

Chemical Safety and Biosafety Progress Report



No. 44
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I. Provision of Knowledge and Information

1. Methodologies for Hazard Assessment

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

Integrated Approaches to Testing & Assessment

The Integrated Approaches to Testing and Assessment (IATA) case studies project continues under a project team of the Working Party on Hazard Assessment (WPHA). Two case studies in the 8th review cycle were published in Q1 2023:

- Case Study on the Use of Integrated Approaches for Testing and Assessment for skin sensitisation of Diethanolamine: Application of a Next Generation Risk Assessment Framework
- Case Study on the use of Integrated Approaches for Testing and Assessment for “Eye hazard identification” of “non-surfactant neat liquids”

The consideration document of the 8th review cycle has been reviewed by the WPHA and will be finalised in Q3 2023.

Two 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

Two case studies have been reviewed in the 8th review cycle in 2022:

- Case study on application of a Next Generation Risk Assessment (NGRA) framework for skin allergy using Diethanolamine
- Case Study on the Use of Integrated Approaches for Testing and Assessment for Chronic Toxicity and Carcinogenicity of Agrochemicals: Spiropidion.

Additional two case studies will be submitted in the 9th review cycle in Q2-Q3 2023.

A webinar on IATA: concepts and OECD case studies was held in December 2022. The video recording and presentations are available on the OECD IATA public site.

Webinar Series on Testing and Assessment Methodologies



Webinar on Integrated Approaches to Testing and Assessment: concepts and OECD case studies

WHEN: 16 December 2022
 14:00 - 16:00 CET
 08:00 - 10:00 EST

 **OECD**
INTERNATIONAL ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

A webinar on IATA concepts and OECD case studies was held in December 2022. The video recording and presentations are available on the OECD IATA public site.



<https://youtu.be/GZ7kVc5693E>



<https://oe.cd/iata>

QSAR Toolbox

The 8th meeting of the IATA Case Studies Project – including a joint session with the OECD QSAR Assessment Framework project - will be held on 15 -16 November, 2022 to discuss the two case studies of the 8th review cycle and one pilot case study. The meeting will also discuss the future evolution of the IATA Case Studies Project, following the feedback from the WPHA.

Version 4.6 of the QSAR Toolbox was released in May 2023. New features include:

- Enhanced connectivity with IUCLID (Harmonised meta data fields (endpoint tree hierarchy), extended IUCLID search)
- Updated Prediction and Data matrix reports

The QSAR Toolbox management group mid-year meeting was held on 21 June 2023 to review the deliverables and to discuss the future development of the Toolbox.

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 first face-to-face meeting and a joint session with the IATA Case Studies Project were held on 15-16 November 2022 to finalise the QAF guidance document and the checklist. The QAF documents has been circulated to the WPHA for approval and is expected to be published in Q3 2023.

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 AOPWiki security report was made available to the Extended Advisory Group on Molecular Screening and Toxikogenomics (EAGMST) in December 2022;
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.

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 is expected to be published in Q3 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) are both in the process of finalisation and are expected to be finalised in Q3 2023. The webpage dedicated to the OECD activities on omics (<https://www.oecd.org/chemicalsafety/testing/omics.htm>) provides additional information and the most recent draft versions of the templates and guidance to complete them. The chemical grouping application module (CG-ARM) is a new project under the WPHA that started in November 2022. 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.

Recent publications in the Series on Testing and Assessment

No. 375: Case Study on the use of Integrated Approaches for Testing and Assessment for "Eye hazard identification" of "non-surfactant neat liquids"

No. 374: Case Study on the Use of Integrated Approaches for Testing and Assessment for skin sensitisation of Diethanolamine: Application of a Next Generation Risk Assessment Framework

No. 373: Case Study on the use of Integrated Approaches to Testing and Assessment for potential Systemic Toxicity and Estrogen Receptor Activation of a Group of Bisphenols and Select Alternatives

No. 369: Report on Considerations from Case Studies on Integrated Approaches for Testing and Assessment (IATA)

Forthcoming events

**7th Meeting of the Working Party
on Hazard Assessment, week of 26
June, 2023**

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www.oecd.org/chemicalsaefity/risk-assessment/hazard-assessment.htm

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
2. ESD for uses of fluorocarbon substitutes – Refrigeration
3. ESD for uses of fluorocarbon substitutes – Mobile Air Conditioning
4. ESD for chemicals used in hydraulic fracturing,
5. ESD on chemicals used in fabric finishing, and
6. ESD on 3D Printing

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), the data are being collected through the WPEA.
- 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.

The WPEA is also working on the development of a biomonitoring database on chemicals measured in humans in collaboration with the EU's IPChem project.

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 is scheduled to be published in Q3 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 endorsed by the WPEA in June 2023. The next phase, building software based on the proposal, will be led by Canada and Norway.

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 is scheduled to be published in Q3 2023.

Recent publications

No. 376

Assessing the risk of chemicals to Children's Health: OECD-wide survey 2021 Survey Report

No. 370

Occupational Biomonitoring Guidance Document

Forthcoming event

**22-23 June 2023,
7th Meeting of the Working Party
on Exposure Assessment,
OECD, Paris**

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[www.oecd.org/chemicalsafety/
risk-assessment/
exposureassessment.htm](http://www.oecd.org/chemicalsafety/risk-assessment/exposureassessment.htm)

[www.oecd.org/chemicalsafety/childrens-
health.htm](http://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. At the same time, the programme seeks 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).

One of the focus areas of the WPMN is to support the work on the development and update of Test Guidelines (TG) and Guidance Documents (GD) to ensure their applicability to nanomaterials. To support this work, 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 TGs and GDs for nanomaterials, there are a number of sections that deserve a revision to reflect the current scientific knowledge. 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 is currently being reviewed. The revision of the GD is done in coordination with the Working Party on Hazard Assessment (WPHA) to ensure alignment. Both reviews aim to integrate advances in science and new knowledge gained.

The WPMN is finalising the draft scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in environmental organisms minimising the use of higher tier vertebrate tests. The scoping paper is close to finalisation and is expected to be published in 2023.

Regarding exposure of nanomaterials, a project was initiated to develop guidance 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. 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 should be discussed in early 2023. Finally, the WPMN is reviewing a project proposal aiming to develop guidance on the use of exposure models/tools for manufactured nanomaterials and emerging advanced materials. This project is a follow-up of the evaluation of exposure tools and models completed in 2021.

In 2022, the WPMN completed a working description of advanced materials and initiated the development of a strategic approach for ensuring the safe use of advanced materials for which existing (nano) assessment tools are not adequate. The strategy is aligned with the work on the Safe(r) and Sustainable Innovation Approach (SSIA) and incorporates the concepts of Regulatory Preparedness (RP) and Safe and Sustainable by Design (SSbD).

The aim is to 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). At the same time, working description on Sustainability and on SSbD were also completed and should help operationalise SSIA. Specific case studies on advanced materials will be developed in 2023 with the aim to further refine the strategic approach for their safe use.

The case studies will also be used to apply the SSIA approach and further develop the concepts of Trusted Environment and Regulatory Preparedness. With this in mind, the projects on advanced materials and SSIA are implemented in close collaboration to ensure convergence. A workshop was organised in collaboration with the EU project HARMLESS to work on a case study on Fibre-aerogel-mats for façade insulation. The intention was to compare different approaches and to further refine the WPMN strategic approach on advanced Materials Early4AdMa. Additional case studies are planned on nanocarriers, 3D printing and graphene-based materials to learn more about different types of advanced materials with a view to improve regulatory preparedness.

Finally, the WPMN agreed in June 2022 to update the annex of the OECD Council Recommendation on Nanomaterials. A draft is currently being prepared by the Secretariat and it is expected to be circulated to the WPMN for input and agreement.

Recent publications in the Series on Nanomaterials

No. 105:

Sustainability and Safe and Sustainable by Design:
Working Descriptions for the Safer Innovation Approach

No. 103:

Important Issues on Risk Assessment of Manufactured
Nanomaterials

No. 104:

Advanced Materials: Working Description



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

**14-15 June 2023,
OECD WPMN Workshop on
Advanced Materials: Nanocarriers
Online workshop**

**26-28 June 2023
23rd Meeting of the Working Party
on Manufactured Nanomaterials,
OECD, Paris**

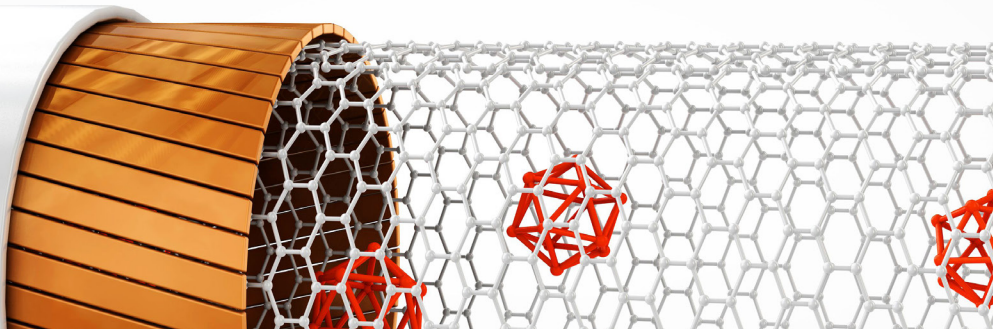
**4 October 2023,
Webinar Early4AdMa Safer and
Sustainable Innovation Approach
(SSIA)
OECD, Paris**

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[www.oecd.org/chemicalsafety/
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 nine OHTs from different Series, revised for covering new/revised Test Guidelines issued in June 2022, 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. Following the publication in December 2020 of the revised OHT 201, this template needed further revision to include revised TG 442C adopted in June 2022. In due course, further developments are contemplated to extend OHT 201 to other *in vitro/in chemico* Test Guidelines on endocrine disruptors notably. In parallel, the OECD developed a new OHT 75-2 'Endocrine disrupter screening – *in vitro*'. This new template has been sent to the CBC for endorsement in May 2023 and will be published at the OHTs website soon.

The European Chemicals Agency (ECHA) led a project on splitting OHT 50-2 'Toxicity to Terrestrial Arthropods' into three new templates: (1) OHT 50-3 'Toxicity to bees', (2) OHT 50-4 'Toxicity to terrestrial arthropods other than bees' and (3) OHT 50-5 'Toxicity to soil arthropods'. Another ECHA-led project was on the development of "endpoint study summaries" for each of the existing OHTs with the aim to use harmonised reporting formats for conclusions on individual hazard endpoints in case more than one study result is available. These two projects are now complete and the three new OHTs for reporting studies in arthropods and the 105 harmonised endpoint study summaries are expected to be published in Q3 2023.

In a joint effort by ECHA and the OECD, some technical and editorial improvements will be brought to several OHTs during 2023, in order 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, will propose the extension of OHTs to improve the usability of QSAR-based data. Annual updates to cover recently updated/new Test Guidelines will be carried out on nine OHTs in 2023. Activities to improve the use of OHTs for both biopesticide and pesticide submissions will continue. Furthermore, a possible extension of the Series of Use and Exposure Information as well as the update of the Series on Use and Exposure Information (OHTs 301-306) could result from a project of the Working Party on Exposure Assessment on collecting exposure and release information from products. In the longer run, OHT changes/extension could result from the ECHA led project on the improvement of Robust Study Summaries.

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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 version 6.27 was released in February 2023. This service release included bug fixes and configuration updates relevant to all or specific user groups. The IUCLID Updater was also released in February.

IUCLID version v6.7 was released in May 2023. This major release included updates to the IUCLID format, for example to the latest OECD Harmonised Templates (OHT) and harmonisation of 105 endpoint summary templates and updates relevant to specific user groups (e.g. relevant to the New Zealand EPA, EU, and UK REACH), and included new functionalities.

In Q4 2022 and Q1 2023, the OECD IUCLID User Group Expert Panel prioritised potential requirements for development, as well as activities on the following topics to define future requirements:

1. User interface improvements
2. Reporting
3. Using the same dataset for multiple recipients
4. Data availability / Dissemination
5. Use of ontologies / extension of the format



The [3rd edition of the Customisation Opportunities of IUCLID 6 for the Management of Chemical Data](#) was published in June 2023.

Forthcoming event

**23 September 2023,
Meeting of the UCLID User Group
Expert Panel,
OECD Paris and online**

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<https://oe.cd/iuclid>

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 following new, updated and corrected Test Guidelines were approved in April and May 2023 by the Working Party of the National Coordinators of the Test Guidelines Programme:

New Test Guidelines

Section 1: Physical-Chemical properties

126: Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement

Section 4: Health effects

444A: *In vitro* immunotoxicity: Il-2 Luc assay

Updated Test Guidelines

Section 2: Effects on Biotic Systems

218: Sediment-water Chironomid Toxicity Test Using Spiked Sediment

219: Sediment-water Chironomid Toxicity Test Using Spiked Water

240: Medaka Extended One-Generation Reproductive Toxicity Study

Section 4: Health Effects

442C: *In Chemico* Skin Sensitisation

442E: *In Vitro* Skin Sensitisation

Corrected Test Guidelines

Section 1: Physical-Chemical properties

125: Particle Size and Particle Size Distribution of Nanomaterial

Section 3: Environmental fate and behaviour

316: Phototransformation of Chemicals in Water – Direct Photolysis

Section 4: Health effects

405: *In vivo* Eye Irritation test

437: BCOP Test Method for Eye Hazard Potential

438: ICE Test Method for Eye Hazard Potential

456: H295R Steroidogenesis Assay

458: Androgen Receptor TransActivation Assays for Detection of Androgenic Agonist and Antagonist

Activity of Chemicals using Stably Transfected Cell Lines
460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants

487: *In Vitro* Mammalian Cell Micronucleus Test

491: Short Time Exposure *In Vitro* Test Method For Eye Hazard Potential

492: Reconstructed Human Cornea-Like Epithelium (Rhce) Test Method

496: *In vitro* Macromolecular Test Method

497: Defined Approaches for Skin Sensitisation

498: *In vitro* Phototoxicity: Reconstructed Human Epidermis Phototoxicity test method



TEST GUIDELINES

WNT workshop on how to adapt the Test Guidelines Programme to emerging technologies, 1-2 December 2022 (hybrid format)

The workshop was preceded by a series of six awareness-raising webinars between June and November 2022. The WNT was able to prioritise six topics for discussion at the workshop itself:

1. readiness of methods for TG development,
2. evolution of the concept of performance standards for methods that use different technological platforms but measure the same (biological) response,
3. need (or not) for a dedicated section of Test Guidelines for non-standalone methods (i.e. methods that address a key event rather than an adverse outcome),
4. need for guidance on the validation of batteries of assays,
5. incentives for participation and funding of validation studies,
6. improvement of the reporting of validation study results for re-usability.

The workshop split in breakout groups for discussion and met in plenary on the second day to identify points of agreement and recommend actions. The workshop was a starting point in the evolution of processes and practices of the Test Guidelines Programme. The report is scheduled to be published in July 2023 in the Series on Testing and Assessment.



<https://youtube.com/playlist?list=PLJNHHjqEVlIdVJUEu3QD1AaY3Z230OepY>



<https://oe.cd/webinars-emerging-science>

35th Meeting of the Working Party of the National Coordinators of the Test Guidelines Programme (WNT), 25-28 April 2023 (hybrid format)

The WNT discussed and approved 12 new project proposals. Twenty-one new, updated and corrected Test Guidelines were approved (see above). One Detailed Review Paper, one study report, two validation reports, one peer-review report, three revised Performance Standards, two guidance documents and one workshop report were approved at the meeting (see the list/titles below); approved documents are expected to be published in July or August 2023. Among the new projects, a proposal to update the Guidance Document 34 on validation was approved, co-led by the EU, the US and the Netherlands. Among the documents approved, is a document providing initial recommendations on data evaluation from an *in vitro* battery of developmental neurotoxicity (DNT-IVB) assays; the co-leads will continue to work on the DNT-IVB to enable the development of a definitive guidance document. The meeting approved the establishment of a new Advisory group on Emerging Science in Chemicals Assessment (ESCA), and approved the organisation of a stakeholder workshop on operational and financial aspects of validation in December 2023.

Documents approved by the WNT:

- Guidance Document on Juvenile Medaka anti-androgen screening assay;
- Detailed review Paper on the thyroid hormone system in fish and identification of potential thyroid hormone system related endpoints for inclusion in existing OECD fish test guidelines;
- Initial recommendations on evaluation of data from the Developmental Neurotoxicity *in vitro* battery (DNT IVB);
- Updated Performance Standards 216 for TG 492B RhCE *in vitro* methods for eye hazard potential;
- Corrected Performance Standards 356 for TG 498 RhE *in vitro* methods for phototoxicity;
- Validation and Peer-review reports for the EpiSensA method for skin sensitisation.



Meeting of the Expert Group on Thyroid Disruption Methods (TDM EG), 15-16 May 2023 (hybrid format)

A major initiative for inter-laboratory transferability of more than ten key event based methods was just completed in October 2022, coordinated by EURL-ECVAM. Small assessment groups under the OECD TDM EG are evaluating the validation status of individual assays and making conclusions/recommendations on the additional work or the readiness for TG development. The TDM EG met to review progress with the assays assessments. Individual assays assessment reports will be gradually submitted to the WNT for endorsement. A clear regulatory need for *in vitro* methods on thyroid disruption exist in OECD countries. Member countries will be encouraged to take the lead at the WNT level in the development of Test Guidelines and supporting guidance for use and interpretation of assays.

Meeting of the Expert Group on *in vitro* Developmental Neurotoxicity, 19 May 2023 (hybrid meeting)

The Expert Group contemplated the recent WNT approval of the “Initial Recommendations on the Evaluation of Data from the In Vitro Battery on DNT”, and work ahead to develop a definitive guidance document, in particular the inter-laboratory transferability of the DNT-IVB assays and the reproducibility of the data as the critical aspects to address for the regulatory implementation. Resources from both EFSA and US EPA, are engaged in the work. More resources from other countries would certainly help accelerate the pace of the assay validation process. The Expert Group is also working on the development of a flexible/context -dependent tiered testing strategy, including guidance on *in vitro* to *in vivo* extrapolation (IVIVE) for the DNT-IVB application. As regards the IVIVE, the EG appreciated the effort to develop a tiered exposure modelling approach and noted that it will be most helpful to provide “stop criteria”, such as chemical structure/physio-chemical properties, tools or models (e.g., placental barrier or brain-blood barrier). The EG established a plan for a consensus list of positive and negative chemicals (training set of compounds) for DNT-IVB assay transfer. The zebrafish DNT group reported on the standardization efforts of the dark-light transition test and the testing of chemicals. Finally, there was a proposal to reflect on the lessons learnt through the work on DNT-IVB and especially the IATA case studies and organise a workshop to leverage on the lessons learnt from the IATA case studies where the DNT-IVB was used.

Webinar Series on Testing and Assessment Methodologies



Webinar on particle size and particle size distribution of nanomaterials: OECD Test Guideline No. 125

WHEN: 7 February 2023
14:00 - 16h00 CET
08:00 - 10h00 EDT

NANOMET

OECD
BETTER POLICIES FOR BETTER LIVES

With the financial assistance of the European Union

On 7 February, the OECD organised a webinar to present the methods described in Test Guideline No. 125 to determine the size and size distributions of nanomaterial particles and fibres spanning from 1 nm to 1000 nm. It also presented the use and limitation of this Test Guideline, as well as on the validation exercise that was done to support its development. The webinar was delivered in both English and Spanish.



<https://oe.cd/testing-assessment-webinars>

Webinar Series on Emerging Science to Improve Chemical Safety



Emerging Science to improve Chemical Safety

OECD
BETTER POLICIES FOR BETTER LIVES

The Series has been populated with 6 webinars organised between June and November 2022 in preparation for the WNT workshop on emerging technologies in December 2022. The webinars were made publicly available in January 2023.



<https://oe.cd/webinars-emerging-science>

Forthcoming events

29-30 June 2023
**1st meeting of the Advisory Group on Emerging
Science in Chemicals Assessment**

14-15 December 2023
**Stakeholders workshop on operational and financial
aspects of validation**

23-24 October 2023
**18th of the Validation Management Group for
Ecotoxicity Testing**

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

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www.oecd.org/chemicalsafety/testing/

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 evaluation visits were conducted in 2022: Korea, Norway, US-EPA, India, Argentina, Japan (Pesticides, Veterinary Products and Feed Additives) and France (Industrial Chemicals). Seven on-site evaluations visits are scheduled in 2023: Malaysia, Australia, Finland, Greece, Japan (Industrial Chemicals), Netherlands and Belgium. As of June 2023, the OSE for Malaysia was held.

Guidance Documents

In 2020, the Working Party 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 is scheduled to be published in Q3 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. This document will be 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 proposed that checklists/decision trees for GLP inspectors should be developed. 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 and February 2023. The next webinar will be held in September 2023.

The **16th OECD GLP training course** in Mexico City, Mexico will be held 28-31 October 2024. The first steering group meeting was held on 12 March 2023 prior to the 37th meeting of the Working Party on GLP. A steering group 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 Group
on GLP,
OECD, Paris**

**28-31 October 2024,
OECD GLP Training Course,
Mexico**

**1-3 April 20245
39th Meeting of the Working Group
on GLP,
OECD, Paris**

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Contacts

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Website

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

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 now 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 [[OECD/LEGAL/0203](#)]), 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 [[ENV/CBC/MONO\(2022\)18](#)].

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 two meetings since its establishment and will present an outline of the best practice guide to the CBC at its meeting in July 2023.

Contacts

Bob DIDERICH
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Legal acts related to chemical accidents

The [new Decision-Recommendation of the Council concerning Chemical Accidents Prevention, Preparedness and Response](#) was adopted by the Meeting of the OECD Council at Ministerial Level (MCM) on 8 June 2023. This legal Act updates and consolidates in a single instrument three previous Acts related to chemical accidents issued in 1988 and 2004. The new instrument sets out key elements to support the development of a chemical accidents programme covering the fields of prevention, preparedness, and response. It aims at helping Adherents to respond to the continued occurrence of chemical accidents with loss of life, injuries and damage to property and the environment.

To support the implementation of the new Decision-Recommendation, the [“OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response”](#) have been updated in a Third Edition in June 2023. This publication serves as technical guidance for public authorities, industry and other stakeholders for developing and implementing a strong chemical programme, as it addresses the wide range of measures necessary to ensure effective chemical process safety.

Another OECD Act pertaining to chemical accidents is the [Council Recommendation concerning the Application of the Polluter-Pays Principle to Accidental Pollution](#) (1989). The Working Party for Chemical Accidents will have first discussions starting in mid-2023 to initiate the review process of the Recommendation.

Contacts

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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. Provisional agreement to proposed changes was reached on most provisions. The draft document will be refined by the WP-HROB and WP-SNFF in the coming months. Once finalised at the level of the two Working Parties, it will be forwarded to the CBC for approval before transmission to Council for adoption.

Contacts

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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 \[OECD/LEGAL/0256\]](#) ("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 will be discussed by the CBC in July 2023.

Contacts

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Decision-Recommendation on Council Acts related to Chemical Risk Assessment

Work has started 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. An interim progress report was presented at the 3rd CBC meeting in November of 2022 and an interim draft of the consolidated, revised Decision-Recommendation will be presented at the 4th CBC meeting in July 2023. The revision is expected to be finalised by the end of 2024.

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.

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

eChemPortal version 3.10 was released in October 2022, including an upgrade of the substance search engine, improved results for selected data sources in vague substance searches (retrieving many records), and greater efficiency in selecting a hazard category in the GHS Classification Query dropdown menu.

eChemPortal added links to the OECD Fact Cards of Major Groups of Per- and Polyfluoroalkyl Substances (PFASs) in December 2022.

The eChemPortal Guidance for New Participants was made available in April 2023. The Guidance provides concise and practical information to help organisations identify the type of chemicals information shared on the eChemPortal and to define the best strategy to participate as a data source.

The Steering Group for the Development of the Global Portal met virtually on 18-19 April 2023 and provided input on future requirements and agreed priorities for the 2023/24 eChemPortal development contract that focuses on maintenance, fixes, and small improvements.

Read the eChemPortal Guidance for New Participants



This Guidance provides concise and practical information to help organisations identify the type of chemicals information shared on the eChemPortal - the Global Portal to Information on Chemical Substances and to define the best strategy to participate as a data source.



<https://oe.cd/guide-echemportal>

Forthcoming event

Contact

Website

2024 (TBC)
Meeting of the Steering Group for the
Development of the Global Portal

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



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).

Phase 3 of the project ended in October 2022 and a new phase has started on 1 January 2023 thanks to a contribution from the EU.

Capacity building activities are in preparation and a call for tender was organised for the maintenance of the platform.

A webinar on PRTR was organised for Kenya and a webinar on chemicals accidents prevention, preparedness and response was organised for Kenya and the Philippines in early 2023. Support for developing/updating chemicals policy/framework law was given to Kenya and Viet Nam. A workshop was held in March 2023 in Kenya to consolidate outputs from previous not in-person capacity-building activities.

Contacts

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Websites

<http://iomctoolbox.oecd.org>
www.oecd.org/env/ehs/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.

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

Risk Management Approaches Used for Chemicals Management

A report was published in December 2022 on “**Government Risk Management Approaches Used for Chemicals Management**”. This synthesis document outlines various risk management approaches and options that are used by member country chemical regulatory programmes to manage the risk of chemicals. The scope of the document focuses on the management of risks of industrial and consumer chemicals, i.e. chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals.

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 has begun.

To advance methodological approaches a scoping study on valuation of environmental endpoints was developed and published in December 2022.

Recent publication

[No. 75: Valuing the Impacts of Chemicals on Environmental Endpoints: A Scoping Study](#)

Contacts

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Websites

<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.

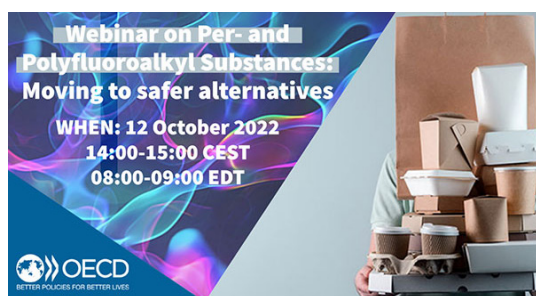
The OECD recently published two reports:

- A report on **PFASs and Alternatives in Coatings, Paints and Varnishes (CPVs): Commercial Availability and Current Uses**. A report on the hazard profile of the alternatives identified is under development.
- A report on **Understanding Side Chain Polymeric PFAS and Their Life Cycle**.

The OECD's PFAS web-portal was updated with new risk reduction information from countries and OECD publications in 2022.

The Group regularly organises webinars to share information on PFASs and risk management. The recording of all webinars can be accessed from the OECD PFASs webportal at: oe.cd/pfas-videos.

Watch our latest webinar: Moving to safer alternatives



On 12 October 2022, the OECD presented the main conclusions of the two published OECD reports on Commercial Availability and Current Uses of Alternatives in Food Packaging (paper and paperboard) and in Coatings, Paints and Varnishes (CPVs). It also presented the work of the venture capital company Safer Made looking at means of investments in risk reduction projects.



<https://youtu.be/eoVgVua3Zkk>

Recent publications - Perfluorinated Chemicals

[No. 73](#)

Synthesis Report on Understanding Side-Chain Fluorinated Polymers and Their Life Cycle

[No. 70](#)

Per- and Polyfluoroalkyl Substances and Alternatives in Coatings, Paints and Varnishes (CPVs)

Forthcoming event

Contacts

Website

2-3 October 2023,
3rd Meeting of the Working Party on
Risk Management,
Hybrid meeting

Eeva LEINALA
Marie-Ange BAUCHER

[http://oecd.org/env/ehs/risk-
management](http://oecd.org/env/ehs/risk-management)

12-13 February 2024
Global Forum on PFAS,
Hybrid event

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

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

Substitution of harmful chemicals

Three reports were published in 2023 to support substitution of chemicals of concern on:

A workshop was held on 20-21 September 2022 on government/regulatory approaches put in place by countries to incentivise and lead substitution or risk reduction and where governments can learn from non-regulatory approaches. This includes discussion of lessons learned and where countries have seen their policy approaches successfully supporting substitution. Three reports were developed in the framework of the workshop:

- Economic instruments to incentivise substitution of chemicals of concern;
- Lessons Learned from Third-Party Approaches that Support Substitution of Chemicals of Concern;
- A Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern – 2nd edition.

A project was initiated to develop a Landscape Study on Additional Attributes Beyond Safer for Chemical Selection and Substitution. The study will examine 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 content of the SAAToolbox was transferred to a new platform using Power BI, which includes new visual and search functionalities.

Sustainable plastics

A report from a Workshop on Flexible Food-Grade Plastic Packaging organised in 2022 was published in Q1 2023.

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.

Recent publications

[No. 79](#)

Economic instruments to incentivise substitution of chemicals of concern – a review

[No. 78](#)

Lessons Learned from Third-Party Approaches that Support Substitution of Chemicals of Concern

[No. 77](#)

Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern – 2nd edition

[No. 76](#)

OECD Workshop report on Flexible Food-Grade Plastic Packaging

[No. 74](#)

Government Risk Management Approaches Used for Chemicals Management

Forthcoming events

2-3 October 2023
3rd Meeting of the Working Party
on Risk Management

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Website

<https://www.oecd.org/chemicalsafety/risk-management/>

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. 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. 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. The RCEG started to work on two more projects that involve the revision of the TG 506 on stability of residues in stored commodities and the revision of the Guidance Document on pesticide residue analytical methods.

OECD Network on Illegal trade of Pesticides

The **OECD Network on Illegal trade of Pesticides (ONIP)** met on 27 February 2023 to discuss the possible revision of the Best Practice Guidance to identify illegal trade of pesticides (BPG), continued ONIP activities in the SAICM context and possibilities for future ONIP activities. ONIP also convened a dedicated session about online illegal trade, an area of increasing concern for ONIP.

Expert Group on the Electronic Exchange of Pesticide Data (EGEPPD)

The **Expert Group on Pollinator Testing and Assessment (EG-PTA)** met within the context of the 15th International Symposium of the Bee Protection Group of the International Commission for Plant Pollinator Relationships (ICPPR), on 18-21 October 2022. During the meeting the EG-PTA had an initial discussion on future activities and decided on their mandate, which was subsequently agreed by the 38th Meeting of the Working Party on Pesticides.

Drone Subgroup

The **Drone Subgroup** advising an Industry Task Force that is implementing 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. The data will contribute toward the development of new Unmanned Aerial Vehicle (UAV) focused models that may be considered by regulatory authorities to assess the risks associated with applying pesticides using drone technology. Many members of the Subgroup participated in May 2023 in the Conference and workshop: applying pesticides using drones of the Chemicals Regulation Division of the UK's Health Safety Executive supported by the OECD Co-operative Research Programme. The Workshop provided an opportunity for stakeholders to share information on work to address the OECD Report recommendations. The Conference and workshop: applying pesticides using drones was held by the Chemicals Regulation Division of the Health Safety Executive of the United Kingdom supported by the OECD Co-operative Research Programme: Sustainable Agricultural and Food Systems (CRP) in May 2023 [<https://solutions.hse.gov.uk/health-and-safety-training-courses/crd-conference-and-workshop-applying-pesticides-using-drones?cg=31600>].

The Conference and Workshop provided an opportunity for stakeholders to share the latest thinking and to help develop a recommended approach to assessing and mitigating the risks associated with the application of pesticides by drone. Drones are recognised as a technology that affords an opportunity to apply pesticide in a more sustainable way than traditional methods, but there is a need to improve understanding of the risks to human health and the environment associated with their use. The event contributes to the work of the OECD Working Party on Pesticides Drone/UASS Subgroup, which is overseeing a programme of work designed to develop a risk assessment framework that can be recommended to regulatory authorities, addressing the OECD the recommendations in the [Report on the State of the Knowledge – Literature Review on Unmanned Aerial Spray Systems in Agriculture](#) (November 2021).

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. 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 is expected to prepare 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. The guidance documents on bacteriophages was published in November 2022 and the one on baculoviruses is under WPP review. A revision of the Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products 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 is scheduled to be published in Q3 2023.

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. 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 is expected to prepare 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. The guidance documents on bacteriophages was published in November 2022 and the one on baculoviruses is under WPP review. A revision of the Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products 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 is scheduled to be published in Q3 2023.

Ad Hoc Expert Group on RNAi-based Pesticides

The **Ad Hoc Expert Group on RNAi-based Pesticides** finalised the Working Document on Human Health Risks from the Application of sprayed or externally applied dsRNA-Based Pesticides and is scheduled to be published in Q3 2023.

Expert Group on Minor Uses (EGMU)

The **Expert Group on Minor Uses (EGMU)** is finalising the Guidance Document on addressing minor uses.

Recent publications - Series on Pesticides

[No. 108](#)

Guidance Document for the Regulatory Framework for the Microorganism Group: Bacteriophages



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 events

27 February – 3 March 2023,

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

28- 29 September 2023 (tentative)

**Meeting of the Expert Group on the Electronic
Exchange of Pesticide Data, face-to-face (& hybrid)
or virtual to be determined**

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Website

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.

Two Guidance Documents, on the efficacy of insecticides against bed bugs and tropical ants respectively, have been published in February 2023, in both the Series on Biocides and the Series on Testing and Assessment.

The Working Party on Biocides (WPB) approved the revised Guidance on Principles for Claim Development of Treated Articles (Series on Biocides No. 15) in September 2022, which was amended to include information about insecticides claims. The revised guidance was published on 2 June 2023.

The WPB has developed a first draft of a document on general principles for a sustainable management of harmful organisms.



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. 20](#)

Guidance Document on Laboratory and Simulated-use Testing the Efficacy of Baits and Repellents against Tropical Ants for Indoor Use.

[No. 19](#)

Guidance Document on Laboratory Product Performance Testing Methods for Bed Bug Biocide Products.

[No. 15](#)

Guidance on principles for claim development of treated articles.

Forthcoming event	Contacts	Website
<p>18-19 September 2023 7th Meeting of the Working Group on Biocides? Leiden, The Netherlands</p>	<p>Sylvie PORET</p> <p>Leon VAN DER WAL</p> <p>Paula VICENTE BENITO</p>	<p>www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm</p>

**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).

A new Decision-Recommendation concerning Chemical Accident Prevention, Preparedness and Response and its supporting technical guidance the Third Edition of the Guiding Principles on Chemical Accident Prevention, Preparedness and Response, were published in June 2023.

- The Decision-Recommendation was adopted by the OECD Council at Ministerial level on 8 June 2023. This legal instrument sets out key high-level elements to support the development of a chemical accidents programme covering the fields of prevention, preparedness, and response. It addresses critical issues such as the identification of hazardous installations, the development of safety objectives and a control framework, land-use planning and siting of hazardous installations, investigation of accidents and the development of lessons learnt, communication and engagement with the public, transboundary accidents, and cooperation and technical assistance. The Decision-Recommendation is a consolidation and update of three original OECD legal instruments from 1988 and 2004.
- The Guiding Principles sets out detailed technical guidance for industry and public authorities for the safe planning and operation of installations where there are hazardous substances. It covers the wide range of measures necessary to ensure effective chemical safety. This third edition reflects on lessons learnt from major accidents worldwide since the previous edition in 2003, as well as emerging issues such as those linked to climate change adaptation, and response to unexpected crisis.

Work continues to finalise two documents: the joint OECD/EU-JRC/UN Guidance on Managing Natech Accident Risk: A Guide for Senior Leaders in Industry and Public Authorities; the Guidance on the Benefits of Regulations for Chemical Accidents Prevention, Preparedness and Response. Publication for both documents is planned for 2024.

Two online seminars were organised on 27-28 June 2023 for delegates to exchange on challenges in the management of hazardous substances at port areas. The first seminar provided examples from different ports focusing on how these ports are run, the different types of regulatory regimes operative at different points of the transport flow, the key risk management elements that seem to cause concern, and good practice examples for management of risks. The second seminar provided information on chemical accidents management, different types of chemical accidents occurred at port areas and lessons learnt, and the particular challenges in ports for emergency preparedness and response.

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 event

Contacts

Website

**15 September 2023,
Joint EU-OECD webinar on
Hydrogen Fuel Risks**

Bertrand DAGALLIER
Marie-Ange BAUCHER

[www.oecd.org/chemicalsafety/
chemical-accidents/](http://www.oecd.org/chemicalsafety/chemical-accidents/)

**24-26 October 2023
33rd Meeting of the Working Party
on Chemical Accidents**

Christiana OLADINI-JAMES

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. The draft scoping document was circulated in the WP-PRTRs in Q1 2023. 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.

To promote the use of PRTR data, the WP-PRTRs compiled information on the Use of PRTR Data and Tools for their presentation. The collected information is presented in a newly developed web database and summarised in a report, which were published in May 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.

Regarding capacity-building, an online workshop on establishing PRTRs for Kenya was conducted in January 2023.

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	Contact	Website
29-31 January 2024, 7th Meeting of the Working Party on PRTRs, OECD, Paris	Koki TAKAKI	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 that already have BAT-based policies and provide assistance to governments that seek to adopt BAT-based permitting. The Expert Group on BAT, which meets face to face once a year, provides the necessary advice to implement the project.

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

- Activity 7, a cross country analysis of BAT Reference Documents (BREFs) and associated emission levels for Iron & Steel production, Paper & Pulp production and Waste Incineration. This report intends to promote international benchmarking and increase the potential for harmonisation of BAT-AELs across countries.
- Activity 8, capacity building workshops on BAT policies. The Secretariat offers an introduction to BAT, followed by tailor-made workshops in the areas of BAT. A first workshop is planned in Vietnam in October 2023.
- Activity 9, a BAT study on emerging technologies. This report will assess how countries identify innovative technologies for installations, and manages these emerging technologies that have the potential to become BAT. A network of technology providers will be developed.

[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 BREF 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.

Recent publications - Series on BAT

[No. 72](#)

Best Available Techniques (BAT) to Prevent and Control Mercury Releases to Land and Water Series on Risk Management

Forthcoming event	Contacts	Website
<p>15 June 2023 Webinar on BAT</p>	<p>Berrak ERYASA Koki TAKAKI</p>	<p>oe.cd/BAT</p>

**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.

The Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) met in April 2023 and agreed on next steps for preparing several consensus documents: Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants (led by the WP-HROB Bureau); revised Biology of wheat (led by Australia and United States), both expected for publication in 2023; biology of mosquito *Anopheles gambiae* (leads: Australia, AUDA-NEPAD and AFSI); Photoautotrophic micro-algae for biomass production (leads: Canada and United States). In addition, two proposals for new projects on the biology of mosquito 1) *Anopheles Albimanus* and 2) *Anopheles Stephensi* were agreed (leads: United Kingdom, Brazil and AUDA-NEPAD).

Three projects jointly developed by the WP-HROB and the Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) 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 for most 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; and
- The proposal on “Safer-Innovation-Approach” in biotechnology, which was formally approved by the WP-HROB in follow-up to a 2 year pilot project.

The OECD Product Database, containing information on genetically-engineered (G.E.) plant varieties approved for being cultivated or used in foods and feeds, continued to be completed and updated. A total of 393 entries of 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. 42:](#) December 2022, Biotechnology Update' / ICGB Newsletter - OECD Internal Co-ordination Group on Biotechnology

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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www.oecd.org/biotrack

2 • The Global Forum on Biotechnology

The Global Forum on Biotechnology, established in 2010, is one of 16 Global Forums created by OECD Committees. Global Forums are generally not official OECD bodies, but are best described as broad communities or networks of stakeholders in the areas of responsibility of one or more Committees. OECD Committees have an interest in hearing the views of these stakeholders, but their capacity to accommodate (non-Member) partners as participants is limited.

Collaboration continues with partner countries and international organisations involved in biosafety, in particular on the occasion of the annual meetings of the OECD Working Parties i) on the Harmonisation of Regulatory Oversight in Biotechnology, and ii) for the Safety of Novel Foods and Feeds in April 2023. Due to resource shortage, no support could be provided to non-member delegates for their participation this year. However, these events were attended (mostly online) by delegates from Brazil, Croatia, South Africa, Argentina, Paraguay, Philippines, Uruguay, the African Biosafety Network of Expertise (AUDA-NEPAD), and other observer Organisations.

Thanks to this co-operation developed under the umbrella of the Global Forum on Biotechnology, experts of non-member economies contribute to on-going projects by drafting documents, providing comments, and sharing information on their latest biosafety and novel food/feed safety developments in the published annual 'tour-de-table' documents. In addition, several Partner countries share information on approved GE plant varieties on regular basis for inclusion into the OECD BioTrack Product Database.

Contact

Bertrand DAGALLIER



3 • 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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Website

www.oecd.org/biotrack

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- ▶ www.oecd.org/ehs/publications

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

- ▶ **Email:** ehscont@oecd.org
- ▶ **Fax:** +33 (0)1 44 30 61 80

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
Hazard Assessment	www.oecd.org/env/hazard
Mutual Acceptance of Data (MAD)	www.oecd.org/ehs/mad
New Chemicals	www.oecd.org/env/newchemicals
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/
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.

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