



## Interagency Coordinating Committee on the Validation of Alternative Methods

# Current Ecotoxicity Testing Needs Among Selected U.S. Federal Agencies

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# Ecotoxicity testing

- U.S. agencies use ecotoxicology data to protect human and animal health and natural resources, or to assess the impact of human activity on the environment.
- To do this they determine the hazards and risks presented by substances that may enter the environment, including but not limited to industrial chemicals, pharmaceuticals, pesticides, food additives, and cosmetics.
- Ecotoxicity tests include a broad spectrum of U.S. standardized and internationally harmonized test methods using differing species, exposure media, and effects measurements.

The focus of this summary is to identify agency needs that currently rely on or consider test methods that routinely require use of animals so that these methods may be targeted for eventual refinement, reduction, or replacement by NAMs.



# EcoWG member agencies



**NIST**  
National Institute of  
Standards and Technology  
U.S. Department of Commerce



# Information Gathering

- Which federal statutes and regulations consider ecotoxicology data.
- Which test guidelines and guidance documents use multicellular organisms.
- What are commonly used test species and endpoints in those guidelines.
- Which agencies require, use, or consider ecotoxicology data and how those data are used.
- Whether some federal agencies have flexibility to use alternative methodologies.
- Whether any non-animal alternative data are currently accepted by their federal agency.
- Challenges to the development and/or adaptation of non-animal alternatives for ecotoxicology testing.

Table 1. Statutes/Regulations and Agencies

| U.S. statute/regulation                                                      | Applicable Agency |
|------------------------------------------------------------------------------|-------------------|
| Animal Damage Control Act                                                    | DOI, USDA         |
| Animal Welfare Act                                                           | USDA              |
| Bald and Golden Eagle Protection Act                                         | DOI, USDA         |
| Comprehensive Environmental Response, Compensation, and Liability Act        | DOD, DOI          |
| Clean Water Act                                                              | DOD, DOI, EPA     |
| Endangered Species Act                                                       | DOI, EPA, USDA    |
| Federal Insecticide, Fungicide, and Rodenticide Act                          | DOI, EPA, USDA    |
| Federal Land Policy and Management Act of 1976                               | DOI               |
| Food Quality Protection Act                                                  | EPA               |
| General Mining Act of 1872                                                   | DOI               |
| Marine Protection, Research, and Sanctuaries Act                             | DOD               |
| Migratory Bird Treaty Act                                                    | DOI               |
| National Environmental Policy Act                                            | DOI, FDA, USDA    |
| National Wildlife Refuge System Administration Act                           | DOI               |
| Oil Pollution Act of 1990                                                    | DOD, DOI, EPA     |
| Outer Continental Shelf Lands Act                                            | DOI               |
| The Organic Act Establishing the U.S. Geological Survey as a Research Entity | DOI               |
| Toxic Substances Control Act                                                 | EPA, USDA         |

# Cross-taxa Extrapolation and Toxicity Endpoint Classifications

- A relatively narrow selection of surrogate test species is used to represent many different species across taxonomic groups.
  - For example, data from the medaka one generation test are extrapolated to hundreds of other ray-finned fish species.
- To facilitate discussion on cross-taxa extrapolation the 87 ecotoxicity guidelines that were identified were broadly classified as follows:
  - Endpoints: acute, chronic/growth/reproduction, bioaccumulation, microcosm, field testing
    - Endpoints were further subclassified into those using aquatic (freshwater and/or marine) or terrestrial organisms
  - Systems: amphibians, avians, bioaccumulation, field-testing, fish, invertebrates, mammals, microcosm, or pollinators.

| Endpoint       | Test guideline or guidance document title                 | Avians | Fish  | Invertebrates | Mammals | Pollinators | Guideline identifier |
|----------------|-----------------------------------------------------------|--------|-------|---------------|---------|-------------|----------------------|
| Acute Toxicity | <i>Aquatic Organisms [Freshwater (FW)/Saltwater (SW)]</i> |        |       |               |         |             |                      |
|                | Freshwater and Saltwater Fish Acute Toxicity Test         | -      | FW/SW | -             | -       | -           | EPA OCSPP 850.1075   |
|                | <i>Daphnia</i> sp., Acute Immobilisation Test             | -      | -     | FW            | -       | -           | OECD 202             |
|                | Oyster Acute Toxicity Test (Shell Deposition)             | -      | -     | SW            | -       | -           | EPA OCSPP 850.1025   |
|                | <i>Terrestrial Organisms</i>                              |        |       |               |         |             |                      |
|                | Avian Acute Oral Toxicity Test                            | X      | -     | -             | -       | -           | EPA OCSPP 850.2100   |
|                | Earthworm, Acute Toxicity Tests                           | -      | -     | X             | -       | -           | OECD 207             |
|                | Wild Mammal Toxicity Testing                              | -      | -     | -             | X       | -           | EPA OCSPP 850.2400   |
|                | Honeybees, Acute Oral Toxicity Test                       | -      | -     | -             | -       | X           | OECD 213             |

# Cross-taxa Extrapolation

- Advances in bioinformatics, non-animal test methods, and adverse outcome pathways provide opportunities to strengthen cross-taxa extrapolation
  - For example, in silico methods to predict toxic effects can provide additional valuable information to support decisions

## Waiving the Need for Certain Ecotoxicity Tests

- Agencies have identified circumstances where in vivo tests for certain ecotoxicity tests can be waived, resulting in the reduction of animal use.
  - Chemical registrants can request a waiver of data requirements or can bridge information from one data set to another.
  - Federal agencies may waive the need for ecotoxicity tests when existing data for risk assessment and regulatory decisions are adequate.

# Conclusions

- The breadth of data used to support U.S. Federal ecological risk-based decisions varies with each program.
- The broad nature of these needs, the limitations of cross-taxa extrapolation, and the large number of test endpoints captured within existing guidelines represents challenges in the development of non-animal methods challenging.
- Alternative test methods can facilitate cross-taxa extrapolation or provide bridging data to support experimental waivers.
- While there are challenges to the development and use of non-animal ecotoxicology tests, U.S. Federal agencies remain committed to their development and use in appropriate contexts.