SAB Science Integration for Decision Making Fact-Finding Meeting
Office of Water, Office of Ground Water and Drinking Water (OGWDW)
EPA West, Washington, DC
January 20, 2010

Four members of the SAB Committee on Science Integration for Decision Making conducted two interviews in EPA's Office of Ground Water and Drinking Water (OGWDW): Drs. James Johnson and Gary Sayler in person, and Drs. 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 OGWDW'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 and thanked Mr. Thomas Carpenter for coordinating with the SAB Staff Office in planning the meetings.

Meeting with the Office of Water, OGWDW Office Director and Director, Standards and Risk Management Division (12:45 p.m. - 2:00 p.m.) Participants:

Ms. Cynthia Dougherty, Director, Office of Ground Water and Drinking Water
Ms. Pamela Barr, Director, Standards and Risk Management Division

OGWDW relies on many different kinds of science, e.g., health science, economic analyses of costs and benefits, and engineering, to do its primary job, implementing the Safe Drinking Water Act (SDWA). The Office Director recommended that one of the conclusions of the SAB's science integration study be that "OGWDW relies almost solely on the Office of Research and Development (ORD) to develop health effects research needed to do our job." SDWA specifically requires that decisions be made on the best available science. The legal test is the "best available" science, not "perfect science" and courts have interpreted this language strictly. For example, EPA was sued and lost in court over a chloroform Maximum Contaminant Level Goal (MCLG) where the court found that EPA had set an MCLG but had not used a published study showing a threshold for chloroform effects.

Because of its legal mandate, OGWDW continually identifies science questions related to decision making, evaluates the best available science, explains EPA's decisions in light of the best available science, and identifies the science needed for the future. OGWDW is involved in different kinds of decisions where science is involved: Principal decisions include:

- whether to include chemicals on the Chemical Contaminant List (CCL),
- whether to monitor unregulated contaminants,
- whether to regulate chemicals on the CCL (if the chemical has adverse effects on the health of persons, occur in water systems, and if there meaningful opportunity for health risk reduction if EPA decides to regulate).

- Where to set MCLGs and Maximum Contaminant Levels (an enforceable and measurable goals, based on the feasible protective level that systems can achieve).

Scientific assessments help OGWDW decide when to take different kinds of action to regulate chemicals. Different kinds of decisions may be supported by different kinds of science (e.g., the science needed to list a chemical on the CCL may differ from the science needed to set a MCL; formal benefit-cost analyses are required to support rulemakings). Where science is not strong enough to take action, OGWDW makes an explicit decision to get stronger science to support future decisions. OGWDW described areas of scientific uncertainty relating to decisions in several areas:

- Risk assessments for chemicals not yet complete or uncertainties associated with available risk assessments [OGWDW generally looks to IRIS numbers, pesticide assessments, ATSDR, or numbers generated by OW's Office of Science and Technology (OST)]
- Lack of nationally representative occurrence data and how to characterize the representativeness of available regional data. This information feeds into exposure analyses used for benefit-cost analyses.
- Robust monitoring methods that can be used by drinking water treatment facilities
- Benefits cannot be characterized in some cases in monetized ways, as supported by available science. In the case of the arsenic analysis, for example, EPA was able to monetize bladder cancer effects, but not non-cancer effects, such as high blood pressure.

OGWDW uses many different processes to integrate science.

- Sometimes the public has pointed to new bodies of knowledge. In the case of the microbial disinfectant byproducts rule, the first advisory committee consulted by OGWDW recommended that EPA conduct more monitoring. EPA and the industry invested over $100 million in monitoring and data gathering on treatment technology and disinfectant byproducts. A large external group helped OGWDW interpret the data and reached that conclusion that different parts of that country varied widely in the kind and levels of disinfectant byproducts. As a result, OGWDW considered different regulatory options than initially envisioned.
- The Administrative Procedures Act provides opportunities for public comment on Agency rulemakings.
- OGWDW sought external science advice from multiple advisory committees on the CCL: from the National Research Council (NRC), National Drinking Water Advisory Committee (NDWAC), and the SAB's Drinking Water Committee.
    - For the third CCL, OGWDW obtained expert input at key decision points to identify a universe of 7,500 drinking water contaminants then screen this universe to a preliminary CCL 3 of almost 600 contaminants that warranted further evaluated and then select 116 contaminants for the final CCL 3
- For the 2001 review of the arsenic rulemaking, OGWDW brought different aspects of the problem to different advisory groups and managed the process so that EPA received advice from each group within 6 months.
    - The NRC provided advice on health assessments
    - The SAB provided advice on benefit assessment and related uncertainty
    - The NDWAC provided advice on costs

OGWDW noted the importance of planning carefully where it brings issues to different advisory committees and how to frame charge questions carefully to get the advice and review needed to make sure that the science supports our decisions.

OGWDW has a team devoted to identifying research needs to support its activities. The group coordinates with ORD on EPA Drinking Water Research Program, including the STAR grant program, and also with other research organizations, such as the Water Research Foundation. In collaboration with OST, OGWDW keeps informed about research conducted by the World Health Organization, Dutch Water Research Foundation, and with other international organizations.

Barriers to science integration include:

- Limitations of regulations: SDWA doesn't give EPA regulatory authority over source water, but safe drinking water often depends on quality of source water and treatment needed to provide drinking water
- Sometimes regulatory time constraints make it difficult to address all NRC, SAB, or NDWAC recommendations
- Lack of flexibility in ORD research plans and researchers' willingness to shift resources to priority OGWDW program needs
- Lack of effective communication about the execution and status of ongoing drinking water research. Can be often difficult to know which research projects are actually underway and on track to support decision-making.
- Potential concern that ORD's multi-disciplinary research initiative may shift resources away from the well-identified research needs of the Drinking Water Research Program.

OGWDW has made limited use of social science other than economics. It has recently worked on message mapping to help with risk communication in the area of water security. The process involved "laying out questions from the public" and identifying responses at different levels of complexity. The process worked well but was difficult and time consuming. It trained OGWDW in communicating more effectively and may be useful for underground injection issues. Although OGWDW has some expertise in communication, not all communicators are adequately trained. This issue will become more important as OGWDW reaches out increasingly to stakeholders outside NDWAC, especially to people in environmental justice communities who may be less informed and engaged in drinking water issues. The OGWDW Director noted the value of accessing expertise through post-doctoral fellows with training in communication and social science.

Meeting with the Office of Water, OGWDW Managers and Scientific Staff (2:15 p.m. - 3:30 p.m.) Participants:

Eric Burneson, Chief, Target Analysis Branch
Jeanne Briskin, Chief, Standards and Risk Reduction Branch
Stig Regli, Policy Advisor, Standards and Risk Management Division

The managers started the discussion by describing the decisions their branches participate in and how science is integrated into those decisions. The Standards and Risk Reduction Branch

evaluates scientific and technical data to support decisions related to pathogens, disinfection and disinfection byproducts. The branch has experts from multiple disciplines, including chemistry, microbiology, statistics, economics, engineering, and policy analysis. The branch works with OST and ORD to monitor current science related to the potential occurrence and health effects of pathogens and disinfection by-products. The branch works with the decision rules provided by SDWA to determine prudent, science-based approaches and engages the NDWAC, SAB, and other advisory committees to get input from stakeholders and scientists on science assessments. One recent example of this process is the revised total coliform rule, where OGWDW held open public meetings, including collaboration through a Federal Advisory Committee (FAC) and consulted with the SAB

Science assessments for decision making often involve integration of complex science and multiple uncertainties. Sometimes it OGWDW does not have monitoring information on pathogens in distributed water and must use models to estimate occurrence of pathogens in distributed water, given different source water treatment technologies. Analyses based on this information inform default assumptions used to set the National Primary Drinking Water Regulations (NPDWRs). There are many "grey areas" with important uncertainties. Another important uncertainty relates to risk/risk tradeoffs, unintended consequences of controlling for pathogens that introduce byproducts with potential adverse effects. OGWDW must often conduct "simultaneous" risk assessments, because issues are so complicated. In these cases, it is very useful to have to have different external perspectives inform the assessment and decision process.

The Target Analysis Branch has responsibility for chemical contaminants beyond disinfection byproducts. Like the Standards and Risk Reduction Branch, the Target Analysis Branch is a multi-disciplinary team of economists, engineers, health scientists, and public policy experts. The statutory drivers for integrating science and policy are "quite clearly laid out in SDWA." For the CCL, OGWDW sought advice from the NAS, which provided three reports on prioritizing drinking water contaminants, and then asked for input from NDWAC, which provided stakeholder input for implementing the NAS recommendations and finally consulted with the SAB on how well EPA had carried out the NAS and NDWAC recommendation in preparing the CCL 3. EPA also sought input from the NDWAC on how to best make regulatory determinations for CCL contaminants. OGWDW also consults with the SAB when proposing Maximum Contaminant Levels Goals and national primary drinking water regulations. SAB input on rulemakings has been sought on issues including benefit-cost analyses. The risk management processes required under SDWA are iterative. SDWA requires EPA to review and evaluate national primary drinking water rules every six years to determine whether revisions of the rules are appropriate which will maintain or improve public health protection. Any proposed new or revised standards must at least maintain or improve public health protection and have a public comment process. EPA sometimes uses advisory meetings provide opportunities for stakeholder analysis for more significant rulemakings.

Participants agreed that different kinds of decisions required different thresholds for the science needed in terms of breadth, depth, and level of stakeholder involvement. For the CCL, for example, the release of a contaminant into the environment is a surrogate for presence of that

chemical in drinking water. For a regulation, in contrast, EPA provides measured national occurrence of that chemical in finished water. EPA must also assess adverse health effects. There is significant stakeholder involvement in CCL, regulatory determinations and development of NPDWRs. Public involvement intensifies as OGWDW involves Federal Advisory Committees. The greatest degree of stakeholder involvement has occurred through the special regulatory negotiation process for the microbial disinfectant byproducts rules.

Research planning to support OGWDW's need for integrated science is a priority. OGWDW has a dedicated research team that focuses on the research "big picture" -- the key regulatory drivers, research questions and time frames -- where OGWDW needs answers to make decisions. This effort has informed ORD's Drinking Water Multi-Year Plan and OGWDW's periodic visits to ORD laboratories, which allows an exchange of information and builds ORD's understanding of OW's research needs and OGWDW's understanding of the potential for ORD's research. OGWDW's research planning process has also informed OW's recent *Office of Water Research Strategy*, which has stimulated the work of the Water Research Foundation. OGWDW and ORD are both interested in low-dose issues and have "periodic dialogues" to coordinate analytical needs and efforts.

OGWDW has a strong desire to optimize research developed by ORD's research groups. For example, OGWDW's Water Security Division works closely with ORD. OW works with the National Homeland Security Research Center especially in modeling and monitoring of drinking water distribution programs. ORD has also completed a significant comprehensive assessment of microbial risk assessment.

Barriers to science integration include:

- Slow development of health assessments for some chemicals, like MTBE
- Concern that ORD's Integrated Multidisciplinary Research Transformation may assign specific drinking water research needs a low priority
- STAR grant projects (e.g., in the area of disinfection impacts on distribution systems) not always managed so that awards were made to projects with program relevancy. Sometimes it seems that technical peer review screens out relevant projects
- Statutory deadlines that make it difficult to generate and assimilate all needed science
    - One example: the NAS recommendations to improve the CCL process were sweeping recommendations that EPA could not adopt within one year. EPA adopted many of the recommendations when developing CCL 3. The NDWAC recommended using an adaptive management approach to consider the remaining recommendations in future CCLs.

The work force appears to be nimble because OGWDW's work requires a multidisciplinary approach. For example, engineers have been required by assignments to acquire knowledge of public health and staff generally is expected to collaborate with other disciplines when they conduct an assessment. When OGWDW recruits new staff, it specifically looks for flexible individuals who can learn new information and work in teams. Promotions and career path are determined by analysts' contributions to the work of their division. Branches include staff working in social sciences, including economics and communications, but no psychologists or sociologists.

OGWDW invites regions to participate in rulemakings, the CCL, regulatory determination, and review of existing regulations. EPA also invites State Drinking Water Administrators to participate in the development of proposed rulemakings. When regions participate, they offer valuable practical experience. OGWDW also organizes a monthly call for regional drinking water branch chiefs. OGWDW views states as co-regulators and partners in environmental protection. State drinking water contacts participate in Agency work groups in the early development of rules up to the proposal stage. After that point, they become stakeholders and can comment on proposed rules through the formal notice and comment process.