The OECD work related to biocides

Sylvie Poret, OECD Secretariat

Asian-European Biocides Regulatory Summit
1-2 September 2014, Singapore
What is OECD?

The Biocides Programme

Work on emerging issues

Nano safety

Integrated approaches to testing and assessment (IATA)

OECD tools on chemicals useful to the biocides community
WHAT IS OECD?
The OECD...

• ...is the global organisation that drives **better policies for better lives**

• ...analyses, measures and compares experiences and policies to give advice that helps **raise living standards** globally

• ...aims for a **stronger, cleaner, fairer world**
What is the OECD?

- An intergovernmental organization
- A forum in which governments:
  - work together and with representatives from business and civil society
  - compare and share policy experiences (social, economic, environmental)
  - seek answers to common problems & identify good practices
  - promote decisions and recommendations
- Key words at OECD: dialogue, consensus, peer review & pressure
Fast facts

• Established: 1961
• Headquarters: Paris
• OECD Centres: Berlin, Mexico City, Tokyo, Washington
• Members: 34
• Secretary-General: Angel Gurría (Mexico)
• Secretariat staff: 2 500
• Annual budget: 347 € million (2012)

• Nearly 300 expert committees and working groups with participation of +100 countries
OECD’s global reach

34 member countries

New members: Chile, Estonia, Israel, Slovenia

Key Partners: Brazil, China, India, Indonesia, South Africa

Ongoing membership talks with Russia, Colombia, Latvia
Part of a global community
Who does what?

**Council**
Oversight and strategic direction, presided by the Secretary-General

**Committees**
National experts discussion, monitoring and peer review

**Secretariat**
Research, analysis and policy recommendations
Better lives from every angle

Cleaner
Stronger
Fairer

Competition
Trade
Education
Employment
Healthcare
Migration
Finance
Tax evasion
Corruption
Fiscal policy
Energy
Innovation
Climate change

Development assistance
Education Healthcare
Pensions
Employment
Competition
Governance
Entrepreneurship
Agriculture
Finance

Better lives from every angle
OECD’s Work on Biocides: Where does it fit?

OECD
agriculture, development co-operation, education, employment, environment, taxation & trade, science & technology, industry and innovation, energy, etc.

ENVIRONMENT
climate change, biodiversity, water, eco-innovation, outlooks, chemicals, etc.

SAFETY of CHEMICALS
testing, hazard assessment, GLP, HPV, biotechnology, nanomaterials, pesticides, biocides, chemical accidents, Pollutant Release & Transfer Registers, etc.

BIOCIDES
THE OECD BIOCIDES PROGRAMME
Why an OECD Programme on Biocides?

Goals

Reduce risks for human health and the environment

Minimise duplication of effort between countries and reduce barriers to trade

Improve the efficiency of assessment and control

Benefits for all stakeholders: governments, industry, public
OECD Biocides Programme Aims to:

1. Harmonise test methods

2. Facilitate the sharing of data and reviews across governments

3. Share information on new and effective approaches for assessing and managing risk

4. Provide support to help countries perform exposure assessments (via Emission Scenario Documents)

5. Develop risk reduction best practices and recommendations
Diversity of biocidal products and uses pose:

- Scientific challenges
- Regulatory challenges

Roles for OECD:

- Monitoring Emerging Scientific and Policy Areas
- Sharing information
- Developing new approaches and tools

And also…
Who is involved in OECD work on Biocides?

Task Force on Biocides (TFB)
- OECD Countries and European Commission
- Industry associations: CEFIC, ACC

OECD Secretariat

TFB meets around every 12 months
Published work:

- **ESD for Wood Preservatives (2013)**
  Covers emissions from application of preservative to wood, storage prior to shipment and from treated wood in service

- **ESD for Antifoulants (2005)**
  Covers emissions from application of antifoulants and from treated materials in service
Published work (cont’):

- **ESD on Insecticides for Stables and Manure Storage Systems (2006)**
  Covers emissions from application of insecticides in animal housings and manure storage areas

- **ESD on Insecticides for Household and Professional Use (2008)**
  Covers emissions from applications of insecticides, acaricides and products to control other arthropods
Ongoing work:

- **New Guidance Document on Insecticides for Vector Control:**
  - Larvicide & adulticide treatment by portable or vehicle-mounted mist blower or foggers
  - Aerial spray
  - Industrial and general public treatment of bed nets
  - Treatments inside aircrafts
OECD Test Guidelines

to test all chemicals, including biocides

1. Physical chemical properties
2. Effects on wildlife (ecotoxicity)
3. Degradation, accumulation and leaching (environmental fate)
4. Effects on human health (toxicity)
5. Efficacy (for biocides only)
Work initiated in 2004/2005

A survey of OECD member countries found:

- few commonalities of methods or claims for hard surface products;
- treated articles are generally not regulated

Work on:

- Test methods for biocides used on hard surfaces;
- TG for biocides used to treat articles/materials;
- Guidance for pool and spa disinfectants;
- Guidance for insecticides.
Published work:

- Guidance Document on Quantitative Methods for evaluating the activity of **Microbicides used on hard non-porous surfaces** (2013) containing four test methods (bactericidal, mycobactericidal, fungicidal and virucidal)


- Guidance Document on Efficacy of Baits against **Cockroaches** (2013)

- Guidance Document for Demonstrating Efficacy of **Pool and Spa Disinfectants** and Field Testing (2012)
Harmonise Test Methods

Efficacy Testing

Published:

- Draft Test Guideline for assessing efficacy of antimicrobial treated articles – porous surfaces (textiles) and non-porous surfaces (plastics) (2014)

Under development:

- Draft Test Guideline on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-porous Surface (based on experience gained with the use of the GD)

- Draft Guidance Document on the efficacy of insecticides used against bed bugs
OECD Test Guidelines 114 (Viscosity of liquids) and 109 (Density of liquids and solids) (revised and published in 2012)

New Test Guideline on the determination of pH, acidity and alkalinity (2013)

Guidance Document on analytical method validation (2014)

Guidance Document on storage stability (under development)
Joint OECD/EC/KEMI Workshop held in June 2013

- Assessment and management of risks of microbial pesticides

Follow-up work could include:

- Work on waivers
- Description of modes of actions of micro-organisms to help design relevant risk assessment
- GD on analytical methods
- GD on production of secondary metabolites…
Objectives:
- Promote risk reduction policies
- Identify effective risk reduction policies

First step: survey of member country existing or planned policies to define work programme (completed)

Second step: implementation of the work programme
- Cost/benefit analysis of risk reduction measures
- Integrated pest management (IPM) in private area and public health area disinfectants

Risk Reduction for Biocides
WORK ON EMERGING ISSUES
OECD WORK ON MANUFACTURED NANOMATERIALS
OECD Work on Manufactured Nanomaterials (incl. silver nanoparticles)

OECD established a programme of work in 2006

- To promote international cooperation in human health and environmental safety related aspects of manufactured nanomaterials, in order to assist in the development of rigorous safety evaluation of nanomaterials

- Work is carried-out by various Steering Groups:
  - Testing and Assessment
  - Exposure Measurement and Exposure Mitigation
  - Risk Assessment and Regulatory Programmes
  - Environmentally Sustainable Use of MN
OECD members, together with non OECD economies and industry, agreed to pool resources and expertise to test a selected list of manufactured nanomaterials for approximately 59 endpoints relevant to the environment and human health safety.

- **13 manufactured nanomaterials (including silver nanoparticles)**

- Analysis of silver nanoparticles testing to be reviewed in December 2014
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.

Work underway or planned as a priority:

- Workshops on inhalation toxicity (report published), phys/chem properties (report published) ecotoxicology and environmental fate (report published) genotoxicity, toxicokinetics, measurement of phys. chem. parameters, categorization

As a result, development of specific TGs for NM was decided on inhalation, aquatic and sediment toxicology testing, dispersion and dissolution rate in aquatic environment, NM removal from wastewater.
OECD complements the testing programme with the development of guidance on exposure measurement and exposure mitigation.

Exposure Assessment Case-Study on Nano-Silver:

- **Objective:** to obtain exposure data to enable risk assessment
- **What was assessed:**
  - Human occupational exposure
  - Human non-occupational exposure
Four projects are underway:

- Interspecies Variability Factors in Human Health Risk Assessment
- Physical-chemical characteristics in regulatory risk assessments – Dissolution as a function of surface chemistry: case study on silver nanoparticles
- Survey on approaches to develop or use nanomaterial equivalence/grouping/read-across concepts based on physical-chemical properties for regulatory regimes
- Analysis of Physical-chemical properties for Read-across and Risk Assessment Guidance
All publications are available for free at: http://www.oecd.org/env/nanosafety

OECD’s Database on Research into the Safety of Manufactured Nanomaterials http://webnet.oecd.org/NanoMaterials

Contact : nanosafety@oecd.org
FRAMEWORK FOR THE DEVELOPMENT AND USE OF INTEGRATED APPROACHES TO TESTING AND ASSESSMENT (IATA)
Today we base chemical management largely on results from a battery of in vivo tests.

In the future we want to manage chemicals based on results from alternative methods (e.g. in silico, in chemico, and in vitro methods).
An IATA is a concept that incorporates different types of test data and non-test data into the hazard assessment.

An IATA attempts to tie together all the available relevant data on a given chemical or chemical category before the initiation of testing, especially *in vivo* testing.

The main purposes of an IATA is to replace, or at a minimum, reduce animal testing and to gain efficiency.
OECD Framework for the development and use of IATAs

- To improve the harmonisation of IATAs, OECD wants to elaborate an agreed framework for developing and using integrated approaches.

- This framework should provide principles, criteria and guidance to allow common interpretation of the results from alternative methods for characterising (both qualitatively and quantitatively) the adverse effects in animals and humans and/or the environment, so that they can be used for regulatory purposes.
Critical to this effort is the concept of the Adverse Outcome Pathway (AOP). AOPs delineate the documented, plausible, and testable processes by which a chemical induces molecular perturbations (Molecular Initiating Events) and the associated biological responses that describe how the molecular perturbations cause effects at the subcellular, cellular, tissue, organ, whole animal, and population levels of observation.

<table>
<thead>
<tr>
<th>Toxicant</th>
<th>Molecular Interactions</th>
<th>Cellular Responses</th>
<th>Organ Responses</th>
<th>Organism Responses</th>
<th>Population Responses</th>
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<tr>
<td>Chemical Properties</td>
<td>Receptor/Ligand Interaction</td>
<td>DNA Binding</td>
<td>Gene activation</td>
<td>Altered physiology</td>
<td>Lethality</td>
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<td>Protein production</td>
<td>Disrupted homeostasis</td>
<td>Impaired Development</td>
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<td>Altered signaling</td>
<td>Altered tissue development/function</td>
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<td>Structure Extinction</td>
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- Receptor/Ligand Interaction
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- Protein Oxidation
- Gene activation
- Protein production
- Altered signaling
- Altered physiology
- Disrupted homeostasis
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- Impaired Development
- Impaired Reproduction
- Structure Extinction
An example: The Adverse outcome pathway for skin sensitisation (OECD, 2012)
Application of the AOP concept to develop and use IATAs

• AOP/MoA allows categorization of chemicals based on toxicological similarity

• AOPs provide an opportunity to group chemicals based on both intrinsic chemical and biological activity at different levels of biological organisation and not only at apical endpoint level.

• Such categorisation of chemicals based on both the molecular initiating event and early key events gives greater confidence that chemicals induce adverse effects via the same toxicity mechanisms.
Application of the AOP concept to develop and use IATAs

• Solid knowledge of an AOP/MoA allows for interpretation of biological significance of any test method related to a key event and indicates how it is related to the in vivo adverse outcome.

• An AOP could help to decide which further information is needed as part of an overall integrated testing strategy to increase the certainty of linking the initiating event and adverse effect(s).
For more information on Adverse Outcome Pathways

• In 2012, the OECD launched a new programme on the development of AOPs:
  – development of IATAs for defined hazard endpoints
  – identification of new *in vitro* test methods
  – identification of new methods for grouping chemicals

• For more information:
OECD TOOLS OF INTEREST TO THE BIOCIDES COMMUNITY
OECD tools of interest to the Biocides community: eChem Portal

- **eChem Portal**: An internet gateway providing direct free access to information on the properties of chemicals as well as to hazard and risk assessments

- [www.oecd.org/ehs/echemportal](http://www.oecd.org/ehs/echemportal)
eChemPortal - The Global Portal to Information on Chemical Substances, will be the preferred worldwide source of information about chemicals from authorities and international organisations.

www.oecd.org/ehs/echemportal
OECD eChemPortal Activity

• Step towards achieving international commitments
  – SAICM: “Facilitate public access to appropriate information and knowledge of chemicals throughout their life cycle...”.

• OECD Steering Group for development
  – Canada, Japan, United States, EC, ECHA, the OECD Business and Industry Advisory Committee (BIAC), IPCS, UNEP, chemicals and environmental NGOs

• Developed in collaboration with and hosted by European Chemicals Agency (ECHA)
Information prepared for government chemical review programmes

- Property information (e.g. hazard & risk assessments, test data)
- Exposure and use information
- National classification results (GHS)

Existing & new industrial chemicals, pesticides & biocides
eChemPortal’s added value

- Searches data from **multiple sources** simultaneously
- Identifies **relevant** information (databases, review documents, and assessments)
- Provides direct **free** access to information prepared for government chemical review programmes
- Describes the **type of review** the data have undergone
- Allows a **broad search** on substance identification thanks to a database of chemical names, synonyms, trade names, chemical names in different languages
- Implemented with the **common electronic data formats** for reporting chemical test summaries
What eChemPortal is

Internet Portal

Data sources submit enough data to allow queries.

Data Source A

Direct link to information in the data source website.

Data Source B

Data Source C...

Query is executed at Portal itself. Displays homogenous query result.

User
Participating data sources

• **29 data sources participate in substance search**
  – Australia, Canada, Finland, France, Germany, Japan, New Zealand, UK, USA, EU, IOs

• **4 data sources in property data search**
  – Canada (CCR); EU (ECHA CHEM); Japan (J-CHECK); OECD (OECD SIDS IUCLID)

• **The number of data sources participating in eChemPortal is continuously increasing**
Description of data source

The Global Portal to Information on Chemical Substances

Participating Databases

- Participating Databases
- EnviChem

Data Bank of Environmental Properties of Chemicals

Type of information that can be found via eChemPortal:
Property data sets of industrial chemicals, pesticides and biocides.

General information:
EnviChem is a factual database containing test results data on ca. 3000 substances. EnviChem contains data related to the effects, fate and behaviour of chemicals in the environment. The most extensive part of the report is the toxicity data (LC/EC/IC50, LOEC, NOEC etc.) of substances to aquatic organisms. There are also data on physico-chemical properties, degradation, metabolism, bioaccumulation and the effects of the substance to terrestrial species eg. plants and mammals.
Main focus is currently on substances

3 data sources indicate that they include information on Biocides
  - Data Bank of Environmental Properties of Chemicals (EnviChem) (Finland)
  - INERIS-Portail Substances Chimiques (France)
  - European Chemical Substances Information System (ESIS)

Others may contain substances of interest (e.g. US EPA and APVMA databases)

Investigating with ECHA possibility to introduce information on biocidal products to eChemPortal
eChem Portal: Main functionality

- Searches available
  - By substance identification
    - Reference Number (CAS, EC, IUBMB, MITI, UN or NA Number)
    - Chemical name or synonym
    - Query URLs
  - By property and effects criteria
    - Physical Chemical Properties
    - Ecotoxicity
    - Environmental Fate and Behaviour
    - Toxicity
  - By substance and then by property and effect criteria
eCHEM Portal

The Global Portal to Information on Chemical Substances

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 and by chemical property. 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.

How to Use eChemPortal

Under Chemical Substance Search you can search for information by chemical number (recommended) or by chemical name and synonym, including partial names, in several languages.

You can then search for specific endpoint property data for the substances you selected under Search. You can also go directly to Chemical Property Data Search without specifying chemical substances.

Under Chemical Property Data Search you can query the eChemPortal data catalogue by chemical property and can select specific search criteria for this property. You can save search results on chemical properties for different chemicals to your local computer.

See the “Help” text and the list of Frequently Asked Questions to learn more about how to use the Portal.
# Substance Search

**Number:**

CAS, EC, IUBMB, MITI, UN or NA Number.
Example: 108-88-3 for a CAS Number.
Make sure you include the number separators. Do not search on partial Numbers.

**Chemical name or synonym:**

Example: Use `gluta` to find Glutamic acid, use `chloro` to find dichlorobenzene.
To search for `*` as character (non wildcard use) use `**` instead.

## Databases:

- [✓] ACToR
- [✓] AGRITOX
- [✓] CCR
- [✓] CESAR
- [✓] CHRIP
- [✓] ECHA CHEM
- [✓] EnviChem
- [✓] ESIS
- [✓] GHS-J
- [✓] HPVIS
- [✓] HSDB
- [✓] HSNO CCID
- [✓] INCHER
- [✓] J-CHECK
- [✓] JECDB
- [✓] NICNAS PEC
- [✓] OECD HPV
- [✓] OECD SIDS IUCLID
Property Search

Select Query Block Type

Select a section for which to define query criteria.

- Physical and chemical properties
- Environmental fate and pathways
- Ecotoxicological Information
  - Aquatic toxicity
    - Short-term toxicity to fish
    - Long-term toxicity to fish
    - Short-term toxicity to aquatic invertebrates
    - Long-term toxicity to aquatic invertebrates
    - Toxicity to aquatic algae and cyanobacteria
    - Toxicity to aquatic plants other than algae
    - Toxicity to microorganisms
    - Toxicity to other aquatic organisms
  - Sediment toxicity
  - Terrestrial toxicity
(Q)SAR TOOLBOX
OECD tools of interest to the Biocides community: (Q)SAR Toolbox

- (Q)SAR project launched in 2003

- **Aim**: To increase the regulatory acceptance of (Q)SAR methods

- The OECD has developed a **(Q)SAR Toolbox** to make (Q)SAR technology readily accessible, transparent, and less demanding in terms of infrastructure costs
The Toolbox is a software application intended to be used by governments, chemical industry and other stakeholders in filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals.

The Toolbox incorporates information and tools from various sources into a logical workflow.
Seminal features of the (Q)SAR Toolbox

- Identification of structural characteristics and potential mode of action of a target chemical

- Identification of other chemicals that have the same structural characteristics and/or mode of action

- Use of existing experimental data for read-across to fill data gaps
### Seminal features of the (Q)SAR Toolbox

#### Chemical categories

<table>
<thead>
<tr>
<th>Endpoint 1</th>
<th>Endpoint 2</th>
<th>Endpoint 3</th>
<th>Endpoint 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical 1</td>
<td>Chemical 2</td>
<td>Chemical 3</td>
<td>Chemical 4</td>
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</tbody>
</table>

- **Read-across**
- **Interpolation**
- **Extrapolation**

**QSAR model**

- **Reliable data point**
- **Missing data point**
(Q)SAR Toolbox tutorials

- Tutorials are available

<table>
<thead>
<tr>
<th>Title and main features</th>
<th>Slides</th>
<th>Video tutorial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-by-step example on how to predict the skin sensitisation potential approach of a chemical by read-across based on an analogue approach (for beginners)</td>
<td>pdf</td>
<td>Video</td>
</tr>
<tr>
<td>Step-by-step example of how to predict aquatic toxicity for an untested target chemical by the trend analysis approach (for beginners)</td>
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<tr>
<td>Step-by-step example of how to predict Ames mutagenicity for a chemical by a qualitative read-across approach. (for beginners)</td>
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<tr>
<td>Step-by-step example of how to predict acute toxicity to Tetrahymena pyriformis by trend analysis using category pruning capabilities (December 2012)</td>
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<td>Step-by-step example of how to build and evaluate a category based on mechanism of action with protein and DNA binding (December 2012)</td>
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<td>Step-by-step example of how to evaluate an ad-hoc category of aliphatic amines and to predict an ecotoxicological endpoint (December 2012)</td>
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</table>

• Additional functionalities: Extending the capabilities for handling:
  – Organometallic substances
  – UVCB substances
  – Ionisable substances
  – Nanomaterials

• Scientific development:
  – Implementation of Adverse Outcome Pathways
  – General scientific improvement to have better reliability assessment

• Usability improvements:
  – More streamlined and interactive prediction process
For more information

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

http://www.oecd.org/env/ehs/
(general work on chemicals)