paris, OECD

Contact: Sally de Marcellus

TEST GUIDELINES

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

New, updated or corrected Test Guidelines

The following new, updated or corrected Test Guidelines were adopted by OECD Council and published on ***28 July 2015***:

New Test Guidelines:

Section 2: Effects on Biotic Systems

- ***240*** Medaka Extened One-Generation Reproduction Toxicity test
- ***241*** Larval Amphibian Growth and Development Assay

Section 4: Health Effects

- ***490*** *In vitro* Thymidine Kinase Gene Mutation Test (genotoxicity)
- ***491*** Short-Time Exposure test (eye hazard potential)
- ***492*** Reconstructed Human Cornea Like Epithelium test (eye hazard potential)
- ***493*** Estrogen-Receptor Binding Assay (endocrine disruption)

Updated Test Guidelines:

Section 4: Health Effects

- ***404*** Acute Dermal Irritation/Corrosion
- ***430*** *In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)
- ***431*** *In vitro* Skin corrosion: Reconstructed Human Epidermis (RHE) Test Method
- ***435*** *In Vitro* Membrane Barrier Test Method for Skin Corrosion
- ***439*** I*n Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method
- ***455*** Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists and Antagonists
- ***476*** *In Vitro* Mammalian Cell Gene Mutation Tests using the Hprt and xprt genes
- ***478*** Rodent Dominant Lethal Test
- ***483*** Mammalian Spermatogonial Chromosomal Aberration Test
- ***421*** Reproduction/Developmental Toxicity Screening Test
- ***422*** Combined Repeated Dose Toxicity Study with the reproduction/Developmental Toxicity Screening Test

Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)

The Advisory Group met in ***June 2015*** at OECD to review the development of several Adverse Outcome Pathways (AOPs) on the work plan. The Group recommended proceeding with the external review of 8 AOPs by technical experts usually involved in validation and Test Guideline development in specific areas. The external review is underway in October and November this year.

Preceding the meeting in June, **a training session on the development of AOPs using the AOP wiki** was organised and well attended. A training team is currently developing on-line material for experts who want to contribute to the AOP Programme using the AOP wiki and the user handbook.

The next event for **EAGMST** is the teleconference in December; there are discussions to start a survey about priority areas for further AOP development and collection of feedback on existing tools. The AOP-Knowledge Base is available **here**.

Information related to the AOP Development Programme, including a work plan, is available on the public website.

Expert Group on Mammalian Acute Toxicity

Under the leadership of the United States and Canada, the Group has been working on the development of a document on **bridging or waiving of acute mammalian toxicity studies**. Teleconferences have been held in March, September and October 2015 to work on the document; a draft will soon be circulated to the **W**orking Group of the National Coordinators to the Test Guidelines Programme (WNT) and to the Task Force on Hazard Assessment for review.

Joint Expert Group on Inhalation Toxicity Testing for Nanomaterials Safety

A meeting of a Joint WNT-WPMN expert group on inhalation toxicity testing was held on 21-22 September 2015 at the US EPA in Washington D.C. The meeting discussed progress with the update of Test Guidelines 412 (28-d study) and 413 (90-d study) to account for nanomaterial safety testing. The draft updated Test Guidelines will shortly be circulated for commenting.

Validation Management Group on Ecotoxicity Testing (VMG-eco)

The **VMG-eco** met at OECD on ***5-7 October 2015*** to review comments received on two draft Test Guidelines on molluscs partial life-cycle assays; the documents were revised and will be sent for another commenting round before the end of the year. *The expectation is to have the two TGs submitted for approval at the WNT meeting in April 2016*. The meeting also reviewed the status of the update of TG 203 (fish acute toxicity study), including criteria for defining moribund fish as a humane endpoint. The ongoing validation of other projects was reviewed, in particular for the Xenopus Embryo Thyroid Assay and the Zebrafish Embryo for the detection of estrogen activity. The group acknowledged that it is becoming difficult to recruit laboratories to participate on a voluntary basis in multi-centric validation studies.

Advisory Group on Endocrine Disrupters Testing and Assessment

The Group met at OECD on ***8-9 October 2015 to*** review activities in regulatory and research programmes in OECD countries, to provide input for further development of **endocrine-related AOPs** and facilitate future applications, to discuss possible next steps in a US-led project on ER modelling using selected **ToxCast assays**, to review the current status of non-animal test methods development addressing the thyroid pathway, and to discuss updates needed to the **Guidance Document 150** on the evaluation of endocrine disrupting chemicals.

Expert group on skin sensitisation

The expert group on skin sensitisation met at OECD on ***14-15 October 2015*** to discuss several assays on the workplan and new potential assays. The group addressed all issues that had been raised in a previous WNT commenting round on the ***In Vitro Skin Sensitisation human Cell Line Activation Test*** (h-CLAT) and developed a revised draft Test Guideline that will shortly be circulated to the WNT for a new round of comments. The group also reviewed the current status of the ***U937 Skin Sensitisation Test (U-SENS™)*** and the ***interleukin-8 luciferase (IL-8 Luc)*** assay for the detection of skin sensitisation and discussed two project proposals that will be submitted in November to the WNT for inclusion in the workplan in 2016, the Local lymph node assay using flow-cytometry (LLNA: BrdU-FCM) and the SENS-IS assay, based on gene expression analysis for the detection of skin sensitisers.

Recent publication(s):

The following documents were declassified and are or will be published shortly in the Series on Testing and Assessment:

- Guidance Document on Medaka Histopathology Techniques and Evaluation, No. 227
- Guidance Document on Amphibian Histopathology Techniques and Evaluation, No. 228
- Performance Standards for the Assessment of Proposed Similar Methods or Modified *in vitro* Reconstructed Human Cornea like Epithelium test methods for Eye Hazard, based on the Validated Reference Method, EpiOcular TM, No.216
- Three Updated Performance Standards for TG 430, TG 431, TG 439 for *in vitro* Skin Irritation or Corrosion, Nos. 218, 219, 220
- Report of the Inter-laboratory Validation Study supporting the Update of TG 455, No. 225
- Updated Performance Standards for TG 455, No. 174
- Report of the Inter-laboratory Validation Study supporting the new Estrogen Receptor Binding Assay, No. 226
- Performance Standards for the Assessment of Similar or Modified Estrogen Receptor binding Assay, No. 222
- Feasibility Study and Statistical Analysis for the Update of TG 421 and TG 422 with Endocrine-related Endpoints, No. 217
- Guidance Document for the Storage Stability Testing of Plant Protection Products and Biocidal Products (coming from the Task Force on Biocides), No. 223

Forthcoming events:

- Meeting of the Expert Group on Eye Irritation Testing, **9-10 November 2015**, OECD, Paris

- Meeting of the Validation Management Group for Non-Animal Testing, **1-3 December 2015**, Budapest, Hungary
- Meeting of the Expert group on Non-Genotoxic Carcinogenicity, **30-31 March 2015**, OECD, Paris
- Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme,
  19-21 April 2016, OECD, Paris
- Meeting of the Extended Advisory Group on Molecular Screening and Toxicogenomics, **22-23 June 2016**, OECD, Paris

✉ ***Contact:*** Anne Gourmelon, Nathalie Delrue, Marie-Chantal Huet, Leon Van der Wal, Romualdo Benigni, Yukie Saegusa and Christina Quaglio

Website: www.oecd.org/env/testguidelines

GOOD LABORATORY PRACTICE

The Working Group on Good Laboratory Practice (GLP) works to facilitate and support the implementation by Member countries and interested non-members of the Council Acts related to Mutual Acceptance of Data (MAD), by promoting a common understanding of, and harmonised approaches to, technical and administrative matters related to Good Laboratory Practice and monitoring of compliance with the GLP Principles. These Principles are quality standards for the organisation and management of test facilities and for performing and reporting studies.

The **29th meeting of the Working Group on GLP** met on **16-17 April, 2015** in Paris, France. (The meeting also included a joint session with the Working Group of the National Co-ordinators of the Test Guidelines Programme.)

On-site evaluations

Under OECD's on-site evaluation activity, each **GLP Compliance Monitoring Programme (CMP)** in OECD and full adherent countries is evaluated every ten years. These evaluations enhance confidence that data receiving authorities are provided accurate and complete assessments of the conduct of non-clinical health and environmental safety studies and of the quality of the data. The programme of on-site evaluations of **GLP compliance monitoring programmes** in member and adhering non-member countries continues, with three on-site evaluation conducted to date in 2015 – Sweden, Slovak Republic and Spain (pesticides, feed additives and industrial chemicals including biocides) – and one more to be conducted in South Africa in November, 2015. Five on-site evaluations are scheduled for 2016 in Israel, Canada, Poland, Austria (medical

products) and Estonia. The reports of the four on-site evaluations held in 2015 will be reviewed during the 2016 meeting of the Working Group.

Documents being developed

A Working Group drafting group – lead by Austria Federal Office for Safety in Health Care- is developing an ***Advisory Document on the Application of GLP Principles to Computerised Systems*** which will replace the 1995 OECD GLP Consensus Document Number 10 (The Application of the Principles of GLP to Computerised Systems). The new Advisory Document will retain all of the key text from the original Consensus Document where changes are not necessary, but also include new text to reflect the current state-of-the art in this field. A draft of the Advisory Document was posted on the public website for comment in September, 2014, and, by January, 2015, over 300 comments were received from 14 countries and four organisations. Based on the comments received, a revised draft was discussed at the 29th Working Group meeting in April. A final version is under preparation and is scheduled to be submitted for Working Group approval in 2015 followed by declassification in late 2015 or early 2016.

An **Advisory Document on *Test Items*** is being developed by a drafting group under the leadership of Canada. The objective of the document is to consolidate text in existing guidance documents that refer to "test item", as well as promote a consistent approach for performing characterisation of test items. The first draft of the document was reviewed at the 28th meeting (April, 2014), and a revised version was reviewed at the 29th meeting. The drafting group will prepare a revised version to reflect recent comments and submit this draft for an additional round of review by the Working Group. Once the text has been agreed by the Working Group, the draft Advisory Document will be posted on the GLP public website for comments.

The **UK** and **France** are leading efforts by the Working Group to develop **Version Two** of a public web page concerning ***Frequently Asked Questions*** **(FAQ)** raised by testing laboratories about implementation of GLP, along with responses prepared by the Working Group. (Version One of the ***FAQ*** – posted on the public site in July, 2014 - concerns questions about *quality assurance*.) A draft of Version Two, which addresses issues associated with *study reporting* and *method validation*, was considered at the 29th Working Group meeting. Based on the comments raised during the meeting, a revised version will be circulated to members for review and approval, and then declassification.

A ***"Questions and Answers (Q&A)"*** document is under preparation for posting on the public website to address *general* questions typically raised by the public about GLP and MAD. A first draft of the Q&A document was presented at the 29th meeting. The document is scheduled to be published by the end of 2015.

The **12th OECD GLP training course**, was hosted by the **Indian GLP Compliance Monitoring Authority**, and held in Hyderabad, India from 12 October to 15 October, 2015. The training course focused on developing strategies for conducting inspections, and included a tour of a test facility, and breakout sessions which focused on observations made during the tour. The three-day training course was preceded by a one-day basic course on GLP and Mutual Acceptance of Data. Approximately 80 participants, representing 20 countries including six non-members, attended the training course. The next training course will be held in 2017 in Poland.

Forthcoming events:

- 30th Meeting of the Working Group on GLP – Nice, France, 26-27 April 2016

✉ ***Contact:*** Richard Sigman and Yukie Saegusa

Websites: http://www.oecd.org/env/glp

MUTUAL ACCEPTANCE OF DATA

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

A 1989 Council Decision-Recommendation on Compliance with GLP sets the framework for recognition of compliance assurance among governments. The MAD system has been open to non-OECD countries since 1997.

Brazil and MAD

There are six non-members who are full adherents to MAD: **Argentina, Brazil, India, Malaysia, Singapore** and **South Africa**. Non-clinical health and environmental safety data generated in these countries must be accepted for regulatory purposes in OECD and other adhering countries. In March, 2011, **Brazil** joined the OECD system for MAD. When it joined, the scope of Brazil's compliance monitoring programme was limited to non-clinical environment and health safety data developed in Brazil on *pesticides*, *biocides* and *industrial chemicals*. Brazil's scope under MAD has now been expanded to include: *veterinary products, feed additives, cosmetics, pharmaceutical products, sanitizers, wood preservative products* and *treatments of effluents and natural ecosystems.* At the moment, full adherence for Argentina only applies to industrial chemicals, pesticides and biocides.

The Working Group on GLP implements on-site evaluation visits of national compliance monitoring programmes which are provisional adherents to MAD and are ready to be considered for full adherence. Currently, Thailand is a provisional adherent to the MAD system. An on-site evaluation team from Spain, Belgium and India visited the **GLP Compliance Monitoring Programmes** in Thailand in January, 2012. The report from the visit was considered at the 27th meeting of the Working Group on GLP (16-18 April, 2013). The Working Group meeting in April 2015 agreed that a follow-up visit to Thailand should be conducted when sufficient conditions have been met. The follow-up team will include Belgium, India and the Netherlands.

The Secretariat continues to work with several other countries, in view of their possible provisional adherence to the MAD Council Acts as well.

✉ ***Contact:*** Richard Sigman and Yukie Saegusa

Websites: **MAD public website**
http://www.oecd.org/env/glp

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eChemPortal

*The OECD **eChemPortal**, launched in 2007, offers free public access to information on properties and hazards of chemicals. It provides direct access to critical scientific information prepared for government chemical review programmes. eChemPortal allows for simultaneous search of data from multiple international databases and provides clearly described sources and quality of data.*

A new version of **eChemPortal** was released on **12 June 2015** to offer better access to chemical classifications according to the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**. A new search by GHS classification in eChemPortal allows users, for an individual chemical, to view GHS classifications which have undergone a review by a regulatory body or intergovernmental organisation. The first data sources linked to via this search are the C&L inventory of the **European Chemicals Agency (ECHA)** and the **GHS Classification Results** by the Japanese Government. The new release also includes improvements to the eChemPortal application architecture.

Forthcoming events:

- Meeting of the Steering Group for the Development of a Global Portal to Information on Chemical Properties, 20-21 April 2016 - Paris, France

Website: **http://www.oecd.org/ehs/eChemPortal**

DISSEMINATION OF OECD PRODUCTS

All of the products of the OECD Environment, Health and Safety Programme are available free of charge to the general public via the internet. Additional work is devoted to improving the overall dissemination and the use of the products of the Environment, Health and Safety Programme.

OECD Environmental Risk Assessment Toolkit

This Environmental Risk Assessment Toolkit is a set of web pages which give access to practical tools on environmental risk assessment and management of chemicals. It describes the work flow of environmental risk assessment and management with links to relevant OECD products that can be used in each step of the work flow.

Following the new interactive release of the Toolkit in 2012, a new version was published in September 2015. The whole content was revised; three new examples– on metals, air pollution, and POPs/PBTs – have been integrated and a general module on pesticides has been added.

✉ ***Contact:*** Joop De Knecht, Valérie Frison

Websites: www.oecd.org/env/riskassessment/toolkit
http://envriskassessmenttoolkit.oecd.org

Inter-Organization Programme for the Sound Management of Chemicals (IOMC) Toolbox for Decision-Making in Chemicals Management

The IOMC Toolbox is a problem-solving tool that enables countries to identify the most appropriate and efficient national actions to address specific national problems related to chemicals management. The toolbox identifies the available IOMC resources that will help the country address the identified national problem(s) or objectives. Special focus is given to identifying simple cost-effective solutions to national chemicals management issues.

A proof-of-concept version of the toolbox was completed in **June 2012**. Phase 2 of the development of the toolbox officially started in November 2013 and a revised version of the IOMC Toolbox was launched in May 2015. Progress has been made on the following subjects:

- An industrial chemicals management scheme was implemented into the IOMC Toolbox.
- Existing schemes on pesticides, occupational health and safety and managing major chemical accidents were reviewed for updates and revised in the Toolbox.
- A draft scheme for setting up a PRTR has been created in the Toolbox and will be released shortly.
- New functionalities for the Toolbox have been implemented. New collaboration features allow the users to save their navigation, write comments, and share them with colleagues in working groups. Each user has a dashboard on their "MyIOMC" page, which can be used for viewing and managing their navigations and collaborative groups.

The OECD participated in the promotion of the IOMC Toolbox, with the aim of dissemination and receiving feedback on the tool. This included the development of a promotional video and participation in the following events:

- Side event, science-fair and IOMC booth promotion at the Basel, Rotterdam and Stockholm Conventions Conferences of the Parties in May 2015
- Webinars to the Rotterdam convention contact points in June 2015
- Latin American and Caribbean Region Nanosafety Workshop: Presentation of the IOMC Toolbox in Colombia in June 2015
- Presentations and promotion at the International Conference on Chemicals Management 4 (ICCM4) in September 2015

✉ ***Contact:*** Eeva Leinala, Valérie Frison

Website: http://iomctoolbox.oecd.org

Promotional video: https://www.youtube.com/watch?v=YQUGl5hD_BY

TOOLS AND APPROACHES TO SUPPORT DECISION-MAKING FOR THE SUBSTITUTION OF HAZARDOUS CHEMICALS

The Ad Hoc Group on the Substitution of Harmful Chemicals is developing tools and approaches to support decision-making for the substitution of hazardous chemicals. that the current workplan foresees the development of a literature review, an inventory of substitution tools and of an online tool to help users identify the tools best suited for their purpose

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals was established in 2012, with the goal of furthering tools and approaches to support decision making for the substitution of chemicals of concern.

New Toolbox

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals released the OECD Substitution and Alternatives Assessment Toolbox in **January 2015**.

This toolbox is a compilation of resources relevant to chemical substitution and alternatives assessments. Alternative assessments are processes for identifying, comparing and selecting safer alternatives to replace hazardous chemicals with the objective of promoting sustainable production and consumption. The toolbox includes a range of resources where you can learn

more about chemical substitution and alternatives assessments and get practical guidance on conducting them.

An OECD Expert Workshop on ***Alternatives Assessment and Substitution*** was held on **11-12 May 2015** at the OECD Headquarter in Paris. It was an opportunity to discuss what further work the OECD could undertake to further support the area of substitution and alternatives assessment. A workshop report was developed and will be published by the end of 2015.

✉ ***Contact:*** Eeva Leinala, Marie-Ange Baucher

Websites:

- http://www.oecd.org/env/ehs/risk-management/
- www.oecdsaatoolbox.org

RISK MANAGEMENT AND SUSTAINABLE CHEMISTRY

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

Perfluorinated chemicals (PFCs)

The OECD/UNEP Global PFC Group was established in 2012 to facilitate the exchange of information on PFCs and to support a global transition toward safer alternatives. The group presented its workplan at the **International Conference on Chemicals Management (ICCM4)** in ***September 2015*** and recently published two reports.

Two new PFC reports

The report Risk Reduction Approaches for PFASs – A Cross-Country Analysis provides an overview of current activities with regard to the development of risk reduction approaches for per- and polyfluoroalkyl substances in a number of jurisdictions. The report Working Towards A Global Emission Inventory of PFASs: Focus on PFCAs – Status Quo and the Way Forward uses perfluoroalkyl carboxylic acids (PFCAs) as a reference to present an overall picture of global and regional emissions of PFASs and other related fluorinated substances.

Planning for the update of the PFC Web Portal http://www.oecd.org/ehs/pfc/ is underway, and information on previous public webinars held by the group can be found here.

Recent publications:

- 🕮 **Risk Reduction Approaches for PFASs – A Cross-Country Analysis**
- 🕮 **Working Towards A Global Emission Inventory of PFASs: Focus on PFCAs – Status Quo and the Way Forward**

✉ ***Contact:*** Eeva Leinala, Marie-Ange Baucher

Website: **http://www.oecd.org/env/ehs/risk-management/**
http://www.oecd.org/ehs/pfc/

Sustainable Chemistry

The **OECD Issue Team on Sustainable Chemistry** was established in 1999 to address issues, in particular policy issues, linked to the development of sustainable chemistry. The team has been developing a **Sustainable Chemistry Platform**, which is regularly updated. The platform has been set up to facilitate information exchange, review of new developments and further elaboration of incentives for sustainable chemistry and to facilitate networking of stakeholders. This platform intends to identify specific areas and projects of sustainable chemistry that would benefit from international co-operation.

The Issue Team is developing a project on the economic characteristics of chemical leasing. This project will be looking at the range of economic implications the model entails. It will also study the policy and market drivers, which are supporting the use of chemical leasing, building on current needs of consumers and societies for more cost-efficient and sustainable solutions. A report is in development.

✉ ***Contact:*** Eeva Leinala, Marie-Ange Baucher

Websites: http://www.oecd.org/env/riskmanagement

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

OTHER EHS PROGRAMMES

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.

- Meetings and document production

The pesticide **Residue Chemistry Expert Group (RCEG)** met on **7-8 July, 2015** at the OECD in Paris. The purpose of the meeting was two-fold: 1) to revise the **draft *Guidance Document for Crop Field Trials (CFT)***; and 2) to agree on a first draft ***Guidance Document for Residues in Rotational Crops*.** A revised version of the draft Guidance for Crop Field Trials along with annexes with additional information has been posted on the **public website** for comments, with a deadline of 30 November, 2015.

The **Expert Group on Terrestrial Field Dissipation (EG-TFD)** led by Canada, the United States and EFSA (European Food Safety Agency) have developed guidance for the conduct of pesticide terrestrial field dissipation studies and a crosswalk between North American and European Ecoregions**. A draft *Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies*** is scheduled to be submitted before the end of 2015 to both WGP (Working Group on Pesticides) and WNT (Working Group of National Co-ordinators of the Test Guidelines Programme) for approval.

Following the 2014 survey on the current product chemistry requirements, the **New-Zealand**-led **Expert Group on Product Chemistry (EGPC)** is developing guidance on the data requirements for core chemistry and manufacturing properties of chemical active ingredients and formulations.

The **Expert Group on Honey bees toxicity testing** (*ad hoc* group established within the Test Guidelines Programme) met on 22-24 April 2015 at OECD in Paris to progress with the development of two documents:
(1) a **draft *Guidance Document for Honeybees Larval Toxicity Test, Repeated Exposure***; a revised version was circulated to the group for comments in July 2015;
(2) a honeybee chronic oral toxicity test, 10-day feeding test.

As part of the work of the **Expert Group on the Electronic Exchange of Pesticide Data** (EGEEPD), the **Global Harmonised Submission Transport Standard (GHSTS)** *version 01* was published on ***28 May 2014*** on the OECD website at **http://www.oecd.org/chemicalsafety/submission-transport-standard/**. The GHSTS specifies how to assemble electronic files required in the evaluation of submissions for any pesticide package.

After publication of the GHSTS, focus turned to developing supporting tools to assist implementation of the GHSTS. An XML instance of a dossier numbering system (ToC) for chemical pesticides according to OECD dossier guidance (2005) was published in ***September 2015*** on the OECD website with the GHSTS. This XML instance can be included, along with other metadata, in an electronic package to indicate to the receiver the purpose of the electronic files (e.g. Word, PDF) contained in the package. **Canada** is developing a beta-version of a GHSTS "e-dossier" builder. The release is planned for April 2016. BIAC has developed a first version of a GHSTS Viewer and demonstration dossier and will continue to fine-tune the tool.

- Expert group collaboration

As part of the pesticide risk reduction activities, the **Expert Group on Integrated Pest Management (EGIPM)** collaborates closely with the **Expert Group on Pesticide Risk Indicators (EGPRI)** regarding recommendations on PRIs for IPM. Additionally EGIPM is evaluating how IPM tools, including biopesticides can be implemented for high value speciality crops, the so-called minor uses.

The Expert Group on Pesticide Risk Indicators (EGPRI) has completed the first part of its work programme. The *Report on the online Pesticide Risk Indicators and their Evaluation Reports (PRIER) Database* is scheduled to be published by the end of 2015. EGPRI held its fifth meeting on 9th September, 2015 in Brussels, jointly with the Expert Group on Integrated Pest Management. The Meeting progressed with developing guidance on why and how to use recommended PRIs and develop IPM impact indicators.

- Information exchange at Risk Reduction seminar

A seminar on risk reduction of non-professional uses of pesticides was held on ***9 December 2014*** that enabled a good exchange of information on this topic between regulatory authorities and stakeholders. The seminar report is expected to be published by the end of this year.

As regards bio-pesticides, a seminar on issues related to hazard and risk assessment of secondary metabolites produced by microbial pesticides was held on **18 May 2015**. A report on this seminar is in draft and will be published in 2016 in the ***OECD series on Pesticides***.

For other activities on bio-pesticides (biological pesticides such as micro-organisms, fungi, pheromones, invertebrates, etc.), work continues on the following projects:

i) report/background document on hazard and risk assessment of secondary metabolites produced by microbial pesticides;
ii) report on the adequacy of testing methods for data requirements for microbial pesticides;
iii) report on the issue of sensitisation to microbial pesticides based on a 2014 survey;
iv) draft Guidance Document for Microbials Storage Stability;
v) draft Guidance Document on Botanical Active Substances Used in Plant Protection Products,
vi) draft Guidance Document for the Assessment of the Equivalence of Technical Grade Active Ingredients for Identical Microbial Strains or Isolates;
vii) draft Guidance Document on Semiochemical Active Substances Used in Plant Protection Products;

viii) draft Guidance Document for Testing Storage Stability of Microbials, and
ix) survey report on the regulation of macro-organisms biocontrol agents.

Forthcoming events:

- Week of 31 November - 4 December 2015 (Brisbane, Australia):
  - Registration Steering Group Meeting
  - Risk Reduction Steering Group Meeting
  - Workshop on Sustainable Pest Management: Anticipating and adapting to changes in regulatory status and subsequent availability
- 27-28 June 2016- Expert Group on the Electronic Exchange of Pesticides Data (EGEEPD) (OECD, Paris, France)
- 28 June 2016, BioPesticides Steering Group (BPSG) seminar (OECD, Paris, France)
- 29 June 2016, BPSG meeting (OECD, Paris, France)
- 30 June -1 July 2016: Working Group on Pesticides meeting (OECD, Paris, France)

Recent Publications:

📖 **Report of the Fifth Bio-Pesticides Steering Group Seminar on Application Techniques for Microbial Pest Control Products and Semio-chemicals: Use Scenarios and Associated Risks, Series on Pesticides No. 80**

Websites:
http://www.oecd.org/chemicalsafety/pesticides-biocides
http://www.oecd.org/chemicalsafety/pesticides-biocides/biological-pesticides.htm
http://www.oecd.org/env/ehs/pesticides-biocides/minoruses.htm

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BIOCIDES

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

The **Expert Group on Efficacy of Biocides to Treat Articles (EBTA)** is developing guidance for Tier 2 laboratory-based tests to substantiate claims for efficacy of biocide treated articles including porous surfaces (textiles) and non-porous surfaces (plastics). The draft Guidance Document containing two detailed example protocols: ***simulated splash test on textiles and plastics*** and ***non-suspended inoculum method to simulate hand contact*** will be available for review in ***November 2015***

The report resulting from the member country survey on performance standards and related authorised label claims for microbicides has been revised to include further information on how levels of soiling on articles and contact time with the microbicide are taken into account in member countries, and discussed during the **13th TFB Meeting** in ***September 2015***. Finalisation of the report is planned before the end of 2015, and it is expected that this work will lead to a new guidance document.

The **Expert Group on Biocides Chemistry (EGBC)** has started to work on the development of two documents:

1) Guidance for flammability testing
2) Document on waiving and bridging of physical chemistry studies

Regarding work on the risk reduction of biocides, a survey to collect information on current IPM approaches for disinfectants in member countries has been finalised and discussed during the 13th TFB Meeting in September 2015. The report is planned to be finalised by the end of 2015. This could lead to the development of a harmonised **Integrated Pest Management (IPM)** approach for disinfectants.

The **French delegation** leads a project to develop aggregated exposure assessment methodologies, for which a dedicated project group has been formed. This work continues with a comparison of available methodologies to assess human exposure in OECD member countries. A report of this comparative study is planned to be finalised by the end of 2015.

The **US**-led **Expert Group on efficacy of microbicides on hard surfaces** was reactivated in ***January 2015***. The objective of the work is to improve the procedures and performances of the four test methods described in the 2013 ***Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides Used on Hard Non-Porous Surfaces*** so that they can be further adopted as OECD Test Guidelines. The first on-line meeting of the group was held on 2nd July 2015.

Recent Publications:

- **Guidance Document for Storage Stability Testing of Plant Protection and Biocidal Products, Series on Testing and Assessment, No. 223**

http://www.oecd.org/chemicalsafety/pesticides-biocides/

Forthcoming events:

14th Meeting of the Task Force on Biocides, June 2016, ECHA Headquarters, Helsinki, Finland

CHEMICAL ACCIDENTS

The Chemical Accidents Programme works to develop guidance on prevention of, preparedness for, and response to chemical accidents. It facilitates the sharing of information and experiences of both OECD and non-member countries. The Programme is managed by the Working Group on Chemical Accidents (WGCA).

The WGCA is currently focusing its efforts on the following topics:

- **Ownership Change in Hazardous Installations**

This project aims to investigate the effects of a change of ownership on process safety and on the risk of a chemical accident. More generally, it aims to increase awareness by public authorities, industry and other stakeholders on the safety implications of a change of ownership in hazardous facilities. A report from a Special Session on this topic, which was organised in October 2014 at the occasion of the 24th Meeting of the WGCA, is planned for publication in early 2016. Following this publication, the project will continue with more investigation on guidance to help stakeholders during a change of ownership as well as to gather more information on countries' approaches to change of ownership in hazardous facilities;

- **Ageing of hazardous installations**

This project aims to explore countries' approaches toward ageing of hazardous plants. It is looking at aspects such as: the extent to which ageing of hazardous installations is recognised as a potential contributor to major accidents; how ageing is defined, and the breadth of coverage of regulatory or guidance programmes; the level of government intervention; methods to inspect and assess degradations; methods used to measure, and if necessary, drive improvements in, industry's performance in managing ageing issues. A report is being developed that will compile

(i) the results of a survey activity aiming to collect information on countries' approaches to ageing of hazardous installations,

(ii) an analysis of accidents associated with ageing, and

(iii) the results from discussions at a **Special Session on Ageing of Hazardous Installations** that took place on **October 28th, 2015** at the occasion of the **25th Meeting of the WGCA**

- **Inspection approaches for chemical accidents prevention, preparedness and response**

The project aims to collect simple figures on inspection systems across countries for *chemical accidents prevention*, *preparedness* and *response*. The project would gather simple figures on how inspections are being carried out (e.g. how many inspectors/versus number of facilities to inspect); which authorities are involved in the inspections of hazardous facilities (e.g. ministry, agency, etc.) and what overlap their might be between the stakeholders involved; what is the role of government inspectors and how could their role be facilitated; how can knowledge be transferred. A questionnaire and a literature review are now underway to support the development of this project.

The WGCA is also just finalising a scoping report on Major accidents involving manufactured nanomaterials, which is expected for publication in early 2016.

The **WGCA** will next meet on **24-27 October 2016** at the OECD Headquarters in Paris.

Forthcoming Events:

- ***26th Meeting of the Working Group on Chemical Accidents, 24-27 October 2016.***

✉ ***Contact:*** Peter Kearns and Marie-Ange Baucher

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 sharing of data between countries.

The Task Force on PRTRs (TF-PRTRs) focuses on i) improving PRTRs, ii) harmonising PRTRs across the world, and iii) enhancing use of PRTR data on a global scale.

Release estimation techniques

To assist countries in improving their PRTR, the existing guidance documents on release estimation techniques are reviewed and updated. The content of the current compendium on diffuse sources and the compendium on releases from products will be merged and updated. In addition, the current Resource Compendium of PRTR Release Estimation Techniques Part 3: *Summary of Off-Site Transfer* will be updated, focusing on estimation techniques for transfers to wastes or wastewater. These documents are expected to be finalized by 2016.

Harmonisation

Regarding harmonisation of PRTRs across countries, the TF-PRTRs is developing a guidance document on Elements of a PRTR Part II, which provide key elements for developing or revising a PRTR. This document is expected to be published in November 2015. The TF-PRTRs also developing a module for the IOMC Toolbox for Decision Making in Chemicals Management with guidance on how to set up a PRTR.

Finally, the TF-PRTRs is exploring the role of PRTR data as a practical means to assess progress in global sustainability. This discussion continues at the next Task Force meeting and will produce a guidance document in 2016.

Forthcoming events:

- 18th Meeting of the Task Force on PRTRs, 23-24 November, 2015, Madrid, Spain

- 2nd Global Round Table on PRTRs, 24-25 November, 2015, Madrid, Spain

✉ ***Contact:*** Takahiro Hasegawa

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

HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

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

Based on the agreements made at the 29th meeting of the **Working Group on Harmonisation of Regulatory Oversight in Biotechnology** held in **April 2015**, progress was made on the following projects:

- The Consensus Documents on ***The Biology of Common Bean*** (led by Brazil and ILSI-CERA), Cowpea (led by Australia) and ***Sorghum*** (co-led by South Africa and the United States) are near finalisation, and two of them should be published by ***December 2015***;
- The document on **The *Biology of Tomato*** (led by Spain and Mexico) is expected to be completed in the coming months, while the work continues on the Mosquito *Aedes aegypti* project.

Following a Workshop held in Washington D.C. in ***September 2015***, the experts in charge of the document on ***Environmental Considerations*** are developing a full draft that will be considered for agreement at the next meeting of the Working Group in April 2016. The document will contain a series of information items which can usefully guide the approach to the environmental risk/safety assessment of transgenic plants: ***Persistence/weediness and invasiveness; Gene flow; Organisms and food web; Effects on soil function; Crop management practices; Effects on plant health; and Biodiversity.***

The **OECD Product Database**, containing information on genetically-engineered crops approved for being cultivated or used in foods and feeds, was recently completed with entries from Brazil and Paraguay. A second **FAO/UNEP-CBD/OECD Webinar** on the international databases on biosafety, held on 27 May, focused on good practices for effective national communication mechanisms, and was followed by 60 participants from 41 countries worldwide. The next joint webinar, scheduled for 9 December 2015, will propose training on the effective use of data that is available in the three databases. All information on the joint webinars, including reports and registration form, is available at: http://tiny.cc/Biosafety-Events**.**

Recent publications:

- 🕮 OECD (2015), *Biosafety and the Environmental Uses of Micro-organisms –Conference Proceedings*, OECD Publishing, http://dx.doi.org/10.1787/9789264213562-en
- 🕮 Biotechnology Update – Newsletter from the OECD Internal Co-ordination Group for Biotechnology (ICGB) – ***No 29, July 2015***

Forthcoming events:

- 30th meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 13-15 April 2016, OECD

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SAFETY OF NOVEL FOODS AND FEEDS

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

The compendium of the OECD Consensus documents on crop composition issued from 2002 to 2014 was published in April 2015. They cover a total of 19 plant and mushroom species, as well as *key issues* on the safety of novel foods and feeds.

At the 22snd meeting of the Task Force for the Safety of Novel Foods and Feeds held in April 2015, progress was made on the following composition documents:

- **Common bean** (*Phaseolus vulgaris*): the revised draft prepared by an *ad hoc* group led by Brazil is under finalisation for publication in December 2015.

- **Rice** (*Oryza sativa*) composition, project led by Japan: the document, revising the 2004 OECD publication, is under finalisation to include contributions from the Philippines, the United States and the International Rice Research Institute (IRRI). It is expected to be published during the first quarter of 2016.

- **Apple** (*Malus domestica*): The development of a composition document by an *ad hoc* group led by Germany, is in progress. A complete draft will be reviewed at the next meeting of the Task Force in April 2016.

Progress was also made on new projects, namely on "***Animal composition data***" (led by Canada) and "Innovative novel feed ingredients" (co-led by the Netherlands and Canada) for which a collaboration was initiated with FAO during a **FAO/WHO *Expert Meeting on Hazards Associated with Animal Feed*** held in Rome in ***May 2015***.

Forthcoming events:

- OECD Workshop on High Throughput DNA Sequencing in the Safety Assessment of G.E. Plants, 18 April 2016, OECD
- 23nd Meeting of the Task Force on the Safety of Novel Foods and Feeds, 19-21 April 2016, OECD

Recent publications

OECD (2015), *Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 1* (compiling the Consensus documents issued from 2002 to 2008), Novel Food and Feed Safety, OECD Publishing, Paris. **http://dx.doi.org/10.1787/9789264180147-en**

OECD (2015), *Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 2*, (compiling the Consensus documents issued from 2009 to 2014), Novel Food and Feed Safety, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264180338-en

Biotechnology Update – Newsletter from the OECD Internal Co-ordination Group for Biotechnology (ICGB)) – ***No 29, July 2015***

Contact(s): Bertrand Dagallier, Takahiko Nikaido, Peter Kearns

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THE GLOBAL FORUM ON BIOTECHNOLOGY

The Global Forum on Biotechnology, established in 2010, is one of 14 Global Forums created by OECD Committees. Global Forums are generally not official OECD bodies, but are best described as broad communities or networks of stakeholders in the areas of responsibility of one or more Committees. OECD Committees have an interest in hearing the views of these stakeholders, but their capacity to accommodate non-Member observers is limited.

Non-members attend meetings for the first time

Collaboration continued with key non-member partners and other international organisations involved in biosafety, in particular on the occasion of the plenary meetings of the **Working Group on the Harmonisation of Regulatory Oversight in Biotechnology** and the **Task Force for the**

Safety of Novel Foods and Feeds held at the OECD in April 2015. These meetings were attended by delegates from **Argentina, Bangladesh, Brazil, Indonesia, Latvia**, **Paraguay** for the first time, the **Philippines**, the **Russian Federation**, **South Africa**, the **African Biosafety Network of Expertise** (AU-NEPAD) **UNEP** and **FAO**.

Closing workshop to mark end of partnership

The **Partnership for Biosafety Risk Assessment and Regulation** having involved the **World Bank**, the **OECD** and **ILSI-CERA** ended in ***December 2014***. To mark its completion, a closing workshop was hosted by the World Bank in Washington D.C. on ***9 September 2015***. The Partnership was acknowledged to have successfully strengthened the capacity of eight developing countries. It addressed the issue of ensuring science based risk assessment and regulation of genetically engineered crops; partners worked together to strengthen the technical capacity of stakeholders engaged in biosafety risk assessment and regulation to facilitate evidence based decision making.

The Partnership has allowed to involve new countries in the activities of the **biosafety Working Group and the food-feed safety Task Force** (**Bangladesh, Kenya, Colombia and Paraguay**), for mutual benefit. It has also helped to develop Consensus documents and in particular on the biology of cassava (issued in June 2014) and common bean (issue expected in Dec. 2015), and to add information on approved varieties in the **OECD BioTrack Product Database**. More information on the Partnership is available at the following link: **Partnership summary report**.

The third annual **South Asia Biosafety Conference** was hosted in **Dhaka, Bangladesh** in ***September 2015***. The Conference allowed strengthening links with experts and authorities developing national biosafety systems in the countries involved: **Bangladesh, Buthan, India, Pakistan** and **Sri Lanka**. Contact was also taken with the authority of Vietnam, the country having recently granted its first approvals of some genetically-engineered varieties of maize for cultivation, and of maize and soybean for feed use.

Contact(s): Bertrand Dagallier, Peter Kearns

STAFF IN THE EHS DIVISION

Since the last ***Environment, Health and Safety News*** (No. 31, issued in ***March 2015***), the EHS Division has seen the following changes in staffing:

- **Magdalini Sachana** has replaced **Dan Merckel** as an Administrator working on Hazard Assessment and Pesticides.
- **Amanda Mccaffrey-Horeau** has replaced **Marielle Guillaud** as the Resource Management Advisor.
- **Camilla Francis** has replaced **Alastair Wood** as Communications and Publications Co-ordinator.
- **Christina Quaglio** has replaced **Camilla Francis** as the assistant for the Test Guidelines Programme.
- **Terumi Munekane** has replaced **Asako Aoyagi** working on Nanotechnologies.

WEB SITES

Find more information about the EHS work Programme from our homepage and related linked pages:

EHS Homepage	http://www.oecd.org/chemicalsafety
Biocides	http://www.oecd.org/env/biocides
Biosafety and Food/Feed safety	http://www.oecd.org/biotrack
Chemical Accidents	http://www.oecd.org/env/accidents
Exposure Assessment	http://www.oecd.org/env/exposure
Global Portal to Information on Chemical Substances	http://www.oecd.org/ehs/eChemPortal
Good Laboratory Practice	http://www.oecd.org/env/glp
Harmonised Templates	http://www.oecd.org/ehs/templates
Harmonisation of Classification of Labelling	http://www.oecd.org/env/classify
Hazard Assessment	http://www.oecd.org/env/hazard
Mutual Acceptance of Data (MAD)	**http://www.oecd.org/ehs/mad**
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
(Q)SARS	http://www.oecd.org/env/hazard/qsar
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
Sustainable Chemistry	http://www.oecd.org/env/sustainablechemistry
Test Guidelines	http://www.oecd.org/env/testguidelines

Most EHS Publications can be downloaded directly from OLIS or our website:
www.oecd.org/ehs/publications

If you are unable to find what you are looking for, please contact the Secretariat:
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BAUCHER, Marie-Ange	Chemical Accidents, Rick Management	**94.22**	0268
BENIGNI, Romualdo	(Q)SARs, Test Guidelines	**16.76**	0319
DAGALLIER, Bertrand	Food Safety/Biosafety/Harmonised Templates	**84.51**	0283
DE KNECHT Joop	Hazard Assessment, (Q)SARS, Templates, PRTRs	**82.57**	0352
DELRUE, Nathalie	Test Guidelines	**98.44**	0319
DE MARCELLUS, Sally	Hazard Assessment	**19.42**	0320
EL GAOUZI Jihane	Consultant Biosafety, Nano safety	**19.11**	0295
FRANCIS, Camilla	Communications and Publications	**64.39**	0263
FRISON BEAU, Valérie	Hazard Assessment	**89.34**	0334
GIBB, Jill	Assistant to Head of Division and Administrative assistant	**93.16**	0346
GONZALEZ, Mar	Nanotechnologies, Outreach Programme	**76.96**	0295
GOURMELON, Anne	Test Guidelines, Hazard Assessment	**98.49**	0318
HASEGAWA, Takahiro	Exposure Assessment, PRTRs	**79.07**	0320
HOSOKAWA, Mika	Assistant, Nanotechnologies, Biosafety, Food Safety	**17.08**	0263
HUET, Marie-Chantal	Pesticides, Chemical Accidents, Test Guidelines	**79.03**	0283
KEARNS, Peter	Biosafety, Food Safety, Nanotechnologies, Chemical Accidents	**16.77**	0285
LEINALA, Eeva	Hazard Assessment, Risk Management	**76 30**	0318
MACFARLANE Fiona	Assistant, Hazard Assessment, (Q)SAR, PRTRs, Templates and Risk	**17 37**	0263
MASI Nausicaa	Assistant, Hazard Assessment, IATA, Risk Mgt, Sustainable Chem	**64 37**	0263
MCCAFFREY-HOREAU Amanda	Resource Management Adviser	**89 96**	0340
MUNEKANE, Terumi	Nanotechnologies	**14.63**	0295
NIKAIDO, Takahiko	Biosafety, Food Safety	**76.19**	0289
OLADINI-JAMES, Christiana	Assistant, Pesticides, Biocides, GLP, New Chemicals Chemical Accidents	**16.48**	0263
PORET, Sylvie	Pesticides, Biocides, Risk Reduction	**89.45**	0238
QUAGLIO Christina	Assistant, Test Guidelines	**78.48**	0263
SACHANA Magdalini	Hazard Assessment, Pesticides	**64 23**	0332
SAEGUSA Yukie	GLP, Test Guidelines	**76.98**	0332
SAKURATANI Yuki	QSARs and Hazard Assessment	**98.19**	0327
SIGMAN, Richard	GLP/MAD, New Chemicals, Outreach Programme, Exposure Assessment,	**16.80**	0255
SONG, Hoseok	Nanotechnologies	**98.81**	0289
VAN DER WAL, Leon	Biocides, Test Guidelines	**93.10**	0332

The Environment, Health and Safety News is issued every eight months, between the meetings of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. It provides an update on recent publications, as well as the main recent or upcoming events of the EHS Programme. This newsletter is produced for participants in the Programme's activities; but the secretariat hopes that it is also of value to a broader audience with an interest in human health and environmental safety issues connected with the use of chemicals, pesticides and biotechnology.

http://www.oecd.org/ehs