

## THE OECD'S ENVIRONMENT, HEALTH AND SAFETY PROGRAMME

Bob Diderich, OECD

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# OECD ENVIRONMENT, HEALTH AND SAFETY (EHS) PROGRAMME

35 Member countries, many partner countries and other stakeholders work together to develop and co-ordinate activities on chemical safety and biosafety on an international basis.

The main objectives of the Programme are to:

- Assist OECD Member countries' efforts to protect human health and the environment through improving chemical safety and biosafety
- Make chemical control policies more transparent and efficient and save resources for government and industry; and
- Prevent unnecessary distortions in the trade of chemicals, chemical products and products of modern biotechnology.



http://www.oecd.org/env/ehs/



# 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 => 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



## PARTICIPATION IN EHS WORK

- Members (make decisions)
- European Union
- Selected partner countries
- Other Inter-governmental Organisations
- Industry (BIAC)
- Trade Unions (TUAC)
- Environmental NGOs
- Animal Welfare NGOs



### 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"



### Mutual Acceptance of Data and Nonmembers

**Adhering** 

South Africa

Singapore

India

**Brazil** 

Argentina

Malaysia

**Requests** 

Chinese Taipei

Request

**Expected** 

China

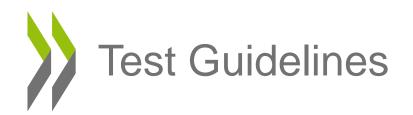
**Discussions** 

Russia

EU non-OECD members

**Provisional** 

**Thailand** 



### **Approximately 150 Test Guidelines:**

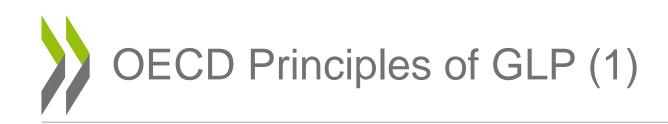
- Physical-chemical properties
- Bio-degradation and accumulation
- Ecotoxicity
- Mammalian toxicity
- Efficacy, Pesticide residue testing



## Test Guidelines Programme

- Every year new and updated Test Guidelines are adopted to meet the regulatory needs in OECD member countries.
- Just Released!
  - In July 2016, the OECD adopted the following new Test Guidelines
    - *in vitro* skin sensitisation
    - endocrine disrupter screening
    - mollusc toxicity testing
  - Updated Test Guidelines Published:
    - soil and avian toxicity testing
    - skin corrosion
    - reproductive toxicity screening
    - endocrine disrupter screening
    - genotoxicity testing.

http://www.oecd.org/env/ehs/testing/



 A single quality standard for test facilities throughout OECD and applied for testing of all chemical substances



## OECD Principles of GLP (2)

#### **Management Tool**

- Address the responsibility of and requirements for a test facility's organisation and personnel, quality assurance programme, physical plant, apparatus, materials and reagents.
- Principles governing the following are provided:
  - conditions for establishing and maintaining test systems;
  - receipt, handling, sampling, characterisation and storage of test and reference substances;
  - standard operating procedures;
  - performance of the study;
  - reporting of results;
  - storage, retention and retrieval of records and materials



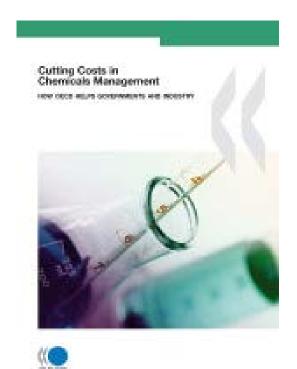
## OECD Working Group on GLP

- Comprises representatives of national Monitoring Authorities (~ 45)
- Meets at least once a year
- Products:
  - Consensus documents
  - Training courses
  - On-site evaluation visits

http://www.oecd.org/env/glp







- BY AVOIDING DUPLICATIVE TESTING:
  - At least € 150 Million / Year
  - Reduction in animal testing
  - More chemicals can be evaluated quicker

www.oecd.org/ehs/publications

## Savings for government and industry offered by the programme (€)

Country costs	11 648 000	New chemicals	Testing	27 576 000
Secretariat costs	3 579 800	New Pesticides	Testing	134 640 000
			Industry reporting	1 546 800
			Government assessment	2 408 700
		HPV chemicals	Testing	1 547 100
			Assessment	508 680
TOTAL (rounded)	15 228 000			168 230 000

**NET SAVINGS DUE TO THE EHS PROGRAMME = EUR 153 000 000** (rounded)



### HAZARD ASSESSMENT



### 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 decisionmaking
  - Adverse Outcome Pathways
  - Integrated approaches to testing and assessment
  - QSAR Toolbox



## OECD IATA Case Studies Project

#### **Objective:**

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

#### **Deliverables:**

Guidance
 documents on
 methodologies
 with associated
 case studies.

Review Year	No.	Title	Type of Assessment	Endpoint	Status
2015	1	In Vitro Mutagenicity of 3,3' Dimethoxybenzidine (DMOB) Based Direct Dyes	Grouping (Read-across)	Mutagenicity	<u>Published</u>
2015	2	Repeat Dose Toxicity of Substituted Diphenylamines (SDPA)	Grouping (Read-across)	Repeated dose toxicity	<u>Published</u>
2015	3	Hepatotoxicity of Allyl Ester Category	Grouping (Read-across)	Repeated dose toxicity	<u>Published</u>
2015	4	Bioaccumulation Potential of Biodegradation Products of 4,4'-Bis (chloromethyl)-1,1'-biphenyl	Grouping (Read-across)	Bioaccumulation	<u>Published</u>
2016	1	Repeated-Dose Toxicity of Phenolic Benzotriazoles	Grouping (Read-across)	Repeated dose toxicity	Under review
2016	2	Pesticide Cumulative Risk Assessment & Assessment of Lifestage Susceptibility	Grouping	Neurotoxicity	Under review
2016	3	90-Day Rat Oral Repeated-Dose Toxicity for Selected n-Alkanols: Read-Across	Grouping (Read-across)	Repeated dose toxicity	Under review
2016	4	90-Day Rat Oral Repeated-Dose Toxicity for Selected 2-Alkyl-1-alkanols: Read-Across	Grouping (Read-across)	Repeated dose toxicity	Under review
2016	5	Chemical Safety Assessment Workflow Based on Exposure Considerations and Non-animal Methods	Other	Repeated dose toxicity	Under review



# Recent publications and on-going Projects

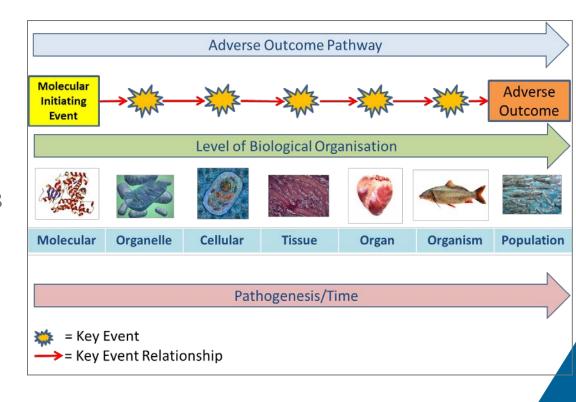
- Guidance Document on the Reporting of Defined Approaches to be Used Within Integrated Approaches to Testing and Assessment
- Guidance Document on the Reporting of Defined Approaches and Individual Information Sources to be Used Within Integrated Approaches to Testing and Assessment (IATA) for <u>Skin Sensitisation</u>
- Use of Adverse Outcome Pathways in Developing Integrated Approaches to Testing and Assessment (IATA)
- Document on Incorporation of Bioavailability Concepts for Assessing the Ecological Risk and/or Environmental Quality Standard Setting of <u>Inorganic Metals and Metal Compounds</u>
- <u>Combined Exposures to Multiple Chemicals</u> Monograph focusing on considerations for assessment of risk from the combined exposure to multiple chemicals



### Adverse outcome pathways Framework for predictive toxicology

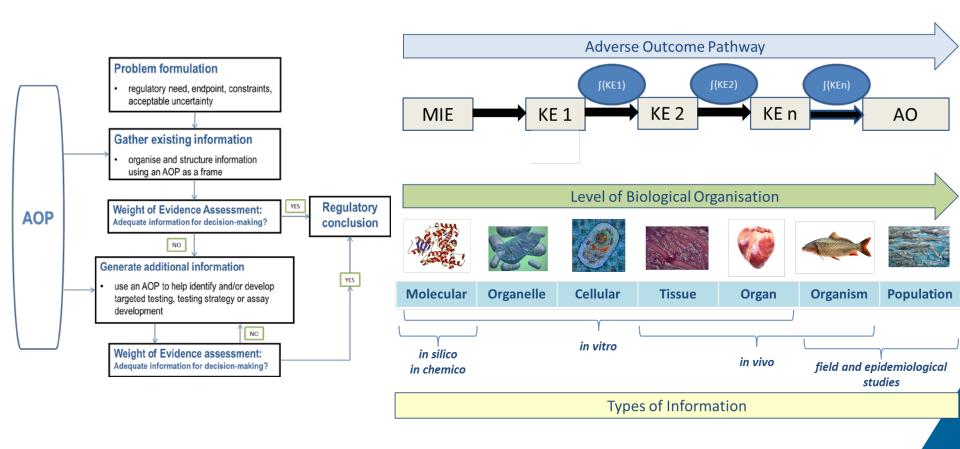
In 2012, the OECD launched a new programme on the development of Adverse Outcome Pathways.

An Adverse Outcome Pathway (AOP) describes a sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect.





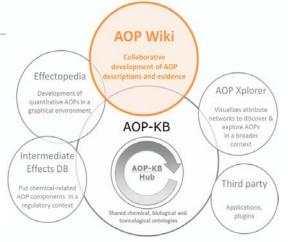
The AOP concept can be used as a framework for the development of Integrated approaches to testing and assessment (IATA)





### Adverse Outcome Pathway Development

- 5 AOPs published
- > 40 AOPs under development



- AOP-Knowledge Base is available at the following URL: https://aopkb.org
- Information related to the AOP Development Programme, including a work plan, is available on the public website at: <a href="http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm">http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm</a>

### QSAR TOOLBOX

- Free software application to predict the properties of chemicals (version 3.4 launched in July)
- Estimate missing experimental values by read-across and trend analysis (grouping of similar chemicals, chemical categories)

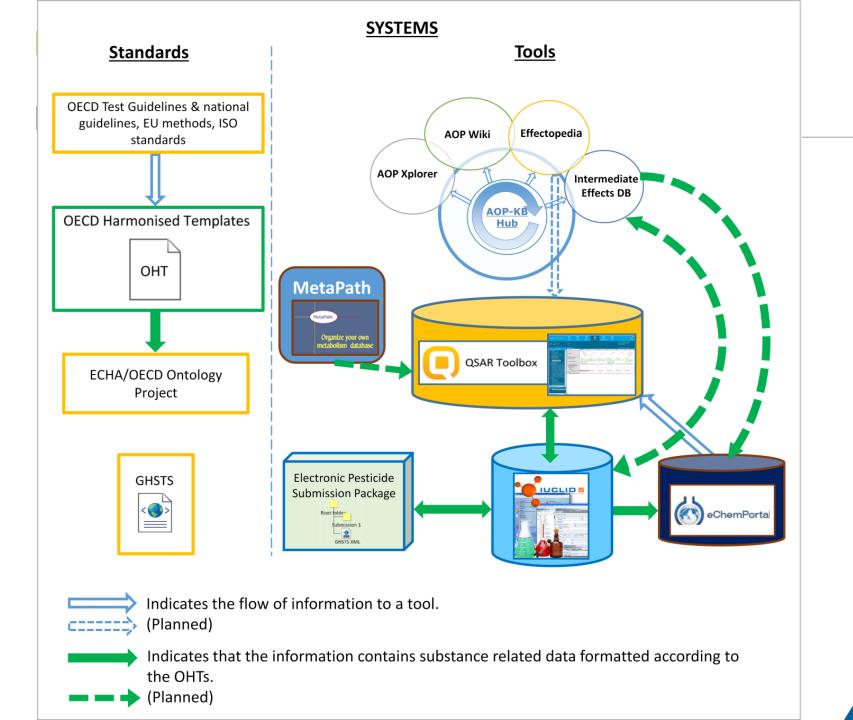
www.oecd.org/env/hazard/qsar

### QSAR TOOLBOX

- Focus of current phase of development
  - usability improvements
  - scientific development, including implementation of grouping mechanisms based on mode of action or adverse outcome pathways (AOPs)
  - additional functionalities
  - IT improvements
- Version 4.0 to be launched in early 2017



### TOOLS FOR NOTIFICATION AND DISSEMINATION OF INFORMATION ON CHEMICALS





## OECD Harmonised Templates

- Standard data formats for reporting information used for the risk assessment of chemicals
  - properties or effects on human health and the environment
  - use and exposure
- Aimed at developers of database systems
  - prescribe the formats by which information can be entered into and maintained in a database
- Governments and industry are easily able to electronically exchange test study summary information.

http://www.oecd.org/ehs/templates/





- Internet portal: www.oecd.org/ehs/echemportal/
- Free public access to health and environmental effects information prepared for government chemical review programmes.
- Links to reports and datasets in participating data sources:
  - Property information (e.g. hazard & risk assessments, test data)
  - Exposure and use information
  - National classification results (GHS)
  - Scheduling information (not in search)



#### The Global Portal to Information on Chemical Substances





Chemical Substance Search Chemical Property Data Search **GHS Search** 

Thirty one data sources participate under Chemical Substance Search. Four data sources participate under Chemical Property Data Search.

Two data sources participate under the GHS Search.

The list of data sources participating in eChemPortal is continuously expanding.

eChemPortal provides free public access to information on properties of chemicals:

- Physical Chemical Properties
- Ecotoxicity

- Environmental Fate and Behaviour
- Toxicity

eChemPortal allows simultaneous searching of reports and datasets by chemical name and number, by chemical property, and by GHS classification. Direct links to collections of chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels are obtained. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are provided when available. In addition, eChemPortal provides also exposure and use information on chemicals.

#### Latest news

German database Information system für gefärliche Stoffe IGS now added to eChemPortal

27 May 2016

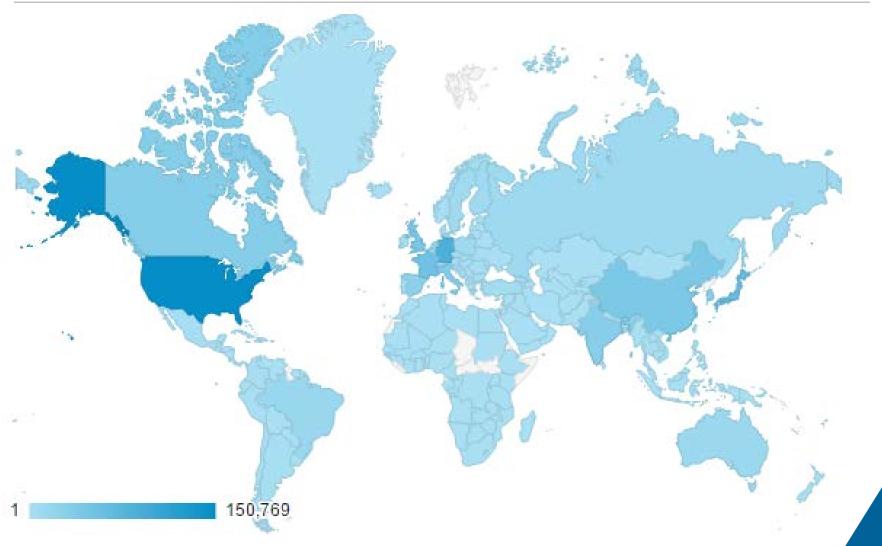
The Chemical Hazards Database of the European Food Safety Authority is now linked to eChemPortal

20 April 2016



## eChemPortal

### Total number of visits per country since 2010





## Priority for further development

- Addition of databases, including ones that can participate in the GHS search functionality
- More user-friendly user interface



#### (International Uniform ChemicaL Information Database)

### Free software application

- Capture, store, submit, exchange data on chemical substances
- Data storage format = OECD Harmonised Templates





## Use of IUCLID by countries



- European tool for
  - Data submission requirements of REACH (Industrial chemicals)
  - Biocidal Products Regulation
- Use by other countries
  - OECD
    - OECD Cooperative Chemicals Assessment Programme
    - eChemPortal www.oecd.org/ehs/echemportal/
  - Japan (as a electronic data development tool)
  - Switzerland (new substance notifications)
  - Canada (used by evaluators to capture, structure and maintain data; other uses in investigation)
  - Other countries examining use of IUCLID



# METHODOLOGIES FOR EXPOSURE ASSESSMENT



### Methodologies for Exposure Assessment

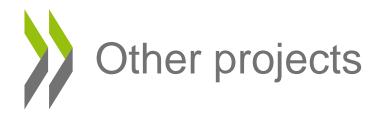
 Development of harmonised methodologies for assessing the exposure of chemicals to the environment and humans

- Types of Outputs:
  - Emission Scenario Documents
  - Tools to assess the exposure to children
  - Tools to assess the exposure from products
  - Information exchange on exposure mitigation (BATs)



## Emission Scenario Documents (ESDs)

- Describe the sources, production processes, pathways and use patterns with the aim of quantifying the emissions (or releases) of a chemical into water, air, soil and/or solid waste.
- New or revised ESDs being developed:
  - Metals released during waste disposal
  - Lube oil additives
  - Use of aqueous film forming foam
  - Hydraulic fracturing
  - Use of vapour degreasers



- Estimation of removal from waste water treatment plants
- Methodologies for risk assessment of combined exposures to multiple chemicals
- Harmonisation of use codes
- Product release and exposure warehouse
- Decision tree for the risk assessment of children
- Estimation of oral exposure of children through mouthing
- Exchange of experience in how countries establish Best Available Techniques



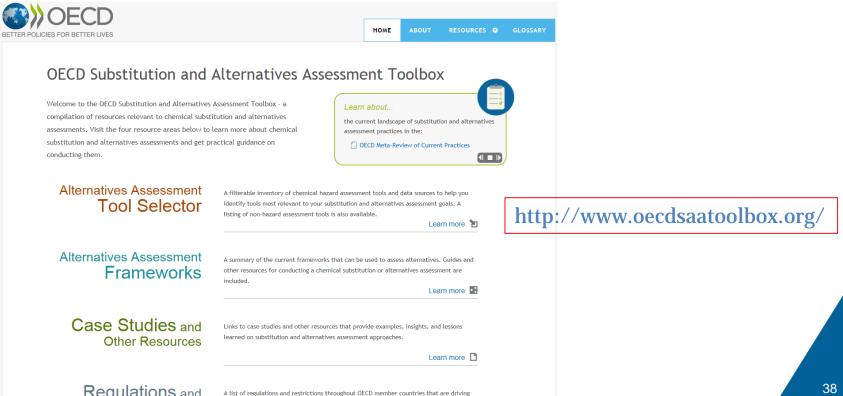
## RISK REDUCTION



## Substitution of Harmful Chemicals

Objective: furthering tools and approaches to support decision making for the substitution of chemicals of concern

Types of Outputs: Reports and the Substitution and Alternatives Assessment Toolbox







## OECD/UNEP Global PFC Group



- Mandate from 2<sup>nd</sup> 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.

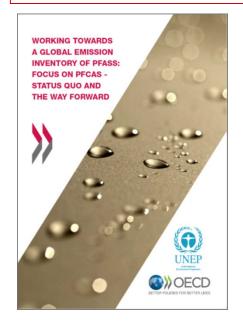
www.oecd.org/ehs/pfc



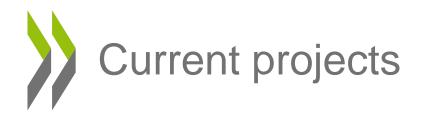
### Recent releases

- Working towards a global emission inventory of PFASs
- Risk reduction approaches for PFASs a cross-country analysis

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







- Update of Web portal
- Knowledge sharing on alternatives
- Dissemination and updating of risk reduction approaches
- Updating of list of PFASs

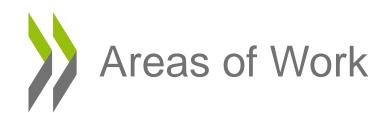


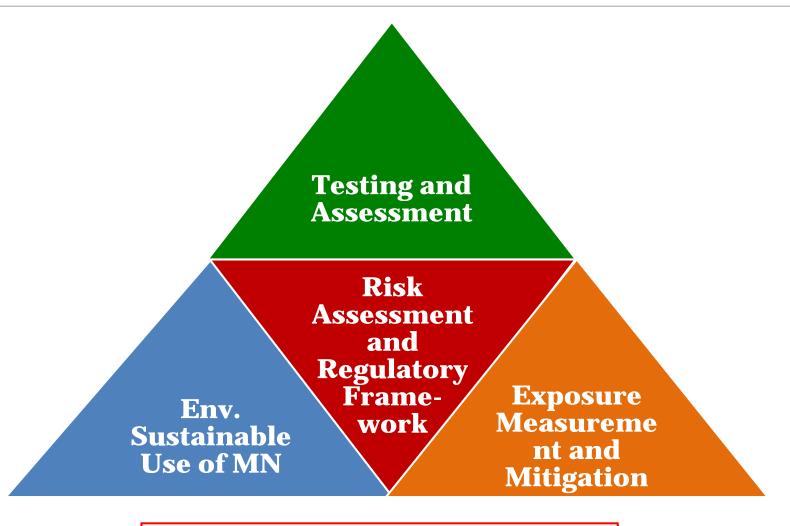
# Assessing the costs and benefits of managing chemicals

- First workshop held in June 2016, hosted by ECHA
- Main recommendations:
  - Establishment of a regular, on-going forum to share risk management case studies, including risk management approaches and associated socioeconomic impact assessment, to inform decision-making
  - Conduct coordinated valuation studies in relation to morbidity and environmental endpoints relevant to chemicals



## MANUFACTURED NANOMATERIALS





http://www.oecd.org/env/ehs/nanosafety/



# OECD Council Recommendation 2013

• "... the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials."

http://www.oecd.org/chemicalsafety/oecdcountries-address-the-safety-ofmanufactured-nanomaterials.htm



## Full data sets on 11 representative MN

#### **Testing Programme Overview**





Learn more about the Programme.

Overview



Download Manufactured Nanomaterials Dossiers or search for Tested Endpoints.

Downloads and searches

#### **Sponsors**

#### More information



Learn more about our sponsoring countries and institutions.

<u>Sponsors</u>



Request additional information about the Programme.

Contact



## Examples of current projects

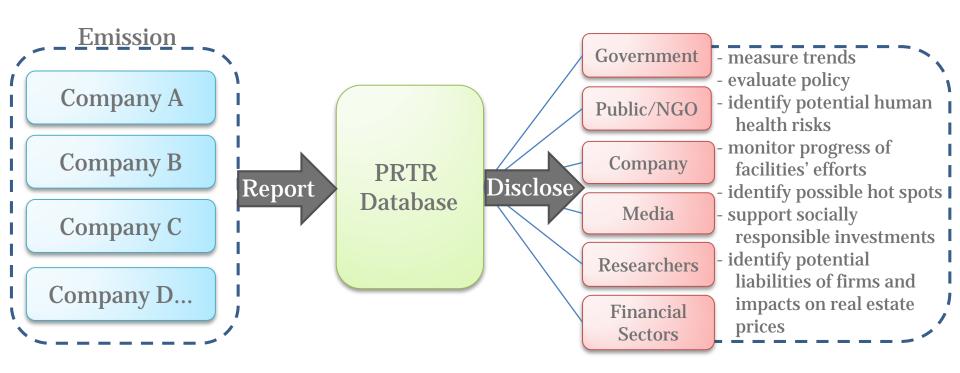
- Summaries of Dossiers of 11 Nanomaterials
- Case study on exposure assessment of nano-gold and nano-silver
- Strategy for distinguishing CNTs from background aerosols
- Update of Test Guidelines for inhalation toxicity
- GD on aquatic and sediment toxicity testing of Nanomaterials
- GD for agglomeration and dissolution of nanomaterials in aquatic media



## POLLUTANT RELEASE AND TRANSFER REGISTER (PRTR)



## What is a PRTR?





## OECD Work on PRTRs

#### Objectives

- help countries in setting up and operating their PRTR
- improve release estimation techniques
- improve use of PRTR data (e.g. as indicators of environmental performance)
- promote harmonisation of PRTRs

#### Recent publications:

- Guidance Document on Elements of a PRTR: Part I & II;
- Global Pollutant Release and Transfer Register, proposal for a harmonised list of pollutants, reporting thresholds and industrial sectors
- Techniques for Estimating Quantities Transferred, Released or Disposed
- Techniques for Estimating Releases of Chemicals from Products

#### Current projects:

Role of PRTR data for global sustainability

http://www.oecd.org/env/prtr



#### Centre for PRTR Data

 national PRTR data from OECD countries at one Internet location

### • Resource Centre for Release Estimation Techniques

 information on available release estimation techniques, overarching documents and general information among OECD countries for estimating releases from various sources

#### PRTR.net

 global portal to PRTR information and activities from countries and organisations around the world



## CHEMICAL ACCIDENTS

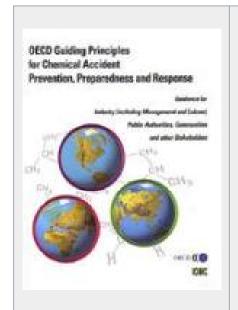


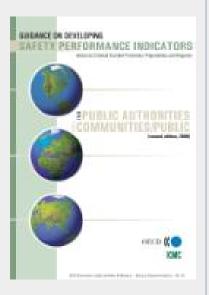
## Chemical Accidents

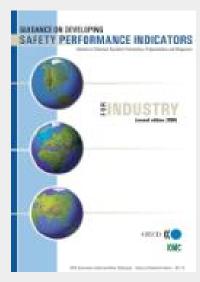
- Objective:
  - Enhance the prevention of, preparedness for, and response to chemical accidents
- Types of Outputs:
  - Guidance on change of ownership
  - Guidance on Natural Hazard Triggered Technological Accidents
  - Methods for estimating the economic benefits of regulation for preventing chemical accidents
- Recent or upcoming work:
  - Synthesis Report on Ownership Change in Hazardous Facilities
  - Report on Ageing of Hazardous Installations

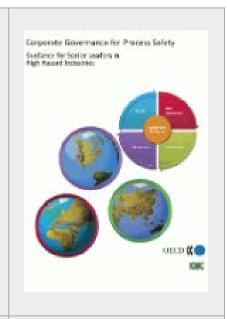


# CHEMICAL ACCIDENTS: FLAGSHIP PUBLICATIONS







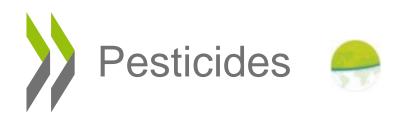


The Guiding
Principles address
all aspects of
preventing and
managing
chemical
accidents.

The Guidance on Safety Performance Indicators serves as a guide for key stakeholders to determine if their implementation of the Guiding Principles has led to improved chemical safety. Corporate
Governance for
Process Safety
Guidance for
Senior Leaders in
High Hazard
Industries



## PESTICIDES



### Objective:

 Cooperation in assessing and reducing risks of pesticides and on sustainable pest management

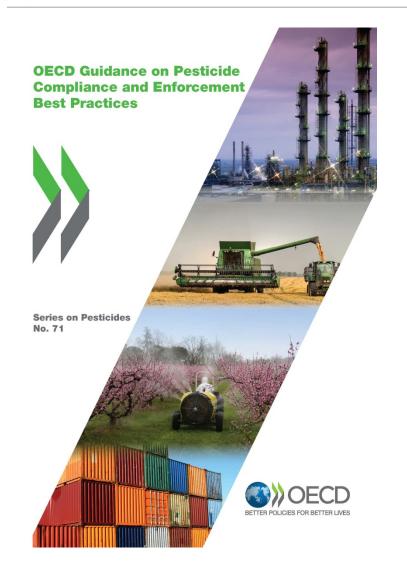
### Types of Output:

- Risk assessment methodologies for novel pesticides
- Tools for registration of bio-pesticides
- Indicators for integrated pest management
- Best practices in fighting illegal trade of pesticides
- Electronic tools for data submission and review

www.oecd.org/env/pesticides



# Guidance on Pesticide Compliance and Enforcement Best Practices



Guidance for promoting and monitoring compliance and for assessing and mitigating risks of noncompliance. It is targeted primarily at pesticide regulators, but may also interest policy makers as well as regulated parties (i.e. pesticide industry).



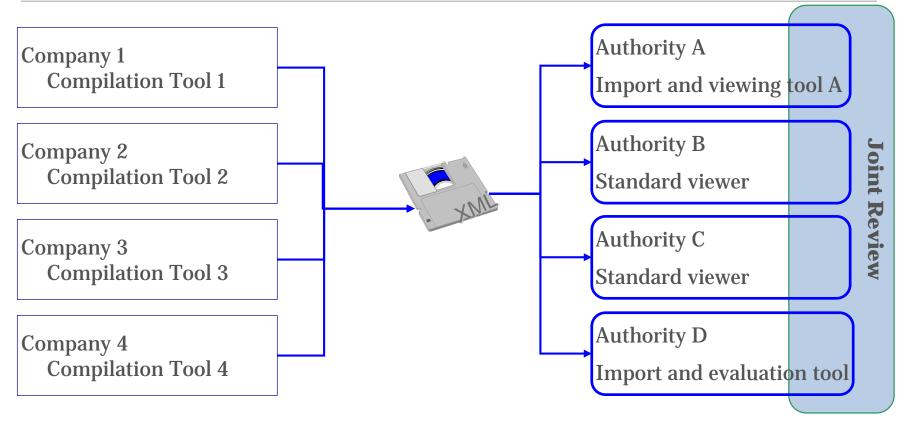
# Guidance on terrestrial field dissipation studies



The harmonised international guidance means that field dissipation/accumulatio n studies carried out in one country can be considered in risk assessments conducted in other countries and regions.



# Globally Harmonised Submission and Transport Standard



• <a href="http://www.oecd.org/chemicalsafety/submis-sion-transport-standard/">http://www.oecd.org/chemicalsafety/submis-sion-transport-standard/</a>



# Examples of recent publications and current projects

- GD on residues in rotational crops
- GD to address and solve minor use gaps
- GD on the risk assessment of secondary metabolites of microbial biocontrol agents
- GD on the sensitisation potential of microorganisms
- Best Practice Guide on fighting illegal international trade of pesticides
- Risk Indicators



## BIOCIDES





### Objectives:

 Harmonisation of risk assessment and management of biocides

## • Types of Outputs:

- Test methods on efficacy for disinfectants and insecticides
- Best practices for integrated pest management



- Test Guideline on efficacy of treated articles
- GD on performance standards and label claims for hard surface microbicides

http://www.oecd.org/chemicalsafety/biocides.htm



## ENVIRONMENTAL BIOSAFETY AND SAFETY OF NOVEL FOODS AND FEEDS



### Objective:

 Assist countries in the evaluation of the environmental safety of transgenic crops, trees, animals, micro-organisms

### Types of Outputs:

- Harmonisation of emerging issues (e.g. gene editing).
- Biology documents
- Biotrack



- Consensus Documents on information relevant to environmental risk assessment:
  - Contains science-based information on specific crops and traits associated with the use of transgenic plants
  - Recent: Cucurbita, sp.; Brassica sp; low-level presence
  - Forthcoming: Atlantic salmon; Aedes Aegypti; Environmental Considerations for Risk Assessment;.

www.oecd.org/biotrack/

# SAFETY OF NOVEL FOODS AND FEEDS

- Consensus Documents on Compositional considerations relevant in risk assessment and comparative approach:
  - Contains science-based information on Nutrients, Anti-nutrients, Toxicants, Allergens for new varieties of crop plants used for food and feed
  - Recent: sugarcane, oilseed rape (update), soybean (update), pleurotus mushroom; common bean; rice (update)



## IOMC TOOLBOX FOR DECISION MAKING IN CHEMICALS MANAGEMENT



# IOMC Toolbox for Decision Making in Chemicals Management

 One stop shopping on the web for resources for countries who wish to set up or improve their chemicals management system to find answers to and ways of dealing with their specific needs and objectives.







## Management Schemes Included:

- A national management scheme for pesticides
- An occupational health and safety system
- A chemical accidents prevention, preparedness, and response system for major hazards
- An industrial chemicals management system
- A classification and labeling system
- A system to support health authorities which have a role in the public health management of chemicals
- Pollutant release and transfer registers (PRTR)



















Inter-Organization Programme for the Sound Management of Chemicals

#### IOMC Toolbox for Decision Making in Chemicals Management

New navigation | Navigation history | Map | Name

IOMC toolbox home

IOMC toolbox home

>

#### **Next Step**

Gap analysis

#### Welcome to the IOMC Toolbox for Decision Making In Chemicals Management

The IOMC Internet based Toolbox for Decision-Making in Chemicals Management (IOMC Toolbox) is aimed at countries who wish to address specific national issues regarding chemicals management.

The IOMC Toolbox 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.

The toolbox identifies the available IOMC resources that will help the country address the identified national problem(s) or objectives. Special focus is given to identifying simple cost-effective solutions to national chemicals management issues.

Please use the left-hand buttons to proceed.

Note: The development of this Toolbox is a work in progress. Only a limited number of issues related to chemicals management are addressed in this version. Future updates will expand the scope of the Toolbox.

Wednesday, September 23, 2015

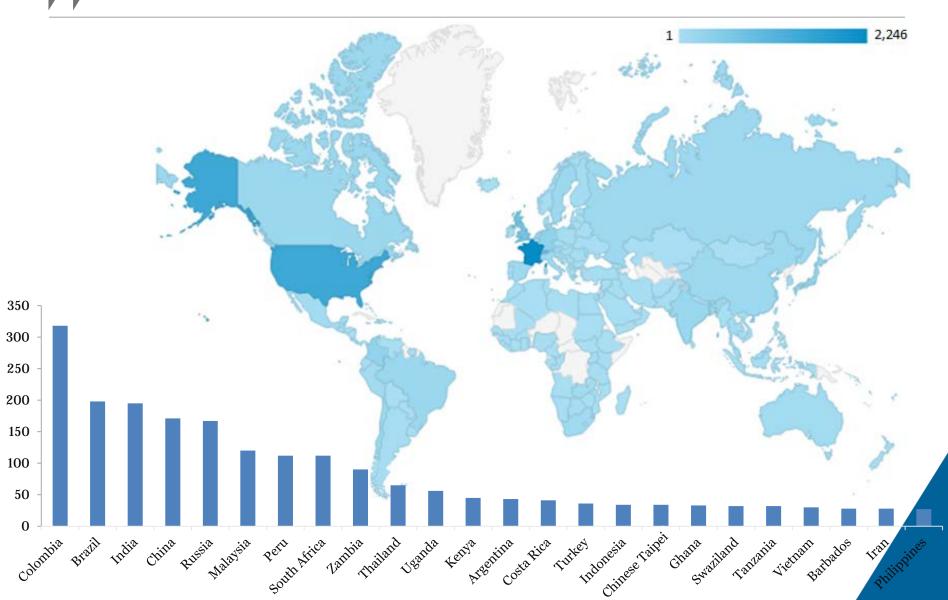
More information

- What's New?
- Acknowledgement
  - IOMC Toolbox Flyer
  - Video tutorial

http://iomctoolbox.oecd.org/ http://youtu.be/YQUGl5hD\_BY



### IOMC Toolbox Number of Visits per Country

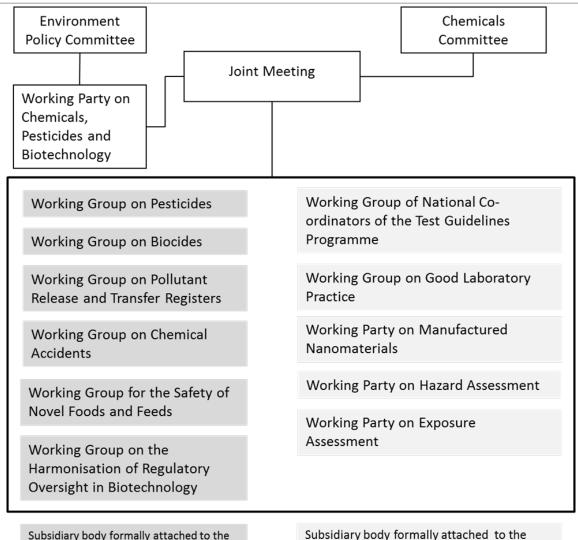




# OVERSIGHT BY COUNTRIES AND STAKEHOLDERS



#### Oversight by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology



Subsidiary body formally attached to the Working Party on Chemicals, Pesticides and Biotechnology

Subsidiary body formally attached to th Chemicals Committee



## FURTHER INFORMATION



- Website
  - <a href="http://www.oecd.org/chemicalsafety/">http://www.oecd.org/chemicalsafety/</a>
- 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/environmenthealth-safety-news.htm

## **THANK YOU!**