The OECD activities on biocides and IATA

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OECD Secretariat

18-20 November 2013, Vienna
What is OECD?

The OECD Biocides Programme

The OECD framework for the development and use of integrated approaches to testing and assessment (IATA)
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

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

Ongoing membership talks with Russia, Colombia, Latvia

34 member countries

New members:
- Chile
- Estonia
- Israel
- Slovenia

Key Partners:
- Brazil
- China
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- South Africa
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

Fairer
- Development assistance
- Migration
- Education
- Healthcare
- Pensions
- Employment
- Corruptions

Stronger
- Trade
- Entrepreneurship
- Governance

Cleaner
- Finance
- Innovation
- Agriculture
- Energy
- Climate change
- Tax evasion
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
And also...

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
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
Exposure Assessment

Ongoing work:

- New Guidance Document on Insecticides for Vector Control
Harmonise Test Methods

**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)**
Harmonise Test Methods

Efficacy Testing

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)
Harmonise Test Methods

Efficacy Testing

Under development:

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

Future work:

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

- Possibly a Draft Guidance Document on the efficacy of insecticides used against bed bugs
Harmonise Test Methods
Physical chemistry methods for biocides and other chemicals


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

- Guidance Document on *storage stability* (under development)

- Guidance Document on *analytical method validation* (under development)
Micro-organisms used as biocides

- 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…
Risk Reduction for Biocides

- **Objectives:**
  - Promote risk reduction policies
  - Identify effective risk reduction policies

- **First step:** survey of member country existing or planned policies
For more information

http://www.oecd.org/env/biocides
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
Meeting the Shift

To move chemical management from an in vivo testing-based process to an alternative methods-based process we must add:

• Transparent mechanistic plausibility, and

• Allow for hypothesis-based testing, especially with rapid and inexpensive screening methods.
Transparent Mechanistic Plausibility

Will be attained by integrating knowledge of the relevant chemicals interactions with biological systems (i.e. the molecular initiating events) with knowledge of the relevant biological responses or perturbations that lead to the apical (e.g. in vivo) outcome of interest.

Critical to this effort is the concept of the Adverse Outcome Pathway (AOP)
**Adverse Outcome Pathways: basis for IATA framework?**

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>
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  - Lethality
  - Impaired Development
  - Impaired Reproduction

- **Population Responses**
  - 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 provides an opportunity to group chemicals based on both intrinsic chemical and biological activity at different level 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).
By linking test guideline proposals for the development of in vitro test methods to key events in an AOP, the relationship to hazard endpoints relevant for regulatory purposes can be established.
In 2012, the OECD launched a new programme on the development of AOPs, which addresses the needs of:

- The OECD Test Guidelines Programme for the identification of new *in vitro* test methods that are candidates to become OECD Test Guidelines;
- The OECD QSAR Project for the identification of new methods/profilers for grouping chemicals;
- The OECD Hazard Assessment activities for the development of IATAs for defined hazard endpoints.
AOPs and IATA at OECD: Next steps

- OECD Workshop (2\textsuperscript{nd} half of 2014)
- AOP Knowledge Base ("wikipedia like" web-based management tool)
For more information on Adverse Outcome Pathways