

**Science Integration for Decision Making Fact-Finding Interviews
EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS)
January 26, 2010,**

Six members of the SAB Committee on Science Integration for Decision Making conducted five interviews with managers and scientists in the Office of Prevention, Pesticides and Toxic Substances (OPPTS). Drs. James Burke, Buzz Thompson, and Penny Fenner-Crisp in person and Drs. James Bus, Jill Lipoti, and Thomas Theis by telephone. For each interview, Dr. Anthony Maciorowski, Deputy Director of the SAB Staff Office, provided a brief introduction to the purpose of the interview and the Designated Federal Officer, Dr. Angela Nugent, took notes to develop a summary of the conversation. All interviewees were provided a copy of the committee's Preliminary Study Plan in advance.

Dr. Maciorowski noted in each interview that the purpose of the interview was to help SAB Committee members learn about OPPTS' current and recent experience with science integration supporting EPA decision making so that the SAB can develop advice to support and/or strengthen Agency science integration efforts. Dr. Maciorowski thanked participants for taking time for the interviews and thanked Dr. Mary Belefski (observer at OPPTS interviews) for serving as liaison with the SAB Staff Office in planning the interviews.

Meeting with Acting Director, Managers, and Scientific Staff, Office of Pollution Prevention and Toxics (OPPT) (9:00 - 11:00 a.m.)

Participants:

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
Mr. Neil Patel, Deputy Director, Economics, Exposure and Technology Division
Dr. Kay Austin, Associate Director, Economics, Exposure and Technology Division
Dr. Jennifer Seed, Deputy Director, Risk Assessment Division

The Office of Pollution Prevention and Toxics (OPPT) implements a wide range of programs. Under the Toxic Substances Control Act (TSCA). TSCA is a risk-benefit statute. Decision makers must consider not only the risks of a chemical, but also the costs and benefits of alternatives. OPPT makes decisions on chemicals that may enter commerce prior to their manufacture within a very short (90-day, and sometimes 45-day) time frame. These decisions are usually taken without detailed exposure and hazard information on the chemicals. The new chemical program uses tools and methods, developed over OPPT's 30-year history in which over 45,000 new chemicals have been evaluated. In OPPT's existing chemical program, there is no mandatory requirement to periodically review chemicals in commerce. The program takes action only when issues are identified. It is difficult to ban or restrict the manufacturing processing, use or disposal of existing chemicals because the statute has a relatively high threshold for this type of regulatory action (i.e., that a chemical " *presents or will present an unreasonable risk*"). In regulating existing chemicals, OPPT has more frequently required

chemical testing, issued significant new use rules (SNURs) or issued information reporting rules to collect hazard and exposure data from companies. These rules have statutory standards that are easier to meet.

OPPT also has chemical-specific programs Polychlorinated biphenyls (PCBs), lead-based paint, and asbestos. The office has the lead for promoting pollution prevention across the Agency. OPPT manages EPA's "Design for the Environment" program, which promotes the use of safer chemicals and safer alternatives.

There is a scientific component to all these decisions that varies, depending on the nature of the decision and the regulatory findings that are necessary to justify it. OPPT conducts screening level assessments for new chemicals, in-depth regulatory risk assessments, and scientific assessments "in-between" that vary in complexity. Similarly, risk management decisions are made at many levels of management. Most decisions in the new chemical program related to premanufacture notifications (PMNs) are delegated to the branch level. Decisions on existing chemicals may be made by the Assistant Administrator for OPPTS or, in some cases, by the EPA Administrator, depending on the scope of the decision.

To evaluate PMNs, OPPT uses a tiered screening process. Science drives most of the decisions. Interdisciplinary groups of toxicologists, economists, and exposure scientists hold a series of meetings to evaluate available information on new chemicals and to recommend whether a chemical should enter into commerce with or without restrictions or testing requirements, or whether it meets one of the 5(h)(4) exemption requirements. If a chemical is a potential concern, scientists develop more detailed exposure and hazard assessments. Decisions may then be made at the Division Director-level about test requirements or other restrictions on a new chemical. OPPT economists typically don't conduct an economic analysis for every chemical, because most chemicals present "no concern."

There is no requirement under TSCA to test a new chemical before a PMN is submitted. PMN submitters must only provide data in their possession. EPA, as a consequence, often seeks information from other sources, most commonly analogue chemicals through use of Structure Activity Relationships. It has also developed models to supplement available data [e.g., the Estimation Programs Interface Suite (EPI Suite™)] and has worked to get these models peer reviewed. If necessary, EPA has the authority to require a PMN submitter to test their chemical as part of the PMN review process.

For nanotechnology products, OPPT is building on its experience in the new chemical program and is exploring how best to evaluate these substances and protect against unreasonable risks. OPPT works closely with the Organization for Economic Cooperation and Development (OECD) and is evaluating whether OECD testing programs for nanomaterials are relevant for TSCA regulatory needs, as well as ORD, which is devoting significant resources towards research on and testing of nanomaterials.. OPPT is currently regulating all nanomaterials reviewed through the new chemicals program to protect against human or environmental exposures, and to generate test data. OPPTS recently announced that it would also be regulating and testing nanomaterials based on existing chemicals as well.

For the existing chemical program, OPPT has mechanisms to coordinate with other EPA offices. In the case of perfluorooctanoic acid (PFOA) and the voluntary phase-out of PFOA, OPPT reached out to ORD and academics and formed a team to develop research to help understand the risks presented by PFOA substitutes coming into the new chemical program. The research group meets once a year to review research and monitor progress. OPPT also coordinated with the Office of Water to assist them in developing water criteria for PFOA. OPPT relies on Agency guidelines (e.g., Risk Assessment Forum guidelines, Economic Analysis Guidelines) in regulatory decision making.

Advances in science pose challenges for OPPT, because it is not clear how some new science will be integrated into the OPPT decision making. Advances in biomonitoring, for example, show presence of chemicals in tissues, but it is hard to make risk management decisions solely on that information. OPPT must also understand the chemical's source and exposure pathways; much additional information must be gathered and analyzed before OPPT can take regulatory action. For example, the new chemicals program has received genomics data and must determine how best to integrate it into a new chemical TSCA Section 5 decision to protect against unreasonable risk of injury to health or the environment. Another developing hazard assessment approach, computational toxicology is a concept familiar to OPPT because of its experience with Structure Activity Relationships (SAR). Computational toxicity has a role as one part of a "weight-of-evidence" analysis, but there is a danger of "overselling" computational toxicology results, especially if EPA cannot back it up with evidence showing a biological basis for toxic action. Science may soon provide reliable computational toxicology results for cancer effects, but animal testing may still be needed for non-cancer effects, especially developmental effects.

Possible reauthorization of TSCA has raised policy issues for which OPPT and EPA may not have adequate science or assessment methodologies or tools. One area is cumulative risk. Different chemicals and different risk management situations may raise very different scenarios and it would not be desirable to have a standard suite of tests or a standard approach to every situation. ORD's work to date on cumulative risk is generic; it considers impacts on a receptor, interactions across chemicals, and interactions across effects, but the analysis discussed to date is not designed to help decision makers in regulatory programs with distinct needs. Under TSCA, for example, EPA regulates uses and needs to consider alternatives. Consideration of cumulative risks in this context is complicated. To be practical, cumulative risk methods need to be designed with EPA statutes and EPA decision makers in mind.

The Risk Assessment Forum is an important Agency mechanism but is not as productive as it should be. Participants do not have enough time to contribute in meaningful ways.

Impediments to science integration include:

- Different and limited authorities across federal agencies to address risk. U.S. Department of Agriculture and the Food and Drug Administration, for example, had limited authorities to supplement EPA in addressing the risks presented by PFOA and PFOS
- Lack of information on exposures. OPPT generally does not know how chemicals are being used and the nature of human exposures and environmental releases. Often even manufacturers have no information about how customers use their chemicals

- Lack of legislation requiring life-cycle information
- IRIS values, if they exist, may not be appropriate for OPPT needs. IRIS values generally assume continuous low exposure, an assumption appropriate for water or ambient air, but OPPT chemical exposure could be intermittent, involve acute 1-day exposures, or a variety of scenarios that may make use of an IRIS Reference Dose inappropriate
- Not all managers and staff are skilled at "asking the right questions" to guide scientists in "putting the science together" for problem solving and risk management decisions. Sometimes there is a need to push for interactions between divisions for a meaningful problem formulation to assist with decision making. OPPT doesn't always employ a formal problem formulation discussion for projects.

It has been difficult to find new scientists to conduct OPPT risk assessments. Toxicologists who have recently graduated have backgrounds in computational toxicology or molecular genetics and often have little or no experience with whole animal toxicology. OPPT needs scientists who can understand and evaluate both kinds of information. OPPT also needs epidemiologists, experts in biomonitoring, environmental fate, and statistics. Participants noted that OPPT scientists were generally lower in grade than ORD scientists and that OPPT had no title 42 positions.

Funds for training are generally available and scientists have the funds and time to attend professional conferences. Scientists are mostly trained "in house" to conduct OPPT-type reviews. OPPT has provided funding for graduate training for personnel in different areas including industrial hygiene.

SAB advisory reports are generally valuable. Peer reviews of specific technical documents are useful for OPPT, but SAB's slow response is an issue. SAB consultations are useful for programs in their early stages. It is helpful when SAB recommendations provide a general framework on a science issue. In contrast, it is difficult when SAB recommendations are specific and do not recognize specific restrictions of legislation. In addition, sometimes the SAB makes recommendations for actions already underway at EPA.

OPPT follows formal notice and comment processes and formal guidance on how to interact with stakeholders.

Meeting with Deputy Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances (OPPTS) (11:00 a.m. - 12:00 p.m.)

Participant:

Mr. James (Jim) Jones, Deputy Assistant Administrator

The Deputy Assistant Administrator drew on his past experience as a Branch Chief, Division Director, and Office Director, as well as his current experience in responding to the committee's science integration questions. He began the discussion with a description of his efforts integrating computational toxicology into the work of OPPTS. His interest in computation toxicology sprang from an awareness developed seven years ago as a Division Director that the Office of Pesticide Program's animal testing regime was unsustainable and that

there was a need for an alternative testing approach. Since that time, he has developed a relationship with ORD scientists pioneering the computational toxicology program. This relationship was reinforced by the 2007 NAS Report, *Toxicity Testing in the 21st Century; a Vision and a Strategy*. As Deputy Assistant Administrator, he has brought the risk assessment and risk management leadership in OPP and OPPT into dialogue with ORD scientists. These interactions have dramatically influenced how ORD is approaching toxicity testing and has made OPP and OPPT aware of the potential applications of computational toxicology.

He noted that the nature and level of his involvement in this emerging science issue was not typical and gave him a unique perspective. He also noted an interest in encouraging other parts of EPA, especially the Office of Water, to deepen their knowledge of the potential of the computational toxicology program for achieving EPA's mission. He expressed appreciation for ORD's receptive response to his desire for more interactions with his office.

To facilitate ongoing interactions between OPPTS and ORD, the Deputy Assistant Administrator asks that a day-long meeting be scheduled for ORD scientists to report on their progress and for OPPTS managers and scientists to talk with them about applications. These sessions are separate from ORD's research planning process. Each time the meetings happen, "new light bulbs go off." OPPTS will have a need to conduct assessments for about 40,000 chemicals and OPPTS managers are beginning to see the potential value of computational toxicology research.

He noted that other agencies, such as the National Institutes of Environmental Health Sciences, are aware of and engaged with ORD's Computational Toxicology Research Center.

The Deputy Assistant Administrator also described his role as a "co-lead" on the Science Policy Council's (SPC) subcommittee for science policy priorities. He volunteered for this project to help focus the agenda of the Science Policy Council to deal with more executive level issues. The Subcommittee's draft science priorities (Climate and Energy, Environmental Contaminants, Security and Emergency Response, and Modernization of Infrastructure) were chosen before the Administration changed and may need to realign with current priorities of the Administrator. In discussions with regions and headquarters, he found that each priority has a research component and a link to decision makers in national program and regional offices.

"Stove-piping" by organization is a barrier to science integration. EPA must organize itself in some fashion to implement its many programs, but any organizational structure creates institutional barriers. Even two programs as similar as OPP and OPPTS are dramatically different institutions and have different cultures that developed from statutory requirements.

If EPA has the authority to hire new personnel, it is not a problem to find the right people. Although there are problems with hiring at EPA, "when we focus energy on hiring the right people, we get them." People are attracted by the mission, want to do meaningful work, and are relatively well paid.

The ORD IRIS system has not historically been critical to OPPTS. In the past 15 years, OPP did not often rely on IRIS. OPP needed so many chemical assessments, largely for

chemicals only regulated by OPP. Historically, OPPT has not regulated existing chemicals, so it has not needed IRIS information. The Deputy Assistant Administrator noted, however, that OPPT will soon become a "big regulator" for chemicals. OPPT plans to conduct safety assessments for 12 industrial chemicals and take action, so OPPT will soon "become a big user of IRIS." The IRIS program fits naturally with the Administrator's concept of "One EPA." Although it will be a challenge to coordinate OPPT's needs with those of other offices, it is a "production issue" similar to others across the Agency. There will be a need for a schedule for generating IRIS assessments that all EPA managers can access and rely on.

At EPA, OPPTS has the most significant need for science to support decision making related to nanomaterials. The Deputy Assistant Administrator acknowledged a need for coordination and integration with the Food and Drug Administration around methods for analyzing the hazard and fate of nanomaterials - "the fundamental approach should be consistent." He noted that approaches have been better coordinated internationally than across the federal government.

Science integration requires managers to make decisions in the face of uncertainty, because science rarely provides absolute answers to questions of interest to risk managers. The Deputy Assistant Administrator spoke about his general approach, which helps him be "comfortable" in the face of uncertainty. He described an intuitive framework for making decisions, informed by the severity of the effect; the potential consequences of the decision in terms of economic impact; the potential for long term impact. All those factors "feed into how much information" is needed before he feels comfortable making a decision. For him, the need is often for understanding all the information EPA has available rather than a need for additional information.

To strengthen science integration, the Deputy Assistant Administrator recommended that leaders at the highest level must communicate and give consistent cues that science integration is important. Science integration won't happen "by chance;" leaders and managers at all levels and across the organization must be motivated to make it happen. EPA's leadership must send repeated signals and check that science integration is happening. Whether the issue is PCBs and caulk, mountain-top mining, maximum contaminant levels, or environmental justice, there is a need for leadership to encourage parts of EPA to work together and a need for problem formulation that will link science to decision making. When the Administrator identifies a priority and consistently follows up with questions, programs and regions will pay attention and incorporate that priority in their work.

Science integration also opens up possibilities for voluntary programs. If science indicates a need for action, EPA can use voluntary programs, such as Design for the Environment, to address environmental problems.

One area where the Agency as a whole could strengthen science integration is in "after-the-fact" mining of the results of Science to Achieve Results (STAR) grants. STAR grant research is a resource for the Agency, but often the connection is not made with program and regional offices. It is a cross-agency management issue that should be addressed.

Meeting with Director and Scientific Staff, Office of Science Coordination and Policy (OSCP) (1:00 p.m. - 2:00 p.m.)

Participants:

Mr. Frank Sanders, Director

Mr. Steve Knott, Director, Exposure Assessment Coordination and Policy Division (EACPD)

Mr. Gary Timm, Senior Scientist (EACPD)

Dr. Kenneth Haymes, Senior Scientist for Dr. J. Thomas McClintock, Director, Hazard Assessment Coordination and Policy Division (HACPD)

Dr. Karen Hamernik, Senior Scientist (EACPD)

The Office of Science Coordination and Policy (OSCP) does not have direct regulatory responsibilities; it manages various technical projects and provides scientific input to decisions made by others. The Endocrine Disruptor Screening Program (EDSP) in OSCP has the responsibility to standardize and validate the assays used in Tier 1 and Tier 2 of the EDSP and is working with the Office of Pesticide Programs to implement the requirements under the Food Quality Protection Act, which mandated a screening program to focus on estrogenic effects on humans and other organisms. The EDSP in OSCP also provides input to OPPT, the Office of Water, and ORD. OSCP also manages the Scientific Advisory Panel (SAP), a federal advisory committee that provides recommendations to the OPP Director on Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) science issues. OSCP also provides input on biotechnology input to OPP and OPPT.

OSCP has had success in "breaking down silos that exist" in implementing the endocrine program. Because of the statutory mandate, OPP is requiring tests for all pesticides for endocrine disruption, including estrogen, androgens, and thyroids. The EDSP has validated assays developed by ORD. These assays have been standardized and validated principally using EPA contracts. The purpose of validation is to measure the performance of a assay. The EDSP is working with OPPT and the Office of Water to extend screening for endocrine disruption to work on industrial chemicals. Drinking water contaminants include pesticides, industrial chemicals, pharmaceuticals, disinfection byproducts and degradates. In 1999, the EDSP received a joint review by the SAB and the Scientific Advisory Panel and the EDSP has requested advice from the Scientific Advisory Panel on multiple issues since that date. The EDSP has a good working relationship with OECD which has provided technical support to the EDSP. The Tier 2 assays and many of the Tier 1 screens have been validated in cooperation with the OECD Test Guidelines Program. Test guidelines could be considered a non-tariff barrier, but the 1983 Mutual Acceptance of Data Treaty is the foundation of the OECD test guideline program.

For biotechnology issues, OSCP coordinates with other governments on policies related to genetically modified organisms. Although EPA is "one of few countries" that were not signatories to the Cartagena Protocol on Biosafety, OSCP staff attend meetings implementing the protocol. OSCP staff also works with OECD on harmonization issues related to regulation of biotechnology products within EPA's jurisdiction. OSCP also monitors the status of review of

biotechnology products by the Food and Drug Administration and the U.S. Department of Agriculture. Within EPA, OSCP also assists OPP as needed and provides comments on OPPT biotechnology rules.

In managing the Scientific Advisory Panel, OSCP provides the pesticide program with an efficient mechanism to provide independent scientific peer review. The panel holds about one meeting per month and will soon begin "web-casting" meetings, an important new development that will enhance transparency.

Science integration for the EDSP was facilitated by the Food Quality Protection Act mandate and availability of science to be integrated into EPA programs. ORD provided support for the program in the past and may provide more support in the future through its Computational Toxicology Program.

Barriers to science integration for OSCP include:

- Hiring scientists with the expertise needed by OSCP is a challenge because of the federal government's "long and difficult process to hire people." The hiring process could be streamlined.
- Not all coordination activities important for OPPT and OPP are located in OSCP. It would be helpful if coordination of national test guidelines were also an OSCP lead responsibility.

Meeting with Acting Office Director, Managers, and Scientific Staff, Office of Pesticide Programs (3:00 p.m. – 5:00 p.m.) Participants:

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. Edward Odenkirchen, Senior Advisor, Environmental Fate and Effects Division

The Office of Pesticide Programs (OPP) has processes in place to encourage science integration. Most OPP decisions rely on team activities. There are approximately 750 people in OPP, and two-thirds have science degrees. OPP's primary legislation calls on the office to address a wide range of pesticide issues, from classic herbicides, to pheromone-disruption of mating behavior, to disinfections in paints. Some divisions (i.e., the Antimicrobial Division and the Biopesticides and Pollution Prevention Division) contain the multi-disciplinary technical experts and policy analysts needed in most cases to accomplish their mission. Other divisions (i.e., Health Effects Division, Environmental Fate and Effects Division, Biological and Economic Analysis Division) contain technical experts who coordinate with managers who have the lead for registration of new pesticides or new uses or reregistration of existing pesticides. No matter how staff are listed in an organizational chart, OPP's work requires integration of multiple disciplines: chemistry, human health, ecology of different kinds, entomology, economics, and

geographic information system expertise. OPP also reaches out regularly to other parts of EPA for help, especially to ORD and the Office General Counsel. OPP also participates actively in the Agency's Science Policy Council and the Risk Assessment Forum, and considers recommendations from expert review panels such as the National Research Council.

Under its pesticide re-evaluation efforts that address currently registered pesticides, OPP has historically used a process for integrating stakeholders' input into risk assessment and management decisions. Recently, OPP began implementing a public participation process for certain registration actions associated with new pesticides, new uses of existing pesticides, and actions determined to be of significant interest to the public. By establishing these processes, the Agency provides an increased opportunity for the public to provide comments on risk assessments and proposed registration actions on registration decisions at points in the regulatory process when comprehensive information and analysis are available. Such participatory processes improve the public dialogue on pesticide registration decisions and increases the understanding of potential risks and benefits, and contribute to meaningful protective measures.

Within the Antimicrobial Division and the Biopesticides and Pollution Prevention Division, scientists interact within those divisions, with each other, and with staff in the policy branches to determine whether data are sufficient to make sound decisions. If a new or controversial issue arises, scientists consult with colleagues in the Health Effects Division, Environmental Fate and Effects Division or reach out to the Centers for Disease Control, Food and Drug Administration, or national associations such as the American Hospital Association. They also consult the Scientific Advisory Panel and experts in OPPT and ORD.

The pesticide law is a licensing law. New pesticides "come on the radar screen" at the initiative of pesticide companies. Reregistration is a re-evaluation program that focuses on pesticides of greatest risk that have not been reviewed recently. Companies that seek registration or that are subject to reregistration bear the responsibility of providing data for OPP to assess. Data requirements are documented in 40 CFR Part 158. Basic requirements depend on the generic formulation of the pesticide and the intended use and related exposure pathways of the chemical. Basic requirements include testing for human health risk, environmental fate, effects on organisms, and physical and chemical properties. Once OPP receives these data, it follows standard methods and procedures to "make a call about the risk picture."

Early in the problem formulation phase, scientists work closely with risk managers to describe what is known and not known and their "comfort" with existing knowledge related to exposure (e.g., magnitude, distribution and characterization of typical exposures) and effects (integrating results from disciplines with risk quotients with results describing effects in risk outcomes). Sometimes scientists describe certainty bounds sometimes numerically, sometimes descriptively. Scientists describe the knowledge lacking for each decision. Consistent consideration of Part 158 data requirements/test guidelines as well as other existing information provides a basis for determining whether additional testing is necessary. This approach provides consistency in applying best professional judgment. The process relies on ongoing discussions with risk managers about risks, including relative risks of alternative pesticides.

In the case of an emerging science issue, like nano pesticides, OPP builds on its existing approach and makes a special effort to integrate science from outside its program. When a registrant recently asked about nanosilver pesticide requirements, OPP asked registrants "what they thought." When the registrant responded that the nano pesticide under development would present no exposures, OPP scientists conferred internally and then conferred with the Food and Drug Administration and ORD. There was no direct precedent or guidance. OPP requested a consultation with the Scientific Advisory Panel, which assembled a group of 30 experts from around the world to identify the data needed for registration and how to assess risks of pesticides containing nanosilver particles.

OPP has an effective organization that encourages science integration.. However, OPP continues to look fo ways to improve its efficiency and effectiveness. OPP staff are encouraged to reach outside their organizational units and regular interactions when new problems arise and when new science is needed. Concerns about degradation of pesticides may prompt ecologists, for example, to consult with statistical experts in the Health Effects Division. There is also a Science Policy Council within OPP that keeps track of emerging issues and is devoted to science integration for those issues. The Council is successful because it has a charter, clear responsibilities, and operating rules. OPP evaluates the Council's workplans every year.

OPP relies on long-range planning for regulatory decisions to help it think through science integration issues and to plan interactions with other parts of EPA. OPP tries to coordinate with ORD on IRIS chemicals of common interest. OPP has an IRIS coordinator and attends Agency Science Policy Council Steering Committee Meetings.

OPP has taken advantage of international opportunities for science integration to reduce duplicative work internationally among regulatory authorities. Many new active ingredients involve work share and global reviews, which facilitates earlier access to the global market of newer and lower risk chemicals. For example, Australia, Canada, and the European Union have been involved. The countries may divide up initial analysis. OPP may do the residue chemistry and human toxicology and then collaborate and communicate with scientists in other governments. Through discussion, they come to agreement on the scientific endpoints of interest, but may not arrive at the same regulatory decisions because regulatory authorities differ. Collaboration involves work in itself, but OPP reaps benefits from the additional peer involvement and peer review resulting from global review. OPP scientists have gained confidence about their science through these interactions. The collaborative work across several countries also results in a higher degree of public confidence in the regulatory system.

Participants discussed strategies for encouraging science integration at EPA, even though Agency programs face deadlines and are unlikely to receive additional funding for integration. Most importantly, Agency staff need to "internalize the desired outcome" and EPA needs leadership at every level to see that science integration is built into EPA's "Everyday way of doing business." If EPA had the "right people, right vision, and core values," science integration could work more broadly. It is important for EPA to develop leadership and staff that "have a broad sense of what the Agency is all about." Participants gave an example. The pesticide statute requires decisions within a certain frame, but it does not explicitly require consideration of impacts on the Clean Water Act's Total Maximum Daily Loads, and coordination with the

National Marine Fisheries Service, and Fish and Wildlife Service. OPP scientists and other staff think "outside the box" about those other dimensions and have processes and relationships in place to integrate information and coordinate decisions with others. There's a need to recruit, nurture, and guide people to make decisions outside the box, while still making timely decisions. Scientists and managers may need training to be knowledgeable about the potential of programs across the Agency that can be used, in conjunction with their own, to achieve EPA's environmental goals.

It is important for scientists to directly interact with each other across the Agency and to form relationships that can facilitate science integration. Both formal and informal discussions are important. Good ideas also can come out of informal interactions (e.g., at professional meetings). It is also important for scientists from different organizations to work together towards a common project. It may be helpful for some organization, perhaps the Science Advisory Board, to sponsor events to build community and enhance networks among scientists at EPA. Workshops on cross-cutting topics might bring scientists together in new ways.

"Individual development plans" are a tool for strengthening science integration. Managers can ask staff about their fundamental interests and discuss how they can leverage that interest in new areas and new capabilities. EPA gets "incredible dividends" from guiding and investing in its scientific staff and broadening their perspectives.

Similarly, managers should listen to staff and check their assumptions about interactions with members of the public. EPA staff may benefit from training or coaching on how to interact with citizens on environmental science issues.

Participants discussed impediments to science integration

- EPA staff and managers often say that "statutes don't give us the flexibility to use good science," but often regulations and statutes have more flexibility than they generally assume
- IRIS database still contains outdated 10-year old pesticide risk assessments. OPP has asked ORD to remove these assessments, but it has not been done.
- Sometimes science integration seems easier across countries than within EPA
- Sometimes it takes a while for EPA staff to fully understand new mandates and related science integration. As understanding evolves science integration within and across programs can develop.
- Many EPA programs focus narrowly on their own objectives and sometimes parochial interests; integration will require leadership from the top and an expectation that science integration will happen. Leaders at the top need to consistently give the message that science integration is important.
- Sometimes EPA lacks a forum for working through fundamental disagreements that are barriers for science integration. An example involves the differences between OPP, the Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) on ecological risk assessment. There has been no forum for these agencies to agree on data requirements for ecological assessments. The agencies differ on how data are to be used and there is a need for a high level agreement that can guide interactions on specific assessments. EPA has a process that quantifies risks and identifies qualitative factors.

Other agencies have a similar process, but weave assumptions about protection of species into the analysis (an assumption that springs from their mission to protect species) in ways that are not transparent. Policy is entwined with FWS and NMFS risk assessments in ways that make them inconsistent with OPP assessments and difficult for OPP to use.

- Lack of investment in social science (decision theory, cultural anthropology, and sociology) that will help EPA and the regulated public understand how to better communicate with each other concerning all the different regulatory programs working at different scales.