



BEST

Board on Environmental Studies and Toxicology

Toxicity Testing in the 21st Century: A Vision and Strategy

Committee on Toxicity Testing and Assessment of
Environmental Agents

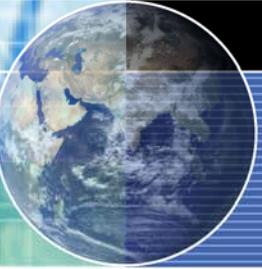
Board on Environmental Studies and Toxicology

Institute for Laboratory Animal Research

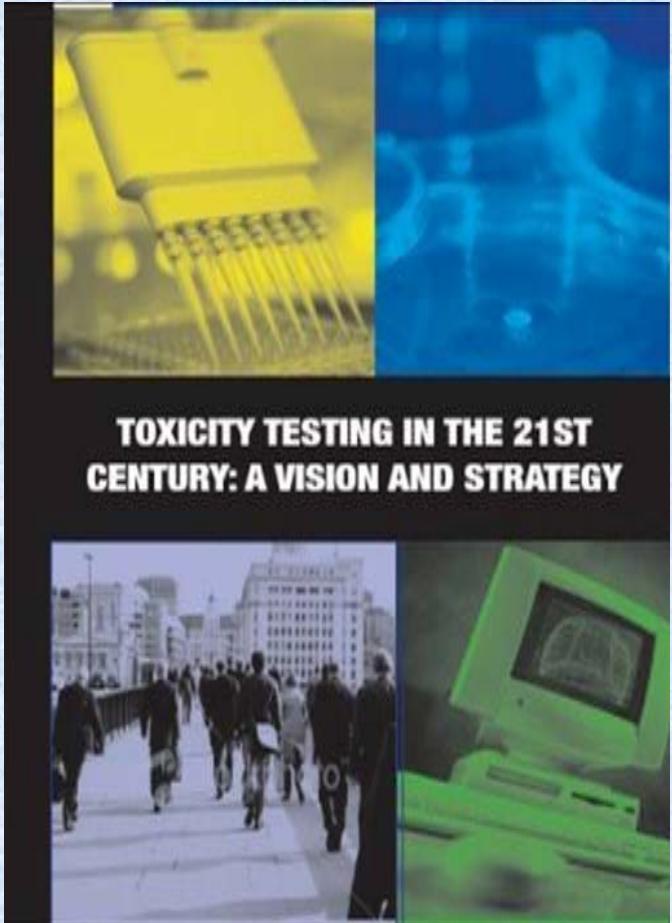
Division on Earth and Life Studies

National Research Council

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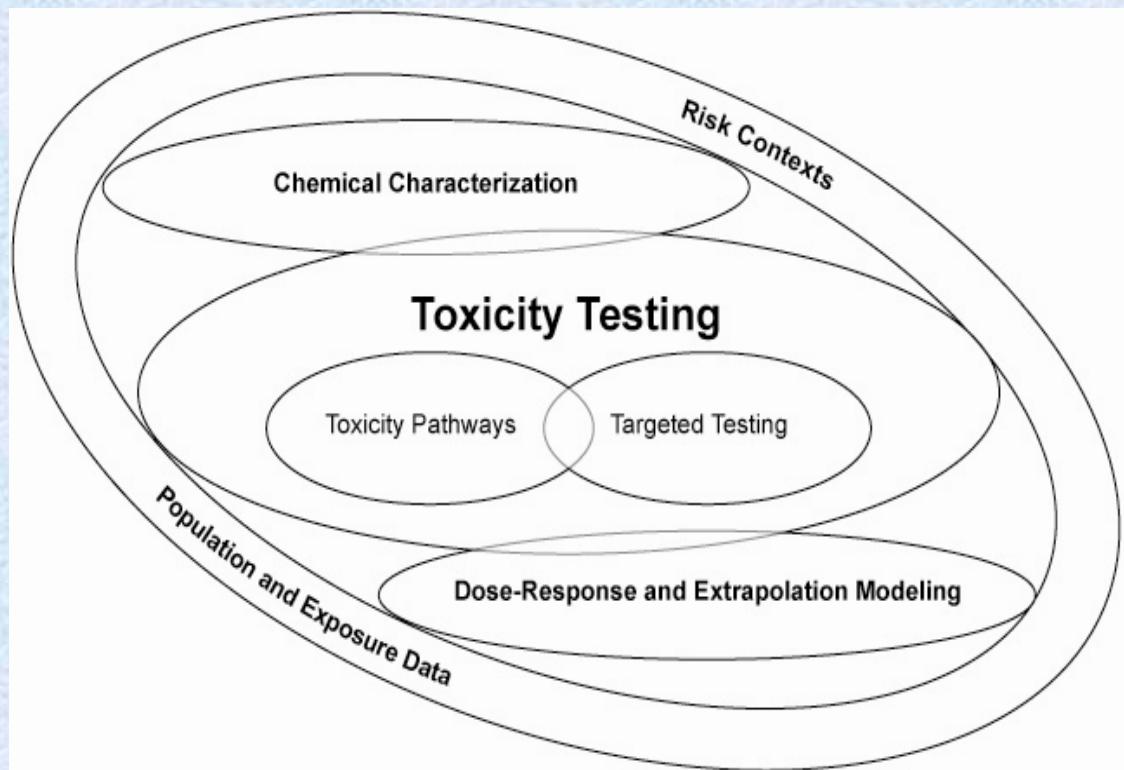
NRC Report (2007)



- Develop efficient, high throughput testing strategies to assess the potential health risks of large numbers of environmental agents to which people may be exposed
- Exploit scientific advances in biology and toxicology to achieve risk assessments that are more relevant to human populations



Components of the Vision

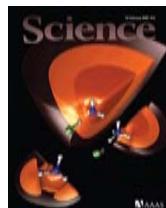
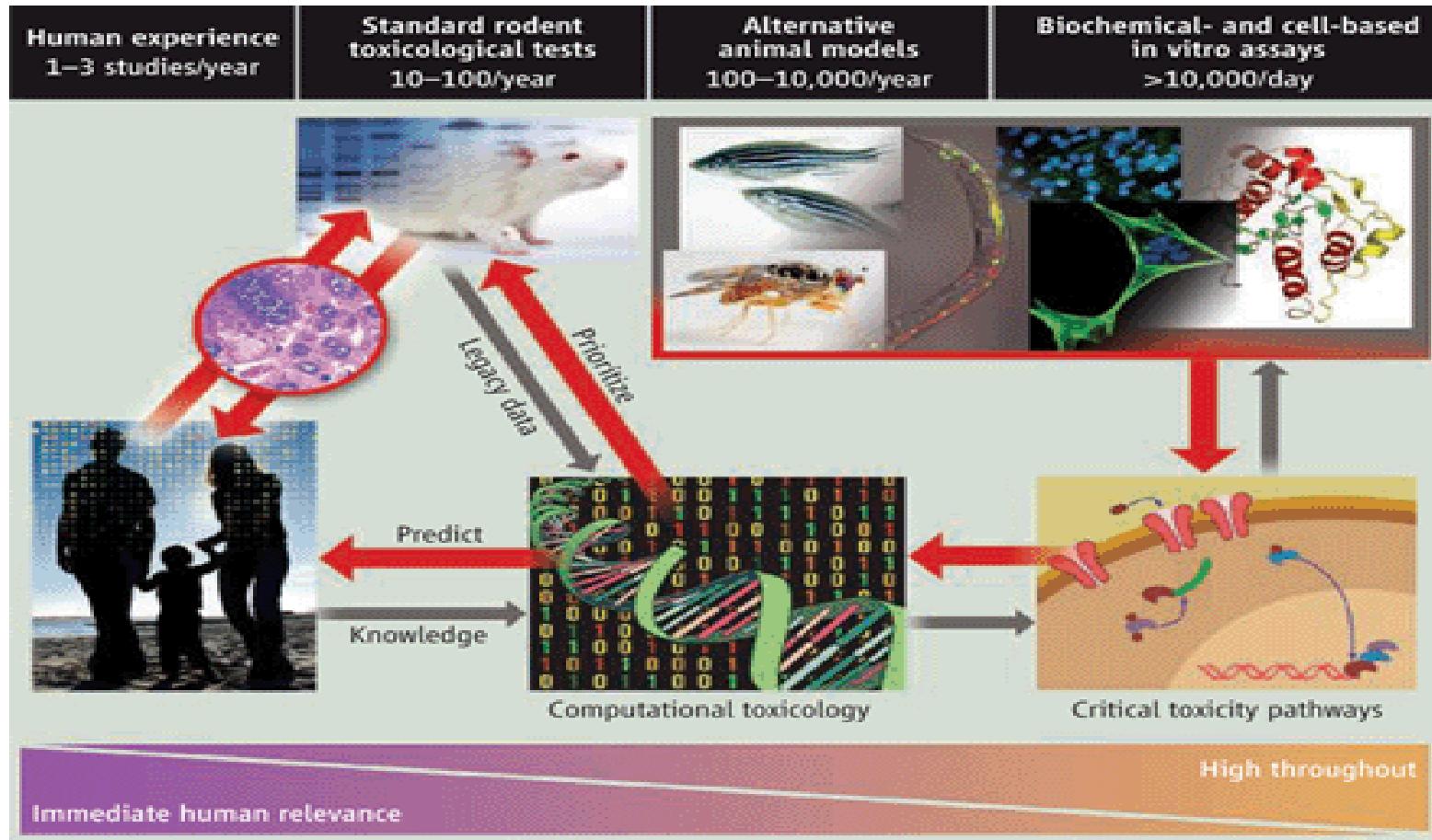


Computational toxicology



In vitro tests

Endorsement by the Scientific Community



Collins, F.S., Gray, G.M. & Bucher, J.R. (2008),
Science (Policy Forum). Vol. 319. pp. 906 - 907

Reaction from the Legal Community

Toxicity Testing in the 21st Century: Better Results, Less Use of Animals

**Legal Obstacles
Are Bumps, Not
Roadblocks**



"Agency rulemaking provides the legal flexibility to implement a new toxicity testing program using existing laws."

Bret C. Cohen

Senior Associate

WILLKIE FARR & GALLAGHER LLP



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Reaction from the Animal Law Community

International Symposia on Challenges and Opportunities in Implementation



uOttawa

June 29-30, 2009



September 12, 2009



November 5, 2009



June 21-23, 2010

"There is widespread support for the NAS vision. There are also real but surmountable challenges in moving the vision into routine regulatory practice. Progress is being made in producing the necessary science and knowledge base — we need to redouble our efforts to see that these insights carry over into the worlds of law and policy."

Paul Locke, Johns Hopkins University
Centre for Alternatives to Animal Testing

Reaction from Experts in Risk Assessment

Risk Analysis, Vol. 29, No. 4, 2009

DOI: 10.1111/j.1539-6924.2008.01150.x

Perspective

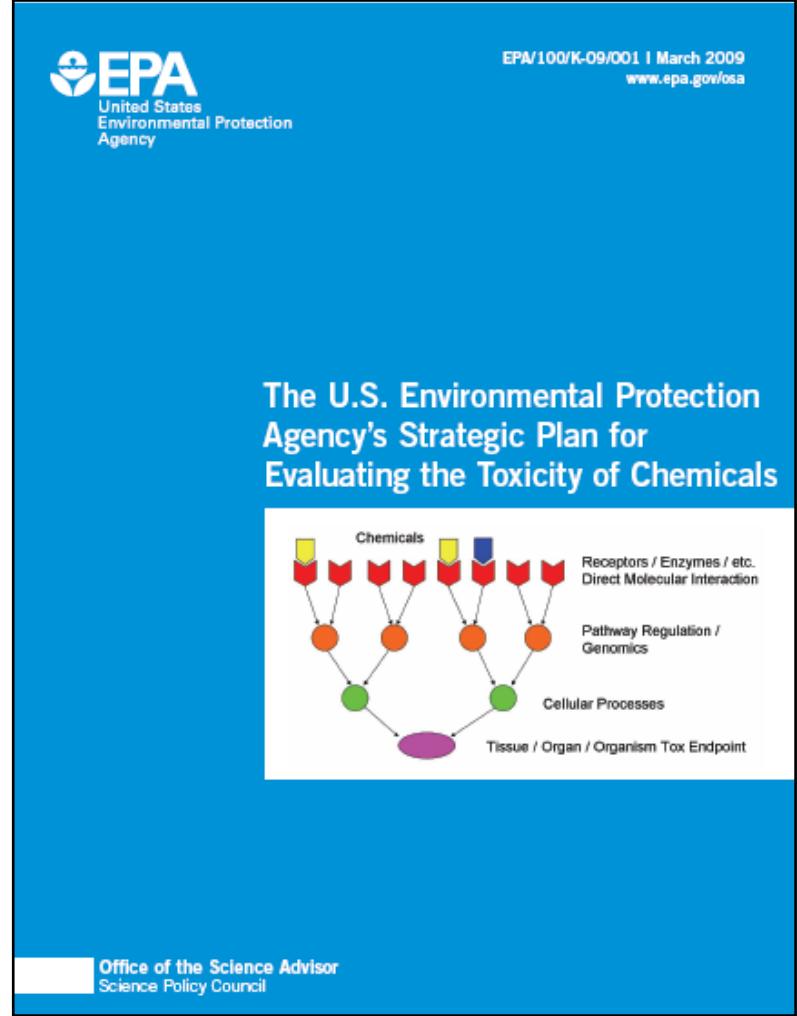
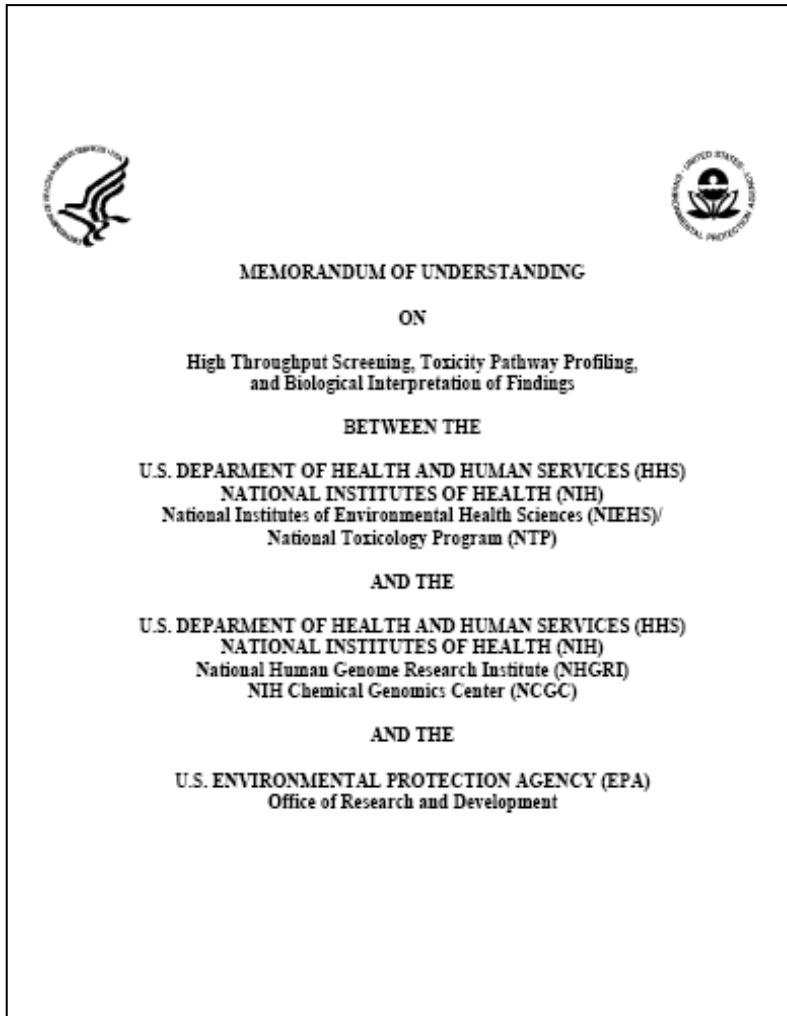
Toxicity Testing in the 21st Century: Implications for Human Health Risk Assessment

Daniel Krewski,¹* Melvin E. Andersen,² Ellen Mantus,³ and Lauren Zeise⁴

"Suresh Moolgavkar, our Area Editor for Health Risk Assessment, asked six experts with different perspectives to comment on the paper. Each praises the vision and offers suggestions for making it more useful."

Michael Greenberg & Karen Lowrie, Editors

Federal Agency Commitment

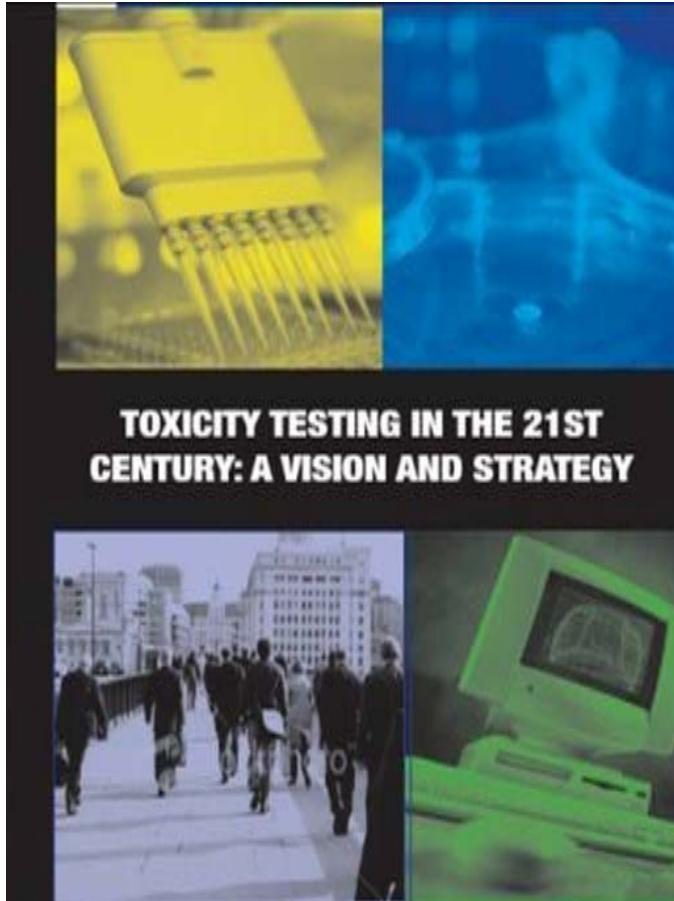


Resources Needed to Implement EPA's Strategic Plan

“This strategic plan describes an ambitious and substantive change in the process by which chemicals are evaluated for toxicity. The NRC (2007) suggested that such a transformation would require up to \$100 million per year in funding over a 10 - 20 year period to have a reasonable chance of reaching its goals.”

U.S. EPA, 2009

Dual Motivation for Change



Better Science

A promotional graphic for AltTox.org. It features a dark header with the text 'A Window into the Future of Toxicity Testing' in white. Below the header is a logo consisting of a blue hexagon with orange dots and the text 'AltTox.ORG'. The main body of the graphic contains text and a list of bullet points. To the left is a photograph of several test tubes containing different colored liquids (red, clear, yellow). At the bottom are logos for The Humane Society of the United States and Procter & Gamble.

A Window into the Future of Toxicity Testing

AltTox.ORG

Log on to AltTox.org and join the online community of scientists and policy experts seeking to accelerate progress on non-animal approaches to toxicity testing:

- Interact with other stakeholders in discussion forums
- Contribute invited commentaries on the way forward
- Access succinct background information

Visit AltTox.org today!

Coordinated by Procter & Gamble and The Humane Society of the United States, in collaboration with an editorial board of distinguished scientists and policy experts.

THE HUMANE SOCIETY OF THE UNITED STATES

P&G

Animal Welfare



Council of Canadian Academies
Conseil des académies canadiennes

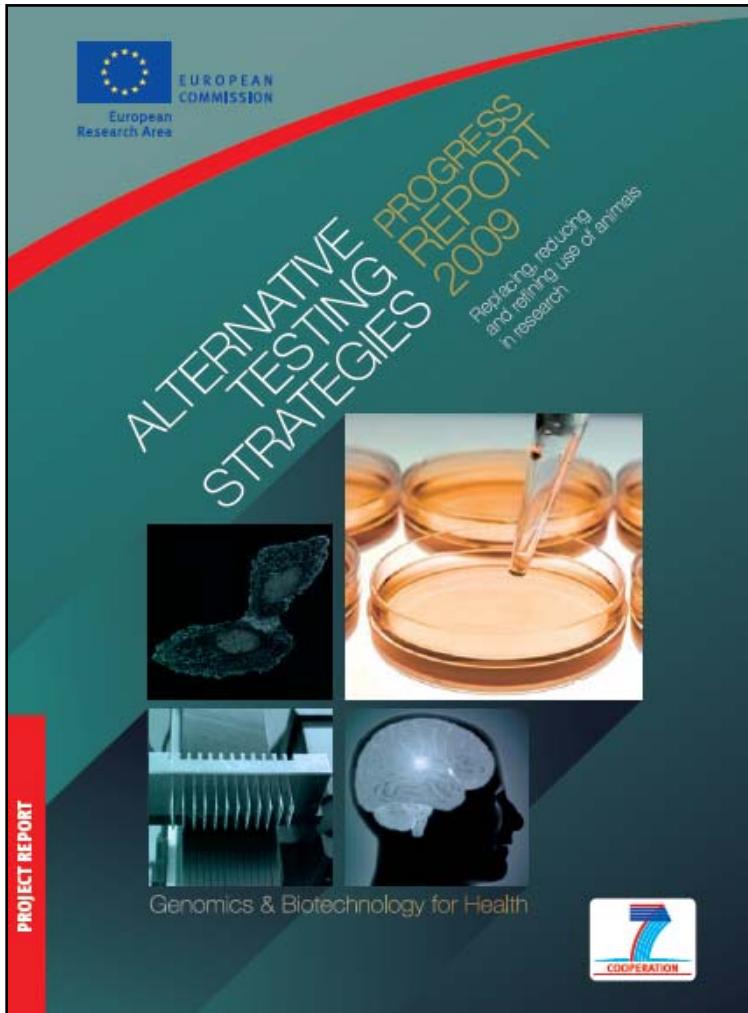


▷ *Science Advice in the Public Interest*

Expert Panel on the Integrated Testing of Pesticides

“Integrated testing, using in vitro data from diverse fields of study, represents an exciting means by which we can refine and reduce in vivo toxicity testing requirements. By this approach, it may be possible to avoid the need for full batteries of animal-based toxicity tests for each pesticide under assessment, while still maintaining defensibility of the assessments.”

Future Directions in the European Union



“This convergence of factors, coupled with the need to evaluate the safety of an increasingly large number of chemicals and their mixtures, has prompted some of the world’s leading scientific authorities to call for a fundamental paradigm shift in toxicology”



Making the Vision a Reality

- National/international coordination of development of the scientific foundation on which the NRC vision rests
- Consideration of the implications of the vision for application of current and future regulatory statutes
- Re-orientation of risk assessment practice to focus on prevention of perturbation of toxicity pathways
- Ongoing oversight by the NRC, with progress reports and mid-course corrections over the next 5 - 10 years

