Implementation of the Strategic Roadmap: Introduction

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SACATM Meeting
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Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

Implementation Plan Outline

Roadmap implementation plans will provide the strategy for the reduction and replacement of animal use for toxicity testing, specific to each endpoint, via six key endeavors:

- Coordinate activities via ICCVAM Workgroups
- Draft a scoping document to identify U.S. agency requirements, needs, and decision contexts
- Coordinate efforts with stakeholders
- Identify, acquire, and curate high quality data from reference test methods
- Identify and evaluate non-animal alternative approaches
- Gain regulatory acceptance and facilitate use of non-animal approaches

Coordinate activities via ICCVAM Workgroups

- Prioritize based on:
  - agency needs
  - expected impact on animal usage
  - mechanistic understanding
  - ability to mitigate obstacles
  - available resources
- Coordinate efforts with international partners (e.g. ICATM, OECD)

Draft a scoping document to identify U.S. agency requirements, needs, and decision contexts

- Identify all agency requirements/expectations for particular endpoint
  - Classification & labeling system(s) (e.g., GHS, EPA)
  - Legal framework for acceptance of alternative methods
- Define chemical and regulatory space for each agency
- Identify validated alternatives and status of acceptance by agency
- Identify gaps associated with the suite of available alternatives (i.e., adequate AOP coverage)
- Identify obstacles to implementation

Coordinate efforts with stakeholders

- Establish public/private partnerships
- Organize workshops to discuss state of the science and implementation progress

Identify, acquire, and curate high quality data from reference test methods

- Facilitate agency-driven data sharing initiatives
- Leverage partnerships with industry
- Curate the scientific literature and publicly available databases

Identify and evaluate non-animal alternative approaches to acute toxicity testing

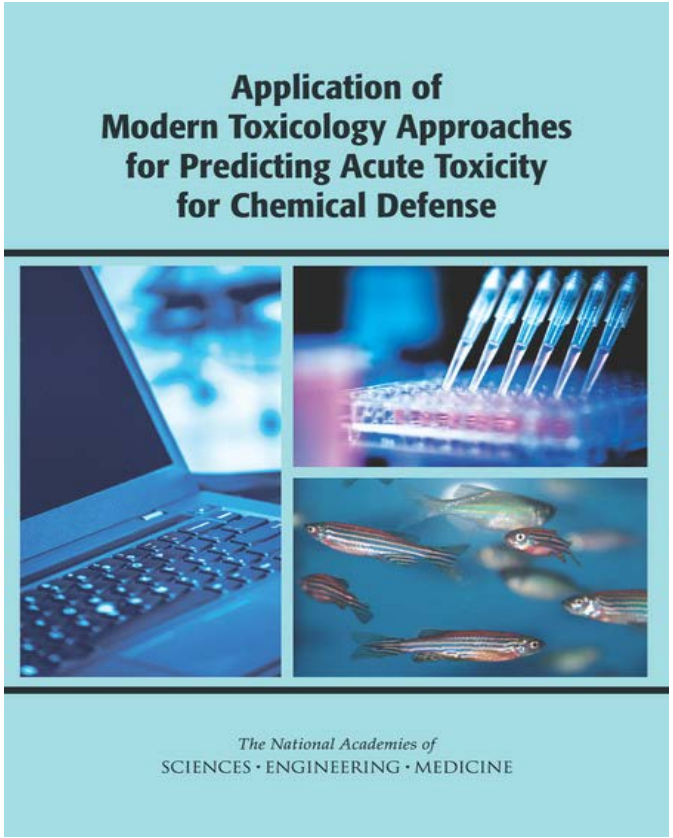
- Develop defined approaches using in silico and/or in vitro features
- Review literature for published defined approaches that can be evaluated
- Interrogate in vivo variability to provide context for confidence in alternative approaches

Gain regulatory acceptance and facilitate use of non-animal approaches

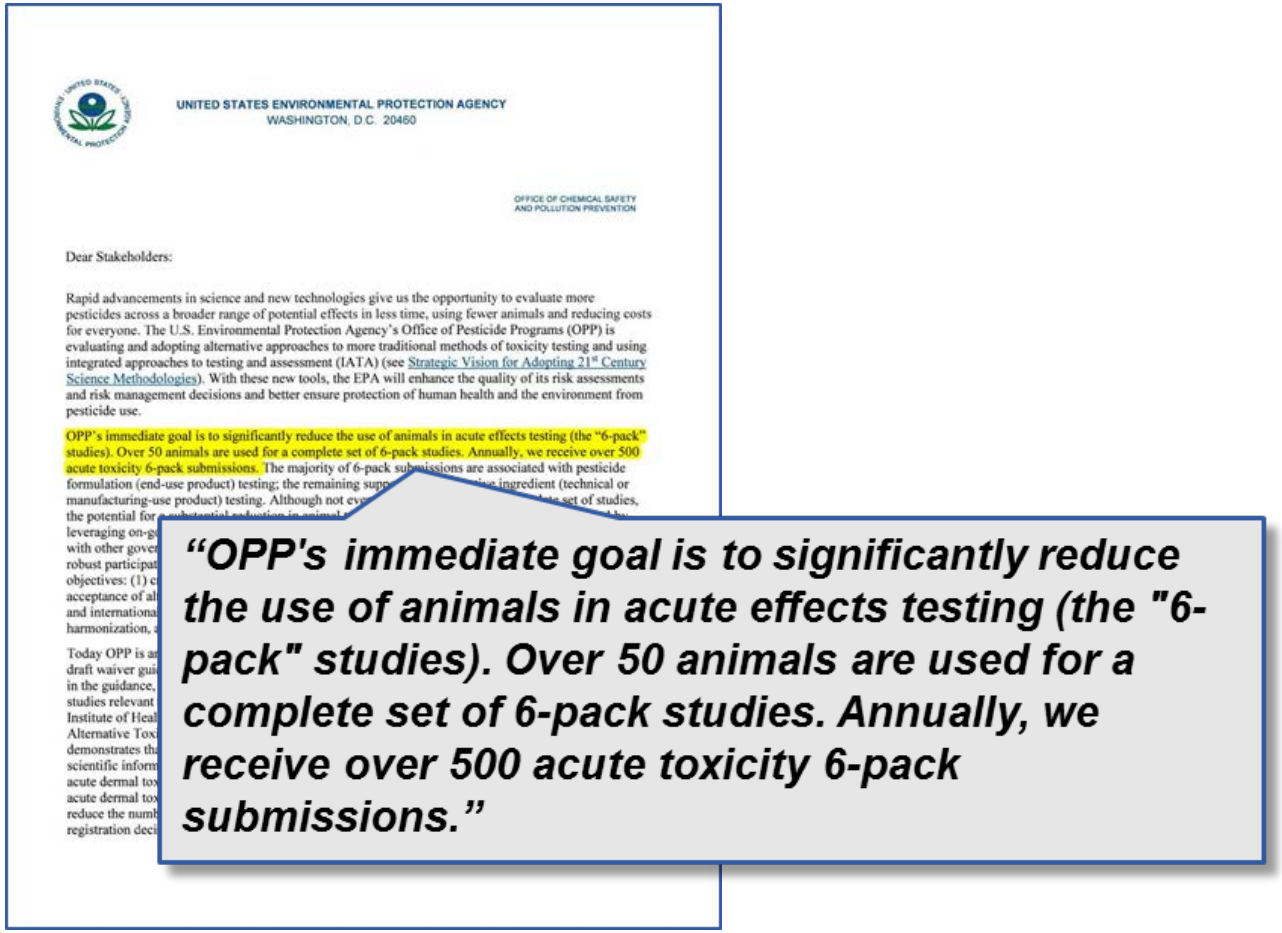
- Validate defined approaches for regulatory decision contexts
- Develop training materials and assist agencies in issuing guidance

Commitment from Federal Agencies

DOD Funded NRC Report



Reducing Animal Use for the "6-Pack"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Dear Stakeholders:

Rapid advancements in science and new technologies give us the opportunity to evaluate more pesticides across a broader range of potential effects in less time, using fewer animals and reducing costs for everyone. The U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP) is evaluating and adopting alternative approaches to more traditional methods of toxicity testing and using integrated approaches to testing and assessment (IATA) (see Strategic Vision for Adopting 21st Century Science Methodologies). With these new tools, the EPA will enhance the quality of its risk assessments and risk management decisions and better ensure protection of human health and the environment from pesticide use.

OPP's immediate goal is to significantly reduce the use of animals in acute effects testing (the "6-pack" studies). Over 50 animals are used for a complete set of 6-pack studies. Annually, we receive over 500 acute toxicity 6-pack submissions. The majority of 6-pack submissions are associated with pesticide formulation (end-use product) testing; the remaining supp... ingredient (technical or manufacturing-use product) testing. Although not ev... set of studies, the potential for ... leveraging on-g... with other gover... robust participat... objectives: (1) c... acceptance of al... and internationa... harmonization, ...

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March 2016 letter to Stakeholders from Jack Housenger on the goal to reduce animal testing

Acute Toxicity Endpoints

- Skin Sensitization
- Acute Oral Lethality
- Acute Dermal Lethality
- Acute Inhalation Lethality
- Skin Irritation/Corrosion
- Eye Irritation/Corrosion

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