

## CHEMICALS PROGRAMME

### INTEGRATED APPROACHES TO TESTING AND ASSESSMENT (INCLUDING THE QSAR TOOLBOX)

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

A new version of the **OECD QSAR Toolbox** has been released in December 2014. It contains several new databases (Human Half-life (kM), ToxCast DB, Developmental and Reproductive Toxicity ), new profilers (Respiratory sensitization, Developmental and Reproductive Toxicity, Chromosomal aberration, Retinoic Acid Receptor Binding), updated profilers and metabolism simulators, external SAR models (Explosive properties and Photoinduced toxicity models with different domains and Developmental and Reproductive Toxicity). The new version also comes with new functionalities and usability improvements.

A detailed project plan for the release of version 4.0 (November 2016) has been developed and agreed at the meeting of the QSAR Toolbox Management Group in October 2014.

As part of the AOP Knowledge Base (AOP KB) the tool **Effectopedia** will be further developed to allow for a sophisticated and quantitative depiction of the relationships between molecular initiating events, key events, and the *in vivo* adverse outcomes with an Adverse Outcome Pathway (AOP). The richer semantic annotations, processable quantitative information and controlled structure of pathway design patterns in Effectopedia will ultimately allow for the development of quantitative AOPs and hence predictive tools for the adverse effects of chemicals. The development of Effectopedia is currently focused on the features needed to describe a quantitative Adverse Outcome Pathway, based on a set of examples. The interface for editing and displaying the various forms of quantitative relationships (dose – response / with reference chemicals, toxicity levels and maximum tested concentrations, linear and response-response curves) was implemented. A visual representation and data model for various test methods (*in chemico*, *in vitro*, *in vivo*, *in silico*) was also introduced. Active regular communication with three expert groups was established to support the development of their quantitative examples. Besides the progress on the quantitative features, several usability functions were introduced.

The Task Force for Hazard Assessment in collaboration with the Task Force on Exposure Assessment launched a formal programme of work on risks from the combined exposures to multiple chemicals. A project team was formed and has begun information gathering, collecting case studies and has held discussions on problem formulation and scoping in the context of combined exposures. Information gathering has begun on hazard characterisation, and elements on exposure characterisation and risk

characterisation will follow. Guidance and consideration documents will be developed based on the discussions.

A workshop on the development and use of integrated approaches to testing and assessment was held in November 2014, hosted by the US-EPA in Washington DC. The objective of this workshop was to discuss the applicability of the Adverse outcome Pathway / Mode of Action (AOP / MoA) concept as part of a framework for developing and using IATAs and to refine the framework as far as possible and define the degree of confidence in an AOP / MoA needed to inform an IATA in a specific regulatory context that can then be communicated throughout the decision making process.

There was a general acceptance from all attendees that AOPs are valuable tools for structuring IATA. It was agreed that AOPs provides the mechanistic credibility and transparency to the IATA and its elements, including the use of non-standard (non-animal) test methods; SAR/QSAR modelling; Chemical categorization and read-across, Test guideline development (both *in vivo* and *in vitro*), and Integrated testing strategies. The case studies presented at the workshop were considered helpful in demonstrating the application of AOP. It was noted that AOPs form a continuum, definition of the continuum by types of AOP, i.e. qualitative, semi-quantitative and quantitative AOPs, would be useful for developers. These different types of AOP are however not necessarily directly related to a specific application in an IATA for a specific regulatory use. Depending on the regulatory context AOPs can already be used in an IATA at a certain stage of development. It is possible that an AOP may be suitable for every regulatory application. It was recommended to develop case studies for IATA for different decision contexts, drawing on AOPs where already progress has been made. Case studies could also be developed where an AOP may have multiple purposes e.g. a quantitative AOP can be used for other purposes than quantitative risk assessment. It was considered important to bring AOP developers, IATA developers and regulators together to discuss these case studies. It was recommended that the OECD provides guidance on how to construct an IATA, which need to be flexible but should also need to provide regulators sufficient degree of consistency.

The report of the workshop was sent to the Task Force for Hazard Assessment for endorsement in February 2015.

In November the drafting group of the guidance document on the Evaluation and Application of Integrated Approaches to Testing and Assessment for Skin Sensitisation met to discuss the second draft of the guidance document and the case studies that have been prepared by several members of the group. The guidance document is scheduled to be finalised in 2015.

***Forthcoming events:***

- 10<sup>th</sup> Meeting of the QSAR Toolbox Management Group, June 10-11, 2015, OECD, Paris
- 8<sup>th</sup> Meeting of the Task Force on Hazard Assessment, June 15-16, 2015, OECD, Paris

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<https://aopkb.org/>

## HAZARD ASSESSMENT

*The Hazard Assessment Programme has evolved from the Existing Chemicals Programme and is concerned with the hazard assessment of industrial chemicals and mainly existing chemicals, i.e. the thousands of chemicals used world-wide that were put on the market before new chemical notification systems were established and whose hazards were not thoroughly evaluated by governments. Data on industrial chemicals is gathered or generated and co-operative assessments are carried out to agree on their hazards. The future activities of the Programme will focus on the practical application of Integrated Approaches to Testing and Assessment (IATA), including grouping approaches; and the exchange of experience on new hazard assessment methodologies, in particular for the assessment of risks from the combined exposure to multiple chemicals.*

Twenty-eight assessments for eighty-five chemicals were published in the OECD Existing Chemicals Database in 2014.

A [“special case” assessment](#) of a chemical’s likelihood to cause skin sensitisation, finalised at the 5th Cooperative Chemicals Assessment Meeting (CoCAM 5), was published as a monograph in the series on Testing and Assessment at the end of June.

An OECD report on [the pilot exercise in applying GHS classifications](#) that was finalised at CoCAM 5 was published as a monograph in the series on Testing and Assessment at the end of September. The report had also been forwarded to the UN sub-group working on a global list of harmonised classifications for their information and to help take this work area forward jointly with the OECD. An addendum to this report on the proposal for the classification of one of the chemicals from the pilot exercise, 2-vinyl pyridine, has been finalized and is scheduled to be published in Q2 2015.

Seventeen draft assessments for 135 chemicals that were agreed at CoCAM-6 in October 2014 in Paris have been declassified by the Joint Meeting and are now published in the [OECD Existing Chemicals Database](#).

The document *Fundamental and Guiding Principles for (Q)SAR analysis of chemical carcinogens with mechanistic considerations* was revised by the lead countries (US and Canada) based on the comments received from the Task Force on Hazard Assessment. The document has been sent to the Task Force for a second round of review. The final draft will be discussed at the next Task Force meeting in June 2015.

The Task Force for Hazard Assessment launched a project on case studies for the development and application of Integrated Approaches to Testing and Assessment (IATA), including grouping approaches. A project group has been formed which will review case studies, in collaboration with national experts, with the aim to create a common understanding of using novel methodologies and the generation of guidance stemming from the case studies. Four case studies will be reviewed in 2015, with a likely face to face meeting held in Q4 2015.

A new project has started to develop a guidance document for Characterising Hydrocarbon solvents for assessment purposes. A first draft has been sent to industry in January for comments.

***Forthcoming events:***

- 8<sup>th</sup> meeting of the Task Force on Hazard Assessment, 15-16 June 2015, OECD, Paris
- Meeting of the project team for IATA case studies, TBC Q4 2015, OECD, Paris

***Recent publication(s)(since the last newsletter):***

-  [Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM](#)
-  [Guidance on selecting a strategy for assessing the ecological risk of organometallic and organic metal salt substances based on their environmental fate](#)
-  [Weight of evidence assessment for the skin sensitisation potential of 4-Isopropylaniline \(Cumidine, CAS 99-88-7\)](#)

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## SAFETY OF MANUFACTURED NANOMATERIALS

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

### **Nanomaterials: Testing and Assessment**

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 and it is expected that they will be published by Q2 2015.

It was also agreed to continue work on the assessment of the physical-chemical, fate, ecotoxicity and toxicity data in co-operation with the Cooperative Chemicals Assessment Programme.

The work of the WPMN on Test Guidelines aims 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. This work builds on a publication from 2009 *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials*, which reviewed 115 Test Guidelines and showed that most are suitable but that, in some cases, modifications will be needed in order to apply them to nanomaterials. Information to assist the work on Test Guideline development has also been derived from seven WPMN expert workshops on: i) Inhalation toxicity (October 2011); ii) Ecotoxicity and environmental fate (January 2013); iii) Physical-chemical properties, held in co-operation with ISO (February–March 2013); iv) Genotoxicity (November 2013); v) Toxicokinetics (February 2014); vi) Physical-Chemical Parameters: Measurements and Methods (June 2014); and vii) Categorisation of nanomaterials (September 2014). The reports of the first four of these workshops, including conclusions and recommendations, have been published; the others will be published during the coming months.

As a result of these workshops, seven projects were initiated in collaboration with the WNT:

- Amendments to the Inhalation Test Guidelines and Guidance to Accommodate Nanomaterials (United States)
- Guidance Document on Aquatic (and Sediment) Toxicology Testing of Nanomaterials (Canada and United States)
- Test Guideline for the Dissolution Rate of Nanomaterials in the Aquatic Environment (United States)
- Guidance Document for Dispersion and Dissolution of Nanomaterials in Aquatic Media – Decision Tree (Germany)

- Guidance Document on Assessing the Apparent Accumulation Potential of Nanomaterials (UK, Finland and Spain)
- Test Guideline for Dispersibility and Dispersion Behaviour of Nanomaterials in Aquatic Media (Germany)
- Development of a Draft Test Guideline for Nanomaterial Removal from Wastewater (United States)

In addition, one additional project proposal, endorsed at WPMN-14, will be discussed at the WNT meeting in April 2015; it was based on an expert meeting on the Expert Meeting on the adaptation of the genotoxicity in vitro micronucleus assay (TG 487) for testing of NMs (October 2014):

- Guidance Document on the Adaptation of In Vitro Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterial

As a separate project, eleven laboratories worldwide have been taking part in an inter-laboratory study on the Colony Forming Efficiency (CFE) assay. One positive control (Na<sub>2</sub>CrO<sub>4</sub>) as well as five different nanomaterials have been tested and a final report was presented to the WPMN-14.

### **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 2013 publication "*Co-operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials*", set priorities for issues in risk assessment . Four pilot projects have since been initiated and WPMN-14 finalised 2 of them:

- Interspecies Variability Factors in Human Health Risk Assessment; and
- Physical-chemical characteristics in regulatory risk assessments – Dissolution as a function of surface chemistry.

These are expected to be published by mid 2015.

For the two remaining pilot projects:

- Survey on approaches to develop or use nanomaterial equivalence/ grouping/ read-across concepts based on physical-chemical properties for regulatory regimes; and
- Analysis of Physical-chemical properties for Read-across and Risk Assessment Guidance,

a progress report will be presented to WPMN-15 in November 2015.

Moreover, it was agreed that one new pilot project would be initiated:

- Investigating the different tiers of risk assessments and identifying different levels of uncertainties used to inform risk assessment outcomes and risk management measures in member countries.

## **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 at WPMN-14 in February 2015 and are expected to be published by mid 2015:

- Exposure assessment: Case studies on nano-silver; 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 and will be reviewed at WPMN-15 in November 2015:

- Exposure assessment: Case studies on nano-gold;
- Biodurability of nanomaterials and their surface ligands; and
- Strategy for distinguishing Carbon Nanotubes from background aerosols.

WPMN-14 also noted progress made with a *survey on consumer and environmental exposures* aimed at identifying priority topics for future projects; an analysis of the survey will be presented at WPMN-15.

## **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 environment.

An expert workshop was held in Zurich, Switzerland, on 20 January 2015 to finalize the draft *Guidance Manual on a life-cycle analysis case study of multi-walled carbon nanotubes*. The final report was presented at WPMN-14 and is expected to be published during the first half of 2015.

## **Sustainable Development of Tyres: Case study involving nanotechnology**

This was a joint project with OECD's Working Party on Nanotechnology (WPN), which is a subsidiary body of the Committee for Science and Technology Policy (CSTP). The final report was published in July 2014 and will be followed up with additional materials including a 'policy brief'.

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

- 15<sup>th</sup> Meeting of the Working Party of Manufactured Nanomaterials, during the week of 2nd November 2015 - Paris, France
- Workshop on Read-Across for Manufactured Nanomaterials (TBA) - Paris, France
- Seminar on *in vivo* inhalation toxicity screening methods (TBA)

***Recent publication(s):***

 **[Report of the OECD Expert Meeting on the Genotoxicity of Manufactured Nanomaterials](#)**

 **[Nanomaterial and Tyres: Greening Industry and Transport](#)**

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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.*

Under the guidance of Task Force on Exposure Assessment (TFEA), nine new or revised Emission Scenario Documents (ESDs) are currently being developed: 1) industrial cleaner, 2) use of adhesives, 3) chemical vapour deposition in the semiconductor industry, 4) textile dyeing, 5) application of paint solvent to industrial coating, 6) case study on plastic additives, 7) metals from waste disposal, 8) lube oil additives, and 9) aqueous firefighting foam. Three ESDs ((1), (2) and (3)) are scheduled to be published in early 2015.

The Task Force on Hazard Assessment in collaboration with the Task Force on Exposure Assessment launched a formal programme of work on risk assessment from combined exposures to multiple chemicals. A project team was formed and has begun information gathering, collecting case studies and has held discussions on problem formulation and scoping in the context of combined exposures. Information gathering has begun on hazard characterisation, and elements on exposure characterisation and risk characterization will follow. Guidance documents will be developed based on the discussions.

The TFEA finalised a draft OECD harmonised template for gathering and electronic exchange of use and exposure information. The template is scheduled to be published in early 2015.

Furthermore, the TFEA is currently developing 1) a database on emissions/releases from products, 2) a matrix of use categories between OECD ESDs and EU Specific Environmental Release Categories (SpERCs), and 3) a database on biodegradation data. The TFEA established subgroups to progress each project.

The TFEA is also investigating the feasibility of a project to evaluate the reliability and user friendliness of occupational exposure assessment models, and will discuss further steps at the next meeting.

### ***Forthcoming event:***

- 7<sup>th</sup> Meeting of the Task Force on Exposure Assessment, 17-18 June 2015, Paris, France

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## 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. OECD has initiated an activity to help support governments assess the risk of chemicals to children.*

The Task Force on Exposure Assessment established a subgroup that is working to finalize a decision tree to determine the need for specific exposure assessments for children and associated case studies. The subgroup will report to the next TFEA meeting in June 2015 about progress made.

In addition, the Secretariat published a public web page with information on OECD's relevant activities and published reports.

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## NOTIFICATION AND REPORTING TOOLS

*The development of I.T. Tools at OECD focuses on the harmonisation 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 Beijing, China, on 9-10 August 2014. For the fifth consecutive year, the annual Clearing House meeting was scheduled in conjunction with the annual meeting of the APEC Chemical Dialog Regulators' Forum to maximise the participation of Clearing House members and APEC members at both meetings.

The Clearing House is currently undertaking a project aimed at increasing the scope of new polymers subject to reduced regulatory requirements, and doing this in a harmonised way across the participating jurisdictions. Under this project, industry has nominated chemical substances to be considered for addition 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. Of the 44 nominated "Equivalency Principle" substances, 21 met the selection criteria, and will be proposed for addition to the polyester monomer lists in each jurisdiction. Of the 59 nominated "new" monomers/reactants, dossiers were submitted for 13 substances. Government agencies (NICNAS, the US EPA, Environment Canada and Health Canada) have completed their assessment of these supporting dossiers. As a result of this review, three substances were considered to meet the requirements for addition to the polyester monomer list without any further information required and two were considered to not meet the requirements. For the remaining eight substances further information is required from submitters before a decision will be made on their eligibility. Submitters will be contacted shortly with the outcome for their nominated substances, including a timeframe for submission of further information (where required).

The Clearing House has also been exploring the feasibility of developing 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 (with the individual information elements identified via XML "tags"). An analysis of existing new chemical notification processes in Australia, Canada, Japan and the US was undertaken and used to develop a systems requirements document and a rough estimate of the costs to complete the design, development and implementation of the system. This information is being presented to potential industry users as sponsors are sought for developing the system.

The Clearing House continued planning for two new initiatives. The first would be a workshop (or series of workshops) that would bring together international expertise to share current methods for analogue identification and evaluation in the context of new chemicals notifications and assessments. In light of discussions with the Task Force on Hazard Assessment, the Clearing House is re-drafting the workshop

proposal to clarify the scope and objectives and to maximise the value for the intended participants involved in new chemicals notifications.

The second new initiative would be to conduct a survey to explore the ways new chemical exposure assessments are conducted in each jurisdiction, including what information is considered, what uses are included in the regulatory framework, and what tools and resources are used. It was agreed to review previous work on this issue by the OECD Task Force on Exposure Assessment during the development of the CHNC survey and to liaise with them on future activities once the survey results are obtained. This project has been put on hold until planning of the analogue workshop has been completed.

***Forthcoming Events:*** Meeting of the Clearing House on New Chemicals (2015; North America)

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## **Harmonised Templates**

Three revised templates on Health effects (Repeated dose toxicity-oral, Carcinogenicity, Toxicity to reproduction) and one new OHT 75-3 on “Endocrine disrupter screening-*In vivo* (level 3)”, were published in February 2015.

The new OHT 201 on intermediate effects, was finalised in February 2015. It is designed to report non-apical observations and will be used for data population of the Adverse Outcome Pathway–Knowledge Base. The template will allow reporting results from non-classical test methods. The new template is scheduled to be published in the first half of 2015.

The new OHT 301 on chemical use and exposure information, developed by the OECD Task Force on Exposure Assessment over the course of 2014, was finalised in February 2015. It will enable the reporting on a new range of information on chemicals. After final formatting , the new template is scheduled to be published later in 2015.

An overall set of improvements to OHTs was approved in February 2015. The changes affect all templates and revised files are currently being tested. This general update will provide an opportunity for renovating the OHT public website by simplifying the html template files and associated welcome pages, to be made available to users during the second half of 2015.

Collaboration continued with the Metapath project by comparing the developed "Data Evaluation Report" composers with the corresponding OHTs. The work started on metabolism and pesticide residues in livestock. As a first follow-up project, the OECD predefined tables will be completed, and all details will be converted in the future into electronic elements to complete the templates.

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## **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 met on 24-25 September 2014 and reviewed the outcome of the analysis performed in 2014 for specific ICULID 6 functionalities (reporting and printing, filtering / dissemination, data validation, search), main priorities for IUCLID 6.1 and any additional business requirements, as well as the planned use of IUCLID 6 by different countries and any need for specific customisations of IUCLID.

The Expert Panel took part in the second testing phase (functional testing and security management) of external testing of IUCLID 6 in May/June 2014 and the third testing phase (functionalities related to IUCLID 5 data migration and import) in September/November 2014.

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

- Meeting of the IUCLID User Group Expert Panel, 29-30 September 2015, Paris, OECD

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## TEST GUIDELINES

*The Test Guidelines Programme develops Test Guidelines and related documents needed to generate new data when required, using state-of-the-art harmonised methods, to address regulatory needs for the determination of hazards to human health and the environment.*

### **New, updated or corrected Test Guidelines**

The following new, updated or corrected Test Guidelines were adopted by OECD Council and published.

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

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

- 238 [Sediment-free \*Myriophyllum spicatum\* Toxicity Test \(published 26/09/2014\)](#)  
239 [Water-sediment \*Myriophyllum spicatum\* Toxicity Test \(published 26/09/2014\)](#)

##### **Section 4: Health Effects**

- 489 [\*in vivo\* Mammalian Alkaline Comet Assay \(published 26/09/2014\)](#)  
442C [\*in chemico\* Skin Sensitisation: Direct Peptide Reactivity Assay \(DPRA\) \(published 4/02/2015\)](#)  
442D [\*in vitro\* Skin Sensitisation: ARE-Nrf2 Luciferase Test Method \(published 4/02/2015\)](#)

#### **Updated Test Guidelines:**

##### **Section 4: Health Effects**

- 431 [\*in vitro\* skin corrosion \(human skin model\) \(published 26/09/2014\)](#)  
473 [\*in vitro\* Mammalian Chromosomal Aberration Test \(published 26/09/2014\)](#)  
474 [\*in vivo\* Mammalian Erythrocyte Micronucleus Test \(published 26/09/2014\)](#)  
475 [\*in vivo\* Mammalian Bone Marrow Chromosomal Aberration Test \(published 26/09/2014\)](#)  
487 [\*in vitro\* Mammalian Cell Micronucleus Test \(published 26/09/2014\)](#)

#### **Corrected Test Guidelines:**

##### **Section 3: Degradation and Accumulation**

- 310 [Ready Biodegradation – CO<sub>2</sub> in Sealed Vessels \(Headspace test\) \(published 26/09/2014\)](#)

## **Information on other issues and projects**

### ***Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)***

The Advisory Group met in June 2014 at OECD to review the development of several Adverse Outcome Pathways (AOPs) on the work plan. The internal review was an opportunity to measure the adequacy between the AOP wiki platform, the user handbook and the current status of AOPs. After some adjustments, the AOP wiki platform was launched publicly on 25 September 2014 (<https://aopkb.org>). The public can see the AOPs under development and provide their comments on an associated discussion page. A teleconference of the EAGMST took place in December to collect feedback on the user handbook and AOP wiki, to discuss training activities, and to set objectives for 2015, including the plans for external reviews of AOPs. Information related to the AOP Development Programme, including a work plan, is available on the public website at: <http://www.oecd.org/env/ehs/testing/molecularscreeningandtoxicogenomics.htm>.

### ***Bioaccumulation in fish***

An expert meeting on bioaccumulation in fish was held on 16-17 June 2014 in Utrecht in the Netherlands to discuss a first draft Guidance Document for the OECD Test Guideline 305. The next step will be the circulation of the draft guidance for comments by the Working Group of the National Coordinators to the Test Guideline Programme (WNT). It is anticipated that the draft Guidance Document will be submitted to WNT for approval at its 28<sup>th</sup> meeting in April 2016.

### ***Avoidance Testing in Birds***

An expert meeting was held on 13-14 October 2014 at the Food and Environment Research Agency (FERA) in York, United Kingdom, to discuss the 2012 draft Guidance Document on Avoidance Testing in Birds and solve the remaining issues. The meeting still could not agree on 'final' guidance. As no consensus has been reached on this topic after many years, the Secretariat will propose to the WNT Meeting in April 2015 to stop the activity. In order not to lose the knowledge developed and have it accessible to risk assessors, a proposal to create a specific public web page on avian toxicity testing will be discussed; the web page could contain the 2012 draft document and other avian avoidance testing related documents.

### ***Advisory Group on Endocrine Disrupters Testing and Assessment***

The Group met at OECD on 16-17 October 2014 to discuss opportunities to move the EDTA Conceptual Framework forward and to build integrated approaches to testing and assessment using AOPs under development by EAGMST (see above). The group also discussed the possibilities to update existing Test Guidelines with relevant endocrine endpoints. The absence of non-animal Test Guidelines for the detection of thyroid effects was identified as a critical gap in the current Conceptual Framework by the Group (see [link](#)). Some concrete proposals for new projects (e.g. update of TG 414 with ED-related endpoints, detailed review paper on the retinoids pathways, guidance on development and integration of AOPs for endocrine-related pathways) emanating from the EDTA AG meeting will be discussed at the upcoming meeting of the Working Group of the National Coordinators of the Test Guidelines Programme in April 2015.

### ***Expert Group on skin and eye hazard potential***

A combined meeting of the skin irritation/corrosion and eye irritation expert groups was organised on 6-7 November 2014 at OECD. Revision of all skin irritation/corrosion Test Guidelines was addressed;

increased harmonisation across Guidelines, reference to the newly published IATA, and separation between Guideline and Performance Standards were the main objectives of the revision process. Two new draft *in vitro* Test Guidelines for eye hazard potential were also discussed by the experts. All draft documents will be submitted for approval at the next meeting of the Working Group of the National Coordinators of the Test Guidelines Programme in April 2015.

### ***Feasibility Study for a Guidance Document on Study Designs***

A workshop was organised by the Netherlands in Amsterdam on 20-21 November 2014. The objective of this project is to explore the possibility to improve study designs by making use of the benchmark dose. This initiative could initially apply to selected studies where the current design does not offer good statistical power to detect effects. A drafting group, led by the Netherlands, was established and will progress on the feasibility study in 2015.

### ***Validation Management Group for Non Animal Testing***

The Validation Management Group for Non-Animal Testing met on 2-4 December 2014 at OECD in Paris. The group finalised two draft Test Guidelines (human recombinant estrogen receptor binding assay and updated TG 455), prior to submission for approval at the upcoming meeting of the Working Group of the National Coordinators of the Test Guidelines Programme in April 2015, and discussed the progress in the development and validation status of several other Test Guideline proposals. The discussed test methods mostly dealt with transactivation assays for the detection of estrogen receptor agonist and antagonists and transactivation assays for the detection of androgen receptor agonist and antagonists. Updates on progress with other methods, not yet included on the Test Guideline workplan - in particular methods for the detection of thyroid disrupters - were also presented.

### ***Validation Management Group on Ecotoxicity Testing***

The Validation Management Group on Ecotoxicity Testing met at OECD on 10-12 December 2014 and discussed the progress in the development and validation status of several Test Guideline proposals. The discussed Test Guidelines dealt with protocols for the determination of endocrine effects in fish, molluscs and amphibians, biotransformation in fish and on how to reduce the amount of animals used in acute toxicity testing for fish. In addition, member country efforts to develop two new endocrine assays were discussed and supported by the group. The upcoming meeting of the Working Group of the National Coordinators of the Test Guidelines Programme in April 2015 will be informed of the discussions and results from this meeting.

### ***Recent publication(s):***

-  [Guidance Document for Describing Non-Guideline In Vitro Test Methods, No. 211](#)
-  [Validation report on Bhas cell transformation assay, No. 208](#)
-  [Scoping document on \*in vitro\* and \*ex vivo\* assays for the identification of modulators of thyroid hormone signalling, No.207](#)
-  [Validation report on Myriophyllum test sediment-water, No. 206](#)
-  [Validation report on Myriophyllum test water phase, No. 205](#)
-  [Single-laboratory validation of quantitative analytical methods, No. 204](#)
-  [Integrated Approach to Testing and Assessment for skin irritation and corrosion, No. 203](#)
-  [Quantitative method for evaluation of antibacterial activity of porous and non-porous antibacterial treated materials, No. 202](#)
-  [Copepod development and reproduction test, No.201](#)
-  [Report on Statistical Issues Related to OECD Test Guidelines \(TGs\) on Genotoxicity, No. 198](#)
-  [Peer-review report on the Comet assay, No. 197](#)

 [Report of the JACVAM Initiative International Validation Studies of the in vivo Rodent Alkaline Comet Assay for the Detection of Genotoxic Carcinogens, No. 196](#)

 [Report of the JACVAM Initiative International Pre-Validation Studies of the in vivo Rodent Alkaline Comet Assay for the Detection of Genotoxic Carcinogens, No. 195](#)

***Forthcoming events:***

- Meeting of the Expert Group on Honey Bee Testing, 22-24 April 2015, OECD, Paris
- Meeting of the Expert Group on Acute Mammalian Toxicity Studies, 27-28 April 2015 (TBC)
- Meeting of the Expert group on Biotransformation Assays, 11-12 May 2015, OECD, Paris
- Meeting of the Extended Advisory Group on Molecular Screening and Toxicogenomics, 17-18 June 2015, OECD, Paris
- Meeting of the Validation Management Group on Ecotoxicity Testing, 5-7 October 2015, OECD, Paris
- Meeting of the Advisory Group on Endocrine Disrupters Testing and Assessment, 8-9 October 2015, OECD, Paris
- Meeting of the Expert Group on Eye irritation/corrosion, 9-10 November 2015, OECD, Paris
- Meeting of the Validation Management Group for Non Animal Testing, 1-3 December 2015, Budapest, Hungary

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

**Website:** [www.oecd.org/env/testguidelines](http://www.oecd.org/env/testguidelines)

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## 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.*

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. Five on-site evaluations were conducted in 2014 and the reports of these evaluations will be reviewed during the 2015 meeting of the Working Group on GLP. Five evaluations are scheduled for 2015: Sweden, South Africa, Slovak Republic, Slovenia and Spain (pesticides and chemicals).

Advisory Document number 16 on [GLP Requirements for Peer Review of Histopathology](#) was published in September 2014. The document provides guidance on how pathology peer reviews should be planned, conducted and reported under GLP.

A web page with *Frequently Asked Questions* (FAQ) was posted on the GLP public site on 15 July (<http://www.oecd.org/env/ehs/testing/glp-frequently-asked-questions.htm>). This webpage gives information about a series of questions raised by testing laboratories about implementation of GLP, along with responses prepared by the Working Group on GLP. This current version concerns questions about *Quality Assurance*, and the FAQ document will be amended, from time-to-time, to include new questions and answers.

A draft *Advisory Document on the Application of GLP Principles to Computerised Systems* was posted on the GLP public web site, and members of the public were invited to comment by 14 November 2014. Commenters were invited to provide their comments via a template, and to submit them to their national compliance monitoring authority. Based on the comments received, a revised version of the draft Advisory Document will be reviewed at the April meeting of the Working Group.

On 1 January, 2015, the scope of Sweden's national monitoring authority for industrial chemicals and pesticides (Swedish Board for Accreditation and Conformity Assessment - SWEDAC) was expanded to include pharmaceutical, cosmetics and veterinary products.

The 12<sup>th</sup> OECD GLP training course is scheduled for 12-15 October 2015 in Hyderabad, India and will focus on strategies for performing GLP inspections and study audits. It will comprise a one-day basic course, and a three-day advanced course.

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

- 29<sup>th</sup> Meeting of the Working Group on GLP – Paris, France, 16-17 April, 2015
- 12<sup>th</sup> OECD GLP training course – Hyderabad, India, 12-15 October, 2015

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

 [Advisory Document number 16 on GLP Requirements for Peer Review of Histopathology](#)

**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.*

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*.

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 visited the GLP Compliance Monitoring Programmes in Thailand in 2012 and a follow-up visit is under consideration.

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](#)

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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.*

### **Addition of new databases**

One new data source was added as a participant in the search by chemical substance functionality of eChemPortal: The Joint Substance Data Pool of the German Federal Government and Federal States (GSBL) provides reliable chemicals information in support of all activities to prevent and avert danger and to protect humans and the environment.

Currently eChemPortal contains approximately 1,660,000 links to records in participating data sources. Currently in eChemPortal there are:

- 839,030 records (search by substance ID)
- 822,273 records (endpoint data)

The database of chemical names contains approximately 800,000 synonyms, trade names and chemical names in Chinese, Czech, Danish, Dutch, French, German, Greek, Italian, Japanese, Korean, and Portuguese, Slovak, Spanish.

A new version of eChemPortal was released on 20 June 2014 including the addition of a filter to data sources which contain specific types of information (property information, exposure and use information, or classifications according to the Globally Harmonized System of Classification and Labelling of Chemicals [GHS]) as part of the search by substance. Other releases are expected in 2015, including improvement to the eChemPortal application architecture and a query by classification according to the GHS.

Two video tutorials were published in June 2014 on how to perform a property search on a specific chemical in eChemPortal and how to find GHS classification information on a specific chemical in eChemPortal ([YouTube](#)).

### **Forthcoming events:**

- Meeting of the Steering Group for the Development of the Global Portal, 15-16 April 2015, Ottawa, Canada

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

**Contact:** Sally de Marcellus

## OUTREACH: 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 is under preparation for a public launch in May 2015. The whole content is being revised; three new examples– on metals, air pollution, and POPs/PBTs – will be integrated and a general module on pesticides will be published. In addition, the toolkit will become a collaboration platform where the users will be able to save their navigation, write comments, and share them with colleagues in collaborative groups. Each user will have a dashboard on their “MyIOMC” page, which can be used for viewing and managing their navigations and collaborative groups.

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

**Websites:** [www.oecd.org/env/riskassessment/toolkit](http://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 will be released in May 2015. Progress has been made on the following subjects:

- An industrial chemicals management scheme is being implemented into the IOMC Toolbox.
- Existing schemes on pesticides, occupational health and safety and managing major chemical accidents were reviewed for updates and are being revised in the Toolbox.
- The Task Force on PRTRs is building a scheme for setting up a PRTR as part of the Toolbox.
- New functionalities for the Toolbox have been identified, and the development has started. New collaboration features will allow the users to save their navigation, write comments, and share

them with colleagues in working groups. Each user will have a dashboard on their “MyIOMC” page, which can be used for viewing and managing their navigations and collaborative groups.

In addition, OECD participated in three side events to promote, and receive feedback on, the IOMC Toolbox:

- at the Meeting of the Parties to the Protocol on PRTRs, Maastricht, 4 July 2014
- at the XX World Congress on Safety and Health at Work 2014 in Frankfurt on 26 August 2014
- at the Open-Ended Working Group of the International Conference on Chemicals Management in December 2014

The new version of the IOMC Toolbox is scheduled to be launched in May 2015 at the Basel, Rotterdam and Stockholm Conventions Conferences of the Parties, where OECD will participate in several demonstrations of the new schemes and functionalities.

**Contact:** Eeva Leinala, Valérie Frison

**Website:** <http://iomctoolbox.oecd.org>

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## 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. The OECD Ad Hoc Group on the Substitution of Harmful Chemicals recently released the **OECD Substitution and Alternatives Assessment Toolbox** ([www.oecd-saatoolbox.org](http://www.oecd-saatoolbox.org)).

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 will be held on 11-12 May 2015 at the OECD Headquarter in Paris. It will be an opportunity to discuss what further work the OECD could undertake to further support the area of substitution and alternatives assessment.

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

**Websites:**

- <http://www.oecd.org/env/ehs/risk-management/>
- [www.oecd-saatoolbox.org](http://www.oecd-saatoolbox.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 is now focusing its activity on three particular projects:

- A policy paper that will aim to highlight the remaining gaps and uncertainties in measuring PFC emissions worldwide;
- An analysis of risk reduction approaches for PFCs across countries (including OECD members and non-member countries);
- The further development of the PFC Web Portal (<http://oecd.org/ehs/pfc/>).

The group published in 2013 a [Synthesis Paper on Per and Polyfluorinated Chemicals](#). This synthesis paper looks at (i) the historical and current major uses of PFASs, (ii) scientific evidence regarding source, exposure, environmental fate and potential adverse effects of PFASs, (iii) recent developments on alternatives to long-chain PFASs, and (iv) regulatory approaches with respect to PFASs. Webinars have been organised to communicate the conclusions of this paper. The last, to date, was held on December 3<sup>rd</sup> 2014, and covered risk reduction approaches for PFCs. More webinars will be organised in 2015. Information on these webinars can be found [here](#).

### Recent publications:

 [OECD/UNEP Global PFC Group, Synthesis paper on per- and polyfluorinated chemicals \(PFCs\)](#)

**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 now 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 under development and is scheduled to be published in 2015.

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

**Websites:** <http://www.oecd.org/env/riskmanagement>  
<http://www.oecd.org/env/sustainablechemistry>

### **Policy Drivers Influencing Decision Making in the Management of Chemicals**

Two preliminary scoping studies on policy drivers influencing decision making in chemicals management were discussed by the Joint Meeting in November 2014. Based on submissions provided by member countries, the analysis outlines experiences that can assist member countries in developing efficient and effective regulatory regimes. These include experiences regarding transitioning to a new chemical management regime and the (re)assessment of historical chemical approvals/notifications; and comparing policy objectives of different countries' chemical management regimes. This preliminary analysis also aids members in identifying opportunities for future collaborative work and may be of interest and use to non-OECD members. The preliminary analysis will be published as a document in 2015.

**Contact:** Eeva Leinala

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## 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.*

The Residue Chemistry Expert Group (RCEG) continues its work on: i) revision of the 2012 Crop Field Trial Guidance Document; and ii) the development of a Rotational Crop Field Trial Guidance Document. An expert meeting will be held on 7-8 July 2015 to progress with these two documents.

The Expert Group on Terrestrial Field Dissipation (EG-TFD) led by Canada, the United States and EFSA (European Food Safety Agency) is developing a draft Guidance Document for the conduct of terrestrial field dissipation studies, including a crosswalk between North American and European Ecoregions.

The New-Zealand-led Expert Group on Product Chemistry (EGPC) is in charge of developing guidance on the core chemistry and manufacturing properties of chemical active ingredients and formulations. A questionnaire on the current product chemistry requirements – with a focus on agricultural pesticides – was circulated to member countries in June-October 2014.

The Expert Group on Pesticide Effects on Insect Pollinators (EG-PEIP) was established in 2013. The Pollinator Incidents Information System and the website Managing Pesticide Risk to Insect Pollinators (<http://www.oecd.org/chemicalsafety/risk-mitigation-pollinators/>) were launched in the first half of 2014. Regarding testing and hazard/risk assessment needs, work is continuing within the Pesticides Programme and the Test Guidelines Programme in the following areas: i) honeybee chronic oral toxicity, 10-d feeding test; and ii) honeybee larval toxicity test, repeated exposure. An expert meeting to progress with the development of these test methods will be held on 22-24 April 2015 at OECD in Paris.

As part of the work of the Expert Group on the Electronic Exchange of Pesticide Data (EGEEDP), 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. The different GHSTS components available for download on the website are:

- Format specification
- Schema definition (XSD)
- Picklist XSD
- Table of Contents (ToC) XSD

As part of the pesticide risk reduction activities, the Expert Group on Integrated Pest Management (IPM) continues implementing specific activities in the areas of i) communication - an OECD website on IPM was made public at the end of March 2014 (<http://www.oecd.org/chemicalsafety/integrated-pest-management/>) ii) incentives (a guidance document is being developed), and iii) IPM indicators (as a

follow-up to the November 2012 Seminar on IPM indicators that addressed both “uptake” and “impact” indicators).

Also, as part of the pesticide risk reduction activities, the OECD Expert Group on Pesticide Risk Indicators (EGPRI) held its fourth meeting on 21<sup>st</sup> November 2014 at the OECD in Paris. The Meeting reviewed the results of the survey on PRIs, progressed with the development of guidance on why and how to use (recommended) PRIs, and discussed cooperation with the Expert Group on Integrated Pest Management (EG-IPM) for the development of IPM impact indicators.

In the area of compliance and enforcement, the network of government officials (NOPCE) has developed an OECD website aimed at sharing information (on laws and programmes in member countries) and best practice. The website was made public at the end of March 2014 (<http://www.oecd.org/chemicalsafety/pesticide-compliance/nopce-authorities.htm>).

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.

For activities on biopesticides (biological pesticides such as micro-organisms, fungi, pheromones, invertebrates, etc.), work continues on the following projects: i) development of guidance for hazard and risk assessment of secondary metabolites produced by microbial pesticides; ii) the adequacy of testing methods for data requirements for microbial pesticides; iii) follow-up to the July-September 2014 survey on the issue of sensitisation to microbial pesticides; iv) finalisation of the draft Guidance Document for Microbials Storage Stability; and v) follow-up to the October-December 2014 survey on regulation of macro-organisms biocontrol agents.

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

- 21-22 May 2015, Meeting of the Expert Group on the Electronic Exchange of Pesticides Data (EGEEDP) (OECD, Paris, France)
- 7-8 July 2015, Meeting of the Expert Group on Pesticide Residues Chemistry, OECD, Paris
- 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

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

-  [Report of an OECD survey on the assessment of the risks from obsolete pesticides in OECD countries, Series on Pesticides No. 79](#)
-  [Report of an OECD survey on risk management/mitigation approaches and Options related to agricultural pesticide use near residential areas, Series on Pesticides No. 78](#)
-  [Globally harmonised submission and transport standard \(ghsts\) format specification, Series on Pesticides No. 77](#)
-  [The Programme on Pesticides and Sustainable Pest Management: Vision for the Future](#)

**Contact:** Sylvie Poret, Marie-Chantal Huet, Leon van der Wal and Sally de Marcellus

**Websites:** <http://www.oecd.org/env/pesticides>

<http://www.oecd.org/chemicalsafety/integrated-pest-management/>

<http://www.oecd.org/chemicalsafety/pesticide-compliance/>

<http://www.oecd.org/chemicalsafety/risk-mitigation-pollinators/>

<http://www.oecd.org/env/spraydrift/>

<http://www.oecd.org/chemicalsafety/submission-transport-standard>

<http://www.oecd.org/chemicalsafety/pesticide-compliance/nopce-authorities.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.*

Work on efficacy of biocides focused on biocides used to treat articles – porous surfaces (textiles) and non-porous surfaces (plastics): a Guidance Document for "Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-porous Antibacterial Treated Materials" was published in July 2014.

The report resulting from the member country survey on performance standards and related authorised label claims for microbicides is being 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. It is expected that this work will lead to a new guidance document.

The Expert Group on Biocides Chemistry (EGBC) has developed guidance on the validation of analytical methods and on the storage stability of biocidal products. A Guidance Document for "Single Laboratory Validation of Quantitative Analytical Methods – Guidance used in support of Pre- and Post-Registration Data Requirements for Plant Protection and Biocidal Products" was published in July 2014. A draft Guidance Document for Storage Stability Testing of Plant Protection and Biocidal Products is also under preparation.

Work being led by France on estimating emissions for insecticides for vector control continues, and will result in a Guidance Document that will pull together all available information on scenarios and models, and will contain a tiered approach to exposure assessment for this use pattern.

Work regarding risk reduction of biocides continued with a survey to collect information on current IPM approaches for disinfectants in member countries. 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. Case studies will first be developed to aid in the comparison of available methodologies in OECD member countries.

**Recent Publications:**

- 📖 [Guidance Document for Single Laboratory Validation of Quantitative Analytical Methods – Guidance Used in Support of Pre-and-Post-Registration Data Requirements for Plant Protection and Biocidal Products, Series on Biocides No. 9](#)
- 📖 [Guidance Document for Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-Porous Antibacterial Treated Materials, Series on Biocides No. 8](#)

**Forthcoming events:**

- 13<sup>th</sup> Meeting of the Task Force on Biocides, Third quarter of 2015

**Contact:** Sylvie Poret, Leon van der Wal and Marie-Chantal Huet

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

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## 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 OECD Working Group on Chemical Accidents (WGCA) aims to share experiences amongst governments and other stakeholders and recommend policy options for enhancing the prevention of, preparedness for, and response to, chemical accidents. This programme assists public authorities, industry, labour and other interested parties to prevent chemical accidents and respond appropriately if one occurs.

The OECD WGCA recently published a second Addendum to the [Second edition of the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response](#). This [second addendum](#) was published in January 2015, and addresses Natural Hazards Triggering Technological Accidents (Natech) Risk Management. The addendum consists of a number of amendments to the Guiding Principles and of the addition of a new Chapter to provide more detailed guidance on Natech prevention, preparedness and response. It takes into account the results of the Workshop on Natural Hazards Triggering Technological Accidents (Natechs) Risk Management held on 23-25 May 2012, in Dresden, Germany that was held under the auspices of the OECD WGCA.

Current projects of the OECD WGCA include work on:

- Ageing of hazardous installations;
- Facilities handling hazardous substances that are going through a change of ownership;
- Major accidents involving manufactured nanomaterials;

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

The WGCA will next meet on 27-29 October 2015 at the OECD Headquarter in Paris. This meeting will host a special session on *Ageing of Hazardous Installations*.

***Forthcoming Events:***

- 25<sup>th</sup> Meeting of the Working Group on Chemical Accidents with a special session on Ageing of Hazardous Installations; 27-29 October 2015

***Recent Publications:***

 [2nd Addendum to the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response \(2nd ed.\) To address Natural Hazards Triggering Technological Accidents \(Natech\) Risk Management No.27](#)

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

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

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## **POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTRs)**

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

The Task Force on PRTRs (TF PRTR) focuses on; i) improving PRTRs through reviewing and updating release estimation techniques, ii) developing guidance toward harmonised PRTRs and iii) exploring applications of PRTR data on a global scale.

The TF PRTR is revising two Resource Compendia for PRTR Release Estimation Techniques. On non-point sources, the contents of the current compendium on diffuse sources and the compendium on releases from products will be updated and merged. On off-site transfers, the Task Force is updating the estimation techniques for transfers to wastes or wastewater. These documents are expected to be finalized by 2016.

The TF PRTR published two documents on global PRTRs in late 2014: (1) [Guidance Document on Elements of a PRTR: Part I](#); and (2) [Global Pollutant Release and Transfer Register, Proposal for a harmonised list of pollutant](#). The TF PRTR is currently developing a *Guidance Document on Elements of a PRTR: Part II*, which focuses on the implementation aspect, i.e. how to initiate and operate a PRTR.

The TF PRTR is also exploring the role of PRTR data as a practical means to assess progress in global sustainability. This discussion will continue at the next Task Force meeting in November 2015.

The OECD public webpage has been updated to provide easy-comprehensible and direct access to the PRTRs webpages.

Back-to-back with the next TF PRTR meeting, the 2nd Global Round Table workshop will be organised (jointly with the UNECE Working Group of the Parties to the Protocol on PRTRs) to discuss how PRTRs contribute to sustainable development as well as the problematic issues in implementing PRTRs.

***Forthcoming events:***

- 18<sup>th</sup> Meeting of the Task Force on PRTRs, November, 2015, Madrid, Spain

***Recent Publications***

- 📖 [Global pollutant release and transfer register, proposal for a harmonised list of pollutants \(ENV/JM/MONO\(2014\)32\)](#)
- 📖 [Guidance document on elements of a PRTR: Part 1 \(ENV/JM/MONO\(2014\)33\)](#)

**Contact:** Takahiro Hasegawa

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

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## **HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY**

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

Based on the discussion and agreements made at the 28<sup>th</sup> plenary meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, progress was made on the following projects:

- The first draft of the Consensus Documents on the Biology of Common bean was circulated to the Working Group in January 2015;
- The Consensus Documents on the Biology of Tomato (led by Spain and Mexico) and Sorghum (led by South Africa and the United States) are expected to be completed in the coming months;

Significant progress was also made on other projects, including the development of the document on Environmental Considerations which is expected to be completed in the coming months; and the first draft of the Mosquito document which is expected to be circulated to the Working Group in advance of the 29<sup>th</sup> meeting of the Working Group (April 2015).

A Webinar, jointly organised by FAO, UNEP-CBD and OECD was held on 12 November 2014 to present the databases on biotechnology products developed by the three Organisations. These databases include elements on genetically-engineered organisms approved in countries for environmental safety as well as food/feed safety. These tools for risk assessment are as complementary as possible, with easy-to-share data. The Webinar was attended by 120 experts from 55 countries.

***Recent publications:***

- 📖 Biotechnology Update – Newsletter from the OECD Internal Co-ordination Group for Biotechnology (ICGB) – [\*No 28, December 2014\*](#)
- 📖 OECD (2015), *Biosafety and the Environmental Uses of Micro-organisms –Conference Proceedings*, OECD Publishing, <http://dx.doi.org/10.1787/9789264213562-en>

***Forthcoming events:***

- 29th meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 20-22 April 2015, OECD

**Contact:** Takahiko Nikaido, Bertrand Dagallier, Peter Kearns,

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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.*

As agreed at the 21<sup>st</sup> plenary meeting of the Task Force for the Safety of Novel Foods and Feeds, activities related to composition documents continued in the following projects:

- Apple (*Malus domestica*): development of a complete document by an *ad hoc* group led by Germany, to be discussed at the 22<sup>nd</sup> plenary meeting in April 2015.
- Common bean (*Phaseolus vulgaris*): the revised draft prepared by an *ad hoc* group led by Brazil is under finalisation. It will be submitted to the 22<sup>nd</sup> plenary meeting for final agreement.
- Rice (*Oryza sativa*) composition, project led by Japan: at the invitation of the Philippines, an expert Workshop was hosted by the International Rice Research Institute, Los Baños, in October 2014. Updated data on rice constituents identified in recent databases (Japan NFRI, ILSI-CERA, Feedipedia and others) was included in the draft document. The revised version will be submitted to the 22<sup>nd</sup> plenary meeting for final agreement.

Progress was also made on new projects, namely on “Animal composition data” (led by Canada) and “Innovative novel feed ingredients” (Netherlands and Canada, co-leads) for which a revised proposal is being elaborated to include recent developments at FAO. A focus session on enabling “Joint Reviews” of novel foods and feeds derived from rDNA plants is being prepared for the 22<sup>nd</sup> plenary meeting.

The compendium of the OECD Consensus Documents on crop composition, covering issues from 2002 to 2014, is being prepared for publication during the first quarter of 2015.

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

- ILSI-HESI-PATC Workshop on Molecular and Genetic Basis of Potential Unintended Effects in Modified Plants, 14 April 2015, OECD
- 22<sup>nd</sup> Meeting of the Task Force on the Safety of Novel Foods and Feeds, 15-17 April 2015, OECD

### ***Recent publications***

 Biotechnology Update – Newsletter from the OECD Internal Co-ordination Group for Biotechnology (ICGB) – [No 28, December 2014](#)

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

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

## THE GLOBAL FORUM

*The Global Forum on Biotechnology, established in 2010, is one of 16 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.*

Collaboration continued with key non-member partners, and in particular on the occasion of the meeting of the parties to the Cartagena Protocol on Biosafety held in Korea, followed by the ISBGMO Conference in South Africa in October-November 2014. Links were strengthened with participants from Argentina, Bangladesh, Brazil, Colombia, India, Indonesia, Kenya, Latvia, Moldova and the COMESA African Biosafety Network for participation in the next 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 to be held at the OECD in April 2015.

At the Workshop for revising the document on rice (*Oryza sativa*) composition held at IRRI Philippines in October 2014, non-member experts and the OECD Secretariat participated under the auspices of the Global Forum.

The 3-year OECD-World Bank-CERA Partnership on biosafety issues ended in December 2014. An evaluation of implemented activities and lessons learned from the project are being prepared and will be finalised in the coming months. Invitations to the next biosafety and food safety meetings for ten to fifteen participants from non-member economies were sent in January 2015.

**Contacts:** Bertrand Dagallier

## STAFF IN THE EHS DIVISION

Since the last Environment, Health and Safety News (No. 31, issued in June 2014), the EHS Division has seen the following changes in staffing:

- Eeva Leinala arrived as a Principal Administrator working on Hazard Assessment, Risk Management and Sustainable Chemistry, New Chemicals, Children's Health, and the IOMC Toolbox.
- Jill Gibb has returned as the assistant to the head of division and to the Joint Meeting.
- Marielle Guillaud became the Resource Management Advisor on a temporary assignment.
- Alastair Wood replaced Melita Gilbey as Communications and Publications Co-ordinator.
- Christiana Oladini-James became the assistant for Pesticides, Biocides, GLP, New Chemicals, and Chemical Accidents
- Nausicaa Masi became the assistant for Hazard Assessment, Risk Management and Sustainable Chemistry.
- Fiona Macfarlane became the assistant for Hazard Assessment, (Q)SAR, PRTR, Templates and Risk Management
- Takahiro Hasegawa replaced Hirofumi Aizawa as an Administrator for Exposure Assessment and PRTR
- Yukie Saegusa replaced Kenji Nakano as an Administrator working on Good Laboratory Practice and Test Guidelines.
- Jihane El Gaouzi replaced Carolina Valencia-Tronco working on Manufactured Nanomaterials and Chemical Accidents.
- Yuki Sakuratani has become an Administrator working on (Q)SARs and Hazard Assessment.

## WEB SITES

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

EHS Homepage	<a href="http://www.oecd.org/chemicalsafety">http://www.oecd.org/chemicalsafety</a>
Biocides	<a href="http://www.oecd.org/env/biocides">http://www.oecd.org/env/biocides</a>
Biosafety and Food/Feed safety	<a href="http://www.oecd.org/biotrack">http://www.oecd.org/biotrack</a>
Chemical Accidents	<a href="http://www.oecd.org/env/accidents">http://www.oecd.org/env/accidents</a>
Exposure Assessment	<a href="http://www.oecd.org/env/exposure">http://www.oecd.org/env/exposure</a>
Global Portal to Information on Chemical Substances	<a href="http://www.oecd.org/ehs/eChemPortal">http://www.oecd.org/ehs/eChemPortal</a>
Good Laboratory Practice	<a href="http://www.oecd.org/env/ntp">http://www.oecd.org/env/ntp</a>
Harmonised Templates	<a href="http://www.oecd.org/ehs/templates">http://www.oecd.org/ehs/templates</a>
Harmonisation of Classification of Labelling	<a href="http://www.oecd.org/env/classify">http://www.oecd.org/env/classify</a>
Hazard Assessment	<a href="http://www.oecd.org/env/hazard">http://www.oecd.org/env/hazard</a>
Mutual Acceptance of Data (MAD)	<a href="http://www.oecd.org/ehs/mad">http://www.oecd.org/ehs/mad</a>
New Chemicals	<a href="http://www.oecd.org/env/newchemicals">http://www.oecd.org/env/newchemicals</a>
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Sustainable Chemistry	<a href="http://www.oecd.org/env/sustainablechemistry">http://www.oecd.org/env/sustainablechemistry</a>
Test Guidelines	<a href="http://www.oecd.org/env/testguidelines">http://www.oecd.org/env/testguidelines</a>

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[www.oecd.org/ehs/publications](http://www.oecd.org/ehs/publications)

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

→ Email: [ehscont@oecd.org](mailto:ehscont@oecd.org)

→ Fax: +33 (0)1 44 30 61 80

**ENV/EHS Staff Directory**  
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<b>SIGMAN, Richard</b>	GLP/MAD, New Chemicals, Outreach	<b>16.80</b>	0255
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