

October 2nd - 3rd

**INTERNATIONAL
CHEMICAL
CONFERENCE** **2018**

CIS Center Russia



THE OECD STANDARD SETTING REVIEW

Bob Diderich



OECD ENVIRONMENT, HEALTH AND SAFETY (EHS) PROGRAMME

Objectives

Protect human health and the environment

Efficiency

Type of outputs

Harmonized policies and instruments of high quality

Work sharing;
avoid duplication;
avoid non-tariff trade barriers; shorten time to market

Examples of outputs

- Test Guidelines, Principles of Good Laboratory Practice
=> Mutual Acceptance of Data
- Standards for exchange of information
- Global Portal to Information on Chemical Substances
- Guidance for Hazard and Exposure Assessment
- Tools for predicting the effects of chemicals (alternative test methods, QSARs)

Scope

Chemicals, nanomaterials, pesticides, biocides, chemical accidents, PRTRs, GMOs

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UNDERLYING BASIS: ABOUT 20 OECD LEGAL INSTRUMENTS FOR CHEMICAL SAFETY

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Several types of legal instruments

- Decision: legally binding
- Recommendation: morally binding



MUTUAL ACCEPTANCE OF DATA, TEST GUIDELINES AND GOOD LABORATORY PRACTICES

Mutual Acceptance of Data

OECD Test Guidelines

OECD Principles of GLP and
Compliance Monitoring Procedures

Mutual Acceptance of Data

**Avoids duplication of testing by industry and
non-tariff trade barriers**

MAD Council Decisions open to non-members

“data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment”

SAVINGS FROM MAD



Cutting Costs in Chemicals Management

HOW OECD HELPS GOVERNMENTS AND INDUSTRY



• BY AVOIDING DUPLICATIVE TESTING:

- At least € 150 Million / Year
- Reduction in animal testing
- More chemicals can be evaluated quicker

www.oecd.org/ehs/publications



REVIEW OF LEGAL INSTRUMENTS

POLLUTANT RELEASE AND TRANSFER REGISTERS

Recommendation on Pollutant Release and Transfer Registers

- Objectives of Update
 - Common core elements of PRTRs (e.g. list of substances, reporting thresholds, industrial sectors)
 - Recommendations for implementation (e.g. release estimation techniques)

- Adopted April 2018

<https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0440>

Current focus of technical work

- Update list of target chemicals
- Improve application, use and presentation of PRTR data
- Lessons learned from outreach activities by member countries

<http://www.oecd.org/chemicalsafety/pollutant-release-transfer-register/>

RISK ASSESSMENT AND RISK REDUCTION

Decision-Recommendation on the co-operative investigation and risk reduction of chemicals (1)

- Part A : Cooperative investigation of chemicals
- Objectives of Update
 - Emphasis on development of novel methods for assessing the hazards of chemicals

Methodologies for Hazard Assessment

- Development of harmonised novel methodologies for assessing the hazards of chemicals
 - ensure consistency
 - generate confidence and support for integrating novel tools and approaches into regulatory decision-making
 - increase the mutual acceptance of hazard assessments in order to avoid duplication of efforts
- Types of Output:
 - Case studies on using novel methods for regulatory decision-making
 - Adverse Outcome Pathways
 - Integrated approaches to testing and assessment
 - QSAR Toolbox

<http://www.oecd.org/env/ehs/risk-assessment/>



OECD IATA Case Studies Project

Objective:

- Increase experience with the use of Integrated Approaches for Testing and Assessment by developing case studies, which constitute examples of predictions that are fit for regulatory use
- Create common understanding and develop guidance

Deliverables:

- Guidance documents on methodologies with associated case studies

Year-No. (Lead)	Assessment approach	Endpoint	IATA topics				References
			AOP* ¹	UR* ²	NAM* ³	L/N* ⁴	
2016-1 (Japan)	Read-across	Repeated dose toxicity		X	X		OECD, 2017a
2016-2 (US)	Grouping for cumulative risk assessment	Neurotoxicity	X		X		OECD, 2017b
2016-3 (ICAPO)	Read-across	Repeated dose toxicity		X	X	X	OECD, 2017c
2016-4 (ICAPO)	Read-across	Repeated dose toxicity		X	X	X	OECD, 2017d
2016-5 (JRC/BIAC)	Safety assessment workflow	Repeated dose toxicity	X		X		OECD, 2017e
2015-1 (Canada/US)	Read-across	Mutagenicity	X	X			OECD, 2016b
2015-2 (Canada)	Read-across	Repeated dose toxicity		X	X		OECD, 2016c
2015-3 (Japan)	Read-across	Repeated dose toxicity	X	X			OECD, 2016d
2015-4 (Japan)	Read-across	Bioaccumulation		X		X	OECD, 2016e

*¹: AOP: Use of mode of action/adverse outcome pathways
*²: UR: Uncertainty reporting
*³: NAM: Use of new approach methodologies
*⁴: L/N: Low/no toxicity prediction

Examples of on-going Projects

- Guiding Principles for establishing weight of evidence for chemical assessment
- Guidance document for PBK models



- Free software application to predict the properties of chemicals (version 4.2 launched in 2018)
- Estimate missing experimental values by read-across and trend analysis (grouping of similar chemicals, chemical categories)

www.oecd.org/env/hazard/qsar



- continuous development
 - usability improvements
 - scientific development, including implementation of grouping mechanisms based on mode of action or adverse outcome pathways (AOPs)
 - additional functionalities
 - IT improvements

Decision-Recommendation on the co-operative investigation and risk reduction of chemicals (2)

- Part B : Risk Reduction or Prevention
- Objectives of Update
 - Strengthen the instrument
 - Strengthening of national programmes
 - Implementation of GHS
 - Concerted action
- Adopted May 2018

<https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0441>

OECD/UNEP Global PFC Group

SYNTHESIS PAPER ON
PER- AND POLYFLUORINATED
CHEMICALS (PFCs)



- Mandate from 2nd International Conference on Chemicals Management
- ... encourage the development, facilitation and promotion in an open, transparent and inclusive manner of national and international stewardship programmes and regulatory approaches to **reduce emissions and the content of relevant perfluorinated chemicals (PFCs) of concern in products and to work towards global elimination**, where appropriate and technically feasible.

www.oecd.org/ehs/pfc

Recent release

- update of the OECD list of per- and polyfluoroalkyl substances (PFASs)

<http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/>

INTELLECTUAL PROPERTY RIGHTS

Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals

[http://acts.oecd.org/Public/Info.aspx?lang=en&infoRef=C\(83\)96/FINAL](http://acts.oecd.org/Public/Info.aspx?lang=en&infoRef=C(83)96/FINAL)

- Objectives of the review:
 - Expand to all chemicals?
 - Improve use of data i.e. improve safety while maintaining proprietary rights
- Scoping document for discussion by member countries in November 2018

CHEMICAL ACCIDENTS

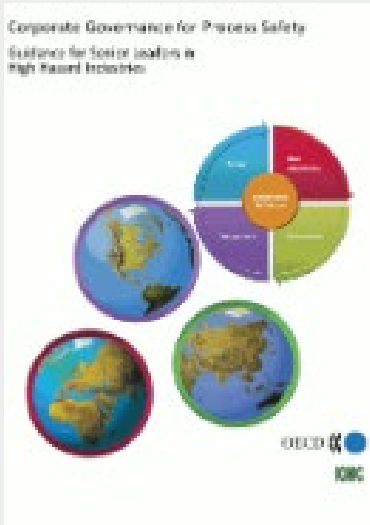
Several legal instruments

- Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage [[C\(88\)84/Final](#)]
- Decision-Recommendation concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances [[C\(88\)85/Final](#)]
- Recommendation on the Application of the Polluter-Pays Principle to Accidental Pollution [[C\(89\)88/Final](#)]
- Recommendation concerning Chemical Accident Prevention, Preparedness and Response [[C\(2003\)221](#)]

Objectives of Review

- Merge?
- Strengthen?
- Discussion with countries in November 2018

Flagship publications

		
<p>The Guiding Principles address all aspects of preventing and managing chemical accidents.</p>	<p>Corporate Governance for Process Safety Guidance for Senior Leaders in High Hazard Industries</p>	<p>Guidance on Change of Ownership in Hazardous Facilities</p>

Ongoing Projects

- Natural Hazard Triggered Technological Accidents : Good Practices for Risk Management
- Guidance on the Benefits of Regulations for Chemical Accidents Prevention, Preparedness and Response
- Update of Guiding Principles for Chemical Accidents Prevention, Preparedness and Response

FIGHT AGAINST ILLEGAL TRADE OF PESTICIDES (NEW)

Objectives

- Reduce distortion of pesticide markets
- Reduce economic impacts:
 - on farmers
 - on pesticide manufacturers
- Reduce threat to human health and the environment
- Uphold national legislations on pesticide registration and the credibility of regulatory authorities

Development of a Council Recommendation

Work towards the establishment of a legal framework to strengthen activities against illegal trade in pesticides, that would:

- Encourage countries to fight illegal international trade of agricultural pesticides at national level
- Encourage countries to facilitate international cooperation

Best Practice Guidance (BPG)

The BPG describes best practices for identifying, and responding to, illegal trade throughout the life cycle of a pesticide.

- i.e. manufacture, formulation, export, transportation, import, wholesale/retail, use and disposal.
- For inclusion in the Council Recommendation as a tool to develop national programmes.

Rapid Alert System

Rapid Alert System, in place since 2012.

- 106 notifications of suspicious shipments.
- One illegal shipment seized due to notification.
- Provides useful intelligence.

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FURTHER INFORMATION

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Further Information

- Website
 - <http://www.oecd.org/chemicalsafety/>
- EHS Programme Brochure
 - <http://www.oecd.org/env/ehs/Environment-Health-Safety-Brochure.pdf>
- EHS Newsletters (sign up to receive automatically)
 - <http://www.oecd.org/chemicalsafety/environment-health-safety-news.htm>

Thank you!

