

Chemical Safety and Biosafety Progress Report



No. 45
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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.

OECD work on UN Globally Harmonised System of Classification and Labelling

The OECD work to determine if existing UN GHS hazard classes adequately identify endocrine disruptors for human health and the environment began in 2023. Following a request for nomination of experts to an ad hoc group in July, a kick-off meeting was held in September of 2023. The group will review first the well-studied estrogen, androgen, thyroid and steroidogenesis (EATS) endocrine pathways and then non-EATS pathways. Following the gap analysis, the group will review the state of the science of available methods to address the gaps.

Following the initial kick-off meeting, five additional teleconferences of the ad hoc group have been convened to discuss the details of the charge to the group and walk through examples of endocrine assessments conducted by different authorities. An update was presented by the OECD Secretariat at the 45th Session of the ECOSOO GHS Subcommittee meeting in December 2023.

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 (WPHA). The consideration document for the 8th review cycle was published in Q3 2023.

Four case studies have been reviewed by the IATA case study project members in the 9th review cycle in 2023:

- Case Study on the Use of Integrated Approaches for Testing and Assessment for Chronic Toxicity and Carcinogenicity of Agrochemicals: Saflufenacil
- Case Study on the Use of Integrated Approaches for Testing and Assessment for Chronic Toxicity and Carcinogenicity of Agrochemicals: Spiropidion
- Case Study on the use of Integrated Approaches for Testing and Assessment for "Eye hazard identification" of "surfactants"
- Case study on the use of Integrated Approach for Testing and Assessment for Bioaccumulation

QSAR Toolbox

The 20th meeting of the OECD QSAR Toolbox Management Group was held on 16-17 November 2023. The group expanded its scope to include general QSAR topics. At the meeting, in addition to the QSAR Toolbox development, the group discussed the possible next steps for the QSAR Assessment Framework (QAF) project (e.g. an update of Guidance Document No.69 on the Validation of (Quantitative) Structure-Activity Relationship [(Q)SAR] Models, especially an update of the QMRF template and additional clarifications on how to validate QSAR models).

Since the beginning of 2021, the QSAR Assessment Framework (QAF) project team has been discussing the development of a systematic and harmonised assessment framework for (Q)SAR model predictions. The QAF documents was published in Q3 2023 along with the webinar held in Q3 2023. The webinar recording is available on the [OECD website](#).

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 (AOP-KB) v2.0. The AOP-KB 2.0 project contains three strands of activities

1. Further development of the **AOP-XML format** that would reflect any AOP-Wiki major feature addition, including its promotion in the AOP stakeholder community.
2. **AOP-Wiki maintenance**, taking care of the hosting and smooth operation of the AOP-Wiki, as well as the addition of smaller, quick-win features that are prioritised and implemented in a yearly planning cycle. The 2.6 release of AOP-Wiki in April 2023 included an updated license for AOP-Wiki content, removal of author and SAAOP status fields, assigning a handbook version to all AOPs, adding coaches to the AOP page, adding the ability to search for Prototypical Stressor by PubChem ID, and updating the AOP display table. The electronic AOP handbook has also been updated to reflect the changes in the AOP-Wiki. An AOP-Wiki security report was made available to the Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) in December 2022. The next release of the AOP-Wiki is expected in March 2024.
3. **AOP-Wiki major feature addition**, exploring, together with the stakeholder community, the requirements for additional functionalities and their potential implementation that might lead to a new data model (Version 3.0). One workshop was organised in Canada in 2023. There are ongoing discussions on how to better capture stressors and test methods in the AOP-Wiki. A series of Society for Advancing AOPs (SAAOP) webinars and workshops (spring and summer 2023) were organised to collect user input and to inform the development of AOP-KB 3.0, planned for 2024 and beyond.

Biomarker and occupational exposure

The Working Party on Exposure Assessment (WPEA) and the WPHA are proceeding with two projects. The first is the AOP biomarker project, which is developing Guiding Principles for AOP applications with relevant effect-biomarkers to address combined exposures to chemicals, based on selected Case Studies and focused on specific MOAs/endpoints. The second meeting of an ad hoc expert group was held in June 2023 to discuss case studies.

The second is a project on setting occupational exposure limits (OELs). A workshop was held in October 2022, and the report was published in September 2023.

Omics activities

The draft Transcriptomic reporting framework (TRF) and the draft Metabolomics reporting framework (MRF) that are part of the OECD Omics Reporting Framework (OORF) were published in November 2023. The [webpage](#) dedicated to the OECD activities on omics provides additional information and the published versions of the templates and guidance to complete them. The development of the chemical grouping application module (CG-ARM) is progressing and a first draft is expected to be available in Q2 2024. The aim of the project is to provide guidance on how to report the use of molecular biomarker data - typically generated using 'omics approaches - for grouping chemicals based on mode of action similarity. Three new projects under the WPHA started in November 2023. Two of them will enrich the OORF by developing modules to capture the reporting of proteomics data and enrichment analysis of various omics data. The third aims to develop a guidance on best practices and standardisation of omics samples.

Recent publications in the Series on Testing and Assessment

No. 390: OECD Omics Reporting Framework (OORF): Guidance on reporting elements for the regulatory use of omics data from laboratory-based toxicology studies

No. 387: Occupational Exposure Limit (OEL) online workshop report

No. 386: (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure – Activity Relationship models, predictions, and results based on multiple predictions (Glossary)

No. 385: Report on Considerations from Case Studies on Integrated Approaches for Testing and Assessment (IATA)

Forthcoming events

24-26 June, 2024 (TBC)
**8th Meeting of the Working Party
 on Hazard Assessment,
 OECD Paris and Online**

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 assessment/](https://www.oecd.org/chemicalsafety/risk-assessment/)

[www.oecd.org/chemicalsafety/
 risk-assessment/iata-integrated-
 approaches-to-testing-and-
 assessment.htm](http://www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm)

www.qsartoolbox.org

<http://aopkb.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. The OECD assists 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. The 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 six Emission Scenario Documents (ESDs):

1. ESD for uses of fluorocarbon substitutes – Foam Manufacturing (the first draft is under preparation)
2. ESD for uses of fluorocarbon substitutes – Refrigeration (the first draft is under preparation)
3. ESD for uses of fluorocarbon substitutes – Mobile Air Conditioning (the first draft is under preparation)
4. ESD for chemicals used in hydraulic fracturing (the second draft was submitted for review in Q3 2023)
5. ESD on chemicals used in fabric finishing (the first draft was submitted for review in Q2/Q3 2023), and
6. ESD on 3D Printing (the first draft is under preparation)

Exposure to humans and the environment

A survey report on exposure assessment methodologies for children (led by the Netherlands) was published in April 2023. Two other projects on children's health are ongoing:

- The development of a "Children exposure factor database" (led by Korea), in which the data were collected through the WPEA and a draft database is currently under review.
- The development of case studies on crafts and toys by Canada with Denmark, Germany and the Netherlands, focusing on children's exposure to chemicals in such products. A first draft was submitted for review in Q2/Q3 2023.

Two activities on exposure models are on-going. The first is the compilation of exposure models. A survey was conducted in Q3 2021. Japan and the US have drafted a summary report, which was published in October 2023.

The second is the update of the OECD Pov and LRTP Screening Tool. A report with technical proposals for updating the Tool was prepared by an expert group and published in September 2023. The next phase, building software based on the proposal, is being led by Canada, Norway and Switzerland.

Regarding the joint project on occupational exposure between the WPEA and the Working Party on Hazard Assessment, the guidance document on occupational biomonitoring was published in December 2022. A workshop on approaches for establishing OELs was held in October 2022, and the workshop report was published in September 2023.

The revision of the OECD Harmonised Templates (OHTs 301-306) on use and exposure information is ongoing led by EU. The first draft was submitted for review in Q3 2023. Also, the revision of the OHTs regarding the data structure for reporting measured (monitoring) data led by EU has started and the scoping document was circulated in Q4 2023. The activity links to the OECD IUCLID User Group Expert Panel and the OHT Steering Group.

Recent publications

[No. 389](#): Report from the Survey of Exposure Assessment Models Used in a Regulatory Context

[No. 388](#): Review of the OECD POV and LRTP Screening Tool 15 years after its release

[No. 387](#): OECD OEL online workshop report

Forthcoming event

Contact

Website

**20-21 June 2024,
8th Meeting of the Working Party
on Exposure Assessment,
OECD Paris and Online**

Naoko MORITANI

www.oecd.org/chemicalsafety/risk-assessment/exposureassessment.htm

www.oecd.org/chemicalsafety/childrens-health.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, and more recently advanced materials. Its objective is to assist countries in their efforts to assess the safety implications of nanomaterials.

The OECD work on nanosafety is driven by 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 the safety testing and assessment of chemicals as described in existing [OECD Council Acts on chemicals](#). It is therefore part of its aims to develop guidance on possible approaches that can assist regulators in assessing the specificities of nanomaterials and other advanced materials. This programme is implemented by the Working Party on Manufactured Nanomaterials (hereafter WPMN).

Since the establishment of the WPMN, one of the focus areas has been to support the work on the development and update of Test Guidelines (TG) and Guidance Documents (GD) to ensure their applicability to nanomaterials. While the development of these standards is overseen by the Working Party of the National Coordinators to the Test Guidelines Programme (WNT), the WPMN has, and continues to play a crucial role in providing the expertise to their revision, identifying the specificities of nanomaterials and advanced materials, as well as the regulatory relevance of further standards development. In parallel, the WPMN develops complementary documents. For instance, the WPMN is currently updating the OECD Guidance on Sample Preparation and Dosimetry published in 2012. While it is recognised that some information sections are now addressed by recently published Test Guidelines and Guidance Documents for nanomaterials, there are several sections that deserve a revision to reflect the current scientific knowledge. An ad hoc group of experts was launched in 2023 and leads for the different sections have been appointed. A new structure and text for the revised document is now completed. It is expected that the first draft be presented at the WPMN in June 2024 with the aim to finalise it in 2025. Another project underway is the update of the section 6.9 on the Guidance on Grouping of Chemicals which is dedicated to nanomaterials. A draft has been completed by the WPMN. As a next step, the WPMN will continue working with the Working Party on Hazard Assessment (WPHA), leading the revision of the GD, to ensure alignment and harmonised terminology. An advanced draft, if not final, will be presented at the WPHA and WPMN in June 2024. Both reviews aim to integrate advances in science and new knowledge gained.

The WPMN finalised a scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in the environment while minimising the use of vertebrate tests. The scoping paper provides evidence-base options for seeking alternatives to using live fish. This document complements the project underway which seeks to develop guidance for assessing the bioaccumulation of nanomaterials in aquatic organisms. The document was recently declassified and will be made publicly available in January 2024.

Another area of work for the WPMN has been on the exposure of nanomaterials covering workers, consumers, and environmental exposure. Currently, the WPMN has three documents under development. The first one is a guidance document on release tests for manufactured nanomaterials. The aim will be to facilitate the choice of suitable release tests when addressing the safety of consumer products. Laboratory tests were performed to support the development of the project and results are being collected. The WPMN expects to review the first draft during Q4 2024. A second project is currently reviewing existing factors that can be measured to evaluate exposure to Nano-Objects and their Aggregates and Agglomerates (NOAA) in the workplace. A draft report has already been circulated and comments received are being integrated in a revised draft. A revised draft will be presented at the WPMN in June 2024. A second commenting round is expected to take place between June and September 2024 which should

help to finalise the draft for its approval in 2025. Finally, another guidance is under development to provide insight on the use of existing consumer exposure models/tools for manufactured nanomaterials and emerging advanced materials. This project is a follow-up of the Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials published in 2021. The project is expected to be completed in 2025 with the publication of a Guidance Document. In 2024, the work on exposure will also be linked to the work on advanced materials, with the topics of 3D printing and Graphene Based Materials being a connecting point. To this end, a literature review on graphene family materials is being developed to have a better understanding of the diversity of graphene and to decide on the focus of a case study.

In 2022, the WPMN completed a working description of advanced materials and in 2023 completed the [Early Awareness and Action System for AdMa \(Early4AdMa\)](#) and its associated [Early4AdMa Excel tool](#) which provides regulators with an anticipatory risk governance tool to allow for timely decision-making. This tool offers a step-wise approach (in two tiers and seven steps) allowing an overview of the material describing the context, potential issues on their safety and sustainability, and identify potential concerns, knowledge gaps as well as safety and sustainability aspects of the proposed applications of advanced materials at an early stage of innovation and to identify actions needed to overcome them (for example improve certain assessment methods, including Test Guidelines). A number of case studies on specific advanced materials (Graphene Oxide, Mxene (2D), 3D printing, Graphene Based Materials, and Nanocarriers) will be developed in 2024 and 2025 to further integrate safety and sustainability issues associated to a single material. Furthermore, the WPMN will be using these case studies to identify common issues to different AdMas and develop a strategy for the implementation of the actions identified by the Early4AdMa system.

Finally, as part of the work on the Safer and Sustainable Innovation Approach (SSIA), a review of existing tools and frameworks aiming to support Safe and Sustainable by Design (SSbD) implementation has been completed. The report is currently being reviewed and recommendations on the next steps will be discussed at the WPMN in June 2024. Finally, a template for a Confidential Agreement (CA) has been developed and will also be discussed at the next WPMN. The aim of this document is to enhance the establishment of Trusted Environments between SMEs, Start-ups, Industry and / or regulators at the very early stage of the design of materials. The work on advanced materials and SSIA are implemented in close collaboration to ensure convergence. At the same time, it is worth noticing that strong linkages have been established with different EU projects addressing complementary actions aiming at the implementation of SSbD. A recent example was the joint OECD-Harmless work on a case study on Fibre-aerogel-mats for façade insulation. Another joint effort is underway with the EU Project SUNSHINE to identify complementarities between Early4AdMa (targeting regulators) and SUNSHINE (targeting SMEs).

Finally, the annex of the OECD Council Recommendation on Nanomaterials is being amended to reflect the most recent version of the document Important Issues on Risk Assessment, which was made publicly available in 2023.

Recent publications in the Series on Nanomaterials

[No. 110](#): Scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in the environment whiles minimising the use of vertebrate tests.

[No. 109](#): Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials – Tour de Table (July 2022- June 2023)

[No. 108](#): Early Awareness and Action System for Advanced Materials (Early4AdMa): Pre-regulatory and anticipatory risk governance tool to Advanced Materials (Glossy - Mono)

[No. 107](#): Advanced Materials Assessment Schemes HARMLESS - OECD Working Party on Manufactured Nanomaterials (WPMN) Workshop Report



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

**March 2024,
Early warning and SSbD methods
for advanced materials. Joint EU-
SUNSHINE – WPMN Workshop,
OECD Paris**

**May 2024,
OECD WPMN Workshop on
Advanced Materials: MXenes
OECD Paris**

**25-26 June 2024
OECD WPMN Workshop on
Advanced Materials: 3D Printing-
OECD Paris**

**26-28 June 2024,
24th Meeting of the Working Party
on Manufactured Nanomaterials,
OECD Paris**

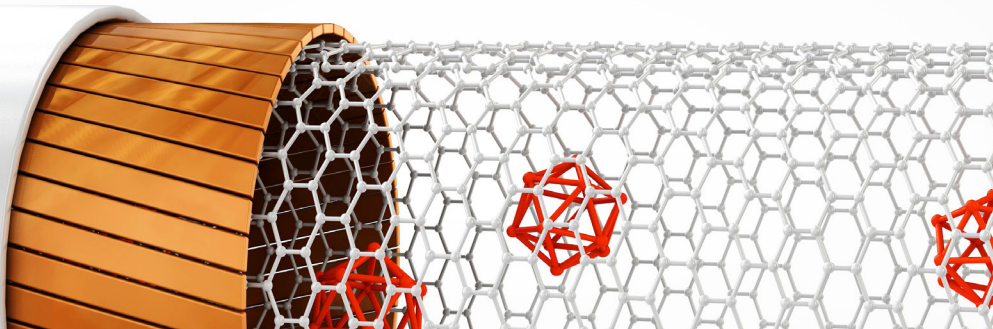
**October 2024,
OECD WPMN Workshop on
Advanced Materials: Graphene
Based Materials
OECD Paris**

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nanosafety/](http://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 continues to adapt the OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) to new or revised Test Guidelines. A total of eleven OHTs from different Series, revised for covering new/revised Test Guidelines issued in June 2022 and July 2023, are being reviewed by the OHTs Expert Group.

The European Union is leading a project to extend 'OHT 201 on Intermediate Effects' to cover the reporting of tests made according to OECD *In vitro/In chemico* Test Guidelines. This orientates the use of OHTs when dealing with reporting of non-apical observations (i.e., mechanistic information) from *in vitro* tests. Further developments are contemplated to extend OHT 201 to other *in vitro/in chemico* Test Guidelines on endocrine disruptors notably.

A new OHT 75-2 'Endocrine disrupter screening – *in vitro*' was published at the OHTs website in July 2023. In addition, three new templates on the toxicity to arthropods were published (OHTs 50-3, 50-4, and 50-5), and OHT 50-2 'toxicity to arthropods' was removed as it was split into the three new templates. Also, changes to all OHTs related to the IUCLID format update (May 2023) were implemented involving a major website update (130 templates). Finally, 105 harmonised endpoint study summaries templates resulting from an ECHA-led project were published and are now available for download at the OHTs website.

Some technical and editorial improvements will be brought to several OHTs during 2024, to fulfil requests and suggestions from users of IUCLID and align the templates with the specificities of the next IUCLID version. In line with this effort, a project led by EFSA and ECHA, proposed the extension of OHTs to improve the usability of QSAR-based data in Q4 2023. Annual updates to cover recently updated/new Test Guidelines will be carried out in 2024.

Activities to improve the use of OHTs for both biopesticide and pesticide submissions will continue, there is an ongoing plan by EFSA and Germany (BfR) to merge OHT 85-5 and OHT 85-9 from the Pesticides Residue Series. Furthermore, the Series on Use and Exposure Information (OHTs 301-306) will be updated under a project of the Working Party on Exposure Assessment.

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www.oecd.org/ehs/templates/

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.

IUCLID 6 version 7.10.1 was released in October 2023. This service release included new functionalities as well as fixes, including improvements to performance, management of data, reports, and the user interface. New versions of IUCLID Data Extractor and Text Analytics were released in December with fixes and improvements.

The OECD IUCLID User Group Expert Panel met in September 2023 and reported on the use of IUCLID including in Australia, the United States, the European Chemicals Agency, and the European Food Safety Agency, and provided feedback on the planned scope of IUCLID releases in 2023 and 2024. The Meeting also reported on progress of activities, prioritised in Q4 2022 and Q1 2023, to define future requirements regarding:

1. User interface improvement
2. Reporting (the extraction of IUCLID data to report in formats such as PDF, RTF, CSV or XML)
3. Using the same dataset for multiple recipients (reducing technical complexities)
4. Data availability / Dissemination
5. Use of ontologies (management of externally defined lists that have to be kept up to date in IUCLID) / extension of the format (in an ad hoc way to store extra information)

The Meeting agreed to revise the 3rd edition of the [Customisation Opportunities of IUCLID for the Management of Chemical Data](#) document, published in June 2023, to publish a 4th edition in 2025.

Forthcoming event

Contact

Website

1-2 October 2024 (TBC) in Helsinki hosted by ECHA, back-to-back and one joint session with the Meeting of the Steering Group for the Development of the Global Portal (eChemPortal) meeting 30 September - 1 October 2024.

Sally DE MARCELLUS

<https://oe.cd/iuclid>

II. Assistance with Governance

1 ● Test Guidelines

Meeting of the Validation Management Group for Ecotoxicity Testing (VMG-eco), 22-23 October 2023 (hybrid format)

The VMG-eco discussed several projects where draft documents are mature for approval, including the REACTIV assay (estrogen modality detected in fish embryo), the JHASA assay (juvenile hormone activity in *Daphnia*) and the HYBIT assay (*Hyalella* bioaccumulation assay). Other projects where validation studies are on-going or planned were also presented and discussed. Validation works to update the fish Test Guidelines with the addition of thyroid-related endpoints was presented to the VMG-eco and the TDM EG (see below).

Meeting of the Expert Group on Thyroid Disruption Methods (TDM EG), 26 October 2023 (virtual format)

The group discussed progress with the completed assessment of additional *in vitro* assays emanating from the EU-NETVAL initiative, i.e. the ZETA assay (zebrafish embryo thyroid assay) and the GLUC-LCMS assay (glucuronidation assay), and also the on-going assessment of TR and T-SCREEN assays (thyroid receptor assays). The TDM EG aims to complete most assays assessments in 2024 (still to be done are: NIS, MCT-8, TSH receptor activation, vasculo-angiogenesis assays). An assay developed in the US on thyroid micro-tissue for thyroid hormone synthesis disruption was presented and validation is on-going. The TDM EG also discussed the pros and cons of having individual assays as Test Guidelines versus developing defined approaches. Two project proposals for individual assays (i.e. deiodinase 1 assay and thyrosine binding assay) are being proposed to the Working Party of the National coordinators to the Test Guidelines Programme (WNT) by France/Germany and the Netherlands, respectively.

Workshop on operational and financial aspects of validation, 14-15 December 2023 (hybrid format)

The workshop discussed the outcome of a stakeholders' survey conducted in Q3 2023 on issues related to the funding of validation (e.g. sources, responsibilities, costing) and operational aspects (e.g. responsibilities, good practices, case examples). More than 100 participants joined the presentations and discussions in breakout sessions and in plenary. The outcome is a series of recommendations that will be discussed by the Chemicals and Biotechnology Committee in February 2024. The workshop steering group will aim to finalise the recommendations in time for the WNT meeting in April 2024.

Other activities

Expert Groups (EG) working in the following areas are meeting virtually on a regular basis (e.g. every 2 months in average) and/or are solicited for comments on draft documents, to keep the community of experts engaged in projects:

- EG on eye irritation, EG on defined approaches on skin sensitization and EG on individual skin sensitisation methods; EG on *in vitro* immunotoxicity; EG on developmental neurotoxicity; EG on honeybee testing; EG on physical-chemical properties of nanomaterials.

The Advisory Group on Emerging Science in Chemicals Assessment (ESCA) has been established to work in close collaboration with the WPHA and the WNT in areas of emerging methodologies, approaches and technologies. The ESCA is intended to be responsive to specific requests and needs defined by the WPHA and the WNT and forward-looking, with regard to application of emerging science to regulatory chemicals assessment.

Webinars in the Series on Testing and Assessment Methodologies:



14 November: This webinar is an introduction to the validation of in vitro methods which explains why validation is important in the context of OECD Test Guidelines. The modular approach to validation is explained, the optimal design of an inter-laboratory study is presented, common hurdles and how to address them, and important resources are shared. This webinar is for individuals who are not yet familiar with validation and have questions about its utility in the regulatory context.



<https://youtu.be/vRV3c2XexWE?si=Aqe7aLHO5CkG5Mle>



27 November: This webinar is for researchers who have developed a new method and wonder if it is ready to be used outside their laboratory. You will hear experience of research teams who have evaluated the readiness of a large set of in vitro methods, and experience of an organisation that regularly evaluates readiness of a method before embarking on inter-laboratory testing.



<https://youtu.be/FS9DRA7D-UA>

Recent Publications in the OECD Series on Adverse Outcome Pathways

[No. 35: Adverse Outcome Pathway on Androgen receptor agonism leading to male-biased sex ratio](#) | Authors: Kelvin J. Santana Rodriguez, Daniel L. Villeneuve, Kathleen M. Jensen, Gerald Ankley, David H. Miller

[No. 34: Adverse Outcome Pathway on Aromatase inhibition leading to male-biased sex ratio via impacts on gonad differentiation](#) | Authors: Kelvin J. Santana Rodriguez, Daniel L. Villeneuve, Kathleen M. Jensen, Gerald Ankley, David H. Miller

[No. 33: Substance interaction with the pulmonary resident cell membrane components leading to pulmonary fibrosis](#) | Authors: Sabina Halappanavar, Monita Sharma, Silvia Solorio-Rodriguez, Hakan Wallin, Ulla Vogel, Kristie Sullivan, Amy J. Clippinger

[No. 32: Adverse Outcome Pathway on deposition of energy leading to lung cancer](#) | Authors: Samantha Sherman, Zakara Said, Baki Sadi, Carole Yauk, Danielle Beaton, Ruth Wilkins, Robert Stainforth, Nadine Adam and Vinita Chauhan

[No. 31: Disruption of VEGFR signaling leading to developmental defects](#) | Authors: Thomas B. Knudsen, Katerine Saili, Jill Franzosa, Nancy Baker, Richard Spencer, Tamara Tal, Nicole Kleinstreuer, Tuula Heinonen, Rob Ellis-Hutchings, Neil Vargesson and Maria Bondesson

[No. 30: Adverse Outcome Pathway on impaired interleukin-1 receptor type I \(IL-1R1\) signaling leading to impaired T-cell dependent antibody response](#) | Authors: Yutaka Kimura, Setsuya Aiba, Takao Ashikaga, Takumi Ohishi and Kiyoshi Kushima

[No. 29: Oxidative DNA damage leading to chromosomal aberrations and mutations](#) | Authors: Eunnara Cho, Ashley Allemang, Marc Audebert, Vinita Chauhan, Stephen Dertinger, Giel Hendriks, Mirjam Luijten, Francesco Marchetti, Sheroy Minocherhomji, Stefan Pfuhler, Daniel J. Roberts, Kristina Trenz, Carole L. Yauk



Recent Publications in the OECD Series on Testing and Assessment

[No. 384](#): Epidermal Sensitisation Assay (EpiSensA) Validation Study Report

[No. 383](#): Epidermal Sensitisation Assay (EpiSensA) Peer review Report

[No. 382](#): Study Report on Applicability of the key event-based TG 442D for *in vitro* skin sensitisation testing of nano-materials

[No. 381](#): Detailed review paper (DRP) on the thyroid hormone system in fish and identification of potential thyroid hormone system related endpoints for inclusion in existing OECD fish Test Guidelines

[No. 380](#): Validation of the Juvenile Medaka anti-androgen screening assay (JMASA)

[No. 379](#): Guidance Document on a Juvenile Medaka anti-androgen screening assay (JMASA)

[No. 378](#): Report on the WNT Workshop how to prepare the Test Guidelines Programme for emerging technologies

[No. 377](#): Initial Recommendations on Evaluation of Data from the Developmental Neurotoxicity (DNT) In-Vitro Testing Battery

[No. 356](#): Performance Standards for the Assessment of Proposed Similar or Modified *In Vitro* Phototoxicity: Reconstructed Human Epidermis (RhE) Test Methods for Testing of Topically Applied Substances, as described in Test Guideline 498

[No. 303](#): Second Edition, Performance Standards for the assessment of proposed similar or modified *in vitro* skin sensitisation DPRA and ADRA test methods

Forthcoming events

**23-26 April 2024,
36th Meeting of the Working Party of the National Co-ordinators of the Test Guidelines Programme**

**11 April 2024,
Expert Group on Developmental Neurotoxicity (DNT) *In Vitro* Battery**

**Week of 24 June 2024,
2nd Meeting of the Advisory Group on Emerging Science in Chemicals Assessment**

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www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm

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. 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.

Seven on-site evaluations visits were conducted in 2023: Malaysia, Australia, Finland, Greece, Japan (Industrial Chemicals), Netherlands and Belgium. Five on-site evaluations visits are scheduled in 2024: Italy, France (Veterinary Products), Spain (Medical Products), Switzerland and UK.

Guidance Documents

In 2020, the Working Party on GLP established an informal sub-group – lead by Belgium, France (Medical Products) and Switzerland - to follow up on **new and emerging technologies** that may pose a challenge for regulatory GLP compliance (cloud-based solutions, artificial intelligence for histopathology analysis, block chain, predictive models (e.g. (Q)SAR) and other advanced technology equipment). The aim of the sub-group is to monitor the status and issues associated with these technologies, and, when appropriate, propose the development of specific guidance to the Working Party for eventual publication. A **document on GLP and Cloud-computing**, was drafted by a sub-group led by Belgium and France (Medical Products) and was published in June 2023. The document addresses issues raised by the use of cloud applications that need to be solved by GLP test facilities and outlines what GLP inspectors expect to be available to allow the compliance verification of such technical solutions. The document was published as Supplement 1 to the Document Number 17: Advisory Document on the Application of GLP Principles to Computerised Systems. Regarding the **other emerging technologies**, a drafting group is developing checklists/ decision trees for GLP inspectors. This checklist/decision tree will be used as an information gathering tool to share experiences of the inspection of emerging technologies. According to the reflections shared, the Working Party will consider developing new FAQs or guidance documents.

In 2018, Working Party members agreed there would be value in developing a Best Practice Guide (BPG) or other approaches for imparting knowledge to individuals who may participate in **on-site evaluation visits** in the future, and what such guidance should include. An informal ad hoc subgroup, under the leadership of New Zealand, organised a training session for new or less experienced on-site evaluators just prior to the 36th Working Party meeting in April 2022. A similar session will be held at the 38th Working Party meeting in April 2024. The subgroup also prepared internal guidance for participating in on-site evaluations as an observer, including a check-list for observers and internal guidance for selecting on-site evaluation team members.

At the 35th Working Party meeting it was agreed to further share experience related to IT inspections. A community site to share informal discussions and documents related to IT inspections was created in 2021 for nominated GLP inspectors. In addition, webinars of case studies on IT inspection by experienced inspectors were held to share approaches in October 2021, January 2022, September 2022, December 2022, February 2023 and September 2023.



The next webinar is planned for 2024.

Based on the release of recent guidance documents, the set of Frequently Asked Questions on GLP have been updated and consolidated and will be made available on the website in Q1 2024.

The 16th OECD GLP training course in Mexico City, Mexico will be held on 4-7 November 2024. A steering group has been formed and will continue to organise the training course.

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Forthcoming events
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**16-18 April 2024,
38th Meeting of the Working Party
on GLP
OECD Paris**

**4-7 November 2024,
OECD GLP Training Course
Mexico**

**1-3 April 2025
39th Meeting of the Working Party
on GLP
OECD Paris**

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Contacts
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**[www.oecd.org/chemicalsafety/
testing/good-laboratory-
practiceglp.htm](http://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm)**

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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 seven partner countries that are full adherents to MAD: **Argentina, Brazil, India, Malaysia, Singapore, South Africa and Thailand.** 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 Secretariat continues to work with several other countries in view of their possible provisional adherence to the MAD Council Acts.

Contacts

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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.

Best Practice Guide on sharing of safety data between companies

In 2021, the OECD Council revised its legal instrument on proprietary rights of chemical safety data (i.e. Recommendation of the Council Concerning Access and the Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals), extending its scope to cover all types of chemicals. A Best-Practice-Guide (BPG) was developed to support its implementation by describing effective approaches used by both governments and industry for disclosing health, safety, and environmental data while protecting the proprietary rights of data and information.

In November 2022, the Chemicals and Biotechnology Committee approved a proposal to develop an OECD guidance or best practice document to improve the process of sharing of chemical safety data between companies. An ad hoc group was set up under the CBC to identify best practices in exchanging data between companies. It held three meetings since its establishment and will present an outline of the best practice guide to the CBC at its meeting in November 2024.

Contacts

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Recommendation of the Council Concerning Access and the Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals [[OECD/LEGAL/0203](#)]

Legal acts related to chemical accidents

The Council Recommendation concerning the Application of the Polluter-Pays Principle to Accidental Pollution (1989) will be reviewed and updated. At the end of 2023, the Working Party for Chemical Accidents initiated the review process of the Recommendation

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Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution (1989) [[OECD/LEGAL/0251](#)]

Recommendation on the Safety of Recombinant-DNA Organisms

The responsibility for the Recommendation of the Council Concerning Safety Considerations for Applications of Recombinant-DNA Organisms in Industry, Agriculture and Environment (1986) was transferred from the Committee for Scientific and Technological Policy to the Chemicals and Biotechnology Committee in January 2020. The update of the instrument is conducted jointly by the Working Party on the Harmonisation of the Regulatory Oversight in Biotechnology (WP-HROB) and the Working Party on the Safety of Novel Foods and Feeds (WP-SNFF). A second draft revised Recommendation was discussed at a joint WP-HROB/WP-SNFF session in April 2023 and subsequently presented at the meeting of the Chemicals and Biotechnology Committee in July 2023. The two Working Parties are in the process of resolving final issues and will submit the final version to the CBC for approval in Q2 2024.

Contacts

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Recommendation of the Council Concerning Safety Considerations for Applications of Recombinant-DNA Organisms in Industry, Agriculture and Environment (1986) [[OECD/LEGAL/0225](#)]

Recommendation on Integrated Pollution Prevention and Control

The Environmental Policy Committee (EPOC) meeting in December 2021 discussed updating OECD standards on the environment, including revising the Recommendation of the Council on integrated pollution prevention and control ("IPPC Recommendation"). The revision of the IPPC Recommendation was envisaged to be done together with the Chemicals and Biotechnology Committee (CBC). In October 2022, the Chemicals and Biotechnology Committee and EPOC agreed upon the general direction for the revision of the IPPC Recommendation and in particular to enhance the provisions related to Best Available Techniques. A draft updated IPPC Recommendation was discussed by the CBC in July 2023. It is expected to be adopted by Council in Q1 2024.

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Recommendation of the Council on integrated pollution prevention and control [[OECD/LEGAL/0256](#)]

Decision-Recommendation on Council Acts related to Chemical Risk Assessment

Work has progressing on consolidating and updating three Acts concerning collection of data and assessment of new and existing chemicals. The three Acts are:

- Recommendation establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [[OECD/LEGAL/0154](#)]
- Decision concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals [[OECD/LEGAL/0199](#)]
- Decision-Recommendation on the Systematic Investigation of Existing Chemicals [[OECD/LEGAL/0232](#)]

All three Acts concern the need for data and assessment of chemicals. The first focuses on chemicals in general, the second on new chemicals, while the third, on existing chemicals. There is some overlap between the three Acts, which has caused some confusion, particularly for non-Members looking for international standards and good practices to support their development of a domestic chemical assessment framework. Furthermore, updating of the Acts provides an opportunity to consider relevant information and advances in risk assessment methodologies, as evidenced by the work done by the CBC on these issues since their adoption in the 70s/80s. A proposal for how to progress with the update was presented and endorsed at the 2nd meeting of the Chemicals and Biotechnology Committee in February 2022. The CBC set up an ad hoc Steering Group to provide input on the project, and several teleconferences were convened in 2022 and 2023. A final updated draft Decision-Recommendation which will be discussed by the Chemicals and Biotechnology Committee in February 2023.

Contact

Patience BROWNE

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, exposure and use and reviewed chemical classification information. 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 goal of eChemPortal, the Global Portal to Information on Chemical Substances, is to provide all stakeholders access to information of regulatory relevance on chemical properties, classifications, and exposure and use. To support development and determine whether eChemPortal is meeting the needs of regulators, members of the OECD Working Parties on Hazard Assessment (WPHA), Exposure Assessment (WPEA), and Pesticides (WPP) answered a short survey on the use of eChemPortal (17 May - 21 July 2023).

eChemPortal data is continuously maintained, and implementation and testing of maintenance and small improvements to the software, particularly to align with the OECD Harmonised Templates, has continued in Q3-Q4 2023, with the next maintenance release expected in Q1 2024.

The Steering Group for the Development of the Global Portal has continued discussions to identify potential future improvements in feeding data to eChemPortal and to support the Substance Search.

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Forthcoming event

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Contact

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Website

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To be confirmed: 30 September -1 October 2024 in Helsinki hosted by ECHA, back-to-back and one joint session with the OECD IUCLID User Group Expert Panel on 1-2 October 2024

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**Sally DE MARCELLUS
Kamila LIS**

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 and Waste

Tailor-made capacity building activities are organised by the Secretariat within the IOMC Toolbox project, the OECD Country Programmes or upon simple request by non-member countries (budget allowing).

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). This first year of the phase 4 of the project was dedicated to the preparation of capacity building activities that will take place in 2024 and to the initiation of reviewing the existent Management schemes and drafting the structure of future new management schemes. Following the call for tender for the maintenance of the platform, a contractor has been selected.

In parallel, capacity building activities are being prepared and several took place since July 2023:

- Four webinars on chemical accidents prevention, preparedness and response for Kenya
- Two webinars on risk assessment and a workshop on biocides management in the Philippines
- One webinar on QSAR & read across for the Philippines and Thailand
- One workshop on BAT in Viet Nam

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<http://iomctoolbox.oecd.org>
<https://www.oecd.org/chemicalsafety/development-cooperation-sound-management-chemicals.htm>

IV. Risk Management

1. Risk reduction (including socio-economic analysis)

The activities of the programme on risk management of chemicals are focused on how to manage the use of chemical products so that society can take advantage of their benefits while minimising risks. This includes: the sharing of risk management approaches; collaboration to advance sustainable chemistry; the development and sharing of methodologies and approaches for alternatives and socio-economic assessment as well as to support substitution of harmful chemicals; and the collaboration on risk management approaches on specific chemicals.

Risk Management Approaches Used for Chemicals Management

Case studies have been developed by Canada, the United States, and the EU on risk management approaches focusing on two specific chemicals: methylene chloride and decaBDE. These facilitated discussions within the WPRM on approaches applied.

Valuation of health effects and environmental impacts

The Chemicals and Biotechnology Committee's Working Party on Risk Management and the Environmental Policy Committee's Working Party on Integrating Economic and Environmental Policies are collaborating on the design of coordinated valuation studies. This entails the conduct of 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.

Five survey instruments for endpoints including asthma, chronic kidney disease, I.Q. loss, fertility loss, (very) low birth weight have been implemented with results published in June 2023. In addition, survey instruments have been developed for the next five endpoints and field implementation is underway.

To advance methodological approaches a scoping study on valuation of environmental endpoints was developed and published in December 2022. A workshop was held in October 2023 with a view to develop pilot scenarios for valuation of environmental endpoints to test in 2024.

Contacts

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[http://www.oecd.org/chemicalsafety/costs-benefits-](http://www.oecd.org/chemicalsafety/costs-benefits-chemicals-regulation.htm)

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[chemicals-regulation.htm](http://www.oecd.org/chemicalsafety/costs-benefits-chemicals-regulation.htm)

Perfluorinated chemicals

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.

A Report on Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishes (CPVs): Hazard Profile was published in December 2023. This complements the report on PFAS and alternatives in CPVs that was previously published.

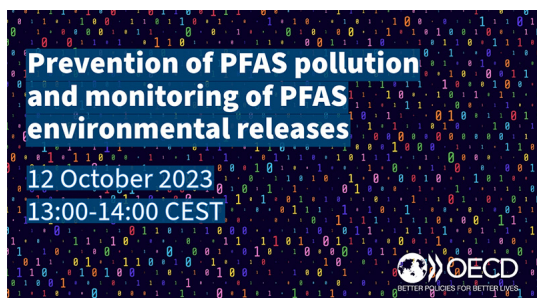
Two reports are being finalised and planned for publication in Q1 2024:

- Commercial Availability and Current Uses of Alternatives in Cosmetics;
- Understanding the Life Cycle of Perfluoropolyethers.

The Group regularly organises webinars to share information on PFASs and risk management. The recording of webinars can be accessed from the [OECD PFASs webportal](#) and from the [OECD Chemical Safety and Biosafety Youtube channel](#).

The most recent webinar was in October 2023 on Prevention of PFAS Pollution and Monitoring of PFAS Environmental Releases.

Watch our latest webinar: Prevention of PFAS Pollution and Monitoring of PFAS Environmental Releases



On 12 October 2023, the OECD/UNEP Global PFC Group organised a webinar to share examples of approaches to measure PFAS environmental releases, as well as on the collection of information on toxic releases and the development of pollution prevention measures.



<https://youtu.be/l6XRGRWGrSA>

Recent publications - Perfluorinated Chemicals

[No. 80](#): Report on Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishes (CPVs): Hazard Profile

Forthcoming events

Contacts

Website

**12-13 February 2024,
Global Forum on PFAS
OECD Boulogne and Online**

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[https://www.oecd.org/
chemicalsafety/risk-management/](https://www.oecd.org/chemicalsafety/risk-management/)

**25-26 September 2024
4th Meeting of the Working Party
on Risk Management**

[https://www.oecd.org/
chemicalsafety/portal-
perfluorinated-chemicals/](https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/)

2 Sustainable chemistry (including sustainable plastics, alternatives assessment and substitution)

The Working Party on Risk Management was formed in early 2021. The Working Party oversees the work on risk reduction and sustainable chemistry.

Substitution of harmful chemicals

A Landscape Study on Additional Attributes Beyond Safer for Chemical Selection and Substitution is being finalised and planned for publication in Q1 2024. The study examines what attributes companies are using to support decision-making in order to capture what is currently actionable in practice. The report will include circumstances where chemical substitution is occurring and is supported by information within companies.

The new upgraded SAAToolbox has been updated with new tools and frameworks to support substitution and alternatives assessment.

Sustainable plastics

A project was initiated to develop a synthesis report on Cost-Efficient Chemical Content Validation of Recycled Plastics. The report will present existing certifications/quality control measures/standards regarding the chemical quality of a plastic recyclate, the analytical approaches used as well as a discussion of the main economic, technological and practical hurdles in implementation. The report is being finalised and will be published in Q1/Q2 of 2024.

Forthcoming events

**23-24 September 2024,
Workshop on additional attributes
beyond safer for chemical
selection and substitution
OECD Paris**

**25-26 September 2024
4th Meeting of the Working Party
on Risk Management**

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[https://www.oecd.org/
chemicalsafety/risk-management/
substitution-of-hazardous-
chemicals/](https://www.oecd.org/chemicalsafety/risk-management/substitution-of-hazardous-chemicals/)

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 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 finalising the work on a revision of the 2009 Guidance Document on Definition of Residue (Lead EU, US, Canada & BIAC). Chapters have been drafted to address general topics as well as specific matters related to residue definitions for enforcement, residue definitions for risk assessment, Threshold of Toxicological Concern (TTC), conversion factors, exposure considerations, and interpretation of results from studies with multiple radiolabel positions. The group is also finalising the development of a new Guidance Document and study protocols on residues in honey (Lead France, New Zealand & BIAC). The document will contain a decision tree to set Maximum Residue Limits in honey, considerations on the use of the plant residue definition for risk assessment and in certain circumstances the processed commodities residue definition for honey, protocols suitable to quantify residues in honey and flowcharts/scenarios dealing with infield weeds, off field crops and rotational crops. A calculator was developed to estimate the rate of active substance reaching the non-target plant and criteria for identifying critical Good Agricultural Practices among different crops were developed. A draft document is being reviewed by the expert group. The RCEG started to work on two more projects that involve the revision of the TG 506 on stability of residues in stored commodities (Lead Germany Australia & BIAC) and the revision of the Guidance Document on pesticide residue analytical methods (Lead Germany & BIAC).

OECD Network on Illegal trade of Pesticides

In the context of the **OECD Network on Illegal trade of Pesticides (ONIP)** a Report on the Implementation of the OECD Recommendation on Countering the Illegal Trade of Pesticides is being developed. Adherents were asked to complete the survey in October of 2023, with follow-up requests in late 2023. Nineteen countries plus the EU responded. The information gathered by the Secretariat, and the collected survey responses suggest that Respondents, domestically and in the context of collaborative work at the OECD, have made significant and ongoing efforts to implement the Recommendation, including continued efforts in raising awareness about the dangers of illegal trade in pesticides through ONIP and larger OECD documents and meetings.

Drone/UASS Subgroup

The Drone/UASS Subgroup (Lead UK) of the Working Group on Pesticides (WGP) oversees a programme of work to set out a framework that will enable regulatory authorities to assess the risks associated with applying pesticides using drone technology, and to provide guidance to an industry Task Force and other Unmanned Aerial Vehicle (UAV) groups, as appropriate, on addressing the recommendations to fill data gaps included in the 2021 [OECD Report on the State of the Knowledge – Literature Review on Unmanned Aerial Spray Systems in Agriculture](#). In Q3 and Q4 2023, the Subgroup progressed work on developing guiding principles, processes, and criteria under which information and data considered in the work plan of the OECD Drone/UASS Subgroup will be deemed acceptable by OECD Members in order that all parties are aware of expectations and kept abreast of the progress of the Industry Task Force.

Expert Group on Bio-Pesticides

The **Expert Group on Bio-Pesticides (EGBP)** organised a Conference on ‘Innovating Microbial Pesticide Testing’ that was held in September 2022 in Paris, France and the proceedings of the conference were published in June 2023. Using as a base the recommendations of the conference and also the input from the CBC meeting in November 2022, the group has prioritised the ideas for projects and prepared project proposals to be considered by the upcoming meetings of the Working Party in Pesticides and the Working Party of the National Coordinators to the Test Guidelines Programme scheduled for 2024. The guidance documents on baculoviruses (Lead Germany) was published in October 2023. The revision of the Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products (Lead Germany & Canada) and the document providing an overview of approaches used by member countries to handle the issue of antimicrobial resistance potentially related to application of microbial pesticides were published in July and November 2023, respectively.

Expert Group on Pollinator Testing and Assessment (EG-PTA)

The **Expert Group on Pollinator Testing and Assessment (EG-PTA)** met virtually in June 2023. During this meeting the EG-PTA discussed a first draft of a document describing progress in the development of pollinator testing, including new testing proposals for bumblebees and solitary bees. The EG-PTA also invited the National Coordinators of the Test Guidelines Programme responsible for developing these projects as part of the Test Guidelines programme to facilitate the exchange between the two Working Parties.

Ad Hoc Expert Group on RNAi-based Pesticides

The Working Document on Human Health Risks from the Application of sprayed or externally applied dsRNA-Based Pesticides prepared by the **Ad Hoc Expert Group on RNAi-based Pesticides** was published in August 2023 (Lead US).

Expert Group on Minor Uses (EGMU)

The Guidance Document on addressing minor uses prepared by the **Expert Group on Minor Uses (EGMU)** was published in November 2023 (Lead US, Australia and Canada).

Recent Publications in the Series on Pesticides:

[No. 113](#): OECD Guidance Document on addressing minor uses

[No. 112](#): Overview of approaches used by member countries to handle the issue of antimicrobial resistance potentially related to application of microbial pesticides

[No. 111](#): Guidance document on Baculoviruses as plant protection products

[No: 110](#): Considerations for the Human Health Risk Assessment of Externally Applied dsRNA-Based Pesticides

[No: 109](#): Innovating Microbial Pesticide Testing: Conference Proceedings

[No: 65](#): Second Edition released in 2023. OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products



The OECD project on Pesticides 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 event

Contacts

Website

**26-29 February 2024,
Meeting of the Working Party
on Pesticides, the Expert Group
on Bio-Pesticides, and of the
OECD Network on Illegal trade of
Pesticides (ONIP)**

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Elizabeth DUCKETT DELL OSSO

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[chemicalsafety/pesticides-](https://www.oecd.org/chemicalsafety/pesticides-)

[biocides/agriculturalpesticides.](https://www.oecd.org/chemicalsafety/pesticides-biocides/agriculturalpesticides)

[htm](#)



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.

During the 7th meeting of the Working Party on Biocides (WPB), on 18-19 September 2023, the WPB approved the 10 general principles for a Sustainable Management of Harmful Organisms. These principles, published in December 2023, provide a holistic approach that includes a prioritisation and combination of available effective measures to minimise harm of harmful organisms for humans and the environment.

At this meeting, the WPB continued the exchange of information on antimicrobial resistance and discussed potential activities under the work programme for 2025-2028. The WPB is continuing the development of the Best Practice Document on Management of Emergency Situations, of Harmonised Study Review Forms on OECD Test Guidelines 429, 437 and 491 and of the Guidance Document on the efficacy of aerosols against insects.



The OECD project on Biocides 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.

Recent publications - Series on Biocides

[No. 21](#): 10 general principles for a Sustainable Management of Harmful Organisms (SuMaHO)

Forthcoming events

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Website

**25 March 2024,
interim Meeting of the Working
Party on Biocides
Online**

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[www.oecd.org/chemicalsafety/
pesticides-biocides/biocides.htm](http://www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm)

Leon VAN DER WAL

Paula VICENTE BENITO

**2-3 October 2024,
8th Meeting of the Working Party
on Biocides
Paris, France**

**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).

On 15 September 2023 a joint EU-OECD webinar was organised as an exchange between inspectors and hydrogen experts on how hydrogen risks may be evolving in the chemical hazardous site domain. It covered issues such as what uses and adaptations of current uses do hydrogen inspectors and risk experts see emerging? Of all the innovative possibilities, which ones are more realistic and which ones are less so? In terms of risk, what do we know and what don't we know? This was the first webinar of a series that will continue in 2024.

Four documents are being finalised that are planned for publication in 2024:

- Synthesis Report from the Thematic Session – Looking Ahead: How to Make Lessons Learning from Chemical Accidents Work? Challenges and Issues Arising from Decarbonisation and the Energy Transition;
- A report on the management of hazardous substances at port areas;
- A joint OECD/UN/EC-JRC guidance on **Managing Natech Accident Risk: A Guide for Senior Leaders in Industry and Public Authorities**;
- A document on the **Benefits of Regulation for Chemical Accident Prevention, Preparedness and Response: Presenting the Case for Senior Policy Makers and other**

Recent publications - Series on Chemical Accidents

[No 35: Guiding Principles on Chemical Accident Prevention, Preparedness and Response – Third Edition](#)

[Decision-Recommendation of the Council concerning Chemical Accident Prevention, Preparedness and Response \[OECD/LEGAL/0490\]](#)

Forthcoming events

**14 February 2024,
Joint EU-OECD webinar on
Hydrogen Fuel Risks**

**22-24 October 2024
34th Meeting of the Working Party
on Chemical Accidents**

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2. Pollutant Release and Transfer Registers (PRTRs) and Best Available Techniques (BAT)

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.

Furthermore, the programme has started activities on exchanging experience and developing guidance on using Best Available Techniques or similar concepts to reduce environmental pollution.

Pollutant Release and Transfer Registers

The Working Party on Pollutant Release and Transfer Registers (WP-PRTRs) focuses on i) improving PRTRs, ii) harmonising PRTRs across the world, and iii) enhancing the use of PRTR data.

The Working Party has started to update the Resource compendium of PRTR release estimation techniques Part I: Summary of techniques for point sources (led by Canada). The information on the release estimation techniques used by the WP-PRTRs members is being collected via an online questionnaire.

To assist countries in improving and harmonising their PRTRs, the WP-PRTRs is reviewing and updating the guidance document on elements of a PRTR, including the module of the IOMC-Toolbox for Decision-Making in Chemicals Management dedicated to PRTRs. The draft scoping document was circulated to the WP-PRTRs in Q1 2023 and will be further discussed by the WP-PRTRs in January 2024. The WP-PRTRs is also developing a methodology to assess the reporting coverage led by Japan, and the draft scoping document was discussed in January 2023.

In 2023, the WP-PRTRs initiated a new activity on the use of PRTR data to track cross-border transfers, led by the Commission for Environmental Cooperation, Canada, and the US. The WP-PRTRs is continuing to maintain the interactive database of information on the use of PRTR data and tools for their presentation.

The WP-PRTRs has continued to maintain three databases, Centre for PRTR data, the PRTR Resource Centre, and PRTR.net.

Recent publications - Series on PRTRs

No. 27: Uses of PRTR Data and Tools for their Presentation

Forthcoming event

**30-31 January 2024,
7th Meeting of the Working Party
on PRTRs
OECD, Paris**

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[www.oecd.org/chemicalsafety/
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register/](http://www.oecd.org/chemicalsafety/pollutant-release-transfer-register/)

Best Available Techniques (BAT)

The OECD's project on Best Available Techniques (BAT) for preventing and controlling industrial pollution aims to exchange best practices across countries with BAT-based policies and assist governments that seek to adopt BAT-based permitting. The Expert Group on BAT meets face-to-face once a year and provides the necessary advice to implement the project. The project is in its third phase (2022-2024) with three activities planned;

The project is in its third phase (2022-2024) with three publications planned:

- A cross-country analysis of BAT Reference Documents (BREFs) and associated emission levels for iron and steel production, paper and pulp production, and waste incineration. This report intends to promote international benchmarking and increase the potential for harmonisation of BAT-AELs across countries. A final draft version of the report is scheduled to be discussed by the Expert Group in June 2024.
- Capacity building workshops on BAT policies. The Secretariat offers an introduction to BAT, followed by tailor-made workshops in BAT in interested countries. The first workshop was held in Vietnam in October 2023. .
- A global study on emerging techniques. This report will assess the approaches of how countries identify emerging techniques for potential BAT determination. A Webinar on the Future of Best Available Techniques (BAT) in Industrial Pollution Prevention was organised on 8 November 2023 to raise interest in relevant stakeholders and highlight OECD work.

[The List of BREFs by sectors and activities covered by each jurisdiction](#) is under revision to become more user friendly, to update access links with revised BREFs and to add new BREFs from other jurisdictions, such as Kazakhstan and Belgium.



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 events

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June 2024
Webinar on BAT
Online

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Q3/4 2024 (To be confirmed)
9th EG meeting

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

● 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.

The OECD Consensus Document on Environmental Considerations for the Release of Transgenic Plants, was published in July 2023. This document deals with the environmental risk/safety assessment of transgenic plants at a broad level. Its purpose is to describe an approach and provide illustrative examples for planning and structuring risk/safety assessments for the release of transgenic plants into the environment. It provides general information on key concepts and important points that risk/safety assessors should focus on when planning such assessments. These key features include the comparative approach, the familiarity with the biology of the unmodified plant species, the general protection goals, the assessment endpoints, the potential adverse effects associated with the environmental release, the pathways to harm and corresponding risk hypotheses, relevant information elements, and the use of environmental considerations in planning such assessment.

Work continues on consensus documents addressing the biology of three mosquito species *Anopheles gambiae* (Lead AUDA-NEPAD and Australia), *Anopheles Albimanus* and *Anopheles Stephensi* (Lead UK, Brazil and AUDA-NEPAD). The consensus document on wheat biology (Lead Australia and US) is expected to be declassified and published in early 2024. The consensus document on micro-algae for biomass production (Lead Canada and US) is currently being revised based on feedback received. The project to revise the consensus document on maize biology (Lead Belgium and South Africa) has been resumed.

The Safer Innovation Approach Project (SIA) (Lead Netherlands) is currently working on two cases studies: Bt Maize from a food/feed safety perspective and Plant Molecular Farming (PMF). The second version of the information exchange on new breeding techniques survey (Lead Japan) is currently being circulated and the document providing a summary of developments in Delegations on biosafety issues for the period of June 2022-April 2023 was finalised and published in June 2023.

The OECD Product Database, containing information on genetically-engineered plant varieties approved for being cultivated or used in foods and feeds, continued to be completed and updated. A total of 393 entries for 26 crops, flowers and trees are now available in the system, keeping pace with new information provided by member countries as well as a number of non-members.

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

[No. 73](#): Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants

[No. 72](#): Developments in Delegations on Biosafety Issues, June 2022 – April 2023

Forthcoming event

**20-22 March 2024,
38th meeting of the Working
Party on the Harmonisation
of Regulatory Oversight in
Biotechnology
OECD Paris**

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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 Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) held its annual meeting in April 2023. The draft Consensus Document on Considerations for Collaborative Work on the Safety Assessment of Novel Foods and Feeds, prepared under the co-leadership of Canada, Australia, the African Biosafety Network of Expertise of AUDA-NEPAD, and BIAC, was reviewed at the meeting; the final draft was further developed and circulated for last remarks. It is scheduled to be published in Q3 2023. The proposal by the Netherlands to develop a new document on *Vicia faba* (faba bean, broad bean) composition was approved, and the Ad hoc expert drafting group is being established. The revised Maize composition consensus document (lead: United States) will be finalised in the coming months.

Three projects jointly developed by the WP-SNFF and the Working Party for the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) were reviewed at a joint session in April 2023:

- Revision of the OECD Council Recommendation on the safety of recombinant-DNA organisms (2006) for which a revised draft was provisionally agreed except for two provisions. A progress report will be delivered at the CBC meeting in July 2023;
- Enhanced information exchange on new breeding techniques for which a first set of information has been collected from delegations through a questionnaire circulated to the WP-HROB for the time being – the WP-SNFF will continue to observe the development of the project and its possible participation will be re-discussed at the 2024 Joint session;
- *Moving towards 'Safe(r)-Innovation-Approach' in biotechnology proposal* which was approved by the WP-HROB in follow-up to a 2-year pilot project, and is now circulated to the WP-SNFF for contemplating potential participation in the future.

The document providing a summary of developments occurred in Delegations on the safety assessment of novel foods and feeds for the June 2022-April 2023 period was finalised and is expected to be published in Q3 2023.

Forthcoming event

18-20 March 2024
31st Meeting of the Working Party
for the Safety of Novel Foods and
Feeds,
OECD, Paris

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Most EHS Publications can be downloaded directly from OLIS or our website:

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- ▶ **Email:** ehscont@oecd.org
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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/
Hazard Assessment	www.oecd.org/env/hazard
Mutual Acceptance of Data (MAD)	www.oecd.org/ehs/mad
Pesticides	www.oecd.org/env/pesticides
Pollutant Release and Transfer Registers	www.oecd.org/env/prtr
(Q)SARS	www.oecd.org/env/hazard/qsar
Risk Assessment	www.oecd.org/env/riskassessment
Risk Management	www.oecd.org/env/riskmanagement
Safety of Manufactured Nanomaterials	www.oecd.org/chemicalsafety/nanosafety/
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

