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I. Provision of knowledge and information
1 Methodologies for Hazard Assessment

The Hazard Assessment Programme is concerned with the hazard assessment of industrial chemicals. The current focus of the programme is on the development and application of Integrated Approaches to Testing and Assessment (IATA) and the exchange of experience on new hazard assessment methodologies. IATA are frameworks used for hazard identification, hazard characterisation and/or safety assessment of a chemical or group of chemicals, which integrate and weigh all relevant existing data and guide the targeted generation of new data where required to inform regulatory decision-making regarding potential hazard and/or risk. The OECD is already actively working on the development of tools and approaches such as chemical categories and (Q)SARs which are methods for estimating properties of a chemical from its molecular structure and have the potential to provide information on hazards of chemicals, while reducing time, monetary cost and animal testing currently needed. The OECD (Q)SAR Project is developing guidance material and a “Toolbox” for practical applications of (Q)SARs by governments and industry in specific regulatory contexts.

Integrated Approaches to Testing & Assessment

The Integrated Approaches to Testing and Assessment (IATA) case studies project continues under a project team of the Working Party on Hazard Assessment.

Five case studies reviewed in the second review cycle (2016) of the IATA Case Studies Project were published along with a considerations document highlighting the lessons and learnings stemming from the case studies.

The following four case studies are under review by the project team in the third review cycle (2017):

- Estrogenicity of Substituted Phenols [Canada & the United States]
- Prioritisation of chemicals using the Integrated Approaches for Testing and Assessment (IATA)-based Ecological Risk Classification [Canada]
- Case study on grouping and read-across for nanomaterials genotoxicity of nano-TiO2 [JRC]
- A Case Study on the Use of Integrated Approaches for Testing and Assessment for Sub-Chronic Repeated-Dose Toxicity of Simple Aryl Alcohol Alkyl Carboxylic Esters: Read-Across [ICAPO]
- Chemical Safety Assessment Workflow Based on Exposure Considerations and Non-animal Methods [JRC/BIAC].

These case studies will be discussed at the 3rd Meeting of the IATA Case Studies Project to be held on 27-28 November 2017 in order to identify lessons-learned and areas for further development of guidance.

QSAR Toolbox

Version 4.0 of the QSAR Toolbox was released in April 2017 and includes the following main new features:

- Streamlining of workflows;
- IT refactoring of the Toolbox source code;
- Introduction of the reliability score for profilers and databases; and
- Enhancement of the ADME information.

Version 4.1 of the QSAR Toolbox was released in August 2017.
Version 4.2 of the QSAR Toolbox will be released in November 2017.

A face-to-face meeting of the QSAR Toolbox management group, which will include discussions on the development and maintenance of the tool, will be held from 29-30 November 2017.
As part of the AOP Knowledge Base (AOP-KB), the tool Effectopedia, which allows quantitative depiction of the relationships between molecular initiating events, key events, and the in vivo adverse outcomes within an Adverse Outcome Pathway (AOP), after its v. 1.0 release in December 2016 was updated in June 2017 with:

a. new data templates allowing the use of time-dose responses;
b. a new interface allowing users to add modifying factors and feedback/feedback forward loops in the quantitative descriptions of the key event relationships;
c. an aggregation function (additive, synergistic, antagonistic) for key events with more than one input.

Effectopedia’s new release in December 2017 will also have the following new features:

- The support of the AOP-XML format, a standard format for data exchange between the AOP-KB modules as well as with third-party applications;
- A completely intuitive and user-friendly interface which integrates an update of the quantitative modelling tool.

Updated guidance, training materials, webinars and video tutorials are available on http://effectopedia.org/.

The search engine eAOP Portal, which allows end user search capabilities between different modules of the AOP-KB (i.e. AOP wiki and Effectopedia), was further improved and its v 2.0 was released in February 2017. This search engine houses the status of all AOPs in the OECD workplan, the official copy of published AOPs and allows browsing of external review reports for individual AOPs.

A project team under the Working Party on Hazard Assessment (WPHA) and the Working Party on Exposure Assessment (WPEA) continued to work on the topic of assessing risks from the combined exposures to multiple chemicals. A draft guidance document has been developed on considerations for problem formulation, hazard assessment, exposure assessment, and risk characterisation. The document is currently under review by the project team and Working Parties. It is expected that the document will be finalised in 2017.

A new project was started to develop a document with Guiding Principles for Establishing Weight of Evidence for Chemical Assessment. The project aims to establish basic guiding principles to formulate a weight of evidence (WoE) for both the prioritisation and assessment of chemicals under different regulatory and non-regulatory contexts.

The development of a guidance document on the characterisation, validation and reporting of physiologically based models for regulatory applications was initiated. This project is a joint initiative between the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics.
Series on Testing and Assessment:

This Series includes publications related to testing and assessment of chemicals; some of them support the development of OECD Test Guidelines (e.g. validation reports, guidance documents, detailed review papers).

No. 270

No. 271
Case Study on the Use of an Integrated Approach to Testing and Assessment for the Repeated-Dose Toxicity of Phenolic Benzotriazoles.

No. 272
Case Study on the Use of Integrated Approaches for Testing And Assessment for Pesticide Cumulative Risk Assessment & Assessment of Lifestage Susceptibility.

No. 273
Case Study on the Use of Integrated Approaches for Testing And Assessment of 90-Day Rat Oral Repeated-Dose Toxicity for Selected N-Alkanols: Read-Across.

No. 274
Case Study on the Use of Integrated Approaches for Testing And Assessment of 90-Day Rat Oral Repeated-Dose Toxicity for Selected 2-Alkyl-1-Alkanols: Read-Across.

No. 275

For the latest information, please visit the OECD websites:

- [http://aopkb.org/](http://aopkb.org/)
- [https://www.effectopedia.org/](https://www.effectopedia.org/)

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Methodologies for 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 humans and the environment. 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.

Estimating the release of chemicals

The Working Party on Exposure Assessment (WPEA) is currently developing nine Emission Scenario Documents (ESDs) or related documents:

1. Release of plastic additives during the use of end products: Complementing document to the ESD on plastic additives;
2. ESD on smelting and disposal of metals used in electrical and electronic products;
3. ESD on chemical additives used in automotive lubricants;
4. ESD for the use of aqueous film forming foam (AFFF);
5. Compilation of case studies of uses of Fluorocarbon substitutes in refrigeration, air conditioning, electronics, metal cleaning and foam blowing;
6. ESD for chemicals used in hydraulic fracturing;
7. ESD for the use of vapor degreasers;
8. ESD on chemicals used in fabric finishing, and;
9. ESD on compounding of carbon nanotubes.

WPEA is furthermore developing a table on the relationship between lifecycle stage and use descriptors to analyse similarities and differences between the OECD ESDs and the EU Specific Environmental Release Categories (SpERCs).

The document is under final review by the WPEA, and is expected to be finalised in 2017.

Combined exposure to multiple chemicals

A project team under the Working Party on Hazard Assessment and the WPEA continues to work on the topic of assessing risks from the combined exposures to multiple chemicals.

A draft guidance document has been developed on considerations for problem formulation, hazard assessment and exposure assessment, and risk characterisation. The document is currently under review by the project team and Working Parties. It is expected that the document will be finalised in 2017.
The WPEA finalised a document on International Harmonised Use Codes, which compares function and consumer product codes in different countries and it was published in May 2017.

The WPEA is also developing a “Product Release and Exposure Data Warehouse”, led by the United States, designed to house existing data on releases from, and exposures to, chemicals used in commercial and consumer end products. This tool and relevant documents are expected to be finalised in 2017.

To improve and further develop wastewater treatment removal prediction methods, Canada as lead country initiated an experimental study to measure half-lives of different types of chemicals under activated sludge conditions.

The WPEA is also working on the development of a biomonitoring database on chemicals measured in humans compiling information on publicly available biomonitoring data across countries. The project is collaborating with other similar initiatives such as IPCheM in the EU to avoid any duplication.
3. Approaches for determining 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, the OECD Working Party on Manufactured Nanomaterials (WPMN) was established to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials. Its objective is to assist countries in their efforts to assess the safety implications of nanomaterials.

Testing & Assessment

The WPMN continues its assessment of the test methods used in the Testing Programme. The European Chemicals Agency (ECHA) is leading an evaluation of the applicability of in vivo methods for human health and the environment that were applied in the Testing Programme.

At the same time, the EU Joint Research Centre (JRC), Italy and The International Council for Animal Protection in OECD Programmes (ICAPO) are leading the assessment of the in vitro methods used.

The results from these projects will be used to update the preliminary review on the applicability of Test Guidelines/Guidance Documents to nanomaterials, and to prioritise further needs.

In October 2017, the OECD published the first Test Guidelines developed specifically for nanomaterials.

- Test Guideline 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media provides a simple and effective tool that can analyse the dispersion stability of nanomaterials in aqueous media. It is one of the prerequisites for a subsequent robust and reliable safety testing of nanomaterials.

- Test Guideline 412: 28 days (Subacute) Inhalation Toxicity Study and Test Guideline 413: 90 days (Subchronic) Inhalation Toxicity Study have been updated to allow testing and hazard identification of inhaled nanomaterials.

Furthermore, Germany is leading a project to assess the need for a (new) Test Guideline or Guidance on particle size and size distribution. Japan and BIAC are leading the development of a “Technical Document on in vivo Short-Term Exposure Methods for Inhalation Toxicity Testing of Manufactured Nanomaterials”.

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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.

A new project was initiated on “Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation”. This project benefits from the participation of experts from the OECD Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST).

The United States are leading a project on “different types of risk assessments, tools available for risk management measures, and uncertainties, which guide additional nano-specific data needs in member countries”. A final draft report will be discussed at the next WPMN meeting in February 2018.

The WPMN is updating the 2012 document on “Important Issues on Risk Assessment of Manufactured Nanomaterials” and a first revision is being prepared for discussion at the WPMN meeting in February 2018.

Exposure Measurement and Exposure Mitigation

The objective of this activity is to exchange information on (or develop) guidance for exposure measurement and mitigation.

The WPMN started a project for the “Compilation of available tools and models used for assessing environmental and consumer exposures to NMs” led by Canada. A progress report will be provided at the WPMN meeting in February 2018.

The WPMN is currently working on two projects related to the physical chemical properties of nanomaterials. The purpose of these closely related projects is to develop a framework to identify the appropriate methods for characterising physico-chemical endpoints for different manufactured nanomaterials, or categories of nanomaterials, for regulatory purposes.

The three areas addressed are:

i. Nanomaterial Identification and Information Gathering;
ii. Physicochemical Properties for Exposure and Fate Assessment; and
iii. Physicochemical Properties for Hazard Assessment. It is expected that this work will facilitate progress for the development of guidance for the categorisation of nanomaterials.

A report is due to be presented at the WPMN-18 in February.

The WPMN also agreed to undertake a new project on “‘Safe-by-Design’ for sustainable innovation in nanomaterials and nano-enabled products: Overview of existing risk assessment tools and frameworks” led by France, the Netherlands and BIAC. A progress will be reported at the WPMN meeting in February 2018.
Recent publications - Series on Safety of Nanomaterials

The purpose of the OECD Series on the Safety of Nanomaterials is to provide up-to-date information on the OECD activities related to human health and environmental safety.

No.81: Developments in Delegations on the safety of manufactured nanomaterials (March 2017 - August 2017).

No.82: Strategies, Techniques and Sampling Protocols for Determining the Concentrations of Manufactured Nanomaterials in Air at the Workplace.

No.83: Strategies, Techniques and Sampling Protocols for Determining the Concentrations of Manufactured Nanomaterials in Air at the Workplace.

Forthcoming Event

14-16 February 2018
OECD Paris,
17th Meeting of the Working Party on Manufactured Nanomaterials

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Notification & Reporting Tools

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

The Series of OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) dealing with the residues of pesticides were updated and re-organised by merging elements on crops and rotational crops in single OHTs, and creating three new templates to cover the reporting needs for Test Guidelines 506 to 509 (Crop field trial, Residue Nature & Magnitude in processed commodities, and Residue Stability in stored commodities).

Coordination with the Metabolism Pathway Database MetaPath system and databases (managed by the U.S. Environmental Protection Agency) was established during the revision process led to a high level of compatibility with the OHTs dealing with metabolism. Some changes that affect the reporting of test results for biocides were also included. Predefined tables and executive summaries associated to OHTs were updated and completed. The full set of OHTs 85-1 to 85-10 will be published on the OECD website in October 2017.

Work is in progress to update the following OHTs and adapt them to new or revised Test Guidelines, aiming for their publication by the end of 2017: four OHTs on biotic systems effects (dealing with toxicity to aquatic invertebrates, aquatic plants and terrestrial arthropods), four OHTs on health effects (relating to repeated-dose toxicity (oral, inhalation, dermal) and toxicity to reproduction), and the OHT on genetic toxicity in vitro.

A consultation was launched in April 2017 proposing to extend the current ‘OHT 201 on Intermediate Effects’ to cover the reporting of tests made according to OECD In vitro/In chemico Test Guidelines. This proposal corresponds to a ‘shift in philosophy’ and will orientate future update of OHTs when dealing with reporting of non-apical observations from in vitro tests. There was an overall agreement on the principle of individually reporting intermediate effects in OHT 201 instead of within an apical endpoint template, but such a change would need to be accompanied by clear guidance to data providers to use in practice. The need to be able to readily link these effects to the apical endpoints (e.g. in IUCLID) was also recognised, so the data user is provided all information relevant to the endpoint. Drafting a revised OHT 201 (including ontology updates) started in September 2017 (Lead: European Union). A skin sensitisation Test Guideline will be used as a pilot case on what type of information should be captured. Experts will be regularly consulted during the development of the draft revised OHT in the upcoming months.

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www.oecd.org/ehs/templates/
The International Uniform Chemical Information Database (IUCLID) is a software tool used to capture and store, submit, and exchange data on chemical substances 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 Expert Panel provided feedback for:

- IUCLID 6 v1.2.0, published in January 2017 (which included a IUCLID hyperlink feature allowing users to refer to IUCLID information across a single IUCLID server, a Derived No-Effect Level (DNEL) calculator and a public Application Programming Interface (API));
- IUCLID 6 v1.3.0, published in April 2017 (which includes a Predicted No-Effect Concentration calculator, re-use of the dossier header and a report manager); and
- The user interface for the IUCLID 6 Cloud for European Small and Medium Enterprises as a potential generic web user interface for IUCLID 6 in the future.

In September 2017, the Expert Panel provided ideas for future IUCLID development (2018-2023).

IUCLID 6 offers new possibilities for customisation for use in different jurisdictions, such as creating jurisdiction specific templates and reports in IUCLID 6. The Expert Panel is currently drafting a document on the customisation possibilities of IUCLID 6 and use cases, expected to be published in 2018.

An IUCLID 6 Provider Agent has been developed to populate eChemPortal.

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**Forthcoming Event**

TBD September-October 2018,
OECD Paris,
Meeting of the UCLID User Group Export Panel.

**Contact**

Sally DE MARCELLUS
II. Assistance with Governance
The Test Guidelines Programme develops Test Guidelines and related documents needed to undertake the first step in chemical regulation – testing for health and environmental hazards.

The following Test Guidelines were adopted by the OECD Council and published on 9 October 2017:

### New Test Guidelines

**Section 2: Effects on Biotic Systems**
- **No. 244**: Potamopyrgus antipodarum Reproduction Test.
- **No. 245**: Lymnaea stagnalis Reproduction Test.
- **No. 246**: Test Guideline on Acute Contact Toxicity to bumble bees.
- **No. 247**: Test Guideline on Acute Oral Toxicity to bumble bees.

**Section 3: Environmental Fate and Behaviour**
- **No. 318**: Dispersion Stability of Nanomaterials in Simulated Environmental Media.

**Section 4: Health Effects**
- **No. 433**: Acute Inhalation Toxicity Test: Fixed Concentration Procedure.
- **No. 405**: Acute Eye irritation/Corrosion.
- **No. 437**: BCOP Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.
- **No. 438**: ICE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.
- **No. 460**: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants.
- **No. 439**: STE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.
- **No. 412**: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage.
- **No. 402**: Acute Dermal Toxicity Test: Fixed Dose procedure.
- **No. 412**: Subacute Inhalation Toxicity: 28-Day Study.
- **No. 413**: Subchronic Inhalation Toxicity: 90-Day Study.
- **No. 442E**: In Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation.

### Updated Test Guidelines

**Section 4: Health Effects**
- **No. 405**: Acute Eye irritation/Corrosion.
- **No. 437**: BCOP Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.
- **No. 438**: ICE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.
- **No. 460**: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants.
- **No. 491**: STE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage.

### Deletion of a Test Guideline

**Section 4: Health Effects**
- **No. 415**: One Generation Reproductive Toxicity Test.
Expert Group on the Miniaturised Ames Test

This project is led jointly by Belgium, the Netherlands and the United States. The Expert Group had its first meeting on 28 February-1 March 2017 at OECD in Paris. The objective of the project is to assess the available miniaturised versions of the Ames test, and provide recommendations on whether the/some miniaturised versions of the bacterial gene mutation test can be included in an OECD TG (revised TG 471 or new TG). The Expert Group developed a list of information and data that need to be collected for a retrospective validation. A prospective validation might be necessary if the data collection shows data gaps and retrospective validation is not sufficient; nine laboratories represented at the meeting accepted to be on board for a prospective validation if needed.

The Expert Group decided to start with two tasks:

i. A survey of useful data for the retrospective validation exercise, and
ii. The drafting of a Detailed Review Paper describing methods available.

Expert Group on the Good In Vitro Method Practice

This project is led by the JRC’s EURLs ECVAM. The aim is to describe current best practices for the development and reliable implementation of cell and tissue culture-based in vitro methods for use in human safety assessment, and includes topics on in vitro method development, standardisation, harmonisation, and international acceptance. A draft of the Guidance Document was circulated to the Working Group on GLP, the WNT, and various expert groups for two commenting rounds in Q4 2016 and Q3 2017; a meeting of the Expert group was held in March 2017 to address comments from the first round. The draft Guidance Document is planned to be submitted for approval to the WG GLP in December 2017 and to the WNT in April 2018.

Expert Group on Non-Genotoxic Carcinogenicity (NGTxC)

This project is led by the United Kingdom and was included in the work plan in 2015. The objective of the project is to develop an Integrated Approach to Testing and Assessment (IATA) to assist regulators in their assessments of Non genotoxic Carcinogens (NGTxC). The Expert Group had its second meeting on 29-30 March 2017, at the OECD in Paris. Progress is made on several chapters of the document on an IATA for NGTxC, such as on regulatory aspects, the identification of assays for NGTxC and assay evaluation, and the uncertainty analysis. Regular teleconferences are organised with the Expert group to progress with the various tasks and the next face-to-face meeting is foreseen in June 2018.

Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA AG)

The EDTA AG met in May and in October 2017. One important discussion point was the update of the OECD Guidance Document 150 on the Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption, originally published in 2012. The Document is being updated to include recently adopted Test Guidelines, and to better reflect experience gained in countries and regional regulatory programmes. The draft updated document was submitted to a commenting round in Q3 2017, and outstanding issues were addressed in October at the face-to-face meeting. Another commenting round will start at the end of 2017, and it is expected that the document will be approved by the WNT in April 2018. The EDTA AG also discussed the update of Test Guideline 408 (90-day repeated dose toxicity study) and 414 (prenatal developmental toxicity study) to include relevant endpoints for the identification of chemicals endocrine activity. There are expectations that these updated TGs will be approved in April 2018 as well.
29th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT-29)

The 29th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme was held at OECD on 25-28 April 2017. The WNT approved several new, updated and corrected Test Guidelines, as well as the deletion of one Test Guideline no longer used (see above). The WNT also approved a number of guidance documents and reports that have been published in the OECD Series on Testing and Assessment in Q3 2017.

The WNT agreed to communicate more clearly to potential developers the policy of the Test Guidelines Programme regarding the integration of test methods similar to existing Test Guidelines that contain protected elements. Additionally, the WNT decided to start addressing more specifically the issue of protected elements in Test Guidelines and their accessibility to users.

All relevant information is regrouped on a webpage: The WNT decided to organise a workshop with experts in the subject matter of intellectual property in regulatory standards later in 2017 to better understand this emerging issue (see below).

The WNT reviewed several new project proposals Most of them were included on its workplan, which was published in August 2017 on the OECD Internet site.

Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)

The EAGMST met in June 2017 at the OECD to discuss the development and review of Adverse Outcome Pathways (AOPs), as well as guidance and IT tools available. About a dozen AOPs have progressed to the stage of external review and endorsement and they are expected to be published in 2018 in the OECD Series on AOPs. The external review process has been standardised to enable others than the OECD Secretariat to manage the review in an open and transparent way.

The EAGMST also had a discussion on the future developments of the AOP-Knowledge Base (AOP-KB); there is a willingness to centralise the current modules, while retaining the good features of the current AOP-wiki and Effectopedia. An online survey was sent out in September to collect information to guide the AOP-KB team in the development of AOP-KB version 2.0.

The EAGMST also discussed a new project to elaborate OECD templates for the reporting of ‘omics data’, starting with transcriptomics. The project is led by the United Kingdom along with Canada and the United States.
A workshop was convened at OECD on 21-22 September 2017 to gather IP experts from OECD countries with the view to collect advice and best practice in place in other sectors related to IP and regulatory standards. The workshop report will be published in 2018, and the outcome was a recommendation to develop best practice for licensing of protected elements in OECD Test Guidelines. A project proposal will be discussed at the WNT meeting in 2018.

The VMG-NA met on 3-4 October 2017 at OECD to discuss progress with a number of in vitro androgen receptor transactivation assays currently on the work plan or recently adopted as Test Guidelines.

Also, the meeting discussed updates to TG 458 to include proposed performance standards, review updates on the development of a Performance Based Test Guideline for Androgen Receptor transactivation, and discuss progress in countries with initiatives to validate in vitro assays for the detection of thyroid active chemicals.
Recent publications - Series on Testing and Assessment

Series on Testing and Assessment

This Series includes publications related to testing and assessment of chemicals; some of them support the development of OECD Test Guidelines (e.g. validation reports, guidance documents, detailed review papers).

No. 277
Report of the Validation Study for the Standardisation of a 10 day Feeding Test on Honey Bees.

No. 276
Report of the validation study supporting the development of the TG 318 on dispersion behavior of nanomaterials in different environmental media.

No. 269
Report of the international Ring-Test for the Standardisation of an Acute Oral and Contact Test on Bumblebees in the Laboratory.

No. 268
Report of the Peer Review Panel for the IL-8 Luciferase (IL-8 Luc) Assay for in vitro skin sensitisation.

No. 267
Validation report for the international validation study on the IL-8 Luc assay as a test evaluating the skin sensitizing potential of chemicals conducted by the IL-8 Luc Assay/

No. 266
Effects of chemicals on waste water treatment: Final validation study of the protozoan activated sludge test to establish an OECD Test Guideline.

No. 265
Background Review Document Supporting the Development of the Test Guideline 433 on Acute Inhalation Toxicity – Fixed Concentration Procedure Harmonised Submission.

No. 264
Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation.

No. 263
Guidance Document on an Integrated Approach on Testing and Assessment (IATA) for Serious Eye Damage and Eye Irritation.

The Test Guidelines project is funded by The European Union.
Forthcoming Events


13-15 December 2017, JRC, Ispra, Italy, Special session of the WNT on Defined Approaches for Skin Sensitisation.

24-27 April 2018, OECD Boulogne, Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT-30).

Contacts

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2. Good Laboratory Practice and Compliance Monitoring

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.

Guidance Documents

The webpage OECD GLP Frequently Asked Questions (FAQ) – Volume 3 (Software programmes and Peer Review of Histopathology) was published on 27 March 2017.

Version three of the FAQ includes three topics related to whether software programmes developed by outside vendors to support calculations by test facilities using OECD Test Guidelines need to be validated by such facilities, and clarification regarding two issues raised after the publication of the OECD's Guidance Document No. 16 on the GLP Requirements for Peer Review of Histopathology.

Volume 4 of the Frequently Asked Questions (FAQ) document will aim to respond to comments gathered from industry and trade associations and quality groups on areas on GLP compliance that may be of concern due to a lack of harmonisation across governments. A revised final document was circulated for review by the Working Group members in September, 2017. It is scheduled to be published in Q4 2017 or Q1 2018.

Volume 5 of the FAQ is being developed to describe monitoring authority expectations of test facility management (TFM) concerning the selection of test sites and claims of GLP compliance for study phases. The document is being developed by a drafting group under the leadership of the Netherlands and the United Kingdom. The FAQ will provide guidance to test facility management on the implications of selecting a test site that is not a member of a national GLP compliance monitoring programme or has not been inspected by a national compliance monitoring authority. The draft document will be discussed at the next Working Group meeting (March, 2018).

An Advisory Document on Test Items is being developed by a drafting group under the leadership of the UK, France (Pharmaceuticals), Denmark (Pharmaceuticals) and Italy. The objective of the document is to consolidate text in existing guidance documents that refers to “test item”, as well as promote a consistent approach for performing a characterisation of test items. The first draft of the Document was reviewed at the 28th Working Group meeting in April 2014. At the 31st Working Group meeting, members reviewed the latest draft. The drafting group collated the comments raised by members during and after the meeting. A revised version was posted on OECD’s website for public comment in May, 2017 and comments were due by 31 July, 2017. The document will now be revised before a final draft is produced for circulation and approval by the Working Group members.

An Advisory Document on Data Integrity - Definition and Guidance for Industry - is being developed by a drafting group under the leadership of the United Kingdom. Initially, a draft paper was prepared by the UK Medicines and Healthcare products Regulatory Agency (MHRA), for public consultation in the United Kingdom in 2016. The 31st Working Group meeting reviewed the United Kingdom’s draft paper and agreed that there would be value in developing this paper into the OECD Advisory Document. A drafting group was formed and a first draft of the Advisory Document, based on the United Kingdom paper, will be discussed at the next Working Group meeting (March, 2018).
A new Guidance Document for Receiving Authorities for verifying the GLP status of submitted studies is being developed by a drafting group under the leadership of the Netherlands. A receiving authority is a national body which reviews test submissions and is responsible for the assessment and management of chemicals. The objective of the new guidance is to promote an adequate and time-efficient evaluation of the GLP status of submitted data as well as the GLP status of test facilities that generate non-clinical health and environmental data used for hazard assessments. The Guidance may also help reviewers determine whether it is necessary to request a study audit and/or test facility inspection before the data can be accepted. The drafting group will solicit input from receiving authorities that will help the group prepare a first draft of the guidance document. A first draft of the document will be prepared for review at the next Working Group meeting.

The 13th OECD GLP training course was held in Cracow, Poland from 2 to 5 on October 2017. The course comprised lectures and discussions in plenary, as well as parallel workshops on inspecting computerised systems, practical aspects of a GLP inspection, and practical aspects of non-compliance decisions and compliance reports.

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 receiving authorities are provided accurate and complete assessments of the conduct of non-clinical health and environmental safety studies and of the quality of the data.

The programme of on-site evaluations of GLP compliance monitoring programmes in member and adhering non-member countries continues, with six on-site evaluation conducted in 2016 – Austria (medical products), Canada, Estonia, Israel, Mexico and Poland. At the 31st meeting of the Working Group on GLP (28-30 March 2017), members reviewed five of the six evaluations conducted in 2016. The Working Group reviewed the evaluation of Israel at the 2016 meeting.

Most significantly, the 31st meeting concluded that Mexico’s GLP compliance monitoring programme - which had undergone its first on-site evaluation - fully complies with the 1989 Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice.

Two on-site evaluation visits are scheduled for 2017 in Slovenia and a follow-up visit to Estonia. The reports of the two evaluations held in 2017 will be reviewed during the 2018 meeting of the Working Group.

The 31st Working Group also agreed a second ten-year round of on-site evaluation visits (2018-2027). Six on-site evaluations are scheduled for 2018 – Japan (Medical Products), Japan (Workplace Chemicals), the Czech Republic (Pesticides and Industrial Chemicals), the Czech Republic (Pharmaceuticals and Veterinary Drugs) and Germany.
3. Evaluation and Updating of OECD Legal Instruments on Chemicals

With a view to strengthen and maximise the impact of OECD legal instruments, an OECD-wide standard-setting review was launched by means of letters sent by the Secretary-General to all Chairs of substantive Committees. The goal of the review is to ensure that OECD legal instruments continue to respond, in a timely manner, to the new challenges that governments are facing, thereby strengthening their impact and relevance for the Membership and beyond.

The Joint Meeting is working to update the Council Act on the Co-operative Investigation and Risk Reduction of Existing Chemicals and the Council Act on Implementing Pollutant Release and Transfer Registers (PRTRs).

For the Council Act on Implementing PRTRs, based on feedback received from the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in May/June 2017, the Working Group on PRTRs in June 2017 and the Environment Policy Committee in October 2017, the Secretariat has prepared a final draft of the updated Council Act for endorsement at the next Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in February 2018.

For the Council Act on the Co-operative Investigation and Risk Reduction of Existing Chemicals, based on a discussion of an initial draft at the Joint Meeting in May/June 2017, an updated draft was prepared by the Secretariat and is undergoing comment by the Joint Meeting by written procedure. Based on the nature of the comments the updated Council Act will be submitted for endorsement by the Joint Meeting by the end of 2017.

In July 2017, the OECD Council agreed the abrogation of two Council Acts related to chemicals: Recommendation of the Council of the Determination of the Biodegradability of Anionic Synthetic Surface Active Agents [C(71)83/FINAL]; and Recommendation of the Council on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215]. These Council Acts have been superseded by more recent instruments.

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Methodologies for assessing the costs and benefits of managing chemicals

Work under this broad topic includes analysis of the current methods used to estimate the economic benefits and costs of protecting human health and the environment from chemicals in the context of a chemicals management framework. This addresses cost-benefit methods for regulating individual chemicals as well as methods for estimating the costs and benefits for setting up or improving overall chemicals management systems. Based on this research work, best practices to assess the quantifiable benefits and costs of chemical management programmes could be developed. It is envisaged to be undertaken in collaboration with EPOC and their Working Party on Integrating Environmental and Economic Policies (WPIEEP).

An OECD Workshop on “Socioeconomic Impact Assessment of Chemicals Management” was hosted by the European Chemicals Agency (ECHA) from 6-8 July 2016 in Helsinki, Finland. The workshop was conducted in collaboration with the Working Party on Integrating Environmental and Economic Policies (WPIEEP). A workshop report was published in December 2016. Four background papers prepared and discussed at the workshop were published in Q1 of 2017.

A second workshop examining case studies was held in August 2017 in Ottawa, Canada. A workshop report and 6 documents will be published (case studies on phthalates, PFOA, mercury, formaldehyde and NMP, along with horizontal learnings).

Also, the Joint Meeting supported the commencement of an activity to collaborate on the design of coordinated valuation studies. This would entail the conduct of one or several valuation studies (e.g. studies surveying the willingness to pay to avoid certain health impacts or environmental outcomes) with a focus first on for morbidity endpoints relevant to chemicals exposure in different OECD countries. The concept is to coordinate the development of the survey instrument, implement the survey using the consolidated instrument and analyse and compare the valuation results. Additional endpoints, including environmental endpoints, could then be considered. A project team for this initiative has been established and a scoping document was prepared and discussed to develop a more detailed plan for this project.

Recent publications - Series on Risk Management Series

This Series on Risk Management supports Member countries’ efforts to develop national policies and actions, and develop international risk management measures.

No. 32

No. 33

No. 34
Chemical risk assessment and translation to socio-economic assessments, OECD Environment Working Papers, No. 117.

No. 35
Retrospective evaluation of chemical regulations, OECD Environment Working Papers, No. 118.

No. 36
Possibilities and challenges in transfer and generalisation of monetary estimates for environmental and health benefits of regulating chemicals, OECD Environment Working Papers, No. 119.

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www.oecd.org/chemicalsafety/sacame.htm
III. Support for Capacity Development
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.

The Information Platform for Chemical Monitoring database (IPCheM) of the European Commission was added in July 2017 as a new data source found via the search by chemical substance functionality of eChemPortal.

A new version of eChemPortal containing modernised frameworks, security fixes, and a new search engine for substance search to ensure performance and scalability, was released on 20 February 2017, and a patch version containing small fixes and an upgrade of the Oracle database was released on 2 April 2017. The Steering Group for the Development of a Global Portal to Information on Chemical Substances tested new search engines for the chemical property and classification searches of eChemPortal, planned for release in Q4 2017.

In July 2017, the OECD Working Party on Hazard Assessment endorsed development priorities, which had been agreed by the Steering Group in June for 2017-2018. Development priorities include: to continue to ensure alignment of the eChemPortal catalogue with the revisions to the OECD Harmonised Templates and GHS, to implement improvements to user navigation and analysis for potential modernisation of the user interface.

Forthcoming Event

25-26 April 2018,
OECD, Paris,
Meeting of the Steering Group for the Development of the Global Portal

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www.oecd.org/ehs/eChemPortal
Dissemination of OECD Products

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

Inter-Organisation 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 OECD continues to promote the IOMC Toolbox, with the aim of dissemination and receiving feedback on the tool.
Recent events include:
- a presentation at the meeting of the Executive Programme on Integrated Chemical Management, Shanghai, China, 29 August - 1 September 2017.

Specifications for new functionalities were developed for improving the Toolbox. The new development includes the addition of a “favourite tool” functionality and integration of user comments in the output report, as well as improvement of administration functionalities. These improvements were published in Q2 of 2017.

IOMC promotional video

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http://iomctoolbox.oecd.org
A network of experts on industrial chemicals for capacity-building was established earlier this year and, further to a request from Peru, a series of webinars was organised to help this country establish their industrial chemicals management system.

The first webinar’s objective was the identification of Peru’s needs. A second webinar was organised on the role of inventories in chemicals management and a third one was held in October on the implementation of the Global Harmonised System of Classification and Labelling (GHS).

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IV. Facilitation of Risk Reduction
Tools & 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.

An updated version of the OECD Substitution and Alternatives Assessment Toolbox (SAAToolbox) is now available. This new version includes the following improvements:

- The inventory of non-hazard assessment tools has been further developed by including brief summaries of each tool, and presenting the tools in a searchable/sortable table;
- The case study section in the toolbox has been improved to summarise and present examples of alternatives assessments in a uniform way, with the goal of facilitating the analysis of lessons learned and searchability. Also, a methodology page has been added to the section to describe the criteria for adding case studies.

The SAAToolbox is also being improved by separating data sources from tools in the Tool Selector section of the toolbox. This update is expected to be released in Q4 2017.

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals is also now working on the development of a cross-country analysis to collect experiences amongst countries on policy, regulatory and other approaches used to support alternatives assessment and the substitution of chemicals of concern.

Forthcoming Event


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www.oecd.org/chemicalsafety/risk-management/
www.oecdsaatoolbox.org/
2. Risk Reduction

The Risk Reduction 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 member countries and facilitates information exchange about successful risk management approaches.

Perfluorinated Chemicals (PFCs)

The OECD/UNEP Global Perfluorinated Chemicals Group was established in 2012 to facilitate the exchange of information on PFASs (Per and Poly-Fluoro Alkyl Substances) and to support a global transition towards safer alternatives.

In July 2017, the Group released a new version of its Web Portal. This Portal serves to facilitate the exchange of information on per and poly-fluorinated chemicals, focusing specifically on per- and polyfluoroalkyl substances (PFASs). In order to support a global transition towards safer alternatives, the Portal provides information on the following areas:

i. Introduction to PFASs;
ii. Risk reduction approaches across countries;
iii. Information on Alternatives;
iv. Production and emissions;
v. Information from countries;

The Group has also been engaging in a series of webinars with the goal of gathering and sharing information on the status of development and use of alternatives to PFASs worldwide. In 2017, webinars in the series have included the following topics:

- Activities under activities of the Basel, Rotterdam and Stockholm conventions towards PFAS risk reduction, and guidance on alternatives to PFOS and its related chemicals developed by the POPs Review Committee;
- PFAS Groupings for the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework (Australia).

The Group is also in the process of updating the OECD list of PFASs that was published in 2007 - Lists of Perfluorooctane sulfonate (PFOS), Perfluoroalkyl sulfonate (PFSAS), Perfluorooctanoic acid (PFOA), Perfluorocarboxylic Acid (PFCA), related Compounds and Chemicals that may degrade to PFCA. Publication of the new list is expected for the first quarter of 2018.

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www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/
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 Issue Team on Sustainable Chemistry published in April 2017 a report on the Economic Features of Chemical Leasing.

The report presents the range of economic implications the model entails. It also describes 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.

The Group is organising a workshop on the design of sustainable plastics from a chemicals perspective to be held in May 2018, in Copenhagen. The workshop will cover issues such as what does it mean to be “sustainable” from a chemicals perspective and how to evaluate claims of sustainability.

A new OECD webpage on Sustainable Chemistry was developed.

Recent publications - Series on Risk Management

This Series on Risk Management supports Member countries’ efforts to develop national policies and actions, and to develop international risk management measures.

No. 37
Economic Features of Chemical Leasing.

Forthcoming Event

29-31 May 2018, Copenhagen, Denmark, Workshop on design of sustainable plastics from a chemicals perspective.

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www.oecd.org/env/ehs/risk-management/
www.oecd.org/chemicalsafety/risk-management/sustainablechemistry.htm
V. Development of Instruments for the Assessment and Management of Pesticides and Biocides
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.

Pesticide Residue Chemistry Expert Group (RCEG)

The pesticide RCEG developed a Guidance Document for Residues in Rotational Crops, which is currently undergoing a second round of comments by both the WGP (Working Group on Pesticides) and WNT (Working Group of National Co-ordinators of the Test Guidelines Programme). If no major comments are received, it is expected that the Guidance Document will be published in the last quarter of 2017.

OECD Network on Illegal trade of Pesticides

In the area of the illegal international trade of pesticides, the OECD Network on Illegal trade of Pesticides (ONIP) continues to develop a Best Practice Guide (BPG) to address issues related to fighting illegal trade, and to strengthen a “Global Alliance” against illegal trade of pesticides. As part of this Alliance, work is ongoing to develop an OECD legal instrument which will call for, among other things, establishing or strengthening national procedures aimed at countering the illegal trade of agricultural pesticides in line with the BPG. The BPG and legal instruments should be adopted in late 2018 or early 2019.

Pesticides Effects on Insect Pollinators

On 28 June, 2017, the Seminar on Pollinator Safety was held at OECD headquarters. The objectives of this seminar were to:

- Identify available methodologies and approaches for risk assessment and risk management of chemicals with respect to bees/pollinators across OECD countries;
- Generate a common understanding of available tools for making assessments on a global basis in order to use regulatory agencies’ resources more effectively; and
- Recommend ways to strengthen and streamline processes of internationally-agreed risk assessment and risk management procedures.

Participants made a number of recommendations concerning research on pollinator risk, risk assessment and risk management. At the 29 to 30 June, 2017 meeting of the WGP, members supported the recommendations and agreed to form a small group to further elaborate these recommendations and define how they could be included in possible future WGP activities on pollinator safety. The output of the small group would be considered at the 2018 WGP meeting.

Work is continuing within the Pesticides Programme and the Test Guidelines Programme on test methods for the homing flight test on honeybees after single exposure to sub-lethal doses.
The Expert Group on the Electronic Exchange of Pesticide Data

The Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD) continues its activities regarding the Global Harmonised Submission Transport Standard (GHSTS). The GHSTS specifies how to assemble electronic files required in the evaluation of submissions for any pesticide package. The Expert Group is currently focusing on maintaining the standard (i.e., consider modification requests received), supporting tools to assist implementation of the GHSTS, and developing documentation to promote the use of the GHSTS. Canada developed a “Minimally Viable Product” of a GHSTS “e-dossier” builder (v.1.1), which can create GHSTS XML. BIAC released a new version of the GHSTS Desktop Viewer, “eSubmission viewer” 02.00.01. A GHSTS Benefits document addressed to different audiences has been declassified and is being formatted for publication along with a GHSTS Brochure.

Expert Group on Bio-Pesticides

As regards the work of the Expert Group on Bio-Pesticides (EGBP) - previously called the Biopesticides Steering Group (BPSG) - the following documents are currently under review by the WGP and their publication is expected before the end of the year:

- Guidance Document on the Assessment of Equivalence for Microbials;
- Guidance Document on Semiochemical Active Substances Used in Plant Protection Products;
- Working Document on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents

The Report of the 8th EGBP Seminar on “Niche Uses of Highly Specific Biocontrol Agents” is currently under review by the EGBP.

In addition, two other documents were published earlier in the year: the Report of the 7th Bio-pesticides Steering Group Seminar on Sensitisation Potential of Micro-Organisms (16 March), and the Guidance Document on Botanical Active Substances Used in Plant Protection Products (5 April).

Ad Hoc Expert Group on RNAi-based Pesticides

The Ad Hoc Expert Group on RNAi-based Pesticides is developing a working paper which will document the current state of knowledge of and regulatory considerations by agencies in OECD member countries related to the effects on non-target organisms from exposure to RNAi-based pesticides, including environmental fate of these pesticides. These pesticides cause post-transcriptional gene silencing through an RNA interference (RNAi) mechanism. For this project, RNAi-based pesticides will not include plants genetically engineered to target pest species by an RNA interference mechanism, while still recognising that data available on these GM plants may be useful in evaluating other types of RNAi-based products. The working paper is expected to be published in 2018.

Other

Work is underway to develop an updated version of the Table of Contents/Crosswalk in the OECD Dossier Guidance document, which was last updated in 2005. An updated crosswalk between those data elements that currently exist in the OECD Dossier Guidance and existing data requirements in governments is being being developed.

A Report of the “OECD Survey on Pesticide Regulatory Data Requirements Regarding Product Chemistry of Active Ingredients and End-Use Formulations” was published on 17 May, 2017. Product chemistry data are key information elements that are reviewed by governments during the process of registering pesticides. The aim of the survey was to identify the commonality and differences in core product chemistry data requirements across OECD governments, and to consider whether there is a need to address such differences through greater harmonisation.
Recent publications - Series on Pesticides

**Series on Pesticides**

The objective of the OECD Pesticide Programme is to help governments co-operate in assessing and reducing the risks of agricultural pesticides. The OECD encourages to share the work of pesticide registration and develops tools to monitor and minimise pesticide risk to health and environment.

- **No. 92**: Report of the OECD Survey on Pesticide Regulatory Data Requirements Regarding Product Chemistry of Active Ingredients and End-Use Formulations.
- **No. 91**: Report of the 7th Biopesticides Steering Group Seminar on Sensitisation Potential of Micro-Organisms.

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**Forthcoming Events**


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**Website**

2. Biocides

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

The Expert Group on Claims Development for biocides Treated Articles (EGCDTA) convened for a first teleconference in September 2017 to discuss its work plan. The EGCDTA has started to collect a common library of available legislation in OECD countries as well as of distinctive claims and has started with the development of possible principles of claims development.

A project to inventory available methodologies for a Sustainable Use of Biocides in OECD countries was initiated in May 2017. Best Practice Codes (BPCs) for certain biocidal uses considered to be particularly relevant were collected and differences and commonalities will be discussed during the upcoming 2017 WGB meeting.

The Expert Group on efficacy of microbicides on hard surfaces has, as its objective, to improve the procedures and performances of the four test methods described in the 2013 Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides Used on Hard Non-Porous Surfaces so that they can be further adopted as OECD Test Guidelines. The group held on-line meetings in March and October 2016 to discuss the revision of two of the four methods, i.e. the bacteria and mycobacteria methods.

The Expert Group on Biocides Chemistry (EGBC) is working on the development of two documents:

i. Guidance for flammability testing; and
ii. Document on waiving and bridging of physical chemistry studies.

Forthcoming Event

31-1 June 2018, Dublin, Ireland
Meeting of the Working Group on Biocides.

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VI. Development of instruments to assist countries in dealing with releases of hazardous chemicals from installations and products
1. 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 Working Group will be releasing in the first quarter of 2018 a Guidance on Ownership Change in Hazardous Facilities. This guidance will give a framework by which the main parties involved in a change of ownership can openly acknowledge and discuss the potential for major accidents on the site and, for example, to help the prospective new owners to understand the risks and take them into account when deciding whether or not to take over the facility.

The guidance will provide:

- A list of both the direct and underlying risk drivers associated with a change of ownership in hazardous facilities;
- A set of self-assessment questions for both the current and prospective new owners to help evaluate how well their organisation is managing the ownership change. A traffic light system is suggested to give an overview of the self-assessment;
- A list of factors for the regulators to consider before, during and after the change of ownership is also provided;
- A template for transparency is offered as the basis of a structured approach to carrying out technical due diligence. It is a list of documents and information which those selling a facility should be expected to provide.

The WGCA has other numerous projects under way:

- A guidance on the Benefits of Regulations for Chemical Accidents Prevention, Preparedness and Response, the aim of which will be to provide a framework with a list of possible quantitative and qualitative benefits with a common-language for communicating with policy makers not only on the quantitative benefits of proposed regulations, but also on the non-quantifiable benefits which are often not enough considered. Publication of the guidance is planned for late 2019;
- A project on Natural Hazard Triggered Technological Accidents (Natech) aiming to compile good practices for Natech risk management across countries. Amongst other activities, the project will comprise a workshop on good practices for Natech Risk Management planned for 2018 as well as the development of a record of Natech risk management best practices examples across countries;
- A revision of the 2nd Edition of the Guiding Principles on Chemical Accidents Prevention, Preparedness and Response, which was published in 2003. Discussions are underway to ensure that the revised edition best meets current users’ needs, addresses present and emerging challenges faced in the field, as well as lessons learnt from major accidents over the past decade. The revised edition is planned for publication in 2020;
- A project on Inspection Approaches for Chemical Accidents, which will aim to gather good practices and challenges in establishing inspection systems for hazardous facilities across countries. This project is aimed to start in 2018.

The WGCA continued its efforts to strengthen the reporting of accidents into the eMars database through the joint EU-OECD-UNECE Accident Reporting and Analysis Scheme, to give easy access to reports and associated lessons learned analysis from past chemical accidents.
Recent publications- Series on Chemical Accidents

Series on Chemical Accidents

The OECD series on chemical accidents covers such topics as safety performance indicators, accident prevention, preparedness for accidents and response to accidents.

No. 29: Ageing of Hazardous Facilities.

Brochure on Chemical Accidents

The brochure has been prepared by the Inter-Agency Coordination Group for Industrial and Chemical Accidents.

The Inter-Agency Coordination Group is an informal forum that brings together international organisations and institutions working on prevention of, preparedness for and response to industrial and chemical accidents.

The Inter-Agency Coordination Group aims to:

- Strengthen international cooperation for improving the prevention of, preparedness for and response to chemical and industrial accidents;
- Improve the use of resources and avoid potential duplication of work across the agencies;
- Facilitate understanding and coordination of the programmes of each agency;
- Carry a common message to the international community on the importance of the prevention, preparedness and response to chemical accidents as being among the key elements associated with the sound management of chemicals.

Forthcoming Event

23-25 October 2018,
OECD Paris,
28th Meeting of the Working Group on Chemical Accidents.

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www.oecd.org/chemicalsafety/chemical-accidents/
2. 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 Working Group on Pollutant Release and Transfer Registers (WG-PRTRs) focuses on:

i. Improving PRTRs,
ii. Harmonising PRTRs across the world, and
iii. Enhancing the use of PRTR data.

To assist countries in improving their PRTRs, the WG-PRTRs is currently reviewing Part 2 (diffuse sources) of the guidance document on release estimation techniques (Resource Compendium of PRTR Release Estimation Techniques) and it is expected to be finalised in 2017.

The WG-PRTRs is also conducting several projects to promote the use of PRTR data. As a follow-up to the publication in February 2017 on the role of PRTR data as a practical means to assess progress in global sustainability, the WG-PRTRs is currently working on a project using PRTR data for tracking progress towards the UN Sustainable Development Goals (SDGs) and presented its progress at the Meeting of the Parties to the UNECE Aarhus Convention and its Protocol on PRTRs in September 2017.

The WG-PRTRs is also collecting information and sharing good practice on PRTR data application for local environmental management. This project is expected to be finalised in 2017 or early 2018.

Forthcoming Event

Date to be confirmed
OECD Paris,
Meeting of the Working Group on PRTRs

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www.oecd.org/chemicalsafety/pollutant-release-transfer-register/
VII. Development of instruments in the Harmonisation of Regulatory Oversight of the Safety of Products of Modern 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.

The Consensus Document on the Biology of Atlantic salmon (Salmo salar) was published in May 2017. It is the first biosafety document in the Series on Harmonisation in Regulatory Oversight in Biotechnology to specifically address an animal species, in this case a commonly cultured, domesticated fish that is reared for food production but which also occurs in the wild in undomesticated populations. The document describes the biology and ecology of wild Atlantic salmon in addition to that of the domesticated form. Currently used production and rearing practices are also described at length because they may influence the ability of, and locations where, wild and domesticated forms of Atlantic salmon might interact in the environment. This information is intended to benefit potential risk assessors that may need to consider these potential interactions and their effects, and in assessing the risks that they might pose.

The experts in charge of preparing the document on “Environmental Considerations for Risk/Safety Assessment for the release of Transgenic Plants” held their 8th face-to-face meeting in Berlin in September 2017, at the invitation of Germany. Significant progress was made in the drafting of the seven sections that will constitute the document and a work plan was established up to the publication expected in 2019. Other developments include the preparation of several documents on the biology of crop species (e.g. Apple), and the revision of the draft document on mosquito Aedes aegypti, aiming for publication in 2018.

The OECD Product Database, containing information on genetically-engineered crops approved for being cultivated or used in foods and feeds, continued to be completed and updated. A total of 255 new entries are now available in the database to keep pace with new information provided by member countries as well as a number of non-members. Genome editing techniques have emerged as a major topic related to applications of biotechnology. The OECD Council has allocated funding to a project on Health and Environmental Safety in Genome Editing Applications.

The main event will be an OECD Conference to be held on the topic on 28-29 June 2018.
Collaboration continues with key non-member partners and other international organisations involved in biosafety, in particular on the occasion of the plenary meetings of the OECD Working Groups on:

i. The Harmonisation of Regulatory Oversight in Biotechnology, and


These events were attended by delegates from Brazil, India, Kenya, Lithuania, Philippines, Russian Federation, South Africa, Viet Nam, the African Biosafety Network of Expertise (AU-NEPAD), UNEP, FAO and the ILSI Research Foundation.

The Secretariat promoted the OECD Work on the safety of biotechnology products at the 14th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO) held in Mexico in June 2017, and at two events organised by the Asia-Pacific Economic Cooperation (APEC) in Viet Nam in August 2017: Workshop on ‘Agriculture Biotechnology: Driving from 1G to 5G’, and meeting of the High Level Policy Dialogue on Agriculture Biotechnology.
3. Food and Feed Safety

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 24th meeting of the Working Group for the Safety of Novel Foods and Feeds held in March 2017, activities continue to develop consensus documents on the composition of Apple (Malus domestica) expected for publication by the end of 2017, composition of Cowpea (Vigna unguiculata), and to revise the Maize (Zea mays) document initially issued in 2002.

Based on the responses to the survey on projects developed by the Working Group that were collated in December 2016, the Bureau will continue to explore suggestions for future projects and will establish priorities. Several new project proposals were agreed by the working Group in March 2017:

i. Revision of the ‘Instructions for Authors’ building on the experience of proximate calculation and analysis as reported in recent consensus composition documents;
ii. Discussions and events (workshop) on ‘omics’ techniques and massive parallel sequencing for comparative crop analysis;
iii. Development of a new composition document on Cucurbits species; and
iv. Revision of the existing document on Potato composition.

Recent publications - Series on the Safety of Novel Foods and Feeds

The OECD work on biosafety and food/feed safety assessment aims to assist countries evaluating the potential risks of transgenic products, ensure high safety standards, and foster mutual understanding of relevant regulations.

No. 28: Revised Consensus Document on Compositional Considerations for New Varieties of Rice (Oryza sativa): Key food and feed nutrients, anti-nutrients and other constituents.

Since the last Environment, Health and Safety News (No. 35, issued in March 2017), the EHS Division has seen the following changes in staffing:

- Marit HJORT has joined the Best Available Techniques team;
- Takaaki ITO has taken over the work on Exposure Assessment and PRTRs;
- Soojin JEONG has joined the Chemical Accidents team;
- Ye Lin JUN has joined the Biocides and Pesticides teams;
- Masashi HORIE joined the QSAR and Hazard Assessment team;
- Ryudai OSHIMA has joined the Biosafety team;
- Yoko TAKASU has joined the Biosafety team.
Most EHS Publications can be downloaded directly from OLIS or our website:

▶ www.oecd.org/ehs/publications

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

▶ Email: ehscont@oecd.org
▶ Fax: +33 (0)1 44 30 61 80
# EHS Websites

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

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

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