HARMONISING ENVIRONMENTAL RISK ASSESSMENTS OF PESTICIDES

OECD DEVELOPMENT OF TEST GUIDELINES AND METHODOLOGIES

EFSA Scientific Conference on ERA of pesticides
Parma, 15-16 November 2016

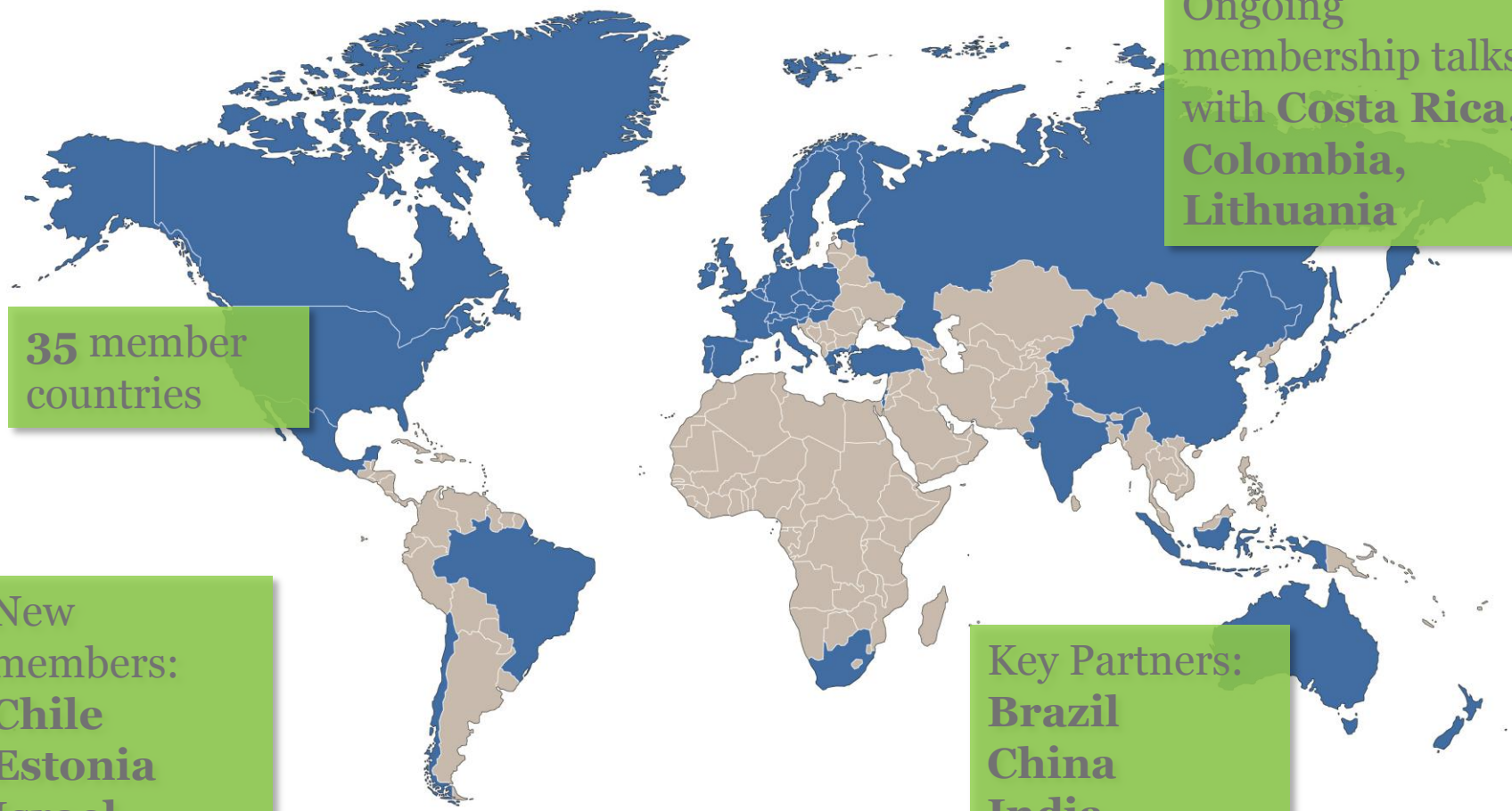
OECD Secretariat

BETTER POLICIES FOR BETTER LIVES

Overview

- OECD
- Working Group on Pesticides
- Test Guidelines and Guidance Documents
- Other activities

The OECD



35 member countries

Ongoing membership talks with **Costa Rica, Colombia, Lithuania**

New members:
Chile
Estonia
Israel
Latvia
Slovenia

Key Partners:
Brazil
China
India
Indonesia
South Africa

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**

Working Group on Pesticides

Pesticides
Vision – strategic objectives for 2024

Pesticides
Vision – strategic objectives for 2024

Working Group on Pesticides

Several Expert groups, Steering groups, e.g.

- Pesticides Effects on Insect Pollinators Expert group (PEIP)
- Bio-pesticides Steering Group (BPSG)
- *e.g. Expert Group on Integrated Pest Management (EGIPM)*

Working Group on Pesticides - Pollinators

Pesticides Effects on Insect Pollinators Expert group (PEIP)

- Pollinators testing requirements and assessment
- Communicating pollinator incidents
- Mitigation of pollinator risks
- Pollinator research database

Working Group on Pesticides - Pollinators

Pollinators testing requirements and assessment:

- priority list for development of test guidelines, includes:
  - honeybee activities
  - non-Apis bee activities
  - microbials

Working Group on Pesticides - Pollinators

- to develop databases to serve as training sets for models to estimate environmental concentrations in relevant bee-related matrices (pollen, nectar, wax, beebread) from various routes of application (foliar, soil, seed).
  - Development of uptake and decline curves for estimating residues in bee-related matrices for systemic pesticides from various routes of application (foliar, soil, seed).

- to develop databases to serve as training sets for predictive models to estimate acute and chronic toxicity endpoints for individual larval and adult bees.

Working Group on Pesticides - Pollinators

- To further refine semi-field testing methods (OECD 75 Guidance) to enhance power of studies to detect effects on brood and adult bees.
- To develop methods for monitoring studies (see also ICP-BR, FAO).
- To develop toxicity testing protocols for non-Apis bees and to identify triggers for recommending these studies;
- To develop a toolbox of mitigation measures and guidance for implementing such measures.

Working Group on Pesticides - Pollinator seminar

Source: © EFSA, #Efsa4Bees website

Working Group on Pesticides – Bio-pesticides

- Bio-pesticides include microbials - bacteria, algae, protozoa viruses, fungi -, pheromones and semiochemicals, macrobials/invertebrates such as insects and nematodes, and plant extracts/botanicals.

Working Group on Pesticides – Bio-pesticides

Working Document on the Evaluation of Microbials for Pest Control(Series on Pesticides No. 43, 2008):

- this document provides a set of examples and case studies aimed at helping regulatory authorities with the assessment of (microbial) biopesticides. This document includes chapters on:

  - Taxonomic identification of micro organisms
  - Genetic toxicity assessment of microbial pesticides
  - Exposure (operators, bystanders, consumers)
  - Microbial metabolite residues in food
  - Efficacy evaluation of microbials

Working Group on Pesticides – Bio-pesticides

- OECD Guidance to the environmental safety evaluation of microbial biocontrol.
  Series on Pesticides **No. 67**
  ENV/JM/MONO(2012)1

- Report of the Second OECD Biopesticides Steering Group seminar on the fate in the environment of microbial control agents and their effects on non-target organisms.
  Series on Pesticides **No. 64**
  ENV/JM/MONO(2011)42

Working Group on Pesticides – publications

- No. 232 Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies
- No. 223 Guidance Document for Storage Stability Testing of Plant Protection and Biocidal Products
- No 204: Guidance Document for Single Laboratory Validation of Quantitative Analytical Methods – Guidance used in Support of Pre-and-Post-Registration Data Requirements for Plant Protection and Biocidal Products
- No 96: Guidance Document on Magnitude of Pesticide Residues in Processed Commodities
- No 72: Guidance Document on Pesticide Residue Analytical Methods
- No 64: Guidance Document on Overview of Residue Chemistry Studies (also Series on Pesticides No 32) (as revised in 2009)
- No 63: Guidance Document on the Definition of Residue (also Series on Pesticides No 31) (as revised in 2009)
- No 11: Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals - Part 1: Report
- No 11: Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals - Part 2: Annexes
- No 9: Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application

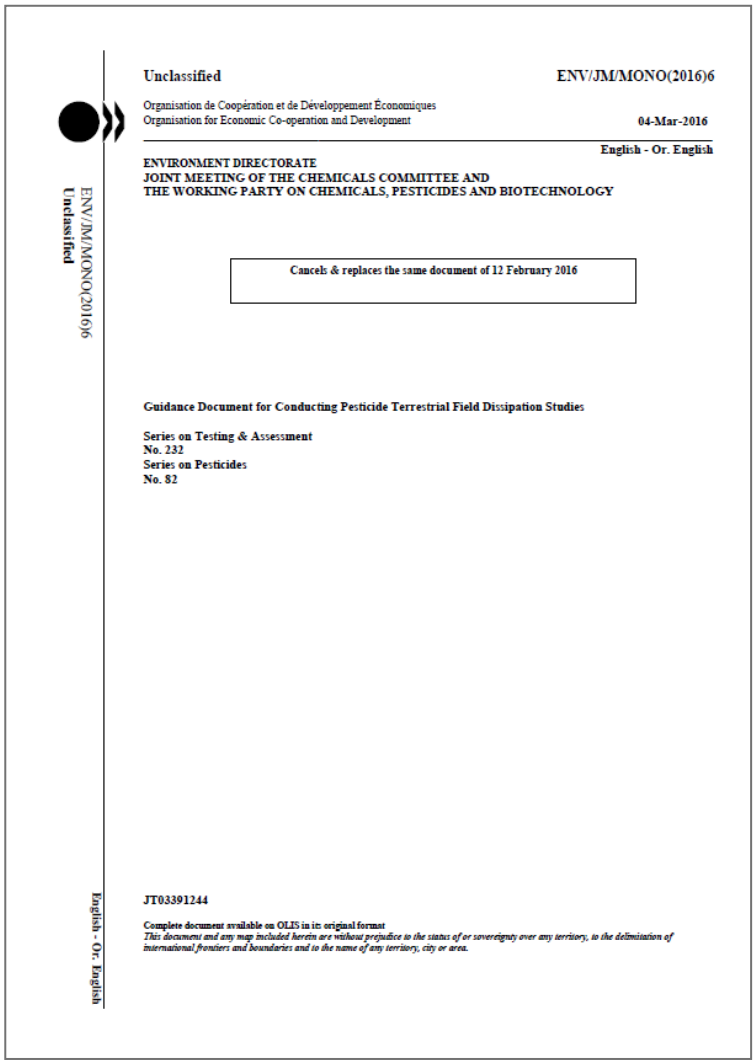
Working Group on Pesticides – publications

Terrestrial field dissipation studies - project

Lead countries: EFSA, the US Environmental Protection Agency and Health Canada.

- The harmonised international guidance means that field dissipation/accumulation studies carried out in one country can be considered in risk assessments conducted in other countries and regions. In particular, it means that studies will be interchangeable between EU Member States and signatories to the North American Free Trade Agreement (NAFTA), as well as other OECD countries.

Guidance Document (GD 232) for Conducting Pesticide Terrestrial Field Dissipation Studies



Unclassified ENV/JM/MONO(2016)6

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development
04-Mar-2016

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Cancels & replaces the same document of 12 February 2016

Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies

Series on Testing & Assessment
No. 232
Series on Pesticides
No. 82

JT03391244

Complete document available on OLIS in its original format
This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

ENV/JM/MONO(2016)6
Unclassified

English - Or. English

Ecoregion crosswalk objectives:

(1) identify similar eco-regions between North America and Europe;

(2) provide a GIS (geographic information systems) - based decision support to assist in the selection of regions for TFD studies; and

(3) provide background information on pesticide use areas (crop-based), soils and climate.

Test Guidelines and Guidance Documents

Test Guidelines and Guidance Documents

Oversight

- Working Group of National Coordinators of the Test Guidelines Programme (WNT)

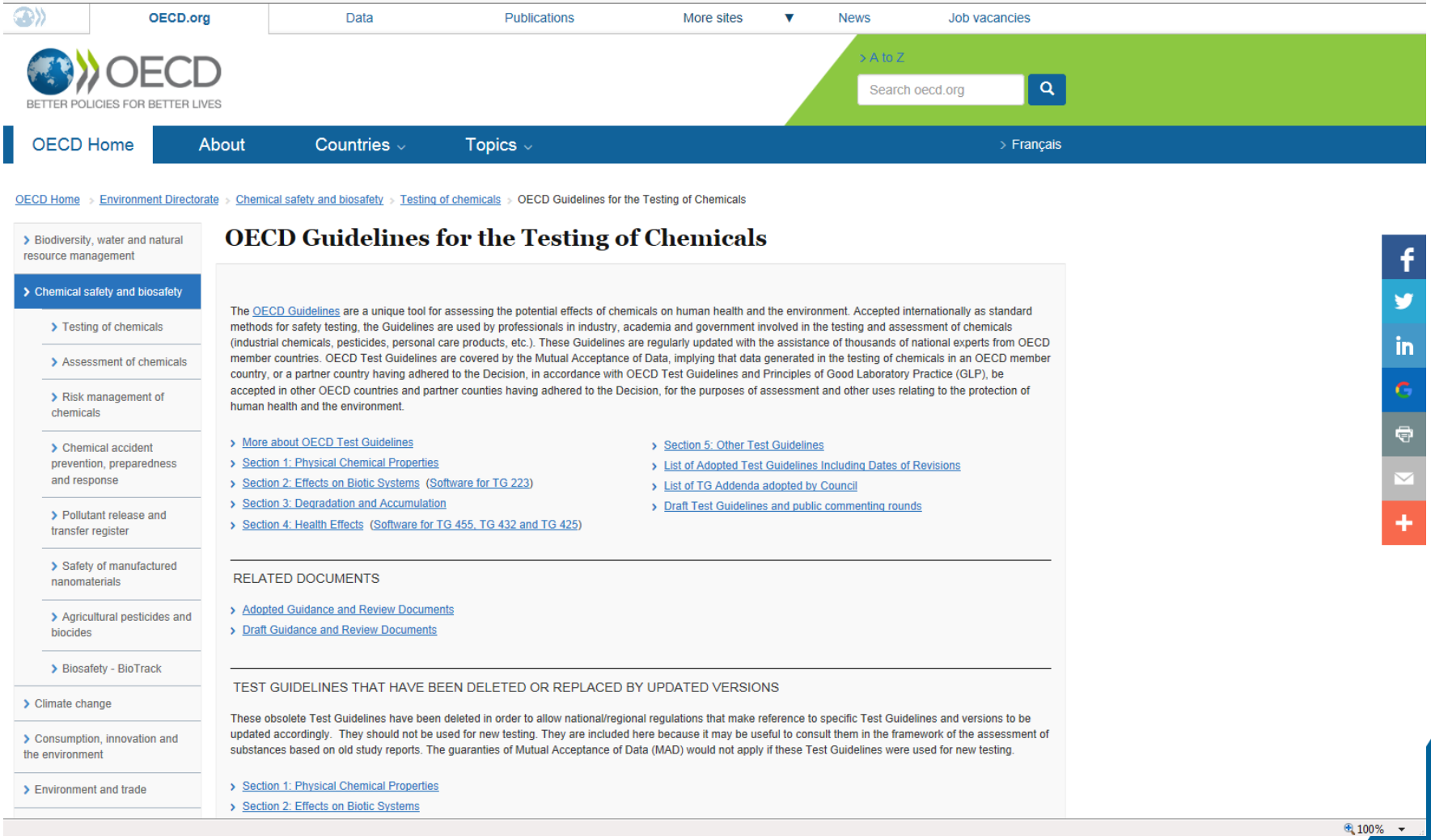
Product

- Test Guidelines (Mutual Acceptance of Data)
- Test Guideline-related documents: Detailed Review Papers (DRPs), Guidance Documents (GDs), Validation reports and Peer review reports, etc. published in the Series on Testing and Assessment

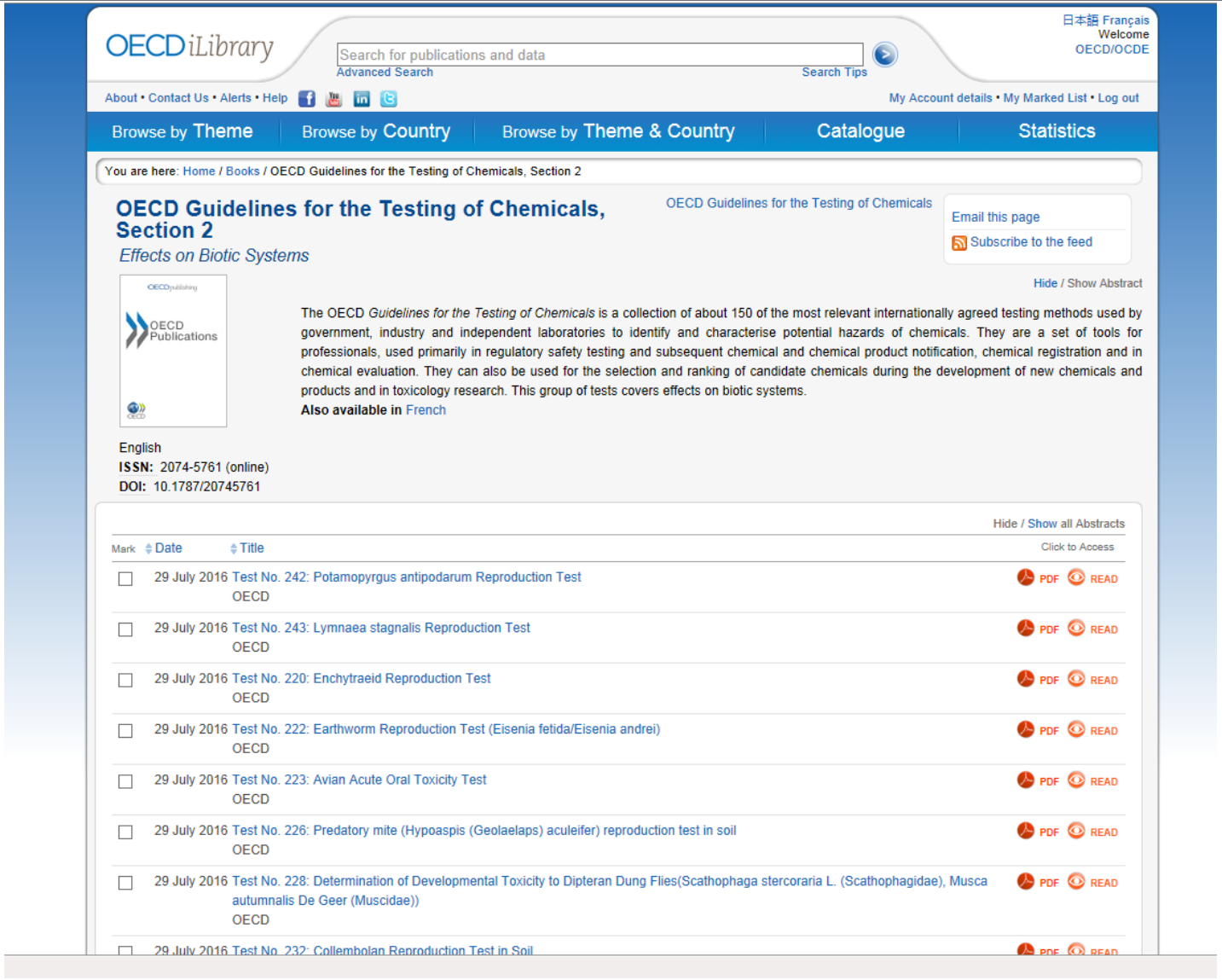
Test Guidelines and Guidance Documents

- The testing of chemicals is labour-intensive and expensive.
- Often the same chemicals are being tested and assessed in several countries.
- The OECD Council Decision on Mutual Acceptance of Data (MAD):
  - test data generated in any member or partner country in accordance with OECD TG and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.

Test Guidelines and Guidance Documents



Test Guidelines and Guidance Documents



Test Guidelines and Guidance Documents – Endocrine disruption

ED work is a high priority for regulatory authorities in most OECD countries/regions

- Harmonise test methods, methodologies and approaches for the hazard assessment of endocrine disrupters
- Ensure relevance and reliability of test methods through participation in concerted efforts to experimentally validate test methods for ED
- Develop a Conceptual Framework for ED testing and assessment, to sort out methods by level of complexity and guide on relevance of specific methods to address specific endocrine pathways

Test Guidelines and Guidance Documents – Endocrine disruption

- Since 1998, development and adoption of OECD TGs and other tools to support countries' regulatory needs related to T&A of chemicals for endocrine disruption
- 2002: Conceptual Framework for Testing and Assessment of ED (revised in 2012)
- 2009: Copenhagen workshop to take stock of country activities and set priorities for further work
- 2012: Publication of a Guidance document on the use of standardised Test Guidelines for the evaluation of endocrine disrupters
- 2012: Detailed Review Paper on Novel Endpoints

Test Guidelines and Guidance Documents – Endocrine disruption

EDTA Conceptual Framework (rev. 2012)

- **Level 1.** Existing data and non test information
- **Level 2.** *In vitro* assays providing data about selected endocrine mechanism(s)/pathway(s)
- **Level 3.** *In vivo* assays providing data about selected endocrine mechanism(s)/pathway(s)
- **Level 4.** *In vivo* assays providing data on adverse effects on endocrine relevant endpoints
- **Level 5.** *In vivo* assays providing more comprehensive data on adverse effects on endocrine relevant endpoints over extensive parts of the life cycle of the organisms.

Test Guidelines and Guidance Documents – Endocrine disruption

Mammalian and non mammalian Toxicology	
Level 1 Existing Data and Non-Test Information	• Physical & chemical properties, e.g., MW reactivity, volatility, biodegradability • All available (eco)toxicological data from standardized or non-standardized tests. • Read across, chemical categories, QSARs and other *in silico* predictions, and ADME model predictions

Test Guidelines and Guidance Documents – Endocrine disruption

	Mammalian Toxicology	Non-Mammalian Toxicology
Level 3 In vivo assays providing data about selected endocrine mechanism(s) / pathway(s)	• Uterotrophic assay (OECD TG 440) • Hershberger assay (OECD TG 441)	• Xenopus embryo thyroid signalling assay (under devt) • Amphibian metamorphosis assay (OECD TG 231) • Fish Reproductive Screening Assay (OECD TG 229) • Fish Screening Assay (OECD TG 230) • Androgenized female stickleback screen (GD 140) • Other assays (e.g. EASZY, Juvenile Medaka Anti-androgen Screening Assay under devt)

Pollinator testing

Available Guidance:

- Test No. 213: Honeybees, Acute Oral Toxicity Test
- Test No. 214: Honeybees, Acute Contact Toxicity Test
- Test No. 237: Honey Bee (Apis Mellifera) Larval Toxicity Test, Single Exposure

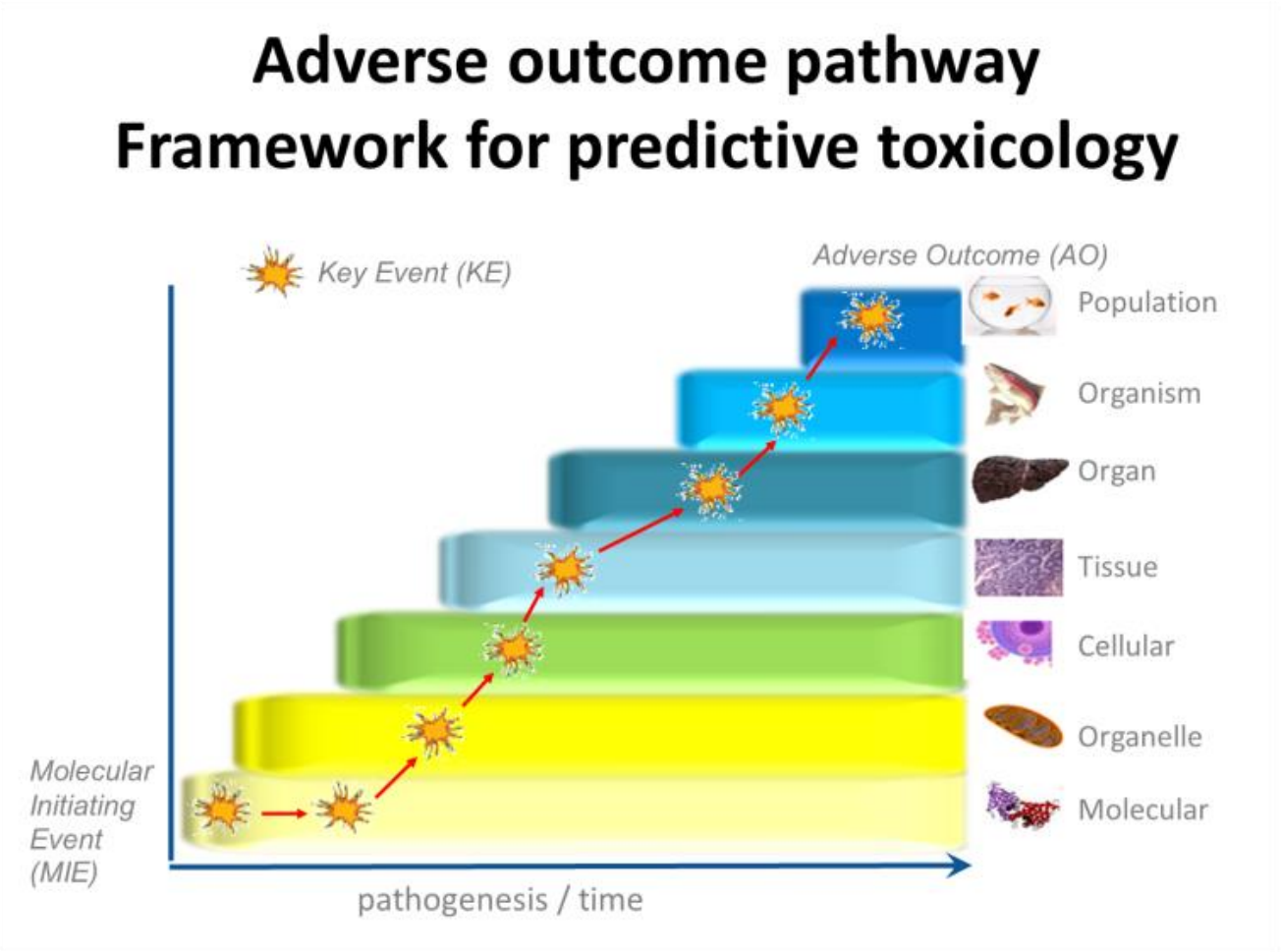
- Guidance Document No 75 on the Honey Bee (Apis Mellifera L.) Brood Test Under Semi-field Conditions
- Guidance Document No. 239 on Honey Bee Larval Toxicity Test following Repeated Exposure

Pollinator testing

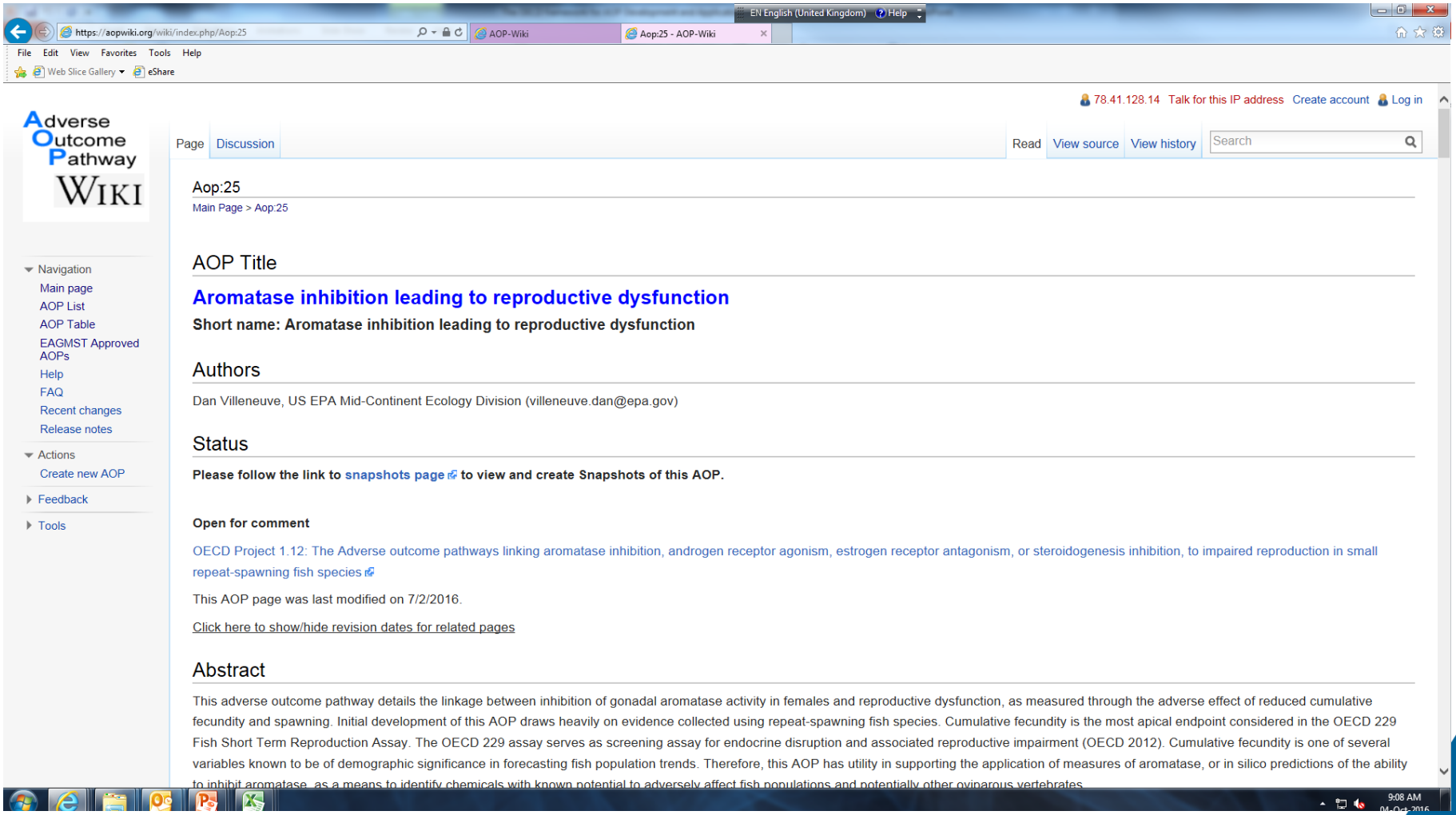
Currently 4 projects dealing with pollinators:

- 2 for bumble bees, acute testing contact and oral exposure (the Netherlands).
- Homing flight test on honeybee (Apis mellifera L.) after single exposure to sublethal doses (France).
- Honey Bee Chronic Toxicity Test, 10-day feeding laboratory test (Germany).

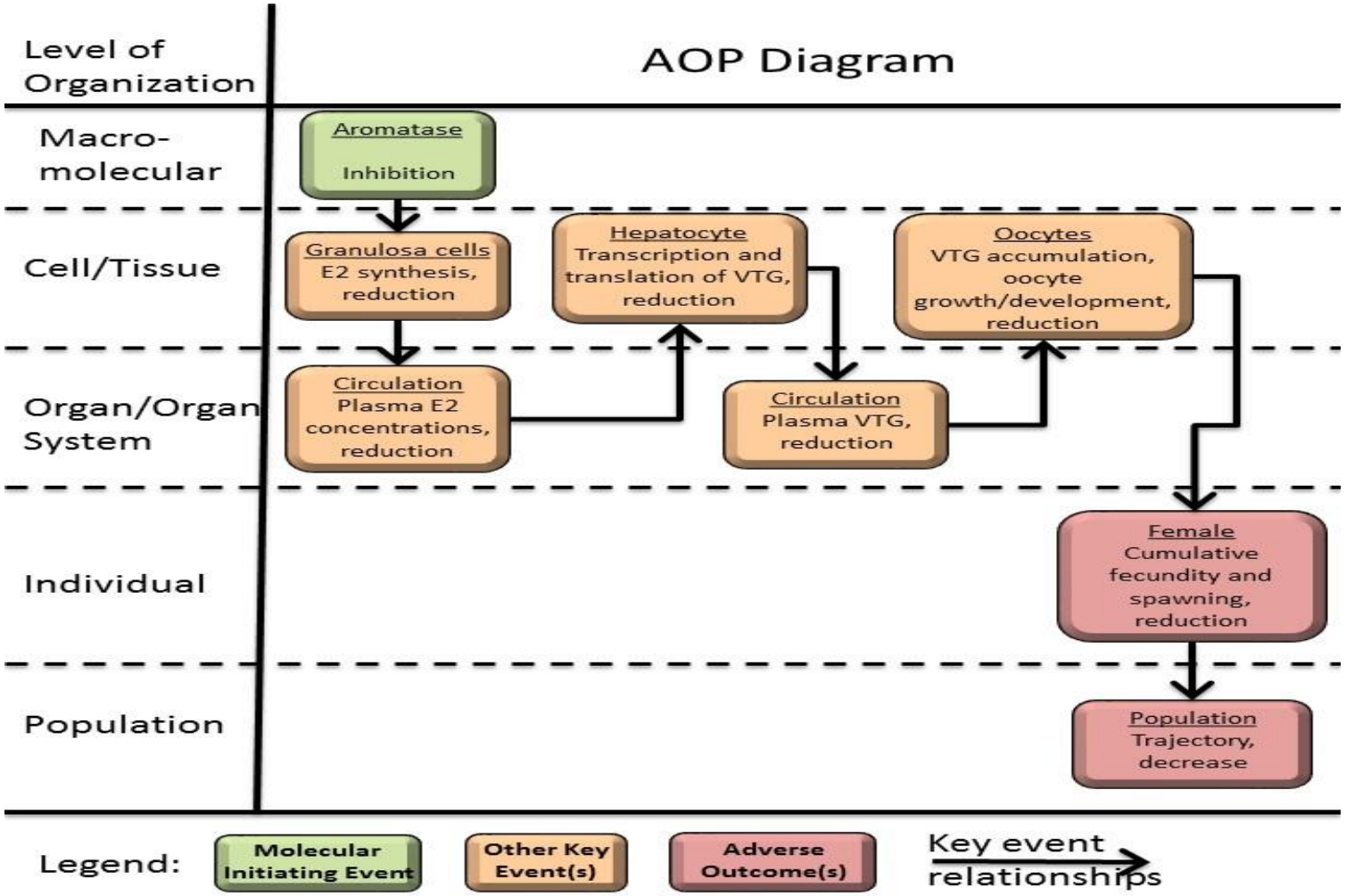
Test Guidelines and Guidance Documents - AOP



Test Guidelines and Guidance Documents - AOP



Test Guidelines and Guidance Documents - AOP



Test Guidelines and Guidance Documents - AOP

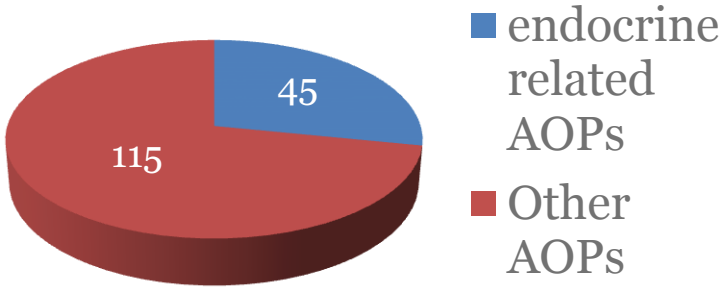
Considerations for Potential Applications of the AOP (optional) [edit]

- The present AOP can provide potential support for the use of alternatives to the fish short term reproduction assay as a screen for aromatase inhibitors.
- The present AOP can serve as a foundation for tiered testing strategies and IATA related to risk assessments on chemicals identified as aromatase inhibitors.
- The present AOP can be used to guide endpoint selection for effects-based monitoring studies at sites where aromatase inhibition has been identified as a relevant biological activity of interest (e.g., through bioeffects prediction or bioeffects surveillance approaches; see Schroeder et al. 2016).

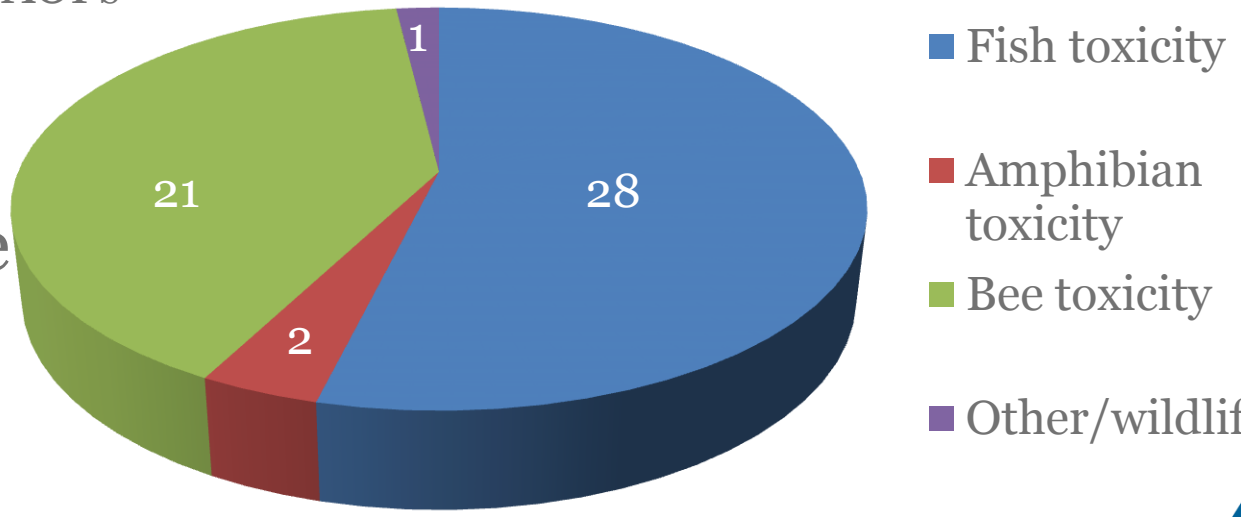
  Schroeder, A. L., Ankley, G. T., Houck, K. A. and Villeneuve, D. L. (2016), Environmental surveillance and monitoring—The next frontiers for high-throughput toxicology. Environ Toxicol Chem, 35: 513–525. doi:10.1002/etc.3309
- A series of computational models aligned with this AOP (i.e., a quantitative AOP construct) can be applied to estimate in vivo bench-mark doses based on in vitro screening results. Case studies evaluating this application are under way.

Test Guidelines and Guidance Documents - AOP

Share of endocrine related AOPs



Ecotoxicity related AOPs



In total about 160 AOPs in the wiki, at various stages of development

Test Guidelines and Guidance Documents - AOP

AOPs ... in summary

- Practical solution to the integration, curation and dissemination of toxicological knowledge for progressing chemical safety assessment.
- Provides a concept for the development of integrated approaches to testing and assessment.
- Directs resources to the development of the most relevant alternative testing methods.
- A powerful means of sharing and collaborating between different scientific communities.

Test Guidelines and Guidance Documents - Priorities

- Better integration of metabolism into in vitro testing to improve hazard assessment
- Improve opportunities for cross-species extrapolation to reduce unnecessary testing
- Make better use of the AOP concept to develop integrated approaches to testing and assessment
- Gap: no in vitro method yet ready for the thyroid pathway - complex pathway, several biological target events for chemicals to interact with biology
- Further explore other pathways/endocrine systems.

Other activites

OECD IT tools

Information for use in environmental risk assessments:

- eChemPortal
- OECD QSAR Toolbox
- MetaPath database
- Environmental Risk Assessment toolkit

OHTs for data developers

1. **Test Guidelines/Guidance Documents**
    1. *Chemicals*/Pesticides
    2. *Nanomaterials*
    3. Bio-pesticides/*GMOs*
2. **Bees/pollinators**
3. *Cumulative risk assessment*
4. *Mixture toxicity*
5. *Sustainable Use/Integrated Pest Management (IPM)*
6. *Mechanistic understanding, AOP/IATA*
7. *Read-across, grouping, QSAR*
8. *Biodiversity*
9. *Facilitate review through harmonised templates, databases,*

Further Information

- Website: www.oecd.org/env/pesticides and www.oecd.org/env/ehs/testing

- Email: leon.vanderwal@oecd.org

Thank you for your attention !

Source: © EFSA, #Efsa4Bees website