Approaching Genomics From a Regulatory Perspective

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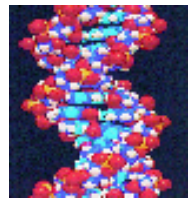
Outline of Presentation



- Science Policy Decisions at EPA
- EPA Interim Policy on Genomics
- Genomics Action Plan
- Genomics Task Force
- Computational Toxicology

EPA Science Policy Decisions

- Science Policy Council (SPC)
  - Chair – EPA Science Advisor (Dr. Paul Gilman)
  - Cross-Agency senior managers – DAA and Office Director Level
- Science Policy Council Steering Committee
  - Rotating Chairmanship
  - Cross-Agency senior scientific staff

EPA Interim Genomics Policy

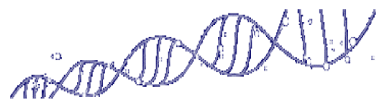
- Supports continued genomics research as a powerful tool
  - understanding the molecular basis of toxicity
  - developing biomarkers of exposure, effects, and susceptibility
- Genomics data alone insufficient for risk assessment and management decisions

EPA Interim Genomics Policy

- Possible use in a weight-of-evidence approach for human health and ecological risk assessments
- Issued June 25, 2002
- http://www.epa.gov/osa/spc/htm/genomics.htm

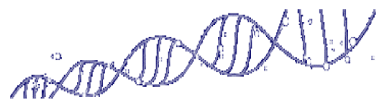
EPA Genomics Action Plan

- Genomics Data
  - QA, standardization of methods and databases, bioinformatics
- Bioethics
  - Privacy and fairness in the use and interpretation of genetic information including responsible use and integration of genetic technology in research
- Risk Assessment
  - Explore ways to incorporate genomic information into Agency risk assessments, refine risk assessment
- Education and Training
  - Broad introductory and specialized training



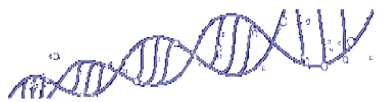
Genomics Action Plan: Progress

- EPA Science Advisory Board (SAB) Bioethics Panel
- Genomics Task Force
  - Develop Agency White Paper on regulatory implications
- Science Policy Council (SPC) oversight
  - Genomics Technical Framework Workgroups.



Genomics Task Force White Paper

- Identify applications and implications of genomics use
  - Regulatory and risk assessment
- Overview current Agency science activities
- Identify scientific and research needs



Genomics Task Force White Paper

I: Introduction

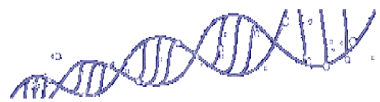
II: Regulatory Applications

III: Risk Assessment Applications

IV: Research Needs and Activities

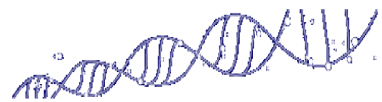
V: Challenges and Recommendations

http://www.epa.gov/osa/genomics.htm



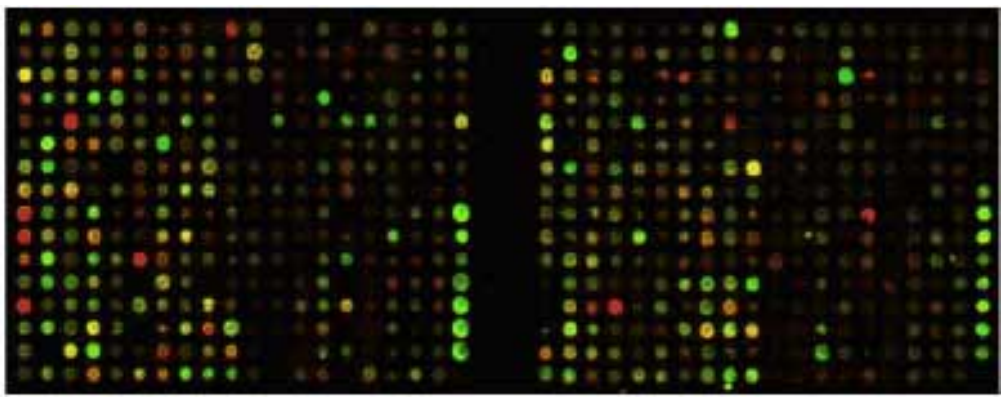
Identified Regulatory Applications

- Monitoring for compliance and assessment purposes
  - Example - water quality designated uses
- Reporting requirements and right-to-know provisions (e.g., TSCA 8(e), FIFRA 6(a)(2))
  - How genomics information triggers reporting requirements
- Prioritization
  - Screening purposes
  - Testing purposes
  - Decision-making



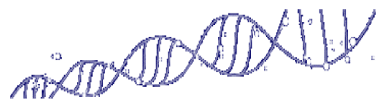
Risk Assessment Applications

- Identify possible mode(s) of action
- Identify and assess impacts on susceptible populations and life stages
- Improve mixtures assessments



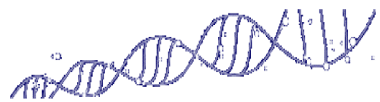
Research: Challenges & Recommendations

- Needs:
  - Linking genomic changes to adverse outcomes
  - Interpreting genomic information for risk assessment
- Actions:
  - Aggressively support genomic research through the ORD Computational Toxicology Initiative
  - Support external research through grants and contracts
  - Encourage industry efforts to develop genomics data
  - Interact with other agencies and institutions, use quality external research



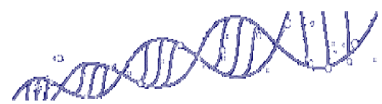
Technical Development: Challenges & Recommendations

- Need:
  - Development of technical framework for analysis and acceptance criteria for genomic information for scientific and regulatory purposes
- Actions:
  - Charge a workgroup with developing technical framework
  - Collaborate with other federal agencies, such as FDA, NIEHS, DOE, as well as scientific community at large, when developing framework



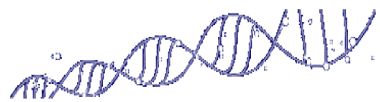
Capacity and Human Capital: Challenges & Recommendations

- Needs:
  - Applying strategic hiring practices to recruit individuals who possess “genomics core competencies”
  - Training EPA risk assessors and managers to interpret and understand genomics data in the context of a risk assessment
- Actions:
  - Offices and Regions should apply strategic hiring practices to recruit individuals trained in genomics
  - Convene a workgroup tasked with developing training modules
  - Collaborate with other agencies and institutions regarding workshops and training tools

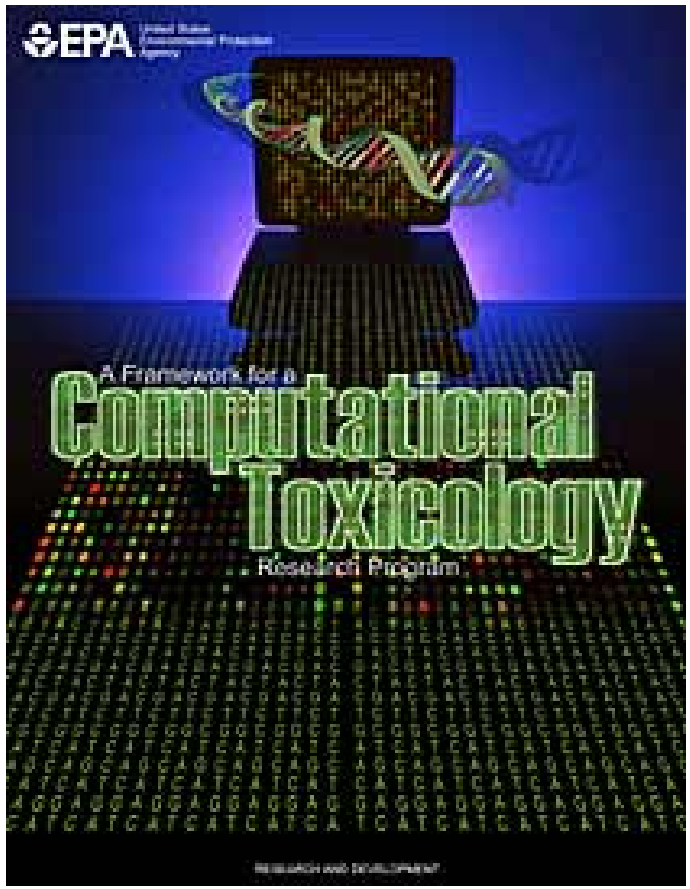


EPA Genomics Workgroups

- Technical Framework Workgroups
  - Coordinating Committee
  - Performance-based Quality Assurance
  - Data Analysis
  - Data Submission
  - Data Management & Storage
  - Microbial Source Tracking
  - Genomics Training



EPA's Computational Toxicology Program



- Integrate modern computing and information technology with the technology of molecular biology and chemistry
- Improve EPA's prioritization of data requirements and risk assessments for toxic chemicals

www.epa.gov/comptox

Comp Tox Overarching Themes

- A technology-based, hypothesis-driven effort to increase the soundness of risk assessment decisions within EPA
- Build the capacity to prioritize, screen and evaluate chemicals by enhancing the predictive understanding of toxicity pathways
- Success measured by ability to produce faster and more accurate risk assessments for less cost relative to traditional means and to classify chemical by their potential to influence molecular and biochemical pathways of concern

Computational Toxicology: General Objectives

- Improve linkages in the source-to-outcome paradigm
- Provide predictive models for screening and testing
- Enhance quantitative risk assessment
  - Dose-response assessments
  - Cross-species extrapolation
  - Chemical mixtures

Office of the Science Advisor Web Site

www.epa.gov/osa