

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

HIGHLIGHTS AND PROGRESS IN THE EHS PROGRAMME

**52nd Joint Meeting of the Chemicals Committee and the Working Party on Chemicals,
Pesticides and Biotechnology**

**4-6 November 2014, at the OECD Conference Centre, 2 rue André Pascal, Paris,
beginning at 9h30 on 4 November.**

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This document provides an update on progress made since the last Joint Meeting in the work areas of the Environment, Health and Safety Programme which are not the subject of a specific agenda document at this Joint Meeting.

- ACTION REQUIRED:*** ***The Joint Meeting is invited to:***
- i) take note of the progress report; and***
 - ii) take any further action as appropriate.***

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I. GENERAL ISSUES

Environmental Policy Committee

1. The Environmental Policy Committee (EPOC) met on 23-25 April 2014 in Paris [[ENV/EPOC/M\(2014\)1](#)]. Most of the meeting was dedicated to discussing the 2015-2016 PWB. EPOC

- Requested the Working Party on Integration of Environment and Economic Policy (WPIEEP) to explore:
 - Integrating issues related to shipping in the work on Urban Air Quality, and should this require additional resources, to return to the Committee with an indication of the resources necessary.
 - Extending the work on economic valuation of morbidity impacts of air pollution and the associated welfare effects to include the impacts of chemicals, subject to receipt of additional resources.
- Requested the WPIEEP and the Working Party on Climate, Investment and Development (WPCID) to explore:
 - Including a developing country aspect in the work on Typology and Analysis on Selected Spatial Instruments.
- Requested the Working Party on Biodiversity, Water and Ecosystems to explore:
 - The possibility of a workshop on Biodiversity and Development, subject to receipt of additional resources.
 - Agreed to consider timing and agenda topics for the next Environment Ministerial Meeting when it next meets in February 2015.
 - Agreed to request to the Council that the Output Area 2.3.6 “Globalisation and Environment” be deleted from the OECD Strategic Management Framework.
 - Endorsed the Draft Work Programme presented in [ENV/EPOC\(2014\)1/ANN1](#) for submission to the Secretary General.

2. EPOC furthermore:

- Reviewed on-going work on the Costs of Air Pollution from Road Transport [[ENV/EPOC\(2014\)5](#)] and supported further work on the value of morbidity, subject to the provision of voluntary contributions.
- Reviewed on-going work on Environmental Policies and Productivity Growth [[ENV/EPOC\(2014\)6](#)]; recognised this is ground-breaking work focused on analysing the link between stringency of environmental policies and the effect on economic growth and expressed support for continued work in this area to further refine the methodology and tools.

IOMC

3. The Participating Organisations of the IOMC met in Geneva on 5-6 May 2014. Most of the meeting was dedicated to organising IOMC contributions to the Open-Ended Working Group meeting of SAICM scheduled for December 2014. IOMC contributions will focus on:

- *An Analysis of Assessment of Work Done to Implement the SAICM GPA: IOMC Review*, in particular to include the eight “successes and gaps”, i.e. highly hazardous pesticides; GHS; mainstreaming; PRTR; poisons centres; availability of information on chemicals and harmonized assessment methodologies; chemical accidents; emergency response.
- Four “key issue” documents on GHS; mainstreaming; highly hazardous pesticides; and (combined) chemical accidents and emergency response.
- IOMC short summary reports on emerging issues.

4. IOMC also launched a vast coordination activity in support of the implementation of the Minamata Convention.

II. ENVIRONMENT, HEALTH AND SAFETY PROGRAMME AREAS

CHEMICALS

I. Provision of Knowledge and Information

i. Integrated Approaches to Testing and Assessment (including the QSAR Toolbox)

5. The development of the QSAR Toolbox version 3.3 is fully on track. A mechanism-based profiling scheme consisting of structural alerts associated with respiratory sensitisation, and a QSAR model for predicting the phototoxic potential of chemicals will be implemented. Other additions will be, among others, a model to predict developmental and reproductive toxicity (developed by P&G), a kM data base (from Environment Canada) and a function to save predictions.

6. A work plan outlining the specific projects for the first two years of the phase 3 development of the QSAR Toolbox was agreed at the meeting of the Management Group in January 2014. A detailed project plan for the release of version 4.0 (November 2016) has been developed.

7. The project on further developing Effectopedia was launched in February 2014 following the agreement by the EAGMST in December 2013. Effectopedia will be a part of the AOP knowledge base (AOP-KB) together with the AOP wiki. Effectopedia development is currently focused on the features needed to describe a quantitative AOP, 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, including: automatic proxy detection (for better internet connectivity), an interface for exploration and visualization of revisions of a pathway, and a mechanism for the creation and use of permanent links to specific revisions. Integration efforts with the AOP-KB were initiated by the development of a data model and a list of supported API services for internal exchange.

8. In April and May the informal discussion group on combined exposure to multiple chemicals discussed next steps of the project. It was decided to start investigating how to group phthalates based on the mode of action and to perform a pilot exercise on how to consider biomonitoring data. This project is proposed as part of the new activities of the Co-Operative Chemicals Assessment Program activities, which will be discussed by the Joint Meeting in November 2014 [see [ENV/JM\(2014\)21](#)].

9. In April 2014 an invitation was sent to the Joint Meeting to participate in a workshop to test whether the AOP/MoA concept can be used as a framework for developing and using IATAs. A thought starter document and case studies have been prepared.

10. In February 2014 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 draft as well as the case studies that have been prepared by several members of the group. It was agreed that the case study contributors use the reporting template which is part of the draft guidance document to present their case studies in a harmonized manner and provide feedback on its suitability and usefulness. The templates and revised guidance were discussed in June 2014. Members were invited to submit comments on the document by the end of July. Some members of the group volunteered to further improve several sections

in the document and the IATA standard reporting template. Based on the input received, JRC will revise the document which will be further discussed at a face-to-face meeting in November 2014.

Forthcoming events:

- Meeting of the QSAR Toolbox Management Group, October 2014, OECD, Paris

Recent publication:

 [No. 184, Guidance Document on Developing and Assessing Adverse outcome Pathways](#)

Contact: Joop DeKnecht, Aldo Benigni, Yuki Sakuratani

Websites: <http://www.oecd.org/env/hazard/qsar>
https://community.oecd.org/community/toolbox_forum

ii. Hazard assessment (Policies and instruments & Cooperative hazard assessments)

11. Twenty-eight assessments for eighty-five chemicals were published in the OECD Existing Chemicals Database since the last Joint Meeting in February 2014. Nineteen draft assessments for a hundred and thirty-seven chemicals were agreed at CoCAM-6 in October 2014 in Paris.

12. A “special case” assessment of a chemical’s likelihood to cause skin sensitisation, finalised at CoCAM 5, was published as a monograph in the series on Testing and Assessment at the end of June.

13. 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.

14. The OECD Secretariat presented at the 51st Joint Meeting a draft outline on future cooperative work on hazard assessment of chemicals. The Joint Meeting agreed to the proposed objectives and activities, and recommended that the Task Force on Hazard Assessment should further discuss the proposed working areas in more detail, including work process/organisation, tangible deliverables and timelines allocated, before assigning lead countries/organisations. The TFHA discussed these projects in June 2014 and proposed work plans focused on two areas for discussion by the 52nd Joint Meeting in November 2014 - case studies for Integrated Approaches to Testing and Assessment and a formal project on combined exposures to multiple chemicals.

15. The second edition of the Guidance document on the grouping of chemicals was published in April 2014.

16. The US and Canada prepared a QSAR document on the Fundamental and Guiding Principles for (Q)SAR analysis of chemical carcinogens with mechanistic considerations which was discussed at the 7th meeting of the Task Force on Hazard Assessment. The TFHA was invited to submit comments by the end of July 2014. Based on the comments received the document will be revised before mid-November.




17. The report and factsheets on member countries that responded to the survey on the status of hydraulic fracturing operations in different countries and legislative/regulatory approaches towards

chemical usage in hydraulic fracturing were updated following two further submissions (from Germany and the Slovak Republic, making 11 responses in total). These documents are available to the Joint Meeting and selected member country experts on a dedicated OECD Community site (formerly Clearspace). The Secretariat has completed a preliminary project to collate chemical identities from various public-domain lists of hydraulic fracturing chemicals. This project has resulted in two searchable spreadsheets (based on an underlying Access database) that link chemical identity to two databases that give an indication of what hazard information may be available for the chemicals. The report of this preliminary project, the two spreadsheets and the Access database are available on the same dedicated HF Community site.

Forthcoming events:

- 8th meeting of the Task Force on Hazard Assessment, 15 -17 June 2015, OECD, Paris

Recent publications:

-  [Weight of evidence assessment for the skin sensitisation potential of 4-Isopropylaniline \(Cumidine, CAS 99-88-7\), No 199 OECD Series on Testing and Assessment](#)
-  [Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at CoCAM, No 210 OECD Series on Testing and Assessment](#)
-  [Guidance on Grouping of Chemicals, Second Edition, No 194 OECD Series on Testing and Assessment](#)

Contact: Joop DeKnecht, Eeva Leinala, Sally de Marcellus, Valerie Frison-Beau and Yuki Sakuratani

Websites: <http://www.oecd.org/env/hazard>
<http://www.oecd.org/env/hazard/data>

iii. Approaches for determining the Safety of Manufactured Nanomaterials

Nanomaterials: Testing and Assessment

18. As a result of the 13th meeting of the Working Party on Manufactured Nanomaterials (WPMN-13) held in June 2014, some further changes were made to the Steering Group structure. There are now four steering groups as opposed to the original nine. They are: i) Testing and Assessment of Manufactured Nanomaterials; ii) Risk Assessment and Regulatory Programmes; iii) Exposure Measurement and Exposure Mitigation; iv) Environmentally Sustainable Use of Manufactured Nanomaterials. WPMN-13 also agreed that the Database on Manufactured Nanomaterials was to be decommissioned and has since been removed from the OECD public website.

19. As part of the work on Testing and Assessment, WPMN-13 agreed that the dossiers prepared as a result of the *Sponsorship Programme for Testing Manufactured Nanomaterials* will be presented to WPMN-14 (to be held in February 2015) for review.

20. 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 on Test Guideline development has also been derived from seven

WPMN expert workshops held to date 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 three of these workshops, including conclusions and recommendations, have been published; the others will be published during the coming months.

21. As a result of these activities, seven Standard Project Submission Forms (SPSFs) were endorsed at WPMN-12 and approved at the WNT meeting in April 2014:

- 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 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); and
- Development of a Draft Test Guideline for Nanomaterial Removal from Wastewater (United States).

22. An additional expert meeting will be held in Paris (13th-14th October 2014), on the adaptation of the genotoxicity in vitro micronucleus assay (TG 487) for the testing of nanomaterials.

23. 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 (Na₂CrO₄) as well as five different nanomaterials have been tested. The laboratory work on this project has been completed, though some statistical analysis remains to be done. The final report on this project will be made available to WPMN-14 (to be held in February 2015) and considered for approval.

Risk Assessment and Regulatory Programmes

24. This project aims: i) to identify regulatory needs for the risk assessment and risk management of manufactured nanomaterials; and ii) to develop risk assessment approaches to strengthen and enhance regulatory risk assessment capacity.

25. As part of this programme, a document was recently published entitled *Report of the questionnaire on regulatory regimes for manufactured nanomaterials 2010-2011*. This report presents the results of a survey on Regulatory Regimes for Manufactured Nanomaterials in various OECD jurisdictions with a focus on future regulatory challenges and collaboration among countries.

26. Based on the publication of *Co-Operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials - Final Report* in 2013, four pilot projects have already been initiated:

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

27. A progress report on these pilot projects will be presented to WPMN-14.

Exposure Measurement and Exposure Mitigation

28. The objective of this programme is to exchange information on (or develop) guidance for exposure measurement and mitigation. The following projects are in various stages of development and will be considered at WPMN-14 in February 2015:

- Exposure assessment: Case studies on nano-silver and nano-gold;
- Assessment of biodurability of nanomaterials and their surface ligands; and
- Harmonised tiered approach to measure and assess the airborne exposure to engineered nano-objects in the workplace.

29. The following projects will be forwarded to the Chemicals Committee with a request for declassification during the next few weeks.

- Measurement of manufactured nanomaterials in air; and
- Disposal and treatment technologies of manufactured nanomaterials.

Environmentally Sustainable Use of Manufactured Nanomaterials

30. This project addresses the potential of nano-based applications to cope with 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. Currently, a Guidance Manual on an LCA case study of multi-walled carbon nanotubes is in preparation. A draft report will be considered at WPMN-14 in February 2015.

Sustainable Development of Tyres: Case study involving nanotechnology

31. 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 draft on the

sustainable use of manufactured nanomaterials in tyres was presented to WPMN-12. The Chemicals Committee and the Committee for Science and Technology Policy subsequently agreed to its declassification. The final report was published in July 2014.





Joint Study Group on Environmental and Human Health Relevance

32. WPMN-13 agreed to establish a Joint Study Group that will look at environmental and human health relevance, which will in turn appropriately feed into regulatory decision making. This will be a joint study between the projects on: Testing and Assessment; Regulatory Programmes and Risk Assessment; and Exposure Measurement and Exposure Mitigation. The Chairs of the three steering groups involved will further discuss the scope, timelines and agree the next steps. This will be considered at WPMN-14.

Forthcoming Events:

- OECD Expert Meeting on The adaptation of the genotoxicity in vitro micronucleus assay (TG 487) for the testing of nanomaterials, 13th-14th October 2014, Paris, France.
- 14th Meeting of the Working Party of Manufactured Nanomaterials, 4th-6th February 2015.

Recent publications:

-  [Ecotoxicology and Environmental Fate of Manufactured Nanomaterials: Test Guidelines;](#)
-  [Report of the OECD Expert Meeting on the Physical Chemical Properties of Manufactured Nanomaterials and Test Guidelines;](#)
-  [Report of the questionnaire on regulatory regimes for manufactured nanomaterials 2010-2011;](#) and
-  [Sustainable Development of Tyres: Case study involving nanotechnology](#)

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iv. Methodologies for Exposure Assessment

33. The 6th meeting of the Task Force on Exposure Assessment (TFEA) was held on 4-5 September, 2014 in Tokyo. The TFEA reviewed the following activities:

34. Nine new or revised Emission Scenario Documents (ESDs) are currently being developed: 1) Chemical Vapor Deposition in the Semiconductor Industry, 2) Use of Adhesives, 3) Textile Dyeing, 4) Lube Oil Additives, 5) Aqueous Firefighting Foam, 6) Plastic additives (mainly emissions from products), 7) Application of Paint Solvent to industrial coating, and, 8) Metals from waste disposal. The draft ESD on Industrial use of cleaners will be sent to the Joint Meeting for declassification in 2014.

35. The TFEA circulated two questionnaires to members to collect information on: 1) available guidance used for assessing combined exposures to multiple chemicals; and 2) available testing guidelines used for assessing exposure to chemicals emitted or migrated from products. The results of the survey will be integrated into the formal project on combined exposures to multiple chemicals in collaboration with the Task Force on Hazard Assessment as discussed at the TFEA meeting.

36. The TFEA discussed the development of an OECD harmonised template (OHT) on use and exposure, and agreed on the draft OHT at its meeting pending some revisions. A revised draft OHT should be prepared for review by the OHT Expert Group in early 2015.

37. The TFEA also agreed to develop a database with information on emissions/releases from products including plasticizers and a matrix of use categories vs. available OECD ESDs and Specific Environmental Release Categories (SpERCs).

38. The report on efficiencies of wastewater treatment technologies/plants was finalised and published in May 2014.

39. The TFEA agreed to conduct follow-up projects on the efficiency of wastewater treatment technologies, and especially related to data sharing and experimental biodegradation data, and will discuss further details of the project at the next meeting in 2015.


40. The TFEA also discussed possible activities on occupational exposure, and agreed to evaluate the reliability and user friendliness of occupational exposure assessment models and databases, and will discuss further steps at its next meeting in 2015. At the next meeting of the International Occupational Hygiene Association in 2015 in London, TFEA activities will be introduced by a number of OECD member countries.

41. Finally, the TFEA agreed to host the draft database on biomonitoring or dermal exposure (probably on an OECD community site, formerly Clearspace) and to put additional data or national biomonitoring programs into the database in 2014.

Forthcoming event:

- 7th Meeting of the Task Force on Exposure Assessment, June or July, 2015, Paris

Recent publication:

 [Emission Scenario Document on Formulation and Application of Thermal and Carbonless Copy Paper](#)

Contact: Takahiro Hasegawa

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v. Methodologies for Assessing the Risks of Chemicals to Children

42. A report of the *Workshop on Children's Exposure to Chemicals* which was hosted by the Netherlands in Utrecht on 7-8, October, 2013 was published in September 2014.

43. At the September 2014 meeting of the TFEA, potential follow-up projects resulting from the recommendations of the workshop were discussed. The Task Force agreed that the focus of the follow-up work should be on the further development and improvement of the decision tree to determine the need for a specific exposure assessment for children.

Recent publication:

 [Report on OECD Workshop on Children's Exposure to Chemicals, No 209 OECD Series on Testing and Assessment](#)

Contact: Eeva Leinala

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

vi. Notification and Reporting Tools

New Chemicals

44. The OECD Clearing House on New Chemicals (which has replaced the OECD Task Force on New Chemicals) was established in early 2009 to manage activities that focus on work related to the notification and assessment of new chemicals (including polymers). The main objectives of the Clearing House 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.

45. 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 has been scheduled in conjunction with the annual meeting of the APEC Chemical Dialog Regulators' Forum to enable Clearing House members and APEC members to attend both meetings.

46. Recently, the work of the OECD Clearing House has focused on two major activities. The first of these is the project to identify common candidate substances for the lists of approved polyester reactants. 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. Of the 59 nominated "new" monomers/reactants, dossiers were submitted for 13 substances by the closing date which had been extended to July 15 2014. The initial review of the dossiers submitted to Australia NICNAS, Health Canada, Environment Canada, and the US EPA is underway.

47. 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 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"). Work began in May 2014 on an analysis of existing notification processes in Australia, Canada, Japan and the US in order to develop a systems requirements document and a rough estimate of the costs to complete the design, development and implementation of the system. The document is expected to be completed in the last quarter of 2014.

48. 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 discuss current methods for analogue identification for new chemical and data-poor substance assessments. The workshop would compare current approaches used by jurisdictions for predicting hazards and properties of new chemical

substances from analogue data, assess the usefulness of existing OECD approaches in the context of new chemicals, and share case studies of assessments to explore strengths/weaknesses of different approaches. The Clearing House briefed the Task Force on Hazard Assessment (TFHA) on this activity at the June 2014 meeting of the TFHA. In light of discussions at the TFHA meeting, the Clearing House is re-drafting the workshop proposal to clarify the scope and objectives.

49. 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.

50. At the 2014 meeting in Beijing, stakeholders acknowledged the value of the Clearing House as a forum that enables regulators and industry to share technical expertise, build consensus on regulatory issues, and to share work. The stakeholders expressed their intent to tap into that resource for additional future projects that would benefit from closer collaboration and that may initially be government only projects to develop a common understanding of how different jurisdictions are approaching various issues.

- **Forthcoming Events:** Meeting of the Clearing House on New Chemicals, 2015, North America

Contact: Richard Sigman, Eeva Leinala

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Harmonised Templates

51. Twelve revised OECD Harmonised Templates (OHTs) were published on the public website in May 2014. They include three OHTs from the Series on degradation and accumulation, four OHTs relating to effects on biotic systems, and five OHTs on Health Effects. This set of updates allows template users to cover the reporting needs for a total of 22 OECD Test Guidelines issued or revised in recent years.

52. A new draft OHT 201 on intermediate effects was developed by the EC-JRC, enabling to report non-apical observations and to start populating the Adverse Outcome Pathway–Knowledge Base. This new type of template will allow reporting results from non-classical alternative test methods (*in vitro*, *in silico*, *in chemico*), and will potentially lead the way towards less animal-centred hazard assessment. The OECD Experts Groups are being consulted and their feedbacks expected by the end of September 2014. The new template might be published by the end of the year.

53. Three OHTs on Health effects (Repeated dose toxicity-oral, Carcinogenicity, Toxicity to reproduction) are being revised and one new template has been drafted on “Endocrine disrupter screening-*In vivo* (level 3)”. The consultation of the OHT Expert Group on the draft files will be closed on 10 October 2014. Depending on the comments received, the four templates could be published by the end of the year.

54. A new draft OHT for enabling reporting of chemical use and exposure information, developed by the OECD Task Force on Exposure Assessment over the past months, was examined by the relevant groups. Some improvements were identified by the TFEA in September 2014. The final version will be developed for possible approval and release in the course of 2015.

55. Fifteen delegations (from countries, EC-JRC and Industry) provided comments on a set of improvements to templates proposed by ECHA and the OECD Secretariat. Suggestions received are being reviewed. Revised proposals will be subject to a second consultation round by the end of the year.

56. Four OHTs on physico-chemical properties (Density, pH and Viscosity) and degradation-accumulation (Phototransformation in water) were revised by the Secretariat for alignment to recent updates of OECD Test Guidelines. They will be submitted to the OHT Expert Group before the end of the year. Work for revising a dozen templates from other Series is continuing.

57. Collaboration continued with the Metapath project for comparing the Data Evaluation Reports generated by Metapath with the existing OHTs. The work started on the metabolism and expression of pesticide residues in livestock, before revising the full OHT Pesticide Series. In particular the OECD predefined tables need to be completed, and all details will be converted in the future into electronic elements to complete the templates.

Contact: Bertrand Dagallier

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

IUCLID

58. 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 Users Group Expert Panel is to collect and discuss user needs in terms of the User Interface of IUCLID, to develop additional guidance documents for users for entering data into IUCLID using the Robust Study Summary format and to develop training course materials for instructing new users on using the IUCLID software and the Guidance Documents.

59. IUCLID 5.6.0 was published in April 2014 including an update to the Classification and Labelling section according to the fourth revision of the GHS and the ability to transfer annotations from one dossier to another. Files generated with IUCLID 5.6.0 remain compatible with IUCLID 5.5 if the updated GHS elements are not used.

60. The development of IUCLID 6 started in 2012 for a duration of 2 years.

61. The IUCLID User Group Expert Panel met on 24-25 September 2014 and was invited to provide feedback on the outcome of the analysis performed in 2014 for specific IUCLID 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.

62. The 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 will be held from 30 September to 15 November 2014.

- Phase 4: correction of issues, document selection panel, other improvements will be held in November/December 2014
- Phase 5: installation and regression will be held in February/March 2015.

Forthcoming events:

- Meeting of the IUCLID User Group Expert Panel, September 2015 (tentative), Paris, OECD

Contact: Sally de Marcellus

II. Assistance with Governance (implementation of OECD Council Acts)

i. Test Guidelines

Outcome of the Twenty Sixth Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT-26)

63. In April 2014, a special session on the AOP Development Programme was held for half-a-day on 8 April, prior to the start of the WNT-26. The objective was to inform the WNT of on-going activities, increase clarity on working procedures and AOP documents work-flow, and allow exchange of views between WNT members and co-chairs of the Advisory Group on Molecular Screening and Toxicogenomics in charge of the AOP Development Programme. At the WNT-26, several TGs and TG-related documents were submitted for approval. Nine new and updated TGs were approved, as well as seven TG-related documents (see below publications). There was a discussion on the Syrian Hamster Embryo (SHE) Cell Transformation Assay (CTA), proposed as a draft Test Guideline; the WNT did not reach agreement on the approval of the draft TG, but supported that it should be transformed into a guidance document describing the procedure and limitations of the method. Seventeen new project proposals were included in the work plan of the Test Guidelines Programme. The work plan was endorsed and declassified in July 2014.

Information on some other issues and projects

Advisory Group on Molecular Screening and Toxicogenomics (including work on AOP development)

64. The Advisory Group met on 12-13 June 2014 at OECD in Paris. The Advisory Group is progressing rapidly on various activities related to Adverse Outcome Pathways (AOP) development. The Advisory Group carried out an internal review of all draft AOPs in the work plan to amplify the benefits of learning-by-doing. The Advisory Group oversees the development of the AOP-Knowledge-Base, including the AOP wiki and Effectopedia, to enable progress with AOPs. The development of the Knowledge Base is led by the EU Joint Research Centre and the US Environmental Protection Agency. A public version [www.aopkb.org] was released on 25 September 2014 [see [link](#)]. A user handbook is available to assist AOP developers in describing their AOPs using the wiki platform. Information related to the AOP development Programme, including an outline work plan is also available on the public website at: <http://www.oecd.org/env/ehs/testing/molecularscreeningandtoxicogenomics.htm>.

65. The Advisory Group is also overseeing the development of a guidance document on describing non-standard *in vitro* test methods. The annual teleconference of the Advisory Group will take place on 9

December 2014 to plan the next steps in the Programme and design the agenda of the next meeting in May 2015.

Activities on in vitro methods for skin sensitisation

66. A meeting of the Expert Group on skin sensitisation was held at OECD on 13-14 February 2014 to address comments and revise two draft Test Guidelines for in vitro skin sensitisation: the Direct Peptide Reactivity Assay (DPRA) and the ARE-Nrf2 Luciferase Test Method (previously known as the Keratinosens test method). The projects are led by the European Commission and Switzerland. The two draft Test Guidelines were approved by the WNT via written procedure in June 2014. The draft documents have been submitted to the Joint Meeting for endorsement by mid-October 2014.

New, updated or corrected Test Guidelines

67. The following new, updated or corrected Test Guidelines were adopted by OECD Council on 26 September 2014 and published.

New Test Guidelines:

Section 2: Effects on Biotic Systems

238: [Sediment-free *Myriophyllum spicatum* Toxicity Test](#)

239: [Water-sediment *Myriophyllum spicatum* Toxicity Test](#)

Section 4: Health Effects

489: [In vivo Mammalian Alkaline Comet Assay](#)

Updated Test Guidelines:

Section 4: Health Effects

431: [In vitro skin corrosion \(human skin model\)](#)

473: [In vitro Mammalian Chromosomal Aberration Test](#)

474: [In vivo Mammalian Erythrocyte Micronucleus Test](#)

475: [In vivo Mammalian Bone Marrow Chromosomal Aberration Test](#)

487: [In vitro Mammalian Cell Micronucleus Test](#)


Corrected Test Guidelines:




Section 3: Degradation and Accumulation

310: [Ready Biodegradation – CO₂ in Sealed Vessels \(Headspace test\)](#)






Recent publications:

68. The following documents were approved by the WNT-26 (8-11 April 2014) and published in the Series on Testing and Assessment in July 2014.

- Four new guidance documents:
 -  [Copepod development and reproduction test, No.201](#)

-  [Quantitative method for evaluation of antibacterial activity of porous and non-porous antibacterial treated materials, No. 202](#)
-  [Integrated Approach to Testing and Assessment for skin irritation and corrosion, No. 203](#)
-  [Single-laboratory validation of quantitative analytical methods, No. 204](#)

- Five reports:

-  [Peer-review report on the Comet assay, No. 197](#)
-  [Validation report on Myriophyllum test water phase, No. 205](#)
-  [Validation report on Myriophyllum test sediment-water, No. 206](#)
-  [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](#)

Forthcoming events:

- Meeting of the Expert Group on Avian Avoidance Testing, 13-14 October 2014, York, United Kingdom
- Meeting of the Advisory Group on Endocrine Disrupters Testing and Assessment, 16-17 October 2014, OECD
- Meeting of the Expert Group on Eye Irritation/Corrosion, 6-7 November 2014, OECD
- Meeting of an Expert Group on Developing Guidance for Study Designs, 20-21 November 2014, Amsterdam, Netherlands
- Meeting of the Validation Management Group on Non-Animal Testing, 2-4 December 2014, OECD
- Meeting of the Validation Management Group on Ecotoxicity Testing, 10-12 December 2014, OECD

Contact: Anne Gourmelon, Nathalie Delrue, Marie-Chantal Huet, Leon Van der Wal, Romualdo Benigni and Kenji Nakano

Website: www.oecd.org/env/testguidelines

ii. Good Laboratory Practice and Compliance Monitoring

69. The 28th meeting of the Working Group on GLP met on 7-8 April, 2014 in Las Vegas, U.S. The next meeting of the Working Group will be held on 16-17 April, 2015 in Paris. The programme of on-site evaluations of GLP compliance monitoring programmes in member and adhering non-member countries continues with five on-site evaluations scheduled for 2014 in Portugal (chemicals and pesticides), Spain (medical), Switzerland and the UK. Six on-site evaluations are scheduled for 2015 in Sweden (Chemicals and Pesticides), Sweden (Medical Products), South Africa, Slovak Republic, Slovenia and Spain (Pesticides and Chemicals). The reports of the five on-site evaluations held in 2014 will be reviewed during the 2015 meeting of the Working Group.

70. Advisory Document number 16 on *GLP Requirements for Peer Review of Histopathology* was published on 26 September, 2014. The document provides guidance on how pathology peer reviews should be planned, conducted and reported under GLP. Following Joint Meeting declassification, a web page with *Frequently Asked Questions* (FAQ) was posted on the GLP public site on 15 July. 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.

71. 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 are invited to comment by 14 November, 2014. This will be the first time the GLP Programme has solicited public comments via the public web site. Commenters have been invited to provide their comments via a template, and to submit them to their national compliance monitoring authority (CMA). Each CMA which receives comments would be responsible for summarising the comments and submitting these summaries and the CMA's response to these comments to the relevant group which is drafting the Advisory Document. The approach for collecting and consolidating public comments on the draft Advisory Document would be a *test case*, and the results from this experience would be discussed at the next Working Group meeting.

72. The Working Group is also developing a Guidance Document on *Test Items*, and a position paper regarding the *Relationship between the OECD Principles and ISO/IEC 17025*.

73. The 12th OECD GLP training course will be held in Hyderabad, India from 12-15 October 2015. The focus of this advanced course will be on strategies for performing GLP Inspections and study audits. The first day, which will be optional for participants, will provide a basic overview of GLP and compliance monitoring.

Forthcoming events:

- 29th Meeting of the Working Group on GLP – Paris, France, 16-17 April, 2015 [Part 2]
- 12th OECD GLP training course – Hyderabad, India, 12- 15 October, 2015

Recent Publications

 [Advisory Document of the Working Group on Good Laboratory Practice - Guidance on the GLP Requirements for Peer Review of Histopathology](#)

Contact: Richard Sigman and Kenji Nakano

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

iii. Mutual Acceptance of Data and Adherence of Non-Members to MAD

74. There are six non-members that 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. At the moment, full adherence for Argentina and Brazil only applies to industrial chemicals, pesticides and biocides. Currently, Thailand is a provisional adherent to the Mutual Acceptance of Data system. The Secretariat continues to work with China, Chinese Taipei, and Latvia and several other countries, in view of their provisional adherence to the MAD Council Acts as well.

75. 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. An on-site evaluation team from Spain, Belgium and India visited the GLP Compliance Monitoring Programmes in Thailand in January, 2012 and the report was considered at the 27th meeting of the Working Group on GLP (16-18 April, 2013). The Working Group meeting in April 2014 discussed plans for a follow-up visit to Thailand. The follow-up team will include Belgium, India and the Netherlands.

Contact: Richard Sigman and Kenji Nakano

Websites: [MAD public website](#)

III. Support for Capacity Development

i. eChemPortal

76. Two new data sources were added as participants 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.
- The INERIS Portail Substances Chimiques is a French portal which provides data on chemicals in the following areas: identification, regulations, physico-chemical properties, behavior (fate in environment, degradation, accumulation...), ecotoxicity (acute and chronic), toxicity (accidental and chronic) and technico-economic data.

77. 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)

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

New releases

79. eChemPortal was re-released twice in 2014:

- with the addition of a new logo, additions to the drop-down lists of the property and effects search, and improvements to the administrative tools to manage eChemPortal (21 February 2014)

- with 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 (20 June 2014).

80. Other releases are expected in 2014 including a query by GHS classification and improvements to the eChemPortal application architecture.

81. An on-line survey was published in February 2014 to collect eChemPortal user feedback.

82. 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.

83. The Steering Group for the Development of the Global Portal refined specifications for development in 2014, agreed the text of the two new pages and agreed a new logo.

84. The Steering Group for the Development of the Global Portal met on 8-9 April 2014 at OECD Headquarters in Paris, OECD. The meeting reviewed draft modifications implemented in 2013/2014, refined analysis to be done in 2014/2015 for potential new features for eChemPortal, and brainstormed proposals for development in 2015/2017, as well as discussed how to promote eChemPortal.

85. The final report was received (16 September 2014) on a series of interviews held with users of eChemPortal to receive feedback on the current functionalities of eChemPortal.

Forthcoming events:

- Meeting of the Steering Group for the Development of the Global Portal, April 2015 (tentative).

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

Contact: Sally de Marcellus

ii. Dissemination of OECD Products

OECD Environmental Risk Assessment Toolkit

86. This Environmental Risk Assessment Toolkit is an interactive web application which gives 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.

87. In October 2013, text for three new examples – on metals, air pollution, and POPs/PBTs – with a glossary was circulated for review by both the Task Force on Exposure Assessment and the Task Force on Hazard Assessment. The revised draft examples have been commented by the Task Forces and revised accordingly. They will be implemented by the end of 2014. Furthermore, back-office functionalities have been developed in order to facilitate the work of content editor consultants and were deployed in July 2014. Finally, the entire content has been revised and an additional general module on pesticides has been developed in August 2014. This content update will be sent to the Task Forces for review.

Contact: Joop De Knecht, Valérie Frison

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

IOMC Toolbox for Decision-Making in Chemicals Management

88. Phase 2 of the development of the toolbox officially started in November 2013. Progress has been made on the following subjects:

- A first proposal for building a module for setting up an industrial chemicals management system was submitted to the 51st Joint Meeting for review and a revised version, based on comments received, was sent to the Joint Meeting delegates in April 2014. The scheme is being implemented into the IOMC Toolbox and will be pilot tested in 2015.
- New functionalities for the Toolbox have been identified and specifications for updates are being drafted.
- Existing schemes on pesticides, occupational health and safety and managing major chemical accidents were reviewed for updates and will be revised in the Toolbox.
- The Task Force on PRTRs commented on the “Draft guidance on elements of a PRTR”. This will be the basis for building a module for setting up a PRTR.

89. To date, 210 delegates participated in hands-on trials of the toolbox, gave positive feedback and provided valuable suggestions for improving the content and functionalities of the toolbox. Further to a November 2013 workshop at the African Regional SAICM meeting, two more have taken place:

- in March 2014 at the UNIDO/UNEP Meeting on Cleaner Production Centres (By OECD)
- in March 2014 at the Asia-Pacific Regional SAICM Meeting (by UNITAR/OECD)

90. In addition, OECD participated in two side events:

- 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.

Contact: Eeva Leinala, Valerie Frison

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

IV. Facilitation of Risk Reduction

i. Tools and Approaches to support decision-making for the substitution of hazardous chemicals

91. The OECD Ad Hoc Group on the Substitution of Harmful Chemicals was established in 2012 and brings together policy makers, experts from academia, industry, trade unions and NGOs. The group focuses its work on tools and approaches to support decision-making for the substitution of hazardous chemicals.

92. The Ad Hoc Group is developing an online toolbox that will provide an inventory of assessment tools and an online selector tool that will allow the user to identify the assessment tools that are best suited for his/her purpose. The tool selector is designed to provide information on tools that can be used in conducting chemical substitutions or alternatives assessments. All tools included in the tool selector address chemical hazard assessment (CHA), and may address other comparative attributes. The toolbox is now in development and being populated. About 50 CHA tools will be included in the tool selector. A first step is the review of the CHA tools; in a second step other categories of tools will be evaluated (e.g. life-cycle assessment, cost/benefit analysis, etc.). The beta version of the toolbox and tool selector was demonstrated and feedback sought during a webinar that was held in June 2014. The toolbox and tool selector are expected to be made publically available in the fourth quarter of 2014.

Contact: Sylvie Poret, Marie-Ange Baucher, Eeva Leinala

Website: <http://www.oecd.org/env/ehs/risk-management>

ii. Risk Reduction (general methodologies and policies and analysis of approaches, as well as on specific chemicals)

Perfluorinated chemicals

93. 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 supported by the OECD and UNEP and brings together policy makers, experts from academia, industry and NGOs from both OECD member countries and emerging economies. Its key activities are developed around:

- The exchange of information through webinars and events;
- The development of a [PFC Web Portal](#);
- The production of analytical papers on policy issues relevant to the risks associated with PFCs and the transition to safer alternatives;
- The development of regular surveys/estimates on the releases and use of PFCs across countries.

94. The group meets regularly through teleconferences to discuss its ongoing and future activities and projects. The group is now focusing its activity on two particular projects: an update of the PFC Web Portal with more information on PFCs alternatives (chemical and non-chemical alternatives), and on an analysis of risk reduction approaches for PFCs across countries.

95. The group recently published 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 are being organised to communicate the conclusions of this paper. The last to date was held on April 30th, and covered the latest developments on alternatives to long chain PFASs. A fourth webinar is planned for the 4th quarter of 2014 on risk reduction approaches for PFCs. Information on these webinars can be found on the PFC Web Portal [here](#).

Contact: Sylvie Poret, Marie-Ange Baucher, Eeva Leinala

Website: [http://www.oecd.org/env/ehs/risk-management/PFC Web Portal](http://www.oecd.org/env/ehs/risk-management/PFC%20Web%20Portal)

Sustainable Chemistry

96. 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 developed a [Sustainable Chemistry Platform](#), which continues to be 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.

97. Recent projects of the group also include research on the economic features of Chemical Leasing. A report is in development on this topic and should be available in 2015.

Contact: Sylvie Poret, Marie-Ange Baucher, Eeva Leinala

Websites :

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

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

Policy Drivers Influencing Decision Making in the Management of Chemicals

98. The conduct of a scoping study by New Zealand on policy drivers influencing decision-making in chemicals management was endorsed by the Joint Meeting in June of 2013. New Zealand, Australia, the European Commission (EC), United States, Canada and Japan provided case studies for a preliminary comparative analysis. This initial analysis was discussed at the 51st Joint Meeting in February 2014 and an updated analysis was prepared and potential project areas identified for discussion by the Joint Meeting in November 2014.

Contact: Eeva Leinala

OTHER EHS PROGRAMMES

I. Development of instruments for the assessment and management of Pesticides and Biocides

i. Pesticides

99. Member countries adopted their Vision for the OECD work on pesticides and sustainable pest management: a cooperative global approach to the regulation of agricultural pesticides and sustainable pest management. The Vision is available on the OECD web site: <http://www.oecd.org/chemicalsafety/pesticides-biocides/OECD-Pest-Vision-Final.pdf>

100. The Residue Chemistry Expert Group (RCEG) continues its work on the revision of the Crop Field Trial (CFT) Guidance Document and development of a Rotational Crop Field Trial Guidance Document. A first Guidance Document on CFT was published in 2011 (series on Pesticides, No. 66; series on Testing and Assessment, No. 164). At the same time, outstanding issues related to the CFT studies were raised following an OECD survey on Maximum Residue Limits (MRL) policies in member countries (survey results published in 2010, series on Pesticides, No. 51). Further work on these issues was discussed and agreed upon at the September 2011 Pesticides Registration Steering Group (RSG) Meeting (Ottawa, Canada). The objective is to update the Guidance Document with respect to the following points: i) crop groups and representative commodities; ii) considering the use of the proportionality principle for adjusting crop field trial values relative to application rate; and iii) further direction on the collection and preparation of field trial samples. The draft GD is being reviewed by the Registration Steering Group and the WNT (comments requested by 31 October).

101. The Expert Group on Terrestrial Field Dissipation (EG-TFD) led by Canada, the United States and EFSA (European Food Safety Agency) has been developing guidance for pesticide TFD studies (component 1 led by US) and constructing an ecoregion crosswalk between North America and Europe (component 2 led by Canada). The ecoregion crosswalk objectives are to: (i) identify similar eco-regions between North America and Europe; (ii) provide a GIS-based decision support system to assist in the selection of regions for TFD studies; and (iii) provide background information on pesticide use areas (crop-based), soils and climate. The draft GD is being revised further to comments received from the WGP and the WNT.

102. The New-Zealand led Expert Group on Product Chemistry (EGPC) is developing product chemistry guidance for agricultural chemical pesticides; the group works in cooperation with the Biocides Chemistry Expert Group (EGBC) established under the Task Force on Biocides. The document being developed is envisioned to provide guidance on core product chemistry properties of active ingredients and end-use formulations, and outline differences between national authorities / regulatory jurisdictions. As a first step of the work, a survey of OECD countries has been conducted.

103. The Expert Group on Pesticides Effects on Insect Pollinators (EG-PEIP) was established in 2013. The Pollinator Incidents Information System – a rapid alert system for regulatory authorities – was launched in March 2014 (PEIP-Theme 1 activity). The PEIP-Theme 2 activity on testing requirements and risk assessment has started in the following areas, in co-operation with the Test Guidelines Programme: i) development of a 10-d laboratory toxicity test on adult honeybees; ii) revision of OECD Guidance Document, series on Testing and Assessment No. 75: Honeybee tunnel test under semi-field conditions; and iii) development of honeybee larval toxicity test, repeated exposure. The Website “Mitigating Pesticide Risk to Insect Pollinators” of the PEIP-Theme 3 activity was launched in April 2014: <http://www.oecd.org/chemicalsafety/risk-mitigation-pollinators/>.

104. Information sharing between the Metapath project and the OECD Harmonised Templates continued, including a comparison between Metapath Data Evaluation Reports and OHTs (see ‘Harmonised Templates’ section).

105. 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

106. As part of the pesticide risk reduction activities, the Expert Group on Integrated Pest Management (IPM) continues implementing specific activities according to its work plan, in particular in the areas of i) incentives (i.e. a guidance document is being developed), and ii) IPM indicators (as a follow-up to the November 2012 Seminar on IPM indicators that addressed both “uptake” and “impact” indicators).

107. Also as part of the pesticide risk reduction activities, the OECD Expert Group on Pesticide Risk Indicators (EGPRI) has been tasked with recommending pesticide risk indicators for policy monitoring at OECD level. As a first step of the work, a survey of member countries on the pesticide risk indicators in use has been conducted. A web-based questionnaire on the pesticide risk indicator evaluation reports (PRIERs) was circulated on 20th May 2014 with a deadline for response of 31st August, 2014. The survey outcome will be an overview of existing PRIs. It will also offer help in selecting appropriate PRI for individual member countries and identifying areas for which PRIs need to be developed.

108. The OECD website on pesticide compliance and enforcement that was made public at the end of March 2014 (<http://www.oecd.org/chemicalsafety/pesticide-compliance/nopce-authorities.htm>) has been updated periodically as information has been submitted by member countries.




109. The OECD Network on Illegal Trade of Pesticides (ONIP) continues to develop options for strengthening the fight against illegal international trade of agricultural pesticides [see [ENV/JM\(2014\)20](#)].

110. For OECD activities on biopesticides (biological pesticides such as micro-organisms, fungi, pheromones) under the BioPesticides Steering Group (BPSG), the following specific projects are underway: secondary metabolites; the adequacy of test guidelines and guidance for data requirements for microbial pesticides; guidance for criteria for not requiring MRLs (maximum residue limits); a template for technical equivalence; and a member country survey on the issue of sensitisation for microbial pesticides. A seminar on secondary metabolites is planned to be held directly before the 2015 BPSG meeting. In addition, OECD guidance documents on botanicals, *trichoderma* species of fungal pesticides and on pre-submission consultations are at various stages of development within the BPSG. A report on the 5th BioPesticides Steering Group seminar on application techniques for microbial and semiochemical pesticides is in draft format and should be published later this year within the OECD series on Pesticides.

Forthcoming events:

- Meeting of the Expert Group on Pesticide Risk Indicators (21 November 2014, OECD, Paris, France)
- Week of 8-11 December 2014 (OECD, Paris, France):
 - 8th December Risk Reduction Steering Group Meeting
 - 9th December Joint Registration and Risk Reduction Steering Group Seminar on non-professional uses of pesticides
 - 10 – 11th December Registration Steering Group Meeting
- 3rd meeting of the OECD Network on Illegal Trade of Pesticides (ONIP)] (30-31 March 2015, OECD, Paris, France)
- Meeting of the Expert Group on the Electronic Exchange of Pesticides Data (EGEPPD) (May 2015 tbc, OECD, Paris, France)
- Working Group on Pesticides and Bio-Pesticides Steering Group Seminar and meeting (Week of 18 – 22 May 2015)

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 presidential areas, Series on Pesticides No. 78](#)
-  [Globally Harmonised Submission and Transport Standards \(GHSTS\) Format Specification, Series on Pesticides No. 77](#)

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

Website: <http://www.oecd.org/env/pesticides>

ii. Biocides

111. Work on efficacy of biocides focused on treated articles – porous surfaces (textiles) and non-porous surfaces (plastics), including a Tier 1 test (proof of principle) and Tier 2 tests (laboratory-based tests to substantiate claims). A Guidance Document for a "Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-porous Antibacterial Treated Materials" (Tier 1) was published in July 2014 in both the series on Testing and Assessment (No. 202) and Biocides (No. 8). The work continues with the development of Tier 2 tests.

112. The member country survey on performance standards and related authorized label claims for microbicides is being carried-out. It is hoped that this work will lead to a new Guidance Document.

113. 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 draft 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 approved by the 26th WNT Meeting in April 2014. It was declassified and published in July 2014 in both the series on Testing and Assessment (No. 204) and Biocides (No. 9). A draft Guidance Document for storage stability

studies of a pesticidal / biocidal formulated product with regard to temperature, humidity, light, etc. is in development.



114. Work led by France on exposure models for insecticides used for vector control continues, and will result in a Guidance Document that will pull together all available information on scenarios and models for both human and environmental exposure.

115. Work regarding risk reduction continues with the development of a harmonised Integrated Pest Management (IPM) approach for biocides. A survey to collect information on current IPM approaches for disinfectants in member countries will be circulated at the end of 2014.

Forthcoming events:

- 13th Meeting of the Task Force on Biocides, 3rd quarter 2015

Recent publications:

-  [Series on Testing and Assessment No. 204, series on Biocides No. 9](#): 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 Testing and Assessment No. 202, series on Biocides No. 8](#): Guidance Document for Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-Porous Antibacterial Treated Materials

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

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

II. Development of instruments to assist countries in dealing with releases of hazardous chemicals from installations and products

i. Chemical Accidents

116. The OECD Working Group on Chemical Accidents (WGCA) supports public authorities, industry, labour and other interested parties to prevent chemical accidents and to respond appropriately if one occurs. The group is now focusing its work on three particular areas:

- **Ageing of hazardous installations:** This project explores a number of aspects linked to the risk of accidents in the case of ageing installations. In particular it is looking at the systems in place to manage ageing installations, and the factors that can influence the ageing process. This project is led by France and aims toward the development of guidance material for supporting the prevention of, preparedness for and response to ageing installations-related accidents;
- **Management of hazardous substances handling facilities with ownership change:** This project aims at getting a better understanding of the potential safety implications of a change of ownership in facilities handling hazardous substances. This includes, for example, the potential

risks caused by a change of ownership from a company with high safety standards to a company with limited understanding of process safety. This project is led by Norway and is composed of different activities amongst which a survey aiming at gathering specific information with regard to the management of safety risks when a facility handling hazardous substances is going through a change of ownership.

- **Accidents involving manufactured nanomaterials:** This project, led by Switzerland, looks at accident scenarios involving nanomaterials. It aims to study the potential risks for health, safety and the environment if accidents involving nanomaterials occur and the potential need for guidance for the prevention, preparedness and response to these accidents.

117. The WGCA is also working toward the finalisation of a draft addendum to the OECD Guiding Principles on Chemical Accident Prevention, Preparedness and Response for the consideration of Natural hazard Triggered Technological Accidents (Natech) Risk Management.

118. The WGCA next meets on 22-24 October 2014. This meeting hosts a special session on Hazardous Substance Handling Facilities with Ownership Change. This special session aims to illustrate the extent to which ownership change is a potential risk factor for the occurrence of accidents in facilities handling hazardous substance, with possibly examples of accidents in which ownership change might have been in cause. It will be looking at issues such as how ownership change is being considered in current chemical accidents prevention programmes and what further policy might be needed to improve prevention in the case of ownership change. It will try to untangle the role of different stakeholders (e.g. acquiring company, selling company, public authorities, etc.) in managing possible risks when a hazardous handling facility is going through a change of ownership.

Forthcoming Events:

- 24th Meeting of the Working Group on Chemical Accidents with a special session on Hazardous Substance Handling Facilities with Ownership Change (22-24 October 2014)

Recent Publications:

- 📖 Korean version of the [Corporate Governance for Process Safety - Guidance for Senior Leaders in High Hazard Industries](#) (also available in Arabic, Chinese, English, French, German, Norwegian, Russian, and Swedish)

Contact: Marie-Ange Baucher and Peter Kearns

Websites: <http://www.oecd.org/env/accidents>

ii. Pollutant Release and Transfer Registers (PRTRs)

119. Work on PRTR continues, with a focus on improving the generation and use of PRTR data through: i) reviewing and updating the published Resource Compendium for PRTR Release Estimation Techniques; ii) developing guidance on the elements of a global PRTR; iii) maintaining and updating the web-based portal and databases; and iv) exploring the role of PRTR data in global sustainability.

120. The Task Force on PRTRs (TFPRTR) has agreed on a proposal to restructure the Resource Compendium for PRTR Release Estimation Techniques from the current four parts into three parts by

merging ‘Part 2 diffuse sources’ and ‘Part 4 releases from products’. The TFPRTTR will discuss draft updated components of the Resource Compendium at the next meeting.

121. The TFPRTTR agreed on (1) a draft Guidance Document on Elements of a PRTR: Part I; and (2) a modification of the document, Global Pollutant Release and Transfer Register, Proposal for a harmonised list of pollutant, specifically to add all the substances under the Kiev Protocol to the “short list (common substances)”. The Part I document has been sent to the Joint Meeting for endorsement, and the draft Part II document is to be discussed at the next meeting of the TFPRTTR.

122. The TFPRTTR agreed to develop a framework that defines the role of PRTR data and information for assessing progress towards global sustainability. The draft outline of such a document was discussed at the TFPRTTR, and a final document would be expected to be completed in 2016.

123. The TFPRTTR agreed to develop an HTML version of the Resource Centre for PRTR RETs, as the platform software has become outdated. The HTML version is expected to be developed in 2014.

124. The 17th TFPRTTR was held in October 2014 in Santiago de Chile. The OECD collaborated with the Economic Commission for Latin America and the Caribbean (ECLAC) to organize a workshop for Latin America and the Caribbean countries to promote the establishment of PRTRs in the region. The meeting was an opportunity to discuss the achievements and difficulties encountered in the region and explore new means of cooperation which would allow advancing towards the development of PRTRs.

Forthcoming events:

- 18th Meeting of the Task Force on PRTRs, date and venue to be decided

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III. Development of instruments to assist in the harmonization of regulatory oversight of the safety of products of modern biotechnology

i. Environmental Safety




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

- the Consensus Documents on the Biology of Cassava and Eucalyptus were published in June and August 2014, respectively;
- the Consensus Documents on the Biology of Tomato (led by Spain and Mexico) and Sorghum (led by South Africa and the United States) are being finalised and are expected to be completed by the end of 2014 or early 2015.

126. 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; the agreement for developing proceedings following the Workshop on New plant Breeding Techniques held in February

2014; and the drafting of several sections of the Mosquito document for which a comprehensive first draft should be circulated to the Working Group by the end of the year.

Recent publication:

-  Biotechnology Update – Newsletter from the OECD Internal Co-ordination Group for Biotechnology (ICGB), [No. 27 of July 2014](#).
-  [Consensus document on the biology of cassava \(*manihot esculenta crantz*\)](#)
-  [Consensus document on the biology of eucalyptus spp](#)

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,

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

ii. Global Forum on Biotechnology

127. Collaboration continued with key non-member partners, and in particular on the occasion of the 2nd Annual South Asia Biosafety Conference held in Colombo, Sri Lanka in September where the OECD Secretariat presented the biosafety and novel food safety activities. Links were strengthened with participants from India for contributing to some *ad hoc* expert groups (cowpea biology, mosquito biology). Bangladesh agreed to contribute to the BioTrack Database with the information on a few GE cotton and eggplant varieties grown in the country. Other contacts included Pakistan, Bhutan, Sri Lanka, and the African organisation COMESA.

128. The OECD Secretariat participated as an observer in the UNEP-CBD COP-MOP7 (meeting of the parties to the Cartagena Protocol on Biosafety) that was held in Korea in October, and will participate at the next meeting of the International Symposium on Biosafety of Genetically Modified Organisms (ISBGMO) to be held in South Africa in November 2014.

Contacts: Bertrand Dagallier

iii. Safety of Novel Foods and Feeds

129. The 21st plenary meeting of the Task Force, held in February 2014, was attended by 73 participants, increasing from previous years. This included the first participation of Bangladesh, Colombia and Kenya that was made possible with the support of the OECD-World Bank-CERA partnership, within the framework of the Global Forum on Biotechnology.

130. The proposal to develop a document on Apple (*Malus domestica*) composition was formally agreed, and an initial pre-draft was circulated by Germany, the lead country; many countries from different parts of the world agreed to provide their expertise in preparing the next version.

131. New documents on the composition of Common bean (*Phaseolus vulgaris*) and Rice (*Oryza sativa*) were examined. Since the meeting, four delegations provided substantive comments on the revised draft common bean document (lead country Brazil), aiming to its declassification by the end of the year. With Japan, leader of the Rice project, a meeting was held in October 2014 in order to include a broader range of data in the document, such as key information collated by the International Rice Research Institute (IRRI, Philippines).

132. The Task Force agreed to launch projects on “Animal composition data” (Canada lead) and “Innovative novel feed ingredients” (Netherlands and Canada, co-leads) to be developed in the coming months. It was also decided to hold a focus session on enabling “Joint Reviews” of novel foods and feeds derived from rDNA plants at the next plenary meeting of the Task Force in 2015.

Forthcoming events:

- 22nd Meeting of the Task Force on the Safety of Novel Foods and Feeds, 15-17 April 2015, OECD

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