Chemical Safety and Biosafety Progress Report

No. 38
April 2019

OECD
BETTER POLICIES FOR BETTER LIVES

Contents

I. Provision of Knowledge and Information

1. Methodologies for Hazard Assessment

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

Integrated Approaches to Testing & Assessment

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

Four case studies in the third review cycle (2017) were published along with a considerations document highlighting the lessons learned stemming from the case studies.

The following two case studies were discussed at the 4th meeting of the project team on 27 November 2018 and were agreed by the project members to be published. The considerations document from the review experience of the case studies is under development.

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

The following six case studies have been nominated for the 5th review cycle in 2019:

- Acute transcriptomic dose-response modelling for protective estimates of chronic points of departures for estrogenic chemicals in fish [Canada]
- Case study on Parabens based on chemical safety assessment workflow [BIAC – Cosmetics Europe]
- Case study on Phenoxyethanol based on chemical safety assessment workflow [BIAC – Cosmetics Europe]
- Case study on caffeine based on chemical safety assessment workflow [BIAC – Cosmetics Europe]
- Case study for assessing hepatotoxicity of Chlorobenzenes by read-across [BIAC - Kao]
- Case study for assessing hepatotoxicity of p-Alkylphenols by read-across [BIAC - Kao]

The project team also discussed a draft Overview Document on Concepts and Available Guidance for Integrated Approaches to Testing and Assessment (IATA) and their Components in order to serve as an overarching reference document for IATA and give an overview of existing guidance on IATA, IATA components and relating cross-cutting topics. It is expected that the document will be finalised in Q2 of 2019.

In addition, the project team had a joint meeting with the QSAR Toolbox Management Group to discuss the following topics for the QSARs in the context of a defined approach (DA) for skin sensitisation:

- Applicability domain of DAs
- Validation and transparency for QSAR prediction
- Instructional information for QSAR in the context of DAs
- GLP for QSAR in the context of DAs

Weight of evidence

This project aims to develop a document with Guiding Principles for Establishing Weight of Evidence for Chemical Assessment. The document will describe basic guiding principles to formulate a weight of evidence (WoE) for both the prioritisation and assessment of chemicals under different regulatory and non-regulatory contexts. The document is expected to be submitted to the Working Party on Hazard Assessment for comments and approval in June 2019.

Physiologically Based Kinetic Models

The development of the guidance document on the characterisation, validation and reporting of physiologically based models for regulatory applications is advancing. This project is a joint initiative between the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics. A face-to-face meeting of the expert group took place in September 2018 to discuss the case studies and progress with the drafting of the guidance document. It is expected that the document will be submitted to the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics for comments and approval in June 2019.

Priority Setting

The development of a document to capture international best practices for identification of priorities for risk assessment was initiated in January 2018. This project commenced with a survey of priority setting frameworks and tools used in countries. The survey data is being analysed to draft a report.

QSAR Toolbox

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

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

A face-to-face meeting of the QSAR Toolbox management group was held on 29-30 November 2018. The QSAR Toolbox management group agreed to principles and a process for developing and donating new extensions including QSARs, profilers and databases and the concept of an external repository for additional extensions. In addition, the participants agreed to explore where updating or creation of guidance for QSARs would be beneficial.

A survey on the QSAR Toolbox was conducted to further understand the breadth of its current usage. This survey focused on the extent of the OECD QSAR Toolbox usage and the collection of case studies (examples) of OECD QSAR Toolbox application in a regulatory context.

The survey consisted of two set of questions:
o Part 1: Case studies (examples) of the OECD QSAR Toolbox application in a regulatory context
o Part 2: General questions regarding use of the OECD QSAR Toolbox

An overview of the results was reported at the face-to-face meeting in November. It was concluded that the QSAR Toolbox is used in a broad regulatory context covering industrial chemicals, cosmetics, biocide, pesticide, medical devices etc. and that there is a high level of overall satisfaction with regards to the Toolbox from survey respondents along with suggestions for improvement of functionalities and databases.

Adverse Outcome Pathways Knowledge Base (AOP-KB)

The European Commission – DG Joint Research Centre (JRC), the US Environmental Protection Agency and the OECD Secretariat work together on the development of the AOP Knowledge Base (AOPKB) v2.0. The project will proceed in three phases: a) Requirements capturing, b) System specifications, and c) System development. The first phase is led by the JRC and the study/survey is anticipated to deliver results in Q4 2019.

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

Combined Exposures to Multiple Chemicals

Under the Working Party on Hazard Assessment and the Working Party on Exposure Assessment a document was published in December 2019 on Considerations for assessing the risk of combined exposures to multiple chemicals.

Forthcoming Events

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

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

Contacts

Eeva LEINALA
Magdalini SACHANA
Masashi HORIE

AOP-KB & Effectopedia:
Anne GOURMELON
Magdalini SACHANA

Websites

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

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

http://aopkb.org/

https://www.effectopedia.org/

2. Methodologies for Exposure Assessment

Risk to human health and the environment posed by chemicals is determined by chemical-specific hazard properties and the extent of exposure to chemicals. OECD assists member countries in developing and harmonising methods for assessing the exposure of chemicals to humans and the environment. Children are more vulnerable than adults to environmental hazards, such as those presented by chemicals, owing to their different physiological, metabolic factors and activity levels. OECD has initiated an activity to help support governments assess the risk of chemicals to children.

Estimating the release of chemicals

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

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

The draft ESD on plastic additives was discussed at the Second Meeting of WPEA in September 2018, and is expected to be finalised in Q2 2019.

In addition, the WPEA published in September 2018 a matrix on the relationship between lifecycle stage and use descriptors to analyse similarities and differences between the OECD ESDs and the EU Specific Environmental Release Categories (SpERCs).

Combined exposure to multiple chemicals

Under the Working Party on Hazard Assessment and the Working Party on Exposure Assessment a document was published in December 2019 on Considerations for assessing the risk of combined exposures to multiple chemicals.

Exposure to humans and the environment

The WPEA developed a "Product Release and Exposure Data Warehouse", led by the United States, designed to house existing data on releases from, and exposures to, chemicals used in commercial and consumer end products. The database (Access file) and a user guide is available from http://www.oecd.org/chemicalsafety/risk-assessment/product-release-and-exposure-data-warehouse.htm

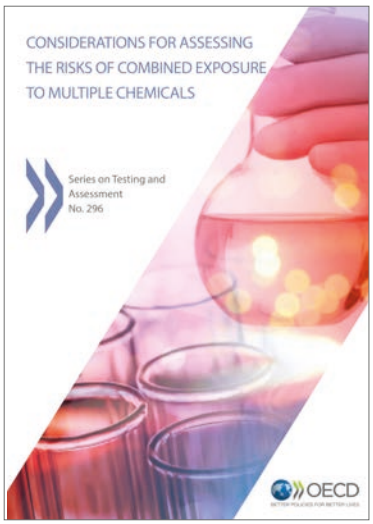
The WPEA is also discussing issues around children's health with two projects. The first project aims to develop a decision tree to determine the need for specific exposure assessments for children using relevant case studies. This decision-tree is expected to be published in Q3 2019. The second project aims to develop an in silico exposure tool that facilitates estimation of oral exposures of children via the mouthing of objects and to develop an associated guidance document. This tool and document is expected to be finalised in Q2 2019.

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

The WPEA is also working on the development of a biomonitoring database on chemicals measured in humans. The project is managed in close collaboration with the EU's IPCheM project with the aim to integrate and disseminate the biomonitoring data through IPCheM.

After the launch of a project on dermal exposure and absorption in June 2018, the WPEA approved the scope and outline of this project in September 2018, and the project team started the collection of relevant data.

Recent publications in the Series on Testing and Assessment



No. 296:
Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals

No.295:
OECD Product Release and Exposure Data Warehouse

No. 294:
Matrix Between Emission Scenario Documents (ESDs) and Specific Environmental Release Categories (SpERCs)

Forthcoming Event

13-14 June 2019
OECD, Paris
3rd Meeting of the Working Party on Exposure Assessment,

Contact

Takaaki ITO

Website

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

3. Approaches for determining the Safety of Manufactured Nanomaterials

On the nano-scale, typically within the range of 1-100 nm in at least one dimension, the properties of materials can be different from those on a larger scale. The novel properties of nanomaterials can be applied to diverse application areas, such as in medicine, environment and energy production. Manufactured nanomaterials are already used in a number of commercial applications; which raises questions regarding potential unintended hazards to humans and the environment and whether nanomaterials need special measures to deal with potential risks. There is a need for a responsible and co-ordinated approach to ensure that potential safety issues are being addressed at the same time as the technology is developing. Therefore, the OECD Working Party on Manufactured Nanomaterials (WPMN) was established to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials. Its objective is to assist countries in their efforts to assess the safety implications of nanomaterials.

The applicability of Test Guidelines for nanomaterials continues to be a major concern of the work of the WPMN. Six projects have been submitted for consideration by the WNT in April 2019. In addition, the WPMN agreed to work on three new projects related to testing manufactured nanomaterials and addressing: i) the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies; ii) the determination of dissolution rates of nanomaterials in environmental media (dynamic method); and iii) supplementary guidance for the use of Test Guidelines 201, 202 and 203 for the determination of the ecotoxicity of MNs. Work will continue to complete the compilation of information on biopersistent/biodurable manufactured nanomaterials, as well as on the development of a project proposal to address the toxicokinetics of manufactured nanomaterials. In addition, the WPMN identified a number of issues relevant for the development of all the TGs for nanomaterials (i.e. updating the *Guidance on Sample Preparation and Dosimetry* and the section on nanomaterials in the *Guidance on Grouping*).

The WPMN has completed the two projects related to the physical chemical properties of nanomaterials: i) *Physical-Chemical Decision Framework to Inform Decisions for Risk Assessment*; and ii) *Guiding Principles for Measurements and Reporting for Nanomaterials: Physical Chemical Parameters*. The WPMN agreed that these document should be declassified as living documents and that end users should have opportunities to provide feedback. The purpose of these documents is to identify the appropriate methods for characterising physico-chemical endpoints for different manufactured nanomaterials, or categories of nanomaterials, for regulatory purposes. The three areas addressed are: i) Nanomaterial Identification and Information Gathering; ii) Physicochemical Properties for Exposure and Fate Assessment; and iii) Physicochemical Properties for Hazard Assessment. This document also aims to facilitate progress for the development of guidance for the categorisation of nanomaterials. To finalise the development of these document, the OECD hosted a meeting on Physical Chemical Properties of Nanomaterials in September 2018, which benefited of the participation of experts from the EU H2020 projects Nanoreg2 and Gracious.

Regarding the work on the risk assessment and regulatory programmes, the WPMN completed and published the document *Investigating the Different Types of Risk Assessments of Manufactured Nanomaterials*, which gathered information concerning risk assessment approaches in different countries. The purpose of this document was to better understand the current situation and identify common areas of work that can assist countries in further implementing the OECD Council Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials [C(2013)107]. Work continues to update the 2012 document on *Important Issues on Risk Assessment of Manufactured Nanomaterials*.

Revisions should be completed towards the end of 2019. Lastly, progress has been made with the project on "Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation", which is being led by Canada. A workshop to will be held in September that should gather the expertise from the OECD Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST), as well as from experts participating at relevant EU H2020 projects.

As for the work on Exposure Measurement and Exposure Mitigation, the objective of this activity is to exchange information on (or develop) guidance for exposure measurement and mitigation. The WPMN is working on three complementary projects: i) Assessing the global readiness of regulatory and non-regulatory models for assessing occupational exposure to MNs; ii) Compilation of Available Tools and Models Used for Assessing Consumer Exposure to MNs; and iii) Compilation of Available Tools and Models Used for Assessing Environmental Exposure to Manufactured Nanomaterials. These projects aim to evaluate the performance of available exposure models to estimate nanomaterial exposure for three target population groups: workers, consumers and the environment. In order to conduct the evaluations of the models, the WPMN is collecting/generating exposure data in a structured format. At the WPMN held in February 2019, the group discussed ways to structure the exposure data so that it can be collected by existing OHTs, as well as potential areas of work to be considered in collaboration with the Working Party on Exposure Assessment.

The WPMN continues the implementation of the project " Moving towards a 'Safer Innovation Approach' for more sustainable NMs and nano-enabled products: Overview of existing risk assessment tools and frameworks, and their applicability in industrial settings" led by France, the Netherlands and BIAC. It is expected that the outcomes of this project can further the knowledge to anticipate regulatory challenges posed by innovations, in this case from nanomaterials and nano-enabled products.

Recent publications - Series on Manufactured Nanomaterials

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

No. 88
Investigating the Different Types of Risk Assessments of Manufactured Nanomaterials

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

Forthcoming Event

10-12 September 2019
OECD Paris,
Workshop on Advancing Adverse Outcome Pathways (NanoAOP) Development for Nanomaterial Risk Assessment and Categorisation

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

16-19 June 2020
20th Meeting of the Working Party on Manufactured Nanomaterials, 19-22 February 2019 Paris, France

Contacts

Peter Kearns

Mar Gonzalez

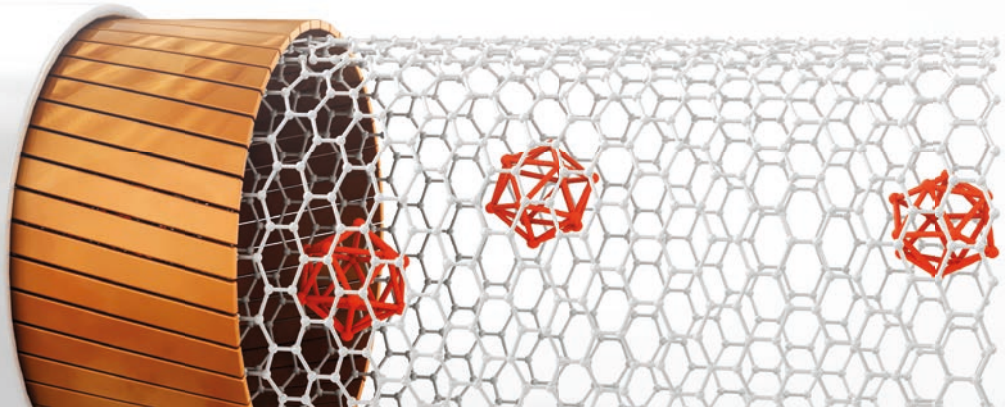
Tatsuki Izawa

Bertrand Dagallier

Emily Seftel

Website

www.oecd.org/chemicalsafety/nanosafety/



4 • Notification & Reporting Tools

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

Harmonised Templates for Reporting Test Summaries

The work continued to adapt the OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) to new or revised Test Guidelines. Four OHTs on health effects (dealing with acute toxicity–inhalation, acute toxicity–dermal, repeated-dose toxicity–inhalation, and genetic toxicity in vivo) and one OHT on biotic system effects (toxicity to micro-organisms) were updated and published on the website in August 2018. A new template on dispersion stability of nanomaterials was developed and added to the Series on degradation/accumulation (environmental fate and behaviour) in December 2018.

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

In a joint effort by ECHA and the OECD, some technical and editorial improvements were brought to the OHTs. Among specific changes, a new field 'Confidential details on test material' was added to the 'Test material information' section of each template. The OHTs on toxicity to soil microorganisms, on specific investigations: other studies, and on emissions from preservative-treated wood benefitted also from targeted improvements. The Series of OHTs on use and exposure Information was updated to align them with internationally agreed 'Article categories', 'product codes' and 'Technical function' phrase groups. The full set of revised templates was published on the OECD website in December 2018.

Contact	Website
Bertrand DAGALLIER	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.

The IUCLID User Group Expert Panel met in October 2018 and discussed continuing activities and planned next steps for future IUCLID development (2018-2023) and presented how IUCLID is being used in different jurisdictions. In particular, Australia showcased the customisation of IUCLID for use in its reformed assessment scheme.
A new version of IUCLID 6 (v3) was released in October 2018. This new version includes a new user interface that requires only a standard web browser and updated formats to include the latest OECD Harmonised Templates, incorporate specific elements for microorganisms datasets, support of European Poison Centres notifications and Australian Industrial Chemicals assessment.

Recent publications - IUCLID

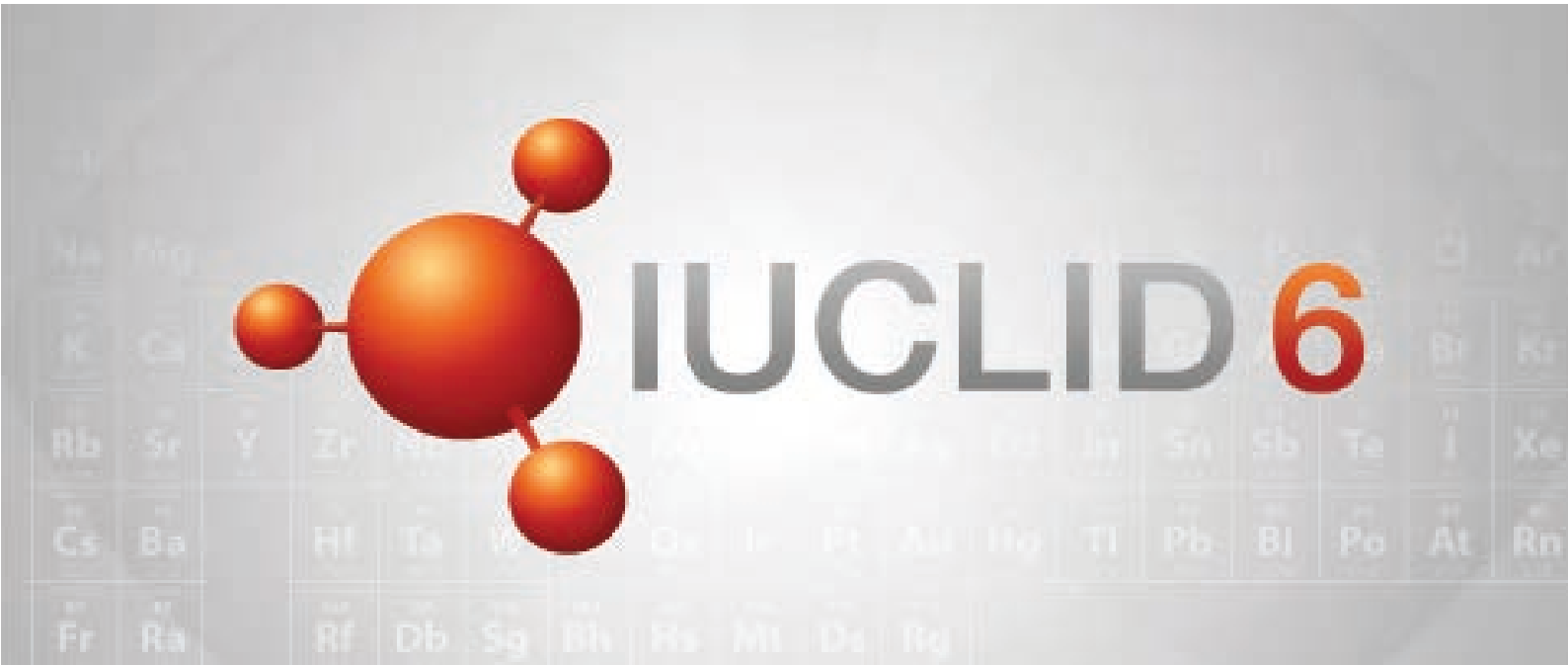
The OECD released in February 2019 a document, Customisation Opportunities of IUCLID for the Management of Chemical Data, outlining the customisation opportunities for IUCLID 6 and giving an overview of what IUCLID offers to regulatory bodies and industry for the management of data on chemicals.

Forthcoming Event

25-26 September 2019
OECD Paris,
Meeting of the UCLID User Group Export Panel.

Contact

Sally DE MARCELLUS



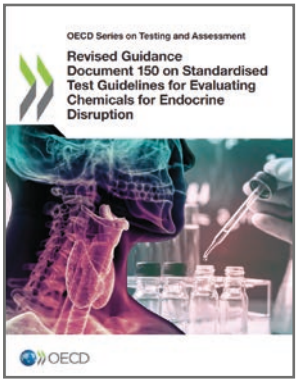
II. Assistance with Governance

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 second half of 2018 and early 2019 have been busy with a large number of expert and advisory group meetings, to advance projects in the area of endocrine disrupters testing methods, skin and eye irritation and phototoxicity test methods as well as skin sensitisation testing approaches. Several of the resulting draft documents will be submitted for approval at the upcoming meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) in April 2019.

Endocrine Disrupters Testing and Assessment (EDTA AG) - 22-23 October 2018



The meeting was an opportunity for information exchange and review of on-going activities at OECD and in countries. The Secretariat presented the just published Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption (GD 150); in addition to updating the content, efforts have been made to improve the user friendliness of what is a very large document. The EDTA AG also reviewed some of the draft chapters of the *Detailed Review Paper on Retinoid Pathways* prepared by Sweden, and elaborated a plan towards completion of other chapters in 2019. The current status of the EURL-ECVAM project on *in vitro* methods for thyroid disruption was presented; about 17 candidate assays are considered for further standardisation and grouped by key event along the thyroid pathway, as presented in the OECD Scoping Document (No. 207 in the Series on Testing and Assessment).

Workshop on the Use of Existing Data and Systematic reviews for Endocrine Disrupting Chemicals - 24 October 2018

A workshop was organised to discuss the use of existing data for evaluating endocrine disrupting chemicals, "Level 1" of the OECD conceptual framework. The workshop included seven invited speakers to introduce the principles of systematic literature review and best practices, software tools to facilitate the review process, application of existing data for evaluating endocrine disrupters, and development of new tools using existing data. The workshop was attended by over 100 registered participants, primarily from the EDTA and VMG-Eco expert groups. Participants were asked to provide input on member country experiences with systematic review and if there is a role for OECD to play in facilitating standardised approaches to systematic review or sharing information resulting from reviews. The workshop was well received and participants were strongly supportive of OECD helping to develop standardised protocols for systematic review in the context of endocrine disruption. The US EPA's IRIS program offered to assist in this effort, as they have a protocol under development that could be easily adapted for this purpose. As a first step, the secretariat will compile resources discussed during the workshop and make links available on the OECD website. Further efforts in this area may be directed by proposals from member countries.

The OECD Endocrine Disrupting Chemicals project 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.

Ecotoxicity Testing (VMG-eco) - 25-26 October 2018

The meeting discussed in particular two Test Guidelines: the TG 203, which is being modernised; but the original purpose of the project to introduce 'moribundity' in lieu of 'lethalitý' has been compromised because member countries could not reach a consensus on clinical signs for the new endpoint, despite several years of discussions. The VMG-eco also discussed a draft new Test guideline on the Xenopus Embryo Thyroid Assay (XETA), which will be submitted for approval to the WNT in April 2019; this assay has the capacity to identify potential thyroid active chemicals in a short period of exposure of transgenic tadpoles (i.e. 96-h).

Non-Animal testing (VMG-NA) - 6-8 November 2018

The meeting discussed the development of a new *in vitro* androgen receptor transactivation Test Guideline, led by Korea. The project was relatively mature and also provided an opportunity for the VMG-NA Study Management Team to provide input on the project in the margins of the main meeting. The meeting was also an opportunity for information exchange between experts on ongoing activities in their respective countries. Many of these activities may lead to future OECD projects. For example, EURL-ECVAM provided updates on developments of *in vitro* thyroid methods and the validation of an androgen receptor CALUX assay, which when completed, will be part of an OECD performance based test guideline including the current guideline method and method in the validation process by Korea.

Skin and Eye Irritation and Phototoxicity testing - 15-16 November 2018

The Expert group discussed two new draft Test Guidelines using in vitro test systems to identify chemicals not requiring classification according to the UN Globally Harmonised System. Draft updated Test Guidelines 431 (*in vitro* skin corrosion), 439 (*in vitro* skin irritation), 492 (*in vitro* eye irritation) were also discussed for the inclusion of similar *in vitro* methods to augment the portfolio and availability of *in vitro* methods across OECD member countries. Finally, a new *in vitro* Test Guideline for phototoxicity testing was reviewed (the Reactive Oxygen Species assay), as well as the existing TG 432 (3T3 NRU) for phototoxicity testing. All these new or updated TGs will be submitted to the WNT for approval in April 2019.

Joint meeting of the IATA Case Studies team and QSAR Toolbox Management Group to discuss QSARs in the context of defined approaches for skin sensitisation - 28 November 2018

A joint session of the IATA case study and QSAR Management groups was convened to discuss considerations for *in silico* data included in defined approaches (DAs) for skin sensitisation that would be covered by the OECD system of Mutual Acceptance of Data (MAD). Experts were asked to provide input on defining the applicability domain of DAs that includes *in vitro* and *in silico* information sources, and on the principles of validation, transparency and quality assurance standards for in silico models. Key recommendations from the group emphasised that existing guidance (e.g. OECD GD 49 and GD 69 and published guidance documents from the cosmetics and pharmaceutical sectors) can be used for the near term, but there is more work needed on model quality standards and good modelling practices needed in the QSAR world. There was also a recognition that there should be flexible levels of transparency for different users, but at a minimum, the algorithm, training set, and applicability domain should be available to reviewers and regulators upon request. The group agreed that Good Laboratory Pr&ctice principles are not applicable to *in silico* data, but rather, the data should follow a documentation quality standard. The group recommended that a description of the in silico model using the OECD QMRF (QSAR Model Reporting Format) and a protocol for generating predictions could constitute a documentation standard similar to a Test Guideline and a QPRF (QSAR Prediction Reporting Format) could be analogous to a test report for in silico data included in a DA. The newest version of the OECD QSAR ToolBox will include an automated workflow for predicting chemicals that meet specified criteria for analogues, and for those that do not, a standardised workflow will be provided to assure reproducible predictions for other chemicals.

Defined Approaches (DAs) for Skin Sensitisation - 6-7 December 2018

The Expert Group discussed issues raised during the first commenting round on the draft new Guideline and supporting documents, organised in October 2018. The Expert Group on Defined Approaches for Skin Sensitisation is composed of skin sensitisation experts, test method developers, regulators, and statisticians. The purpose of the meeting was to identify ways to improve the presentation of all analyses performed so far and review the utility of the first set of DAs included in the current draft Guideline. The main issues under discussion currently include the traceability and transparency of prediction model/software programme that are part of DAs, the definition of the applicability domain of the DAs, the analysis of uncertainty/reproducibility, and the role of human data in determining the performance of individual DAs. The set of draft documents will be re-circulated in April 2019 for review. The WNT will discuss in April the best course of action in 2019.

Ecotoxicity and fate testing of nanomaterials - 13-14 December 2018

A meeting of the Joint WNT/WPMN expert group on Ecotoxicity and Fate of Nanomaterials was convened to discuss and review the nano-related projects that are currently underway within the WNT programme of Work (Fate and Ecotoxicity). The following projects were discussed in detail: i) Guidance Document (Decision-Tree) on agglomeration and dissolution behaviour of NMs in aquatic media; ii) Test Guideline for the removal of NMs from wastewater; iii) Guidance Document on assessing the apparent accumulation potential for NMs; and iv) Guidance Document to support implementation of TG 312 for the safety testing of NMs. In addition, the experts had an opportunity to discuss a new project proposal on Aquatic (Environmental) Transformation of Nanomaterials submitted by Austria. A number of synergies were identified and the timeline for completion of these projects is now defined.

Intellectual Property issues in OECD Test Guidelines - 13-14 February 2019

The OECD Expert Group finalised a document on Guiding Principles for the distribution and availability of protected elements contained in OECD Test Guidelines. These Guiding Principles will be instrumental to communicate the need of the OECD Test Guidelines Programme to test method developers wishing to propose innovative techniques containing protected elements. The document elaborates on terms and conditions (Fair, Reasonable and Non-Discriminatory) that developers will have to adhere to when proposing a new test method. The Guiding Principles will be submitted for approval to the WNT in April 2019. The Expert Group also reviewed case studies that illustrate practical issues encountered by key players when dealing with protected or restricted elements proposed in test methods. It is anticipated that this EG will continue to serve as an advisory group from time to time, based on issues that arise.

Recent publications - Series on Testing and Assessment

Series on Testing and Assessment

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

No. 292
Guidance Document on Use and Development of Tier-2 Laboratory Based Tests Used to Substantiate Claims for Efficacy of Biocide Treated Articles.

No. 286
Guidance Document on Good *In Vitro* Method Practice.

No. 285
Feasibility Study for Minor Enhancements of TG 414 with ED Relevant Endpoints.

No. 284
Report of the Peer Review of the validation of the Local Lymph Node Assay: BrdU-FCM (LLNA: BrdU-FCM) test method.

No. 283
Report of the validation study of the Local Lymph Node Assay BrdU-FCM (LLNA: BrdU-FCM) test method.

No. 282
Report of the peer-review of the validation of the LabCyte Cornea-Model 24 eye irritation test.

No. 281
Validation Report of the two new Test Guidelines on determination of *in vitro* intrinsic clearance using cryopreserved rainbow trout hepatocytes or liver S9 sub-cellular fractions.

No. 280
Guidance on Determination of *in vitro* intrinsic clearance using cryopreserved rainbow trout hepatocytes (RT-HEP) or liver S9 sub-cellular fractions (RT-S9) from rainbow trout and extrapolation to in vivo intrinsic clearance

No. 278
Report of the OECD Workshop on Intellectual Property Issues in OECD Test Guidelines.

Recent publications - Series on Adverse Outcome Pathways

Series on Adverse Outcome Pathways

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

No. 9
Adverse Outcome Pathway on Androgen receptor agonism leading to reproductive dysfunction (in repeat-spawning fish)

No. 8
Adverse Outcome Pathway on chronic binding of antagonist to N-methyl-D-aspartate receptors during brain development leading to neurodegeneration with impairment in learning and memory in aging

No. 7
Adverse Outcome Pathway on Inhibition of the mitochondrial complex I of nigro-striatal neurons leading to parkinsonian motor deficits

Forthcoming Events

5-6 March 2019
OECD Paris,
Meeting of the Expert Group on Developmental Neurotoxicity

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

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

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

4 October 2019 (TBC)
OECD Boulogne,
Meeting of the Joint WNT-WPMN Expert Groups on Ecotoxicity and Fate Testing of Nanomaterials

Contacts

Anne GOURMELON

Nathalie DELRUE

Leon Van DER WAL

Kanako ITO

Mar GONZALEZ

Magdalini SACHANA

Patience BROWNE

Christina QUAGLIO

Website

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.

Guidance Documents

An *Advisory Document on Data Integrity - Definition and Guidance for Industry* - is being developed by a drafting group under the leadership of the UK Medicines and Healthcare products Regulatory Agency (MHRA). The guidance will aim to promote a risk-based approach to data management which includes data risk, criticality and lifecycle. The 33rd meeting of the Working Group on GLP (6-7 March, 2019) will review the latest draft and, after agreement is reached, a draft will be posted on the OECD's public website for comments, before a final draft is produced for circulation and approval by the Working Group and eventual publication.

A new *Guidance Document for Receiving Authorities for verifying the GLP status of submitted studies* is being developed by a drafting group under the leadership of the Netherlands. (A receiving authority is a national body which reviews test result submissions and is responsible for the assessment and management of chemicals.) The objective of the new guidance is to promote an adequate and time-efficient evaluation of the GLP status of submitted data as well as the GLP status of test facilities that generate non-clinical health and environmental data used for hazard assessments. The Guidance may also help reviewers determine whether it is necessary to request a study audit and/or test facility inspection before the data can be accepted. The latest draft will be reviewed at the 33rd meeting of the Working Group.

Work is underway on the development of the fifth volume of Frequently Asked Questions (FAQs). It is anticipated that the volume will be published later in 2019 or early 2020.

Preparations continue for the 14th OECD GLP training course that will be held in Cape Town from 7-10 October 2019. The course will comprise lectures and discussions in plenary, as well as parallel workshops on data integrity, test item, company culture and IT validation/e-archiving.

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. The programme of on-site evaluations of GLP compliance monitoring programmes in member and adhering non-member countries continues, with fi ve on-site evaluations conducted in 2018 – Czech Republic, Germany, Japan (Medical Products), Japan (Workplace Chemicals) and a follow-up visit to Thailand. Reports from the last four will be considered at the 33rd meeting of the Working Group on GLP (6-7 March 2019). The visit to the Czech Republic will be considered at the 34th meeting. Six on-site evaluation visits are scheduled for 2019 – Brazil, Denmark (Chemicals and Pesticides), Denmark (Medical Products), France (Medical Products), Singapore, and the US (Medical Products).

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

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

No. 19

Management, Characterisation and Use of Test Items

Forthcoming Events

6-7 March 2019
OECD Paris,
33rd Meeting of the of the Working Group on GLP

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

Contacts

Richard SIGMAN
Kanako ITO

Website

www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm

3. MUTUAL ACCEPTANCE OF DATA

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

There are six partner countries that are full adherents to MAD: **Argentina, Brazil, India, Malaysia, Singapore and South Africa**. Non-clinical health and environmental safety data generated in these countries must be accepted for regulatory purposes in OECD and other adhering countries. At the moment, full adherence for Argentina only applies to industrial chemicals, pesticides and biocides.

The Working Group on GLP implements on-site evaluation visits of national compliance monitoring programmes which are provisional adherents to MAD and are ready to be considered for full adherence. Currently, Thailand is a provisional adherent and an on-site evaluation team from Spain, Belgium and India visited the GLP Compliance Monitoring Programmes in Thailand in January, 2012. Following the visit, the Working Group meeting in April 2015 agreed that a follow-up visit to Thailand could be conducted once the follow-up team - Belgium, India and the Netherlands – felt it was prudent to do so.

A follow-up visit was conducted from 3-7 September 2018, and the outcome of that visit will be considered at the 33rd Working Group on GLP meeting.

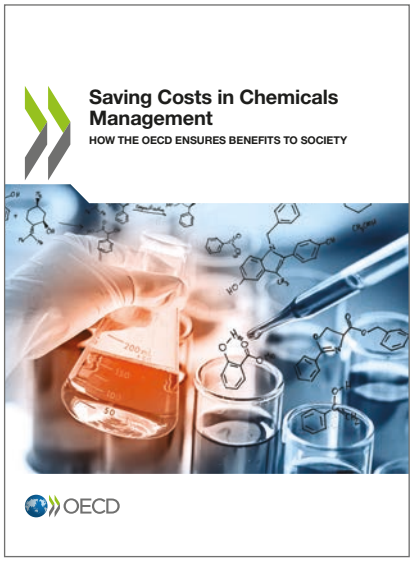
With a growing number of countries in Latin America that have expressed an interest in GLP and MAD, and in an effort to assist OECD members from Latin America who have yet to establish a GLP compliance programme, the Secretariat, working with members in the region, organised a seminar that was held in Bogota, Colombia from 13-14 February, 2019. The **seminar focused on the basic elements of GLP and the MAD system**, how they works in practice, the benefits from adherence to MAD, and the steps countries could take if they wish to pursue adherence. The seminar was open to government officials from Latin American countries as well as experts from industry who work in test facilities that conduct non-clinical tests on chemical substances. Approximately 180 experts attended the meeting representing governments and test facilities in Argentina, Brazil, Chile, Colombia, Costa Rica, Mexico and Paraguay.

Contact

Richard SIGMAN

4. Methodologies for evaluating the performance of chemicals management schemes

This work focuses on strengthening the methodology to measure the effectiveness and efficiency of chemical management schemes in meeting their objectives - protecting human health and the environment. Robust performance measurement informs policy making, programme development and design and can support justification for continued or new funding of programmes.

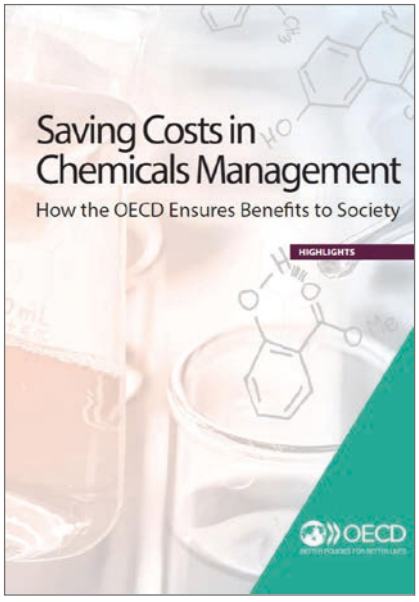


On 28 January 2019, the OECD issued the third in a series of reports dating back to 1998 that have quantified the net financial benefits that accrue to governments and industry from the work of OECD's Environment, Health and Safety (EHS) Programme (i.e. quantifying the overall benefits and subtracting the costs of the EHS Programme).

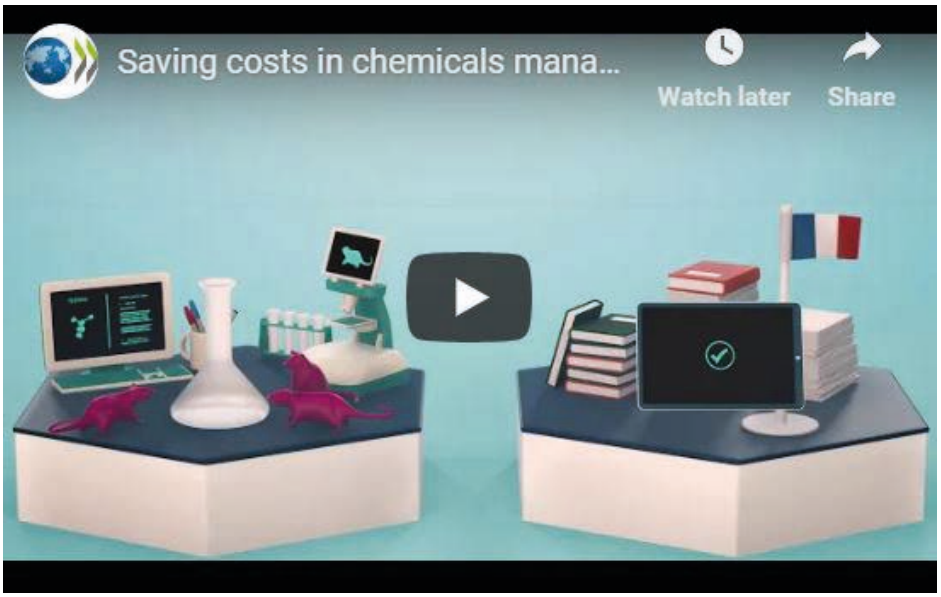
The 1998 report estimated benefits of EUR 90 million per year and the 2010 report estimated those savings had grown to EUR 177 million per year (both figures have been adjusted for inflation). The current report – Saving Costs in Chemicals Management: How the OECD Ensures Benefits to Society **- estimates the savings now at more than EUR 309 million a year**. A significant portion of the total savings are attributable to the OECD Mutual Acceptance of Data (MAD) system, which allows the results of non-clinical safety testing done on chemicals to be shared across OECD members and non-OECD members having adhered to the relevant Council Acts on MAD, thereby reducing duplicative testing.

In addition to the monetary savings, by reducing the need for duplicative testing of chemicals due to the MAD system and the OECD's support for non-testing methodologies, almost **33 000 less animals are needed every year to test new industrial chemicals**. Some activities within the EHS Programme can currently only be described in qualitative terms; however, these benefits – described in the report - are just as real and important as the quantifiable benefits (e.g., harmonising the safety assessment methodologies for products of modern biotechnology).

Highlights brochure



Video: Saving costs in chemicals management



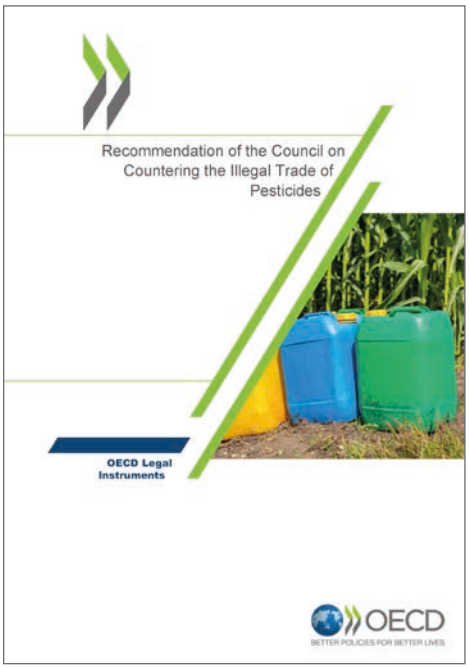
Contacts

Richard SIGMAN
Marit HJORT

5. 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.

Countering Illegal Trade of Pesticides



On February 20th 2019 the OECD Council adopted a **Recommendation on Countering the Illegal Trade of Pesticides**. This Recommendation calls for, among other things, establishing or strengthening national procedures aimed at countering the illegal trade of agricultural pesticides in line with a Best Practice Guide. The Best Practice Guidance helps countries identify illegal pesticides throughout their lifecycle to ensure the safety of consumers and the environment.

> Read the Recommendation
> Read the Best Practice Guide

Contacts

Richard SIGMAN
Leon VAN DER WAL

Intellectual Property rights related to chemical safety data

The 58th Joint Meeting in November 2018 considered a scoping paper addressing issues associated with intellectual property rights and chemical safety data, which had been developed by an ad hoc group, consisting of government, NGO and industry representatives. The group was established following the 57th Joint Meeting's endorsement of an initiative to address issues concerning finding ways for governments to review industry-sponsored studies in an open and transparent fashion, while also protecting the intellectual property rights (IPR) of the companies that generated the data. To that end, the ad hoc group will prepare a draft updated version of the 1983 *Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals* [C(83)96/FINAL] for consideration by the 59th Joint Meeting (June 2019) along with other possible options.

Contacts

Richard SIGMAN
Marit HJORT

6. Methodologies for assessing the costs and benefits of managing chemicals

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

Risk management discussions including socioeconomic analysis

The expert group on Risk Management Discussions, Including Socioeconomic Analysis aims to share experiences and develop lessons learnt on a range of topics such as health and environmental impacts of regulation, including economic valuation of impacts; cost of regulating substances; and economic assessments in chemicals management.

The expert group was established in early 2018. The group first met on 22-23 January 2019 at the OECD Headquarters in Paris. The workshop aimed for delegations to share experiences on approaches to risk management of chemicals, addressing issues such as: the process of risk management and related socio-economic analysis, how are PBT addressed in risk management, measuring the effectiveness of regulations and programmes for risk management, and the costs considered when determining risk management activities.

Contacts

Eeva LEINALA
Marie-Ange BAUCHER

III. Support for Capacity Building

1 • eChemPortal

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

Tutorial video: How to find GHS information in eChemPortal?

A new video tutorial is available on how to find GHS classification information on a specific chemical in eChemPortal.

eChemPortal version 2.0 was released in October 2018 with updated search fields in the user interface, property data catalogue, and data notification ticket XML aligned with the revisions to the OECD Harmonised Templates in 2016 and GHS in 2015 and 2017.

Version 2.1 was released in January 2019 including fixes and improvements to navigation and the substance search result.

Fothcoming Event

10-11 April 2019,
Tokyo, Japan
Meeting of the Steering Group for the Development of the Global Portal

Contact

Sally DE MARCELLUS

Website

www.oecd.org/ehs/eChemPortal

2 • Dissemination of OECD Products

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

Capacity-Building for the Sound Management of Chemicals

The IOMC Toolbox for Decision-Making in Chemicals Management is a problem-solving tool that enables countries to identify the most appropriate and efficient national actions to address specific national problems related to chemicals management. It is managed by the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

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

- a webinar presentation at the meeting of the Executive Programme on Integrated Chemical Management, London, United Kingdom, 26 September 2018
- a webinar presentation at the WHO/EURO workshop to enhance health sector role in the management of chemicals, 29 to 31 October 2018, Minsk, Belarus
- Presentation at the WHO Workshop to enhance the health sector Role in the Management of Chemicals, 17-19 December 2018, Cairo, Egypt

The IOMC Toolbox is being redesigned and will be more powerful and fast, the layout will be more modern and the content will be more easily accessible and searchable. The content will also be synthesised in order to remove unnecessary steps and allow the user to access the content in fewer clicks. The new platform will become live in Q2 2019.

Contacts

Sylvie PORET
Valérie FRISON

Websites

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

IV. Facilitation of Risk Reduction

1 Tools & Approaches to support decision-making for the Substitution of Hazardous Chemicals

The Ad Hoc Group on the Substitution of Harmful Chemicals is developing tools and approaches to support decision-making for the substitution of hazardous chemicals.

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals published two reports in February 2019:

- A synthesis report from a *Workshop on Approaches to Support Substitution and Alternatives Assessment* that was organised in May 2018. The workshop discussed issues such as approaches used to support alternative assessments and substitution; the strengths of the approaches and challenges to design and implementation, the link between innovation and progress in substitution and alternatives assessment; and initiatives to facilitate data sharing and other collaborative efforts;
- A *Cross Country Analysis of Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern* that describes and gives a list of approaches developed across countries and by different stakeholders to support alternatives assessment and substitution of chemicals of concern.

Recent publications - Series on Risk Management Series

The series on Risk Management covers methodologies for both governments and industry to manage risks posed by chemicals and, when appropriate, to harmonise risk management activities. The OECD provides information on the following areas: perfluorinated chemicals, substitution of hazardous chemicals, sustainable chemistry and others.

No. 51

Synthesis Report: OECD Workshop on Approaches to Support Substitution and Alternatives Assessment

No. 50

Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern

Contacts

Eeva LEINALA

Marie-Ange BAUCHER

Websites

www.oecd.org/chemicalsafety/risk-management/

www.oecdsaatoolbox.org/

2. Risk Reduction

The Risk Reduction Programme is concerned with the final step in chemical oversight: how to manage the use of chemical products so that society can take advantage of their benefits while minimising risks. It develops tools for OECD member countries and facilitates information exchange about successful risk management approaches.

Perfluorinated Chemicals (PFCs)

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

The Group regularly organises webinars to share information on PFASs and risk management.

Webinars will continue to be organised throughout 2018, the next topic in the series will be on Best Environmental Practices and is expected to be held in September 2018.

The most recent webinars were on:

- Best Environmental Practices for Class B Firefighting Foams;
- Toward greener water and oil repellents in the textile industry;
- Best Environmental Practices for Textiles.

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

Recent publications - Series on Risk Management Series

No. 39
New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs) and its accompanying methodology report.

Contacts

Eeva LEINALA
Marie-Ange BAUCHER

Website

www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/

3. Sustainable Chemistry

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

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

The Global Forum on the Environment - Plastics in a Circular Economy - Design of Sustainable Plastics from a Chemicals Perspective was held in Copenhagen, Denmark on the 29-31 of May, 2018. The workshop covered issues such as what does it mean to be "sustainable" from a chemicals perspective and how to evaluate claims of sustainability.

The workshop report was published in Q4 of 2018 and two of the three final background papers were published in Q1 2019, with the third pending publication. The documents and presentations from the workshop are available on the Global Forum website.

OECD wins a silver award at the 2018 Global Chemical Leasing

On 6 November 2018, the OECD was awarded the Silver Award in the research category at the 2018 Global Chemical Leasing Award for the report on the Economic Features of Chemical Leasing. The award ceremony was organised by UNIDO in partnership with the Austrian Federal Ministry of Sustainability and Tourism (BMNT), the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the German Environment Agency (UBA), the Swiss State Secretariat for Economic Affairs (SECO) and the Swiss Federal Office for the Environment (FOEN).

The report for which we received this award presents a review of the literature on the economic aspects of chemical leasing and of similar business models, focusing on the drivers and barriers and comparing their functioning to traditional contracts. It looks at the contracting conditions under which the model operates, its economic impacts, and the relating challenges that might arise to its use and implementation. Chemical Leasing is a service-orientated business model that intends to shift the focus from increasing the sales volume of chemicals towards an innovative and functional-based approach, leading to a more efficient use of chemicals.

Contacts

Eeva LEINALA

Marie-Ange BAUCHER

Websites

www.oecd.org/env/ehs/risk-management/

www.oecd.org/chemicalsafety/risk-management/sustainablechemistry.htm

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

1. Pesticides

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

Pesticide Residue Chemistry Expert Group (RCEG)

The pesticide **Residue Chemistry Expert Group** (RCEG) is currently working on an update of *TG 509 Crop Field Trials* and a revision of the 2009 *Guidance Document on Definition of Residue*. A face-to-face meeting to discuss the definition of residue took place in December 2018 in Geneva and brought together OECD, FAO and WHO experts who decided on a path forward. Furthermore, the RCEG plans to initiate the development of a Guidance document on residues in honey.

OECD Network on Illegal trade of Pesticides

In the area of the illegal international trade of pesticides, the **OECD Network on Illegal trade of Pesticides (ONIP)** developed a Best Practice Guide (BPG) to address issues related to fighting illegal trade, and to strengthen a "Global Alliance" against illegal trade of pesticides. The BPG was approved by the Joint Meeting in November 2018 and subsequently published on the Pesticides Programme public website.

On February 20th 2019 the OECD Council adopted the *Recommendation on Countering the Illegal Trade of Pesticides*. This Recommendation calls for, among other things, establishing or strengthening national procedures aimed at countering the illegal trade of agricultural pesticides in line with the BPG. The Recommendation and BPG are available on the OECD website.

Pesticides Effects on Insect Pollinators

With respect to pollinators, work is continuing within the Pesticides Programme and the Test Guidelines Programme on test methods for the homing flight test on honeybees after single exposure to sub-lethal doses.

Expert Group on Bio-Pesticides (EGBP)

As regards the work of the Expert Group on Bio-Pesticides (EGBP), the Working Document on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents was published in November 2018. The Report of the 9th EGBP Seminar on "Testing methods for micro-organisms" is expected to be published in April 2019.

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

The Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD) continues its activities regarding the Global Harmonised Submission Transport Standard (GHSTS).

The GHSTS specifies how to assemble electronic files required in the evaluation of submissions for any pesticide package. The Expert Group maintains the Standard (i.e., considers modification requests) and plans to finalise GHSTS version 2 in the first half of 2019. This version will be an extension of version 1 to allow input for products other than plant protection products (e.g., feed additives) and will include improvements to lifecycle management of documents in submissions.

Ad Hoc Expert Group on RNAi-based Pesticides

The Ad Hoc Expert Group on RNAi-based Pesticides is finalising a working paper, which will document the current state of knowledge of RNA interference (RNAi) as it relates to the potential use of this mode of action in agricultural pesticides and regulatory considerations by agencies in OECD member countries related to the effects on non-target organisms from exposure to RNAi-based pesticides, including the environmental fate of these pesticides. A conference on "Regulation of Externally Applied dsRNA-based Products for Management of Pests" is scheduled for 10-12 April 2019, in Paris. The abovementioned working paper will serve as background document to this conference and is expected to be published thereafter.

Other

Work is underway to develop an updated version of the Table of Contents/Crosswalk in the OECD Dossier Guidance document, which was last updated in 2005. At the June, 2018 WGP meeting, a revised document was developed for review by delegates. Next steps will be to establish new OECD data point numbers based on the additional data requirements that were submitted by the countries and complete the cross-walk. The June, 2019 Working Group on Pesticides will decide a path forward for this project.

Recent publications - Series on Pesticides

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

No. 99: Best Practice Guidance to Identify Illegal Trade of Pesticides

No. 98: Working Document on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents Series on Pesticides; ANNEX

Fothcoming Events

10-12 April 2019
OECD Paris,
Conference on Regulation of Externally Applied dsRNA-based Products for Management of Pests

12 April 2019
OECD Paris,
Ad Hoc Expert Group on RNAi-based pesticides meeting

14-15 May 2019
OECD Paris,
Expert Group on the Electronic Exchange of Pesticides Data

24 June 2019
OECD Paris,
Expert Group on Bio-Pesticides (EGBP) seminar on Bioinformatics

25 June 2019
OECD Paris,
EGBP meeting

26 June 2019
OECD Paris,
Risk Reduction Seminar

27-28 June 2019
OECD Paris,
Working Group on Pesticides

Contacts

Richard SIGMAN
Leon VAN DER WAL
Magdalini SACHANA
Sally DE MARCELLUS
Chrsitiana OLADINI-JAMES

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.

The Harmonised Study Review Forms & Standard Operating Procedure for reviewing the study reports of the so called "Acute Toxicology 6 Pack" were published in January 2019.

The **Expert Group on Claims Development for Biocides Treated Articles** (EGCDTA) continues to collect a common library of available legislation in OECD countries as well as of distinctive claims and has started with the development of possible principles of claims development.

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

1) Guidance Document for flammability testing; this Guidance Document has been submitted for a combined review to the Working Group of National Coordinators of the Test Guidelines Programme, the Working Group on Pesticides and the Working Group on Biocides and is expected to be published in early 2019.

2) The Guidance Document on waiving and bridging of physical chemistry studies will be developed further.

Guidance Documents on the efficacy of insecticides against various pests such as bed bugs and tropical ants are currently under development. Application methods of the insecticides include baits and various contact insecticides. A new project to develop a guidance on determining the efficacy of pressurized aerosols for the control of flying and crawling insects has been approved. A dedicated Expert Group has been formed; it will hold the kick-off meeting for this project in April 2019, to discuss how to determine and optimise the efficacy of biocidal products targeting insects as vectors of disease.

Recent publications - Series on Biocides

No. 14: Sharing of Government Biocides Reviews: Standard Operating Procedure and Harmonised Study Review Forms of the "6 pack" Acute Studies

Forthcoming event

25-26 September 2019
Seoul, Korea
3rd Meeting of the Working Group on Biocides

Contacts

Sylvie PORET

Leon VAN DER WAL

Website

www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm

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

1. Chemical Accidents

The Chemical Accidents Programme works to develop guidance on prevention of, preparedness for, and response to chemical accidents. It facilitates the sharing of information and experiences of both OECD and non-member countries. The Programme is managed by the Working Group on Chemical Accidents (WGCA).

The Working Group on Chemical Accidents is working on two translations of its *Guidance on Change of Ownership in Hazardous Facilities*, in French and in Norwegian, which should be available in the second quarter of 2019. This Guidance is a concise document providing a framework to assist stakeholders to identify, understand and minimise the risks during and after a change of ownership at a hazardous facility, and help make the change of ownership a better informed process.

The report from the joint OECD/UN Workshop on Natech Risk Management that was held in September 2018 in Potsdam, Germany, is being prepared and will be published in the third quarter of 2019. The workshop report will be published together with the results from a survey aiming to collect good practices for Natech risk management across countries.

Recent publications - Series on Chemical Accidents

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

Guidance on Change of Ownership in Hazardous Facilities.

Forthcoming event

22-24 October 2019
OECD, Paris
29th Meeting of the Working Group on Chemical Accidents

Contacts

Peter KEARNS

Marie-Ange BAUCHER

Website

www.oecd.org/chemicalsafety/chemical-accidents/

2. Pollutant Release and Transfer Registers (PRTRs)

PRTRs are databases of selected pollutant releases to air, water and soil, and of wastes transferred off-site for treatment or disposal. The programme aims to help individual countries in developing PRTRs, improving release estimation techniques and sharing of data between countries.

Pollutant Release and Transfer Registers

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

To assist countries in improving and harmonising their PRTRs, the WG-PRTRs is currently reviewing Part 2 (diffuse sources) of the guidance document on release estimation techniques: *Resource Compendium of PRTR Release Estimation Techniques* and it is expected to be finalised in Q4 2019. In addition, the WG-PRTRs discussed the review and update of the harmonised list of pollutants, reporting sectors and thresholds at the Second Meeting of WG-PRTRs in November 2018. The WG-PRTRs also exchanged experiences on outreach activities by the member countries for assisting other countries to establish and implement their PRTRs at this meeting.

In regard to promoting the use of PRTR data, the WG-PRTRs discussed an action plan for tracking progress towards the UN Sustainable Development Goals (SDGs). This action plan is expected to be finalised in Q3 2019. In addition, the WG-PRTRs discussed the revised document on collecting information and sharing good practice on PRTR data application for local environmental management, which is expected to be finalised in Q2 2019. The second meeting of WG-PRTRs and the third Global Round Table on PRTRs in November 2018, discussed further use of PRTR data including the possibility to conduct an international analysis of PRTR data.

Forthcoming Event	Contact	Website
15-17 October 2019 Geneva, 3rd Meeting of the Working Group on PRTRs	Takaaki ITO	www.oecd.org/chemicalsafety/pollutant-release-transfer-register/

Best Available Techniques to prevent and control industrial pollution

The 58th Joint Meeting endorsed a new work plan for the project on Best Available Techniques (BAT) for preventing and controlling industrial pollution. The work plan was developed by the OECD's Expert Group on BAT and builds on the previous phase of the project, which started in the 2016. Three reports have been developed under this project:

- *Policies on BAT or Similar Concepts Across the World* (2017), analysing how BAT is defined and embedded into national legislation in different countries;
- *Approaches to Establishing BAT Around the World* (2018), presenting procedures to establish BAT in various countries (i.e. collection of information on available techniques, involvement of relevant stakeholders in assessing environmental, economic and social aspects of the techniques, and identification of certain techniques as BAT); and
- *Methodologies and Data for the Effectiveness Evaluation of BAT Policies* (forthcoming), describing available approaches to assessing the impact of BAT policies.

The new phase of the project will last for three years and consist of the following three activities:

1. Developing a guidance document on how to determine BAT, derive associated emission levels from BAT (BAT-AELs) and translate these into emission limit values in permits;

2. Conducting a study on value chain approaches to determining BAT for industrial installations;

3. Comparing BAT reference documents for selected industrial sectors across countries.

The BAT project aims to exchange best practices across countries that have a BAT-based policy in place, and to provide assistance to governments that are interested in adopting this approach. Furthermore, the project seeks to achieve progress towards relevant Sustainable Development Goals, notably Target 12.4 on the environmentally sound management of chemicals and wastes. The project is overseen by the OECD's Expert Group on BAT, which meets face to face once a year.

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

Forthcoming Event

23-24 October 2019
Seoul, Korea
4th Meeting of the OECD Expert Group on BAT

Contact

Takaaki ITO
Marit HJO

Website

oe.cd/BAT

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

1. Environmental Safety

The programme on the Harmonisation of Regulatory Oversight in Biotechnology is focused on environmental risk/safety assessment of transgenic (genetically modified) crops as well as other organisms of commercial interest. It aims to ensure that the information used in risk/safety assessment, as well as the methods used to collect this information, is as similar as possible among regulatory authorities. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort. It also reduces barriers to trade.

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

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

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

The OECD Product Database, containing information on genetically-engineered crops approved for being cultivated or used in foods and feeds, continued to be completed and updated. A total of 303 entries are now available in the system, keeping pace with new information provided by member countries as well as a number of non-members. 49 new entries or updates were reported by Australia, Brazil, Canada and Switzerland between July 2018 and February 2019. Information on the products of safflower, sugarcane and eucalyptus was added for the first time to the database.

Genome editing techniques have emerged as a major topic related to applications of biotechnology. The OECD Council has allocated funding to a project on Health and Environmental Safety in Genome Editing Applications. The main event was an OECD Conference to be held on the topic on 28-29 June 2018, and the proceedings will be published soon on the website.

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

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

Volume 8 : Safety Assessment of Transgenic Organisms in the Environment, Consensus Document on the Biology of mosquito *Aedes aegypti*, 2018.

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Forthcoming Events

14-15 March 2019
Addis Ababa, Ethiopia,
Kick-off meeting of the Ad-hoc Expert Group for developing the Consensus Document on the Biology of Mosquito *Anopheles gambiae*

8 April 2019
OECD Paris,
10th face-to-face meeting of Steering Group for "Environmental Considerations for Risk/Safety Assessment for the release of Transgenic Plants"

8 April 2019
OECD, Paris
Joint WG-SNFF/WG-HROB Workshop: Environmental and Food/Feed Safety Assessment of Biotechnology Products, Four Decades of OECD Work – achievements, experience gained, and looking forward

9-11 April 2019
OECD, Paris
33*rd* meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

Contacts

Peter KEARNS
Bertrand DAGALLIER
Ruydai OSHIMA
Yoko TAKASU
Emily SEFTEL

Website

www.oecd.org/biotrack

2. Safety of Novel Foods and Feeds

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

The new consensus document on the composition of cowpea (*Vigna unguiculata*), finalised under the leadership of Australia, was published in December 2018. Activities continued to develop the consensus document on Apple (*Malus domestica*) composition expected for publication in the upcoming months, and to revise the Maize (*Zea mays*) and the Potato (*Solanum tuberosum*) documents initially issued in 2002. Canada with Germany, the United States and Sweden are the respective leads of these projects.

Other proposals will be discussed at the next meeting of the Working Group for the Safety of Novel Foods and Feeds to be held on4-5 April 2019, in particular for developing new composition documents, e.g. on high-glucosinate/high-erucic acid rapeseed, on Cucurbits species (Squashes, Pumpkins, Zucchinis and Gourds). The Working Group will continue to explore suggestions for future projects on new topics such as emerging feed ingredients, food/feed and new breeding techniques, safe-by-design concept applied to biotechnology products, and will establish priorities.

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

Series on the Safety of Novel Foods and Feeds

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

No.30: Consensus Document on Compositional Considerations for New Varieties of Cowpea (*Vigna unguiculata*): Key Food and Feed nutrients, Anti-nutrients and other Constituents.

Forthcoming Events

4-5 April 2019
OECD Paris,
26th Meeting of the Working Group for the Safety and Novel Foods and Feeds.

8 April 2019
OECD Paris,
Joint WG-SNFF/WG-HROB Workshop: Environmental and Food/Feed Safety Assessment of Biotechnology Products, Four Decades of OECD Work – achievements, experience gained, and looking forward

Contacts

Peter KEARNS
Bertrand DAGALLIER
Ryudai OSHIMA
Emily SEFTEL

Website

www.oecd.org/biotrack

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

- www.oecd.org/ehs/publications

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

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

WEBSITES

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

EHS Homepage	www.oecd.org/chemicalsafety
Biocides	www.oecd.org/chemicalsafety/biocides.htm
Biosafety and Food/Feed Safety	www.oecd.org/chemicalsafety/biotrack/
Chemical Accidents	www.oecd.org/env/accidents
Exposure Assessment	www.oecd.org/env/exposure
Global Portal to Information on Chemical Substances	www.echemportal.org/echemportal
Good Laboratory Practice	www.oecd.org/env/glp
Harmonised Templates	www.oecd.org/ehs/templates/
Harmonisation of Classification of Labelling	www.oecd.org/env/classify
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

ENV/EHS Staff Directory
E-fax Number: +33 (01) 44 30 61 80

NAME	PROGRAMME	PHONE
ABADIE, Fabienne	Resource Management Adviser	19.66
BAUCHER, Marie-Ange	Chemical Accidents, Risk Management, Sustainable Chemistry	94.22
BROWNE, Patience	Test Guidelines	19.11
DAGALLIER, Bertrand	Food Safety/Biosafety	84.51
DE MARCELLUS, Sally	Hazard Assessment, Pesticides	19.42
DELRUE, Nathalie	Test Guidelines	98.44
DIDERICH, Bob	Head of Division	14.85
DOCKINGS, Laura	Assistant, Hazard Assessment, IATA, Risk Mgt, Sustainable Chemistry, Biocides	74.84
FRISON BEAU, Valérie	Hazard Assessment	89.34
GIBB, Jill	Assistant to Head of Division and Administrative assistant	93.16
GONZALEZ, Mar	Nanosafety, Test Guidelines, Outreach Programme	76.96
GOURMELON, Anne	Test Guidelines, IATA	98.49
HJORT, Marit	Best Available Techniques	74.01
HORIE, Masashi	QSARs and Hazard Assessment	98.19
ITO, Kanako	GLP, Test Guidelines	76.98
ITO, Takaaki	Exposure Assessment, PRTRs, Best Available Techniques	79.07
IZAWA, Tatsuki	Nanosafety	14.63
KEARNS, Peter	Biosafety, Food Safety, Nanosafety, Chemical Accidents	16.77
LANDRY-PARE, Estelle	Assistant, Hazard Assessment, (Q)SARs, Exposure Assessment	17.37
LEINALA, Eeva	Hazard Assessment, Risk Management, Sustainable Chemistry, IATA, (Q)SARs	76.30
OLADINI-JAMES, Christiana	Assistant, Pesticides, GLP, Chemical Accidents	16.48
OSHIMA, Ryudai	Food Safety/Biosafety	76.19
PORET, Sylvie	Biocides, Capacity Building	89.45
QUAGLIO, Christina	Assistant, Test Guidelines	78.48
SACHANA, Magdalini	Hazard Assessment, Pesticides	64.23
SEFTEL Emily	Assistant, Biosafety, Food Safety, Nanosafety	74.47
SIGMAN, Richard	GLP/MAD, Pesticides	16.80
TAKASU, Yoko	Biosafety, Biotechnology	87.21
THABET, Hannah	Communications and Publications co-ordinator	64.39
VAN DER WAL, Leon	Biocides, Test Guidelines, Pesticides	93.10

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 newsletter is produced for participants in the Programme's activities; but the secretariat hopes that it is also of value to a broader audience with an interest in human health and environmental safety issues connected with the use of chemicals, pesticides and biotechnology.

www.oecd.org/chemicalsafety