

# Meeting the Needs of a Paradigm Shift: A Regulatory Perspective

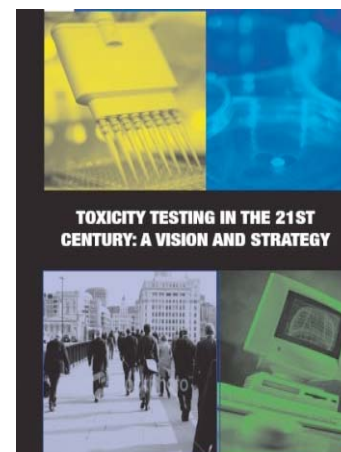
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# NRC 2007 “Toxicity Testing in the 21st Century: A Vision and Strategy



## **Objective:**

Foster transformative paradigm shift based largely on increased use of *in vitro* and *computer* systems:

- Broaden coverage of chemicals, end points, and life stages.
- Provide more robust scientific basis for risk assessment.
- Increase effectiveness, reduce cost, and time of testing.
- Use fewer animals.

# EPA's Strategic Plan for Evaluating the Toxicity of Chemicals

[www.epa.gov/osa/spc/toxicitytesting](http://www.epa.gov/osa/spc/toxicitytesting)

Improve our chemical risk management approach by transitioning to new integrative and predictive 21st century techniques for human health and ecological assessments

Evolve from current application of computational toxicology tools used to evaluate risks and assign priorities.

# Managing Chemical Risks

- Near Term ( $\leq 5$  years) -- Chemical Prioritization and Screening.

“Enhanced Tool Box” - Create means to efficiently and credibly predict toxicity and exposure levels to focus information needs and follow up actions.

- Long Term (5-15 years) -- Mechanism-Driven Risk Assessment.

Move in a credible and transparent manner to full use of mechanism-based approaches that provide more accurate characterizations of the most likely risks.

# How do we get there?

- Integrated regulatory and research programs.
- Early engagement of stakeholders.
- Transparency and scientific integrity.
- National and international partnerships.



## Pesticides: Science and Policy

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### Strategic Direction for New Pesticide Testing and Assessment Approaches

To better protect human health and the environment, EPA is developing and evaluating new technologies in molecular, cellular, and computational sciences to supplement or replace more traditional methods of toxicity testing and risk assessment.

This Web page illustrates the approach EPA's Pesticide Program is using to pursue new technologies that predict and characterize potential human health and environmental hazards and exposures from pesticides. This page describes the current status as well as future plans for this rapidly changing area of research and regulatory science.

#### On this page:

- [Vision for Enhancing Integrated Approaches to Testing and Assessment](#)
- [Understanding Integrated Approaches to Testing and Assessment](#)
- [Tools Matrix](#)
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The new technologies will result in:

- A broader suite of computer-aided methods to better predict potential hazards and exposures, and to focus testing on likely risks of concern,
- Improved approaches to more traditional toxicity tests to minimize the number of animals used while expanding the amount of information obtained (See [Tools Matrix \(PDF\)](#) (7 pp, 92k, [About PDF](#)) for examples),
- Improved understanding of toxicity pathways to allow development of non-animal tests that better predict how exposures relate to adverse effects, and
- Improved diagnostic biomonitoring and surveillance methods to detect chemical exposures and identify causes of toxic effects

No single new technology can address all situations. However, by using a suite of tools and approaches in combination, EPA's Pesticide Program will be able to improve hazard and exposure assessments that form the basis for understanding potential pesticide risks. With these improvements EPA can better achieve its goal of ensuring reliable protection of human health and the environment from adverse effects resulting from pesticide use.

#### Quick Resources

- [In the Spotlight](#)
- [Glossary of Terms](#)
- [ToxCast™ Research Program](#)
- [Overview of National Research Council Toxicity Testing Strategy](#)
- [National Academy of Sciences Report on Toxicology Testing in the 21st Century \(PDF\)](#)  
(4 pp, 418k, [About PDF](#))  
[EXIT Disclaimer](#)

http://www.epa.gov/pesticides/science/testing-assessment.html



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## Pesticide Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies Workgroup

August 2008

You will need Adobe Reader to view some of the files on this page. See [EPA's PDF page](#) to learn more.

For more information contact [Vera Au](mailto:au.vera@epa.gov) (au.vera@epa.gov).

### Meeting dates scheduled for the remainder of 2009.

- November 18, 2009, 2:00 - 4:00 pm ET, One Potomac Yard South, Room N-4830
- December 9, 2009, 2:00 - 4:00 pm ET, One Potomac Yard South, Room N-4830

- [Previous Meetings](#)
- [Objectives](#)
- [Workgroup Members](#)
- [EPA Workgroup Members](#)

### Previous Meetings

- October 13, 2009
  - [Agenda](#)
  - **New!** [Medical Management of Pesticide Poisoning: Why We Need Diagnostic Tools \(PDF\)](#) (30 pp, 177.24K) by, James R. Roberts, MD, MPH
  - **New!** [Why Do We Need Diagnostic Tests and Biomarkers for Pesticides? \(PDF\)](#) (27 pp, 486.69K) by, Matthew Keifer MD, MPH
- September 9, 2009
  - [Agenda](#)
  - [Executive Summary \(PDF\)](#) (1 p, 27.28K)

### Related Links

- [Symposium on Toxicity Pathway-Based Risk Assessment](#) [\[EXIT Disclaimer\]](#)
- [Transforming Environmental Health Protection \(PDF\)](#) by Francis Collins, George Gray, and John Bucher in Science
- [OPPT models & methods developed to screen chemicals for potential hazards or risks](#)
- [Use of Structure-Activity Relationship Information and Quantitative SAR Modeling for Fulfilling Data Requirements for Antimicrobial Pesticide Chemicals and Informing EPA's Risk Management Process - EPA-HQ-OPP-2008-0110-0045](#)

<http://www.epa.gov/pesticides/ppdc/testing/index.html>

- June 10, 2009
  - [Agenda](#)
  - [Executive Summary\(PDF\)](#) (1 p, 23.27K)
- May 20, 2009

# Stakeholder Engagement

## Over-arching Questions:

- Why are changes needed in the current paradigm?
- How will the new paradigm change risk assessments or risk-based decisions?
- What is the expected timeline for transition to use of the new tools?
- What are the expected improvements in health and environmental protection?
- How will we recognize successes and failures in the new paradigm?



# Partnerships



## National & International Organizations

- Collaborate on development and application of predictive computational models.
- Promote development of common databases.
- Harmonize frameworks/guidance.
- Build a common application tool box.



# Paradigm Shift

- Where we need to be in the near-term:
  - Accelerated and enhanced priority setting/screening and focused animal testing.
- Where we would like to be in the long-term:
  - Greater reliance on mechanism-based assessments.
- What needs to happen:
  - Advance collaborative research agenda to develop scientific basis.
  - Partnerships, stakeholder input, peer review, consensus building, and development of new regulatory polices.