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SAB Science Integration for Decision Making Fact Finding Interviews
Meeting with Office of Prevention, Pesticides and Toxic Substances (OPPTS)
January 26, 2010

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Overall Logistics and Schedule

8:00 SAB members meet at at the entrance to Ariel Rios North (1200 Pennsylvania Avenue, entrance near the Federal Triangle Metro station) for initial coordination discussion.

8:30 a.m. – OPPTS Contact Meet SAB participants in EPA East Lobby (1201 Constitution Ave.) and escort to 4128

8:55-9:00 a.m. - Escort participants to 3371A EPA East

9:00-11:00 a.m. – Office of Pollution Prevention and Toxics (OPPT) Interviews

11:00 -11:05 a.m. - Escort participants to 4128 EPA East

11:05 a.m. -12:00 p.m. – Office of Science Coordination and Policy (OSCP) Interviews

12:00 – 12:55 p.m. – LUNCH on own or bring to room 4128

1:00-2:00 p.m. -- Participants meet in 3130C EPA East for Office of Prevention, Pesticides and Toxic Substances (OPPTS) Deputy Administrator

2:00-2:25 p.m. BREAK/Leave EPA East for Shuttle stop on Constitution Ave.

2:30 p.m. – Take EPA shuttle to Potomac Yards

2:50 p.m. – Meet SAB participants in EPA Potomac Yard Lobby

3:00 – 5:00 pm – Office of Pesticide Programs (OPP) Interviews

**SAB Science Integration for Decision Making Committee Fact Finding
Meeting with Office of Pollution Prevention and Toxics (OPPT)
9:00 -11:00 a.m.
Room 3371A EPA East**

Study Objectives:

- Evaluate EPA practices for integrating science to support decision making
- Evaluate consideration of public, stakeholder, external scientific, and other governmental input in science assessment for decision making
- Evaluate drivers and impediments to implementing past recommendations for science integration
- Evaluate ways EPA receives feedback on how science is used in decision making
- Evaluate EPA workforce to support science integration for decision making

Agenda

1. Introductions facilitated by SAB Staff
2. Discussion of study objectives and questions facilitated by SAB members
3. Follow-up Actions and Timeline facilitated by SAB staff

Planned Participants:

Office of Pollution Prevention and Toxics (OPPT)

Ms. Wendy Cleland Hamnett, Acting Director
Ms. Barbara Cunningham, Acting Deputy Director
Mr. Jim Willis, Director, Chemical Control Division
Mr. Ward Penberthy, Deputy Director, Chemical Control Division
Dr. Tala Henry, Acting Deputy Director, National Program Chemicals Division
Dr. Robert Lee, Director, Economics, Exposure and Technology Division
Mr. Neil Patel, Deputy Director, Economics, Exposure and Technology Division
Dr. Kay Austin, Associate Director, Economics, Exposure and Technology Division
Dr. Oscar Hernandez, Director, Risk Assessment Division
Dr. Jennifer Seed, Deputy Director, Risk Assessment Division

SAB Committee on Science Integration for Decision Making Members:

Dr. Thomas Burke, Chair, Johns Hopkins University
Dr. Penny Fenner-Crisp, Independent Consultant
Dr. Barton H. (Buzz) Thompson, Jr., Stanford University

Other Committee Members by Telephone:

Dr. Jill Lipoti, New Jersey Department of Environmental Protection
Dr. Deborah Cory-Slechta, University of Rochester
Dr. Wayne Landis, Western Washington University
Dr. Thomas Theis, University of Illinois at Chicago

SAB Staff Office:

Dr. Anthony (Tony) Maciorowski, Deputy Director
Dr. Angela Nugent, Designated Federal Official

Observer:

Dr. Mary Belefski, Special Assistant, Office of Science Coordination and Policy

OPPT Materials:

1. Organizational Chart (Attachment A)

2. Program website information:

Basic Information: <http://www.epa.gov/oppt/pubs/opptabt.htm>

New Chemicals Program: <http://www.epa.gov/oppt/newchems/>

Existing Chemicals Program: <http://www.epa.gov/oppt/existingchemicals/>

Collecting and Assessing Information:

<http://www.epa.gov/oppt/existingchemicals/pubs/collectinfo.html>

Chemicals: Scientific Review, Assessment:

http://www.epa.gov/oppt/pubs/chem_sci_rev_assmnt.htm

Enhancing EPA's Chemicals Program, including new chemical action plans:

<http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html>

Managing Chemical Risks:

<http://www.epa.gov/oppt/existingchemicals/pubs/managechemrisk.html>

International activities:

<http://www.epa.gov/oppt/existingchemicals/pubs/intlactivities.html>

Administration Principles for reform of chemicals legislation:

<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>

**SAB Science Integration for Decision Making Committee Fact Finding
Meeting with Office of Science Coordination and Policy (OSCP)
11:00 a.m. -12:00 p.m.
Room 4128 EPA East**

Study Objectives:

- Evaluate EPA practices for integrating science to support decision making
- Evaluate consideration of public, stakeholder, external scientific, and other governmental input in science assessment for decision making
- Evaluate drivers and impediments to implementing past recommendations for science integration
- Evaluate ways EPA receives feedback on how science is used in decision making
- Evaluate EPA workforce to support science integration for decision making

Agenda

1. Introductions facilitated by SAB Staff
2. Discussion of study objectives and questions facilitated by SAB members
3. Follow-up Actions and Timeline facilitated by SAB staff

Planned Participants:

OSCP:

Mr. Frank Sanders, Director
Mr. Steve Knott, Director, Exposure Assessment Coordination and Policy Division (EACPD)
Mr. Gary Timm, Senior Scientist (EACPD)
Dr. J. Thomas McClintock, Director, Hazard Assessment Coordination and Policy Division (HACPD)

SAB Committee on Science Integration for Decision Making Members:

Dr. Thomas Burke, Chair, Johns Hopkins University
Dr. Penny Fenner-Crisp, Independent Consultant
Dr. Barton H. (Buzz) Thompson, Jr., Stanford University
Other Committee Members by Telephone:

Dr. Jill Lipoti , New Jersey Department of Environmental Protection
Dr. Deborah Cory-Slechta, University of Rochester
Dr. Wayne Landis, Western Washington University
Dr. Thomas Theis, University of Illinois at Chicago

SAB Staff Office:

Dr. Anthony (Tony) Maciorowski, Deputy Director
Dr. Angela Nugent, Designated Federal Official

Observer:

Dr. Mary Belefski, Special Assistant, Office of Science Coordination and Policy

OSCP Materials:

1. Overview (Attachment E)
2. Biographies (Attachment F)
3. Program website information:
 - General: <http://www.epa.gov/scipoly/>
 - EDSP: <http://www.epa.gov/endo/>

**SAB Science Integration for Decision Making Committee Fact Finding
Meeting with Deputy Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances (OPPTS)
1:00 - 2:00 p.m.
Room 3130C EPA East**

Study Objectives:

- Evaluate EPA practices for integrating science to support decision making
- Evaluate consideration of public, stakeholder, external scientific, and other governmental input in science assessment for decision making
- Evaluate drivers and impediments to implementing past recommendations for science integration
- Evaluate ways EPA receives feedback on how science is used in decision making
- Evaluate EPA workforce to support science integration for decision making

Agenda

1. Introductions facilitated by SAB Staff
2. Discussion of study objectives and questions facilitated by SAB members
3. Follow-up Actions and Timeline facilitated by SAB staff

Planned Participants:

OPPTS/Immediate Office

Mr. James (Jim) Jones, Deputy Assistant Administrator

SAB Committee on Science Integration for Decision Making Members:

Dr. Thomas Burke, Chair, Johns Hopkins University

Dr. Penny Fenner-Crisp, Independent Consultant

Dr. Barton H. (Buzz) Thompson, Jr., Stanford University

Other Committee Members by Telephone:

Dr. Jill Lipoti, New Jersey Department of Environmental Protection

Dr. Deborah Cory-Slechta, University of Rochester

Dr. Wayne Landis, Western Washington University

Dr. Thomas Theis, University of Illinois at Chicago

SAB Staff Office:

Dr. Anthony (Tony) Maciorowski, Deputy Director

Dr. Angela Nugent, Designated Federal Official

Observer:

Dr. Mary Belefski, Special Assistant, Office of Science Coordination and Policy

OPPTS Materials:

1. Overview (Attachment G)
2. Biography (Attachment H)

**SAB Science Integration for Decision Making Committee Fact Finding
Meeting with Office of Pesticide Programs
3:00 – 5:00 p.m.
Potomac Yards, Arlington, Virginia
Room 12100**

Study Objectives:

- Evaluate EPA practices for integrating science to support decision making
- Evaluate consideration of public, stakeholder, external scientific, and other governmental input in science assessment for decision making
- Evaluate drivers and impediments to implementing past recommendations for science integration
- Evaluate ways EPA receives feedback on how science is used in decision making
- Evaluate EPA workforce to support science integration for decision making

Agenda

1. Introductions facilitated by SAB Staff
2. Discussion of study objectives and questions facilitated by SAB members
3. Follow-up Actions and Timeline facilitated by SAB staff

Planned Participants:

OPP:

Dr. Steven P. Bradbury, Acting Director
Mr. William (Bill) L. Jordan, Senior Policy Advisor
Dr. Vicki L. Dellarco, Science Advisor
Ms. Joan Harrigan-Farrelly, Director Antimicrobials Division
Mr. Keith Matthews, Acting Director, Biopesticides and Pollution Prevention Division
Dr. Donald Brady, Director, Environmental Fate and Effects Division
Dr. Tina Levine, Director, Health Effects Division
Dr. Jennifer McLain, Chief, Policy and Regulatory Services Branch
Mr. Edward Odenkirchen, Senior Advisor, Environmental Fate and Effects Division

SAB Committee on Science Integration for Decision Making Members:

Dr. Thomas Burke, Chair, Johns Hopkins University
Dr. Penny Fenner-Crisp, Independent Consultant
Dr. Barton H. (Buzz) Thompson, Jr., Stanford University

Other Committee Members by Telephone:

Dr. Jill Lipoti, New Jersey Department of Environmental Protection
Dr. Deborah Cory-Slechta, University of Rochester
Dr. Wayne Landis, Western Washington University
Dr. Thomas Theis, University of Illinois at Chicago

SAB Staff Office:

Dr. Anthony (Tony) Maciorowski, Deputy Director
Dr. Angela Nugent, Designated Federal Official

Observer:

Dr. Mary Belefski, Special Assistant, Office of Science Coordination and Policy

OPP Materials:

1. Organizational Chart (Attachment I)
2. Biographies (Attachment J)
3. OPP Science Policy Council Fact Sheet (Attachment K)
4. Program website information:

General:

<http://www.epa.gov/pesticides/science/index.htm>

<http://www.epa.gov/scipoly/sap/>

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

Examples of some currently active issues:

Ag Health Study:

<http://www.epa.gov/opp00001/health/ag-health.html>

Antimicrobial Testing Program:

<http://www.epa.gov/oppad001/antimicrobial-testing-program.html>

<http://www.epa.gov/oppad001/>

Colony Collapse Disorder:

<http://www.epa.gov/opp00001/about/intheworks/honeybee.htm>

<http://www.epa.gov/pesticides/ecosystem/pollinator-protection.html>

Endangered Species:

<http://www.epa.gov/espp/>

Nanotechnology:

<http://www.epa.gov/pesticides/about/intheworks/nanotechnology.htm>

Semi-volatile Chemicals (bystander exposure):

http://www.epa.gov/opprrd1/reregistration/soil_fumigants/

http://www.epa.gov/pesticides/reregistration/soil_fumigants/buffer-zones-fs

Spray Drift Labeling:

<http://www.epa.gov/opp00001/factsheets/spraydrift.htm>

Office of Prevention, Pesticides and Toxic Substances (OPPTS) Coordination for
Interviews with the Science Advisory Board (SAB)
Committee on Science Integration for Decision Making
January 26, 2010
Attachment D

**Biographies of OPPT Managers, Science Team, and Staff Planning to Attend SAB
Meeting on January 26, 2010**

Office of Pollution Prevention and Toxics, OPPTS, U.S. EPA:

Ms. Wendy Cleland-Hamnett, Acting Director -- Wendy Cleland-Hamnett is currently serving as the Acting Director for the Office of Pollution Prevention and Toxics (OPPT) in EPA's Office of Prevention, Pesticides, and Toxic Substances. From April, 2004, to December 2008, Wendy served as the Deputy Director for OPPT. She began her career at EPA in OPPT and spent her first 10 years with the Agency in a variety of jobs within OPPT, including Attorney-Advisor, Branch Chief, and Deputy Division Director positions. Wendy has been the Deputy Director of the Office of Information Collection, in the Office of Environmental Information (OEI) since the creation of the Office in October, 1999. She led the successful effort to create EPA's Central Data Exchange for electronic reporting of environmental data, a key element of the Agency's E-Government strategy. She also co-chaired efforts with State partners to design and implement the National Environmental Exchange Network, a cutting-edge approach to improving the quality, quantity and accessibility of environmental and program data shared among EPA, States and other Federal partners. Prior to the creation of OEI, she held several positions in the Office of Policy, including: Director of the Center for Environmental Information and Statistics (April 1998 to Oct. 1999); Director of the Office of Sustainable Ecosystems and Communities (1995 to 1998), and Deputy Director of the Office of Regulatory Management and Evaluation (1992 to 1995). From 1989 to 1992, Ms. Cleland-Hamnett was a Special Assistant in the Office of the EPA Administrator. Her assignments included work on pesticides and toxics programs, research and development issues, the Agency's Risk Assessment Council, the EPA Science Advisory Board, and a special panel reporting to the Administrator on the quality of science at EPA. Ms. Cleland-Hamnett attended Bates College in Lewiston, Maine, and received a B.A. in Political Science from Earlham College in Richmond, Indiana. She received a law degree from George Washington University, and is a member of the District of Columbia Bar.

Mr. Jim Willis, Director, Chemical Control Division -- Since October 2004, Jim Willis has been Director the Chemical Control Division (CCD) in EPA's Office of Pollution Prevention and Toxics (OPPT). CCD is responsible for the implementation of EPA's new and existing chemicals programs, the chemical testing program, and special activities such as oversight of Nanotechnology. Jim co-chaired EPA's nanotechnology white paper development and, from 2006 to 2009, chaired the OECD Working Party on Manufactured Nanomaterials. Prior to his current position, he was Director of Chemicals for the United Nations Environment Programme, a position he held since November, 1995. At UNEP he facilitated the negotiations of, and served as Executive Secretary of the Rotterdam Convention on Prior Informed Consent and the Stockholm Convention on Persistent Organic Pollutants. He also directed UNEP's mercury program, its chemical safety capacity building program, and its efforts to develop a "Strategic Approach to International Chemicals Management". Jim joined EPA in 1984 and served in a variety of staff and management roles in OPPT before his 9-year interlude in the United Nations.

Mr. Ward Penberthy, Deputy Director, Chemical Control Division - Ward Penberthy currently serves as the Deputy Director the Chemical Control Division (CCD) in EPA's Office of Pollution Prevention and Toxics (OPPT). CCD is responsible for the implementation of EPA's new and existing chemicals programs, the chemical testing program, and special activities such as oversight of nanotechnology. He has over seen the development of numerous proposed and final rules addressing human health and environmental concerns. Prior to his current position, he was Chief of OPPT's Chemical Engineering Branch. While in the Chemical Engineering Branch he supervised the development of worker and environmental exposure assessments. Ward joined EPA over 20 years ago and has held a variety of other staff and management positions in OPPT. Prior to coming to EPA he worked for 7 years at Exxon Chemicals in their Linden, New Jersey plant.

Office of Prevention, Pesticides and Toxic Substances (OPPTS) Coordination for
Interviews with the Science Advisory Board (SAB)
Committee on Science Integration for Decision Making
January 26, 2010
Attachment D

**Biographies of OPPT Managers, Science Team, and Staff Planning to Attend SAB
Meeting on January 26, 2010**

Dr. Tala Henry, Acting Deputy Director, National Program Chemicals Division - Dr. Tala Henry has been with the U.S. Environmental Protection Agency for over 15 years. She is currently Acting Deputy Director of the National Chemicals Program Division within the Office of Pollution Prevention and Toxics working on a variety of issues related to assessment and management of industrial chemicals. Dr. Henry is also a member of EPA's Risk Assessment Forum. Previously Dr. Henry worked in EPA's Region 8 office conducting risk assessments for RCRA and Superfund hazardous waste sites, in the Office of Water where she led the team that develops Ambient Water Quality Criteria and in the Office of Research and Development where she conducted research on chemical toxicity and endocrine disruption in aquatic organisms. Dr. Henry has also represented the U.S. in international chemical assessment and management activities, such as the Organization for Economic Cooperation and Development's Existing Chemicals Task Force and QSAR Management Group and the United Nations POPs Review Committee. Dr. Henry received a Ph.D. in pharmacology from the University of Minnesota and completed a 2-year post-doc at the University of Wisconsin-Madison before joining the U.S. EPA.

Dr. Robert Lee, Director, Economics, Exposure and Technology Division – Dr. Robert Lee is the Director of the Economics, Exposure and Technology Division in the Office of Pollution Prevention and Toxics. His division houses five branches, four of which are responsible for providing chemistry, engineering, exposure and economics support to the Office. In addition to the analytical work provided by these branches, he is also responsible for the Green Chemistry and Green Engineering programs. The fifth branch houses the Design for Environment program which utilizes EPA scientific expertise to foster the adoption of less toxic chemicals in the manufacture of products and transfer knowledge about best practices for reducing exposures. Prior to his current position, Dr. Lee served as Branch Chief of the Economic and Policy Analysis Branch in the division, and earlier served in management and as a senior analyst in the Economic Analysis Branch in the Office of Pesticide Programs in EPA. Before joining EPA he served as the economist on a policy and research team in the Illinois Department of Conservation. Dr. Lee received his doctoral and masters degrees in resource economics from the University of Massachusetts, and bachelor's degree from Rutgers.

Mr. Neil Patel, Deputy Director, Economics, Exposure and Technology Division - Neil Patel has been Deputy Director of the Economics, Exposure and Technology Division (EETD) in the Office of Pollution Prevention and Toxics (OPPT) since 2000. Working with the director of EETD, Neil provides leadership for planning, implementation and completion of all technical analyses in the areas of economic, industrial chemistry, engineering and exposure assessments in support of all OPPT regulatory and non-regulatory programs along with management of Green Chemistry, Green Engineering and Design for the Environment programs. Prior to OPPT, Neil worked in the Office of Water for over ten years as Chief of the Economic and Statistical Analysis Branch and managed technical support for development of National Effluent Guidelines promulgated under the authority of the Clean Water Act. He also worked in the Office of Air and Radiation for three years as a Senior Chemical Engineer developing alternatives to chlorofluorocarbons implicated in the depletion of the ozone layer. Prior to EPA, Neil worked for PPG and Celanese chemical companies for eight years as process engineer and development engineer both in manufacturing and research operations. Neil received his B.Tech in Chemical Engineering from the Indian Institute of Technology (1972), MS in Chemical Engineering from the University of Texas at Austin (1974) and MBA (Management/Marketing) from the Corpus Christi State University (Texas A & I) (1979).

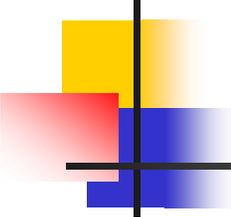
Office of Prevention, Pesticides and Toxic Substances (OPPTS) Coordination for
Interviews with the Science Advisory Board (SAB)
Committee on Science Integration for Decision Making
January 26, 2010
Attachment D

**Biographies of OPPT Managers, Science Team, and Staff Planning to Attend SAB
Meeting on January 26, 2010**

Dr. Kay Austin, Associate Director, Economics, Exposure and Technology Division - Since Feb. 2009, Dr. Kay Austin has been Associate Director of the Economics, Exposure and Technology Division (EETD) in EPA's Office of Pollution Prevention and Toxics (OPPT). EETD provides technical and science support for the implementation of EPA's new and existing chemicals programs, special programs for Nanotechnology, and such voluntary programs as Design for the Environment, Green Chemistry, and Green Engineering. Prior to her current position, Kay was Senior Ecologist for the U.S. Section of the International Joint Commission (IJC), a U.S.-Canada bi-national organization under the Boundary Waters Treaty of 1909 which was authorized to prevent and resolve disputes over their shared waters (August 2000 – January 2009). At the IJC, she advised Commissioners and staff on science/policy matters and assisted the Commission in meeting its requirements under the Great Lakes Water Quality Agreement addressing: water quality issues, legacy pollutants and on-going contamination from chemical spills, aquatic invasive species, remediation of designated contaminated sites, and human health issues related to chemical pollution. Prior to joining the IJC, Dr. Austin served in the EPA's Office of Research and Development (April 1993 - August 2000) in various positions including developing ecological indicators, conducting ecological risk assessment, and serving as a Special Assistant for Ecology to the Director of the National Center for Environmental Assessment. Kay initially joined the OPPT serving as an exposure assessor (1989-1993) determining the potential risk to humans and the environment from exposure to genetically engineered microorganisms and new and existing chemicals.

Dr. Oscar Hernandez, Director, Risk Assessment Division – Dr. Oscar Hernandez has been Division Director, Risk Assessment Division (RAD) since August 1999. Prior to assuming that role, he served as Associate Division Director, RAD. Oscar has over twenty years of professional experience in areas ranging from research on biological mechanisms to the assessment of health and environmental hazards and risk of chemicals. He holds a Ph. D. in Chemistry from the University of Virginia and complemented his education with a Post-doctoral Fellowship at the National Institutes of Health, Bethesda, MD. He continued to pursue his research interests on mechanisms of chemical carcinogenesis at the National Institute of Environmental Health Sciences. He is the author and co-author of numerous scientific publications based on the results of his research activities.

Dr. Jennifer Seed, Deputy Director, Risk Assessment Division - Dr. Jennifer Seed is Deputy Director of the Risk Assessment Division in the Office of Pollution Prevention and Toxics. Prior to that, she was Branch Chief of the Existing Chemicals Assessment Branch in the Risk Assessment Division for 10 years, and staff scientist for many years working on a variety of hazard and risk assessments of industrial chemicals. She also worked for several years at the Risk Science Institute within the International Life Sciences Institute on a variety of risk assessment issues. Dr. Seed is a member of the Risk Assessment Forum, and chaired the Human Health Oversight Committee for four years. She represents OPPT on the Science Policy Council Steering Committee, and is involved in a variety of risk assessment projects both domestically and internationally. Dr. Seed received a PhD in developmental and cellular biology from the University of Washington.



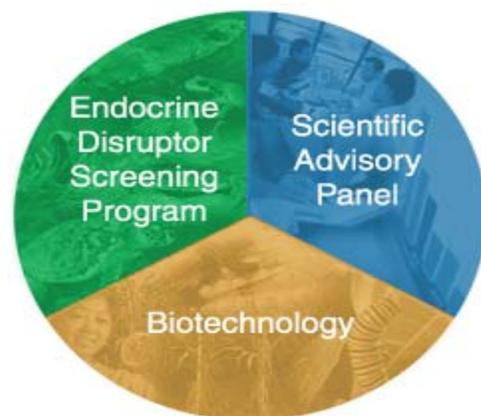
OPPTS: Office of Science Coordination and Policy (OSCP)

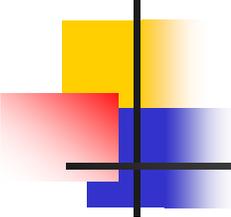
Frank Sanders, Director
Office of Science Coordination and Policy

Overview for Science Advisory Board (SAB)
Committee on Science Integration for
Decision Making
January 26, 2010

Office of Science Coordination and Policy (OSCP)

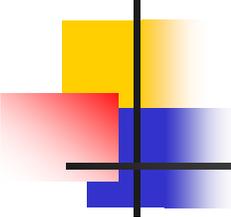
- The Office of Science Coordination and Policy (OSCP) provides coordination, leadership, peer review, and synthesis of science and science policy within the Office of Prevention, Pesticides, and Toxic Substances (OPPTS). OSCP assures sound scientific decisions are made regarding safe pesticide and chemical management through the leadership of the Scientific Advisory Panel. The office also coordinates emerging exposure and hazard assessment topics such as endocrine disruptors and biotechnology.





OSCP Organization

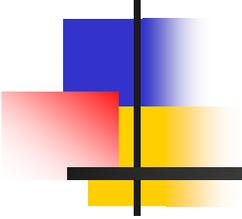
- Office of the Director (Frank Sanders, Director)
- FIFRA Scientific Advisory Panel (Laura Bailey, Executive Secretary)
- Exposure Assessment Coordination and Policy Division (Steve Knott, Division Director)
- Hazard Assessment Coordination and Policy Division (Dr. Tom McClintock, Division Director)



OSCP Major Programs

Endocrine Disruptors Screening Program
Science Policy and Coordination

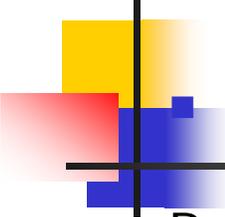
- FIFRA Scientific Advisory Panel (SAP)
- Science Policy/Biotechnology



Endocrine Disruptor Screening Program (EDSP)

Steve Knott

202-564-0103



EPA's Statutory Authority

Food Quality Protection Act (FQPA)

Requires EPA to: Develop a screening program using validated assays to identify pesticides that may have estrogenic effects in humans.

Authorizes EPA to include:

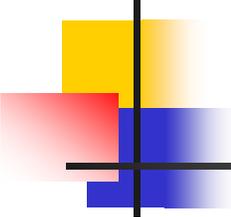
Other endocrine effects, as designated by the EPA Administrator (e.g., androgen and thyroid; endocrine effects in species other than humans).

Other non-pesticide chemicals that:

- Have “an effect cumulative to that of a pesticide,” and
- To which a substantial human population may be exposed.

■ Safe Drinking Water Act (SDWA) Amendments

Allows EPA to require testing of chemical substances found in sources of drinking water, if a substantial human population may be exposed.



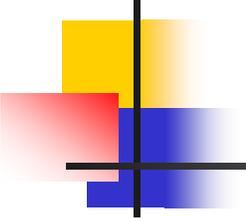
EDSP Scope and Structure

■ Scope

- Estrogen, Androgen, Thyroid Hormone Systems
- Human Health and Wildlife

■ Two-Tiered Approach

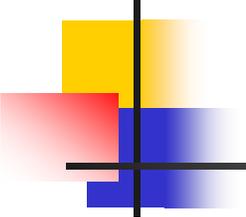
- Tier 1
 - In vitro and in vivo screens
 - Detect potential to interact with endocrine system
- Tier 2
 - Tier 2 data called in only after review of Tier 1 data
 - Multi-generation studies covering a broad range of taxa
 - Provide data for hazard assessment



Endocrine Disruptor (ED) Activities



- Assay Validation - Development and validation of test assays (Tier 1 screening & Tier 2 testing)
- Priority Setting - Selecting chemicals to be screened
- Procedures - Developing implementation procedures for requiring testing



Completed Validations

Tier 1

In Vitro

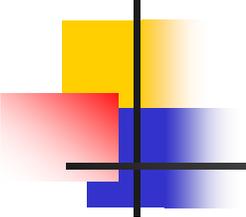
- | | |
|--|----------|
| ■ ER Binding | Complete |
| ■ ER α Transcriptional Activation | Complete |
| ■ AR Binding | Complete |
| ■ Steroidogenesis | Complete |
| ■ Aromatase | Complete |

In Vivo

- | | |
|--------------------------------|----------|
| ■ Uterotrophic | Complete |
| ■ Hershberger | Complete |
| ■ Pubertal Male | Complete |
| ■ Pubertal Female | Complete |
| ■ Amphibian Metamorphosis | Complete |
| ■ Fish Short Term Reproduction | Complete |

Tier 2

- | | |
|--------------------------|----------|
| ■ Mammalian 2 Generation | Complete |
|--------------------------|----------|



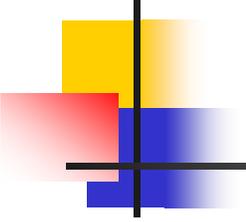
Ongoing & Future Validations

Tier 1 (Potential Replacement Assays)

- Less intensive use of animals; greater sensitivity; shorter duration; less expensive
- Example – Human Recombinant ER Binding

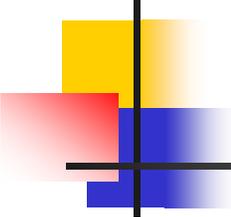
Tier 2

- Avian 2-generation Dec. 2011
- Amphibian Growth/Reproduction Dec. 2011
- Fish 2-generation Dec. 2011
- Mysid 2-generation Dec. 2011



Ongoing & Future Priority Setting

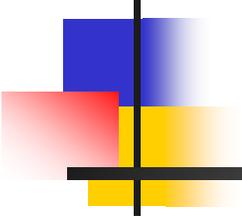
- Next list of 100 Pesticide Chemicals
- Drinking Water Contaminants Including Chemicals other than Pesticide Chemicals
 - House Report for 2010 appropriations



Current EDSP Activities

- Continue Tier 2 Assay validation

- Test Orders
 - Approximately 750 test orders will be issued for 67 chemicals.
 - EPA will issue test orders over the next four months.
 - Test Orders for chemicals will require all the assays in the Tier 1 battery.
 - Responses to Test Orders due 90 days from receipt
 - Agency notifies industry what tests must be run
 - Test data due 24 months from issuance of Test Order
 - Agency review of Tier 1 and Other Significantly Relevant Information (OSRI)
 - Notification of Agency decisions regarding the need for Tier 2 testing



FIFRA Scientific Advisory Panel (SAP)

Laura Bailey

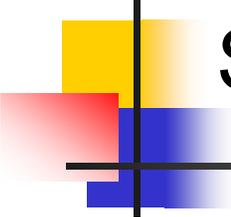
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FIFRA §25(d)

Scientific Advisory Panel - Purpose

Provide independent scientific evaluations, comments, and recommendations (scientific peer review) for the EPA Office of Prevention, Pesticides, and Toxic Substances (OPPTS) on issues related to:

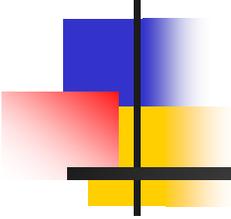
- The science underlying certain pesticide regulatory activities
- EPA reports and operating guidelines to improve the effectiveness and quality of scientific analyses made by Agency scientists
- Major scientific studies and related issues



FIFRA §25(d) Scientific Advisory Panel - Purpose

Example Topics Reviewed by the FIFRA SAP

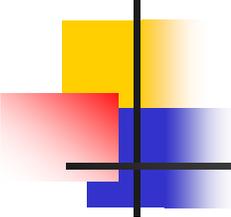
- Safety Factors for Childhood Dietary Risk Assessment
- Common Mechanisms of Toxicity for Cumulative Risk Assessment
- Probabilistic Ecological and Human Health Risk Assessment Models
- Residential Exposure to Pesticides
- Spray Drift from Pesticide Applications
- Research with Human Subjects
- Ground Water Monitoring Studies
- Terrestrial Field Dissipation Studies
- Endocrine Disruptor Screening and Testing
- Acute Oral Toxicity Testing
- Plant Incorporated Protectants – Resistance Management and Non-Target Insect Issues



Science Policy and Biotechnology

Thomas McClintock, PhD

202-564-8488



Biotechnology

- Develop Compliance Regulation appropriate for Plant Incorporated Protectants (PIP).
- Plants are genetically modified to produce desirable traits such as enhanced resistance to certain pests.

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**Biographies of OSCP Managers, Science Team, and Staff Planning to Attend SAB
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Office of Science Coordination and Policy, OPPTS, U.S. EPA:

Mr. Frank T. Sanders, Director - Frank Sanders has been a chartered member of the U.S. Environmental Protection Agency since its inception of 1970. During that time he has had the opportunity to work in every major program area within the Office of Pesticide Programs; from Product Chemist for insecticides, Fungicides and Antimicrobials; to Product Manager for the Insecticides and Rodenticides Branch; to Branch Chief for the Fungicide and Herbicides Branch; to Deputy Chief of the Special Review Branch; to Director of the Office of Program Management and Support Division and the Director of the Antimicrobial Division to his current position as the Director of the Office of Science Coordination and Policy (OSCP). Mr. Sanders was appointed as Director of OSCP in the fall of 2008, with responsibilities for managing the Endocrine Disruptor Screen Program, Science Advisory Panel and Genetic Engineering (Plant Incorporate Protectants). Prior to Mr. Sanders appointment as Director of OSCP, his appointment as Director of the Antimicrobials Division in the summer of 1996 marked a turning point in antimicrobial pesticide registrations. The enactment of the 1996 Food Quality Protection Act imposed exceedingly tight deadlines and pressures on the Agency to make regulatory decisions faster than the program had typically been able to achieve and the passing of Pesticide Registration Improvement Act in March 2004 expanded these requirements. Mr. Sanders received his B.S. Degree in Chemistry from A&T State University in 1968 and did his graduate studies at the NC State University in 1973. He is also the recipient of numerous EPA and government-wide awards including the Presidential Rank Award of 2000.

Dr. J. Thomas McClintock, Director, Hazard Assessment Coordination and Policy Division -- Dr. J. Thomas McClintock is responsible for leading and managing a staff of varying levels of scientists responsible for a range of “cutting-edge” and highly complex science and technical issues that re crucial to current and future health and environmental protection policies of OPPTS and the Agency. These include the development of several regulatory options for the deployment of Plant Viral Coat Protein-Incorporated Protectants (PVCP-PIPs) and other biotechnology-based products, and for the development of regulatory approaches for “Option Selections” by the Assistant Administrator for the PIPs Compliance Workgroup. The Advance Notice of Proposed Rulemaking (ANPRM), published previously, announced EPA's intention to pursue rulemaking to address compliance issues that arise because of the inherent differences between PIPs (*i.e.*, plants that have been engineered to include genetic material that imparts pesticidal properties to the plant) and traditional pesticides that current regulations were written to address. Dr. McClintock has also held positions in the Office of Prevention, Pesticides, and Toxic Substances (OPPT) and in the Office of Pesticide Programs (OPP). Dr. McClintock received a Bachelor of Science degree from the Department of Biology at James Madison University, Harrisonburg, VA, a Masters of Science degree from the Department of Entomology, and a Doctorate of Philosophy degree from the Department of Microbiology at the University of Maryland, College Park, MD. After completing a Postdoctoral Fellowship at U.S. Department of Agriculture, Dr. McClintock became Group Leader/Senior Staff Scientist at Digene Diagnostics, Inc. where he directed the research on the development and use of DNA probes for the detection and diagnosis of human pathogens.

Mr. Steven Knott, Director, Exposure Assessment Coordination and Policy Division (EACPD) - Steve Knott is currently the Director of the Exposure Assessment Coordination and Policy Division (EACPD) within the Environmental Protection Agency's (EPA) Office of Science Coordination and Policy, Office of Prevention Pesticides, and Toxic Substances. Steve began his federal career in 1984, initially working part-time as a physical science technician and later working full-time as an analytical chemist with the Department of Defense. In 1988, Steve began working in the EPA Region 3 Environmental Services Division laboratory as an Analytical Chemist. Steve then moved to EPA Headquarters to work in the Office of Pesticide Programs (OPP), Health Effects Division (HED). Steve's work in HED involved evaluating occupational and residential exposures to pesticides. In June 1992, Steve began supervising a multidisciplinary team of scientists within HED who were responsible for conducting these exposure evaluations. In October 1995, Steve began work as the Exposure Science Coordinator for the Agency's Risk Assessment Forum staff. This position provided the opportunity to participate in a variety of consensus building activities designed to address complex scientific issues faced by a number of EPA programs. While working with the Forum Staff, Steve completed his Masters degree in Technology Management (Environmental and Waste Management track) at the University of

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Maryland, University College. In June 2002, Steve accepted the position of Assistant Executive Secretary with the FIFRA Scientific Advisory Panel (SAP) staff. As the Assistant Executive Secretary, Steve served as the backup for the Executive Secretary, performing many of the day-to-day management functions for the organization. In January 2006, Steve was asked to serve as the Acting Executive Secretary of the FIFRA SAP staff and in May 2006 was selected for this position. Steve continued to serve as the FIFRA SAP Executive Secretary during a time when numerous complex reviews were conducted by the Panel, including reviews of the In Utero Through Lactational Assay and the Proposed Tier-1 Screening Battery for the Endocrine Disruptor Screening Program. In July 2009, Steve moved to his current position as Director of EACPD. EACPD has responsibility for implementing the Agency's Endocrine Disruptors Screening Program as mandated by the Food Quality Protection Act of 1996.

Mr. Gary E. Timm, Senior Scientist, Exposure Assessment Coordination and Policy Division (EACPD) - Mr. Timm has been with the EDSP since its inception and served as a senior staff member for the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) which developed the screening and testing strategy that became the basis for the EDSP. He represents the U.S. on the Endocrine Disruptor Testing and Assessment Working Group and several assay validation management groups organized under the Organization for Economic Cooperation and Development Test Guidelines Program. He was the project manager for the validation of several Tier 1 assays of the EDSP including assays to detect chemicals that bind to the androgen receptor, inhibit aromatase, and interfere with steroidogenesis. He recently worked in the OECD Secretariat where he developed an OECD performance based test guideline for estrogen receptor transcriptional activation assays and a test guideline for the H295R steroidogenesis assay.



U.S. Environmental Protection Agency

Office of Prevention, Pesticides
and Toxic Substances
Overview for SAB Committee on Science
Integration for Decision Making

The Office of Prevention Pesticides, and Toxic Substances

- Regulates pesticides and industrial chemicals to ensure protection of public health and the environment, and promote innovative programs to prevent pollution.
- Science is foundation for regulatory decisions.



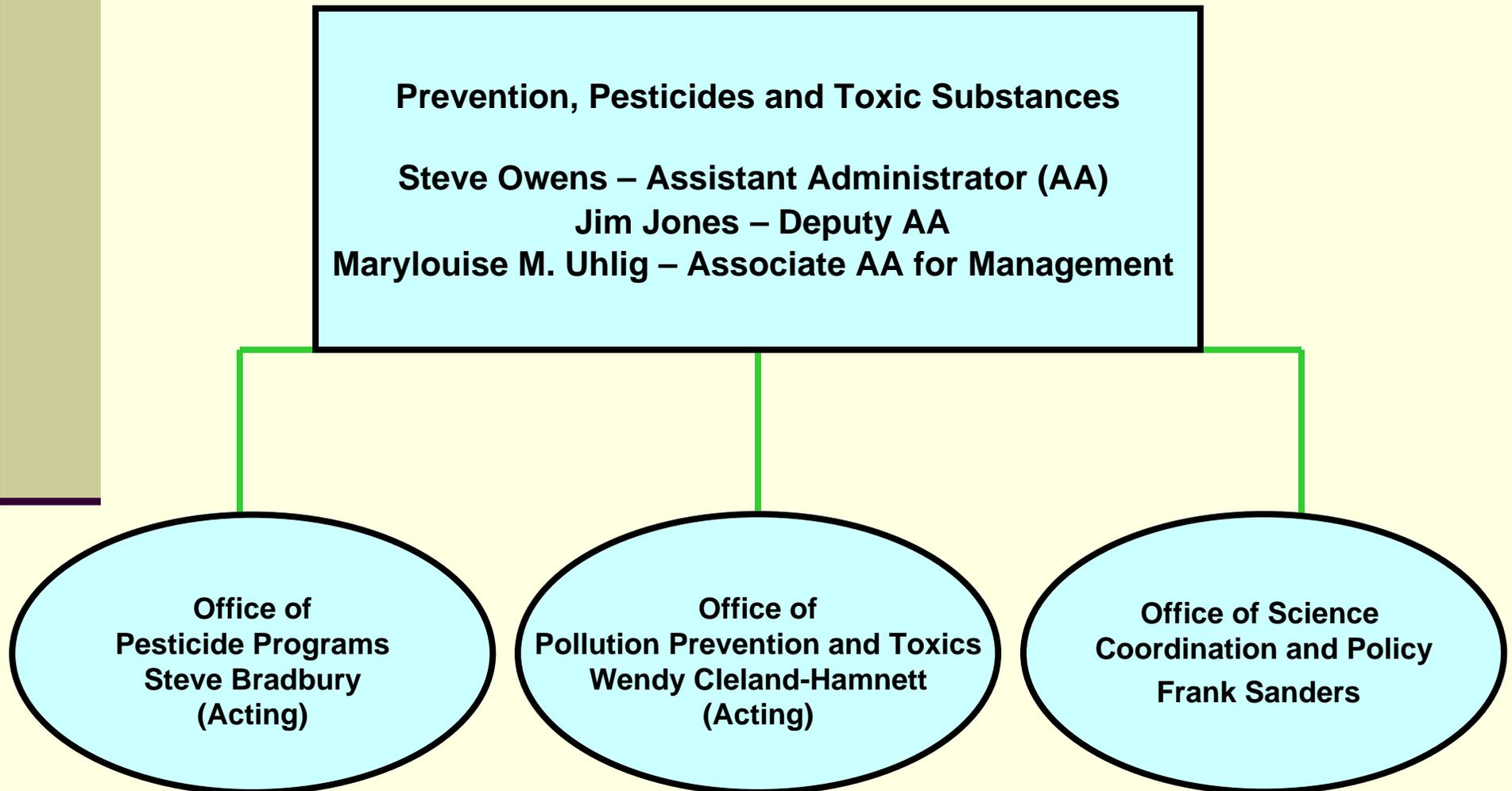
OPPTS – Key Responsibilities

- Promotes pollution prevention through State and tribal capacity building and innovative partnerships and collaboration.
- Evaluates applications for registration of new pesticide products, reevaluates existing products to ensure they meet current standards, and promotes product stewardship and risk reduction.
- Reviews and manages risks of new and existing chemicals, and promotes the use of safer chemicals, processes, and technologies.

OPPTS – Key Responsibilities

- Regulates legacy chemicals like lead, mercury and PCBs, as well as older pesticides like carbofuran and endosulfan, but also addresses emerging technologies like nanotechnology and biotechnology.
- Collaborates extensively with international counterparts on science and regulatory issues related to global chemical and pesticide issues
- Utilizes a transparent science process to develop the Endocrine Disruptors Screening Program

OPPTS Organizational Structure



Office of Pollution Prevention and Toxics

Wendy Cleland-Hamnett
Acting Director



Office of Pollution Prevention and Toxics

- General Budget (FY 2010; HQ only): \$81 Million, 335 FTEs
- Key Responsibilities
 - ◆ Manages programs under the Toxic Substances Control Act and the Pollution Prevention (P2) Act
 - ◆ Evaluates and addresses new and existing chemicals and their potential risks
 - ◆ Addresses children's exposure to lead-based paint hazards, including new Lead Renovation, Repair and Painting Rule
 - ◆ Regulates legacy chemicals, like PCBs, mercury and asbestos.
 - ◆ Reviews and regulates nanoscale materials
 - ◆ Promotes safer chemicals, e.g., Design for the Environment, (DfE), green chemistry, and P2 grants
 - ◆ Complements regulatory programs with a range of environmental stewardship programs encouraging communities and companies to reduce and prevent pollution
 - ◆ Supports research for enhancing science and understanding of exposure and hazard-related issues

Office of Science Coordination and Policy

Frank Sanders
Director

Office of Science Coordination and Policy-The Facts

- General Budget (FY 2010; HQ only): \$11.4 Million, 26.5 FTEs
- Key Tasks:
 - ◆ Provides coordination, leadership, peer review and synthesis of science and science policy within OPPTS
 - ◆ Oversees the Endocrine Disruptor Screening Program (EDSP)
 - ◆ Manages the Scientific Advisory Panel (SAP) to ensure independent scientific peer review for pesticides
 - ◆ OPPTS is developing a list of chemicals to be screened under the EDSP which will include pesticides, inerts and industrial chemicals.

Office of Pesticide Programs

Steve Bradbury
Acting Director



Office of Pesticide Programs

- General Budget (FY 2010; HQ only): \$111 Million, 743 FTEs
- Key Responsibilities
 - ◆ Makes thousands of regulatory decisions each year on new and existing pesticide products in accordance with the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA) and the Pesticide Registration Improvement Act (PRIA).
 - ◆ Collaborates with Regional, State and Tribal partners to promote pesticide stewardship and to ensure that effective applicator and worker training programs are in place.
 - ◆ Oversees four laboratories located at Fort Meade, MD and Stennis Air Force Base, MS. All laboratories are actively engaged in homeland security issues (e.g., disinfection/decontamination), and other applied research.
 - ◆ Program enforced primarily through State Departments of Agriculture.

Pesticides Regulated by EPA are used in:

- Food Production – Agricultural Crops
- Food Processing Facilities – Pathogen Control
- Hospitals – Disinfectants
- Disease Vector Control Programs – Mosquitoes and Ticks
- Residential Pest Control – Rodents, Roaches, Fire Ants
- Homeland Security – Anthrax
- Property Protection – Termiticides; Wood Preservatives; other material preservatives (paint/caulk/textiles, etc.)
- Invasive Species Control Programs – Ballast Water; Waterways; Endangered Species Protection
- Landscaping and Recreation – Ornamentals and Flowers; Turf (lawns, golf courses, playing fields, parks)

Office of Pesticide Programs – Workload Registration

FY08 Statistics:

- 20 new chemicals
- 339 new uses of existing chemicals
- 3823 label amendments and new products
- 2729 notifications
- 263 state registrations
- 11 experimental use permits
- 93 State requests for emergency use
(average 38-day turn-around)

Office of Pesticide Programs – Workload Reevaluation

In 2006 and 2008, respectively, OPP met 2 statutory mandates:

- 1) Nearly 10,000 pesticide tolerances for residues in food commodities were reevaluated under the 1996 Food Quality Protection Act safety standard; and
- 2) Over 600 pesticide active ingredients were reevaluated for compliance with the risk/benefit standard of the Federal Fungicide, Insecticide and Rodenticide Act.

Registration Review is the new “reevaluation program:

- ◆ **1,135 active ingredients must be reevaluated by 2022**
- statutory mandate in PRIA II
- ◆ Robust public participation process in place
(minimum of three public comment periods per decision).

Office of Pesticide Programs

Risk Assessment Considerations

Human Exposure – *routine consideration of environmental justice*

- Food and Drinking Water
- “Residential”
- Occupational – *Applicators, Mixer/Loaders, Farm Workers*
- Bystanders

Other Non-target Effects:

- Terrestrial
- Aquatic
- Endangered Species

All data guidelines and risk assessment methods used by OPP, as well as many complex risk assessments for specific actions are peer reviewed by external expert scientific panels (Scientific Advisory Panel), in a public, transparent (FACA) setting.

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Biography of OPPTS Senior Manager Interviewed

Office of Prevention, Pesticides and Toxic Substances, U.S. EPA:

Mr. James J. (“Jim”) Jones, Deputy Assistant Administrator - Jim Jones is the Deputy Assistant Administrator of EPA’s Office of Prevention, Pesticides and Toxic Substances. He is responsible for managing the day-to-day operations of the office which implements the nation’s pesticide, toxic chemical, and pollution prevention laws. The office has an annual budget of \$230 million and more than 1,200 employees. Before assuming this post in March 2007, Jim served for four years as the Director of the Office of Pesticide Programs. He was responsible for the regulation of pesticides in the United States with a budget of about \$150 million, and about 850 employees. Jim’s career with EPA spans more than 20 years. He has an M.A. from the University of California at Santa Barbara and a B.A. from the University of Maryland, both in Economics. He is married and has two children.

Office of Pesticide Programs Organizational Chart Management Structure

as of January 2010



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Office of Pesticides Programs, Office of Prevention, Pesticides and Toxic Substances, U.S. EPA:

Dr. Steven P. Bradbury, Acting Director -- Dr. Steven Bradbury was named Deputy Director for Programs, Office of Pesticide Programs (OPP) in January 2009. In this position, he is responsible, with the Director, for the overall leadership and management of the pesticide programs under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, as well as the Pesticide Registration Improvement Act. Dr. Bradbury has management and operational responsibilities, along with the Director, over EPA's largest Headquarters' program office, with approximately 850 employees and a budget of about \$150 million. Advancing and implementing emerging scientific and technical capabilities in pesticide risk assessment and management is a programmatic focus area. From 2007 to 2008, Dr. Bradbury was Director of OPP's Special Review and Reregistration Division, and from 2003 to 2007, he served as Director of OPP's Environmental Fate and Effects Division. As Director of these two divisions, Dr. Bradbury led risk managers, who develop regulatory decisions in support of pesticide re-evaluation programs that meet statutory requirements of FFDCA/FQPA and FIFRA, and scientists who prepare pesticide drinking water exposure characterizations and ecological risk assessments. Leadership responsibilities included refining information requirements and methods to support pesticide risk assessments and developing scientific policies and procedures for the endocrine disrupter screening program. Dr. Bradbury also served as a senior executive lead for developing and implementing outcome measures for pesticide regulatory decisions and associated strategic goals. Program accomplishments are advanced through collaboration across EPA, Federal, State, and international governmental organizations, as well as diverse groups of stakeholders. From 1999 to 2002, Dr. Bradbury was the Director of the Mid-Continent Ecology Division in EPA's Office of Research and Development (ORD). As Director, Dr. Bradbury played a key role in establishing ORD's computational toxicology program; advancing ecological risk assessment science; and leading the EPA's Great Rivers Assessment. In partnership with Ojibwe bands in the Upper Midwest, Dr. Bradbury also implemented an environmental training program. Dr. Bradbury joined EPA's ORD in 1985 and served as a research toxicologist, Branch Chief and Associate Division Director. During his time with ORD, Dr. Bradbury also served as Regional Scientist in EPA's Denver Office, where he provided expert advice to support regulatory programs and helped to establish the Agency's National Regional Science Council. Dr. Bradbury has a B.S. in Molecular Biology from the University of Wisconsin-Madison and M.S. and Ph.D. degrees in Toxicology and Entomology from Iowa State University. Dr. Bradbury has received numerous Agency awards and has authored or co-authored over 75 peer-reviewed journal articles and book chapters.

Mr. William (Bill) L. Jordan, Senior Policy Adviser -- William L. Jordan currently serves as the Senior Policy Adviser to the Director of EPA's Office of Pesticide Programs (OPP). He works on cross-cutting science and policy areas such as food safety, biotechnology, human subjects research, pesticide labeling, and nanotechnology. In addition, he has been responsible for coordinating the development of documents describing major science policies EPA applies in its pesticide regulatory program. Mr. Jordan has worked in OPP since 1988, where he played a major role in the development of the legislation which became the Food Quality Protection Act of 1996, and he has been involved in a wide variety of policy and regulatory actions affecting pesticides, from the implementation of the worker protection standard to trade policy to data requirement regulations. He has served throughout OPP as Director of the Policy and Special Projects Staff, acting Director of the Field Operations Division, and Associate Director of the Antimicrobials Division. Prior to joining OPP, Mr. Jordan worked in EPA's Office of General Counsel on pesticide and water program activities. He was also a staff member of the President's Council for a National Agenda for the Eighties. He has a law degree from Georgetown University and an undergraduate degree from Princeton University. In 2007 he received the Presidential Rank Award of "Meritorious Senior Professional," one of the highest awards made to career public servants in the federal government.

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Dr. Vicki L. Dellarco, Science Advisor -- Dr. Vicki Dellarco is the Science Advisor to the Director, Office of Pesticide Programs (OPP) at EPA. She has considerable experience in developing methodologies for and evaluating health-related data on environmental chemicals, including pesticides. Dr. Dellarco has numerous publications and years of experience in assessing the human relevance of animal modes of action, conducting cumulative risk assessments, developing toxicity testing strategies for improving and refining health risk assessments, and increasing efficiency in assessments through problem formulation and early peer review and stakeholder engagement. She is frequently invited to speak about these topics at national and international meetings. She is a member of the international Joint Meeting on Pesticide Residues, the Chair of EPA's Risk Assessment Forum's Human Health Oversight Committee, Co-Chair of the Pesticide Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies Workgroup, and the Co-Chair of the EPA's Office of Pesticide Program's Science Policy Council. Dr. Dellarco received her Ph.D. in genetics from Iowa State University in 1980 and began working at EPA that same year. In 2008, Dr. Dellarco received the Arnold J. Lehman award from the Society of Toxicology for her contribution to risk assessment and the regulator of chemical agents. In 2009, Dr. Dellarco was recognized by EPA with an individual Gold Medal for her scientific leadership in advancing mode of action analysis as a standard for risk assessments. Prior to her current position in the Pesticide Program, Dr. Dellarco has served as a senior science advisor in other EPA programs including the National Center for Environmental Assessment and the Office of Water. She has led the development of several major science policies and risk assessments involving the implementation of the 1996 Safe Drinking Water and Food Quality Protection Acts. She serves on national and international expert advisory committees at the International Life Sciences Institute, Organization for Economic Cooperation and Development, and the World Health Organization.

Ms. Joan Harrigan-Farrelly, Director, Antimicrobials Division - Joan Harrigan-Farrelly has been with the U.S. Environmental Protection Agency for over 10 years and has had the unique opportunity to work in various leadership positions across the Agency. Joan has served as the Director, Resources Management Division in the Superfund Program; as Branch Chief in the Office of Ground Water and Drinking Water; and as Senior Advisor in EPA's Office of Homeland Security. Prior to her service with the U.S. EPA, Joan also worked with USAID as a Senior Fellow in the Policy Bureau; and as Director, Coastal Zone Management Program in the United States Virgin Islands. In her current position as the Director of the Antimicrobials Division in the Office of Pesticide Programs (OPP) at the U.S. EPA, Joan is responsible for all regulatory activities and science analysis associated with antimicrobial pesticides, including new chemical and product-specific registrations, registration review, efficacy analysis for public health products, and environmental fate and human health analysis. Joan's vision is to ensure seamless coordination with all regulatory and science partners so that the highest level of efficiency is achieved as AD ensures the use of the best science in its mission to protect human health and the environment in its registration and re-evaluation of chemicals used against microbiological pests. Joan holds a Bachelors degree from Rutgers University and a Masters degree from New York University.

Mr. Keith A. Matthews, Acting Director, Biopesticides and Pollution Prevention Division - Keith A. Matthews has been the acting Director of the Biopesticides and Pollution Prevention since August 3, 2009. From 2003 to 2009, Keith served as Assistant General Counsel for Biopesticides, Human Studies, Science and the Toxics Release Inventory (TRI), in EPA's Office of General Counsel (OGC). In this position, he oversaw and provided a wide range of legal counsel to OPP, the Office of Environmental Information, and the Office of Research and Development. He began his EPA career in 1996 when he joined OGC to provide legal counsel to the Office of Air and Radiation. In this role, Keith was responsible for a variety of topics, including matters related to regulation of radionuclides, mobile sources, ozone-depleting substances and regulatory flexibility issues. Also, from May to August 1991, Keith served as an American Association for the Advancement of Science Environmental Science and Engineering Fellow in OGC where he analyzed FIFRA to determine whether EPA had authority to regulate the introduction of transgenic plants expressing pesticidal substances into the environment. Keith graduated Cum Laude with a B.S. in Biology from Jackson State University in Mississippi, and also holds an M.S. in Biology from the California Institute of Technology as well as a J.D. from the Georgetown University Law Center.

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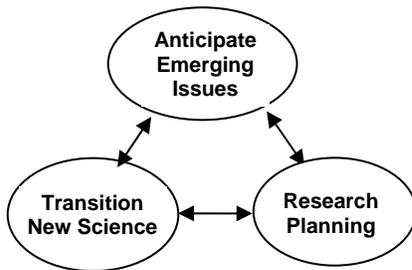
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Dr. Donald Brady, Director Environmental Fate and Effects Division (EFED) - Donald Brady has been Director of the pesticide Environmental Fate and Effects Division since January 2008. As director of EFED, he is responsible for managing the assessment of ecological risk and drinking water exposure from the use of pesticides in the United States. Prior to coming to OPP, Don served as the Chief of the Municipal Branch in EPA's Water Permits Division where he managed the wet weather permitting programs under section 402 of the Clean Water Act (CWA). In the Office of Water, Don also served as the Chief of the Watershed Branch in EPA's Office of Wetlands, Oceans and Watersheds, where he was responsible for management of the Total Maximum Daily Load program required by section 303(d) of the CWA. Dr. Brady has a B.A. in political science from Fordham University and both a Masters and Ph.D. in government from Georgetown University.

Dr. Tina Levine, Director, Health Effects Division -- Tina E. Levine, Ph.D. currently serves as the Director of the Health Effects Division in the Office of Pesticide Programs at EPA. The Division is responsible for human health risk assessments for conventional pesticide active ingredients. She began her career at EPA on New Year's eve, 1979, working as a neurotoxicologist in the Office of Toxic Substances. Her assignments included overseeing the development of the first neurotoxicity test guidelines. She also drafted the first guideline for developmental neurotoxicity testing. For the past 30 years, she has held a variety of positions in the Office of Pesticide Programs. These have included working on food safety policy during the Alar crisis of 1989, overseeing the review of inert ingredients and product labeling for acute toxicity, serving as the Chief of the Insecticide-Rodenticide Branch. Tina also served as Associate Director of the Biological and Economic Analysis Division (BEAD) where she had lead management oversight of three OPP laboratories, including a microbiology laboratory and two analytical chemistry laboratories. Dr. Levine received an A.B. degree with honors in Experimental Psychology from Bryn Mawr College and a Ph.D. in Toxicology from the University of Rochester School of Medicine and Dentistry. She is a member of the Society of Toxicology and serves on the Boards of the Toxicology Forum and the Johns Hopkins Center for Alternatives to Animal Testing.

Dr. Jennifer McLain, Chief, Policy and Regulatory Services Branch – Dr. McLain has many years of experience developing environmental policy and regulation founded on science. In her current position she leads the development of regulations for pesticide data requirements and policies for public health pesticides, focusing on insect repellent efficacy. Dr. McLain has a Bachelor of Science in Chemistry from the University of Notre Dame (1991) and a Master of Arts in Chemistry (1993) and Ph.D. in Chemistry from Princeton University (1997). While attending Princeton she also received a Certificate in Science Technology, and Public Policy from the Woodrow Wilson School of Public and International Affairs. Dr. McLain joined the US Environmental Protection Agency in 1997. She worked in the Office of Ground Water and Drinking Water for ten years, focusing primarily on drinking water regulations, particularly for microbial pathogens and disinfection byproducts.

OPP's Science Policy Council (SciPoC)



Charter: To enhance the consistent use of the best available science in our regulatory decisions and policies by providing a central forum that assists OPP in identifying critical issues in pesticide safety, formulating solutions, and in transitioning new science, methodologies, and policies into our program.

The Council focuses on cross-cutting science issues with relevance across divisional lines and its key functions are:

- **Anticipating and Proactively Addressing Emerging Issues**
 - Predict future challenges in pesticide safety, determine priorities for attention, devise strategies to address (e.g., communication, analyses, research), and make recommendations to update OPP's policies and scientific project portfolio.
 - Anticipate and develop solutions for cross-cutting science issues.
- **Providing Integrative and Unified Office Research Priorities**
 - Provide strategic approach to research planning
 - Facilitate ORD-OPP interactions and communicates a consistent message to ensure research meets current programmatic priorities and reflects emerging issues.
- **Transitioning New Science Policies and Methods**
 - Evaluate the state-of-science and prepare programmatic plans for integrating and implementing new approaches.
 - Promote transition to and Integrated Approach to Testing and Assessment (IATA) aka 21st C Toxicology.
 - Promote the harmonization of human health and environmental risk assessment and testing strategies.

Operating Procedures

- The SciPoc advises the Office Director, Division Directors, and Senior Staff
- Membership consists of Co-Chairs (Vicki Dellarco and Jennifer McLain) and ~20 senior staff. Others participate as needed depending on the issue. All divisions are represented.

Example Accomplishments

- Developed the “Integrated Approach to Testing and Assessment in the Pesticide Program” website (<http://www.epa.gov/pesticides/science/testing-assessment.html>).
- Developed voluntary pilot program to evaluate use of a non-animal testing approach to EPA labeling for eye irritation for certain antimicrobial products with cleaning claims (<http://www.epa.gov/oppad001/>).

Office of Pollution Prevention and Toxics Organizational Chart

