Chemical Safety and Biosafety Progress Report

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OECD
BETTER POLICIES FOR BETTER LIVES

Contents

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.

The following two case studies were published along with a considerations document highlighting the lessons learned stemming from the case studies.

- Case study on the Use of Integrated Approaches for Testing and Assessment for Testicular Toxicity of Ethylene Glycol Methyl Ether (EGME)-Related Chemicals [Japan]
- Case study on the Use of an Integrated Approach to Testing and Assessment for Estrogen Receptor Active Chemicals [US]

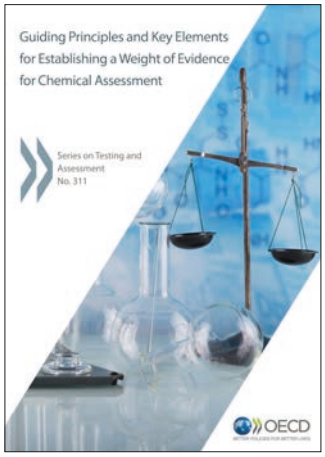
The following eight case studies are under review in the 5th review cycle in 2019:

- Case study on the use of New Approach Methods to inform a Theoretical Read-Across for Propylparaben using an Integrated Approach to Testing and Assessment exploring the Endocrine Activity of Parabens [BIAC – Cosmetics Europe]
- Case study on the use of Integrated Approaches for Testing and Assessment for Systemic Toxicity Arising from Cosmetic Exposure to Caffeine [BIAC – Cosmetics Europe]
- Case study on the Use of Integrated Approaches for Testing and Assessment for 90-Day Rat Oral Repeated-Dose Toxicity of Chlorobenzene-Related Chemicals [BIAC - Kao]
- Case study on the Use of Integrated Approaches for Testing and Assessment for Repeated-Dose Toxicity of p-Alkylphenols [BIAC - Kao]
- Prediction of a 90 day repeated dose toxicity study (OECD 408) for 2-Ethylbutyric acid using a read-across approach to other branched carboxylic acids [BIAC – EU-ToxRisk]
- Read-across based filling of developmental and reproductive toxicity data gap for methyl hexanoic acid [BIAC – EU-ToxRisk]
- Identification and characterization of parkinsonian hazard liability of deguelin by an AOP-based testing and read across approach [BIAC – EU-ToxRisk]
- Waiving of repeat-dose neurotoxicity study (TG 424) for azoxystrobin based on Read-Across to other strobilurins [BIAC – EU-ToxRisk]

The 5th meeting of the IATA Case Studies Project was held on 19-20 November to discuss the eight case studies and to summarise the considerations in the 5th review cycle.

The project team also discussed a draft Overview Document on Concepts and Available Guidance for Integrated Approaches to Testing and Assessment (IATA) and their Components in order to serve as an overarching reference document for IATA and give an overview of existing guidance on IATA, IATA components and relating cross-cutting topics. It is expected that the document will be finalised in Q1 of 2020.

Weight of evidence



The outcome of this project is a document that intends to provide universal Guiding Principles that should be considered when developing or augmenting systematic approaches to Weight of Evidence (WoE) for chemical evaluation and Key Elements to formulating a systematic approach to WoE. The ultimate goal is to facilitate that regulators follow a consistent, clear and transparent delivery of evidence using the Principles and Elements described in this document. This can be especially helpful for countries with no existing WoE frameworks or those looking to augment their approaches. It also allows for stakeholders to understand a WoE decision-making process, including the potential for unreasonable bias. These Guiding Principles and Key Elements can be employed to develop frameworks that range from simple and pragmatic approaches to more elaborate systems, depending on the context.

Read the Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment.

Physiologically Based Kinetic Models

The development of the guidance document on the characterisation, validation and reporting of physiologically based models for regulatory applications is advancing. This project is a joint initiative between the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics. It is expected that the document will be submitted to the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics for comments and approval in Q4 2019.

Priority Setting

The development of a document to capture international best practices for identification of priorities for risk assessment was initiated in January 2018. This project commenced with a survey of priority setting frameworks and tools used in countries. The document is undergoing review and declassification and is expected to be published by the end of 2019.

QSAR Toolbox

Version 4.3 of the QSAR Toolbox was released in February 2019 along with an updated website: qsartoolbox.org. New features of the QSAR Toolbox version 4.3 include:

- 2 New Databases (pKa OASIS and ADME database)
- 5 New Profilers (Acute Oral Toxicity, Blood brain barrier (beta), Oral absorption (beta), Skin permeability (beta), Uncouplers (MITOTOX))
- 2D parameters: 5 new methods for assessing pKa
- 159 new (Q)SAR models including pre-calculated online Danish QSAR DB models and new pKa models
- The Toolbox Application Program Interface (API) is now publicly available allowing for:
    - Enrichment of the Toolbox tools library with additional parameter calculators, profilers, (Q)SAR models and metabolism simulators
    - Use of the new (Q)SAR Editor – to create custom (Q)SAR models or to dynamically link to external online QSAR computational platforms
    - Connection between Effectopedia and the Toolbox via the new Effectopedia Wizard

A face-to-face meeting of the QSAR Toolbox management group was held on 21-22 November 2019 and discussed the next development period of the QSAR Toolbox.

Adverse Outcome Pathways Knowledge Base (AOP-KB)

The European Commission – DG Joint Research Centre (JRC), the US Environmental Protection Agency and the OECD Secretariat work together on the development of the AOP Knowledge Base (AOPKB) v2.0. The project will proceed in three phases: a) Requirements capturing, b) System specifications, and c) System development. The AOP Framework-related survey was launched by the European Commission's JRC in August 2019. Background information can be found here and the survey itself is available here. The results of the survey are expected to be available by the end of 2019.

Updated training materials, webinars and video tutorials are available on https://learning.aopkb.org/

Recent publications in the Series on Testing and Assessment

No. 311:
Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment (Glossy - MONO).

No. 309:
Case Study on the Use of an Integrated Approach to Testing and Assessment for Identifying Estrogen Receptor Active Chemicals, Annex 1.

No.308:
Case Study on the use of Integrated Approaches for Testing and Assessment for Testicular Toxicity of Ethylene Glycol Methyl Ether (EGME)-Related Chemicals.

No. 307:
Report on Considerations from Case Studies on Integrated Approaches for Testing and Assessment (IATA) - Fourth Review Cycle (2018).

Forthcoming events

19-20 November 2019,
OECD Boulogne,
6th Meeting of the IATA Case Studies Project

21-22 November 2019,
OECD Boulogne,
16th Meeting of the QSAR Toolbox Management Group Meeting

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www.oecd.org/env/ehs/risk-assessment/hazard-assessment.htm

www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm

http://aopkb.org/

https://www.effectopedia.org/

2. 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) published an Emission Scenario Document (ESD) on the release of plastic additives during the use of end products in May 2019, as a complementing document to the "Emission Scenario Document on Plastic Additives".

In addition, the WPEA is currently developing eight Emission Scenario Documents (ESDs) or related documents:

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

Exposure to humans and the environment

The WPEA published two documents on children's health. The first document, *Considerations when Assessing Children's Exposure to Chemicals from Products*, guides risk assessors in determining the necessity of a separate assessment for children, and presents a decision tree to facilitate such decisions. The second document, *Estimating Mouthing Exposure in Children,* presents a comprehensive analysis of methods for estimating children's exposure to chemicals through direct object mouthing.

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. The project is managed in close collaboration with the EU's IPCheM project with the aim to integrate and disseminate the biomonitoring data through IPCheM.

Regarding dermal exposure, the WPEA in June 2019 discussed the results of a scoping survey and agreed to conduct case studies for certain parameters and exposure scenarios, e.g. retention factor and transfer coefficient for dermal exposure from consumer products, occupational parameters for the exposure from spraying.

The WPEA and WPHA agreed on a new project on biomonitoring and derivation of human biomonitoring guidance or limit values such as Derived No-Effect Levels (DNEL).

Recent publications in the Series on Testing and Assessment

No. 310:
Considerations when Assessing Children's Exposure to Chemicals from Products

No. 306:
Estimating Mouthing Exposure in Children – Compilation of Case Studies

Recent publications in the Series on Emission Scenario Documents

No. 38:
Complementing Document to the Emission Scenario Document on Plastic Additives: Plastic Additives during the Use of End Products

Forthcoming event

29-30 June 2020
OECD, Paris
4th Meeting of the Working Party on Exposure Assessment

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www.oecd.org/env/ehs/risk-assessment/exposureassessment.htm

3. Approaches for determining the 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.

One of the main drivers of the OECD work on nanosafety is the OECD Council Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials, which aims to align the safety testing and assessment of nanomaterials with measures for the safety testing and assessment of chemicals as described in existing OECD Council Acts on chemicals. At the same time, the programme seeks to develop guidance on possible approaches that can assist regulators in assessing the specificities of nanomaterials, such as the recently published Physical-Chemical Decision Framework to Inform Decisions for Risk Assessment and its accompanying Guiding Principles for Measurements and Reporting for Nanomaterials: Physical Chemical Parameters.

The Working Party on Manufactured Nanomaterials (hereafter WPMN) continues its work on Test Guidelines and Guidance Documents for their applicability to nanomaterials. In addition to the projects being developed under the Test Guidelines Programme, the nanosafety programme is exploring how to move forward on:
i) the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies;
ii) the determination of dissolution rates of nanomaterials in environmental media (dynamic method);
iii) develop supplementary guidance for the use of Test Guidelines 201, 202 and 203 when testing nanomaterials;
iv) an integrated *in vitro* approach for the intestinal fate of orally ingested nanomaterials;
v) toxicokinetics of manufactured nanomaterials; and
vi) a review on biopersistent/biodurable manufactured nanomaterials.

Regarding the work on the risk assessment and regulatory programmes, a revision of the 2012 document on "Important Issues on Risk Assessment of Manufactured Nanomaterials" is expected to be finalised and published in 2020.
Lastly, progress has been made with the project on "Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation", which is being led by Canada. A workshop was held on 11 September that gathered the expertise from the OECD Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST). This was also a good opportunity to exchange expertise with participants of the H2020 project PATROLs that was held on 12 September 2019.

As for the work on exposure measurement and mitigation, the WPMN is working on projects to assess exposure tools and models for three target receptors: workers, consumers and the environment. On the one hand a project seeks to assess the global readiness of regulatory and non-regulatory models for assessing occupational exposure to nanomaterials. As a first step, a library of existing tools and models was completed and the minimum criteria for global readiness and regulatory acceptance were established. The WPMN is collecting high-quality measurement data from occupational exposure scenarios to assess the sensitivity and performance of models in the library. On the other hand, a compilation of available tools/models was completed to address exposure to consumer and the environment. The WPMN is assessing the models and should finalise the draft report in 2020.

The WPMN continues the implementation of the project " Moving towards a 'Safer Innovation Approach' (SIA) for more sustainable NMs and nano-enabled products: Overview of existing risk assessment tools and frameworks, and their applicability in industrial settings". This project is led by France, the Netherlands and BIAC. The outcomes of this project are expected to further the knowledge and contribute anticipating regulatory challenges posed by innovations, in this case from nanomaterials and nano-enabled products. Progress was made on drafting terminology elements relating to this concept and its applications. A survey was launched in June 2019 to collate information on existing SIA tools and frameworks, as well as regulatory preparedness, and the responses are being examined with a view to prepare related inventories. A half-day workshop will be held with WPMN delegates on these issues in December 2019.

Finally, the WPMN will meet in December 2019 with a view to discuss its future programme of work and in particular how to draw lessons learned in view of assessing the safety of new emerging materials on the market.

Recent publications in the Series on the Safety of Manufactured Nanomaterials

No. 91:
Guiding Principles for Measurements and Reporting for Nanomaterials: Physical Chemical Parameters

No. 90:
Physical-Chemical Decision Framework to inform Decisions for Risk Assessment of Manufactured Nanomaterials

The OECD project on the Safety of Manufactured Nanomaterials is being implemented with the financial assistance of the European Union. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

Forthcoming events

16-18 December 2019
WPMN Roadmap Programme of Work (and Back-to-Back Meetings for the Projects)

16-19 June 2020
20th Meeting of the Working Party on Manufactured Nanomaterials,

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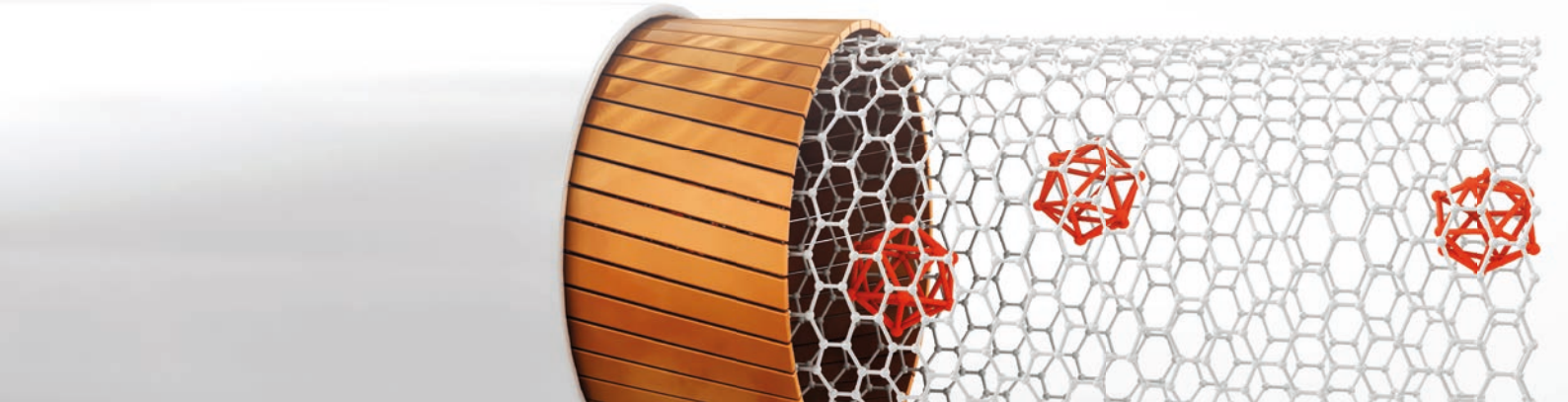
www.oecd.org/chemicalsafety/nanosafety/



4 • 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.

Harmonised Templates for Reporting Test Summaries

The work continued to adapt the OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) to new or revised Test Guidelines. Five OHTs on health effects (dealing with basic toxicokinetics, eye irritation, skin sensitisation, repeated-dose toxicity–oral, developmental toxicity/teratogenicity) and two OHTs on biotic system effects (on short-term toxicity to fish; and endocrine disrupter screening in aquatic verterbrates) are being updated for a publication expected in December 2019. A new template on in vitro phototoxicity is under development to cover two related Test Guidelines, and should be added to the OHT Series on health effects during the first quarter of 2020.

Led by the European Union, the project aiming to extend the current 'OHT 201 on Intermediate Effects' to cover the reporting of tests made according to OECD I*n vitro/In chemico* Test Guidelines continues to progress. This will orientate future updates of OHTs when dealing with reporting of non-apical observations from *in vitro* tests. A draft revised OHT 201 (including ontology updates) is under development, using Test Guidelines on skin sensitisation as a pilot case on what type of information should be captured and how to report it within the extended template.

In a joint effort by ECHA and the OECD, some technical and editorial improvements will be brought to several OHTs during the first half of 2020, in order to fulfil requests and suggestions from users and align the templates with the specificities of the next IUCLID version. In addition, also following suggestions from users considering improvements will be made to the OHT standard definition and the technical information made available on the public website in the coming months to take into account the use of GHSTS, OHTs and IUCLID to improve pesticide submissions,

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IUCLID

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 identify world-wide IUCLID user needs, particularly those identified by users in regulatory settings.

A service release of IUCLID 6 (v3.16.1) occurred in April 2019 and includes improvements to the web interface, a new guided dossier preparation for European Poison Centre Notifications. A major version release of IUCLID 6 (v4) occurred in October 2019.

Recent publications - IUCLID

The OECD released in February 2019 a document, Customisation Opportunities of IUCLID for the Management of Chemical Data, outlining the customisation opportunities for IUCLID 6 and giving an overview of what IUCLID offers to regulatory bodies and industry for the management of data on chemicals.

Forthcoming event

Q3 2020 (TBC)
OECD Paris,
Meeting of the UCLID User Group Export Panel.

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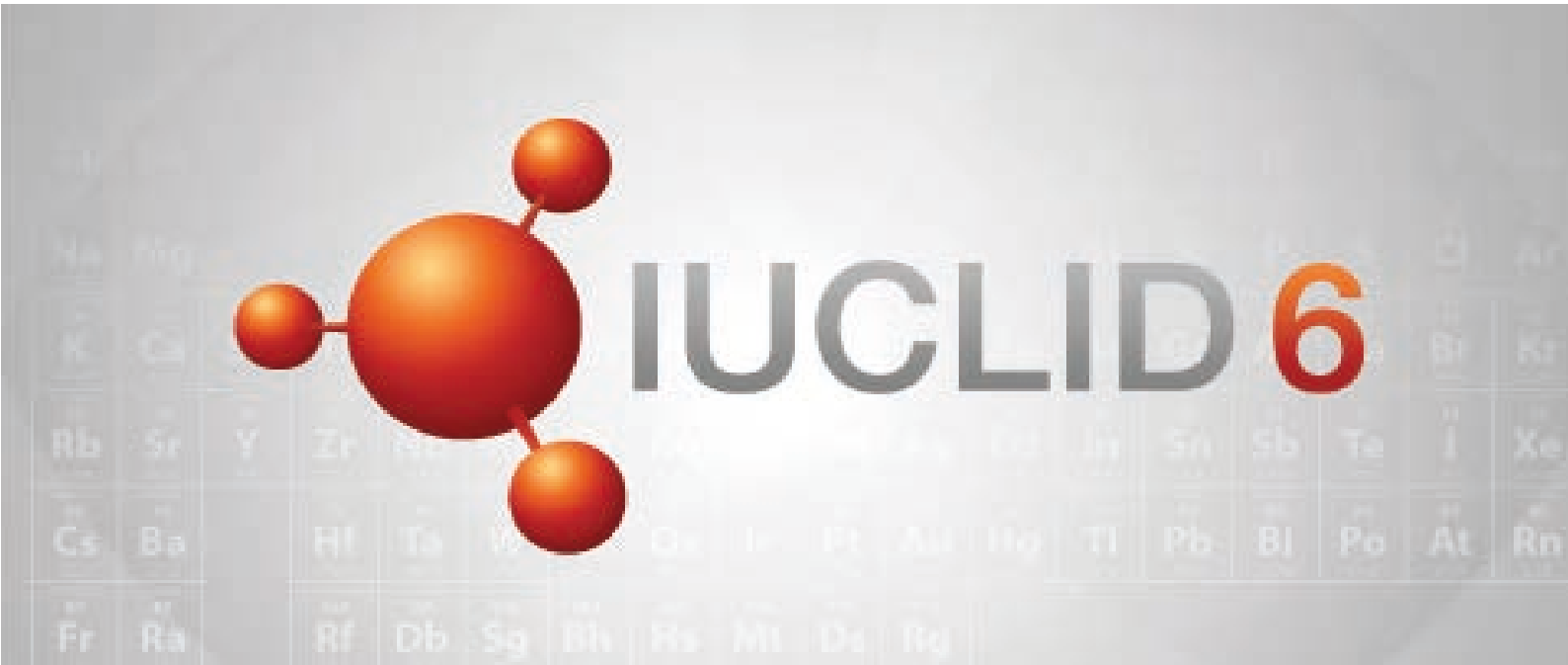


II. Assistance with Governance

1 • Test Guidelines

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

The year has been busy with a large number of expert and advisory group meetings and teleconferences, to advance projects in the area of endocrine disrupters testing methods, genotoxicity test methods, skin and eye irritation and phototoxicity test methods as well as skin sensitisation testing approaches. Several of the resulting draft documents will be submitted for approval at the upcoming meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) in April 2020.

The following new, updated and corrected Test Guidelines were published in June 2019:

New Test Guidelines:

Section 2: Effects on biotic systems

248: *Xenopus* Eleutheroembryo Thyroid Assay (XETA)

Section 4: Health Effects

495: Reactive Oxygen Species (ROS) Assay for phototoxicity

494: Vitrigel for Eye Irritancy Test

496 *In vitro* Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classific ation for Eye Irritation or Serious Eye Damage

Corrected Test Guidelines:

Section 4: Health Effects

456: H295R Steroidogenesis Assay

Updated Test Guidelines:

Section 2: Effectsonbioticsystems

203: Fish Acute Toxicity Test

Section 4: Health Effects

431: *In vitro* Skin Corrosion, Reconstructed Human Epidermis Test Methods

432: 3T3 Nru For Phototoxicity Testing

439: *In vitro* Skin Irritation, Reconstructed Human Epidermis Test Methods

442C: *In Chemico* Skin Sensitisation Assays Addressing The Adverse Outcome Pathway Key Event On Covalent Binding To Proteins

492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classifica tion and labelling

Another new Test Guideline was recently published, the *In vitro Macromolecular Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage*.

The 31st Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) also approved a document on Guiding Principles on Good Practices for the Availability/Distribution of Protected Elements in OECD Test Guidelines (No. 298 in the Series on Testing and Assessment). This Document provides best practice for better characterising protected elements integrated in OECD Test Guidelines, and for ensuring their sustainable and broad availability to the users.

The Test Guideline Programme work plan approved in April with new projects and updates on existing one was declassified in June.

Expert Group on Developmental Neurotoxicity (DNT), 5-6 March 2019

This project is led jointly by the EU (EFSA & JRC), Denmark and the United States. A face to face meeting took place in March 2019 and the Expert Group agreed on the scope and outline of the guidance and the assays that should be included, described/characterised in the guidance. At the meeting, a number of case studies were discussed and it was further agreed to establish a dedicated subgroup to work on the harmonisation of DNT assessment in zebrafish. The experimental work to support the guidance is expected to be concluded by Q4 2019 and a complete draft for WNT and WGP commenting/approval is anticipated for the end of 2020.

Workshop on ethical issues associated with the use of human-derived products and reagents in OECD TG, 18-19 March 2019, OECD

Discussions related to the ethical use of human-derived products and reagents in in vitro Test Guidelines (TGs) started in 2017 in the context of a proposal for the adaptation of several *in vitro* test methods on skin sensitisation to animal-free conditions, i.e. the use of human serum as an alternative to foetal calf serum, the traditional cell culture media. A workshop dedicated to these issues was held at OECD on 18-19 March 2019. The main recommendation from the workshop was to work towards the implementation of a traceability audit scheme in order to guarantee that human serum used in OECD Test Guidelines would not compete with the medical use. The workshop also recommended short-term actions such as the development of a checklist to make sure the serum used has been sourced in an ethical manner, the development of a donor informed consent model, and the identification of expired blood sources as a potential source of serum for *in vitro* assay.

Joint session of the Working Party on Hazard Assessment (WPHA), the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) and the Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST), 18 June 2019, OECD

This joint session was organised to discuss how the outputs of the OECD AOP programme can be better aligned to support regulatory needs of countries and how limited resources available for AOP reviews can be focused. The main conclusion of the session was that regulatory relevance should be an overarching consideration for AOP development and review, and good coordination between OECD groups is of great importance. Regulators noted that in order to increase regulatory uptake of AOPs, those that are selected for review need to be integrated with test methods and IATA under development in other on-going projects.

Meeting of the Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST), 19-21 June 2019, OECD

The EAGMST developed an implementation plan of the prioritisation approach recommended at the joint session. In particular, a consultation step of the WPHA and WNT will be introduced for new AOP project proposals submitted to EAGMST. This will help to assess regulatory relevance, raise awareness and encourage engagement. In addition, the subgroup structure of the EAGMST was enhanced, and the scope and roles of the subgroups more precisely defined in order to get new/more people involved and increase work sharing. Beside the AOP programme management, the EAGMST aims to have a role in exploring new areas of other science-based activities.

The EAGMST also received an update of the activities aiming at the development of reporting templates for 'omics-type of data. Draft formats are still under development and used in case studies to test the fitness of the current draft formats.

Second meeting of Expert Group for the development of a Detailed Review Paper on the miniaturised versions of the bacterial gene mutation test

The Expert Group discussed the outcome of the analysis of data collected in 2018 on five different versions of the miniaturised bacterial gene mutation test. The data analysis showed clear differences in the amount of data collected for these 5 assays. In order to improve the quality of the dataset and hence of the data analysis, a second and complementary call for data has been launched at the end of September 2019. Following refinement of the data analysis, it is expected that a first version of the draft DRP is circulated to the WNT for a first commenting round in Q3 2020.

Virtual meeting of the Expert Group on Dermal Absorption, 26 September 2019

The project to revise OECD Guidance Notes No. 156 on Dermal Absorption Studies, led by the European Food Safety Authority (EFSA) and the German BfR, was discussed among the Expert Group on a teleconference on 26 September. The leads presented recent revisions that take into account 15 years of experience with in vitro studies using human skin for pesticides risk assessment. A new commenting round was launched early October for 6 weeks; the revised draft will be made publicly available for review.

Virtual meeting of the Expert Groups on Skin and Eye Irritation and Phototoxicity testing, 24-25 October 2019

The Expert Group met via two consecutive webex sessions to get updates on the following projects: 1) updates of TG 437 on the BCOP using histopathology as an additional endpoint and using the LLBO device in place of OP-KIT, 2) progress with the list of curated reference in vivo data for eye irritation for their use in the development and predictive capacity determination of Defined Approaches for eye irritation, 3) phototoxicity testing using RhE skin tissue, 4) UN GHS working Group on Chapter 3.3 on eye irritation/serious eye damage, and 5) possible future project proposals.

Virtual meeting of the Validation Management Group for Non-Animal testing (VMG-NA), 7 November 2019

Test Guideline 458 for *in vitro* detection of chemicals that interact with the androgen receptor has undergone a revision to include a second "me-too" method validated in 2019 by EURL- ECVAM. The JRC has led the TG 458 revision and has circulated a draft for commenting. Korea has also independently validated a new *in vitro* androgen receptor transactivation assay in 2019 which has also undergone a commenting round. Because no new projects were proposed this year, the VMG-NA held a virtual meeting to discuss comments on these two drafts and provide updates on on-going activities in their respective countries. Following the meeting, the androgen receptor assays will be combined in the revised TG 458, sent for a second commenting round in Q4 2019, and approved by the WNT in 2020.

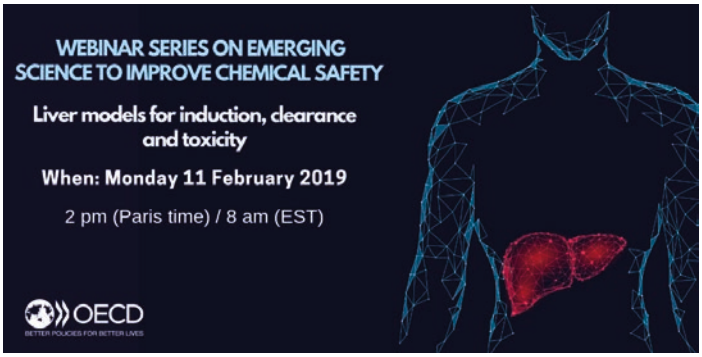
Meeting of the Expert Group on Retinoid Pathway Signalling, 12-14 November 2019, OECD Paris

A draft detailed review paper on chemical effects on retinoid pathway signalling was circulated for a commenting round Q3 2019. The document is intended to be a review of the biology of the retinoid pathway, and effects of retinoids on male reproduction, female reproduction, central nervous system, nad skeletal development. The document is also a preliminary scoping effort describing *in vitro* assays and *in vivo* endpoints that could be developed as new test guidelines or added to existing test guidelines to evaluate effects of chemicals that interfere with retinoid pathway signalling. An Expert Group met to discuss comments on the document and made recommendations for the next steps of the project. The recommendations will be included as a chapter in the DRP and circulated for an additional commenting round.

Virtual meetings of the Expert Group on Defined Approaches (DAs) for Skin Sensitisation, 17-18 November 2019

A revised draft Test Guideline and supporting document was circulated for commenting in Q3 2019. Several teleconferences are being organised to discuss the updated drafts and comments received. At this point, the Expert Group is anticipated to provide input for finalisation of the draft Guideline. Barring outstanding technical issues, the Guideline may be available for WNT approval in 2020.

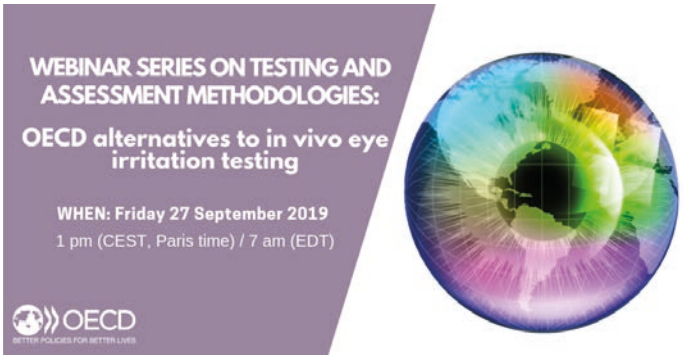
Webinar Series on Emerging Science to Improve Chemical Safety: liver models



On 11 March 2019, the OECD launched the webinar Series on Emerging Science that aims at providing some insights into new science offering future prospects for regulatory hazard assessment. The first event was on liver models (3D tissues, spheroids, microphysiological systems) and was attended by 200 participants.

https://oe.cd/science-webinars

Webinar Series on Emerging Science to Improve Chemical Safety: liver models



On 27 September 2019, the OECD held a webinar on OECD alternative eye irritation test methods and guidance on Integrated Approaches to Testing and Assessment ofr eye irritation. The webinar was also the occasion to share on-going projects aiming at closing gaps and addressing limitations of current in vitro and ex vivo methods.

https://oe.cd/testing-webinars

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. 305
Report of the Peer Review Panel on the Validation of the Amino acid Derivative Reactivity Assay (ADRA).

No. 304
Validation Study Report Of The Amino Acid Derivative Reactivity Assay (ADRA).

No. 303
Performance Standards for the assessment of proposed similar or modified in vitro skin sensitisation DPRA and ADRA test methods.

No. 302
Validation Report Of The Xenopus Eleutheroembryonic Thyroid Signaling Assay (Xeta) For The Detection Of Thyroid Active Substances.

No. 301
Report of the Validation Study and Report Of the Peer Review of the Validation of the Vitrigel Eye Irritancy Test Method in Test Guideline 494.

No. 300
Report Of The Validation Study Of The Mctt Human Corneal-Like Epithelium Eye Irritation Test Model And Report Of The Validation Peer-Review.

No. 299
Reports of the Peer Reviews of the Epics and Skin+ Test Methods in View of their Inclusion in Test Guideline 439 on in Vitro Skin Irritation.

No. 298
Guiding Principles on Good Practices for the Availability/Distribution of Protected Elements in OECD Test Guidelines.

Recent publications - Series on Adverse Outcome Pathways

Series on Adverse Outcome Pathways

An Adverse Outcome Pathway describes a lopical sequence of causally linked events at different levels of biological organisation; which follows exposure to a chemical and leads to an adverse effect in humans and or wildlife.

No. 16:
Adverse Outcome Pathway on Aryl hydrocarbon receptor activation leading to early life stage mortality, via reduced VEGF, Amani Farhat I 30 July 2019.

No. 15:
Adverse Outcome Pathway on Aryl hydrocarbon receptor activation leading to uroporphyria, Amani Farhat, et al I 20 July 2019.

No. 14:
Adverse Outcome Pathway on inhibition of Na+/I-symporter (NIS) leads to learning and memory impairment, Alexandra Rolaki, et al I 30 July 2019.

No. 13:
Adverse Outcome Pathway on inhibition of Thyroperoxidase and subsequent adverse neurodevelopmental outcomes in mammals, Kevin M. Crofton, et al I 30 July 2019.

No. 12:
Adverse Outcome Pathway on aryl hydrocarbon receptor activation leading to early life stage mortality via increased COX-2, Jon Doering, et al I 30 July 2019.

No. 11:
Adverse Outcome Pathway binding to the picrotoxin site of ionotropic GABA receptors leading to epileptic seizures in adult brain, Ping Gong and Edward J. Perkins I 30 July 2019.

No. 10:
Adverse Outcome Pathway on antagonist binding to PPARa leading to body-weight loss, Kurt A. Gust, et al I 30 July 2019.

Forthcoming events

12-14 November 2019
OECD Paris,
Meeting of the Expert Group on Retinoid Pathway Signalling

18-19 December 2019
OECD Boulogne,
Meeting of the Joint WNT-WPMN Expert Group on physical-chemical properties of nanomaterials

8-9 April 2020
Konstanz, Germany,
Meeting of the Expert Group on Developmental Neurotoxicity

9-12 April 2019
OECD Paris,
Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT)

27-28 April 2020
OECD Paris,
Meeting of the Endocrine Disrupters Testing and Assessment Advisory Group

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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.

On-site evaluations

Under OECD's on-site evaluation activity, each GLP Compliance Monitoring Programme (CMP) in OECD and full adherent countries is evaluated every ten years. (The current ten-year phase began on 1 January 2018 and will conclude on 31 December, 2027.) 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 five on-site evaluations conducted in 2018 – Czech Republic, Germany, Japan (Medical Products), Japan (Workplace Chemicals) and a follow-up visit to Thailand. Reports from the last four were considered at the 33rd meeting of the Working Group on GLP (6-7 March 2019).

The following on-site evaluations were completed in 2019: France (Medical products) (11-15 March); Brazil (1-5 July); United States (Medical Products) (5-9 August); Denmark (Chemicals and Pesticides, Medical Products) (4-15 November), Singapore (17-22 November) and Turkey (4-8 November). Six on-site evaluation visits are scheduled for 2020: Korea, Norway, United States (Industrial Chemicals and Pesticides), India, France (industrial Chemicals and Pesticides) and Colombia.

Guidance Documents

An *Advisory Document on Data Integrity - Definition and Guidance for Industry* - is being developed by a drafting group under the leadership of the UK. The guidance aims to promote a risk-based approach to data management which includes data risk, criticality and lifecycle. The guidance primarily addresses data integrity and not data quality since the controls required for integrity do not guarantee the quality of the data generated. At the 33rd meeting, the Working Group reviewed the latest draft and agreed that members be given more time to submit additional comments, in writing, to the drafting group. The drafting group will revise the document that will then be submitted to the Working Group for a final review. Finally, the document will be revised and posted on the public website for comments.

At the 32nd meeting, the Working Group agreed to re-start the **Discussion Group on Harmonisation Issues** and consider possible next steps, as the main activities associated with the Discussion Group were nearly completed. (This group was developed to serve as a forum for industry involved in the organisation and conduct of GLP studies, to communicate and comment on concerns that impact on their business.) The Secretariat invited industry representatives to provide feedback on the output to date from the Discussion Group, and invited those representatives to identify other issues that could be considered by the 33rd Working Group meeting. All total, stakeholders raised 39 questions or issues. In addition, the French Society of Quality Assurance (SOFAQ) responded to a survey conducted by France ANSM and raised additional questions and issues. At the 33rd Working Group meeting, a drafting group was formed to prioritise the questions/issues raised by the OECD Industry Discussion Group as well as the SOFAQ and prepare draft responses which would be considered at the 34th meeting for the possible development of a new Frequently Asked Questions publication.

At the 32nd meeting of the Working Group, the Working Group agreed there would be value in developing a **Best Practice Guide (BPG) for conducting on-site evaluations** and discussing that report at the 33rd Working Group meeting. To support the development of the draft Guide, after the meeting the Secretariat submitted two questionnaires to members to collect relevant information. Based on the responses, at the 33rd meeting the Netherlands introduced suggestions for the elements that could be included in a BPG in addition to existing guidance. A steering group was formed to develop the BPG or other tools for imparting knowledge to individuals who may participate in on-site evaluation visits in the future. That is, whether it would be best to present this information in a BPG, on-line/e-training, in-person training, or a combination of these approaches.

The **14th OECD GLP training course** will be held in Cape Town, South Africa from 7-10 October, 2019. A steering group organising the training course met on 5 March before the 33rd meeting of the Working Group and agreed the scope and plan for the training course, which was later agreed by the Working Group.

Recent publications - Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring

The OECD Principles of Good Laboratory Practice (GLP) ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations. The principles have been created in the context of harmonising testing procedures for the Mutual Acceptance of Data (MAD).

No. 20
Guidance for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies.

Forthcoming events

7-10 October 2019
Cape Town, South Africa
OECD GLP Training Course

6-7 March 2020
Sendai, Japan
4th Meeting of the Working Group on GLP

7-9 April 2021
OECD Paris
35th Meeting of the Working Group on GLP

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3. Mutual Acceptance of Data (MAD)

The 1981 OECD Council Decision on the Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines and Principles of Good Laboratory Practice (GLP). It requires OECD governments to accept non-clinical environment and health safety data developed for regulatory purposes in another country if these data were generated in accordance with the Test Guidelines and GLP Principles, thus increasing efficiency and effectiveness of chemical notification and (re-) registration procedures for governments and industry. A 1989 Council Decision-Recommendation on Compliance with GLP sets the framework for recognition of compliance assurance among governments. The MAD system has been open to non-OECD countries since 1997.

There are six partner countries 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 only applies to industrial chemicals, pesticides and biocides.

The Working Group on GLP implements on-site evaluation visits of national compliance monitoring programmes which are provisional adherents to MAD and are ready to be considered for full adherence. Currently, **Thailand** is a provisional adherent and an on-site evaluation team from Spain, Belgium and India visited the GLP Compliance Monitoring Programmes in Thailand in January, 2012. The report from the visit was considered at the 27th meeting of the Working Group on GLP (16-18 April, 2013). The Working Group meeting in April 2015 agreed that a follow-up visit to Thailand could be conducted once the follow-up team - Belgium, India and the Netherlands – felt it was prudent to do so. A follow-up visit was held on 3-7 September, 2018. The evaluation was considered at the 33rd meeting of the Working Group. The Working Group concluded (and the Joint Meeting agreed) that the Thailand CMP programmes fully complied with the 1989 Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice. Based on a Joint Meeting recommendation, the OECD Council agreed to invite Thailand to become a Full Adherent to the Council Acts related to the Mutual Acceptance of Data (MAD) in the assessment of chemicals and to participate as an Associate to the Working Group on GLP, the Working Group of the National Coordinators of the Test Guidelines Programme and to those parts of the Joint Meeting directly related to MAD. Full adherence will begin following a formal exchange of letters between OECD and Thailand.

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

Contact

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4. Evaluation and updating of legal instruments ("acquis") 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.

Intellectual Property rights related to chemical safety data

The 58th Joint Meeting in November 2018 considered a scoping paper addressing issues associated with intellectual property rights and chemical safety data, which had been developed by an ad hoc group, consisting of government, NGO and industry representatives. The group was established following the 57th Joint Meeting's endorsement of an initiative to address issues concerning finding ways for governments to review industry-sponsored studies in an open and transparent fashion, while also protecting the intellectual property rights (IPR) of the companies that generated the data. To that end, the Joint Meeting supported work to develop an updated version of the Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals [C(83)96/FINAL]. The Joint Meeting also agreed to consider developing a separate Best Practice Guide that could accompany an updated Act, in parallel with, or subsequent to, updating the Act. At the 59th Joint Meeting (June, 2019), members discussed a paper prepared by the ad hoc group that described possible elements that could be included in a draft Council Act. The ad hoc group will revise the draft to reflect the comments raised, as well as any additional text that that is currently under consideration by the group, and the revised draft be discussed at the next Joint Meeting in 2020.

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5. 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).

Design of coordinated valuation studies

The Joint Meeting and the Environmental Policy Committee's Working Party on Integrating Economic and Environmental Policies are collaborating on the design of coordinated valuation studies. This will 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 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 workshop was held in September 2019 to discuss initial draft survey instruments of a first set of 5 endpoints

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III. Support for Capacity Building

1 • eChemPortal

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

eChemPortal - The Global Portal to Information on Chemical Substances is a web portal that provides free public access to information on properties of chemicals.

Version 2.2 was released in July 2019 including fixes and an improvement to allow more automatic submission of data from IUCLID to eChemPortal. eChemPortal v3.0 is planned for release in early 2020 with an updated user interface technology and design.

Fothcoming event

21-22 April 2020
OECD, Paris
Meeting of the Steering Group for the Development of the Global Portal

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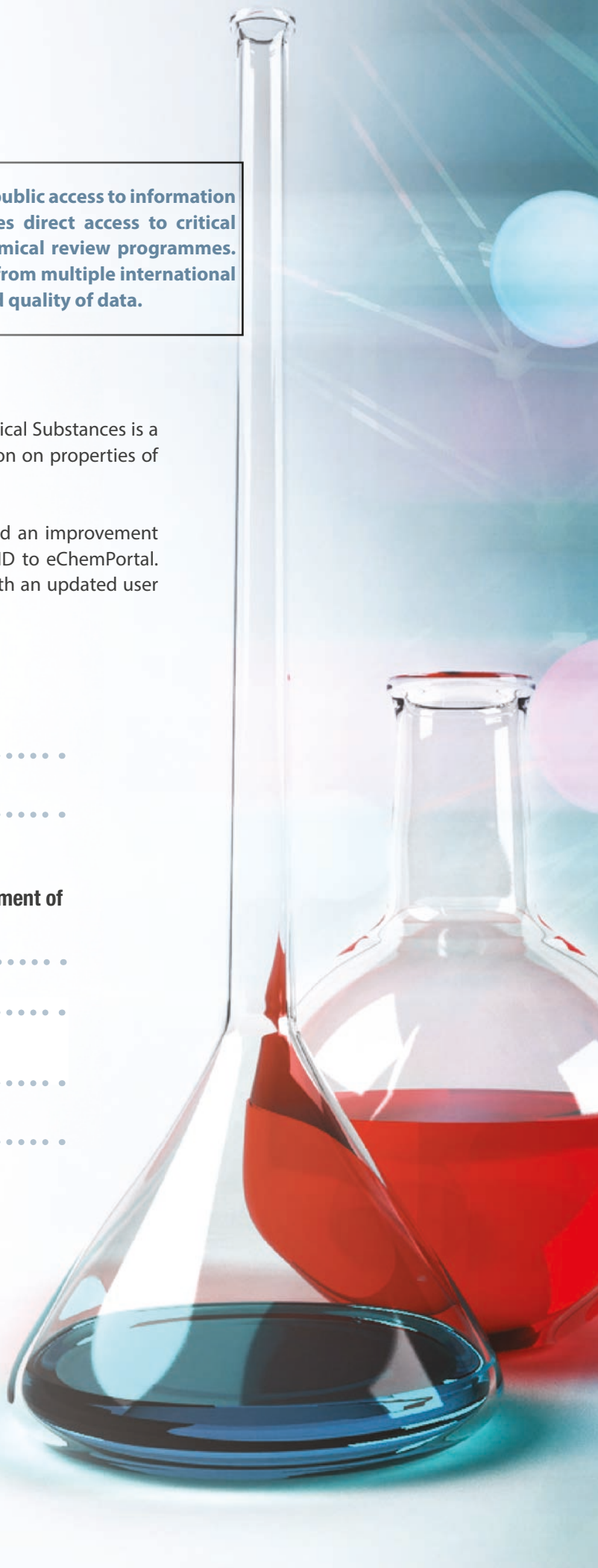
www.oecd.org/ehs/eChemPortal



2 • 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.

Capacity-Building for the Sound Management of Chemicals

The IOMC Toolbox for Decision-Making in Chemicals Management 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. It is managed by the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The OECD continues to promote the IOMC Toolbox, with the aim of dissemination and receiving feedback on the tool. Recent events include:

- *Regional training workshop*: 30-31 May 2019 – Peru – Web demo from OECD on the Industrial chemicals management scheme in the new IOMC Toolbox
- 1st Webinar for Indonesia on PRTRs - What is a PRTR? Benefits of a PRTR - 21 May 2019
- 2nd Webinar for Indonesia on PRTRs – PRTR Initiation and PRTR Operation – 25 June 2019
- 3rd Webinar for Indonesia on PRTRs – Demo of the PRTR scheme in the new IOMC Toolbox – 25 July 2019
- *National training workshop*: 17-18 July 2019 – Sri Lanka – Industrial Chemicals - Web session from OECD on Waste management
- *National training workshop*: 7-8 August – Indonesia – PRTR
- Webinar for Executive Programme On Integrated Chemicals Management, Thailand, 3 September 2019 - Web demo from OECD on the Industrial chemicals management scheme in the new IOMC Toolbox
- Webinar on Chemical accidents for Sri Lanka – 11 September 2019

The IOMC Toolbox is being redesigned and will be more powerful and fast, the lay-out will be more modern and the content will be more easily accessible and searchable. The content will also be synthesized in order to remove unnecessary steps and allow the user to access the content in fewer clicks. The new platform will become live in Q1 2020.

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http://iomctoolbox.oecd.org
www.oecd.org/env/ehs/development-cooperation-sound-management-chemicals.htm

IV. Facilitation of Risk Reduction

1 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.

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals is working on two projects at the moment:

- A **collection of priorities for alternatives assessment and substitution across countries**. The activity aims to list the chemicals/groups of chemicals that have been identified as priorities for substitution and alternatives assessment in countries/regions, as well as provide some context on the identification and timelines, if they have been set. Information collected through this project will be made available on the OECD SAAToolbox by the end of 2019.
- The development of a **Guidance on Key Considerations for the Identification of Safer Alternatives**. The guidance aims to provide key points to consider for the identification of safer chemicals, also reflecting on particular risk trade-offs during the decision making process. The guidance would principally focus on the identification of "safer" chemicals but would also touch upon life cycle aspects. Publication of the guidance is planned for the last quarter of 2020.

Fothcoming event

28-29 April 2020
OECD, Paris
OECD Ad Hoc Group on Substitution of Harmful Chemicals Workshop

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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 Perfl u orinated 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.

New information on risk reduction initiatives is now available in the Country Information section in the PFASs WebPortal.

Work is underway to develop a report regarding "Expanding the Current PFAS Terminology". The ultimate goal of this project is to provide guidance to all stakeholders with regard to the terminology of various PFASs so that they may communicate around PFASs using the same or a similar language. The report is anticipated to published in Q1/Q2 of 2020.

The Group regularly organises webinars to share information on PFASs and risk management. The most recent webinars were on:

- Finding Alternatives to Per- and Polyfluoroalkyl Substances of Concern: A Difficult and Continuing Challenge, a presentation by W.L. Gore & Associates, Inc.
- Best Environmental Practices for Class B Firefighting Foams;
- Toward greener water and oil repellents in the textile industry;
- Best Environmental Practices for Textiles.

The recording and presentations of all webinars can be accessed from the OECD PFASs webportal at: oe.cd/pfas-videos.

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oe.cd/pfass

3. Sustainable Chemistry

The OECD Issue Team on Sustainable Chemistry was established in 1999 to address issues, in particular policy issues, linked to the development of sustainable chemistry.

Global Forum on the Environment: Plastics in a circular economy - Design of Sustainable Plastics from a Chemicals Perspective

Two projects are currently being developed linked to sustainable plastics and sustainable chemistry more generally:

- A project on sustainability criteria for plastic design: focusing on particular plastic product sectors, the project will identify the key criteria that should be considered at each step in the product life cycle. Also the potential trade-off between criteria should be identified;
- Case studies on aligning chemicals and waste legislation: the work will focus on identifying the key misalignment issues through a set of case studies. The case studies will expand beyond plastics to other materials or scenarios to highlight real-life cases of misalignment.

Both projects are conducted in cooperation with the OECD Working Party on Resource Productivity and Waste.

Fothcoming event

3 February 2020
OECD, Paris
A workshop will be held to discuss issues and learnings from submitted case studies on aligning chemicals and waste legislation.

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www.oecdsaatoolbox.org/

V. Development of Instruments for the Assessment and Management of Pesticides and Biocides

1. Pesticides

The Pesticide Programme aims to harmonise the testing and assessment of agricultural pesticides and to promote work sharing and risk reduction. It achieves this by helping OECD countries to co-operate in the review of both chemical and biological pesticides used in agriculture.

Pesticide Residue Chemistry Expert Group (RCEG)

The pesticide **Residue Chemistry Expert Group (RCEG)** is currently working on an update of TG 509 (Crop Field Trials) and a revision of the 2009 Guidance Document on Definition of Residue. Furthermore, in June 2019, the RCEG initiated the development of a new Guidance Document on residues in honey.

OECD Network on Illegal trade of Pesticides

In the area of the illegal international trade of pesticides, OECD's Environment Health and Safety Division together with the UN Food and Agriculture Organisation (FAO), organised a well-attended side event on 10 May 2019 in Geneva, during the meetings of the Conferences of the Parties to the Basel, Rotterdam and Stockholm Conventions (BC COP-14, RC COP-9, SC COP-9). The goal of this event was to raise awareness of the issue of illegal trade in pesticides, OECD and FAO activities against such illegal trade as conducted by the **OECD Network on Illegal trade of Pesticides (ONIP)** and as part of outreach activities. ONIP continues to monitor and act against illegal trade in pesticides for instance by working to develop training for inspectors and to disseminate the recent OECD Recommendation of the Council on Countering the illegal trade of Pesticides and the accompanying Best Practice Guidance.

Expert Group on Bio-Pesticides (EGBP)

As regards the work of the **Expert Group on Bio-Pesticides (EGBP)** - previously called the Bio-pesticides Steering Group (BPSG) –the **Report of the 9th EGBP Seminar** on "Testing methods for micro-organisms" was published in March 2019. The expert group is also working on a scoping document on test methods for micro-organisms and a working paper on bacteriophages.

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The Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD)

The Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD) finalised and published version 2.0 of 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 maintains the Standard (i.e., considers modification requests) and plans to finalise GHSTS version 2 in the first half of 2019. This version will be an extension of version 1 to allow input for products other than plant protection products (e.g., feed additives) and will include improvements to lifecycle management of documents in submissions.

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 Q4 2019. A conference on "Regulation of Externally Applied dsRNA-based Products for Management of Pests" took place on 10-12 April 2019, in Paris and the proceedings are anticipated to be published in 2020. (A webpage devoted to the Conference which includes the Programme and Abstracts from the speakers can be found here.) The Conference not only provided an overview on the current status and future possibilities for the regulation of externally applied dsRNA-based products that are proposed for use as pesticides, but also input and recommendations for guidance(s) to be developed by the Working Group on Pesticides (WGP) and especially by the Ad Hoc Expert Group.

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. At the June, 2019 WGP meeting, a revised document was developed, by introducing new OECD data point numbers only for active ingredients based on the additional data requirements provided by countries. The updated table is currently under technical review and is expected to be completed by Q4 2019.

Recent publications - 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 to monitor and minimise pesticide risk to health and environment.

No. 100 Report of the 9th Biopesticides Expert Group Seminar on Test Methods for Micro-organisms.

No. 77: The Global Harmonised Submission Transport Standard (GHSTS) Format Specification - An XML-based Interchange Format for Registration Applications - Version 02.00.00.

Fothcoming events

TBD 2020
OECD Paris
OECD Network on Illegal Trade of Pesticides (ONIP)

13-14 May 2020
OECD Paris,
Expert Group on the Electronic Exchange of Pesticides Data

9 June 2020
OECD Paris,
Expert Group on Bio-Pesticides (EGBP) seminar

10 June 2020
OECD Paris,
Expert Group on Bio-Pesticides (EGBP)

11-12 June 2020
OECD Paris,
35th Meeting of the Working Group on Pesticides

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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) has drafted principles of claims development for articles treated with disinfectants, which were presented at the Working Group on Biocides (WGB) meeting in September 2019. The EGCDTA intends to further investigate the claim development of insecticidal or insect repellent treated articles.

The Expert Group on Biocides Chemistry (EGBC) is working on the development of two documents: 1) Guidance Document for flammability testing; this Guidance Document was submitted for a combined review to the Working Group of National Coordinators of the Test Guidelines Programme, the Working Group on Pesticides and the Working Group on Biocides and is expected to be published in by the end of 2019. 2) The Guidance Document on waiving and bridging of physical chemistry studies will be developed further.

Guidance Documents on the efficacy of insecticides against various pests such as bed bugs and tropical ants are currently under development. Application methods of the insecticides include baits and various contact insecticides. A new project to develop a guidance on determining the efficacy of pressurized aerosols for the control of flying and crawling insects kicked off in April 2019. A dedicated Expert Group discussed how to determine and optimise the efficacy of biocidal products targeting insects as vectors of disease and reviewed a draft guidance containing four different methods against mosquitoes, cockroaches and house flies.

On 25-26 September 2019 the 3rd meeting of the Working Group on Biocides took place in Seoul, Korea. Delegations informed each other about recent developments for WGB topics and discussed the progress for current projects such as those developing guidance for investigating the efficacy of insecticides, treated articles and disinfectants, the sustainable use of biocides and review sharing. The WGB also continued the discussion in developing its 2021-2024 programme of work.

Forthcoming event	Contacts	Website
September 2020 (TBD) OECD Paris 4th Meeting of the Working Group on Biocides	**Sylvie PORET** **Leon VAN DER WAL**	www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm

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 on Chemical Accidents published the French translation of its Guidance on Change of Ownership in Hazardous Facilities. This Guidance is a concise document providing a framework to assist stakeholders to identify, understand and minimise the risks during and after a change of ownership at a hazardous facility, and help make the change of ownership a better informed process.

Publications relating to Natech Risk Management will soon become available (early 2020). There will be a report from the joint OECD/UN Workshop on Natech Risk Management that was held in September 2018 in Potsdam, Germany, and a collection of good practice examples across countries on Natech Risk Management.

Forthcoming event	Contacts	Website
22-24 October 2019 OECD, Paris 29th Meeting of the Working Group on Chemical Accidents with a discussion on the changing risk landscape in hazardous facilities.	Peter KEARNS Marie-Ange BAUCHER	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.

Pollutant Release and Transfer Registers

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 and harmonising 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 Q4 2019. In addition, the WG-PRTRs is reviewing and updating the harmonised lists of pollutants and reporting sectors and the progress in this project was discussed at the third WG-PRTRs meeting in October 2019.

To promote the use of PRTR data, the WG-PRTRs is developing a draft Action Plan for tracking progress towards the UN Sustainable Development Goals (SDGs) using PRTR data. The Action Plan is in its final review process and expected to be finalised in Q4 2019, and the progress of this project based on the Action Plan will be discussed at the third WG-PRTRs meeting. In addition, the WG-PRTRs is revising the document, Uses of PRTR Data and Tools for their Presentation: A Reference Manual, to present good practices on PRTR data application for local environmental management. This revision is in its final review process and expected to be finalised in Q4 2019. Furthermore, the possible use of PRTR data to conduct an international analysis of PRTR data will be discussed at the third WG-PRTRs meeting.

Forthcoming event	Contact	Website
16-17 October 2020 Geneva, 3rd Meeting of the Working Group on PRTRs	Takaaki ITO	www.oecd.org/chemicalsafety/pollutant-release-transfer-register/

3. Best Available Techniques to prevent and control industrial pollution

The OECD project on Best Available Techniques (BAT) for preventing and controlling industrial pollution aims to exchange best practices across countries that already have BAT-based policies, and provide assistance to governments that seek to adopt BAT-based permitting. Furthermore, the project aims to achieve progress towards relevant Sustainable Development Goals, notably Target 12.4 on the environmentally sound management of chemicals and waste. The project is overseen by the OECD's Expert Group on BAT, which meets face to face once a year. The project started in 2016 and three reports have been published:

- *Policies on BAT or Similar Concepts Across the World* (2017), analysing how BAT is defined and embedded into national legislation in different countries;
- *Approaches to Establishing BAT Around the World* (2018), presenting procedures to establish BAT in various countries (i.e. collection of information on available techniques, involvement of relevant stakeholders in assessing environmental, economic and social aspects of the techniques, and identification of certain techniques as BAT); and
- *Measuring the Effectiveness of BAT Policies* (2019), analysing methodologies and data for the evaluation of the effectiveness of BAT-based policies in a range of countries and regions.

The new phase of the project (2019-2021) consists of the following three activities:

1. Developing a guidance document on how to determine BAT, derive associated environmental performance levels, including emission levels, and translate these into emission limit values and other permit conditions;
2. Conducting a study on value chain approaches to determining BAT for industrial installations;
3. Comparing BAT reference documents for selected industrial sectors across countries.

Draft documents pertaining to Activities 4 and 5 will be considered by the 4th Meeting of the Expert Group on BAT.

The OECD BAT project has been produced with the financial assistance of the European Union. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

Forthcoming event

October 2020 (TBC)
Brussels, Belgium
4th Meeting of the OECD Expert Group on BAT

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oe.cd/BAT

VII. Development of instruments in the Harmonisation of Regulatory Oversight of the Safety of Products of Modern Biotechnology

1. Environmental Safety

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.

Following the publication of the Consensus Document on the Biology of mosquito *Aedes aegypti* in June 2018, Efforts are underway to develop a similar document on *Anopheles gambiae*, the primary vector responsible for the transmission of malaria in sub-Saharan Africa. The document will describe taxonomy, morphology, reproductive biology, genetics, ecology and other aspects of the mosquito species, as well as control measures and human and animal health affected by mosquitoes. This information is intended to benefit potential risk assessors that may need to consider potential effects on environment when releasing engineered Anopheles gambiae in the context of mosquito control programmes.

The experts in charge of preparing the document on *Environmental Considerations for Risk/Safety Assessment for the release of Transgenic Plants* have accelerated their work since their 9th face-to-face meeting in Paris in June 2018, with the aim of finalising a revised full draft Consensus Document, composed of seven sections, to be submitted to the WG-HROB for consideration at its 33rd meeting in April 2019. The current work plan envisages its publication in 2019.

Other developments under the biosafety programme include the preparation of several documents on the biology of crop species (e.g. apple, safflower, revision of wheat, maize and rice documents). A kick-off meeting for the revision of the rice document took place in Japan in December 2018 to elaborate the operational plan for the project.

The OECD Product Database, containing information on genetically-engineered (G.E.) crops approved for being cultivated or used in foods and feeds, continued to be completed and updated. A total of 313 entries are now available in the system, keeping pace with new information provided by member countries as well as a number of non-members. 129 new entries or updates were reported by Colombia (under final check) and Paraguay between April 2019 and October 2019. Information on gypsophila flower G.E. varieties will be added to the database for the first time soon.

Genome editing techniques have emerged as a major topic related to biotechnology developments. The OECD Conference on Genome Editing: Applications in Agriculture - Implications for Health, Environment and Regulation, jointly organised by several OECD Directorates, was held in June 2018 to exchange information, identify challenges and discuss issues associated to this technology. The discussion focussed on regulatory approaches to the safe use of genome editing, as well as public acceptance of genome-edited products. The proceedings of the Conference were published in August 2019, available online at the Conference website together with the conference report, presentations and an article on policy considerations regarding genome editing.

Recent publications - Series on the Harmonisation of Regulatory Oversight in Biotechnology

The OECD series 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.

Proceedings of the OECD Conference "Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation", Transgenic Research, Volume 28, Issue 2 Supplement

Meeting report of the OECD conference "Genome Editing: Applications in Agriculture—Implications for Health, Environment and Regulation", Transgenic Research, Vol.28, Issue 3–4, pp 419–463

Policy Considerations Regarding Genome Editing, Trends in Biotechnology, Volume 37, Issue 10, October 2019, Pages 1029-1032.

'Biotechnology Update' / ICGB Newsletter No.35, June 2019, OECD Internal Co-ordination Group on Biotechnology

Forthcoming events

17-19 March 2020
OECD, Paris
34th meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

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www.oecd.org/biotrack

2. Safety of Novel Foods and Feeds

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

The new OECD consensus document on the composition of apple (*Malus x domestica*), finalised under the co-leadership of Germany and Canada, was published in July 2019. Activities continued to revise the consensus documents on Maize (*Zea mays*) and Potato (*Solanum tuberosum*) composition, both initially issued in 2002. The first project is led by the United States, while the Netherlands and South Africa are co-leading the second one.

The compendium of consensus documents entitled "Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 3" is being prepared. It will collate the documents on compositional considerations issued from 2016 and 2019, dealing with common bean, rice (revised), cowpea and apple. Its publication, expected by the end of year, will provide an additional means of dissemination and outreach of the outputs produced by the OECD Working Group for the Safety of Novel Foods and Feeds.

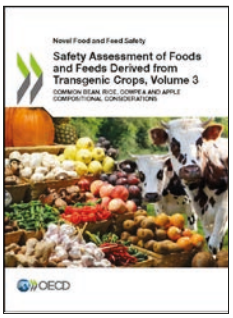
Some projects are contemplated for possible joint development with the Working Group on Harmonisation of Regulatory Oversight in Biotechnology. They include: 1) review the Council Recommendation concerning safety considerations for recombinant DNA organisms (1986), being transferred from Science, Technology and Innovation Directorate to the Environment Directorate, and needing and in-depth update; 2) better assess the quantifiable/non-quantifiable impact of the WG-HROB and WG-SNFF programmes and cost savings made through their implementation; and 3) consider how the concept of "safe-by-design" could be applied to biotechnology products.

Also dealing with novel food and feed issues, recent developments for 1) the OECD BioTrack Product Database and 2) the Proceedings of the *OECD Conference Genome Editing: Applications in Agriculture - Implications for Health, Environment and Regulation* with related documents and articles, can be found in the above section on Environmental Safety.

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.31: Consensus Document on Compositional Considerations for New Cultivars of Apple (*Malus* x *domestica* Borkh): Key Food and Feed nutrients, Anti-nutrients, Allergens, Toxicants and other Metabolites (2019)



Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 3 - Common bean, Rice, Cowpea and Apple Compositional Considerations

Forthcoming event

17-19 March 2020
OECD, Paris
27th Meeting of the Working Group for the Safety and Novel Foods and Feeds.

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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
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WEBSITES

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

EHS Homepage	www.oecd.org/chemicalsafety
Biocides	www.oecd.org/chemicalsafety/biocides.htm
Biosafety and Food/Feed Safety	www.oecd.org/chemicalsafety/biotrack/
Chemical Accidents	www.oecd.org/env/accidents
Exposure Assessment	www.oecd.org/env/exposure
Global Portal to Information on Chemical Substances	www.echemportal.org/echemportal
Good Laboratory Practice	www.oecd.org/env/glp
Harmonised Templates	www.oecd.org/ehs/templates/
Harmonisation of Classification of Labelling	www.oecd.org/env/classify
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New Chemicals	www.oecd.org/env/newchemicals
Pesticides	www.oecd.org/env/pesticides
Pollutant Release and Transfer Registers	www.oecd.org/env/prtr
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Strategic Approach to International Chemicals Management	www.oecd.org/env/saicm
Sustainable Chemistry	www.oecd.org/env/sustainablechemistry
Test Guidelines	www.oecd.org/env/testguidelines

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The Environment, Health and Safety Progress Report 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 report 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.

www.oecd.org/chemicalsafety