



# 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*



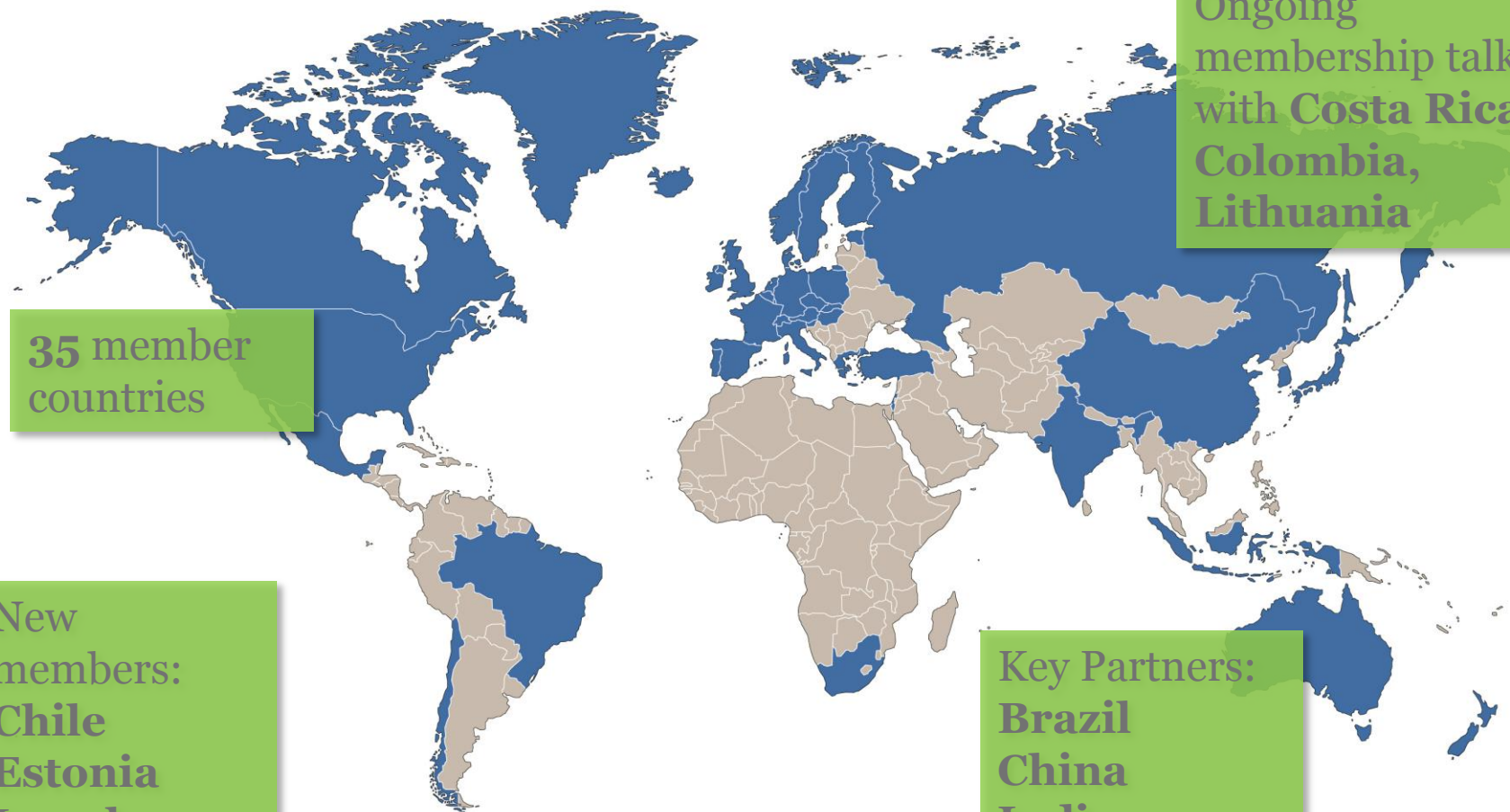
# Overview

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



# The OECD



**35** member countries

New members:  
**Chile**  
**Estonia**  
**Israel**  
**Latvia**  
**Slovenia**

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

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



## The OECD

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- ...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



### WORK ON

IC Enhance protection of humans, animals and environment

### SUSTAINABLE PEST MANAGEMENT

### VISION FOR THE FUTURE

Protection of human health and the environment will be facilitated through:

1. Harmonised science-based data requirements
2. Methodologies for hazard and risk assessment (toxicity and exposure)

A cooperative global approach to the regulation of pesticides and their management.



## Working Group on Pesticides

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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

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## 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

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## 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

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- 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

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- 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





# Working Group on Pesticides – Bio-pesticides

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- 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

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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

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- 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

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- [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

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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
ENV/JM/MONO(2016)6 Unclassified	ENVIRONMENT DIRECTORATE JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY	English - Or. English
	Cancel & 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		
<small>Complete documents available on OLS 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.</small>		
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.



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# Test Guidelines and Guidance Documents



# Test Guidelines and Guidance Documents

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## 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

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- 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

OECD Home > Environment Directorate > Chemical safety and biosafety > Testing of chemicals > OECD Guidelines for the Testing of Chemicals

- > Biodiversity, water and natural resource management
- > **Chemical safety and biosafety**
  - > Testing of chemicals
  - > Assessment of chemicals
  - > Risk management of chemicals
  - > Chemical accident prevention, preparedness and response
  - > Pollutant release and transfer register
  - > Safety of manufactured nanomaterials
  - > Agricultural pesticides and biocides
  - > Biosafety - BioTrack
- > Climate change
- > Consumption, innovation and the environment
- > Environment and trade

## OECD Guidelines for the Testing of Chemicals

The [OECD Guidelines](#) are a unique tool for assessing the potential effects of chemicals on human health and the environment. Accepted internationally as standard methods for safety testing, the Guidelines are used by professionals in industry, academia and government involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of thousands of national experts from OECD member countries. OECD Test Guidelines are covered by the Mutual Acceptance of Data, implying that data generated in the testing of chemicals in an OECD member country, or a partner country having adhered to the Decision, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), be accepted in other OECD countries and partner countries having adhered to the Decision, for the purposes of assessment and other uses relating to the protection of human health and the environment.

- > [More about OECD Test Guidelines](#)
- > [Section 1: Physical Chemical Properties](#)
- > [Section 2: Effects on Biotic Systems \(Software for TG 223\)](#)
- > [Section 3: Degradation and Accumulation](#)
- > [Section 4: Health Effects \(Software for TG 455, TG 432 and TG 425\)](#)
- > [Section 5: Other Test Guidelines](#)
- > [List of Adopted Test Guidelines Including Dates of Revisions](#)
- > [List of TG Addenda adopted by Council](#)
- > [Draft Test Guidelines and public commenting rounds](#)

### RELATED DOCUMENTS

- > [Adopted Guidance and Review Documents](#)
- > [Draft Guidance and Review Documents](#)

### TEST GUIDELINES THAT HAVE BEEN DELETED OR REPLACED BY UPDATED VERSIONS

These obsolete Test Guidelines have been deleted in order to allow national/regional regulations that make reference to specific Test Guidelines and versions to be updated accordingly. They should not be used for new testing. They are included here because it may be useful to consult them in the framework of the assessment of substances based on old study reports. The guaranties of Mutual Acceptance of Data (MAD) would not apply if these Test Guidelines were used for new testing.

- > [Section 1: Physical Chemical Properties](#)
- > [Section 2: Effects on Biotic Systems](#)





# Test Guidelines and Guidance Documents

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## OECD Guidelines for the Testing of Chemicals, Section 2

*Effects on Biotic Systems*

OECD Publications

The OECD *Guidelines for the Testing of Chemicals* is a collection of about 150 of the most relevant internationally agreed testing methods used by government, industry and independent laboratories to identify and characterise potential hazards of chemicals. They are a set of tools for professionals, used primarily in regulatory safety testing and subsequent chemical and chemical product notification, chemical registration and in chemical evaluation. They can also be used for the selection and ranking of candidate chemicals during the development of new chemicals and products and in toxicology research. This group of tests covers effects on biotic systems.

**Also available in French**

English  
ISSN: 2074-5761 (online)  
DOI: 10.1787/20745761

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<input type="checkbox"/>	29 July 2016	Test No. 228: Determination of Developmental Toxicity to Dipteran Dung Flies (Scathophaga stercoraria L. (Scathophagidae), Musca autumnalis De Geer (Muscidae)) OECD	<a href="#">PDF</a> <a href="#">READ</a>
<input type="checkbox"/>	29 July 2016	Test No. 232: Collembolan Reproduction Test in Soil	<a href="#">PDF</a> <a href="#">READ</a>





# Test Guidelines and Guidance Documents – Endocrine disruption

- 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

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



# Test Guidelines and Guidance Documents – Endocrine disruption

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- 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 disruptors
- 2012: Detailed Review Paper on Novel Endpoints



# Test Guidelines and Guidance Documents – Endocrine disruption

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## 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
<b>Level 3 In vivo assays providing data about selected endocrine mechanism(s) )/ pathway(s)</b>	<ul style="list-style-type: none"><li>• Uterotrophic assay (OECD TG 440)</li><li>• Hershberger assay (OECD TG 441)</li></ul>	<ul style="list-style-type: none"><li>• Xenopus embryo thyroid signalling assay (under devt)</li><li>• Amphibian metamorphosis assay (OECD TG 231)</li><li>• Fish Reproductive Screening Assay (OECD TG 229)</li><li>• Fish Screening Assay (OECD TG 230)</li><li>• Androgenized female stickleback screen (GD 140)</li><li>• Other assays (e.g. EASZY, Juvenile Medaka Anti-androgen Screening Assay under devt)</li></ul>



# Pollinator testing

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## 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

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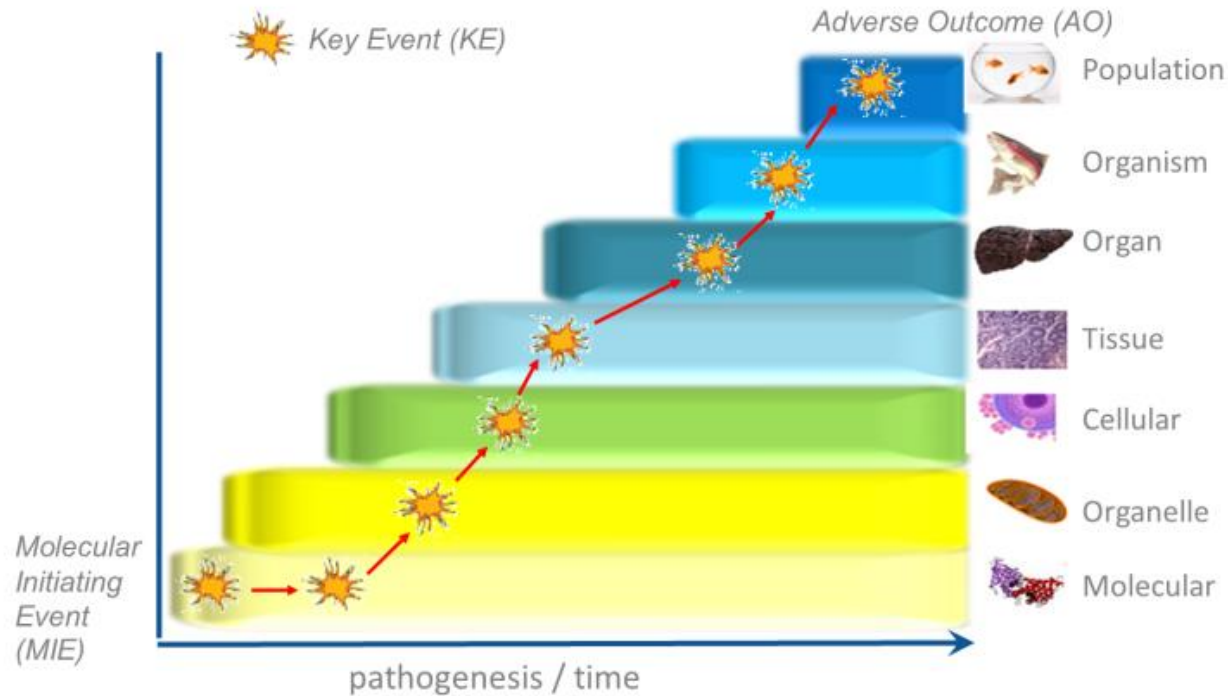
Currently 4 projects dealing with pollinators:

- 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

## Adverse outcome pathway Framework for predictive toxicology







# Test Guidelines and Guidance Documents - AOP

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Main Page > Aop:25

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**AOP Title**

**Aromatase inhibition leading to reproductive dysfunction**  
**Short name: Aromatase inhibition leading to reproductive dysfunction**

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**Authors**

Dan Villeneuve, US EPA Mid-Continent Ecology Division (villeneuve.dan@epa.gov)

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**Status**

**Please follow the link to snapshots page to view and create Snapshots of this AOP.**

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**Open for comment**

OECD Project 1.12: The Adverse outcome pathways linking aromatase inhibition, androgen receptor agonism, estrogen receptor antagonism, or steroidogenesis inhibition, to impaired reproduction in small repeat-spawning fish species

This AOP page was last modified on 7/2/2016.

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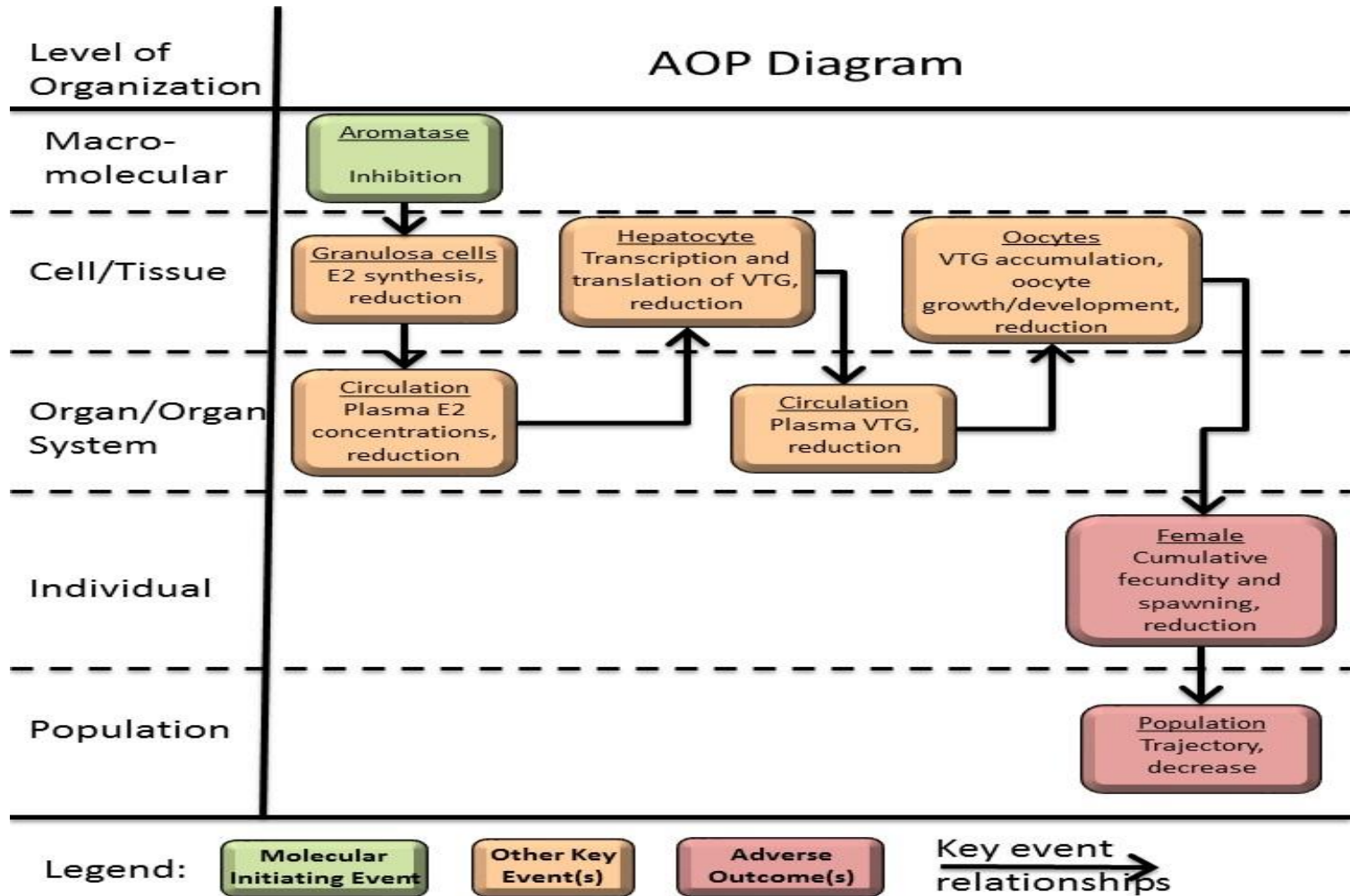
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**Abstract**

This adverse outcome pathway details the linkage between inhibition of gonadal aromatase activity in females and reproductive dysfunction, as measured through the adverse effect of reduced cumulative fecundity and spawning. Initial development of this AOP draws heavily on evidence collected using repeat-spawning fish species. Cumulative fecundity is the most apical endpoint considered in the OECD 229 Fish Short Term Reproduction Assay. The OECD 229 assay serves as screening assay for endocrine disruption and associated reproductive impairment (OECD 2012). Cumulative fecundity is one of several variables known to be of demographic significance in forecasting fish population trends. Therefore, this AOP has utility in supporting the application of measures of aromatase, or in silico predictions of the ability to inhibit aromatase, as a means to identify chemicals with known potential to adversely affect fish populations and potentially other oviparous vertebrates.



# Test Guidelines and Guidance Documents - AOP





# Test Guidelines and Guidance Documents - AOP

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

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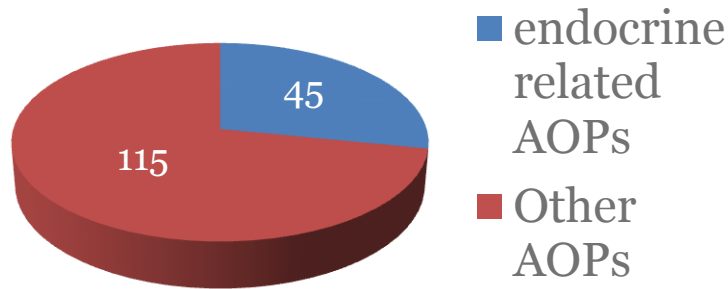
- The present AOP can provide potential support for the use of alternatives to the fish short term reproduction assay as a screen for aromatase inhibitors.
- The present AOP can serve as a foundation for tiered testing strategies and IATA related to risk assessments on chemicals identified as aromatase 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 benchmark doses based on in vitro screening results. Case studies evaluating this application are under way.



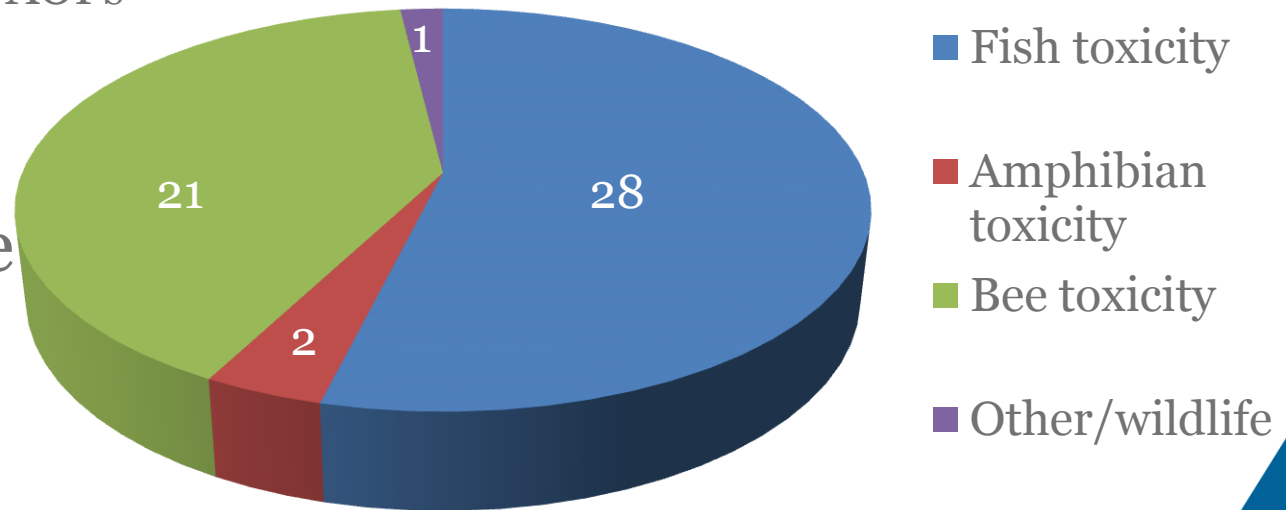
# Test Guidelines and Guidance Documents - AOP

## Share of endocrine related AOPs



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

## Ecotoxicity related AOPs





# Test Guidelines and Guidance Documents - AOP

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## 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

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- 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.



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# Other activites



Information for use in environmental risk assessments:

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





# OHTs for data developers

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## 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

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- Website: [www.oecd.org/env/pesticides](http://www.oecd.org/env/pesticides) and [www.oecd.org/env/ehs/testing](http://www.oecd.org/env/ehs/testing)
- Email: [leon.vanderwal@oecd.org](mailto:leon.vanderwal@oecd.org)



Thank you for your attention !

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