Summary Minutes
United States Environmental Protection Agency (U.S. EPA) Science Advisory Board (SAB)
Committee on Science Integration for Decision Making
Meeting
June 9 - 10, 2009

Committee Members: See Committee Roster provided in Attachment A.

Date and Time: Tuesday, June 9, 2009, 9:00 a.m. - 5:00 p.m.
Wednesday, June 10, 2009, 12:00 p.m.

Location: Ritz-Carlton Hotel
1150 22nd St., NW
Washington, DC 20037

Purpose: The purpose of this meeting was to begin the work of the Committee on Science Integration for Decision Making of the EPA SAB. The primary goal of the meeting was to develop the study plan to guide implementation of the CSIDM's efforts. The Agenda is in Attachment B and the *Federal Register* announcement of the meeting is in Attachment C.

CSID Participants:

Dr. Thomas Burke, Chair
Dr. John Balbus
Dr. Gregory Biddinger
Dr. James Bus
Dr. Deborah Cory-Slechta
Dr. Terry Daniel
Dr. Penelope Fenner-Crisp
Dr. John Giesy
Dr. James H. Johnson
Dr. Cathy Kling
Dr. Wayne Landis
Dr. Jill Lipoti
Dr. Thomas Theis
Dr. Buzz Thompson
Mr. Thomas Theis
Dr. Thomas Wallsten
Dr. Lauren Zeise

SAB Staff:
Dr. Vanessa Vu
Dr. Thomas Armitage
Ms. Kyndall Barry
Ms. Elizabeth Resek
Mr. Thomas Miller

Meeting Summary:

Discussion at the meeting generally followed the issues and timing as presented in the meeting agenda (Attachment B).

Tuesday, June 9, 2009

1. Convene Meeting

Mr. Thomas Miller, SAB DFO, convened the meeting and welcomed the group. He noted that the Committee activity is conducted pursuant to the Federal Advisory Committee Act (FACA) and that committee members are required to comply with all Federal ethics and conflict of interest rules. Mr. Miller stated that the topics discussed at this meeting were of a general nature and that Members were determined to have no ethical or conflict of interest issues with regard to the topic. An important component of FACA is the requirement for public access and that they be permitted to provide information and oral statements for committee consideration. One member of the public submitted written comments for the meeting and requested time to make oral comments to the Board.

Mr. Miller asked members of the Committee to introduce themselves and to state their affiliation and they did so (see roster in Attachment A). Several Members of the Committee were unable to participate in the meeting. They included: Drs. Taylor Eighmy, Rogene Henderson, Gary Sayler, and Bryan Shaw. Dr. Kling participated by telephone. Members of the Public and Agency representatives are shown on the sign-in sheets in Attachment D.

2. Director's Welcome

Dr. Vanessa Vu, SAB Staff Office Director welcomed the group, and thanked EPA and contractor staff. Dr. Vu summarized the project's origin and what the Committee's task would involve.

3. Meeting Purpose and Approach

Dr. Thomas Burke, Committee Chair welcomed members, the Agency, and the public and summarized the purpose of the project. Dr. Burke Chaired the National Research Council (NAS NRC) committee that developed the report *Science and Decisions: Advancing Risk Assessment* (see Attachment E for a link to the report and Attachment F for Dr. Burke's presentation and Exhibit 1 in these minutes) which is one of the foundational works for this project. A summary of his remarks follows.

> The Committee for Science Integration for Decision Making (CSIDM) will consider whether, and to what extent, EPA's scientific assessment practices are integrated into environmental decision-making practices.
>
> Past EPA Administrator Johnson requested this SAB study. Administrator Jackson affirmed the Agency's continued desire for the study and further focused the request to ask that it concentrate on microbial and toxic chemical pollutants. Specifically, the Board was asked to "…undertake a study of how EPA can strengthen scientific assessment practices for environmental decision making" (see Attachment G for the charge and this letter).

The primary focus for the Committee evolved from these past works and others (e.g., developments in risk assessments for ecosystems and microbial contamination, as well as the concepts captured in cumulative risk and comparative risk frameworks). The NRC and SAB studies[1] found that improvements in EPA risk assessment and decision-making processes are necessary to ensure that the best and most relevant information and practice is available and applied in carrying out EPA's mission. Further, the NRC report on "Understanding Risk" introduced the notion that "The analytic-deliberative process leading to a risk characterization should include early and explicit attention to problem formulation…" and that "…representation of the spectrum of interested and affected parties at this early state is imperative." Several criteria were given for an effective analytic-deliberative process (e.g., getting the science right, getting the right science, getting the right participation, getting the participation right, and developing an accurate, balanced, and informative synthesis). These criteria are really about getting appropriate stakeholder involvement.

The recent NRC report *Science and Decisions: Advancing Risk Assessment* (NRC, 2009), provides a new approach that frames the issue in terms of enhancing the utility of science analysis for decision-making (see Exhibit 1). The core of the framework is technical risk analysis that follows the 1983 NRC risk assessment paradigm. The new framework differs primarily from the 1983 framework in its initial and final steps that implicitly ask "What *options* are there to reduce the *hazards* or *exposures* that have been identified," and "How can risk assessment be used to evaluate the merits of the various options?"

Questions embedded within the framework arise from early and careful planning of several types of technical assessments (including risks, costs, and technical feasibility) and the required level of scientific depth needed to evaluate the relative merits of the options that are to be considered. Risk management involves choosing among the options after the appropriate assessments have been undertaken and evaluated." The questions for each of the framework's three phases are in Attachment E page 11).

In summary, the NRC recommendations was that "EPA adopt a framework for risk-based decision-making that embeds the Red Book risk assessment paradigm into a process with

- initial problem formulation and scoping,
- upfront identification of risk-management options, and
- use of risk assessment and other science assessment tools to discriminate among these options.

The challenge to the Committee on Science Integration for Decision Making is to evaluate the extent to which EPA's scientific assessment practices are integrated into environmental decision-making practices, as previously recommended by the NRC and the SAB, and its focus will be on EPA's application of scientific assessments in environmental decisions concerning chemical and microbial pollutants. According to the letter from the EPA Administrator, areas of consideration may include scientific practices, leadership, collaboration across disciplines, as well as

[1] *Risk and Decision Making: Perspectives and Research* (NRC, 1982); *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983); *Issues in Risk Assessment* (NRC, 1993); *Science and Judgment in Risk Assessment* (NRC, 1994); *Toward Integrated Environmental Decision Making* (SAB, 2000, etc.)

workforce expertise. The Committee may make additional recommendations to improve the integration of scientific assessments for decision-making. The advent of a new Administrator provides the SAB with a tremendous opportunity to develop advice that can help advance science integration.

Dr. Burke asked members for comments or questions relative to the presentation and the Committee's goal. A number of comments were made that reinforce the integrated notions of assessment in support of decision making that emerge from both the SAB's "*Integrated Environmental Decision-Making* and the NRC's *Science and Decisions*. Comments included the following:

a) Pollutant Focus (Chemicals, Microbial): Reflects past thinking, not future needs ("So 20th Century"). It may be more effective to focus on overall exposures and not a narrow pollutant focus.

b) "Red Book" envy itself might present problems in our work. We have gone way beyond that paradigm. It may be as dated as the chemical-specific view. Considering things as they occur in the landscape is most appropriate.

c) Thinking beyond pollutant-specific and risk alone focuses on the "nasty" side of issues – we should ensure that we look beyond that to focus on "opportunities" that exist once we respond to immediate situations (e.g., Superfund cleanups).

d) Focusing on individual pollutants does distract from big questions like "human health." Things like focusing on pollutant classes might be appropriate.

e) Human health as a focus might itself be overly narrow. One major challenge is to manage performance in the landscape. Risk assessment itself might point you at risk reduction instead of real land issues. It would be helpful to think about how science comes into decisions and how that can lead us to better performance in our risk management actions.

f) Thinking of "units of analysis" will be important in both human health and landscape. These will ultimately be important to judging performance. Thus, measurement is important in the big decisions (such as what is regulated and how?) as well as the little decisions (who do we hire?).

g) As for this Committee's focus, we could look at things from the "inside out" (i.e., consider the specific mandate first) or the "outside in" (what's broken and how to fix it). The second approach might be the best focus for informing this committee's priorities for consideration.

h) CSIDM could think of recommendations in two stages: Short-Term – where we are now and what we should do (pollutants) or the Long term (a new context for future EPA behavior).

i) Many of the possible processes have actually been around for some time (e.g., there are many ways to approach cumulative risk for phthalates) so it will be important for us to consider what now impedes EPA progress on being more integrative. Resources? Is EPA organized to do integration? Who sets EPA's priorities – internal or external forces? Availability of discretion to EPA decision-makers.

j) It will be important to think as much about how process improves science – Feedback Loops – as it is to think about how science can improve the process. Does science respond to the feedback signals that come from the process side? Such feedback loops are a part of the IEDM and the Science and Decisions frameworks. An important dimension of this is also the need early in the process to consider the state of science on the specific issue.

k) This group should look to other federal agencies, other countries, etc., for existing methods being used for decision-making and risk analyses. For example, agencies such as FAA and the NTSP look at risk differently than EPA does. Paradigms reflecting such reality (not just risk) exist.

l) We could use case studies as a tool (e.g. as a way to look at trends). The commenter acknowledged that these case studies often focus on specific chemicals and preferred that a specific pollutant focus not be encouraged.

m) We should determine how the Agency currently prioritizes issues when there are limited resources (the group realizes that Congress sets priorities in general).

n) Communication at all levels was stressed with respect to how this committee communicates its recommendations to the rest of EPA, as well as how EPA communicates its science, processes and decisions to the public.

Dr. Burke stated that these are important clarifications. Though the Administrator is most frequently presented with issues for resolution that have a narrow, pollutant-specific focus, this Committee will need to ensure that it maintains a focus on how these things actually present themselves in the real world as "use" related issues and how they might be responded to by integrated concepts (e.g., green chemistry, sustainability, etc.). We need to focus on how the pieces fit together.

4. <u>EPA's Regulatory Development Process-Mr. Alexander Cristofaro, Director, Office of Regulatory Policy and Management, EPA Office of Policy, Economics, and Innovation:</u>

Mr. Cristofaro started by giving some statistics on EPA regulation. EPA accounts for about 16% of Federal regulations. There are generally two categories of regulations: those signed by the EPA Administrator and those signed at an "office" level (in 2008 there were 467 office level regulations and 97 actions signed by the Administrator). The EPA Air Program produces the largest volume of EPA regulations. Only "major" rules are signed by the Administrator. Generally, the rigor and cross-office attention to rules reflects the significance of the action. The time needed to complete rule making reflects a number of situations – an important factor being

court ordered deadline. Benefits and costs of rules vary by program. The OMB 2008 "Report to Congress on the Benefits and Costs of Federal Regulations" shows that for 2006 all Federal rule making (93 cases) delivered $122 to $656 billion in benefits against costs estimated to range from $46 to $54 billion. EPA's part of this (for 40 actions) gave benefits ranging from $83 to $593 billion at a cost ranging from $32 to 35 billion.

EPA uses an Action Development Process (ADP) to produce its major actions (see Attachment H). The process involves the following activities: Prioritize Plan, Analyze, Evaluate, Decide, Collaborate, and Communicate. Stages in the process for Tier 1 and 2 actions include (Tier 3 actions do not go through steps b, d, and f below):

a) Commencement/Tiering[2] (Prioritize): Primary decision maker is designated and senior management decides whether work may begin.
b) Analytic Blueprint/Early Guidance (Plan): The work plan is prepared and information needs identified. Senior management decides the direction for the action. Outlines the plans for scientific, economic and legal analysis as well as implementation, enforcement and compliance analysis and stakeholder outreach. Helps get workgroup members on same page, solicits early guidance from senior management and sets the work schedule.
c) Analysis/Consultation (Analyze): Workgroup analyzes and consults on action as required by statutes and Executive Orders. Fills data gaps, seeks to understand stakeholder needs and concerns and develops options for analysis.
d) Options Selection (Evaluate): Senior management decides which option(s) to pursue. Presents options to senior management from participating offices. Managers may select a presented option, request additional analysis or data, or ask for additional options.
e) Drafting: Workgroup prepares a draft of the action and supporting documents.
f) Final Agency Review (Decide): Agency-wide review of final regulatory product. The final package is reviewed (preamble, regulatory text, supporting analyses, communications materials).
g) OMB Review (Collaborate): If required, OMB and other relevant agencies review the action.
h) Signature: Appropriate senior management signs the action
i) FR Publishing (Communicate): Action published in the *Federal Register* and other communications methods can be used as well (press release, web posting, notice in the *Regulatory Agenda*).

SAB Questions and Comments:

a) The process reinforces our notion that much of EPA's action is **narrow**. There is limited opportunity to take a broader view because its action is largely driven by the specificity of its **mandates**. Some of the ADP steps are similar to "Science and Decisions" but they

[2] Tier 1: Administrator's Priorities (involve complex, precedent-setting, and controversial actions. Has active and ongoing involvement by the AO and has a formal workgroup with core offices).
Tier 2: Cross-Agency Actions (require extensive cross-media or cross-Agency involvement and a formal workgroup with core offices).
Tier 3: Lead Office Delegation: Actions of a technical nature or single media. No formal cross-Agency workgroup is required.

occur late. Upstream consideration of different alternatives does not seem to occur. There appears to be little ability to introduce "**novelty**" into a process that seems largely to be an assembly line. The process seems to be "**rule-oriented**" and has little opportunity for **integration** that might make possible identification of "root causes" of conditions in common with other office missions possible.

- Some broader thinking occurs, but the process is dominated by rules and it is rule-oriented. The process might be "made better" by a broader view, but I wonder whether such approaches might make the answer come out differently. Would such change be necessary?

b) There are some similarities between integrated views of decision-making ("silver book") and the ADP although the ADP seems more interested in narrow interpretations of rule development. There are things that happen during and subsequent to development of an action that are important to other offices in EPA and to future EPA actions. Is there a process to learn from specific actions and to feed that information back into other offices, including ORD for research planning purposes?

- There is no formal process to develop reports on such things and it is not clear how this happens informally; however, ORD does participate in most workgroups.

c) Does EPA consider the implementation phase for a rule while it is being developed?

- Implementation and enforcement are considered during rule development.

d) Does the ADP change over time?

- The process changes and a new edition of the guidance are under development now.

e) From activity on BOSC and at the SAB, it is clear that ORD is reinventing itself to reflect integration through the notion of sustainability. Is anyone considering the big picture regarding sustainability?

- Not through this process. In rulemaking, sustainability is more about being sustained in court. The process focuses on rulemaking and the larger view occurs outside this process.

5. <u>Scientific Assessments for EPA Decision-Making: A Program Office Perspective - Dr. Michael Shapiro, Acting AA for Water:</u>

Dr. Shapiro expanded on the points made by Mr. Cristofaro on EPA's discretion to act broadly vs. the need to only follow Congressional strictures on agency activity. While it is true that much of what we do follows Congressional guidance in our legislative mandates, there is also broad discretion available to the agency. For example, EPA is told to do drinking water standards, but we have discretion as to where we focus our standard-setting activity. That process includes development of Candidate Contaminant Listings; decisions on whether to pursue regulation on specific contaminants; information gathering; assessment of risk from exposures to the public; decisions on whether meaningful risk reduction opportunities exist from standards setting; evaluation of public health consequences; to prediction of the costs and

benefits of a rule. Within this rubric, what we focus on (which contaminant, etc.) is largely within EPA's discretion.

SAB Questions and Comments:

a) How do you address big picture issues?
   - The Clean Water Act focus on the Chesapeake Bay pollution provides a good example with regard to how we might address big picture issues where routine application of the CWA might not be practical. For instance, we can work with states to address problems through state action where they have authorities that we do not have, or we might even be able to request new authorities from the Congress. Much of what we do requires strong political leadership to make progress.

b) Is the ADP model used for such issues? How does information feed back into future action?
   - If an issue is intended to lead to rule making, ADP is the model we use. If not, as in an overall office strategy for some issue, we will form an *ad hoc* team of people across EPA and if appropriate other agencies to lay out a general approach to handle the issue.

c) Have integrated frameworks like "Science and Decisions" been used for your work on issues?
   - We have discussed integration and we commonly use the Red Book paradigm once prioritization is complete. Usually the focus is on exposure. We believe that exposure is more issue-specific and that dose-response is generally more in common across situations/programs at EPA. Thus specific program attention to a pollutant tends to consider exposure questions like who is exposed and to how much of the pollutant for the routes of exposure that are of primary interest to that specific program office. We often do try to figure out the possible risk management options before we go too far in the process. As for specific NRC recommendations:

     > Recommendations such as unified dose-response (cancer and non-cancer effects) is appealing since there is a frustration associated with not having as good of quantitation for NCEs.
     >
     > Often the number exposed above or below an RfD is often interpreted as equivalent to body counts for cancer effects. A probability of harm approach would be difficult and quite challenging. Often our decisions require quantitation and not just a general concept such as harm for a basis.
     >
     > Treatment of uncertainty is an important issue for EPA. The Safe Drinking Water Act requires EPA to lay out the key uncertainties and to

do sensitivity analysis on them. We could do better in communicating these uncertainties more consistently.

The multi-stressor notion is useful. We've tried some. Ultimately, we make regulatory decisions on narrow issues. More consideration of multi-faceted issues might delay action because of the complexity involved.

d) EPA's concerns and cautious approach to the concept of integration brings into focus the contrast between current legal definitions of risk and the public health perspective that recognize harm to people's health status. It also recognizes that some communities have little to no exposure to specific pollutants while others might have high exposure. There is a need to recognize the different exposures associated with different places.
    - This is a major driver when we consider the environmental justice implications associated with contaminants. Thus, EPA focuses on those places where there is a problem. Doing more than this for a national rulemaking would be a huge challenge.

e) Issues like the Chesapeake Bay often require actions in local areas upstream from the Bay. How are the needs of these communities factored in when EPA requires actions to protect a resource down stream?
    - Such issues do require upstream action if they are to be successfully resolved. However, there is no federal authority to force local zoning boards to act. Issues then must be handled by states working with local areas to identify actions that can best influence water quality and then to act accordingly.

f) Some issues like phosphorus in water are very low risk situations but which have substantial local activity to control water levels. Is there a mechanism that allows a better focus for scarce control resources to be applied?
    - Phosphorus is one of those issues where Congress set the priority for EPA and for which tradeoffs as envisioned in the question were not considered at that time. It is possible to handle the issue by reclassifying the use of the water body.

g) Are there places in EPA's process where science can and cannot influence decisions better?
    - Science has much influence on setting priorities, criteria determination, and driving our risk-based decision processes. Getting the right science at the right time can be enormously influential when the science is aligned with the needs of decision-makers.

h) Do all decisions reflect "the numbers?" Do public values get factored into decisions?
    - Different programs get at this in different ways. For drinking water, the Administrator has great discretion in deciding what actions/levels make a "meaningful reduction in risk to public health." If we address a situation where there are few people exposed to relatively high levels of a contaminant, we can pursue a tailored local approach in lieu of a national rule. This allows local values

to be factored into the action. However, no standard model is applied across all programs for such situations.

i) What new science are you using in your super regulatory models for large situations like the Chesapeake Bay?
   - With respect to the Bay, our understanding of the situation reflects 20 years worth of science at EPA, USGS, and NOAA. We feel we have a good understanding of the scope of the problem and recognize the need for more work on technological questions for specific situations that affect Bay water quality (CAFOs, agriculture and other land use practices, etc.). We still need more focused data gathering. For new large issues, we would need to start from scratch to build a knowledge base such as that which we now have in the ChesBay program.

j) Welfare issues have been less studied than health issues in the last 20 years. There are social science issues involved when you consider tradeoffs needed to attain better water quality. Do you draw these into the analysis?
   - We do consider some welfare issues such as value of fisheries and property in our models, but we probably do less in this area than for other scienctific components of the problem.

Dr. Shapiro cautioned that the SAB should not try to do too much with cumulative risk assessment. He questioned whether the outcome from additional cumulative risk efforts, with their associated costs, etc., would outweigh the additional time needed to do such assessments. He believed that cumulative risk assessment should not be the only goal, but that it should be done when it makes sense for regulatory goals and mandates. The scoping phase in risk assessment should determine whether to take into account multiple stressors.

Several members of the committee challenged Dr. Shapiro's opinion on the use of cumulative risk assessment.

6. <u>Scientific Assessments for EPA Decision-Making -- A Regional Office Perspective: Dr. Stan Meiburg, Acting Regional Administrator, US EPA Region IV</u>:

Dr. Meiburg discussed integration of science into decision-making from the Regional Office perspective (see Attachment I). He noted the kinds of decisions that Regions make and which are influenced by science, including: Permits (Air, Water, RCRA); State air implementation plans; Superfund cleanups (Site selection and Site cleanups including both Removals and Remedial Actions); Enforcement (Priority areas and Specific actions); Community and Ecosystem Evaluations; Grants and State Oversight.

These decisions usually have specific costs but generalized benefits; must weigh, at least implicitly, costs and benefits; involve a particular legal/regulatory framework; are time constrained; depend on specialized expertise; and are rarely purely "technical" in that their acceptability to the community is a big factor in the decision (e.g., time, quality, acceptability, and the fact that credentialed expertise may not receive deference). Communities may not care

about your expertise, they have their own perceptions that are important to them in accepting decisions.

Experiences has taught us that SAFE is a four letter word that is on peoples' minds but which must be used sparingly. There are too many opportunities for surprise.

Regional Office decisions are easier when there is/are: 1) clear decision rules (bright line national standards); 2) robust environmental and health information exist; 3) consensus on the problem; 4) clearly seen short-term health/ecological effects; 5) clear attribution; and 6) respected/trusted civic leadership exists.

On the other hand, decisions are harder when: 1) decision rules are ambiguous (e.g., narrative water quality standards); 2) environmental or health information is incomplete; 3) there is disagreement about the problem; 4) the issue involves chronic health or ecological effects whose causation is at best ambiguous -- public expectation of direct causal relationships is often the case; and 5) civic leadership is not accepted by the community. These circumstances are far more common than the circumstances involved with easier decisions.

Dr. Meiburg discussed four current examples of decision-making situations in Region 4 that all involve issues of risk. These examples included: the TVA Kingston Ash Release in Tennessee, PFOA contamination in Alabama, the PCS Phosphate Mine in North Carolina; and one special past case: the issue of anthrax in Danbury, Connecticut.

Dr. Meiburg concluded his discussion by noting a number of things that would be helpful to Regional Offices. These include: 1) expedited decisions on numeric standards; 2) reasonable temporal stability (it may be that five year reviews are too soon); 3) expanded support for field assessments for both ecological and health issues; 4) expanded support for risk communication and external involvement, as well as 5) tools that explicitly display judgments on risk management decisions.

<u>SAB Questions and Comments</u>:

a) The four case examples are impressive. What is the science capacity in Regional Offices? Is ORD able to provide assistance in this area?
    - Region 4 is increasing its capacity for applied sciences. ORD periodically considers its role within EPA and its preference is usually for science to address new issues that will move Agency science forward. They provide assistance to the Regions in the form of monitoring protocols, methods, and tools. We understand ORD's exploration of novel issues for the Agency but we would also like to see increased capacity for developing more science for applications that are important to the Regions' daily functions.

b) Does Region 4 get risk assessment support from ORD? Region 10's assessment activity seems to be quite independent from ORD. The level of research on risk assessment is not clear.

- There is some assistance, but much of the guidance on risk comes from the program offices in the form of acceptable levels (e.g., OSWER and clean up levels). Risk information is important for regions because it helps us decide what issues should receive the most attention and how quickly.

c) Do Regions use risk numbers generated by other Regions?
   - Sometimes, but we also develop our own when the underlying assumptions built into existing numbers are not certain and/or our local situation makes it important to come up with numbers that are the best fit for our situation.

d) Many value judgments are a part of decision-making. There are winners and losers in each situation and tradeoffs are necessary. Communities themselves also have values that might be considered. How do these play into your decisions?
   - This issue is very important in our decision-making. We approach each issue on a case-by-case basis. We try to be as transparent and open in our communications as we can be. We tell what we know and what we do not know. We share the burden with the community itself. We want to know their values as we proceed.

e) In risk assessment you need an end point to focus the analysis upon (i.e., what you are to protect against). How do you decide this, especially if the public is concerned with something that you believe to be less important than the endpoint you select for an action? How do you handle the political and social pressure?
   - There really is no specific calculus for this. We start with what we know and find out what we don't know and get help for what we don't know. It is very important to understand what the community understands as well as their history and their values. You learn this and you make a decision and move forward. We share information when there are different perceptions on risk. In a sense, Regional Offices are at the boundary between national consistency and local characteristics. We want to get as much local knowledge and information as we can. We do not tell the public that they are wrong and it us usually the case that they are not wrong.

f) Since the Regions are on the front line, does your experience feed back to national policy makers and influence there future actions and to ORD for its research planning?
   - Regions are generally implementers and do not necessarily drive policy. But we do sometimes provide feedback that can help determine policy directions. ORD has a broad research program and that work is the result of a planning cycle that can easily take two years to go from a plan to implementation. Thus, the timeframe involved from a near-term Regional need to research answers do not mesh well. Often our needs get to ORD through the national program offices. It would be good to have a larger fixed research investment in ORD that would be devoted to Regional assistance.

g) EPA actions are often reactions to some visible event. The short time that Regions usually have for responding to issues suggests a need to find a proactive mechanism to

use the large amount of data that EPA collects to identify "hot spots" for proactive attention. Does that happen at EPA?

- EPA has many demands on its time, both at the Regional and national levels. Even though a specific event might need a "15-day" turnaround for response in the Region, the issues often persist for years. Much of this is because of disagreements about what should be done in the face of available knowledge and information (e.g., some say act others say wait). It is important to look forward and identify significant issues; however, this can be quite difficult in the face of many short-run crises that place demands on Regional staff time. It's a big problem with little answer.

h) A recurring issue with EPA and with the SAB is "ecosystem services" – especially in the research program. The regulatory side seems to have done little with the issue. Would it help or hinder your efforts to have ecosystems services as a goal (i.e., making sustainability a goal)?

- Region 4 has many sensitive ecosystems and ecosystem components. It would be a great help if we had ways to quantify the services provided by those systems. I have no concept of foregone value from loss of certain components or ecosystems. Anything in this area would be a help in informing the judgments we must make. We support the notion, but don't expect anything soon.

i) Are there opportunities for shared decision-making in the Regions?

- Shared decision-making works when there are established relationships in place. Relationships are the sinew, the context for collaboration. Without relationships there is no trust so shared decision-making does not work. We must build a support system for collaboration that builds relationships. The better the relationships the better off you are in this regard.

7. <u>Public Comments:</u>

a) **<u>Mr. Alan Roberson, American Water Works Association</u>**:

Mr. Roberson made an oral presentation summarizing the AWWA's letter dated June 1, 2009 to the Committee (see Attachment J). Major issues covered by the presentation and the letter included:

i) How science is used in decision making for drinking water regulations is critical for EPA, utilities, and consumers.
ii) AWWA has pointed out what it considers deficiencies in EPA economic analyses for some years. The focus is on risk assessments, occurrence profiles, and technology cost documents.
iii) AWWA has pointed out the lack of transparency, replicability and consistency in several drinking water issues.
iv) EPA relies on overly conservative assumptions and default values when estimating risks and benefits.

v) Use of national incremental comparisons of benefits to costs should be extended to showing implications in systems of various sizes.
vi) EPA is reluctant to use "state of the art" measures of risk reduction benefits, such as "Life Years Saved" (LYS) or other alternative measures. They attribute this to past SAB advice. EPA should at least quantify the degree of life extension provided by the variety of options being considered.
vii) Lack of more systematic approaches for considering unquantified benefits and costs within standard setting is a problem.

Mr. Roberson volunteered to provide two papers he had written on these issues. The chair asked him to do so. These are in Attachment K.

b) **Ms. Pat K. Casano, General Electric, Corporate**:

Ms. Casano requested and was granted time to make a statement. She offered the following points:

i) There is a need for a systematic way of reviewing relevant studies. The Committee could make a valuable contribution by developing and recommending new criteria and/or standards for evaluating studies used in decision-making.
ii) The integrity of the process suffers because of this need. Different approaches seem to be applied to studies regarding how they are evaluated and in how they are used in various cases.
iii) There is a need for early public input to the decision-making process; she noted that this occurs in step 15 of the ADP.
iv) The Committee could provide guidance on what triggers a "process" – this is currently not clear.

8. Development of a Study Plan:

Dr. Burke led a series of discussions intended to narrow and bring focus to the general charge provided to the Committee on Science Integration for Decision Making. Discussions focused on how to structure our work effort; teams for conducting fact-finding; overall study goal; objectives to pursue to achieve the goal; questions to ask during fact-finding in order to in support of developing the SAB advisory; and the timeline for the study.

The notes below capture and synthesize discussions that occurred over the remainder of the Committee meeting. The discussion below is aggregated by topic for clarity and it is not necessarily in chronological order as events transpired at the meeting.

a) **Study Goal and Objectives**: The study goal was taken from the Charge to the SAB. The final objectives will be refined by the planning group after the meeting. The following list is a result of initial committee discussions:

i) **Goal:**

The overarching goal of the study is to improve the integration of science in the decision making process. As stated in the existing charge, "…the Agency has requested that the Science Advisory Board undertake a study of how EPA can strengthen scientific assessment practices for environmental decision making…" Specifically the SABA was asked to "…evaluate the extent to which EPA's scientific assessment practices are integrated into environmental decision-making practices as previously recommended by the NRC and the SAB."

ii) **Objectives**:

The Committee developed a series of draft objectives that when pursued will allow it to respond to the charge. The first iteration of potential objectives identified the following possibilities:

1) Define and Determine the Extent of EPA's Integration Practice: The Committee should develop a definition for "integration" that will guide its evaluation of how EPA might practice integration of its science for and with policy-making.

2) Determine the Extent of EPA Integration Practices: Review the legislative and regulatory mandates that drive decision making and assess their impact on science integration.

   Identify the drivers for decision making – the signals for moving ahead with decisions.

   Describe the EPA process for use of science in decision-making (map).

   Examine communication between program offices during decision-making.

   Describe the (problem formulation?)l step that identifies the scope of the scientific analyses needed to support integrated decision-making.

   One approach to begin might be for the Committee to map and document science practices to the decision-making process. The Committee will need to be clear as to what we mean by "science" within the process. After the science components are identified, and fact-finding has determined EPA's practice for bringing it into decision-making, the Committee can evaluate the Agency's extent of science integration within decision-making. Recommendations for any needed enhancement of integration will follow.

3) Social Values in Decision-Making:

How are societal values determined and used in the decision-making process.

Describe the involvement of stakeholders in the integration of sciences in decision-making.

4) Types of Decisions – National Offices vs. Regional Offices

Contrast the role of scientific analyses in major program areas.

The Committee should identify the universe of decision types that it will consider in its fact-finding as well as how decision types vary between and among national and regional offices. What decision-making models are used for each type?

5) Impediments to the Greater Integration of Science for Decision-Making:

The Committee should identify and describe the barriers (things that might be changed) and constraints (things that probably can't be changed) to integrating science for decision-making.

Present and review recommendations from previous reports

Examine and present the perspectives o agency personnel, including managers (this may include discussions with former leaders).

Identify barriers to implementing past recommendations for science integration.

6) Workforce and Capacity for Integration:

Examine the science workforce, including the organization, infrastructure, and "management" of science at the Agency.

Does EPA have the capacity for integration? The science budget shows that workforce allocation is a primary driver of the direction of EPA science. Allocation determines their activities. We could determine who the scientists are in terms of education and expertise; how they are allocated across the Agency; what opportunities they have for collaboration and integration; and if there are incentives for collaboration (how hired, managed, awarded, trained, promoted, etc.). If incentives and opportunities for integration do not exist that could be perceived as an integration barrier.

7) Feedback Systems and Looking to the Future:

Describe the evaluation process used to determine the success of decisions in meeting the goals of the agency, and identify priorities for research to improve future decisions.

Feedback mechanisms are important to learning how to better implement integrated decision-making and to research planning that will develop knowledge for more complex decisions that need to be made. A major factor in this is science that not only forms the backbone of agency action and a source of lessons to improve future actions. Science is also the eyes and ears that EPA uses to detect emerging issues. Is the science enterprise leading innovation and knowledge development forward or is it only stressing the near term?

8) Advice Development:

Examine the mix of sciences necessary to support integrated environmental decision-making. This includes bench and social sciences, for example, toxicology, public health, behavioral sciences, ecology, and economics.

Describe an approach to "Clean Sheet Thinking" to integrate emerging science and overcome past barriers to innovation in the decision process.

b) **Teams and Report Structure**:

Teams: The Committee agreed to use five teams to conduct the fact-finding phase of this project. These Teams will be the lens through which the Committee works to structure its activity, and will not necessarily remain the same for evaluating lessons learned and/or for developing its report to the Administrator. Fact-finding Teams, along with the members include:

1) Pesticides, Toxics and Drinking Water
This group has a health focus on chemical and microbial issues.
(Members Include: Drs. Balbus, Bus, Cory-Slechta, Daniel, Fenner-Crisp, Giesy, Landis, Sayler, and Zeise)

2) Air Pollutants and Radiation
This group has a health and welfare focus.
(Members Include: Drs. Balbus, Daniel, Henderson, Theis, Lipoti, Kling, Shaw, and Johnson)

3) Biofuels and Sustainability
This group has a focus on broad sustainability issues including biofuels that have major sustainability implications.
(Members Include: Drs. Biddinger, Eighmy, Henderson, Shaw, Theis)

4) Water Quality and Critical Ecosystems
This group will mostly focus on Regional Office issues and water quality/ecosystem issues.
(Members Include: Drs. Biddinger, Giesy, Kling, Landis, Thompson, Wallsten)

5) Hazardous Waste and Land Restoration
This group has a restoration and protection focus for contaminated lands.
(Members Include: Drs. Biddinger, Bus, Eighmy, Johnson, Lipoti, Theis, Wallsten, Zeise)

Other perspectives that are cross-cutting and shared by all Teams, include risk assessment and other technical assessments. Members recognized the difference between national program office and Regional office activities and understand that this will need to be recognized in our fact-finding and report. Advice will be tailored to each perspective/mission.

We will need to specifically identify whom we will interview within and outside of EPA. A part of this will be to determine which groups will be interviewed and which will provide perspectives during later Committee meetings/workshop. Note that Dr. Vu suggested that fact-finding outside of EPA should be done during the stakeholder workshop as opposed to tailored interviews for targeted organizations. Potential interviewees could include:

- Representatives at the Assistant Administrator level
- Office Directors or their representatives
- Lead Persons and or Lab Directors in ORD for specific program areas
- Individuals in Program Offices who are heavily involved with policy development
- Spokespersons (DF?) for stakeholder groups and other advisory groups (NDWAC, Pesticide Policy Dialog Committee, etc.)
- Representatives of Regional Offices
- Those in states and other entities that implement policies
- Associations
- Other agencies (FDA, CDC)

Report Structure: The final objectives we agree upon will help to form the structure for our report (not the Team structure). A number of general considerations that will likely influence the structure and content of the Committee's report include:

1) As we work, we will need to consider what might constitute good recommendations and what type of follow up we'd like from the Agency. It will be important to consider what types of decisions science should influence (Regional, National) and whether there needs to be different recommendations for each level. We need to think of the short term and the long term.

2) We need to develop constructive and concrete recommendations and suggest how they might be implemented. The list should be small. We need to strike a balance between being too prescriptive and being too vague. Previous recommendations might not have been implemented because they were not clear. We could focus on a subset of the NRC and SAB recommendations and see if they were implemented and if not what the barriers were to implementation.

3) Once we develop some draft recommendations, we should get EPA reflections on them to see if they can be implemented. This clean slate view of our draft recommendations can tell us whether they should be in the final advice to EPA. We should also work with EPA afterwards to see if the recommendations have been enacted. Feedback might be via a public workshop and this workshop could be extended to get feedback from stakeholders as well.

4) We might think of metrics to use to determine how well EPA has implemented past recommendations for integration.

c) **Questions for Fact-Finding on the Objectives**:

Fact-finding should involve discussions with leading scientists at national and Regional levels, key managers, data systems personnel, the Office of the Science Advisor, and stakeholders. A planning group from this committee will work with SAB office staff to refine and finalize the following list of straw questions.

Several recommendations were made by the committee regarding use of the fact-finding questions:

1) A small group of EPA employees drawn from potential respondents should review the proposed fact finding questions to obtain their reaction and interpretation of the questions.

2) It should be clear how the committee will use the information gleaned from the questions (e.g. can specific responses be quoted, will responses be aggregated, etc.) Decisions on use of the responses should be part of a consent procedure.
3) It is recommended that those interviewed be asked to respond to questions with respect to specific decision or rulemaking processes that they have been involved in.

<u>List of straw fact-finding questions:</u>

1) What types of decisions are made in your office involving actions such as rules, policy statements, guidance, risk assessment, cost-benefit analysis, behavioral/social science assessments, etc.?

2) What models do you use for decision-making (e.g., EPA's Action Development Process, Framework for Integrated Environmental Decision-Making (SAB 2000), Science and Decisions (NAS 2009), logic models, other)?

3) Do the models used by your office contain problem formulation methodologies? If yes, what kinds of activities associated with planning and scoping, and problem formulation occur? Do you conduct preliminary assessments in problem formulation to compare risks and establish goals, and evaluate risk reduction options? What kinds of preliminary assessments are conducted?

4) Are there perceived or actual barriers for developing and/or implementing new or existing decision-making models that integrate the best available science? If yes, what are they?

5) How do you work within your own office, and other EPA Offices and Regions to coordinate the various decision support analyses needed?

6) What role do stakeholders, federal, state and tribal governments play in the decision-making process? If involvement occurs, how is this accomplished? At what steps of the process are stakeholders involved?

7) What types of science assessments are being done (e.g., technical, benefits, human health, ecological, behavioral/social, etc.)?
   - Who does the assessments (e.g., in-house, contractors)?
   - How are different disciplines integrated?
   - Are the social sciences and decision sciences integrated into the assessment process?
   - What are scientists' roles in the final decision-making process?
   - Is there Agency-wide, stakeholder, federal, state and tribal government involvement? If yes, how is this done?

8) How do you assess the level of analysis that is needed for science assessments, and when is the analysis judged to be "completed or adequate to move forward to decision making?

9) Do you conduct a formal analysis of uncertainty? How is the analysis matched to needs of decision makers?

10) How do you monitor environmental results after decisions are made? How is this information used to improve risk assessment and risk management processes?

11) What additional staff expertise is needed by EPA in fields such as social sciences, decision sciences, economics, human and ecological risk assessment, quantitative uncertainty analysis or other disciplinary areas to improve EPA's scientific assessments for decision making?

12) What improvements are needed to both existing science assessments and overall decision-making processes?

13) What perceived or actual barriers exist for improvement or change to existing practices?

14) Questions specific to EPA lab personnel:
Do lab personnel feel a part of how EPA improves knowledge so its mission is more effective, or are they just there to grind out tools and data (this is a major point of tension between research and program communities)?
Is research focused on helping client offices directly or is it done with moving science forward with little thought to near-term program needs?
Should all science be done with an immediate policy need in mind?
How do the activities of EPA scientists influence their rewards/promotions?).

15) Provide the respondents with a list of recent SAB and NAS recommendations. Ask if the respondents are familiar with any of the recommendations listed, and if so, did they affect their decisions. If they affected the decisions or rulemakings, in what ways?

<u>Member Comments on the Draft Questions and Associated Issues</u>:

1) A lengthy discussion on the questions considered how formal the survey and the "survey instrument" would need to be to ensure consistency in how interviews are conducted and to have meaningful comparability of responses across those groups interviewed. Even so,

members agreed that the "questionnaire" we develop should be tailored for specific groups that we interview. The level of formality and rigor in the fact-finding instrument and approach is not yet decided; however, the extremes of how much to do extend from considering the factors to pre-testing and final development of a formal survey instrument. The approach and instrument will be decided as we firm up the Committee's Plan.

The general approach might involve doing case studies that are intended to learn how specific groups translated science into analysis and decision-making for past actions. Our fact-finding can't be seen as inquisitions, rather they must be recognized as learning sessions that will inform our deliberations and discussions of what advice is appropriate for this issue. One thing we might explore in these sessions will be the notion of whether interviewed groups know of past SAB and NRC advice and how it has helped by influencing practices in specific offices. Having appropriate examples in mind as we do each interview would be important if we are to do this.

2) Some factors that influence processes are not transparent (e.g., communications, time limits).

3) A major constraint in implementation of greater integration of science for decision-making could be EPA's culture that seems to follow prescriptive regulations and does not look at the environment as a whole.

4) An interesting thing to learn would be what EPA thinks is science – do they consider social sciences as science? We often encourage EPA to conduct social science research, but it might be that EPA staff does not consider this as science.

5) It appears that there is a divergence in thinking about science. One notion is that we use emerging testing schemes such as omics to learn more about narrow issues that are components of specific health endpoints and the other is the use of systems biology to look at broader health outcomes/a larger view of health status. There is disagreement on whether this divergence is real. The key will likely be how new tox testing regimes are used. If the new systems are applied to the old way of thinking it will be a wrong application. There is a need for clean slate thinking so that the new systems can be applied in ways that will fit better into understanding health outcomes.

6) Diffusion of information to various parts of the agency is a part of the issue of whether EPA can take advice. This is a part of the culture of an organization. Our advice should be built with an awareness of the

literature on diffusion. Does EPA have a mechanism for diffusion of ideas or is this a barrier to integration?

7) EPA organization and structure may constrain the agency's ability to have the science converge on complex issues. There is a literature on organizational and managerial science that speaks to such issues. Our recommendations should be informed by our understanding of the agency structure and this body of information. Expertise on organizational and management might be a good addition to the Committee.

8) There are internal and external motivators of change in organizations. The SAB can be a source of external validation for EPA's movement into integrated science and by doing so help them to change. This is preferable to just assessing blame and point out Agency shortcomings.

9) A good mindset for us to have in preparing advice to EPA is to think of "why should they care about our advice? Dow uses 6-Sigma procedures to take learning from one area of practice and apply it to another. What we are about should attempt to be universally applicable so it can easily be seen to be useful in other places.

10) Mandates can be implemented either tightly or loosely – either approach can affect what processes are followed by the Agency. Also, older legislation tends to be broader and less prescriptive while newer ones tend to be narrower and more prescriptive reflecting Congress's dwindling trust in the Agency.

11) Does EPA engage in "clean sheet thinking" in order to improve on older ways of doing things? For instance, something to force the issue of early stakeholder interactions could reduce the negative reactions to assessment.

12) EPA seems to have a problem in cross-agency communications when it takes up complex issues. ORD has begun to plan integrated multidisciplinary research and this might be extended to all of EPA as a model. We might consider if they need advice on processes that could help them do problem formulation and get the right questions identified and the right people involved in the beginning. EPA has an example where this did occur when it responded to the new mandate in the Food Quality and Protection Act. To respond required that they pretty much turn their program upside down.

13) Determining whether past advice has been taken on integration may not be necessary. We could just say it has not and move on to identify ways in which integration advice could have been implemented.

14) It is possible that advice that has been given in the past, though sound, may not be practical and able to be implemented. Recommendations might be perceived as somewhat vague. Our advice should be pragmatic, clear, and focused. The questions must lead to information that allows this clarity and it might be helpful to provide a rationale that would tell EPA why it is its best interest to take the advice. We should build in feedback and discussions with EPA to see if our recommendations are clear and if they can be implemented.

15) What are the similarities and differences between Regional and National decision-making?

16) Much of EPA's process is carried out by contractors. They often have the expertise that EPA needs. EPA's rewards structure needs to reward change that advances EPA science and science integration.

17) It could be useful to see how EPA catalizes science for the future. What is the strategy for determining where science is converging? How do they proactively address these issues? This plays off of Dave Rejeski's comment at a recent meeting regarding science not just as the backbone of EPA decision making but also the eyes and ears of EPA so it can detect emerging issues.

d) **Tasks and Timeline**:

Windows of opportunity such as the one presented to this Committee do not remain open forever. We should target completion for not later than June 2010, though some members hoped that there might be more time available.

Tasks:

a. Committee meeting #1	June 9-10, 2009
-Develop Draft Committee Study Plan	"
-Straw Questions	"
-Objective Statements	"
b. Fact Finding	Oct-Nov 2009
c. Committee Meeting #2	Nov-Dec 2009
- Lessons learned from fact-finding	
- Workshop planning	
d. Workshop	March 2010
e. Develop a Public Draft of Advisor Report	
f. Chartered SAB Quality Review of Committee Report	
g. Publication of Report	

Planning Groups: Three planning groups were formed (these are not the fact-finding teams) that will assist in finalizing the objectives, fact-finding questions and planning for the fact-finding efforts.

Objectives Group	Questions Group	Planning and Information Gathering Group
Balbus Biddinger Thompson Bus	Wallsten Daniel Lipoti Theis	Cory-Slechta Johnson Landis Fenner-Crisp

9. Adjourn

The meeting was adjourned by the DFO.

Respectfully Submitted:

/ Signed /

Mr. Thomas Miller
DFO
SAB Committee on Science Integration
for Decision Making

Certified as True:

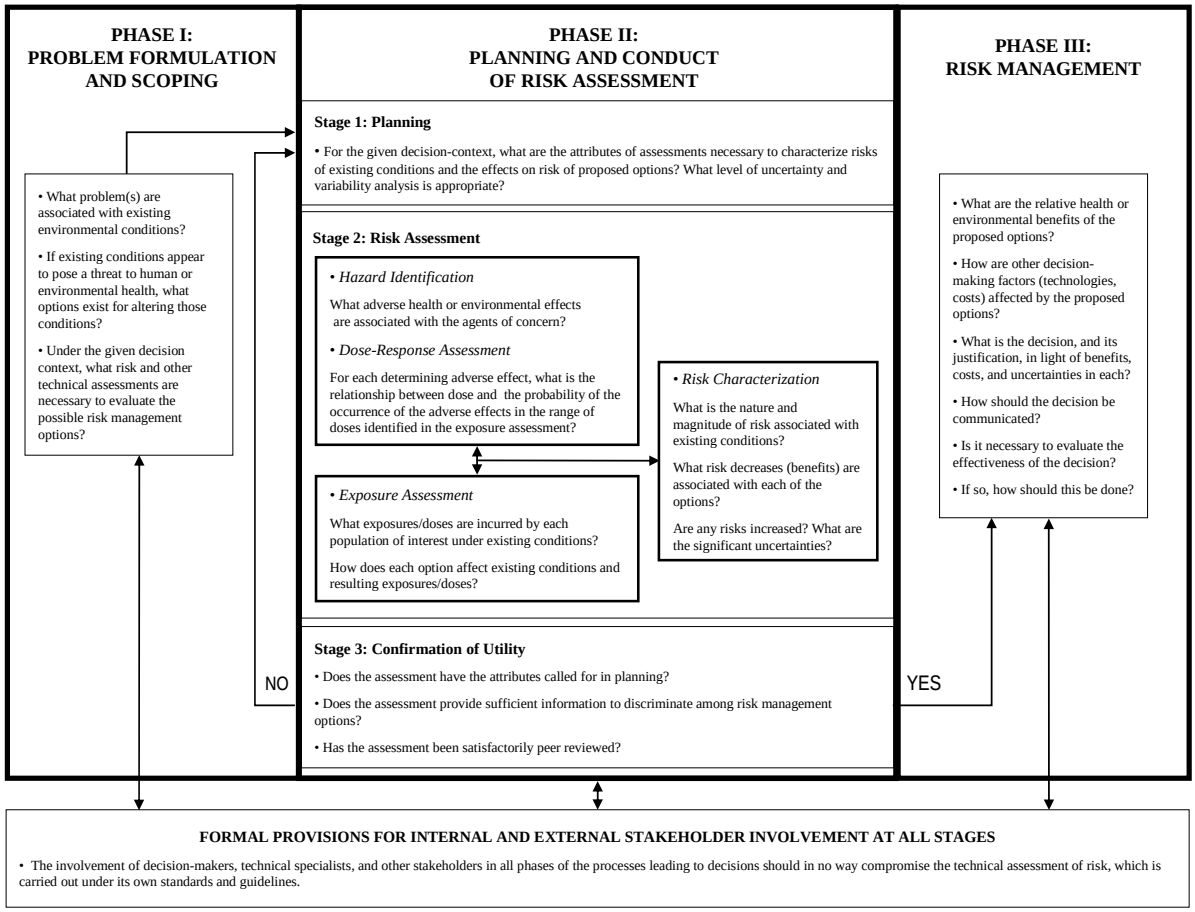
/ Signed /

Dr. Thomas A. Burke,
Chair
SAB Committee on Science Integration
for Decision Making

ATTACHMENTS & EXHIBITS

Exhibit 1:	NRC: A framework for risk-based decision-making that maximizes the utility of risk assessment.
Attachment A:	Committee Roster
Attachment B:	Agenda
Attachment C:	FR Notice
Attachment D:	Sign-in sheets (physical file only)
Attachment E:	*Science and Decisions: Advancing Risk Assessment*
Attachment F:	Dr. Burke's Presentation
Attachment G:	Charge
Attachment H:	Mr. Cristofaro's Presentation
Attachment I:	Dr. Meiburg's Presentation
Attachment J:	AWWA letter from Mr. Thomas Curtis to the Committee, June 1, 2009
Attachment K:	Papers from Mr. Roberson, AWWA

Exhibit 1. A framework for risk-based decision-making that maximizes the utility of risk assessment.



Attachments

Attachment A

U.S. Environmental Protection Agency
Science Advisory Board
Committee on Science Integration for Decision Making

June 9-10, 2009

CHAIR

Dr. Thomas Burke, Professor, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, , Baltimore, MD

MEMBERS

Dr. John Balbus, Adjunct Associate Professor, George Washington University, School of Public Health and Health Services, Washington , DC

Dr. Gregory Biddinger, Coordinator, Natural Land Management Programs, Toxicology and Environmental Sciences, ExxonMobil Biomedical Sciences, Inc., Houston, TX

Dr. James Bus, Director of External Technology, Toxicology and Environmental Research and Consulting, The Dow Chemical Company, Midland, MI

Dr. Deborah Cory-Slechta, Professor, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester , Rochester, NY

Dr. Terry Daniel, Professor of Psychology and Natural Resources, Department of Psychology, School of Natural Resources, University of Arizona, Tucson, AZ

Dr. T. Taylor Eighmy, Vice President for Research, Texas Tech University, Lubbock, TX.

Dr. Penelope Fenner-Crisp, Independent Consultant, North Garden, VA

Dr. John P. Giesy, Professor and Canada Research Chair, Veterinary Biomedical Sciences and Toxicology Centre, University of Saskatchewan, Saskatoon, Saskatchewan, Canada

Dr. Rogene Henderson, Senior Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. James H. Johnson, Professor and Dean, College of Engineering, Architecture & Computer Sciences, Howard University, Washington, DC

Dr. Catherine Kling, Professor, Department of Economics, Iowa State University, Ames, IA

Dr. Wayne Landis, Professor and Director, Department of Environmental Toxicology, Institute of Environmental Toxicology, Huxley College of the Environment , Western Washington University, Bellingham, WA

Dr. Jill Lipoti, Director, Division of Environmental Safety and Health, New Jersey Department of Environmental Protection, Trenton, NJ

Dr. Gary Sayler, Beaman Distinguished Professor, Joint Institute for Biological Sciences, Oak Ridge National Laboratory, University of Tennessee, Knoxville, TN

Dr. Bryan Shaw, Commissioner, Texas Commission on Environmental Quality, Austin, TX

Dr. Thomas L. Theis, Director, Institute for Environmental Science and Policy, University of Illinois at Chicago, Chicago, IL

Dr. Barton H. (Buzz) Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law at the Stanford Law School and Perry L. McCarty Director, Woods Institute for the Environment Director, Stanford University, Stanford, CA

Dr. Thomas S. Wallsten, Professor and Chair, Department of Psychology, University of Maryland, College Park, MD

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Miller, Designated Federal Officer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460, Phone: 202-343-9982, Fax: 202-233-0643, (miller.tom@epa.gov)

Dr. Thomas Armitage, Designated Federal Officer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C., Phone 202-343-9995, Fax: 202-233-0643, (armitage.thomas@epa.gov)

Ms. Kyndall Barry, Designated Federal Officer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460, Phone 202-343-9868, Fax: 202-233-0643, (barry.kyndall@epa.gov)

Ms. Elizabeth Resek, Designated Federal Officer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460, Phone: 202-343-9697, (resick.elizabeth@epa.gov)

Attachment B

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
Committee on Science Integration for Decision Making
Public Meeting, June 9 – 10, 2009
Ritz-Carlton Hotel, 1150 22nd Street, N.W.,
Washington, D.C. 20037

AGENDA

Tuesday, June 9, 2009

9:00 - 9:10 a.m.	**Meeting Convened by the Designated Federal Officer** Mr. Thomas Miller EPA Science Advisory Board Staff Office **Welcome** Dr. Vanessa Vu, Director EPA Science Advisory Board Staff Office
9:10 - 9:25 a.m.	**Introduction of Committee Mmbers** Dr. Thomas Burke, Chair
9:25 – 10:25 a.m.	**Purpose of the SAB Study on Science Integration for Decision Making** - Introductory remarks Dr. Thomas Burke, Chair - Discussion of the study purpose Dr. Thomas Burke, Chair and Committee
10:25 – 10:40 a.m.	**BREAK**
10:40 - 11:30 a.m.	**EPA's Action Development Process** Mr. Alexander Cristofaro, Director Office of Regulatory Policy and Management EPA Office of Policy, Economics, and Innovation
11:30 a.m. – 12:15 p.m.	**Scientific Assessments for EPA Decision Making - Program Office Perspective** Dr. Michael H. Shapiro, Acting Assistant Administrator EPA Office of Water

12:15 – 1:30 p.m.	**LUNCH**
1:30 – 2:15 p.m.	**Scientific Assessments for EPA Decision Making – Regional Perspective** Dr. A. Stanley Meiburg, Acting Regional Administrator EPA Region 4
2:15 – 2:30 p.m.	**Public Comments**
2:30 – 2:45 p.m.	**BREAK**
2:45 – 5:00 p.m.	**Development of Study Plan** Dr. Thomas Burke and Committee - Time line for completion of study - Information to be gathered from EPA Programs and the EPA Office of Research and Development - Interview questions for information gathering - Subgroup assignments
5:00 p.m.	**Recess for Day**

<u>Wednesday, June 10, 2009</u>

8:30 a.m.	**Reconvene**
8:30 – 10:00 a.m.	**Discussion of Draft Study Plan** Dr. Thomas Burke and Committee
10:00 – 10:15 a.m.	**BREAK**
10:15 - 11:30 a.m.	**Discussion of Draft Study Plan (continued)** Dr. Thomas Burke and Committee
11:30 a.m. – 12:00 p.m.	**Review Action Items** Dr. Thomas Burke
12:00 p.m.	**Adjourn**

QA Program''), EPA has approved voluntary laboratories that have demonstrated, and continue to demonstrate, proficient detection and enumeration of *Cryptosporidium* in surface water sources for public water systems. Approved laboratories that do not continue to meet the criteria for the Lab QA Program, including successful participation in tri-annual proficiency tests, may have their status downgraded to ''provisional'' or have their approval suspended.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 74.5 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Public and private water testing laboratories.

Estimated Number of Respondents: 65.

Frequency of Response: Annual.

Estimated Total Annual Hour Burden: 4,843.

Estimated Total Annual Cost: $411,729.40, includes $141,929.00 annualized capital or O&M costs.

Changes in the Estimates: There is an increase of 863 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. Changes in burden have occurred due to re-evaluation of hours for tasks, improved demonstration of capability and growth in the respondent universe. Inflation has increased all operation and maintenance and labor costs accordingly. EPA's original estimates for hours to participate and maintain the Lab QA Program were made before the program began. Because the program has matured and several years of QC data have been collected, the burden has changed for performing improved and refined procedures. The burden for some tasks has been estimated and will be re-evaluated as the program progresses.

Dated: May 12, 2009.

John Moses,

Director, Collection Strategies Division.

[FR Doc. E9–11520 Filed 5–15–09; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8906–3]

Science Advisory Board Staff Office; Notification of an Upcoming Meeting of the Science Advisory Board Committee on Science Integration for Decision Making

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a public meeting of the SAB Committee to develop a work plan for its study.

DATES: The meeting dates are Tuesday, June 9, 2009 from 9 a.m. to 5 p.m. through Wednesday, June 10, 2009 from 8:30 a.m. to 12 p.m. (Eastern Time).

ADDRESSES: The meeting will be held at the Ritz-Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information about this meeting must contact Mr. Thomas Miller, Designated Federal Officer (DFO). Mr. Miller may be contacted at the EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; or via telephone/voice mail; (202) 343–9982; fax (202) 233–0643; or e-mail at *miller.tom@epa.gov.* General information about the EPA SAB, as well as any updates concerning the meeting announced in this notice, may be found on the SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, 5 U.S.C., App. 2 (FACA), notice is hereby given that the SAB Committee on Science Integration for Decision Making will hold a public meeting to develop a work plan for its evaluative study on EPA scientific assessment practices for decision making. The SAB was established pursuant to 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under FACA. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: EPA uses many kinds of scientific assessments for policy analysis and decision making. Previous studies by the SAB and National Research Council (NRC) have recommended improvements to strengthen EPA scientific assessment practices for decision making. In its 2000 report, Toward Integrated Environmental Decision-Making (available on the SAB Web site at *http://www.epa.gov/sab*), the SAB found that an integrated approach to scientific assessment and decision making was needed to effectively address new and complex environmental problems. In its 2008 report, Science and Decisions: Advancing Risk Assessment (National Academies Press, Washington, DC), the NRC recommended improvements in EPA's risk assessment processes to address the complexities of current problems and potential decisions, and ensure that the best available options for managing risks are considered. The SAB is undertaking a new study at the request of the EPA Administrator to evaluate the extent to which scientific assessment practices are integrated into EPA's environmental decision-making processes. The study will build upon the findings of the previous SAB and NRC studies, and recommend actions that EPA could take to improve the integration of scientific assessments for decision making.

To conduct this new study, the SAB Staff Office formed the ad hoc SAB Committee on Science Integration for Decision Making. The Committee is comprised of members of the chartered SAB and its standing committees. The roster and biosketches of members of the Committee are posted on the SAB Web site at *http://www.epa.gov/sab.* The purpose of this meeting is to develop a plan for the new study.

Availability of Meeting Materials: The meeting agenda and other material in support of this meeting are posted on the SAB Web site at *http://www.epa.gov/sab.*

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information on the topic of this advisory activity, and/or the group conducting the activity, for the SAB to consider during the advisory process.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes per speaker, with no more than a total of one hour for all speakers. Interested parties should contact Mr. Miller, DFO, in

writing (preferably via e-mail) at the contact information noted above, by June 2, 2009 to be placed on a list of public speakers for the meeting.

Written Statements: Written statements should be received in the SAB Staff Office by June 2, 2009 so that the information may be made available to the SAB Panel members for their consideration. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format). Submitters are requested to provide two versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Miller at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: May 12, 2009.

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E9–11521 Filed 5–15–09; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget, Comments Requested

May 11, 2009.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before June 17, 2009. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to *Judith-B.Herman@fcc.gov,* Federal Communications Commission, or an e-mail to *PRA@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: None.

Title: Section 10.350, Testing Requirements for the Commercial Mobile Alert System (CMAS).

Form Number: N/A.

Type of Review: New collection.

Respondents: Businesses or other for-profit.

Number of Respondents and Responses: 146 respondents; 1,752 responses.

Estimated Time per Response: 0.00114155251 hours (2.5 seconds).

Frequency of Response: Monthly and on occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 154(i) and (o), 201, 303(r), 403 and 606 of the Communications Act of 1934, as amended, as well as by sections 602(a), (b), (c), (f), 603, 604 and 606 of the WARN Act.

Total Annual Burden: 2 hours.

Total Annual Cost: None

Privacy Act Impact Assessment: No impact.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: As required by the Warning, Alert, and Response Network (WARN) Act, Public Law 109–347, the Federal Communications Commission adopted final rules to establish a Commercial Mobile Alert System (CMAS), under which Commercial Mobile Service (CMS) providers may elect to transmit emergency alerts to the public, *see Second Report and Order and Further Notice of Proposed Rulemaking, FCC 08–164.* In order to ensure that the CMAS operates efficiently and effectively, the Commission will require participating CMS providers to receive required monthly test messages initiated by the Federal Alert Gateway Administrator, to test their infrastructure and internal CMAS delivery systems by distributing the monthly message to their CMAS coverage area, and to log the results of the tests. The Commission will also require periodic testing of the interface between the Federal Alert Gateway and each CMS Provider Gateway to ensure the availability and viability of both gateway functions. The CMS Provider Gateways must send an acknowledgement to the Federal Alert Gateway upon receipt of these interface test messages.

The Commission, the Federal Alert Gateway and participating CMS providers will use this information to ensure the continued functioning of the CMAS, thus complying with the WARN Act and the Commission's obligation to promote the safety of life and property through the use of wire and radio communication.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E9–11537 Filed 5–15–09; 8:45 am]

BILLING CODE 6712–01–P

Attachment E

***Science and Decisions – Advancing Risk Assessment*, NRC, 2009.**

http://www.nap.edu/catalog.php?record_id=12209

Attachment F

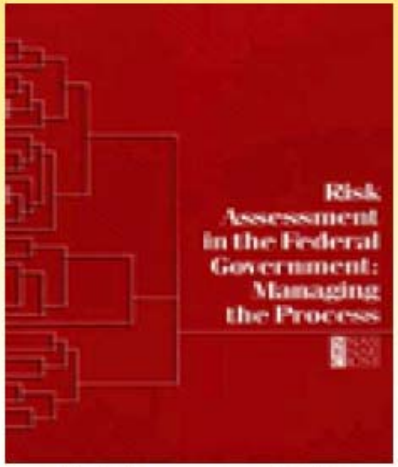
SAB Committee on Science Integration for Decision Making

EPA asked the SAB to "…undertake a study of how EPA can strengthen scientific assessment practices for environmental decision making" (EPA Letter, October 20, 2008).

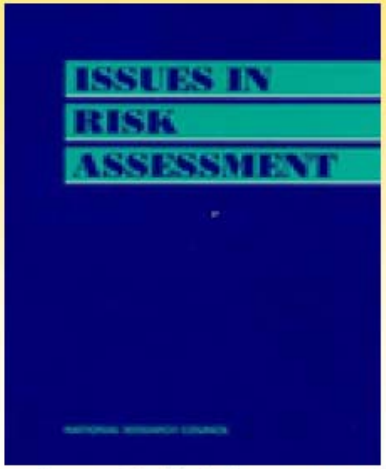
Previous SAB and NRC studies have found that improvements in EPA's risk assessment and decision making processes are needed to ensure that the **best and most relevant** information is available for use in decision making. This new SAB study will build upon findings and recommendations of these previous studies.

Previous Documents

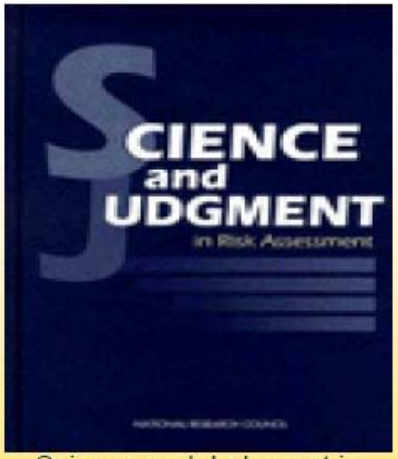
Risk and Decision Making: Perspectives and Research (1982)



Risk Assessment in the Federal Government: Managing the Process (1983)

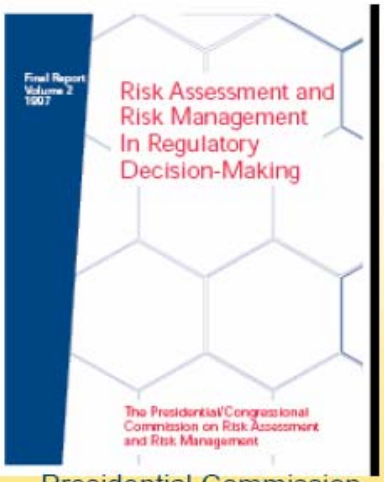


Issues in Risk Assessment (1993)



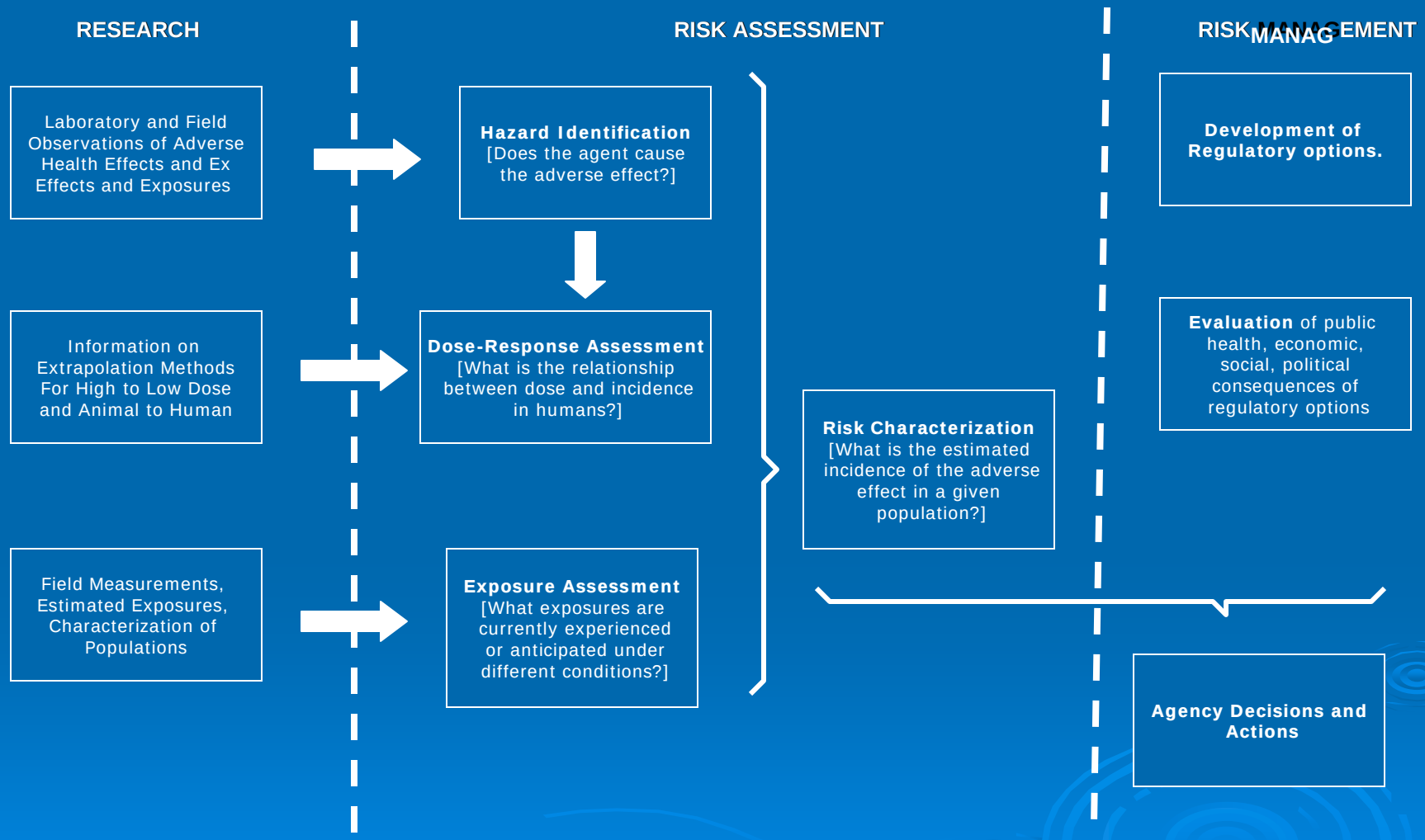
Science and Judgment in Risk Assessment (1994)

Presidential Commission Volume 1 (1997)



Presidential Commission Volume 2 (1997)

The Red Book (NRC, 1983)



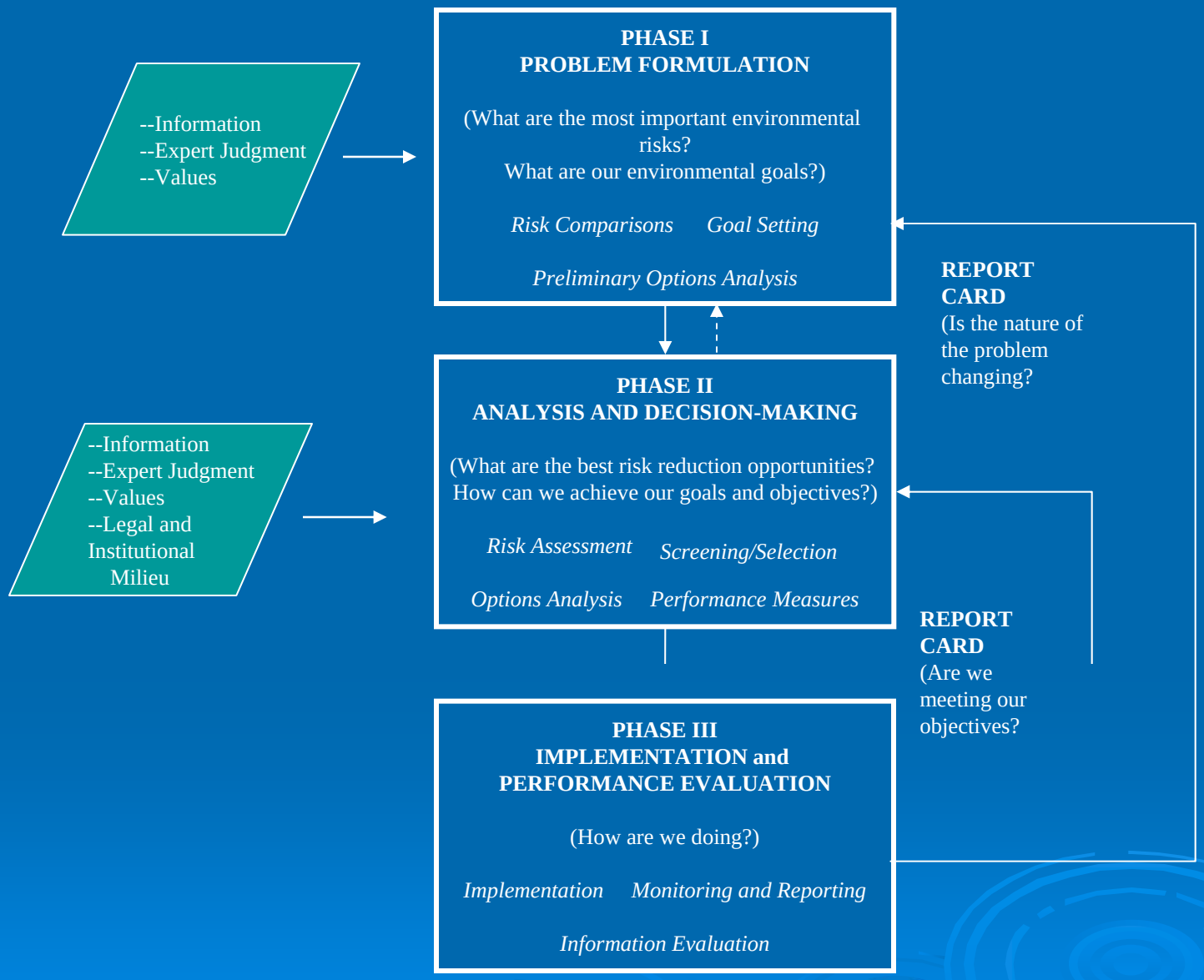


Figure 1. Framework for Integrated Environmental Decision-making (SAB, 2000)

Other Influences

- Comparative risk
- Eco Risk
- Microbial Risk
- Cumulative Risk

Understanding Risk

Problem formulation

The analytic-deliberative process leading to a risk characterization should include early and explicit attention to problem formulation; representation of the spectrum of interested and affected parties at this early state is imperative.

Criteria For An Effective Analytic-Deliberative Process
The Orange Book

- Getting the science right
- Getting the right science
- Getting the right participation
- Getting the participation right
- Developing an accurate, balanced, and informative synthesis

SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT

National Research Council
Committee on Improving Risk Analysis Approaches Used by EPA
Board on Environmental Studies and Toxicology

Social Sciences

PHASE I: PROBLEM FORMULATION AND SCOPING

- What problem(s) are associated with existing environmental conditions?
- If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
- Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?

PHASE II: PLANNING AND CONDUCT OF RISK ASSESSMENT

Stage 1: Planning

- For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?

Stage 2: Risk Assessment

- *Hazard Identification*

What adverse health or environmental effects are associated with the agents of concern?

- *Dose-Response Assessment*

For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?

- *Exposure Assessment*

What exposures/doses are incurred by each population of interest under existing conditions?

How does each option affect existing conditions and resulting exposures/doses?

- *Risk Characterization*

What is the nature and magnitude of risk associated with existing conditions?

What risk decreases (benefits) are associated with each of the options?

Are any risks increased? What are the significant uncertainties?

Stage 3: Confirmation of Utility

- Does the assessment have the attributes called for in planning?
- Does the assessment provide sufficient information to discriminate among risk management options?
- Has the assessment been satisfactorily peer reviewed?

NO

YES

PHASE III: RISK MANAGEMENT

- What are the relative health or environmental benefits of the proposed options?
- How are other decision-making factors (technologies, costs) affected by the proposed options?
- What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
- How should the decision be communicated?
- Is it necessary to evaluate the effectiveness of the decision?
- If so, how should this be done?

FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES

- The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

IMPROVING THE UTILITY OF RISK ASSESSMENT

- Committee proposes a framework for risk-based decision-making.
  - At core is risk assessment paradigm from 1983 Red Book
  - Differs from Red Book primarily in its initial and final steps

- Framework asks implicitly:
  - What *options* are there to reduce the *hazards* or *exposures* that have been identified, and
  - How can risk assessment be used to evaluate the merits of the various options?

IMPROVING THE UTILITY OF RISK ASSESSMENT

- Under this framework, the questions posed arise from
  - early and careful planning of the types of assessments (including risks, costs, and technical feasibility) and
  - the required level of scientific depth needed to evaluate the relative merits of the options being considered.

- Risk management
  - choosing among the options after the appropriate assessments have been undertaken and evaluated.

PHASE I: PROBLEM FORMULATION AND SCOPING

- What problem(s) are associated with existing environmental conditions?
- If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
- Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?

PHASE II: PLANNING AND CONDUCT OF RISK ASSESSMENT

Stage 1: Planning

- For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?

Stage 2: Risk Assessment

- *Hazard Identification*

What adverse health or environmental effects are associated with the agents of concern?

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For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?

- *Exposure Assessment*

What exposures/doses are incurred by each population of interest under existing conditions?

How does each option affect existing conditions and resulting exposures/doses?

- *Risk Characterization*

What is the nature and magnitude of risk associated with existing conditions?

What risk decreases (benefits) are associated with each of the options?

Are any risks increased? What are the significant uncertainties?

Stage 3: Confirmation of Utility

- Does the assessment have the attributes called for in planning?
- Does the assessment provide sufficient information to discriminate among risk management options?
- Has the assessment been satisfactorily peer reviewed?

NO

YES

PHASE III: RISK MANAGEMENT

- What are the relative health or environmental benefits of the proposed options?
- How are other decision-making factors (technologies, costs) affected by the proposed options?
- What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
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- If so, how should this be done?

FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES

- The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

IMPROVING THE UTILITY OF RISK ASSESSMENT

Phase I: Problem Formulation and Scoping

a. What is the problem to be investigated, and what is its source?

b. What are the possible opportunities for managing risks associated with the problem? Has a full array of possible options been considered, including legislative requirements?

c. What types of risk assessments and other technical and cost assessments are necessary to evaluate existing conditions and how the various risk-management options alter the conditions?

d. What impacts other than health and ecosystem threats will be considered?

e. How can the assessments be used to support decisions?

f. What is the required timeframe for completion of assessments?

g. What resources are needed to undertake the assessments?

Phase II
Planning and Conduct of Risk Assessment

Stage 1: Planning

- For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options?
- What level of uncertainty and variability analysis is appropriate?

Stage 2: Risk Assessment

Stage 3: Confirmation of the Utility

- Does the assessment have the attributes called for in planning?
- Does the assessment provide sufficient information to discriminate among risk-management options?
- Has the assessment been satisfactorily peer reviewed?

Phase III
Risk Management

- What are the relevant health or environmental benefits of the proposed risk-management options?
- How are other decision-making factors (technologies, costs) affected by the proposed options?
- What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
- How should the decision be communicated?
- Is it necessary to evaluate the effectiveness of the decision? If so, how should this be done?

IMPROVING THE UTILITY OF RISK ASSESSMENT

Recommendation

EPA adopt a framework for risk-based decision-making that embeds the Red Book risk assessment paradigm into a process with

- initial problem formulation and scoping,
- upfront identification of risk-management options, and
- use of risk assessment and other science assessment tools to discriminate among these options.

SAB Committee on Science Integration for Decision Making

The new SAB study will evaluate the extent to which EPA's scientific assessment practices are integrated into environmental decision-making practices as previously recommended by the by the NRC and the SAB. The study will focus on EPA's application of scientific assessments in environmental decisions concerning chemical and microbial pollutants.

The **SAB will identify barriers to implementing NRC and SAB recommendations** and **suggest** immediate and future actions that EPA could take to develop and institutionalize integrated environmental decision-making.

Areas of consideration may include scientific leadership, scientific practices, scientific collaboration across disciplines, and scientific expertise and workforce. The SAB may also make additional recommendations, beyond those previously provided by the NRC and SAB, to improve the integration of EPA's scientific assessments for decision making.

Attachment G

Improving EPA Scientific Assessment Practices for Decision Making

SAB Charge for a New Study

Effective human health and environmental protection requires a strong foundation of scientific knowledge and EPA therefore uses many kinds of scientific assessments for policy analysis and decision making. EPA decisions about managing risks to human health and the environment are supported by human health and ecological risk assessments, socioeconomic analyses, and other kinds of environmental assessments. Examples of such EPA decisions include determining permissible release levels of toxic chemicals, granting permits for hazardous waste treatment options, and selecting methods for remediating Superfund sites. To ensure that EPA's assessments use the best appropriate available science and meet the increasingly complex information needs of decision makers, the Agency has requested that the Science Advisory Board undertake a study of how EPA can strengthen scientific assessment practices for environmental decision making (attached memorandum from EPA Administrator to SAB Chair, October 20, 2008).

As discussed below, previous studies conducted by the Science Advisory Board (SAB) and the National Research Council (NRC) have found that improvements in EPA's risk assessment and decision making processes are needed to ensure that the best and most relevant information is available for use in decision making. This new SAB study will build upon findings and recommendations of these previous studies.

SAB Report, *Toward Integrated Decision-Making*

In the report, *Toward Integrated Environmental Decision-Making* (EPA Science Advisory Board, 2000) the SAB found that an integrated approach to decision making is needed to effectively address new and complex environmental problems. The SAB noted that such an integrated approach involves a holistic assessment of environmental problems that incorporates traditional human health and ecological science assessments, socioeconomic analyses, use of decision science tools, and methods for assessing cumulative risk. The SAB proposed that EPA adopt a three-phased approach to risk assessment and decision making. In phase I (problem formulation), EPA would conduct preliminary analyses to compare risks and establish goals, and also conduct preliminary analyses of risk reduction options. In phase II (analysis and decision making), EPA would conduct an in-depth analysis of risks and projected risk reduction under possible management scenarios. A preferred risk reduction option, or set of options, would then be selected based upon criteria such as feasibility, cost-effectiveness, seriousness of risks addressed, and equity. In phase III (implementation and performance evaluation), preferred management options would be implemented, and environmental results would be monitored and evaluated. Such monitoring would provide feedback needed to modify and adapt management approaches as necessary. The SAB suggested that the proposed framework would help EPA decision makers consider the trade-offs required to achieve multiple, often competing goals, and select appropriate risk management options.

SAB Advice on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making

In the report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board* (U.S. EPA Science Advisory Board, 2008), the SAB found that EPA could advance the practice of ecological risk assessment for use in decision making by developing new methods and tools to consider such issues such as temporal and spatial scale, biological complexity, and cumulative risk. The SAB also found that the practice of ecological risk assessment could be advanced by: 1) encouraging problem formulation dialogue between ecological risk managers, assessors, and stakeholders, and considering specific management alternatives during problem formulation; 2) linking specific testable hypotheses and questions to management information needs, data collection, and analysis; 3) aligning decision and supporting risk and economic analyses with "what matters to people" by increasing the understanding of and capacity to utilize ecosystem valuation methods in conjunction with decisions; 4) identifying uncertainties that may affect the quality of risk management decisions, and addressing uncertainty in a manner that allows trade-offs in risk management alternatives to be evaluated and communicated to the public; and 5) initiating post-decision audit programs to evaluate the environmental outcomes of risk-based decisions.

National Research Council Report, *Science and Decisions: Advancing Risk Assessment*

In the 2008 report, *Science and Decisions: Advancing Risk Assessment* (National Research Council, 2008) the NRC found that EPA needed a more coherent, consistent, and transparent risk assessment process to address the complexities of current problems and potential decisions, and ensure that the best available options for managing risks are considered. The NRC provided the following key recommendations to strengthen the risk assessment process.

- To improve the utility of risk assessments, EPA should adopt a three-phased framework for risk-based decision making. In phase I (enhanced problem formulation and scoping) available risk-management options would be identified. In phase II (planning and assessment) risk assessment tools would be used to determine risks under existing conditions and under potential risk management options. In phase III (risk management), risk and nonrisk information would be integrated to inform choices among options and make decisions.

- EPA should focus increased attention on the design of risk assessments (e.g., planning, scoping, and problem formulation) to ensure that assessments are more useful to and better accepted by decision makers. In this regard, the NRC recommended that risk assessments include a design stage that is more aggressively focused on informing decisions. The NRC specifically recommended more effective consideration of the potential for risk assessment processes to contribute to unintended consequences such as delays in risk-based decisions that may prolong exposure to risk, and divert attention

away from other important risks within EPA's mandate. In addition, the NRC recommended consideration of the potential for uninformed risk-risk substitutions.

- EPA should address a number of institutional and management issues in order to improve risk assessments. The issues include: 1) the need for proactive identification of studies and data that are most relevant to current risk assessment needs and effective communication of the need for such studies to the research community; 2) hiring needs for additional staff in fields such as epidemiology and quantitative uncertainty analysis important to improving EPA's scientific assessments, and ways to attract and retaining technical staff in these areas; 3) the need to establish and maintain risk assessment and decision-making training programs for scientists and managers responsible for risk assessment activities; 4) the need to expand EPA interoffice and interagency collaboration on risk assessments that support decision making and reduce the effects of compartmentalization resulting from EPA's organization around diverse statutory mandates; 5) the need to expand the scientific and decision-making core in the Agency's regional offices to ensure that they have the capacity to use improved risk-assessment methods to meet obligations for interaction with stakeholders, local agencies, and tribes; and 6) the need to effectively implement existing risk assessment guidelines, revise existing guidelines, and issue supplemental guidance as well as new guidelines.

- EPA should improve the characterization and communication of uncertainty and variability in all key computational steps of risk assessments. In this regard, the NRC recommended that EPA adopt a tiered approach for selecting the level of detail used in uncertainty and variability assessment.

Proposed New SAB Study

The new SAB study will evaluate the extent to which EPA's scientific assessment practices are integrated into environmental decision-making practices as previously recommended by the by the NRC and the SAB. The study will focus on EPA's application of scientific assessments in environmental decisions concerning chemical and microbial pollutants. The SAB will identify barriers to implementing NRC and SAB recommendations and suggest immediate and future actions that EPA could take to develop and institutionalize integrated environmental decision-making. Areas of consideration may include scientific leadership, scientific practices, scientific collaboration across disciplines, and scientific expertise and workforce. The SAB may also make additional recommendations, beyond those previously provided by the NRC and SAB, to improve the integration of EPA's scientific assessments for decision making.

To conduct this study, a new *Ad Hoc* Committee will be formed under the auspices of the SAB. The Committee will be comprised of selected members of the chartered SAB and Standing Committees. The Committee may be organized in subgroups to address different kinds of scientific assessments conducted by the EPA (e.g., human health risk assessments, ecological risk assessments), and/or different kinds of environmental decisions under various EPA programs. The Committee will be chaired by a member of the chartered SAB and supported by a team of SAB staff serving as Designated Federal Officers.

The Committee will hold an initial public meeting to develop a study plan. Subgroups of the Committee will hold informal discussions with EPA offices to conduct fact finding and gather background information as needed. The Committee will conduct a public workshop to seek input from EPA representatives, stakeholders, and interested members of the public and formulate its findings and recommendations. Following the workshop the Committee subgroups will prepare sections of the Committee's advisory report. The Committee will then hold a public meeting to discuss the subgroup findings and prepare its draft advisory report. The Committee's draft report will be then submitted to the chartered SAB for a quality review and approval at a public meeting.

Project Time Frame

Milestone Approximate Time to Complete Milestone

1. Development of the SAB Proposal…….. ……February - May, 2009

    - Approval of Proposed new SAB study
    - Formation of Committee

2. Development of Committee Study Plan ……June - July, 2009

3. Fact Finding and Planning for Public Workshop …….August – December, 2009

4. Conducting a Public Workshop…….January, 2010

5. Development of Public Draft of Advisory Report…….February - March, 2010

6. SAB Quality Review of the Committee Report……April - May, 2010

7. Publication of SAB Report……...June, 2010

References

National Research Council. 2008. *Science and Decisions: Advancing Risk Assessment.* National Academies Press, Washington D.C. [Available at: http://books.nap.edu/openbook.php?record_id=12209&page=R1]

U.S. EPA Science Advisory Board. 2000. *Toward Integrated Environmental Decision-making*. EPA-SAB-EC-00-011. U.S. EPA Science Advisory Board, Washington, D.C. [Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/D33811633594B9D78525719B00656478/$File/ecirp011.pdf]

U.S. EPA Science Advisory Board. 2007. *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board*. EPA-SAB-08-02. U.S. EPA Science Advisory Board, Washington, D.C. [Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/7140DC0E56EB148A8525737900043063/$File/sab-08-002.pdf]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 20 2008

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Request for a Science Advisory Board Study

TO: Dr. Deborah Swackhamer
Chair, Science Advisory Board

At the U.S. Environmental Protection Agency, sound decision-making depends on getting the best available science. During its 30-year history of advising EPA Administrators, the Science Advisory Board has emphasized the need for anticipating future environmental threats and investing in emerging research and science critical for informing decisions. As our understanding of complex environmental problems improves, integrated approaches for delivering the best science need to be developed and implemented.

The SAB's 2000 report *Toward Integrated Environmental Decision-Making* suggested an integrated decision-making framework for evaluating and responding to environmental problems. I ask that the SAB initiate a study that builds on its 2000 study to develop independent advice on how EPA can strengthen scientific assessments for decision making. The SAB might consider EPA's organizational structure and functions in light of how they influence the development and application of science assessments in different decision-making contexts. It would also be valuable for the SAB to recommend how to strengthen EPA's approaches for integrating traditional human health and ecological science assessments with socioeconomics analyses, decision sciences, and technology development and assessments to better support policy development. Finally, as EPA continues to plan for human capital needs, I would like the SAB to provide advice on ways to attract and retain the best diverse technical workforce.

Attached is a brief description of the proposed study. Please feel free to tailor the scope and depth of the study as appropriate. I ask the study be completed in a timely manner for the next EPA Administrator's consideration and implementation.

Stephen L. Johnson

Attachment

Effective human health and environmental protection requires a strong foundation of scientific knowledge. Scientific information often includes considerable uncertainty resulting in a diversity of scientific interpretations. The development and application of scientific knowledge in identifying potential threats, characterizing risks, formulating technological solutions, and evaluating the benefits and costs of U.S. Environmental Protection Agency actions are major science functions at EPA. The scope and depth of such science assessments greatly vary under different legislation and policies.

These functions are carried out by scientists, engineers, and economists with specialized program knowledge. They, in turn, rely on technical support by outside experts procured through Agency's interagency agreements or contracts. In addition, EPA's National Center for Environmental Assessment in the Office and Research Development develops technical assessments for EPA's Integrated Risk Information System which are used throughout the Agency. Summaries of the potential human health effects information that may result from exposure to chemicals in the environment, along with the supporting Toxicological Reviews, are made available electronically on IRIS for use by EPA, states, and tribal governments.

Over the years, reports from the National Research Council, the General Accountability Office, and other organizations point out that, while EPA has knowledgeable experts, the Agency's policies and regulations are too often perceived to lack a strong scientific foundation and EPA's science is of uneven quality. To address these issues, EPA established several science coordinating bodies. For instance:

- the Risk Assessment Forum consists of Agency senior scientists that develop Agency-wide technical guidelines for human health risk assessment, ecological risk assessment, and exposure assessment;
- the Science Policy Council develops Agency position papers on cross-cutting and emerging issues (e.g. peer review practices, data quality guidelines, genomics, nanotechnology); and
- the Council on Regulatory Environmental Modeling guides the development and use of environmental models.

Staff support for these coordinating bodies is now centralized in the newly created EPA Office of the Science Advisor. In addition to these groups, the National Regional Science Council promotes communication and collaboration of regional scientists to identify common regional needs.

Nonetheless, scientists, engineers, economists, and other technical professionals, by necessity, continue to be spread throughout the Agency and have limited opportunity to interact with their peers in other organizational units. Such segregation can result in duplication of effort as well as conflicting scientific approaches to the evaluation of similar environmental agents by different offices. While the Agency has tried to minimize such occurrences through its science and science policy coordinating bodies, existing coordination processes can be slow and tend to occur in the later phases of assessment development and approval. Furthermore, the environmental problems of today are more complex, often cross state and national boundaries, and require consideration of difficult trade-offs and integration of socioeconomic and technological solutions. EPA's existing science and science policy coordinating bodies primarily address immediate scientific needs of the Agency and may miss a longer-term strategic viewpoint.

Proposal

The SAB has provided scientific advice and recommendations to the Agency on a wide variety of scientific issues for more than 30 years. Because of the SAB's unique perspective, it would be of value for the SAB to evaluate the Agency's current organizational structures and functions concerning the development and application of science assessments in different EPA decision-making contexts. The evaluation would result in advice and recommendations on how the Agency might strengthen scientific assessments, communication of uncertainties of the assessments, and how the results are used. Areas for consideration may include: scientific leadership; consistent scientific practices; scientific collaboration within and between disciplines; and multi-disciplinary approaches for integrating natural science assessments with economic and social science assessments.

Attachment H
EPA's Regulatory Development

June, 2009

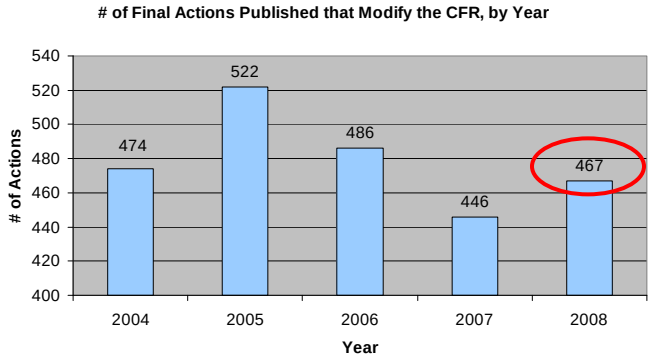
Briefing Outline

- Statistics on the volume of EPA's regulatory output
- The Action Development Process (ADP) at EPA

EPA's Regulatory Production

- Volume -

EPA is 2nd in volume of actions (16% of federal output)

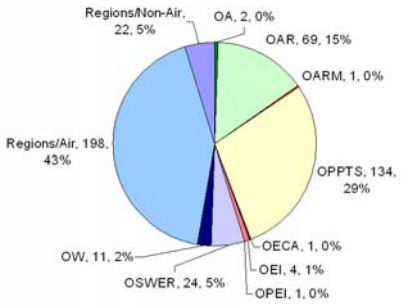


Includes actions such as State Implementation Plans (SIPs), pesticide tolerances, and other routine actions that are not signed by the EPA Administrator.

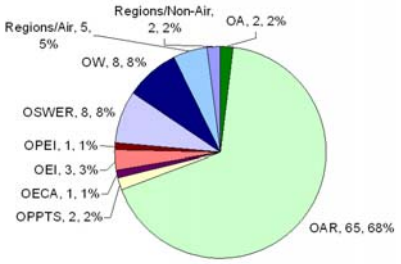
EPA's Regulatory Volume - continued

- A subset of actions receive Administrator signature and cross-agency review
- Largest volume from Air & Radiation (OAR)

2008 Final Actions that Modify the CFR, by Office
(Total: 467 actions)



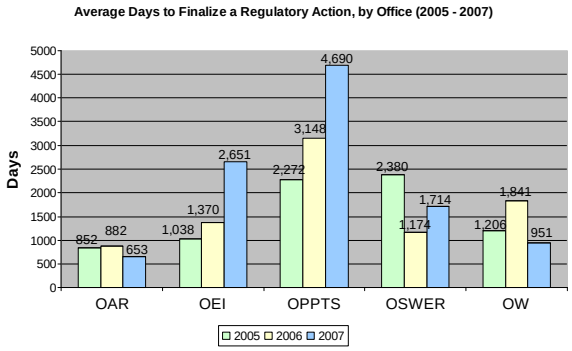
Subset Signed by the Administrator, by Office
(Total: 97 actions)



How long does it take to develop a rule?

- In 2007 – Average of 984 days to finalize actions (2.7 years)
- In 2006 – 1,084 days (3 years)
- Tier 1 & 3 actions move more quickly than Tier 2 actions

Includes only those actions signed by the Administrator. Each year includes actions finalized in that year.



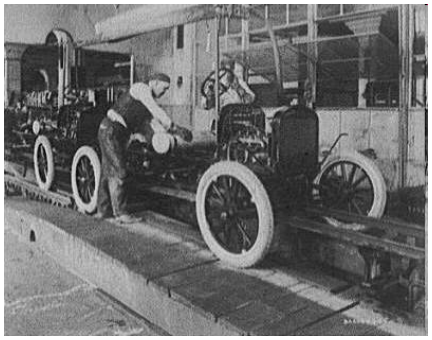
Estimates of the Total Annual Benefits & Costs of Major Federal Rules

October 1, 1996 – September 20, 2006 (billions of 2001 dollars)

	# of Rules	Benefits	Costs
EPA	40	$83.2 – 592.6	$32.2 – 35.1
Health/ Human Services	18	$20.6 – 32.9	$3.8 – 4.3
Transportation	15	$10.4 – 18.1	$5.0 – 8.8
Agriculture	6	$0.9 – 1.3	$1.0 – 1.4
Labor	6	$1.1 – 4.2	$0.4 – 0.5
Energy	5	$4.8 – 5.2	$3.0 – 3.1
Education	1	$0.6 – 0.8	$0.3 – 0.6
Housing / Urban Dev.	1	$0.2	$0.2
Justice	1	$0.3	$0.1
Total	**93**	**$122.2 – 655.6**	**$46.2 – 53.9**

Source: Office of Management and Budget. *Draft 2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, pg. 4. See: http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

The Action Development Process (ADP) – EPA's Production Line



Source: "Assembly." Detroit Publishing Company, 1923 May 7. Touring Turn-of-the-Century America: Photographs from the Detroit Publishing Company, 1880-1920, Library of Congress. See: http://www.americaslibrary.gov/jb/civil/jb_civil_ford_3_e.html

- Prioritize
- Plan
- Analyze
- Evaluate
- Decide
- Collaborate
- Communicate

The ADP

ADP for Tier 1 and Tier 2 Actions

prioritize

Commencement / Tiering

Primary decision-maker designated

Senior mgmt decides whether work may begin

plan

Analytic Blueprint / Early Guidance

The work plan; identify info needs

Senior mgmt decides direction for the action

analyze

Analysis / Consultation

Workgroup analyzes & consults on action as required by statutes and EOs

evaluate

Options Selection

Senior mgmt decides which option(s) to pursue

Drafting

Workgroup prepares a draft of the action and supporting documents

decide

Final Agency Review

Agency-wide review of final regulatory product

collaborate

OMB Review
(only "significant" actions)

If required, OMB and other relevant agencies review the action

Signature

Appropriate senior mgmt signs action

communicate

FR Publishing

Action published in the *Federal Register*

NOTE: Tier 3 Actions

These actions do not require: Analytic Blueprint; Cross-office Option Selection; Final Agency Review.

The ADP

- Commencement / Tiering -

prioritize

Commencement / Tiering

Primary decision-maker designated

Senior mgmt decides whether work may begin

- Regulatory Policy Officer (RPO) approves commencement
- OPEI manages the monthly tiering process
  - Tier 1: Administrator's Priorities
    - Active and ongoing involvement by AO
    - Complex, precedent-setting, controversial
    - Formal workgroup w/ core offices
  - Tier 2: Cross-Agency Actions
    - Need extensive cross-media or cross-Agency involvement
    - Formal workgroup w/ core offices
  - Tier 3: Lead Office Delegation
    - Actions of a technical nature or single media
    - No formal cross-Agency workgroup

The ADP

- Analytic Blueprint / Early Guidance -

plan

Analytic Blueprint / Early Guidance

The work plan

Senior mgmt decides direction for the action

- Outlines plans for:
  - Scientific analysis
  - Economic analysis
  - Legal analysis
  - Implementation, enforcement, & compliance analysis
  - Stakeholder outreach
- Gets workgroup members on the same page
- Solicits early guidance from senior management
- Sets work schedule

The ADP

- Analysis / Consultation -

analyze

Analysis / Consultation

Workgroup analyzes & consults on action as required by statutes and EOs

- Fills data gaps
- Seeks to understand stakeholder needs and concerns
- Develops options
  - Regulatory or voluntary approach?
  - Uniform standard or market-based approach?
  - Costs/benefits of each
  - Feasibility of each

The ADP

- Options Selection -

evaluate

Options Selection

Senior mgmt decides which option(s) to pursue

- Presents options to senior management from participating offices
- Managers may:
  - Select an option presented
  - Request additional analysis or data
  - Ask for additional options

The ADP

- Final Agency Review (FAR) -

decide

Final Agency Review

Agency-wide review of final regulatory product

- Final Agency-wide review of regulatory package:
  - Preamble, including statutory and executive order assessments
  - Regulatory text
  - Supporting analytic/technical documents (e.g., economic analysis)
  - Communication materials
- Meeting is chaired by OPEI
- Each participating office gives their position in writing:
  - Concur
  - Concur with comments
  - Non-concur

The ADP

- Signature & Publication -

Signature

Appropriate senior mgmt signs action

communicate

FR Publishing

Action published in the *Federal Register*

- Each stage of an action is typically considered complete when the Administrator (or delegate) signs it
- Once signed, the action is published in the *Federal Register*
- Other communication methods, as well:
  - Press release
  - Web posting
  - *Regulatory Agenda*
  - …future online tools…

Attachment I

Science Integration in EPA Decision-Making: A Regional Perspective

Presentation to the Science Advisory Board, June 9, 2009

A. Stanley Meiburg, Ph.D.
Acting Regional Administrator
EPA Region 4

My Background

- Joined EPA in 1977
- Headquarters: DC, RTP – 13 years
- Regions: R6, R4 – 16 years
- National EPA Liaison to CDC – 2 years

Kinds of Decisions Regions Make

- Permits: Air, Water, RCRA
- State air implementation plans
- Superfund cleanups
  - Site selection
  - Site cleanups
    - Removals vs. Remedial Actions
- Enforcement
  - Priority areas
  - Specific actions
- Community and Ecosystem Evaluations
- Grants
- State Oversight

Characteristics of These Decisions

- Specific costs, generalized benefits
- Weigh, at least implicitly, costs and benefits
- Have a particular legal/regulatory framework
- Time constrained
- Depend on specialized expertise
- Rarely are purely "technical"
  - Time, quality, acceptability
  - Credentialed expertise may not receive deference

The Four Letter Word

S A F E

What Makes Decisions Easier?

- Clear decision rules (bright line national standards)
- Robust environmental and health information
- Consensus on the problem
- Short term health/ecological effects
- Clear attribution
- Respected/trusted civic leadership

What Makes Decisions Harder?

- Ambiguous decision rules
  - E.g., narrative water quality standards
- Incomplete environmental or health information
- Disagreement on the problem
- Chronic health or ecological effects whose causation is at best ambiguous
- In the face of this, public expectation of direct causal relationships
- Civic leadership which the community does not accept

These circumstances are far more common!

Current Region 4 Examples

- TVA Kingston Ash Release, TN
- PFOA Contamination, AL
- PCS Phosphate Mine, NC

And one special past case:

- Danbury, CT Anthrax

What Would Help?

- Expedited Decisions on Numeric Standards
- Reasonable Temporal Stability
  - Five year reviews: too soon?
- Expanded Support for Field Assessments
  - Ecological and health
- Expanded Support for Risk Communication and External Involvement
- Tools that Explicitly Display Judgments on Risk Management Decisions

Thank You!

Questions?

American Water Works Association

The Authoritative Resource on Safe Water SM

Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005
T 202.628.8303
F 202.628.2846
www.awwa.org

Headquarters Office
6666 W. Quincy Avenue
Denver CO 80235
T 303.794.7711
F 303.347.0804

June 1, 2009

Mr. Thomas Miller
US Environmental Protection Agency Science Advisory Board
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Comments to the Science Advisory Board Committee on Science Integration for Decision Making

Dear Mr. Miller:

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 60,000-plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water.

AWWA and its member utilities are dedicated to providing safe drinking water to the American public, and the drinking water community recognizes the importance of setting health-based standards that are balanced against the need to keep drinking water affordable. How science is used in the decision making process for drinking water regulations is critical for the Environmental Protection Agency's (EPA) Office of Groundwater and Drinking Water (OGWDW), for drinking water utilities, and ultimately for the consumers. AWWA commends the Science Advisory Board (SAB) for forming this committee to provide recommendations to EPA on improving the integration of scientific assessments into regulatory decision making.

For many years, AWWA has been carefully reviewing Economic Analyses (EAs) that are critical in developing numerical standards issued by EPA under the Safe Drinking Water Act (SDWA). We have extensively described many significant scientific, technical, and cost-benefit issues in our lengthy comments on EPA's proposals for radon, radionuclides, arsenic, the groundwater rule, and the multiple rules known as the Microbial/Disinfection By-Product (M/DBP) Cluster. These issues include the underlying risk assessment, the occurrence profiles, and the Technology & Cost (T&C) documents that are ultimately combined into an EA for each drinking water regulation.

In the course of our review of EPA's EAs over the past several years, AWWA has consistently commented on several shortcomings, concerns, and other issues that are summarized below:

- Lack of transparency, replicability, and consistency. In several instances, it is difficult or impossible to follow or replicate the Agency's analyses. Key citations are not always made available (or refer back to other documents until the trail ends short of the key facts). Results from intermediate steps are not always provided, so it is impossible to "put the pieces together" to determine the source of numerical discrepancies. The General Accounting Office (GAO) faced similar difficulties in its 2002 review of the radon regulation (GAO, 2002). This means that in certain instances the public must accept the EPA estimates on faith. This is at odds with sound practice, and also does not conform to the SDWA requirement for public information [Section 1412(b)(3)(B)].

  The Obama Administration is committed to creating an unprecedented level of transparency and openness in the federal government as detailed in the January 26th *Federal Register* (74 FR 4685). President Obama wants the government to be transparent, participatory, and collaborative, and this is not always been the case in the development of past drinking water regulations.

  There also has sometimes been a lack of consistency among studies in terms of data, methods, or assumptions applied. Inconsistency would not be a problem if the changes over time reflected a steady evolution toward improved methods and data. Regrettably, this is not the case for the EAs coming out of EPA's Office of Groundwater and Drinking Water (OGWDW).

- Reliance on overly conservative assumptions and default values when estimating risks and benefits. In the face of uncertainty, risk assessors traditionally apply the precautionary assumptions in determining what exposure levels are "safe." This is done through use of uncertainty factors, reliance on upper confidence limits and a linear dose-response model for carcinogens, and the application of other practices that are intentionally designed to avoid understating risk. The use of such precautionary assumptions is perhaps suitable in defining a risk-free goal such as a Maximum Contaminant Level Goal (MCLG). For setting risk-cost balancing enforceable standards and other risk management purposes, however, it is inappropriate for risk estimated and associated benefit-cost assessments to include such conservative policy judgments.

  For its EAs, EPA should provide unbiased, central tendency estimates of risk that are in turn suitable for risk *management* in standard setting. Otherwise, the risk assessments will lead to a considerable overstatement of benefits. The degree to which benefits (if any at all) are overestimated will vary considerably from contaminant to contaminant, depending on many factors. The General Accounting Office (GAO) nicely summarized these issues surrounding regulatory and other policy decisions that are not always based on the best (most accurate) science information available (i.e., the most likely or central tendency estimates of risks and benefits) (GAO, 2000).

Additionally, benefits analyses need to reflect "best estimates" (or suitable probability distributions) for key exposure, dose-response, latency period, and benefits valuation issues. This is not only sound economics and policy analysis, but it also is required under the SDWA [Section 1412 (b) (3) (B)]. AWWA and other drinking water associations have repeatedly made such recommendations in comments on EPA's recent drinking water proposals. Unfortunately, EPA appears to be hesitant to incorporate these recommendations in its EAs for drinking water regulations.

- Reliance on national *incremental* comparisons of benefits to costs. EPA has started to show national incremental costs and benefits in its EAs, along with the traditional comparison of total benefits to total costs in evaluating MCL options. This is a significant step forward in meeting the requirements of SDWA Section 1412 by comparing incremental benefits to incremental costs and maximizing net social benefits. A comparison of total benefits and costs for all drinking water regulations by each individual system size is needed, as opposed to incremental benefits and costs that indicate only whether or not a single rule is a break-even proposition. This is an insufficient basis for choosing how stringently to set the standard.

  EPA has improved its portrayal of the incremental costs and benefits for each of its community water system size categories. Small systems in particular feel the increasing impacts of compounding regulations such as the disinfection by-products (DBP) rules, the arsenic rule, and the groundwater rule.

- Reluctance to use "state of the art" measures of risk reduction benefits, such as "Life Years Saved" (LYS) or other alternative measures. Reduced risks of premature fatalities need to be viewed in the context of the amount of increased longevity (years of life extension) provided by a regulation. This provides a more meaningful way to interpret regulations, some of which may reduce premature fatalities early in life, and others that are aimed more at risks faced late in life. EPA's OGWDW has steadfastly adhered to the more generic, less informative "lives saved" approach, even though other EPA offices (e.g., for Clean Air Act analysis) and other federal agencies (e.g., FDA) have published more informative EAs using the LYS approach.

  EPA claims it has not used LYS in drinking water regulations because the Science Advisory Board (SAB) once raised some concerns with valuing LYS on the basis of adjusting estimates of the Value of a Statistical Life (VSL). Nonetheless, even if there are concerns about developing a monetary estimate of the value of a statistical life year (VSLY), this is no basis for refusing to at least quantify the degree of life extension provided by regulatory options developed under the SDWA regulatory program.

- Lack of more systematic approaches for considering unquantified benefits and costs within standard setting. In some instances, important benefits or costs may not be readily quantified or portrayed in dollar value terms. In these instances, the unquantified or omitted benefits and costs need to be suitably considered in the regulatory decision-making process -- they should neither be ignored nor given undue weight. Again, EPA's SAB recommended that EPA take a harder look at unquantified benefits in its review of the benefits of the arsenic

rule (August 2001). EPA's EAs for drinking water standards have sometimes failed to use available information on unquantified outcomes in an informative manner, despite examples being provided to the Agency by AWWA and others.

If you have any questions about these comments, please feel free to call Alan Roberson or me in our Washington Office at 202-628-8303.

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

cc: Cynthia Dougherty—USEPA OGWDW
Pam Barr—USEPA OGWDW

BY J. ALAN ROBERSON

Complexities of the new drinking water regulations—everything you wanted to know but were afraid to ask

UPCOMING DRINKING WATER REGULATIONS MAY POSE A SIGNIFICANT COMPLIANCE CHALLENGE TO UTILITIES.

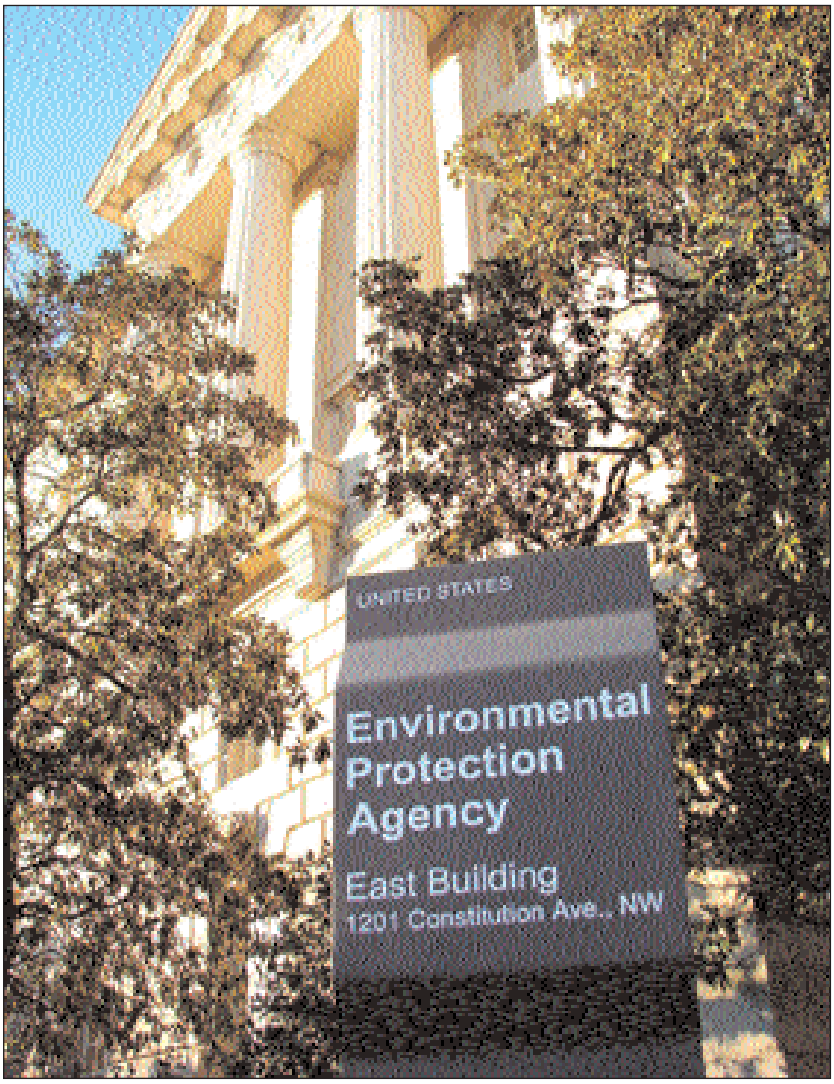
The US Environmental Protection Agency (USEPA) establishes national drinking water regulations under the Safe Drinking Water Act (SDWA). All states, with the exception of Wyoming, act as primacy agencies and are responsible for implementing these regulations by adopting their own regulations that are at least as strict as the federal laws. USEPA directly implements the drinking water programs in Wyoming, the District of Columbia, and the US territories.

The SDWA was initially passed in 1974 and reauthorized in 1986 and 1996 (Pontius, 1997). The initial act and each subsequent reauthorization of the SDWA detailed the process for the establishment of national drinking water regulations and set deadlines for many of these regulations.

"OLD" AND "NEW" REGULATIONS DIFFER IN COMPLEXITY

Nine major water-related regulations enacted in the period 1975–92. Prior to the most recent SDWA amendments in 1996, USEPA had finalized the following regulations:

- National Interim Primary Drinking Water Regulations (NIPDWRs) (USEPA, 1975)
- Total Trihalomethanes (TTHMs) Rule (USEPA, 1979)
- Fluoride Rule (USEPA, 1986)
- Phase I Volatile Organic Compounds Rule (USEPA, 1987)
- Surface Water Treatment Rule (SWTR) (USEPA, 1989a)
- Total Coliform Rule (TCR) (USEPA, 1989b)
- Phase II Rule (USEPA, 1991a)



The US Environmental Protection Agency directly implements drinking water programs in Wyoming, the District of Columbia, and the US territories.

- Lead and Copper Rule (LCR) (USEPA, 1991b)
- Phase V Rule (USEPA, 1992)

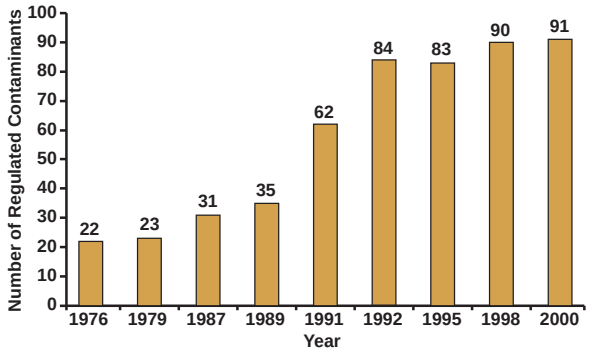
Nine regulations were finalized over a 17-year time frame, starting with the NIPDWRs in 1975 and finishing with the Phase V Rule in 1992. The number of regulated contaminants began with 22 with the NIPDWRs in 1975 and increased to 84 with the Phase V Rule in 1992. No new drinking water regulations were finalized between 1992 and 1998; this gap in regulatory activity was attributable primarily to USEPA waiting for the results of the 1996 SDWA amendments for its regulatory priorities and regulatory deadlines. Additional regulatory actions between 1998 and today (discussed later) increased the number of currently regulated contaminants to 91. Figure 1 tracks the increase in the number of regulated contaminants year by year.

Although these nine regulations significantly increased the number of regulated contaminants, most of these laws simply established maximum contaminant levels (MCLs) for specific contaminants. From a water utility perspective, MCL-based regulations were relatively easy to understand. Even with the large number of regulated contaminants and corresponding MCLs, most utilities had little problem complying with these standards (discussed in detail later). The appropriate sampling and analyses were conducted, and compliance was easy to determine by comparing laboratory results with the MCLs. For example, atrazine, a commonly used agricultural herbicide, was regulated under the Phase II Rule in 1991. To determine compliance with the atrazine MCL, a utility would take four quarterly samples, average these samples, and compare the average with the MCL of 3 µg/L.

For utilities, the TCR, SWTR, and LCR constituted their first experiences with regulations that were treatment technique–based and inherently more complex. These laws regulated only eight contaminants but posed more compliance problems. Finalized in 1989, the TCR and SWTR used treatment techniques for protection against microbial contamination, both through the treatment plant and throughout the distribution system. USEPA used this more complex regulatory approach because of the lack of reliable and readily available analytical techniques for some of the regulated microbial contaminants such as *Giardia lamblia*

From a water utility perspective, the regulations based on maximum contaminant levels were relatively easy to understand.

FIGURE 1 Number of regulated contaminants by year



and viruses. The TCR monitoring and reporting requirements proved particularly problematic for utilities.

Finalized in 1991, the LCR (USEPA, 1991b) was utilities' second experience with a more complex regulation that used a treatment technique regulatory approach. Again, USEPA instituted this regulatory approach because of the potential for lead and copper concentrations to increase within interior plumbing lines, which were not owned by the utility. Utilities were required to determine appropriate monitoring locations within the distribution system and then work with homeowners to obtain "first flush" samples. The 90th percentile of these samples was determined and compared against the lead and copper action levels (ALs). If the 90th percentile was below the AL, then the existing corrosion control practices were assumed to be adequate. If the 90th percentile was above the AL, then the utility was required to take several steps to optimize its corrosion control and, if needed, develop a program to replace lead service lines in the distribution system over several years. During LCR implementation, utilities struggled with issues ranging from soliciting homeowners' cooperation in taking samples year after year to understanding the complexities of corrosion control chemistry.

Ten regulations have been or will be passed. USEPA recently finalized and is in the process of finalizing several "new" drinking water regulations resulting from the 1996 SDWA amendments. Over the next decade, these regulations will significantly affect all drinking water utilities, both surface water and groundwater. Very few, if any, utilities will escape the effects of these regulations. The sheer number of the regulations alone would be a challenge for compliance. These "new" regulations are as follows:

- Stage 1 Disinfectants/Disinfection By-products Rule (D/DBPR) (USEPA, 1998a)
- Interim Enhanced Surface Water Treatment Rule (IESWTR) (USEPA, 1998b)
- Radionuclides Rule (USEPA, 2000a)
- Arsenic Rule (USEPA, 2001a)
- Filter Backwash Recycling Rule (FBRR) (USEPA, 2001b)
- Long-term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) (USEPA, 2002a)
- Ground Water Rule (GWR)—to be finalized in 2003
- Radon Rule—to be finalized in 2003
- Stage 2 DBPR—to be finalized in 2004
- Long-term 2 ESWTR (LT2ESWTR)—to be finalized in 2004

Whereas the 9 "old" regulations were finalized over 17 years (1975–92), 10 "new" regulations are being finalized over a time span of 6 years (1998–2004), an unprecedented level of regulatory activity. Additionally, the author believes that these latest regulations are, and will be, much more complex than the older regulations. The six regulations finalized since the Phase V regulation in 1992 have only increased the number of regulated contaminants from 84 to 91. The future new regulations will likely increase the number of regulated contaminants by only 1 to 92, with a new MCL for radon. Most of these recent regulations are either a treatment technique–based regulation or a mixture of treatment techniques and MCLs. Many of these new regulations, such as the Stage 2 DBPR and the LT2ESWTR, will require utilities to perform significant additional monitoring prior to making a decision about potential treatment and/or operational changes to comply with the future regulations. Some regulations, such as the FBRR, require treatment studies and consultation with the primacy agency as part of the compliance process. Under the GWR, water providers will likely require significant consultation with the primacy agency in order to understand the decision to require disinfection (or not), based on the results of the hydrogeologic assessment and the interpretation of monitoring results.

Over the next decade, these regulations will significantly affect all drinking water utilities, both surface water and groundwater.

COMPLEXITY GROWS AS REGULATIONS PROLIFERATE

Data system tracks compliance. USEPA tracks compliance with federal drinking water regulations with the Safe Drinking Water Information System/Federal (SDWIS/FED). The primacy agencies track the compliance of each regulated water system using their own data management system and transfer the appropriate

data into SDWIS/FED. USEPA compiles the state data into national compliance statistics and posts these statistics on the Office of Ground Water and Drinking Water (OGWDW) website. The national compliance statistics are used to track internal USEPA goals established under the Government Performance and Results Act.

Violation categories on the rise. Violation codes have been established in SDWIS/FED to track compliance. The violation codes are categorized as MCL, treatment technique (TT), monitoring/reporting (M/R), and other. The "other" category is used to track compliance for public notification, variances and exemptions, recordkeeping, operations reports, sanitary surveys (required under the TCR), and Consumer Confidence Reports.

The total number of violation codes is relatively small for the older, MCL-based regulations. Four violation codes are used for these regulations—two MCL violations codes (single sample and average) and two M/R violation codes (regular and check/repeat/confirmation).

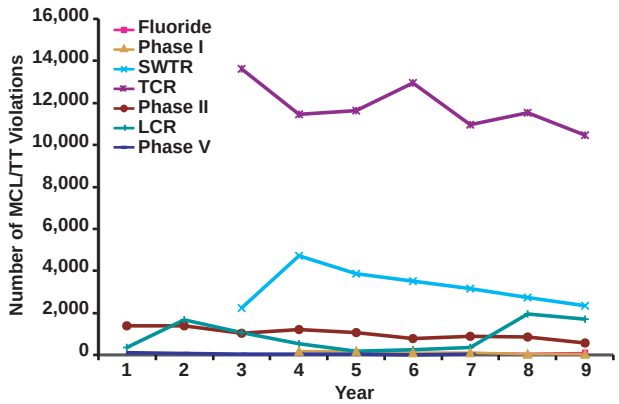
The number of violation codes for the older treatment technique–based regulations (e.g., the TCR, SWTR, and LCR) indicates the start of the trend toward the increasing complexity of compliance. The TCR and SWTR have a total of ten violation codes; two are MCL violation codes, two are TT violation codes, and six are M/R violation codes. The LCR, with its water quality parameter monitoring, source water treatment, optimized corrosion control, lead service line replacement, and public education requirements, takes this complexity a step further with 15 violation codes. Nine are treatment technique violation codes, and six are M/R violation codes.

With the Stage 1 Disinfectants/DBPR, IESWTR, and LT1ESWTR, the complexity of compliance reaches a new level. Four new MCLs have been established. A new violation category—maximum residual disinfectant level (MRDL)—has been established, with four new violation codes. Treatment techniques have been established for DBP precursor removal and turbidity. Disinfection profiling and benchmarking are also required. Between them, these two rules establish 26 violation codes (Siegel, 2002). Four are MCL violation codes, three are MRDL violation codes, six are TT violation codes, and thirteen are M/R violation codes. Utilities will have to maintain vigilance to ensure that they do not trip up on any of these violation codes and fall out of compliance. Table 1 summarizes the increases in violation codes attributable to the increasing complexity of the regulations.

Proposed rules only add to complexity. Depending on how the final rules turn out, the Radon Rule and GWR may or may not continue this trend toward increasing complexity. The complexities of the proposed radon regulation involve the multimedia mitigation (MMM) program and alternative MCL (AMCL) allowed under the radon provisions of the 1996 SDWA amendments (USEPA, 1999). If the final rule is enacted as proposed, states (or utilities if the states opt out of the MMM programs) can establish MMM programs to lower radon risks in indoor air and establish an AMCL (4,000 piC/L in the proposal) for utilities. This MMM regulatory approach would replace traditional compliance with the proposed MCL of 300 piC/L. States and utilities will be breaking new ground in establishing and maintaining these MMM programs, and it will not be a simple process.

The proposed GWR would also contribute to the growing challenge of compliance (USEPA, 2000b). The proposal would require the states to conduct hydrogeologic assessments and analyze well construction data and microbial monitoring data to determine vulnerability of the wells. Utilities will have to assist the states in compiling this information, and states will be challenged to integrate and assess the information. It is not clear at this time whether the final rule will be enacted as proposed or will be simplified.

FIGURE 2 Normalized compliance data



MCL—maximum contaminant level, TT—treatment technique, SWTR—Surface Water Treatment Rule, TCR—Total Coliform Rule, LCR—Lead and Copper Rule

Whereas the 9 "old" regulations were finalized over 17 years (1975–1992), 10 "new" regulations are being finalized over a time span of 6 years (1998–2004), an unprecedented level of regulatory activity.

TABLE 1 Rules and number of violation codes

Rule(s)*	Number of Violation Codes
NIPDWRs, TTHMs Rule, Fluoride Rule, Phases I, II, and V	4
TCR and SWTR	10
LCR	15
Stage 1 D/DBPR, IESWTR, and LT1ESWTR	26
Stage 2 DBPR, LT2ESWTR, Radon, GWR, Revised TCR/DSR	Data not yet available

* NIPDWRs—National Interim Primary Drinking Water Regulations, TTHMs—total trihalomethanes, TCR—Total Coliform Rule, SWTR—Surface Water Treatment Rule, LCR—Lead and Copper Rule, D/DBPR—Disinfectants/Disinfection By-products Rule, IESWTR—Interim Enhanced Surface Water Treatment Rule, LT1ESWTR—Long-term 1 Enhanced Surface Water Treatment Rule, DBPR—Disinfection By-products Rule, LT2ESWTR—Long-term 2 Enhanced Surface Water Treatment Rule, GWR—Ground Water Rule, DSR—Distribution System Rule

The Stage 2 DBPR and LT2ESWTR are likely to continue the trend toward complexity, starting immediately after these rules are finalized sometime in late 2004. New monitoring programs will be established for *Cryptosporidium* and for new DBP compliance monitoring locations. The microbial "toolbox" will offer a variety of compliance approaches that can be used in meeting the LT2ESWTR compliance requirements. Future regulations beyond the ones previously discussed will likely span the range of simple to complex, but the author believes that more will be complex rather than simple.

Data analysis highlights systems' compliance problems. The author downloaded summary compliance data for calendar years 1993–2001 for community water systems (CWSs) from the USEPA website (USEPA, 2002b). These compliance data for MCL and TT violations were resorted for each regulation. M/R violations were not included in this analysis.

The compliance data for each regulation were then normalized so that "year 1" was the first calendar year after the effective date of the regulation. Normalization of all of the past regulations was used to show the effects on utilities once the regulation became effective. For example, the SWTR became effective Dec. 30, 1990; thus "year 1" for the SWTR would be 1991 and "year 3" would be the first year (1993) that compliance data became available. Therefore, for both the SWTR and TCR, only normalized years 3–9 (1993–99) were used in this analysis. For these two rules, the first two years of normalized compliance data (1991 and 1992) were not available. In addition, similar normalized compliance data were not available for the Fluoride Rule and the Phase I Rule because these two rules became effective in 1987 and 1989, respectively. Figure 2 is a graph of the normalized compliance data for the existing regulations.

Violations of the TCR are almost an order of magnitude greater than those for any other regulation. USEPA has recently proposed revising the TCR under its six-year review process (USEPA, 2002c), and the author believes that regulatory compliance issues need to be addressed in any potential future TCR revisions. The second-highest number of violations stems from the SWTR, which underlines the connection between the increasing complexity of treatment technique–based regulations (with an increased number of violation codes) and the resultant increased number of compliance violations.

On the basis of normalized compliance data, a relatively small number of violations occurred from the many older MCL-based regulations. There were no violations for 13 contaminants from these regulations, which raises the separate question of whether these contaminants should be regulated at all. All of the CWSs had zero, one, or two MCL violations each year for almost half (31) of the contaminants regulated under the older MCL-based regulations. Systems had violations in single digits (<10) each year for 42 of these "old" contaminants. Even with 10 MCL violations for a specific contaminant each year, this would be less than 0.02% of the CWSs. Clearly, even with an increasing number of regulated contaminants, only a handful of systems had compliance problems with most of the older MCL-based regulations.

FUTURE REGULATIONS PROMISE EVEN MORE COMPLEXITY

In a recent regulatory action, USEPA elected not to regulate any of the nine priority contaminants identified on the first Contaminant Candidate List (CCL) in its preliminary regulatory determinations (USEPA, 2002d). If CCL contaminants such as perchlorate and methyl tertiary butyl ether (MTBE) are regulated in the future through an "off-cycle" regulatory development process, these regulations are likely to be MCL-based.

Future regulations addressing these difficult-to-treat contaminants will drive utilities to more complex treatment technologies.

Under section 1412(b)(9) of the SDWA, USEPA is required to review all existing drinking water regulations on a six-year review cycle. As previously noted, in another recent regulatory action, USEPA elected to revise only the TCR in its six-year review of 69 individual drinking

water standards. This TCR revision will likely be incorporated into a future Distribution System Rule (DSR) scheduled to be proposed in late 2003 or early 2004. USEPA commissioned a series of nine white papers to cover the "state of the science" of various distribution system issues that are now available on USEPA's OGWDW website. USEPA held a stakeholder meeting in November 2002 and intends to hold more stakeholder meetings in early 2003 to collect stakeholder input on the potential DSR (USEPA, 2002e). Because of inherent complexities in operating and maintaining a typical utility distribution system, the future DSR has the potential to be a relatively complex regulation.

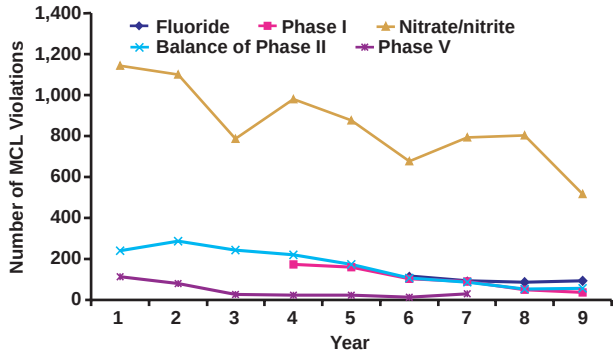
Health effects assessments influence review process. The assessment of new health effects information for several already regulated contaminants was ongoing at the time USEPA made its preliminary decisions for the six-year review. Many of these health effects assessments will be completed in 2003 and 2004 and were not completed in time for USEPA's preliminary regulatory decisions on whether to review the standard. On the basis of the results of these assessments, USEPA could decide to review these existing standards in the future. The timing for such an off-cycle review has not yet been made clear by USEPA. The MCLs for a few existing contaminants such as atrazine, trichloroethylene, and chromium (particularly chromium-VI) could be revised in the future through an off-cycle process. Again, these revised regulations are likely to be MCL-based, i.e., the existing MCL may change based on USEPA's analysis of the new health effects information.

However, some of these future MCL-based regulations, such as a potential change to the atrazine MCL, will likely be based on reproductive and developmental endpoints. Although the health effects data for potential adverse reproductive and developmental endpoints for DBPs are inconclusive (USEPA, 1998b; Reif et al, 2000), the health effects data for atrazine are much more clear (USEPA, 2002f). Atrazine will likely be the first contaminant to be regulated for such a health effect endpoint; others, such as some DBPs and perchlorate, could follow in the future.

Additionally, a common mechanism of toxicity has been discovered for atrazine, simazine, propazine, and three chlorinated metabolites (USEPA, 2002g). The atrazine number may or may not be changed because of uncertainties about the relationships between atrazine and the other five compounds, or a "group" MCL could be established. However, the author believes that monitoring will likely be increased to a more frequent interval during the spring runoff period to address the adverse reproductive and developmental endpoints. The compliance determination will likely be changed to a shorter interval based on the more frequent sampling, as opposed to the typical compliance determination of an annual average based on quarterly samples. A new compliance determination framework with more frequent monitoring and a shorter time frame for the compliance determination could be developed in the future for other contaminants with potential adverse reproductive and developmental endpoints.

Newly regulated contaminants may be harder to treat. Additionally, some of these future MCL-based regulations could address difficult-to-treat contaminants (e.g., MTBE, perchlorate, and chromium-VI) and would require particularly complex treatment. Section 1412(b)(E) of the SDWA requires USEPA to designate a best available technology (BAT) to comply with an MCL. The existing regulations for organics designated either granular activated carbon (GAC) and/or packed tower aeration (PTA) as BATs. Many utilities used powdered activated carbon, GAC filter caps, and PTA to comply with the old regulations, and the author believes that these three methods can be considered relatively simple treatment technologies. Postfiltration GAC absorbers are a more complex treatment technology, but this technology is currently being used at a limited number of water treatment plants. The author believes that future regulations addressing these difficult-to-treat contaminants will drive utilities to more complex treat-

FIGURE 3 Normalized violations (MCL only)



MCL—maximum contaminant level

Drinking water utilities and the consulting engineers that support them will have to quickly learn the details of these new regulations and develop a long-term, integrated compliance strategy.

ment technologies such as postfiltration GAC absorbers and other complex technologies such as ion exchange and reverse osmosis.

Inorganics pose a different treatment challenge. Existing regulations for two inorganics—nitrate and arsenic—provide some insights into future treatment complexities for difficult-to-treat contaminants. Nitrate and nitrite (both separate and combined MCLs) were regulated as part of the Phase II Rule and soon became a significant compliance problem (as indicated by the number of violations). Once the Phase II Rule became effective in 1993, nitrate and nitrite (separate and combined) violations ranged from 70 to 89% of the total MCL violations in 1993–2001. In 2001, nitrate/nitrite violations comprised 85% of the total MCL violations, a decade after the Phase II Rule was finalized. To comply with the nitrate/nitrite regulation, many utilities switched water sources and/or worked with the agricultural community within their watersheds. Several utilities installed ion exchange treatment for compliance. Figure 3 shows the relationship of nitrate/nitrite violations to all of the other MCL-based regulations. Clearly, nitrate/nitrite gave utilities their first experience with a difficult-to-treat contaminant, and this experience resulted in a large number of violations that are ongoing in many instances.

The revised arsenic standard that was finalized in 2001 takes these treatment challenges to a new level in that many systems will likely install relatively complex treatment technologies, such as activated alumina, ion exchange, and coagulation-assisted microfiltration. Many utilities will not be able to switch water sources because of the lack of other sources in arsenic-affected areas such as the arid Southwest. Simply understanding these complex technologies well enough to make a smart technology decision will be a challenge for most utilities because of the limited full-scale implementation experience from which to draw.

Additionally, disposal of the concentrated waste streams from these technologies is proving to be more problematic than originally anticipated (MacPhee et al, 2002). According to MacPhee and colleagues, processes that change pH or result in a reducing environment (e.g., chemical conditioning during dewatering, storage, and lagooning) and ultimate disposal options (e.g., landfilling, land application, and indirect discharge to sanitary sewers) could release arsenic from the solid phase. The difficulties in evaluating treatment technologies and disposal of waste streams will likely be repeated in potential future regulations for perchlorate and chromium-VI.

UTILITIES FACE NUMEROUS CHALLENGES

All systems, both groundwater and surface water, will be affected by the "new" regulations discussed here. The vast majority of CWSs are groundwater systems. Of the total 53,783 CWSs, 42,212 (78%) use groundwater, and most of these are small systems (USEPA, 2002h). For surface water and groundwater CWSs, 45,503 (85%) are defined as small systems serving fewer than 3,300 people; 31,262 of these systems serve fewer than 500 people and are defined as very small systems. Many of these small and very small systems do not even have a full-time operator.

Systems using groundwater will be particularly affected. Groundwater systems will be affected by the following regulations: the Stage 1 D/DBPR, Radionuclides Rule, Arsenic Rule, GWR (to be finalized in 2003), Radon Rule (to be finalized in 2003), Stage 2 DBPR (to be finalized in 2004), and the revised TCR/DSR (to be finalized in 2005). Each of these regulations has its own set of specific compliance dates by which monitoring and treatment must be completed.

At this time, most groundwater systems use no treatment or very simple treatment. Of the groundwater systems that do treat their water, most use only simple chlorine disinfection. To comply with the proposed regulations, however, groundwater systems could potentially have to install more complex treatment. Additionally, more than one treatment process may be needed to remove co-occurring contaminants. For example, a groundwater system might have to install aeration for radon removal and ion exchange for arsenic removal. Disinfection would be required because the groundwater is now open to the atmosphere during aeration. The system would also have to comply with the new DBP regulations. Under this scenario, a groundwater system might go from using no treatment to needing three treatment processes.

Compliance with one regulation can also lead to the need for additional compliance with a second regulation. Groundwater systems that are required to disinfect under the GWR because of nearby sources of contamination would also have to comply with the new DBP regulations. The only good news is that most groundwaters are of relatively high quality with low levels of DBP precursors, so compliance with the DBP regulations should be relatively easy. Of course, there are exceptions to every rule, and groundwater systems with high levels of DBP precursors and some small rural systems with distribution systems stretching over several square miles could face compliance challenges with the Stage 2 DBPR and the revised TCR/DSR.

To comply with the proposed regulations, groundwater systems could potentially have to install more complex treatment.

Groundwater systems, especially small systems, face a number of challenges in complying with these new regulations:

- finding qualified consulting engineers to assist in developing an integrated compliance strategy for the regulations;
- understanding possible effects outside of SDWA requirements, such as from the Clean Water Act and other environmental regulations;
- raising the capital necessary to design and build the required additional treatment;
- understanding the funding assistance programs available through federal agencies such as USEPA and the US Department of Agriculture;
- raising the capital necessary for the operation and maintenance expenses for the additional treatment;
- finding and keeping operators with higher classifications needed to run the more complex treatment; and
- educating elected officials and customers to accept the increased water rates for the construction costs and operation and maintenance expenses.

Surface water systems are not immune to compliance challenges. Unlike small systems, most large systems use surface water. For surface water systems, the DBP regulations (i.e., the Stage 1 D/DBPR and Stage 2 DBPR) and the microbial control regulations (i.e., the IESWTR, LT1ESWTR, and LT2ESWTR) will be the most challenging. Whereas the 1979 TTHM Rule only applied to systems serving more than 10,000 people, small surface water systems serving fewer than 10,000 people will now have to meet DBP standards for the first time. As a general rule, the author believes that most of the surface water systems will not have any significant compliance issues with the Radionuclides Rule, Arsenic Rule, Radon Rule, or GWR, although there will always be exceptions.

The challenge for surface water systems is balancing the short-term (acute) microbial risk with the potential long-term (chronic) risk from DBPs. Through the regulatory development process, USEPA has addressed this risk-balancing by putting out paired regulations, i.e., the Stage 2 DBPR and LT2ESWTR are being proposed and finalized at generally the same time. Specific provisions in these paired regulations prevent a system from complying with the DBP regulation by simply reducing the concentration of applied disinfectant because this action would likely increase microbial risk. For this reason, surface water systems will have to carefully evaluate treatment alternatives to reduce DBPs while maintaining microbial protection. In some cases (i.e., with poor-quality source waters), systems that are required to install additional treatment for microbial protection will have to evaluate treatment alternatives to ensure DBP compliance. Many small surface water systems will ultimately face the same challenges detailed previously for small groundwater systems.

CONCLUSIONS

All drinking water utilities will be affected by the "new" regulations coming out between 1998 and 2004. A total of ten regulations in six years is an unprecedented level of regulatory activity. By contrast, USEPA finalized only 9 regulations in the 22 years between the original passage of the SDWA in 1974 and the most recent SDWA reauthorization in 1996.

Because of inherent complexities, these new regulations will pose a compliance challenge to utilities. These complexities stem from a mixture of treatment techniques and MCLs that increase the number of potential violation codes. Additionally, future MCL-based regulations will likely address difficult-to-treat contaminants such as perchlorate and chromium-VI. Nitrate and arsenic are the first two examples of difficult-to-treatment contaminants, and the compliance data for nitrate/nitrite demonstrate the compliance difficulties encountered by water providers.

Compliance with these regulations will be a challenge for all utilities, particularly for the small systems that may become overwhelmed by this unprecedented regulatory activity.

There are some steps a water system can take to meet the challenges of these new regulations.

- Find a qualified consulting engineer who knows the details of all upcoming regulations
- As a utility, learn enough about the technical details of the regulations to function as an effective project manager for any future capital improvements.
- Educate all personnel at the utility about the challenges of the upcoming regulations; the operators are the ones who ultimately will have to operate the treatment plant and distribution system to comply with the new rules.
- Develop a retention strategy to keep qualified operators within the utility.
- In consultation with the engineer, develop a long-term, integrated compliance strategy for all upcoming regulations.
- Start educating elected officials and customers about potential rate increases that may be necessary to support the required additional treatment.
- Seek out any and all potential sources of funding assistance.

Most of these "new" regulations are more complex, with the potential for more violations. Implemen-

tation of these regulations is leading to an increasing number of violation codes. More complex regulations lead to more violations, and more time is needed by utilities to understand these regulations and to come into compliance. Small groundwater systems in particular will be challenged by these regulations.

Drinking water utilities and the consulting engineers that support them will have to quickly learn the details of these new regulations and develop a long-term, integrated compliance strategy. Early involvement of elected officials and customers will increase the likelihood of success in securing additional funding for construction, operation, and maintenance of the required treatment. Compliance with these regulations will be a challenge for all utilities, particularly for the small systems that may become overwhelmed by this unprecedented regulatory activity.

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ABOUT THE AUTHOR:

J. Alan Roberson *is the director of regulatory affairs, AWWA, 1401 New York Ave. NW, Suite 640, Washington, DC 20005, e-mail aroberso@awwa.org. He holds a BS degree in civil engineering from Georgia Institute of Technology in Atlanta and an MS degree in civil engineering from Virginia Polytechnic Institute and State University in Blacksburg. A winner of the Archie Becher Award, Roberson has 12 years of experience in regulatory affairs at AWWA and another 12 years of experience as a consulting engineer.*

If you have a comment about this article, please contact us at journal@awwa.org.

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Attachment K2

See Journal of the American Water Works Association 98:4, April 2006. Robert S. Raucher, J. Alan Roberson, and Megan Harrod. "Developing Performance Measures for the SDWA Regulatory Program: Melding What's Countable with What Counts." journal@awwa.org.