

Compilation of Individual Comments from Committee Members

(as of February 21, 2012)

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Dr. Allen Burton

USEPA SAB Risk Assessment Forum EPEC Review

G. Allen Burton preliminary review of Charge Questions 2 and 3

February 12, 2012

Charge question 2: Importance of developing an integrated assessment approach

- The integrated assessment approach (IAA) draws heavily from Cormier and Suter (2008), which is the basis for Chapter 3 of EPA's colloquium report Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward. The process presented is very good and quite logical. It identifies some of the primary problems and realities that have confounded the widespread use of EPA's ERA process and how the applications of environmental assessments vary across EPA depending on decision needs.
- It is unclear why EPA ORD's strategy for incorporation of ecosystem services (U.S. EPA SAB 2009) into EPA program decision-making (and the findings/recommendations of the SAB report that reviewed that strategy) has not been mentioned in this RAF process. It is an important aspect of this integrated assessment approach and the SAB report identified some of the same challenges faced by the RAF regarding how to integrate across EPA programs. Those challenges of applying ecosystem services to widely varying, well-entrenched programs and regulations – such as the NPDES, TMDLs, FIFRA, TSCA, RCRA, CERCLA, also apply to this current proposed approach.
- While the IAA is nicely presented with accompanying rationales, it cannot be effectively implemented without the widely varying programs of EPA developing a strategy for its' application and implementation. Indeed, these programs tend to behave as silos and have not incorporated related and useful supporting approaches such as EPA's CADDIS (Burton et al., 2012). If EPA has developed a response to the SAB Ecosystem Services recommendations regarding program implementation, it may well serve this RAF Action Plan.

Charge question 3: Use of the weight-of-evidence approach in ERAs

- The WoE approach has been around for years and the challenges of using it for decision-making well known (Batley et al. 2002; Burton et al. 2002ab; Wenning et al., 2005). We agree that more instructive and consistent guidance is needed for using WoE approaches. The need for, and scientific consensus on using WoE approaches is well established (e.g., Adams et al., 2005) and has been promoted in federal and state efforts (e.g., EPA Superfund Guidance, Environment Canada 200x, State of California). As noted in a review of WoE approaches, they are most often based on "best professional judgments" and vary widely in their scientific rigor and statistical credibility (Burton et al., 2002a). Consequently, they may not reduce uncertainty as they are meant to and may confound

effective decision-making. Useful statistically based WoE approaches have been reported that address many of the weaknesses of qualitative based approaches (Bailer et al. 2002; Burton et al., 2002b; Grapentine et al, 2002; Kapo and Burton 2006; Kapo et al., 2008; Reynoldson et al 2002). Examples such as these provide a solid basis for EPA guidance that can be structured towards unique program needs.

- The WoE process should be described in the Problem Formulation stage of the IAA and ensure credible stakeholder input and a transparent understanding of what constitutes “reference condition”, restoration goals, remedy objectives, and/or ecological impairments in the context of site spatial and temporal variations. This point was highlighted within the SAB report on improving the ERA process, which resulted in this current RAF process (Dale et al, 2008).
- In order to have a scientifically rigorous WoE process it must rely less on BPJ and more on statically based decision points that address the outputs and criteria identified in the previous bullet (e.g., reference condition). This will not be possible without EPA providing WoE guidance that is program specific.

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Dr. Peter Chapman

SAB REVIEW OF USEPA's ECOLOGICAL ASSESSMENT ACTION PLAN: CHARGE QUESTION 2

Importance of developing an integrated assessment approach

This Charge Question requests “comment on how guidance for an approach to assessment that integrates different media and endpoints and different types of assessments might contribute to better decision making (e.g., assessment of complex issues, cumulative risk assessment and sustainability analysis).”

Response

This charge question is answered by the SAB Ecological Processes and Effects Committee (EPEC) response to Charge Question 3 in which we confirm that weight of evidence (WOE) has clear scientific merit but additional guidance in its use and application are required and provide specific recommendations; the above-noted integrative response is in fact a WOE determination. The response to Charge Question 3 will not be repeated here. The “bottom-line” is that integration of different lines of evidence (LOE) is essential given that “today’s environmental challenges are increasingly subtle and complex” (Anastas 2012), particularly so given the reality of global climate change (cf “National Fish, Wildlife & Plants Climate Adaptation Strategy”, January 2012, www.wildlifeadaptationstrategy.gov).

Reference

Anastas PT. 2012. Fundamental changes to EPA’s research enterprise: The path forward. *Environ Sci Technol* 46: 580-586.

SAB REVIEW OF USEPA's ECOLOGICAL ASSESSMENT ACTION PLAN: CHARGE QUESTION 3

Use of the weight of evidence approach in ecological risk assessment

This Charge Question notes that, although ecological risk assessments (ERAs) often involve multiple lines of evidence (LOE), no guidance exists on how to weight those LOE to make inferences. The Action Plan proposes that USEPA develop such guidance. The SAB Ecological Processes and Effects Committee (EPEC) is asked to comment on the scientific merit and limitations of using a weight of evidence (WOE) approach in decision making and offer any guidance on weighing ERA LOE.

WOE has Scientific Merit

The scientific merit of WOE is evidenced by the large number of scientific publications and its consistent and continuing use in ERA. For instance, in 2002 a series of articles on WOE were published in the journal *Human and Ecological Risk Assessment*. Numerous articles on WOE have since been published in a wide variety of journals and books. Reviews of WOE approaches

(e.g., Burton et al. 2002a; Weed 2005; Linkov et al. 2009) uniformly recommend its usage, particularly in ERA, but also note the need for transparency and guidance in its usage. USEPA recognizes that “today’s environmental challenges are increasingly subtle and complex”, and that research must not be just inter-disciplinary but in fact trans-disciplinary, “combining perspectives to form entirely new concepts and reach new levels of scientific understanding” (Anastas 2012). WOE clearly has scientific merit both inside and outside of USEPA; this merit has been affirmed by EPEC in previous advice to the Agency (USEPA SAB 2007).

Limitations to WOE

A uniform definition for WOE does not exist. The definition of Burton et al. (2002b) is likely the best definition at present because it does not unduly limit the concept: “a process used in environmental assessment to evaluate multiple lines-of-evidence concerning ecological condition”. The EPEC has previously (USEPA SAB 2007) also described ERA “as a process, not just a technique.”

WOE depends to a certain extent on best professional judgment (BPJ), which varies depending on the professionals making those judgments (e.g., Bay et al. 2007; Thompson et al. 2012) and which USEPA (2010) has identified as a source of uncertainty. Lack of agreement among experts extends beyond the environmental sciences (e.g., Large and Niessen 2008). Bay et al. (2007) suggest that uncertainty related to the use of BPJ must be recognized in ERA, and will be less important at the extremes (e.g., sites that are clearly contaminated and toxic, and those that are clearly not) than between the extremes. They recommend three steps to reduce uncertainty in the integration and interpretation of multiple LOE:

1. Key elements of the assessment strategy (e.g., relative weight of each LOE, how multiple LOE will be combined [e.g., scores, ranks, logic frameworks], criteria for determining the ERA conclusion) should be determined during the Problem Formulation phase of the ERA.
2. Guidance is required on the specific methodology/methodologies for measuring and assessing each LOE.
3. Training, including guidance documents, is required for individuals interpreting both individual LOE and the overall WOE.

The EPEC has previously (USEPA SAB 2007) similarly recommended, and continues to recommend: development of a consistent approach in ERA to interpreting LOE and WOE, both to reduce uncertainty and to assist in decision-making based on ERA; exploration of the use of such methods as Bayesian analysis and causal argumentation to develop hypotheses or risk questions focused on causal relationships and WOE; and, “case studies and/or standards of practice for interpreting lines of evidence and weight of evidence with an emphasis on application in decision making.” We agree with USEPA (2003) that case studies should in particular focus on whether some LOE carried more weight than others or whether they were ignored or too difficult to interpret or use. This information will assist in future weighting of ERA LOE.

Guidance on Weighting ERA LOE

In terms of weighting ERA LOE, we have three specific recommendations:

1. Building on the recommendations of Wenning et al. (2005) we propose that, in general, chemical LOE receive less weight than biological LOE, and that LOE that involve individual organisms and species receive less weight than LOE that involve resident natural communities and populations of organisms.
2. We counsel against arbitrary numerical weightings as site- and situation-specific considerations will affect weightings. WOE assessments need to be “flexible, transparent and defensible...[with] sufficient flexibility to accept all relevant evidence and generate creative solutions to difficult problems” (Suter and Cormier 2011). We agree with USEPA (2010) that “weighing of evidence should be considered during each problem formulation, and a method for weighing evidence should be included, as appropriate, in the analysis plan.”
3. We suggest further investigation of multicriteria decision analyses (MCDA) as recommended by Linkov et al. (2011): “Each WOE method is based on a unique rationale and capable of considering a different scope of LOEs. Thus, each method has specific benefits and drawbacks. The different nature of methods means that one cannot *a priori* determine the superior method for a particular application. One must consider the method employed in addition to the evidence.”

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These preliminary comments are from individual members of the SAB Ecological Processes and Effects Committee Augmented for Review of the Ecological Assessment Action Plan and do not represent consensus SAB advice or EPA policy.

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Dr. Loveday Conquest

*Charge question 3. Use of the weight-of-evidence approach in ecological risk assessments.
(L. Conquest)*

The term “weight of evidence” (WoE) appears to have a variety of interpretations in the context of risk assessment. It begins with the general idea that more than a single line of inquiry is desirable when assessing risk. At issue is just how to integrate and synthesize evidence from different studies. The studies might not all measure the same thing (e.g., chemical responses, individual organism responses, community responses). Such integration and synthesis could be done subjectively by scientists with the appropriate expertise, considering all available information and exercising best judgment. However, the SAB recommendations may seek something more formal, i.e., the development of methodology that would lead to the implementation of actual weighting schemes and quantitative assessments of risk.

Rothman and Greenland (2005), based on the classic paper by Hill (1965) on causes of occupational diseases, listed the following “causality criteria”:

1. Strength of the association (stronger associations support the notion of causality);
2. Consistency (more studies find similar results);
3. Specificity (specific exposures exert specific effects; at the same time, certain exposures can lead to multiple effects);
4. Temporality (exposure should precede the effect);
5. Biological gradient (a dose-response relationship lends evidence to causality);
6. Plausibility (knowledge of biological processes involved lends evidence to causality);
7. Coherence (other observed biological effects lend evidence to a causal association);
8. Experimental evidence (e.g., does the amount of a toxicant in a body of water decrease following changes in practice by an industrial plant);
9. Analogy (does a similar agent exert similar effects).

The above were originally formulated in the context of potential carcinogens and human disease, and presumably could be interpreted to make sense in terms of ecological risk assessment. Just contemplating all the items on this list serves as a reminder that there is a lot involved in trying to quantify the process involved in the idea of “exposure to something (e.g. a toxicant, a management practice) => resulting effect”. EPA has used a WoE approach in the context of carcinogens and toxicology (USEPA 2005).

WoE is an approach to evaluating and integrating multiple sources of evidence, rather than a single technique. As such, WoE should follow certain principles, but not a particular “recipe” nor algorithm. Any effort that claims to use WoE to reach conclusions should be completely transparent regarding the different sources of evidence considered and any qualitative (e.g., expert opinion) or quantitative weighting schemes used (see Swaen and van Amelsvoort 2009, albeit in an epidemiology/carcinogen setting). Also meriting consideration are data quality and

reliability of different studies. Weed (2005) points out that applying an arbitrary weighting scheme without a solid theoretical foundation to integrate different lines of evidence into a single risk score may not actually improve decision making.

The most specific WoE approach is meta-analysis, used when different studies have provided estimates of the same effect. The estimated effects coming out of the different studies are weighted (inversely proportional to the variance associated with the effect) and combined together to form a weighted average effect (with a weighted variance). In this manner, for instance, the presence of many studies with “almost statistically significant” results can lead to an overall, statistically significant, result. [This is the only WoE approach that I know of that is well defined and universally accepted.]

A really well developed WoE framework would be able to assign quantitative weights to results from different studies (with associated estimates of uncertainty), and to combine them into an assessment of a defined risk. Thus far, this has been largely done in epidemiological contexts. In the area of ecological risk assessment, having quantitative results from adaptive management experiments based on sound principles of statistical design would make it easier to construct WoE arguments on ecological risk.

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Charge Question 6. Use of adaptive management for testing and revising risk management actions. (L. Conquest)

Adaptive management (AM) occurs when natural resource managers apply the principles of rigorous statistical design of experiments to evaluation of management actions. In the best cases, this can result in powerful “management experiments”. Such management experiments may have to occur at large temporal or spatial scales, and therefore require careful thought and planning. In order to compare selected practices or policies, one must be able to state management questions in terms of testable null hypotheses about the system being managed. This usually requires a good deal of knowledge about the particular ecological process(es) being studied.

As part of any project design, there need to be clearly defined study objectives. One has to decide what the different “treatments” being compared are; in AM these could be different risk management practices or policies. There may be ancillary variables (“covariates”) that also affect the response; if so, they must be recorded and included in the data analysis. One has to think carefully about the experimental units to which the different “treatments” are being applied. For example, in comparing different fishery management practices, an experimental unit might be a large region to which a particular management practice has been assigned. Inferences are the most solid when true random assignment of “treatments” to experimental units can actually be done, although this is probably not always the case.

There may be a need to “block”—i.e., to separate experimental material into blocks (e.g., in space or time) such that there is more homogeneity within blocks, more heterogeneity between blocks, and each “treatment” occurs once in each block. (An example is a boat using 3 different types of fishing gear meant to decrease accidental seabird bycatch, in a set time period, in randomized order. Another is using different forest management practices in a relatively homogeneous area of land.)

The concept of a “control” requires some thought. For example, in ecological studies where few areas are really pristine, the concept of regional reference sites as “controls” has been used.

Statistical replication is necessary in order to get useful inference from the results. This means multiple experimental units must receive the same “treatment”. For example, in comparing different fishery management practices, at least two regions would need to be subjected to each management practice. In the forest management example mentioned above, several large blocks of land would be required; and each block would have the different forest management practices occur within it. (One can take measurements on the same experimental unit over time or space; that can add useful information, but that would not be statistical replication in the sense of adding more true experimental units. Accumulating lots of data points is not necessarily the same as adding more statistical replicates.)

The usefulness of the subsequent data analysis depends upon measuring meaningful responses at appropriate scales and using a good sampling design, paying attention to the original objectives. Quality control at every step of the way is crucial.

“What, When, Where, How.” “What” refers to the response variables being monitored; these must be decided with care. Sometimes the response variables are obvious from knowledge of the process being studied, sometimes not (see comment about pilot studies, sample size and power analysis below). “When” and “where” refer to the temporal and spatial aspects of monitoring, and “how” to the actual method of obtaining the data. In the context of AM, this is akin to carefully designing a long-term, or large, or multi-stage monitoring study, with chosen milestones when actual hypothesis testing or estimation of important parameters occurs.

Paying attention to Type I and Type II errors and their costs. In classical statistics, a Type I error occurs when data lead one to reject a specified null hypothesis (i.e. a hypothesis of “no difference”, or “no change”) in favor of an alternative hypothesis, when the null hypothesis is actually the true state of nature. A Type II error occurs when data result in the failure to choose

the alternative hypothesis when the alternative is actually the true state of nature. In AM, attention must be paid to the costs of making each type of error. Pilot studies can yield valuable information in this regard before a large experiment or massive monitoring effort takes place. Pilot studies can also aid in sample size determination, or even in the choice of response variable (e.g. one which has the most statistical power to detect a certain level of change). Results from hypothesis tests or estimation of certain effects can then get incorporated into future decisions. While there are limitations to applying statistical design of experiments principles when comparing management practices, one can still strive to meet such principles.

Adaptive management requires scientists to look at every ecological monitoring effort as a gigantic experiment, through the prism of statistical design, and to implement that monitoring using rigorous statistical principles. This is not a trivial effort. Quoting from the report, “Integrating Ecological Assessment and Decision-Making at EPA”, “The Technical Panel ... believes that directly coupling technical assessments with outcome assessments through feedback loops will promote wider application of adaptive management at EPA. ... Adaptive management is potentially a highly useful strategy, but its implementation would require changes in fundamental Agency science policies and practices.” (U.S. EPA 2010)

Perhaps the biggest point in favor of an adaptive management approach is that by applying statistical design principles to assess and compare ecological risk management practices, any subsequent weight of evidence arguments would then incorporate rigorous quantitative results, with associated estimates of uncertainty. This is the big payoff with the AM approach.

Dr. Richard Di Giulio

Richard Di Giulio's response to charge questions concerning:
Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological
Assessment Action Plan, August 11, 2011

1. Overall technical merit of the proposed science policy and technical practice initiatives.

The six major recommendations do appear to follow logically from the Colloquium Report (December, 2010), and are reasonable. But overall, they come off as rather generic and presented without a strong sense that there are well thought-out approaches for achieving them. However, determining these approaches presumably will be the subject of subsequent forums and committees. This does generate some concern that such discussions can be never ending, and never catch up with the evolution of science underlying ecological assessments and constantly emerging new ecological problems to assess. Of course the issues being addressed by the EPA and the RAF are enormous in complexity and importance, and these recommendations make a good start.

2. Importance of developing an integrated assessment approach.

At this point in time, this recommendation appears rather self-evident. The Cormier and Suter (2008) paper provides a good framework. But again, concrete plans appear to be quite vague, which is a bit disturbing, since that paper was published almost four years ago.

3. Use of the weight-of-evidence approach in ecological risk assessments.

Looking in from the outside, I had presumed that a weight of evidence approach for ecological assessments was the norm, albeit not in a set, formal manner. The apparent objective here, of deriving a more formal approach for ascribing different weights to various lines of evidence, merits consideration. But it seems unlikely that ecological assessments are as amenable to formalization as, say, human cancer risk assessments, which are not totally straight-forward either. But many ecological assessments are inherently unique, and a high degree of flexibility to address the nuances associated with a particular assessment will remain desirable for the foreseeable future.

4. Communication of ecological assessment issues and results to decision-makers and stakeholders.

This recommendation seems intuitive – just good common sense. Again, the difficulty will be achieving an approach that has a high probability of success. Also, as written, it appears that the thrust is entirely upon assessors determining ways to communicate the issues and outcomes of

assessments to policy makers and other stakeholders, with little concern for enhancing communication in the opposite direction.

5. Incorporation of ecosystem services into ecological risk assessment methods.

Similar to the recommendation concerning integrative assessment, this recommendation appears self-evident. The ecosystem services paradigm has been operative for some time and it would seem its integration with ecological assessments is overdue. Thus its inclusion as a recommendation by the RAF is appropriate, Again, however, it's unclear from either this RAF plan or the Colloquium Report, how this will actually be achieved.

6. Use of adaptive management for testing and revising risk management actions.

This is also very appropriate, with similar concerns as above for implementable plans.

7. Strengthening EPA's ecological protection goals.

It's disturbing to read, this many years after the Agencies creation, that: "There is little consensus in the Agency about the goals for protection of the nonhuman environment or the importance of ecological effects." This is particularly disturbing given that for ecosystem protection the EPA is the only game in town, while the federal entities oriented to human health protection are diverse and operate on an entirely different scale. Of course the latter is the Agencies fault. However the relative distribution of resources for human health versus ecosystem protection within the EPA, and the apparent strict demarcation between the two, is perplexing. Perhaps this recommendation should be Priority #1.

Dr. Robert Diaz

Diaz Comments

Charge Question 5. Incorporation of ecosystem services into ecological risk assessment methods.

The concept of ecosystem services has emerged as a means of conveying the total integrated value of our environment to include both market and nonmarket goods and services. Actually most ecosystem services are outside economic market valuation and not monitorized, but there have been attempts to put dollar values on all types of ecosystem services (Costanza et al., 1997). The Millennium Ecosystem Assessment (MA, 2005) uses change to ecosystem services as the central measure of impacts from all types of environmental stressors. This may also be a good strategy for EPA. The concept of ecosystem services can be easily grasped by all stakeholders from scientists to managers to policy makers to informed public.

The Millennium Ecosystem Assessment (MA, 2005) does provide a framework for describing the key environmental issues in terms of ecosystem services (Table 1). But one of the most difficult areas in the use ecosystem service as an endpoint to guide risk assessment relates to trade-offs among services. Often, optimizing delivery of a given service may reduce or impair another (Mooney, 2010). Agriculture provides a primary example. The enhanced provisioning of food can result in loss of clean water and stress to biodiversity that supports other services.

For this to work for EPA, it must fully understand the complexities involved and be able to clearly portray the importance of services to the public, even before there is a discussion of how to apply risk assessment. The first thing EPA should do is incorporate the current ecosystem services concepts and definitions to its RAF and Plan, replacing older terminology and meaning (See Appendix B Table B-1, Generic Ecological Assessment Endpoints for Ecological Risk Assessment 2004). This would provide EPA with continuity of thought and concepts with the published literature on ecosystem services, and would provide clarity as to what constituted ecosystem services. The term ecosystem services is used hundreds of times in the Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward, Results of a Colloquium in Response to Science Advisory Board and National Research Council Recommendations 2010 report, but there is no list of services or discussion of the broad range of tangibles and intangibles included in the term ecosystem services.

Neither the Generic Ecological Assessment Endpoints for Ecological Risk Assessment (2004) or the Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward (2010) captures the full range of concepts embodied by the term ecosystem services. So it is unlikely that the capture the full range of opportunities to incorporate ecosystem services into EPA's ecological risk assessment methods. There needs to be more specifics. It is not clear to me how realistic the plans put forth in the 2010 A Path Forward report are.

These preliminary comments are from individual members of the SAB Ecological Processes and Effects Committee Augmented for Review of the Ecological Assessment Action Plan and do not represent consensus SAB advice or EPA policy.
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Table 1. Global status of provisioning, regulating, and cultural ecosystem services (MA, 2005)

| Service | Sub-category | Status | Notes |
|---|--------------------|--------|---|
| Provisioning Services | | | |
| Food | Crops | + | Substantial production increase |
| | Livestock | + | Substantial production increase |
| | Capture fisheries | - | declining production due to overharvest |
| | Aquaculture | + | substantial production increase |
| | Wild foods | - | declining production |
| Fiber | Timber | +/- | forest loss in some regions, growth in others |
| | Cotton, hemp, silk | +/- | declining production of some fibers, growth in others |
| | Wood fuel | - | declining production |
| Genetic resources | | - | lost through extinction and crop genetic resource loss |
| Biochemicals, natural medicines | | - | lost through extinction, overharvest |
| Freshwater | | - | unsustainable use for drinking, industry, and irrigation |
| Regulating Services | | | |
| Air quality regulation | | - | decline in ability of atmosphere to cleanse itself |
| Climate regulation | Global | - | net source of carbon sequestration since mid-century |
| | Regional and local | - | preponderance of negative impacts |
| Water regulation | | +/- | varies depending on ecosystem change and location |
| Erosion regulation | | - | increased soil degradation |
| <i>Water purification and waste treatment</i> | | | |
| Disease regulation | | +/- | varies depending on ecosystem change |
| Pest regulation | | - | natural control degraded through pesticide use |
| Biological control, trophic structure | | +/- | trophic-dynamic regulations of populations |
| Pollination | | - | apparent global decline in abundance of pollinators |
| Natural hazard regulation | | - | loss of natural buffers (wetlands, mangroves) |
| Supporting Services | | | |
| Soil formation | | + | Weathering of rock and erosion |
| Photosynthesis | | + | |
| Primary production | | + | net primary production has increased |
| <i>Biodiversity</i> | | - | loss of species |
| Nutrient cycling | Nitrogen | - | large-scale changes from general eutrophication |
| | Phosphorus | - | |
| Water cycling | | - | major changes from structural changes in rivers, water withdrawal, and climate change |
| Habitat, refugia | | - | habitat for resident and transient populations |

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Cultural Services

| | | |
|--------------------------------|-----|--|
| Spiritual and religious values | – | rapid decline in sacred groves and species |
| Aesthetic values | – | decline in quantity and quality of natural lands |
| Recreation and ecotourism | +/- | more areas accessible but many degraded |

Status indicates whether the condition of the service globally has been enhanced (+) or degraded (-) in the recent past.

Costanza, R.; R. d’Arge; R. de Groot; S. Farber; M. Grasso; B. Hannon; S. Naeem; K. Limburg; J. Paruelo; R.V. O’Neill; R. Raskin; P. Sutton and M. van den Belt (1997), The value of the world’s ecosystem services and natural capital. *Nature* 387: 253–260.

MA (Millennium Ecosystem Assessment) (2005), *Ecosystems and Human Well-being: Synthesis*. Island Press, Washington, DC. 155 p.

Mooney, H.A. (2010), The ecosystem-service chain and the biological diversity crisis. *Philosophical Transactions of the Royal Society B* 365: 31-39.

Diaz Comments Question 7

Charge Question 7. Strengthening EPA’s ecological protection goals.

Why is there little consensus in EPA about goals for the protection of ecological systems and ecological science principles? The answer to this question will be key to understanding how EPA can move forward on its goal of improved ecological protection. While the details of science can be very complex and difficult for nonspecialists to understand, communication of science and facts can be just as difficult and requires special attention. This is not a problem specific to EPA.

Where are the gaps or problems in the communication chain? This is the first thing to determine. Is it failure to make facts clear or relevant to the problem at hand? or Failure to translate facts into clear management or assessment endpoints? From the documents provided, it seems EPA has both problems. A start at strengthening EPA’s ecological protection goals would be to carry through on the strategies laid out in RAF Ecological Assessment Plan and the Dale et al. 2008 enhanced ecological assessment process.

The problem of coherently communicating and using science to protect ecological status will only become larger with the rapidity at which issues can be presented to the public. This will be made even more difficult by special interests or stakeholders with contrary opinions. Everyone is entitled to their opinion but not their own facts. It is the facts that EPA has to be the best at communicating.

Dr. Lucinda Johnson

EPA SAB Ecological Processes and Effects Committee
Lucinda Johnson

Charge Question 1:

The initiatives proposed appear to be taken faithfully from the recommendations, although the proposed plans appear to fall short of addressing the depth of the issues posed. The advice “The practice of ERA can also be advanced by developing methods and tools that assist risk assessors in designing analyses that appropriately consider the chemical, physical, biological and socioeconomic context of decisions” (Dale et al. 2008: 312) is yet to be realized. Several of the initiatives are interrelated (e.g., communication, ecosystem services, integrated / systems approach). How will these separate panels communicate with one another to achieve their goals?

Ecosystem services are one approach to valuing ecosystems, but the economic basis of such valuation systems have yet to be established. Until we as a society can identify a set of criteria for valuing the externalities associated with the services that ecosystems provide we will never be able to communicate the importance of “changes in assemblages” and “loss of species” to the public in a meaningful way.

In the current political and economic climate I believe the Agency should work diligently to identify “success” stories and communicate those to the public, the managers, and decision makers. This should be a priority for the Agency.

Charge Question 2:

The Framework proposed by Cormier and Suter in 2008 provides an approach for integrating different components of the risk assessment process. Like the three-boxes in the risk assessment framework (problem formulation, risk analysis, risk characterization), the Integrated Environmental Assessment Framework outlines a series of assessments that begin with condition assessment, proceed to causal pathway assessment, then predictive assessment, ending with outcomes assessments. Each assessment type requires use of distinct data and tools- some of which are well defined, readily available, and in common use. The Framework is elegant in its simplicity and logic; however, its full implementation hinges on the integrity of the data and models used in each of the individual assessment types and it is not altogether clear whether there are sufficient data for different situations to fully implement this framework.

Specific issues: Data from condition assessments may not be sufficiently robust and detailed to address many environmental assessment questions. Each state undertakes condition assessments using its established protocols. Condition measures vary and include IBI's, O:E models, and other biological endpoints; physical / chemical endpoints are also commonly used. Some states conduct sampling based on random designs, while others base their assessments on a rotating panel with the anticipation that all waters of the state will eventually be sampled periodically.

Whether or not the condition assessments are conducted at an appropriate spatial scale and return interval to be applicable to the central question is one that I would ask. Further, the monitoring metrics used in the condition assessments may not be applicable to the assessment question. The Framework for Assessing and Reporting On Ecological Condition (EPA SAB 2002) contains pertinent information that I believe has yet to be implemented in a systematic and rigorous fashion.

The same weakness applied to the causal analysis stage of the framework. Input data and models still tend to be based on a restricted set of chemical and biological endpoints. Although I am not as familiar with the predictive and outcomes assessments, I suspect data and tools are also inconsistent in availability and quality.

The integrated assessment proposed by Cormier and Suter provides a descriptive framework that lacks the operational details to move beyond traditional risk assessment, which at its heart, rely heavily on laboratory-based exposure studies to quantify stress-response relationships. Such studies continue to lack ecological relevance, even when multiple species are used. However, the emerging use of field based condition assessment data to enhance the laboratory-based data is an important step forward in incorporating ecological realism with traditional risk assessment. These techniques were applied in the assessment of effects of mountain top mining (Norton et al. 2010) and the development of a conductivity benchmark for Appalachian streams (Cormier et al. 2010). With refined toxicity testing methods that include realistic model species (including use of sensitive life stages as well as a broader representation of species), the use of field data with appropriate methods to characterize local and landscape stressors is gaining traction. The implementation of multiple data types and inputs begs the question of how these will be evaluated. A “weight of evidence” approach seems reasonable, but as noted, there is no guidance on how different components will be weighted. A separate charge question addresses this issue.

The RAF focuses not only on the need for an assessment framework to integrate different parts of the risk assessment process, but also identifies several other needs including: moving beyond media-and chemical-specific assessments; addressing pollutant movement across media; multiple stressors, and cumulative impacts. The framework does not mentioned nor address the need to address the fundamental problems inherent in quantifying multiple stressors and cumulative impacts, the consequences of multiple receptor systems, and the interactions between traditional (chemical) and non-chemical stressors (habitat degradation, loss, fragmentation).

Additional concern:

An “elephant in the room” issue that still must be addressed includes how to predict endpoints in the presence of ongoing non-chemical stressors such as climate change.

Charge question 4: Communication of ecological assessment issues

The Communication Technical Panel plan will develop several products that are based on surveys and interviews with ecological risk assessors and decision makers. From these surveys the team will prepare a series of products aimed at enhancing the use of ERA results. The workgroup will consist of ERA professionals, as well as staff with expertise in communication and risk management.

The plan proposed focuses narrowly on communicating the ERA process and products with respect to practitioners and decision makers. The plan does not appear to address whether the products could be refined to provide information that would facilitate or enhance implementations and decision making, and does not deal with the difficult questions of identifying standards for acceptability, and communicating variability and uncertainty. Furthermore, the description of the proposed plan contains insufficient detail to fully understand the extent to which the surveys are meant to delve into the questions posed by the RAF regarding how to communicate the *significance of the results*, such as the loss of species, changes in community structure, and other endpoints. Results of the ERA consist of the scientific facts, but generally lack the interpretation of how humans will be affected. What does the loss of the most sensitive taxa mean to the ecosystem and to the humans that use them? It is clear that the efforts of this panel will and should be closely linked to the issue of valuation of ecosystem services, and indirectly to that addressing adaptive management issues.

The NGO community has considerable expertise communicating the value of ecosystems and services to the public, it would be useful to tap into that expertise. The panel might also benefit from input from social scientists, ethicists, marketing professionals, and media specialists, in addition to the “communication” staff?

Dr. Thomas La Point

Charge Question 1. Overall technical merit of the proposed science policy and technical practice initiatives. Lead discussants are: Dr. Richard Di Giulio, Dr. Wayne Landis, Dr. Judy Meyer, Dr. William Stubblefield

Overall technical merits are high. The initiatives proposed are responsive to the SAB and NRC recommendations. The focus of the “Integrating Ecological Assessments” report includes the recommendation to include scientists, assessors, and managers early-on in the process. This remains a key recommendation, as do the recommendations to develop a better understanding of perceived versus actual risk, preferably employing “EC” techniques and moving away from point estimates. Of great importance in the recommendation to increase reliance on adaptive management. This approach has been of high value, for example, in the Coeur D’Alene River system, as detailed in the NRC book, *Superfund and Mining Megasites* (2005).

Charge Question 2. Importance of developing an integrated assessment approach. Dr. Lucinda Johnson, Dr. Allen Burton, Dr. Peter Chapman, Dr. Wayne Landis

Given the importance of increasing specificity in the Problem Formulation phase, the ability to implement assessments of condition, causal pathway, predictive or outcome would, I expect, become more clear. As the report states, it is necessary to integrate these approaches, as community integrity and function are increasingly becoming important endpoints in assessments. In any of these, there is a clear need to establish “the power of the test.” It is critical, in my opinion, to state the goal as, “we wish to discriminate a given percentage difference among various group means, with some given probability.” An example might be, “we wish to determine a 10% loss of body weight in a population of fish, relative to reference or control fish, with a 95% probability.”

Charge Question 3. Use of the weight-of evidence approach in ecological risk assessments. Lead discussants are: Dr. Peter Chapman, Dr. Allen Burton, Dr. Loveday Conquest, Dr. Richard Di Giulio

I agree with the necessity of a weight-of-evidence (WOE) approach. However, as we gain better understanding of how to relate scale in time and place to “stressor intensity,” and as we develop better understanding of baseline ecological conditions, the use of WOE should not be as necessary. Presently, there can be much argument over how much weight to give certain lines of evidence. As a better understanding arises concerning multiple and complex stressors, and as these are related to life history parameters (See Charge Question 7, below), I would expect less argument over the strongest lines of evidence.

Charge Question 4. Communication of ecological assessment issues and results to decision-makers and stakeholders. Lead discussants are: Dr. Greg Biddinger, Dr. Lucinda Johnson, Dr. Amanda Rodewald

The consideration of a technical communication panel is a good idea. However, the utility of a peer-review process in planning an ERA, and as an assessment of the process during the conduct of the ERA, is invaluable. However, having said that, I find that the Technical Panel idea is a good one, if it takes the time and effort to relate to the public, as well as to resource managers and the broader scientific community. Often, one of the most critical aspects of an ERA is the component where public input is sought and where the public is educated on the various selected approaches and endpoints. The Technical Panel might do well to incorporate public speakers with a good understanding of risk communication. This is not “dumbing down” for the public; it is a matter of not simply presenting the information and assuming the lay public will follow the train of thought. A genuine outreach must be attained.

Charge Question 5. Incorporation of ecosystem services into ecological risk assessment methods. Lead discussants are: Dr. Judy Meyer, Dr. Greg Biddinger, Dr. Robert Diaz

The devil is in the details on this Charge Question. Structural endpoints (survivorship, extirpation, taxa richness, etc) are typically within the ability of the risk assessor to measure and quantify as endpoints. Further, aspects of biotic community function (rates of energy flow, material cycling, quantifying primary and secondary production) can also be quantified, as long as the base levels had been quantified prior to the change. The recreational and educational aspects come close to a Natural Resource Damage Assessment. If so, it may be necessary to include in the Problem Formulation phase this aspect, in order to plan to measure this *a priori*, rather than as an afterthought.

Ecological services, such as enhancing water quality as a result of a wetland, can be quantified, as the outflow waters can be monitored for success of the remediation. However, for broader issues of ecosystem services, say, water retention stemming from an extant forest, may be much more difficult to quantify because other abiotic and biotic factors may or may not be assessed, given the typically-limited time and funds to do so.

Incorporating ecosystem services into ERA guidances will become more useful when we have progressed much more into the understanding of ecosystem processes. Until then, I think the utility of structural measures will outweigh the potential use of ecosystem services, except in locally-defined situations.

Charge Question 6. Use of adaptive management for testing and revising risk management actions. Lead discussants are: Dr. William Stubblefield, Dr. Fred Benfield, Dr. Loveday Conquest, Dr. Thomas La Point

Six elements of adaptive management were identified by the NRC that are directly relevant to goal setting and research needs: (1) resources of concern are clearly defined; (2) conceptual models are developed during planning and assessment; (3) management questions are formulated as testable hypotheses; (4) management actions are treated like experiments that test hypotheses to answer questions and provide future management guidance; (5) ongoing monitoring and evaluation are necessary to improve accuracy and completeness of knowledge; and (6) management actions are revised with new cycles of learning. Such elements are perhaps difficult to incorporate into the initial problem formulation. However, if the several linked

recommendations concerning peer review, understanding the baseline ecosystem, and linking exposure biomarkers to effects, then changes to a new set of measures or mitigative responses during the remediation program should not be taken as “having made a mistake.” It should be thought of that, during the overall process (typically taking a year or more), that as we learn more of how the ecosystem is structured – and how that structure relates to energy flow, materials cycling, and the maintenance of key species, a change should be seen as both necessary and wise.

Charge Question 7. Strengthening EPA’s ecological protection goals. Lead discussants are: Dr. Robert Diaz, Dr. Thomas La Point, Dr. Fred Benfield

In truth, many of the recommendations listed in Dale, *et alia* (2008) are highly germane to this Charge question. In my opinion, the recommendations all move towards a stronger protection of ecosystem structure and function. Ultimately, the recommendations would not only lead to more robust assessments, but also lead to better understanding of ecosystem structure and function. This understanding, in turn, would lead to better predictability of effects and wider applicability in similar situations.

Summarizing a few of the key recommendations, I would certainly call for:

- 1) Explicitly considering scale, both in time and space. This goes to considering life history and scope-for-growth analyses, as the use of r , the intrinsic rate of natural increase, ultimately is useful in predicting if a population, subject to stressors of a variety of types, will grow, stabilize or shrink in the present conditions.
- 2) Biomarkers of exposure continue to be necessary to link to biomarkers of effect, whether they be metabolic costs (scope for growth), ultrastructural modifications of critical organs (e.g., gill clubbing), or net reproductive output over several generations.
- 3) Incorporate post-remedial assessments and implement adaptive management programs to adjust the remediation approaches, should such be necessary after the assessment.

Dr. Wayne Landis

Wayne G. Landis

General Comments

I have reviewed the overall technical approach outlined in the four-page summary, the colloquium report and so on. Many of us on this committee are co-authors on the SAB report from EPEC and on the Dale et al 2008 paper. I have also been on the Science Policy Integration committee for the SAB and part of our duties was to review the NRC Silver Book. It also seems that Paul Anastas' (2012) recent feature in ES&T is relevant since it sets USEPA's research agenda. Because Anastas cites the recent NAS "Green Book" I also reviewed the on-line version's risk assessment section. The section on risk assessment in the Green Book does not cite "Suter" once, so I am not how reliable to judge the remainder of the text except that it is oriented toward human health and resources.

I understand that EPA has spent a great deal of effort on coming up to these recommendations and I applaud the effort. I think I understand some of the the policy and scientific constraints, especially after being part of the interview process for the Science Integration committee. The importance of continuing education of the scientists in the program office and regions is important and my reading of the report indicates that those scientists would be part of this new approach, not just those of ORD.

In the introduction to the charge questions I was very interested in the discussion of performing cumulative risk assessments. When reading the charge questions I could not find a mention of cumulative risk assessments but found it in some of the other notes. The NRC silver book has a chapter on cumulative risk assessment that discusses methods not used by EPA to accomplish such a goal. For fifteen years cumulative risk assessments that combine chemical and non-chemical stressors have been used across the world. Victor Serveiss (USEPA) has investigated the use of methods used for watershed ecological risk assessment. My collaborators and independent researchers have used the relative risk model to estimate risk for a variety of landscapes. C. Pollino has use Bayesian networks to estimate cumulative risks to Australian

systems. If USEPA is serious then the effort should be expended to broaden the range of tools.

Many of my comments below are in the form of questions that I would need answered to provide a more quantifiable or specific answer. I am not doing this to be a problem or to disrespect my colleagues at the Agency. I am trying to visualize what I would need to build a risk assessment or adaptive management structure using my previous experiences as a database. We in the Puget Sound region are facing similar issues, just replace sustainability with health of the Puget Sound. Both are so normative as to be nearly impossible to characterize.

Specific comments to charge questions

Charge Question 1. Overall technical merit of the proposed science policy and technical-practice initiatives.

I applaud the effort to set specific design goals for the management of ecological services. However I remain to be convinced that sustainability is the vehicle for this. In my reading of the summary report and the Anastas report in ES&T I do not see that this is any more quantitative than ecosystem health or other normative statements. If sustainability is going to be goal then social scientists and others who are trained in precisely defining social norms need to be employed in the effort. Social scientists are rare in the agency.

My understanding is that Anastas is now planning on leaving the agency. Is there a broad range of support for sustainability within the agency or is this mere relabeling of current programs? Without specific design goals it is very difficult to design a vehicle to accomplish them. These design goals are not yet transparent in my reading of the report.

After my review of the documents that support this effort, I find the report dated and primarily limited to the world of EPA and its internal researchers. This comment also applies to many of the charge questions below. They do not even seem to acknowledge the efforts of EPA researchers such as Carriger and Barron (2011) using influence diagrams to minimize risk to ecosystem services from oil spills. Scientists such as these authors are critical to the development of the science in the agency.

Is there an issue with USEPA being so isolated that it is not possible for it to acknowledge the contributions of researchers across other Federal agencies and across the world? In the 1990s to early 2000s I would have seen USEPA as a clear leader in the field. That is no longer the case and is perhaps not a USEPA goal. The science policy recommendations listed on page 1 of the report are already in use in many places across the world in their assessments.

I understand from other SAB committee work that the isolation may be due to the lack of professional development and travel funding within the Agency. If this management issue is not remedied then the proposed transformation of the agency's research agenda has a low probability of success.

I would also like to comment specifically on the response to the suggestions made by the NRC and the EPEC documents. I appreciate the fact that the comments are listed. However and in contrast to what I have seen in the BOSC process there does not seem to be a response to each. Should I take it that no response means that the Agency does not find the comment useful or persuasive?

One of the recommendations from the EPEC report is that EPA looks at risk assessments performed outside the agency. I see no evidence that this has been done. Some of the best risk assessments that I have seen are coming from Australian researchers, both government and academics. They have conducted risk assessments over broad expanses of land and make important decisions based on those assessments. They take a very different approach. The USFS makes a number of "threat" assessments regarding fires, invasives species, and climate change. Bayesian networks and other techniques are being applied. Fishery managers directly manage specific ecosystem services using probabilistic tools. It seems that there is a large source of information and techniques that remain unavailable.

Charge Question 2. Importance of developing an integrated assessment approach.

Why would you not want to integrate the assessment process to make management decisions?
Risk assessment should be able to incorporate a number of assessment types and is used for decision making outside the health and environmental arenas.

The risks of multiple stressors to multiple endpoints and ecological stressors have been calculated for landscapes for over 15 years and by groups across the world. There seems to be no awareness of that type of research although the need for cumulative risk assessment is acknowledged. The NRC Silver Book as an entire chapter on cumulative assessment that makes a number of suggestions but I do not see any movement to address these issues.

If you want a sustainability analysis there needs to be a quantifiable definition. So far I do not see one that I can build a quantifiable model for from the EPA.

Charge Question 3. Use of the weight-of-evidence approach in ecological risk assessments. The document discusses Weights of Evidence as a tool. WoE has progressed over the years but as it is currently practiced a qualitative tool without a probabilistic basis. That is not necessary. In medical diagnosis and in other fields Bayesian tools are used successfully. A WoE is essentially a Bayesian approach without a realization of the calculation. Evidence should be taken that can differentiate between alternative hypothesis. As discussed by Newman et al (2007 *Hydrobiologia* 577:31–40) there are ways to perform specific calculations. One of the co-authors (Carriger) is now using Bayesian networks and influence diagrams to combine evidence and to explore different management alternatives.

My experience in using a more conventional WoE even within a risk assessment framework is that it is much more cumbersome than using Bayesian networks to perform a similar kind of analysis.

One of the key parts of a WoE or one using a Bayesian network is that they can be tied directly to the cause-effect conceptual model that should be generated for every risk assessment. The issues discussed in Suter's presentation on the topic are very germane with conventional WoE approaches. Typical WoE have not been made rigorous enough and the fact that we are still

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debating about how to weigh different lines of evidence probably means that we do not have a proper framework. WoE is probably best in deciding between alternative hypotheses, a very Bayesian approach yet I rarely see the tools used in ecological risk assessment.

Charge Question 4. Communication of ecological assessment issues and results to decisionmakers and stakeholders.

Risk assessment still finds limited use even in USEPA. The recent effort of an SAB to examine methods for the treatment of ballast water did insert language to include risk assessment into process to determine the appropriate methodology and then to manage that process. That recommendation apparently did not make it into the method determination process.

The barriers are many. How many stakeholders or decision makers are comfortable with a quantitative assessment? How much realistic training has the agency put into ensuring that staff can apply risk assessment to a decision making process?

My other thoughts on why risk assessment has found such limited use can be found in:
Landis WG. 2009. Why Has Ecological Risk Assessment Found Such Limited Application?
Human and Ecological Risk Assessment 15:849-857

Charge Question 5. Incorporation of ecosystem services into ecological risk assessment methods.

What the document does not do well is explain how to derive ecosystem services for particular sites. Scale is very important in determining what is important to which stakeholders and where. Descriptions of endpoints in a first step but I need examples and data on how often ecological services are actually used as endpoints. I know that many natural resources agencies routinely include ecosystem services in their management strategies, do we have any data on how often EPA has done this. What is the range of endpoints used and the frequency of each?

There is a risk and threat assessment literature that routinely incorporates ecosystem services in

their calculations. Has EPA tested their document against those efforts and results?

Charge Question 6. Use of adaptive management for testing and revising risk management actions.

Of course adaptive management can be used, the difficulty is in finding clear cut examples. Forestry and fisheries have attempted to do this for at least a decade. The difficulty that USEPA will have is in gathering the data to use in adaptive management. How are data on the effects of atrazine used to adaptively manage the herbicide? Are there data from field studies collected independently? Nutrient and some contaminant data are available as part of the TMDL process, but I have yet to find a TMDL set using a risk assessment process. So can adaptive management be useful? Yes. Does EPA have the mechanisms, not yet clear.

Charge Question 7. Strengthening EPA's ecological protection goals. This is such a normative statement I am not sure what the question actually is. As far as communicating risk assessment it is possible to do so to seniors and first year graduate students. I assume the same is true for decision makers. However, the barriers are manifest. Often there is a poor understanding of modern paradigms for toxicology and ecology. Stability and other Clementian models of ecological structures are common. There also seems to be disconnects between the way that laws and regulations are written and how the world works. Reference sites and baseline measurements are manifestations of antiquated models at work in making environmental policy. EPA is not alone in this corner. If decision makers listen to NPR and hear about the balance of nature or ecosystem health they have probably internalized an inaccurate model of ecological dynamics. Robert Lackey has written eloquently on these issues and a google search will turn up his numerous peer reviewed and other papers, especially on fisheries management.

Other notes:

- Training and Improved Access to Information for Ecological Assessment – Risk assessor and manager training and increased access to information will lead to improved quality of risk assessments.

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I actually do not think it is information (as in data) that is the limiting factor but approach and fundamental knowledge. Quotient calculations and the use of NOECs is a symptom of a deeper issue. In the interview process for the Science Integration committee there also seems to be a lack of empowerment of scientists at the regional offices to take new approaches and to have access to the necessary data.

- Quality Assurance and Data Quality Objectives for Ecological Assessment – Quality assurance and data quality objectives for ecological risk assessment will formalize ecological assessment standards.

How do I set QA objectives without a clear understanding of how risk decisions are made? Tell me how EPA managers are directed to make decisions under uncertainty and then I can start calculating the other numbers.

- Assessing the Risks of Multiple Stressors – Development of guidance is proposed for assessing the risks of multiple stressors.

USEPA needs to take advantage of the numerous studies performed by other US agencies and researchers across the world that successfully deal with multiple stressors before developing its own guidance. The agency is not at the forefront of the field in this area as far as ecological risk assessment. I would find it wasteful for the agency to develop its own approach independent of this literature.

- Receptor-specific and Stressor-specific Guidance - Development of guidance is proposed for common receptor and stressor-specific assessments.—No comment.
- Life Cycle Analysis for Product Safety Evaluations - Development of guidance is proposed for assessing new chemicals and other products using a life cycle approach. This will improve the quality of assessments and decisions.

One a world leader EPA has fallen behind in LCA analysis. LCA should actually be part of the

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integrated analysis and assessment process for more than products. How about expanding the tool so that it can be used to site a power plant, drill a well to frack for natural gas, or for putting in a mall. The more that LCA can be made into a probabilistic model the closer its ties will be with the overall assessment process.

- Uncertainty Characterization and Communication - Guidance is proposed for characterizing uncertainty and preparing risk communication information.

This bullet is really two items. We can characterize uncertainty in a number of ways and there is an extensive literature in both the human health and ecorisk areas. The issue is more how will the decision maker use the information.

- State-of-the Science, Best Practices Reports, Exemplary Case Studies, and Success Stories - This initiative will provide timely information on best practices to risk assessors.

Not without going outside the agency and doing it in a timely basis.

Dr. Judith Meyer

Judy Meyer's response to charge questions evaluating *Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan*

1. Overall technical merit of the proposed science policy and technical practice initiatives.

The 4-page document we were asked to review is extremely vague. It is difficult to see how this constitutes an action plan. The document states that the STPC is going to require more substantive development of policy issues identified in this plan. The plan is largely recommending issue paper development. It is extremely difficult to provide a useful review of a document that is so vague with so few real actions proposed and no timetable. The six policy and seven practice initiatives listed are responsive to the recommendations received from SAB and NRC. They are dealing with subjects that have the potential to greatly improve environmental assessment and decision-making at EPA. But there is no way to evaluate whether that potential has any hope of being realized. It is like being asked to judge the literary merit of a novel for which one has only the title.

The report from the RAF Colloquium (*Integrating ecological assessment and decision-making at EPA: a path forward*) is a more substantive document, and the reasoning behind and some justification for the proposed initiatives are in that report. That report also provides clear responses to the various recommendations made by NRC and SAB. The RAF should be commended for their thoroughness in this.

The following statement in the Colloquium report hits at the heart of the problem: “the science of ecological assessment is stronger than the policies and practices that turn their scientific findings into Agency actions.” This implies that what is needed is greater understanding and appreciation of ecological issues in the decision-makers in the Agency and better ways of using ecological risk assessments in decision-making. I do not see how the actions proposed will achieve that. Rather than more guidance documents for risk assessors, perhaps what is needed is some thoughtful analyses of the successes of ecological risk assessment, how Agency decisions were or could have been improved by the assessments, how ecological risk assessment is an essential part of solutions to some of the complex and tough issues currently facing the Agency (e.g., climate change, multiple stressors). There is currently an emphasis on sustainability at the Agency – where does ecological risk assessment fit into that potential paradigm shift? I recognize that documenting “success stories” is called for as one of the more specific technical practice initiatives, which seem to be given lesser billing in this document. I am suggesting that this be recognized as an important component of all of the broader initiatives.

I found the following statement to be a shocking (but true) assessment of the situation: “There is little consensus in the Agency about goals for protection of ecological systems or the importance of ecological effects. In addition, important and well-developed ecological science principles (e.g., systems analysis, landscape ecology, ecosystems services, and adaptive management) are unfamiliar and have not been systematically integrated into the Agency's science policy

framework.” That is a stunning indictment. I do not think that the actions proposed are adequate to remedy that fundamental problem. What seems to be “broken” is not ecological risk assessment, but ecological risk management. How assessments are used in decision-making is not touched upon in this action plan, and perhaps it should be.

All the actions proposed in the action plan appear to be developing guidelines or recommendations. Given the number of guidance documents that already exist at EPA (I counted over 50 listed in Appendix C of the RAF Colloquium report), are more guidance documents really what is needed? One comment in the Colloquium report suggested that state of the science documents might be more useful than more guidance documents. That seems worthy of further exploration as does the analysis of ecological risk assessment successes discussed above. The traditional EPA approach seems to be to first develop a framework, then write issue papers and case studies, and finally guidance. And that is basically what is being proposed in this action plan. For something as potentially transformational as the subjects identified here, one wonders if some different approaches are needed.

One recommendation from the SAB not addressed in the Action Plan is the need to incorporate relevant methods and analytical techniques being developed outside the agency and in other countries. “The Technical Panel sees no need for specific actions to increase awareness of assessment methods employed by other agencies and countries.” (Colloquium report) That strikes me as myopic. The Colloquium report asserts that EPA is already aware of what is being done elsewhere, but provides only a listing of websites showing that some collaborative associations have been developed. That is not convincing evidence. There are no citations from risk assessments done outside the US and pages upon pages of references to EPA documents. Surely relevant assessments are being done and new methods and approaches being tried elsewhere.

The Colloquium report recognized that any new guidance document developed should include a plan for training. I didn’t see any evidence of that in the guidance documents proposed here.

2. Importance of developing an integrated assessment approach

One can hardly argue against the need to do this. As noted in the document, the issues facing the Agency are complex, large-scale, multi-media, and deal with multiple stressors, and a broader systems approach is essential. But an action plan should state HOW this systems approach is going to be developed. The Cormier and Suter (2008) framework is a fine first step, but it is a bare skeleton of an integrated assessment approach. The case studies discussed in that paper show how existing assessment methods can be placed into the proposed more general framework, but that doesn’t seem like developing a systems approach to ecological assessment. It is just putting existing methods into new boxes. Section 2.1 is correct in stating that a new paradigm is needed. Can a new paradigm be developed using the same old approaches?

3. Use of the weight-of-evidence approach in ecological risk assessments.

Clearly this needs to be done, but the document provides no hint of how such guidance would be developed. Will this be based on existing EPA materials (e.g., as part of CADDIS)? Will

quantitative approaches be investigated? How are other agencies and countries handling this question, and will insights from their efforts be incorporated? This is like trying to evaluate a proposal in which none of the analytical methods that are going to be used are described. The question may be an important one, but until one knows how the question will be answered, one can't determine whether the answer will be worth anything. Just noting that issue papers will be written and guidance provided does not constitute a proposal.

4. Communication of ecological assessment issues and results to decision-makers and stakeholders.

Communication is a two-way street, yet that is not apparent in what has been proposed. It sounds as though what is being proposed is finding ways to more effectively talk to the stakeholders and decision-makers, not so much listen to them. One of the points emphasized in the SAB report is early and continuing engagement of risk assessors with stakeholders and decision-makers, not just telling them what has been learned, but listening to them to understand what they value and what they need to know to effectively make decisions and listening to concerns of the community. The Colloquium report identifies a need to “develop strategies for productively engaging stakeholders.” I see no acknowledgement of that in the action plan.

Given that there is a discipline called “risk communication,” I was very surprised to read that there are no guidelines for risk communication.

Actions 1 and 2 proposed in the committee's technical report sound like a repeat of what was done in the SAB workshop and in the RAF Colloquium.

One communication recommendation identified in the Colloquium was enhancing communication among risk assessors, and that does not seem to be a part of the action plan although it would seem to be a valuable way to evaluate how guidance documents are being used, to work towards standards of practice, and to learn of potentially effective (and ineffective – lessons learned) approaches to assessment.

5. Incorporation of ecosystem services into ecological risk assessment methods.

I agree that ecosystem services offers considerable potential for ecological risk assessment, but this 4 page document really says nothing about how this is going to be done except that a panel has been created and its findings will be incorporated in the guidance document on ecological endpoints. The report from the panel does not provide much additional information. Appendix B in the Generic Ecological Assessment Endpoints (GEAE) document presents a useful overview of the kinds of values worthy of consideration, but how are these going to be put into practice in an ecological risk assessment? The problem with the GEAE is revealed in its title – it is generic, and at this point what is needed is more specifics, e.g. case studies showing how these values could be used in risk assessment and risk management.

Incorporating ecosystem services into risk assessment is of high priority. It takes advantage of the expertise being developed around ecosystem services in ORD, which should benefit both ERA and the ORD program. Incorporating ecosystem services should also stimulate progress in

the first action item, namely incorporation of systems analysis into ERA. It should also help combat the problems identified in section 2.4 (action item 4) of the report.

With respect to the products proposed in the technical panel's report, it makes more sense to me to combine products 1 and 2: 1 is conceptual but 2 shows how the concepts could be implemented. Why a white paper and not a publication? The latter seems more appropriate. And 3 should be relatively straightforward once 1 and 2 are completed. The committee report would benefit from describing how the actions proposed fit into the research on ecosystem services being done in ORD and elsewhere around the world.

The GEAE document lists functions as a possible endpoint, but just for wetlands. Some evaluation of the experience in using this endpoint would be a valuable aspect of the proposed analysis. The GEAE report notes that "a continual, open process for reviewing, amending, and creating new GEAEs" should be developed and maintained. I guess the proposed work to develop ecosystem services endpoints is a step in this direction, although it seems a cumbersome process. Is there not a website or some place where experiences with other endpoints can be posted? That sort of thing was proposed in the GEAE document – does it now exist?

6. Use of adaptive management for testing and revising risk management actions.

The call for post-decision monitoring and assessments has considerable merit. Not only are they needed for adaptive management, they also offer an opportunity to improve practices in ecological risk management and to document successes so that decision-makers have greater appreciation for the practice of ecological risk management. SAB has recommended greater incorporation of adaptive management approaches in the Great Lakes Restoration Initiative Action Plan, and this is a worthwhile goal. What is missing are the steps needed to achieve this.

7. Strengthening EPA's ecological protection goals.

Some of my responses to these questions have been covered in my response to the first question. What is hinted at in the Colloquium report that seems to be a necessary step to strengthen ecological protection goals is to have individuals with a deep understanding of ecological principles and practices in decision-making positions in the Agency. For example, effective representation of ecological perspectives is essential in the STPC.

Dr. Amanda Rodewald

Comments from Amanda Rodewald

Charge Question 1: Overall technical merit of the proposed science policy and technical practice initiatives.

Are the initiatives responsive to SAB and NRC recommendations?

In many respects, yes they are. However, previous recommendations focused much more strongly on the following:

- The need to incorporate social and decision sciences. Relative to other recent reports prepared by the Agency, the RAF plan gives comparatively little attention to social sciences. Failure to sufficiently incorporate social sciences overlooks the reality that ERAs occur within a given social, economic, political context and will be most useful when skillfully aligned with community values and/or management objectives. Moreover, given the emphasis on improving decision-making, the Agency stands much to gain from greater collaboration with decision scientists. I realize that many in the Agency already are doing this, but that did not come through in the document.
- The problem formulation stage as probably the most important point in the assessment process to ensure a systems-level approach. The RAF plan does not explicitly address the problem formulation stage.
- That prior to and during problem formulation, an open dialogue among scientists, risk assessors, risk managers, decision-makers and stakeholders is essential (likewise, broad engagement also sets the stage for effective communication of results). One point highlighted by the 2007 EPA-SAB-EPEC workshop on ecological risk assessment was that ERAs have been most effective when clear management goals were collaboratively developed and incorporated into problem formulation and, from those, information and data needs were derived.
- Peer review at the problem formulation stage would be an excellent strategy to ensure that systems approaches are used. In particular, peer review by ecologists would make it more likely that the ERA sufficiently addressed ecological end points and protected ecosystem health.
- Explicitly defining the most appropriate and realistic temporal and spatial scales is necessary (i.e., what is the scale of concern?). This is especially important for the increasingly complex and systems-level, including entire life-cycle approaches that EPA aims to use.

Do these reflect the most important set of activities?

Yes, if expanded to include those mentioned above & below (especially social & decision sciences and environmental justice).

Other key issues that could be considered.

- Explicit consideration of environmental justice. Although it may not need to be a separate initiative, the concept of environmental justice seems noticeably absent. Aside from being a priority area of the Administrator, environmental justice also illustrates the interdependence of ecological and human health.
- As part of a broad communication strategy, the Agency might consider use of Community based participatory research approaches that engage stakeholders throughout the entire risk assessment process.

Charge Question 2: Importance of developing an integrated assessment approach (i.e., four types of assessments).

- A systems level approach should reflect that risk is the consequence of multiple, diffuse, and indirect interactions among species and their environment.
- In terms of the framework that incorporates the different types of assessments (Cormier and Suter 2008), I am unclear what the outcome assessment is. Does the outcome assessment (the fourth) aim to identify the information that the assessment produced or the outcome/impact in terms of information, or the outcome in terms of the decisions about management and policy?
- The third type of assessment (predictive assessments to estimate environmental, economic and societal risks, and benefits associated with possible management actions) is the one that most requires a systems approach and ecosystems/ecological perspective. Risks and benefits are strongly mediated by ecological interactions and health. This third assessment type also fits with the need to identify and reduce risk for vulnerable populations and environmental justice communities, which due to social-ecological factors (including the absence of certain salutogenic exposures and the presence of certain psychosocial stressors) may have higher exposure and/or health impacts from the same background environmental/ecological conditions.
- Related to this is the question of to what extent should EPA constrain the scope of ERAs to the borders of its statutory and regulatory responsibilities?

Charge Question 3: Use of the weight-of-evidence approach in ecological risk assessments.

Who are the users of the best practices report? This could be made explicit in the document. A structured decision-making framework might be particularly helpful within the context of a weight-of-evidence approach to ensure that the range of goals and desired outcomes are appropriately considered.

Charge Question 4: Communication of ecological assessment issues and results to decision-makers and stakeholders.

The wording in this section sounds surprisingly one-directional, which is not consistent with recommendations from a variety of panels, committees, advisors that emphasize that multi-directional communication is a critical part of risk assessments and should be present from problem formulation stages to implementation and risk management.

Conceivably communication barriers could happen when either individuals do not have the requisite knowledge or familiarity with the topic to communicate the necessary information OR when the information or knowledge is present but simply not communicated effectively. Given that ecological dimensions of risk assessments have been introduced fairly recently to certain groups within the Agency, either possibility seems plausible.

I see the following as a very simplistic and general process of effectively communicating information:

1. Communicator has the necessary knowledge and understanding.
2. Communicator has the skills needed to effectively communicate (in a general sense)
3. The intended receiver is receptive to and values the information.
4. The intended receiver has the background and training necessary to understand and apply the information.
5. The receiver can and is willing to act on the information.

The wording in the initiative implies that only 1 & 2 are the focus, and this leaves me wondering if the communication process doesn't actually breakdown elsewhere. Do we know at what stage in the communication process efforts are best directed? These questions further highlight the importance of working collaboratively with social scientists throughout the ERA process.

As a corollary of the above, different communication strategies need to be used for different groups. Vulnerable populations and environmental justice communities, in particular, may require more specialized communication strategies.

Charge Question 5: Incorporation of ecosystem services into ecological risk assessment methods.

- This requires a shift from the traditional stressor perspective to a values perspective.
- Is the problem that we don't have enough ecological endpoints, or that ecological endpoints are not measured because they are not valued or too costly or complicated?
- As part of this, we might consider salutogenic (beneficial) exposures; that is a point that is coming out of the NRC panel on Exposure Science.

Charge Question 6: Use of adaptive management for testing and revising risk management actions.

- Adaptive management is not easily nor casually implemented. There should be a clear funding mechanism identified to allow its development and implementation.
- Adaptive management requires that a lot of attention be given to the problem formulation stage. Dale et al. 2007 suggested that use of Bayesian approaches, causal argumentation, and probabilistic risk assessment would facilitate the development of hypotheses that could be evaluated as part of the adaptive management process.

Charge Question 7: Strengthening EPA's ecological protection goals.

- Adopting a more holistic perspective that recognizes the interdependency of human and ecological health would be the best starting point, rather than the traditional dichotomy of human or ecological health.
- Environmental justice might be a useful platform to highlight the fact that ecosystems are coupled human-natural systems, particularly because it is a priority area of the Administrator. Poor ecological condition/quality can exacerbate exposure and severity/magnitude of impacts on vulnerable populations and environmental justice communities..
- Peer review by ecologists at the problem formulation stage might be very helpful here.
- To effectively strengthen EPA's ability to protect ecosystems, we need to better identify and quantify vulnerable populations and ecosystems.
- Increase awareness by decision-makers that even small changes in ecological interactions can profoundly mediate exposure risk and outcome. One example is how the invasive round goby (*Neogobius melanostomus*) facilitates movement of contaminants in food webs and increases exposure to humans. The apparent mechanism is that the goby is more tolerant of and likely to occupy polluted or contaminated environments than native species and thereby it attracts predatory fish, which also are popular game species consumed by humans.
- Excellent point about the need to elevate representation and influence of ecological scientists as senior science advisors within the Agency.

Dr. William Stubblefield

**Bill Stubblefield's preliminary response to charge questions:
*Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan***

General Comments

In preparing these comments I have reviewed the 4-page document, *Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan* and the supporting document, *Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward*.

Preliminary responses to charge questions:

1. Overall technical merit of the proposed science policy and technical practice initiatives.

Six specific science policy initiatives and seven technical practice initiatives are described in the Assessment Action Plan and these seem to be consistent with recommendations from the 2009 intra-agency colloquium document. However, the science policy recommendations are very general and it is difficult to evaluate the potential for success of these efforts based on the brief information provided. Furthermore, it is not clear if or how the technical practice initiatives will support the science policy initiatives. Again, the problem is that too few details are provided about how these initiatives are to be implemented. EPA is to be congratulated on recognizing the importance of the issues surrounding the science and utility of ecological assessment and its role in the decision-making process and the recommendations made will further the development of the science in the future.

2. Importance of developing an integrated assessment approach.

As is pointed out, the development of an integrated assessment approach will be necessary to address the complex large-scale assessments that the EPA is currently facing. All of these assessments will require consideration of multiple stressors and receptors and involve complex environmental systems. The agencies previous simplistic media and chemical-specific approaches will not adequately address the concerns inherent to these complex issues. Therefore, new approaches for conducting large integrated assessments will be needed. Approaches such as those published by Cormier and Suter (2008) provide a good framework, but additional work will be required. It is not clear from the action plan how the Agency intends to specifically address these issues moving forward.

3. Use of the weight-of-evidence approach in ecological risk assessments.

Use of the weight-of-evidence approach in conducting ecological risk assessments has long been recognized as a desirable goal. However, weight-of-evidence approaches recommended in the literature for conducting environmental risk assessments have varied broadly covering the range

from simplistic and qualitative to detailed and quantitative. No standard methods or procedures exist that describe how a “weight-of-evidence” process should be incorporated into ecological risk assessments. Papers like that of Burton, Chapman, and Smith (HERA 2002 8: 1657-1673) have attempted to review and summarize the advantages and limitations of different weight-of-evidence approaches, but failed to make specific recommendations for how these approaches might be used in a standardized method. Development of specific quantitative guidance that can be used by risk assessors and risk managers would clearly be a valuable addition to the risk assessment toolbox and is something that should be undertaken by the Agency.

4. Communication of ecological assessment issues and results to decision-makers and stakeholders.

The ability to communicate the results of any ecological assessment to decision-makers and the public is one of the most important aspects of conducting any ecological assessment. However, it has been recognized that this is one area in which we often fall short. It was noted in the Assessment Action Plan that “Currently there is no guidance for communicating ecological risks.” Clearly this is an area that we must improve upon. If the decision-makers and the public fail to recognize the utility of our science in helping make sound understandable decisions about the important environmental issues facing Society, then research funding will decrease and the science will cease to exist. No specific actions are provided for how the agency anticipates addressing the concerns associated with communications.

5. Incorporation of ecosystem services into ecological risk assessment methods.

The incorporation of ecosystem services and benefits in environmental assessments seems fundamental. However, the action plan is vague on how this activity will be implemented. It is not clear that the development of “case studies and guidance on how to relate ecological endpoints to ecosystem services” will be successful in achieving the desired goals. Greater detail is needed to evaluate the potential success of the proposed approach.

6. Use of adaptive management for testing and revising risk management actions.

The six elements of adaptive management, as described in Section 6.3 of *Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward*, seem remarkably similar to the steps typically employed in conducting an ecological risk assessment in accordance with existing EPA policy. Therefore, the use of adaptive management seems to be a logical recommendation and an appropriate application in the risk assessment framework. One of the elements, i.e., ongoing monitoring, is an aspect of adaptive management that is seldom fully implemented in risk management actions. This is likely due to the costs associated with these programs, but the importance of these activities as a measure of assessment “validation” cannot be forgotten and they should be incorporated in any risk management actions.

7. Strengthening EPA’s ecological protection goals.

It is somewhat disheartening to read, “there is little consensus in the agency about goals for protection of the nonhuman environment or the importance of ecological effects.” If the

These preliminary comments are from individual members of the SAB Ecological Processes and Effects Committee Augmented for Review of the Ecological Assessment Action Plan and do not represent consensus SAB advice or EPA policy.

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Environmental Protection Agency does not have a clear mandate to “protect the nonhuman environment” and does not have a clear idea about the “importance of ecological effects,” then there are basic issues that must be addressed regarding the mission of the Agency. Over the last few years it appears that a distinct split has developed between the human and nonhuman environment, with human environmental concerns attracting the lion's share of attention. This may be in part due to the prevailing political and economic climate in the US, with importance dictated on the basis of perceived concerns and regulatory needs. It may, however, be an indication of our failure to communicate the importance and utility of environmental science to decision-makers and the public. If our science is viewed as having limited utility and benefit for evaluating environmental concerns and contributing to the decision-making process regarding these concerns in a meaningful way, then it is understandable that the science would receive limited support.