

**SAB Science Integration for Decision Making Fact-Finding Meeting
Office of Water, Office of Science and Technology (OST)
EPA West, Washington, DC
January 28, 2010**

Five members of the SAB Committee on Science Integration for Decision Making conducted two interviews in EPA's Office of Water (OW), Office of Science and Technology (OST): Drs. James Johnson and Gary Sayler in person, and Drs. Terry Daniel, Wayne Landis, and Thomas Theis by telephone. Dr. Vanessa Vu, 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. Vu noted in each interview that the purpose of the interview was to help SAB Committee members learn about OST's 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. Vu thanked participants for taking time for the interviews.

Meeting with the Office of Water (OW), Office of Science and Technology (OST) Scientific Staff (January 28, 2010, 12:45 p.m. - 1:45 p.m.) Participants:

Ms. Lisa Huff, Team coordinator/Toxicologist
Ms. Mary Reiley, OW Research Coordinator
Ms. Amy Newman, Chief, Regional, Tribal and State Support Branch
Dr. Santhini Ramasamy, Toxicologist

The Office of Science and Technology has three divisions: a Health and Ecological Criteria Division (HECD), a Standards and Health Protection Division (SHPD), and an Engineering and Analysis Division (EAD). HECD develops human health criteria and health advisories to support drinking water regulations under the Safe Drinking Water Act (SDWA); these as well as ecological water quality criteria also support risk management actions under the Clean Water Act (CWA). Under CWA, criteria and advisories are published as guidance for States and Tribes to use in establishing their water quality standards. EPA's science-based ecological and human health CWA criteria are non-enforceable risk assessments. EPA has review and approval authority over the enforceable State and Tribal final standards. In consultation with HECD, SHPD responds to questions from EPA Regions, States and Tribes on the science or scientific defensibility of water quality criteria. Where there are complex science policy issues associated with implementation of water quality criteria, SHPD develops implementation guidance for States and Tribes in consultation with HECD. Examples of such issues are the fish tissue-based methylmercury criteria and criteria that use a biotic ligand model. The Engineering Analysis Division is responsible for effluent guidelines under CWA. An Economic Analysis Branch provides the division with support for guideline development.

To develop water quality criteria or guidance, HECD staff reviews available literature on effect, occurrence, and exposure; identifies needed information; works with ORD, the Office of

Pesticide Programs (OPP) and other Program Offices, and/or contractors to "fill holes" in the data set; and uses standard methodologies (which includes a "good science clause" that allows for use of nontraditional approaches such as the biotic ligand model) to develop draft documents. OST uses externally available data when the needed research involves standard toxicity testing, a task of low interest for ORD. OST may not have the ability to wait for generation of laboratory or epidemiologically based data if there are legislative or court-ordered deadlines for a regulation or other risk management action; risk assessments under CWA and SDWA are based on best available science). OST seeks external peer review and scientific views from the public on draft documents. OST has sought advice from the SAB, for example, on interim steps involved in developing new criteria and approaches. OST works to integrate Agency Risk Assessment Forum guidelines, such as the *Ecological Risk Assessment Guidelines*, into its criteria work.

Development of a criteria document can be costly and ranges from \$50,000 to \$300,000, depending on the complexity of criteria, the amount of toxicity data available, and if additional testing is determined to be appropriate or necessary. For some situations, novel approaches are needed to derive criteria that reflect the unique water quality or biotic dynamics of the pollutant. For example, for two decades OST has been adjusting its criteria derivation approach to protecting aquatic life from the effects of metals. The most recent effort, the biotic ligand model for availability of metals to aquatic life began in 1993. Development has involved time-consuming "proof of principle research" and modeling.

SHPD develops implementation guidance based on traditional "hard sciences," not social or economic sciences. Under section 304(a) of the CWA, water quality criteria are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects; water quality criteria do not consider economic or social impacts. In addition, the litigious nature of American society is a barrier to EPA's explicitly using social science in development of water quality criteria and implementation guidance, as the use of social science can give the impression that science has been diluted or influenced. One perspective is that if EPA analysis focuses on a bright line or range between two extremes, there can be some certainty that a level is protective.

SHPD does, however, consider social and economic science input in making specific decisions, when needed, related to State and Tribal water quality standards. While the CWA requires that States develop water quality criteria that are protective of the designated uses of waters, there are provisions of the Act and associated regulations that enable States to change the designated use of a water body if it can be demonstrated that meeting the standard would result in substantial and widespread economic and social impact. Also, States are not required to adopt 304(a) recommended criteria; they have the option to develop their own water quality criteria. SHPD's Regional, Tribal and State Support Branch, in consultation with HECD, evaluates proposed water quality criteria generated by States and the supporting scientific justification. The key question is whether the proposed criteria are protective of the State's designated uses for waterbodies. If a State does not meet its responsibilities under CWA, EPA may develop water quality standards in their stead. For example OST is currently developing federal water quality standards for nutrients in the State of Florida.

OST sometimes collaborates with States and Tribes to develop aquatic life criteria. Prominent examples are collaborations with Region 7 on chlorides in Iowa, pesticide criteria for Minnesota, and selenium criteria in California. Many State- or site-specific issues arise in implementation of criteria. For example, the unique geography or ecosystems may have dry washes that host a wet aquatic community only during rainy seasons or wet weather events. Between events the area returns to its dry state and limited aquatic community support. OST works with the State or Tribe to examine how much adjustment in either water quality or quantity the aquatic community can withstand and the economic and social aspects of the aquatic life valued by the human community.

OST is collaborating with OPP in stakeholder listening sessions that will help these Programs reach a common health and eco effects assessment for use in regulatory efforts to address toxics. The two offices are jointly preparing a white paper to be sent to the FIFRA Scientific Advisory Panel (SAP).

OST decides the degree of involvement of outside stakeholders and outside scientists based on its judgment of the likely impact of OST science. If OST believes that there will be a major impact, then the OST science or activity receives extra scrutiny, additional investment, additional peer review, and "extra scrubbing of proof of principle." In OST it is often said that if there is lively public interest --and critique -- from different sides of an issue, it generally means that OST got the science right. In some cases, OST has reexamined the science supporting a decision. In the case of tributyl tin, OST reopened its analysis and pulled in more data when the state-of-the-science used in the original derivation was determined to need updating. OST reevaluated the 1999 ammonia criteria because of new data indicating greater sensitivity of freshwater mussels. OST conducted an extensive peer review of the draft ammonia criteria update, which involved ORD, the U.S. Fish and Wildlife Services, U.S. Geological Survey and EPA Regions. In the case of atrazine, OST revised its criteria in light of emerging research funded by EPA on endocrine disruption as well as research funded by the regulatory community showing a lack of effects. OST has sought review from the SAP multiple times and is reevaluating studies because of issues raised by the panel. In general, the peer review process leads to more thoughtful documents.

Limited availability of scientists with the needed expertise is the chief impediment to science integration. EPA has the right expertise to support OST's programs but insufficient numbers of scientists with that expertise leaves them spread too thin. With limited number of scientists with the appropriate expertise available, OST turns to the same scientists in ORD for assistance for multiple and simultaneous efforts. Another impediment is the frequent controversy over water issues in the media; for instance, an article in the Associated Press can divert scientists and analysts from the project to responding to press and congressional inquiries leading to derailed or extended research plans.

To help the focus on science integration, OST staff focus on management priorities; monitor the needs of States, Tribes, and Regions for science support through regional Water Quality Standards Coordinators and through the Water Quality Standards Managers' monthly calls; participate in professional society meetings, and through state organizations (e.g., State FIFRA Issues Research and Evaluation Group and Association of State and Interstate Water

Pollution Control Administrators). OST also partners with research organizations to evaluate research proposals for relevance to water program needs; for example, the Water Environment Research Foundation, the National Academy of Sciences, and the Small Business and Innovative Research grants program,

OST has recently participated in an OW-wide effort to develop a *National Water Program Research Strategy* to identify priority research needs. OW canvassed the needs of all OW offices and Regional offices to identify research needs and related "drivers." The strategy identifies a hierarchy of research needs and identifies critical path research questions. The strategy defines four theme areas (Healthy Watersheds and Coastal Waters Research Needs; Safe Drinking Water Research Needs; Sustainable Water Infrastructure Research Needs; and Water Security Research Needs). Information about the strategy can be found on the web at: <http://www.epa.gov/waterscience/strategy/>. The strategy "cross-walks nicely" with ORD's multi-year plans, but it is aimed at a broader audience; that is, other federal agencies, other funders of research, and external researchers whose work could contribute to meeting the research needs of the National Water Program. OW intends that the strategy will evolve into an electronic inventory of research related to the needs of the national water

Meeting with the Office of Water (OW), Office of Science and Technology (OST) Deputy Office Director and Managers (January 28, 2010, 2:00 p.m. - 3:00 p.m.) Participants

Ms. Denise Keehner, Director, Standards & Health Protection Division
Ms. Suzanne Rudzinski, Deputy Director
Dr. Edward Ohanian, Director Health and Ecological Criteria Division
Dr. Rita Schoeny, Senior Science Advisor, Office of Water

In OST, as in other parts of EPA, good public policy decisions depend on sound science, which depends on data. EPA "runs into criticism" when it makes decisions without "hard science data" and relies instead on assumptions or default procedures. One manager characterized the key question facing decision makers as "how do I get a pretty good answer that is not arbitrary and capricious, which I can defend in a regulatory arena."

OW has "some problems specific to OW."

- None of the statutes it implements provide authority to mandate collection of health effects data.
- The Safe Drinking Water Act (SDWA) gave OW obligations in terms of science: the office must review the "best available peer-reviewed, publicly available data." The definition of "best" is left for OW to define and may be controversial
- SDWA requires EPA to consider sensitive subpopulations: not just children but also other populations that are innately susceptible or that have increased exposure. OW must address aggregate and cumulative risk in assessments that underlie risk management choices.
- Water is a complex mixture and so OW is drawn into analyses and policies involving the impacts of mixtures on human health and the environment.
- OW is obliged to consider potential risks of microorganisms living in water. These risks could be incurred through consuming water as well as through recreational use of waters.

ORD's resources are not sufficient to meet OW 's long list of needs. OW needs applied science, in addition to long term research. Some of the types of research OW critically needs are not within ORD's purview or priority interests. OW timelines may not permit waiting for studies to be designed and completed, and may require the use of existing science generated by EPA or externally to it. Dialogue between OW and ORD is "getting better," but OW's need for science will increase and with it the need for ORD responsiveness. With new risk assessment science, including EPA's 2005 *Cancer Guidelines*, EPA no longer will be relying only on linear low-dose extrapolation for cancer assessment or analyses where cancer trumped all other effects. The *Cancer Guidelines* emphasize the use of data analyses before invoking defaults as part of the need for a "sounder scientific base for human health". OW's science must be defensible in court, as well as in the court of scientific opinion. OW maintains a strong need for ORD data in the short term as the basis for chemical and microbial risk assessments.

OW participates in problem formulation for chemicals under consideration to determine regulatory options available for them. Under SDWA there is a requirement for formal periodic review for chemicals on OW's regulatory agenda for drinking water, the Contaminant Candidate List. There is a less formal periodic evaluation of chemicals under the Clean Water Act (CWA). OST interacts with the Office of Groundwater and Drinking Water in planning assessments needed for drinking water chemicals.

An example of science integration that involved problem formulation and interactions across federal agencies was joint advice developed by EPA and the Food and Drug Administration (FDA) on consumption of fish contaminated with methyl mercury. After evaluating the science, FDA and EPA agreed that the overall message should be that "fish is good food and all fish is contaminated with methyl mercury." Since no one can "extract mercury out of the fish," the fish advice focused on encouraging fish consumption while reducing exposure to mercury. EPA developed a reference dose (RfD); that is, an amount that can be consumed over a lifetime without expectation of adverse effect. This was based on the best publically available science of a methyl mercury effects, and included input from both the National Academy of Sciences as well as another independent expert group. This RfD was used by FDA as a comparison point in analyses to determine the optimal means for promoting fish consumption while minimizing mercury exposure. EPA and FDA initially developed a four-page fish advisory, which was too long and complicated to be understood by the target audience. The Agencies subsequently involved risk communication specialists. FDA held focus groups, and both Agencies engaged stakeholders, as well as asked for and responded to public comments. OMB was also involved as there were economic consequences.

There are many new areas where the integration of science into policy will be important:

- For polyfluorinated compounds (PFOA and PFOS), there is a need for careful communication of risks, based on the limited available data
- For pharmaceuticals and nanotechnology products in water, there will be a need to frame the potential problems related to human health and ecological effects to focus research in this new area

There is a need for ORD to communicate its research to OW managers and senior staff in ways that engage them and help them understand the potential contributions of the research to OW's mission and research priorities. The main purpose of the National Water Program Research Strategy is to facilitate such an interface between ORD and OW. This is especially important for ORD's ecological services research program and the computational toxicology program. These are areas in which it is important that there be translation by scientists and risk assessors of impacts and consequences of the data. This is time- and resource-intensive, but very necessary to ensuring that risk management decisions incorporate the most contemporary, best science.