[EDITOR'S NOTE: This outline provides collated bullets provided by EPEC members and the workshop proceedings. The bullets are intended to provide raw materials for discussion and establishment of writing teams integrate, synthesize, and edit section of the EPEC report]

First Draft Working Outline of SAB Ecological Processes and Effects Committee Report to EPA on Ecological Risk Assessment

1. Introduction

1.1. Workshop (what, why, how, who, structure)

1.2. History

- In EPA's risk management decisions human health concerns have often carried greater weight than ecological concerns. To increase the influence of ecological concerns, it will be important to provide decision-makers with an understanding that human health and welfare are dependent upon ecosystem quality.

- Regarding multi-generational effects, the problem is the linkage between assessment endpoints and measurement endpoints. Thus our assessment endpoints are too subjective. Our assessment endpoints should take into account the long-term dynamics of a population. But measurements fall far short of that. This is a technical problem. The issue is not so much ecological risk assessment designs as it is the problem of what can be measured. Assessment endpoints for pesticides are very generic. They are concerned with aquatic and terrestrial animals and plants while population density and more technical questions are ignored. Better definitions of assessment endpoints are needed.

1.3. EPA experience

- Interagency coordination is a recommendation that makes sense. There is not a lot of EPA policy on ecological effects so an Agency-wide policy on ecorisk would be beneficial. Concrete recommendations concerning a science policy on ecological risk assessment would be appropriate.

- There are ongoing discussions within EPA to look at broader goals. GAO is concerned that EPA and DOI are not on the same page, don't use similar methods and processes. The entire push in government is to make it more efficient, harmonize science, and provide more transparency.

- Guidelines for ecological risk assessment can be developed from three different points of view: 1) assessing stressors, 2) assessing effects, and 3) assessing the resources of concern. Ecological risk assessments that focus on Natural Resource Protection differ from assessments conducted for the purposes of product health and safety evaluation and management of contaminated sites in that assessments for natural resources protection are more closely tied to a "value" initiated paradigm. Product health and safety and contaminated site management risk assessments are often conducted from a "stressor" perspective. Thus, in assessments conducted for natural resources protection there is a need to look very closely at the ecological attributes to be protected.

- Many tools are currently available to conduct accurate screening level risk assessments for product health and safety in a short period of time. Such tools can be applied in risk assessments. There are many sources of information available for conducting these rapid assessments. European Union databases can provide ecotoxicology information. EPA's EPI Suite tool can provide physical and biological parameters to enable a determination of whether a chemical is biodegradable, toxic or bioaccumulative.

- Scale is often not properly considered in problem formulation and ecological risk assessments for product health and safety decisions. Assessors are not conducting multi-generational analyses to determine whether population failures have occurred. There are no legal requirements to conduct this kind of follow-up analysis. There is currently very little ground truthing of risk assessments.

2. Scales as a Driver of Ecological Risk Assessment

- Risk assessments for natural resources protection differ from other kinds of risk assessments. Risk assessments for natural resources protection are more closely tied to a "value" oriented paradigm. Other kinds of risk assessments are conducted from a stressor perspective. In assessments for natural resources protection there is a need to identify the ecological attributes that must be protected and to determine how they can be protected.

- In protecting natural resources it is important to consider "natural" change, or changes driven through global processes (like climate change). There is a need to know how such change will influence other changes that might be noted in the system under study

- In natural resources protection, assessors are looking at broad scales but the specific questions addressed by a study can be local or global. This must be clearly addressed in the problem formulation stage of the risk assessment. Decisions can be made at a very small scale, but they must be made in the context of a much broader scale. It is also important to consider the point that chemicals are not the only stressors to be evaluated in ecological risk assessments for natural resources protection.

- In assessing risks to protect natural resources, it is important to consider using spatial scales that are large enough to see patterns emerging across a landscape. This will provide insight into the assessment of cumulative effects. Examples of emerging effects included declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

- Spatial and temporal scale analysis may help to later integrate a risk assessment into a meta-analysis or assessment of a larger scale impact. Such an analysis may also develop a body of knowledge useful for other risk assessment projects.

- Tools are available to bring spatial and temporal considerations into the analysis. It is not clear whether the number of practitioners with expertise in these areas is sufficient to meet risk assessment needs. Tools include geographic information systems, continuous monitors, models, species life history information. If additional spatial resolution is needed to describe species abundance and distribution, this should be included in the uncertainty analysis.

- Standards of practice are needed for ecological risk assessors and risk managers. These standards of practice should address methods to assure that spatial and temporal scale issues are appropriately addressed.

- Spatial and temporal scale analysis may help to later integrate a risk assessment into a meta-analysis or assessment of a larger scale impact. Such an analysis may also develop a body of knowledge useful for other risk assessment projects.

- Biological scale should be explicit in an assessment endpoint, and it would be useful to develop standard techniques for assessing risks at these higher levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by use of the sediment quality triad (this includes information on: benthic community measures, sediment toxicity tests, and sediment chemistry).

2.1. Spatial boundaries (endpoints to be valued, natural breaks in the environment, geopolitical boundaries, land use)

- Spatial boundaries (endpoints to be valued, natural breaks in the environment, geopolitical boundaries, land use) (note: asking about spatial boundaries is different than asking about spatial scale. Our discussion was about spatial scale, which is what I have written here.)

- If analysis is not done at appropriate scale, important processes and impacts will be missed. For example, in selenium assessment in region 9, downstream impacts were not included. Selenium is flowing downstream and appearing in estuarine food webs, especially those components of the food web that feed on clams, which bioaccumulate selenium. Scaup populations and sturgeon have declined. Risk

assessors did not have enough information initially about the system to protect against these effects.

- Retain spatial distribution information; averages erase valuable spatial information.

- Considering a larger spatial scale allows one to see patterns emerging across the landscape and provides insight to assess cumulative effects (e.g., losing small streams, myriad small point sources such as underground storage tanks).

- Larger spatial scale brings in more stakeholders and blurs the details, whereas too small a scale excludes regional and global trends that affect local conditions and leaves the process more subject to local politics.

- We have the tools (and personnel?) to bring spatial considerations into risk analyses. It is particularly important to do this in ecological risk assessments dealing with stressors other than contaminants.

- Risk assessors should take advantage of recent advances in technology and tools for the analysis and interpretation of data. Application of such tools can enhance ecological risk assessments. These tools include: geographic information system mapping technologies, remote sensing technologies, spatial statistics, population and exposure modeling, and improved access to large databases.

- In assessing risks to protect natural resources, it is important to consider using spatial scales that are large enough to see patterns emerging across a landscape. This will provide insight into the assessment of cumulative effects. Examples of emerging effects included declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

- The scale of ecological risk assessments can be very broad, but often assessments and decisions are made at very small scales. These decisions must, however be made in the context of a broader scale.

- In determining endpoints to be evaluated in ecological risk assessments it is important to keep in mind the fact that exposure to chemicals is not the only stressor that must be considered.

- Site conceptual models of ecological interactions and processes important at the landscape level should be explicitly included in problem formulation.

- It is important to keep in mind “natural” change that is driven through global processes (like climate change). There is a need to know how natural change will influence other changes that might be noted in the system under study.

- Ecological risk assessments for the purpose of natural resources protection generally look at broad scales but a specific study or question to be answered can be either local or global in scale. This must be clearly addressed in the Problem Formulation stage of an ecological risk assessment.

- Spatial issues are critical for sediment sites. Answers depend upon the sampling design and methods (e.g., 1 cm vs. 1 foot vs. grid vs. focused). Assessors may not be able to discriminate at the 1 foot level so that level of sampling may not be needed.

- Many sites are assessed in exclusion of neighboring sites in watersheds so cumulative risks (e.g., total maximum daily loads) are not assessed.

- There is a need to better define realistic spatial distributions of contaminants. The use of bulldozers and dredgers with global positioning systems increases the effectiveness of remediation.

- It is important to first understand the hydrology in flowing systems first. Key issues to be considered include connectivity from upstream to downstream and depositional zones. These issues are particularly important at big complex sites.

- During the problem formulation stage of an ecological risk assessment for managing a contaminated site it is important to consider spatial and temporal scale and representative data collection issues. Spatial scale is important in evaluating exposure routes at contaminated sites. Spatial components have a major influence on large sites, and sampling plans must match the scales of sites. Temporal scale must be considering when determining time frames for remediation of contaminated sites.

2.2. Temporal scales

- The temporal scale of the assessment depends upon the type of chemical stressor (persistence) and water type (e.g., chronic contamination of a river vs. lake vs. episodic events). Depending on the temporal scale something might be considered constant or ephemeral (e.g., a 100 year flood can remove sediments from a site). Other key issues to be considered include the ecological type, receptor, reoccurrence, and recovery time.

- The appropriate temporal scale of a contaminated site risk assessment will depend on the chemical contaminants, media, and episodic events to be considered. Other issues to be considered in determining temporal scale include specific ecological receptors, possible reoccurrence of contamination, and recovery time of the system. It is important to reach agreement with stakeholders on scale issues during the problem formulation stage of the risk assessment.

- The best temporal context is system dependent (e.g., montane stream extreme dynamics vs. wetland). It is important to consider event frequency and determine the appropriate frequency to be included in an assessment. Questions to be answered

must be matched with the design of the assessment or the wrong decisions can be made. In this regard, broad discussions with stakeholders are needed. The scale of the assessment will determine the outcome.

- Assessors could need 25 – 30 years of data to determine temporal patterns. Population levels of organisms may be declining but one or two years of data do not show the trajectory of the population trends.

- It is important to use a temporal scale that is relevant to the endpoint.

- Temporal scale should be compared to the timing of the decision process (e.g., selenium efflux rates and concentrations are sensitive to season; methyl mercury and mercury were initially thought to move together in the environment, but the ratio of methyl-mercury to total mercury varies with season, suggesting different pathways and leading to different control strategies).

- An analysis of appropriate spatial and temporal scale may help later integration of this risk assessment into a meta-analysis or assessment of a large scale impact. It will develop a body of knowledge that should prove useful for other projects.

- Consider both extent and frequency.

- We have the tools (and personnel?) to bring temporal considerations into risk analyses. Stella models have been built for hydrology and contaminants; models like this could be used to bring time-variant values together.

- For contaminated sites, adding a temporal scale to risk assessment is difficult from the standpoint that many sites have slow, chronic releases of contaminants, but there are no data on original conditions to assess the ecological effects that may or may not have occurred. Evaluating how things may risks change in the future may also put constraints on the site. Industry does not view remediation as a long-term business opportunity; they are in the business of removing liabilities from there corporate books. It is very difficult to predict what will a site will look like after implementing a remedy, and generally follow up monitoring is not done, possibly because no one wants to find out they made the wrong decision.

- A suggested alternative to managing decision and temporal uncertainty is to provide a mechanism to make and implement a remedial decision, and then requiring long term monitoring that could trigger additional work if the expected risk reduction is not achieved.

2.3. Biological scales

- The EPA Science Advisory Board's *Framework for Assessing and Reporting Ecological Condition* should be used as a reference checklist to ensure that

appropriate levels of organization are considered in assessments for protection of natural resources.

- Biological scale should be explicit in an assessment endpoint, and it would be useful to develop standard techniques for assessing risks at these higher levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by use of the sediment quality triad (this includes information on: benthic community measures, sediment toxicity tests, and sediment chemistry).

- Ecological risk assessments should more explicitly focus on functional ecological processes at population and community levels.

- For product health and safety decision-making, guidance is needed on the use of models to conduct population level effects assessments, particularly for terrestrial ecological risk assessment.

- It is important to be cognizant of the fact that indirect effects are important in risk assessments and they are revealed at levels of biological organization above populations. Risk assessors should consider effects at the community, habitat, and landscape scales (e.g., a chemical predisposing trees to diseases)

- The utility of a risk assessment is dependent on the linkage of spatial and temporal scale and biological organization.

- Higher levels of biological organization should be evaluated in ecological risk assessments. Regulated parties and many ecologists prefer that ecological risk assessments be conducted using higher levels of organization. EPA's ecological risk assessments generally use organismal attributes because they are easier to evaluate with currently available methods, and they are understandable by decision-makers and the public. However, when organismal attributes have been used, EPA has been criticized for "protecting individuals."

- Organismal, Population, Community, Habitat, Bioregion considerations are important.

- Information on organismal life history is essential; information can be culled from local sources that can help scientists understand life history of species.

- The sooner we rigorously incorporate multiple levels of biological organization, the sooner we'll have a record and a body of knowledge.

- Research is needed to assess value added of moving from the individual to the population level: Is increased uncertainty significant? Are higher-level studies more

variable or more expensive? How do risk managers assess the utility of results at higher levels of organization?

- Indirect effects are important. They are revealed at levels of organization above populations. Hence those higher levels of organization should be incorporated into the risk assessment. A stressor may cause a cascade of effects that are important at the landscape scale (e.g. a chemical may predispose trees to disease).

- Identify the biological level where the effect is most obvious; then consider one level up and one level down in the analysis.

- Increasing uncertainty at higher levels of biological organization.

- Use the Framework as a checklist (see 3.3 below) so the risk assessor makes a conscious decision about spatial and temporal scale and biological level of organization.

- The type of stressor will influence the choice of level of biological organization; for example, stressors like habitat alteration may involve higher levels of organization than would a chemical contaminant

- Regarding the assessment of risks at different biological scales, as noted previously, for most contaminated sites it would be more appropriate to view them as "toxicological risk assessments," and not ecological risk assessments. The group noted that it is easier and cheaper to do small-scale individual studies, and then extrapolate those to populations. The evironmental community view is that shifting the focus to larger populations effects can mask the fact the smaller highly contaminated sites are causing mortality in individuals. Main emphasis should be on how to clean up the site as opposed to determining whether a site should be cleaned up. Industry offered the perspective that while the tools to do population-level studies exist, it is important to understand whether the decision is so important that you want to spend the dollars and time to make those kinds of investigations. The Department of the Interior has started a Natural Resource Damage Assessment and Restoration Advisory Committee under FACA to look at similar issues. One of the objectives is to determine if there is a way of constraining investigations and get to an answer in a reasonable amount of time, and these findings will likely relate to risk assessments

2.4. Constraints (money, resources, regulatory program transparency)

- Risk managers in state agencies are making hundreds of decisions with limited time and limited resources to conduct thorough ecological risk assessments.

- Scale is often not properly considered in problem formulation and ecological risk assessments for product health and safety decisions. Assessors are not conducting multi-generational analyses to determine whether population failures have occurred.

There are no legal requirements to conduct this kind of follow-up analysis. There is currently very little ground truthing of risk assessments.

- There is a need to explore how spatial, temporal, or biological scales can be applied within the constraints imposed on contaminated sites by the regulatory authority of the specific federal program. For example, under CERCLA, the regulatory-defined role of the ERA is that it establishes a legal authority for an action, and develops the information that can be used to set the preliminary remediation goals. While there is sufficient flexibility written into the ERA guidance documents to consider the issues of scale, time, and populations, application of these to contaminated sites are constrained by (1) legal requirements, (2) timing and funding issues associated with conducting the site investigation, and (3) uncertainty by site managers as to how the additional information will assist them in making site management decisions. CERCLA further constrains the ERA process in that it may only consider chemical releases, that the ecological risks must be evaluated within the confines of the site, and that the protective remedies must be to the standard set in the law. Because of these legislative requirements, the Site investigation including the ERA and the remedy must focus on the site, or they are not legal expenditure of resources under the law. This can preclude then looking at larger spatial, temporal, or even population-level effects that would occur outside the site.

- Necessary regulations and policies should be configured to require landscape-level assessments that approach meaningful ecological scales. To conduct such assessments effects should be aggregated at eco-regional levels, and risk predictions should be evaluated with analyses contained in state of the environment reports.

- The scale of decision resolution needs to match the study design (e.g., the scale of remediation activities using dredging and bulldozing is crude).

- It is not possible to assess everything. Assessors have to be concerned about 600 species of birds, 10,000 other species, and cannot look at everything.

- We are not doing ecological risk assessment right in terms of scale, time (at best we do second generation), so how can we look at population failures. There is no money available for followup evaluations and studies. Multigenerational analyses are not being conducted to see what is really happening.

- Decisions to broaden the scope of an assessment can be limited by policy. Assessors may not look at indirect effect because of policy decisions. However, stakeholders can identify previously ignored issues and thus create the need for policy change. Policy needs to be questioned or modified based on the needs of stakeholders.

- Funds are often very limited for a risk assessment at a state level; perhaps only a screening level assessment is needed.

- Resource constraints may limit spatial and temporal scales with an impact on quality and utility of risk assessment.

- Legal constraints may limit the assessor's ability to take cumulative impacts into account. These cumulative impacts could be incorporated into the conceptual model and acknowledged even if they cannot be regulated

- As noted previously, evaluating broader spatial boundaries for contaminated sites under a regulatory program are currently precluded by law. While larger scale can be practicable and applicable to the so-called "mega-sites" (e.g., Hudson River, Clarke Fork River), the majority of Superfund sites are smaller; 2 – 10 acres. Protection of human health and the environment must be achieved within the site boundaries or it is not a legal remedy. This has been established by statute, and has been upheld in the federal courts.

- Contrasting local vs. broader effects (e.g., point discharge vs. watershed) to ecological resources not only represents a regulatory hurdle for site managers, but there are no clear definitions or guidance on how that information would help make site management or remedy decisions. For example, a paradoxical situation arises in the case of point release to a stream. At the local site level, a community level response could be readily demonstrated. However, relative to a population level view in the entire stream, the point impact would not represent a population impact. While the Agency is open to assessing risks at different scales, under CERCLA, the remedy must protect resources at the point release (i.e., "the site"). Thus, there remains a need to explore how the Agency could implement spatial, temporal, and biological scales within the confines of the law.

3. Problem Formulation

- Conceptual model formulation an important step (Kapustka), should that go in this area?

- Using contemporary models of ecological systems for this construction (no ecosystem health etc.). Does this need to be a part of the Problem Formulation discussion or as its own heading?

- It would be useful to use effects concentrations (EC_x) for screening level assessments. Complete response profiles could be used for higher tiered assessments. The use of hazard quotients should be restricted to screening level assessments, and effects response relationships should be used for higher tiered assessments.

- Life cycle analysis in ecological risk assessment is not adequately addressed in regulations and additional guidance is needed in this area. An example is the regulation of nanotechnology. In the past, product life cycles were not considered, but we must now look ahead and correct past mistakes.

- It is important for ecological risk assessors to consider the question of why particular risk assessments for product health and safety should be conducted and what should be protected. As currently described in EPA guidance, the process of problem formulation does not really focus on this important question.

- Integration of ecological risk assessment into the environmental management decision process should be promoted.

- The scope of ecological risk assessments should be expanded to explicitly include biological and physical stressors and put chemical stressors in an ecological context.

- Levels of concern and risk quotients are used to drive problem formulation in product health and safety risk assessments, but they may not represent realistic protection goals. Measurement endpoints must be more closely tied to appropriate assessment endpoints.

- The problem formulation stage of product health and safety risk assessment must address all routes of exposure and tiered assessments. However in some cases problem formulations are generic and therefore all routes of exposure (e.g., dermal exposure) or receptors are not considered. There is a need to consider release pathways, fate and transport, and sensitivity to target the risk assessment and tie measurement endpoints to the appropriate assessment endpoints.

- Ground truthing, follow up to risk assessments and validation should be part of problem formulation in risk assessments for product health and safety decisions. Frequently, problem formulation does not adequately address the complexity of a system in terms of time and space. The need for monitoring should be addressed in the problem formulation stage of a risk assessment. Levels of concern should be re-evaluated and validated with monitoring studies. These concerns should be addressed in EPA's guidance documents.

- Probabilistic risk assessments are not very helpful in communicating uncertainty to managers for CERCLA sites. A summary of the sources and size of major uncertainties would be helpful, however.

- In many ecological risk assessments there has been a lack of problem formulation. Some studies have been designed by considering drivers such as the need for a Total Maximum Daily Load determination or the issuance of a permit. Such studies may measure the wrong thing. Risk assessors can avoid this problem by starting ecological risk assessments with careful problem formulation.

- Careful attention to problem formulation will narrow the focus of questions to be asked and help identify the most appropriate tools for effective support of decision making.

- A primary goal is to apply guidance that is already available.

- If the problem is formulated up front and assessors know what they want to measure, the ecological risk assessment should inform decision making. There are not many proven case studies to follow. It is hard to apply the guidance document and framework.

3.1. Critical steps

- Starting the ecological risk assessment process with consideration of natural resources protection and critical ecological attributes can set up specific endpoints that are based on specific hypotheses. This approach will result in more useful (higher quality) analyses.

- At big sites, spatial issues are most critical so review of associated procedures early on is essential.

- Exposure sampling should be matched with questions of effects to receptors (i.e., what are we assessing risk to?) This issue must be addressed at the problem formulation stage. Terrestrial exposure is patchier than aquatic. It is not possible to complete accurate risk characterization unless exposure is closely linked to effects. Metapopulations – clean refugia of organisms that come into contaminated areas must be evaluated.

- Good guidance is available for problem formulation. Often generic problem formulation is completed where endpoints and exposure pathways are pre-defined. In this case a predefined path is followed whether it makes sense or not. Shortcuts are taken. Better guidance may not be needed but it is important to apply the guidance that is already available. The 1990 EPA guidance is very good.

- There are three issues with problem formulation. 1) It is not oriented to decision making. It is not realistic to ask “is there a risk?” It is better to ask “what is the magnitude of risk?” 2) Tools and available data drive where problem formulation goes (e.g., we don’t have a model of dermal exposure so we don’t look at it). 3) A lot of problem formulations are too generic so all routes of exposure are tackled, or all receptor are tackled. It is important to consider release pathways, fate and transport, and sensitivity to more efficiently target routes of exposure and receptors.

- A streamlined risk assessment process (e.g., a “programmatic” ERA) that would lead to more rapid cleanups would greatly benefit natural resources. From the perspective of the environmental community, there often is too much emphasis on the problem formulation stage, instead of the clean-up and reducing the immediate risks to ecological receptors. When a contaminated site is identified or listed, EPA has already made an assessment that the release of a hazardous substance has occurred and the environment is at risk.

- In the problem formulation stage of ecological risk assessment there is a need to explicitly address the formulation of problems at multiple levels of biological organization.

3.2. Peer review after problem formulation

- Peer review should be completed at the beginning of the ecological risk assessment process (and ideally throughout the process) rather than completing it at the end. If peer review is conducted at the end of the problem formulation stage risk assessors have the opportunity to adjust plans, tools, and endpoints. If peer review is completed at the end of the process inadequacies are identified when it is too late to respond.

- Problem formulation - Pre-survey, adaptive management, and peer review to assess the power of the various lines of evidence (LOE) can enable risk assessors to decide which lines of evidence are useful for decision making.

- Independent peer review is an important mechanism for ensuring and validating the application of science in the ERA. However, in current application, the peer reviews are typically done after the ERA studies are completed and the document is written. These reviews are often constrained by time and resources, which leaves the review of the science in a position of "too little, too late". Practically, the peer reviews are a process to pass through, and not an instrument for aiding the science of the risk assessment.

- A practical recommendation of the workshop is that the problem formulation and study design be submitted to peer review by an independent scientific panel prior to implementation. This independent panel should be given adequate resources to fully evaluate the design, and empowered to compel real change where there is consensus. Peer review would be beneficial at both sites where conflict about the study design is present and at sites where there is no conflict. The determination about at which sites early peer review would be triggered could be based on a 'recommendation' (e.g. 'should consider' language) or could be based on a 'cutoff' set based on a post audit evaluation of prior sites. Panel for problem formulation may be different than the composition of a panel constructed for study design review.

3.3. List of factors to consider (e.g., the EPEC essential ecological attributes)

- The issue of remedy vs. restoration drives different study designs (e.g, Natural Resource Damage Assessment vs. EPA risk assessment). The question of "when is restoration the remedy?" (e.g., in situ remediation) plays into evaluations of project success and outcome.

- The problem of multiple stressors/sources has been discussed for a long time. Explicit suggestions are needed for addressing multiple stressors and cumulative effects.

- In natural resources protection, assessors are looking at broad scales but the specific questions addressed by a study can be local or global. This must be clearly addressed in the problem formulation stage of the risk assessment. Decisions can be made at a very small scale, but they must be made in the context of a much broader scale. It is also important to consider the point that chemicals are not the only stressors to be evaluated in ecological risk assessments for natural resources protection.

- The consequences of making a mistake will also drive the design of a risk assessment (e.g., considering persistent contaminants vs. nutrients).

- Nano-technology is a huge initiative in the federal government. Genetically modified organisms are regulated by EPA's Office of Pollution Prevention and Toxic Substances and USDA. Problem formulation is a process, but the danger of keeping it open-ended is that there is no cross-cutting Agency policy on what to protect. It is important to differentiate policy questions from science questions to avoid becoming mired down. Life cycle assessment and industrial ecology are already initiatives in the Agency. The Agency should focus on ecological risk assessments. It is important to make those connections.

- The screening level assessments have generic aspects but there are also some specific aspects to individual chemicals that should be considered. A dialogue with risk managers is very important, and the use of information can be very different for different chemicals. We often don't have the right information because we don't have the final label. The scope of the problem formulation can be chemical specific.

- To assess ecological condition, one must consider both pattern and process. A list of factors to consider in evaluating ecological condition is provided in Table ES-1 of an earlier EPEC report entitled "A Framework for Assessing and Reporting on Ecological Condition." The first level of the hierarchy in this table identifies 3 process-related attributes (landscape condition, biotic condition, chemical and physical characteristics [water, air, soil and sediment]) and 3 pattern-related attributes (ecological processes, hydrology and geomorphology, and natural disturbance regime) that should be considered. Using this table in the problem formulation step should stimulate the thought experiment of explicitly considering different space and time scales as well as different levels of biological organization.

- Scale must be considered in problem formulation.

- Explicitly incorporate temporal and spatial scale into the conceptual model and report this out transparently. This information should then be incorporated into the uncertainty analysis. If data are insufficient to do analysis at the appropriate scale,

acknowledge this up front (i.e. transparency), and incorporate this into the uncertainty analysis. What was ruled in and ruled out needs to be clearly stated.

- Vulnerability analysis is a potentially useful tool in the problem formulation step to develop the appropriate spatial scale for analysis. For example, one could consider regional patterns of sediment movement and identify vulnerability of different parts of the landscape to erosion/sedimentation.

- Problem formulation could be improved by making measurement endpoints very specific. For example, instead of generally stating no adverse effects on populations, specify what percent of the population would be effected. Whether this is appropriately applied in the problem formulation, or reserved for the DQOs needs to be evaluated. For example, by surveying bull trout to see if there is more than 20% reduction, is that a testable statement for the DQO, or is it a determination by the manager that an action will be taken if there is a >than 20% reduction? The guidelines do not make this distinction, but the problem formulation step does allow the manager to request that the risk assessor provide the risk of exceeding a variety of limits.

- The EPA Science Advisory Board Framework for Assessing and Reporting Ecological Condition should be used as a reference checklist to ensure that appropriate levels of organization are considered in assessments for protection of natural resources.

- An issue of concern is how to do problem formulation when scale changes.

3.4. Involving stakeholders

- It is important to ensure close and frequent communication between risk managers and risk assessors, both need to be involved in problem formulation and developing testable hypotheses.

- See Arvai report

- Risk manager also needs to be included in the discussion.

- Getting the Agency and stakeholders involved and committed to meeting was identified as the most critical element to completing a successful ERA. In one of the breakout sessions, Dr. Ralph Stahl of Dupont noted that often it is difficult to get stakeholders to attend the meetings to work through the details of the problem formulation. An example was provided by Ms. Vicki Meredith of WDEQ where a collaborative process was established that brought together all of the stakeholders to develop the assessment, study, and formulate the remedial decision. While ultimate decision-making rested with the WDEQ, the stakeholders included the RP, the EPA, the U.S. Fish and Wildlife; Wyoming Game and Fish, Wyoming Department of Transportation, and the community (city, county, and citizens groups). The ERA

paradigm was helpful in the context that the process was established, and that the problem formulation and articulation of data quality objectives (DQOs) was done in collaboration with all of the stakeholders, and all decisions were made as transparent and open as possible.

3.5. Creating a checklist for reviewers

- While the Agency has developed a number of important and useful guidelines for conducting ERAs, there is still a great deal of inconsistency, and in some cases lack of application of the guidelines. Possible reasons for this included an incomplete understanding of what is available and/or required by the **guidelines (NOTE: guidelines do not provide "requirements").** One mechanism proposed that would ensure a more universal and consistent application of the guidelines would be to create a publicly-available reviewer checklist. The goal of the checklist is to make sure that various important points in the process (e.g. adequacy of problem formulation, consideration of possible management strategies in problem formulation, connections between assessment and measurement endpoints, consideration of data quality objectives) are adequately addressed at all sites. Other mechanisms proposed for ensuring consistent application included restoration of internal EPA funds for regular meeting and training of the regional risk assessors, and the insertion of a public peer review after completion of Problem Formulation.

4. Improving the Science of Ecological Risk Assessment

- (a general comment was that the state of the science is not the state of the practice, and it is important to facilitate transfer of the state of the science into practical use)

- Weight of evidence approaches enable ecologists to evaluate multiple types of evidence and multiple lines of evidence within a type and should be applied in ecological risk assessments. Most risk assessment practitioners prefer to consider all available relevant evidence but some consider the process of weighing evidence to be too subjective. Additional guidance is needed in this area.

- Contemporary ecological theory and practices should be adopted in defining ecological risk assessment endpoints, conducting analysis steps, interpreting consequences, and proposing risk mitigation/reduction actions.

- There is a need for a national database containing information on ecological risk assessments that have been conducted for management of contaminated sites and other purposes. Case examples could be included in such a database to provide useful information on the strengths and weaknesses of various risk assessment approaches. Central data exchanges are improving. For example, five year EPA Superfund program reviews provide useful abstracts of risk assessment study results.

- In protecting natural resources it is important to consider "natural" change, or changes driven through global processes (like climate change). There is a need to know how such change will influence other changes that might be noted in the system under study

- There is a need to integrate analyses across traditional disciplinary boundaries that may fragment them (e.g., toxicology vs. ecology, and biology vs. chemistry).

4.1. Cumulative effects

- Tools for assessing cumulative risk are not available for product health and safety evaluations. Tiered risk assessment approaches can help risk assessors to foresee the ecological risks of substances like lead, but it there is a need to develop additional tools for evaluating cumulative risks. Contaminants are being released into environmental that are already stressed and regulations do not address cumulative stress.

- In the risk assessment process it is important to advance beyond the single stressor model and explicitly identify multiple stressors.

- Cumulative and aggregate risks are becoming very important. Exposure adds up with multiple exposures to the same chemical in different contexts. Assessors have opportunities to consider aggregate exposure across multiple scales.

4.2. Statistical design

- Both problem formulation and the development of testable hypotheses affect the quality of analyses. Proper attention to both lead to higher quality decisions. However, testable hypotheses can be misused and can lead to degraded decision making.

- Because testable hypotheses may represent "yes/no" answers they may not always be useful in risk assessments for product health and safety decisions. Problem formulation should be designed to provide an evaluation or quantitative description of magnitude of risk along a continuum.

- It is important to change the way ecological risk assessors think about testable hypotheses. It is important to move away from traditional hypothesis testing with null models. Such hypotheses can be easy to manipulate and difficult to formulate. In risk assessment, hypothesis testing can result in null models that are developed without considering how to balance Type I and Type II errors. There is a need to move toward more innovative methods such as Bayesian analysis and causal argumentation. Hypotheses should focus on causal relationships and weights of evidence.

- It is important to move away from the use of traditional hypothesis testing with null models. Traditional hypothesis testing makes it is easy to manipulate information and results. In addition it can be very difficult to formulate the testable hypothesis and collect adequate data to ensure comparability of results. It is recommended that risk assessors begin using more innovative methods for hypothesis testing or alternate analyses such as Bayesian analysis, causal argumentation, and the use of likelihood matrices).

- In the statistical design of a risk assessment it is important to link hypothesis statements to explicitly stated process goals.

- Risk assessors should take advantage of opportunities to use statistical method to better inform the risk assessment process (e.g., Type II, power, sensitivity).

- Does anyone find testable hypotheses to be useful? Risk questions are much more useful because testable hypotheses set up a yes/no answer that is not useful. Well-formulated risk questions are more continuous and not black and white (e.g., what is the probability and magnitude of the effect on endpoint X and a result of pesticide Y?).

- Is the concept of testable hypotheses on quantile?

- In the context of a river, a testable hypothesis would be if water quality at site X is killing fish, that water causes toxicity in the laboratory. So it is not a black and white issue. Toxicity means a statistically significant effect associated with…

- The testable hypothesis above could this be framed as a risk question.

- Measurement endpoints are quantile and provide a risk scale and are not yes/no.

- Some assessors don't have a section in ecological risk assessments spelling out testable hypotheses. Testable hypotheses can be awkward because assessors are going to be judging measurement endpoints in terms of what they indicate in a weight of evidence context.

- The term testable hypothesis was picked up during guidelines development. When we have enough information to answer a question with a degree of certainty then it is phrased in terms of a testable hypothesis.

- Common lines of reasoning are that testable hypotheses in their purest quantile sense should not constrain the consideration of the full continuum of risk.

- Problem formulation should be designed to provide an evaluation of risk along the continuum.

4.3. Terminology

- It is important to have protection goals, but a risk quotient or level of concern are not really protection goals. They are imaginary numbers. It is not a protection goal to state that a risk quotient should be les than 1/10.

- Assessors need a better way to tie measurement endpoints to assessment endpoints. It is important to ensure that measurement endpoints are tied back to assessment endpoints.

- It is important to identify appropriate measures and endpoints for the analysis.

- There is a need to develop a common understanding of what weight-of-evidence means in the ERA. Dr. Glen Suter noted that there were at least four different definitions, but as yet there is no common consensus on what that means. The National Research Council's (1994) Science and Judgment in Risk Assessment advocated the used of weight-of-evidence, without providing context for what that means. A general recommendation from the panel and group was that this is should be the subject for further investigation by the SAB.

4.4. Scales

- There is a need to build links between mechanistic approaches that can be used to address large scale questions. The appropriate mechanistic laboratory approaches should be applied to population-level analyses. This will require more work to identify and assess true links between molecular, cellular, and organismal responses and impacts that can be observed in populations.

- Rapid advances in areas such as GIS mapping, spatial statistics, and exposure modeling will help improve risk assessments. Public access to large databases is also improving and this will provide information to address spatial issues. In addition, advances in remote sensing will improve risk assessments.

- It is important to consider ecological risk assessments from a watershed perspective and not only operable units. Cumulative stressors may be important when multiple small sites are linked together, each of which may not be important ecologically, are linked together.

4.5. Peer review

- The panel believes that independent peer review is an important mechanism for ensuring and validating the application of science in the ERA. However, in current application, the peer reviews are typically done after the ERA studies are completed and the document is written. These reviews are often constrained by time and resources, which leaves the review of the science in a position of "too little, too late".

Practically, the peer reviews are a process to pass through, and not an instrument for aiding the science of the risk assessment.

- A practical recommendation of the workshop is that the problem formulation and study design be submitted to peer review by an independent scientific panel prior to implementation. This independent panel should be given adequate resources to fully evaluate the design, and empowered to compel real change where there is consensus. The panel deemed that peer review would be beneficial at both sites where conflict about the study design is present and at sites where there is no conflict. The determination about at which sites early peer review would be triggered could be based on a 'recommendation' (e.g. 'should consider' language) or could be based on a 'cutoff' set based on a post audit evaluation of prior sites. Panel for problem formulation may be different than the composition of a panel constructed for study design review.

4.6. Ecology

- It is important to bring "ecology" back into the ecological risk assessment process. There are many innovative approaches that can be used to look at risk ecological risk assessment issues from different perspectives. Risk assessors should not remain caught in the paradigm of applying traditional endpoints from toxicity tests.

- Steady state assumptions concerning biota and return to previous state are often assumed, or ignored at sites. A steady-state context can be irrelevant or distracting at some spatial or temporal scales

- There is a need to use population modeling to examine temporal and spatial issues. The models are increasing in number and quality.

- Population modeling is seldom being used in ecological risk assessment. Population modeling is not needed at very highly contaminated "killer" sites, but it is needed where chronic issues dominate. There is a need for guidance on the use of population modeling.

- The main concerns of assessors should be focused on populations but much of the work is now based on assessment of individual organisms.

- Lower level ecological effects are being extrapolated to communities.

- The species distribution of LC50s does not relate to community, but might be protective if they are overly conservative. However they do not consider essential species interactions and interdependencies and secondary effects (e.g., bees vs. pollination, zebra mussel invasion, loss of habitat).

- Assessors are not effectively assessing indirect effects such as from habitat and competition. Indirect effects are not secondary effects. Toxicity studies in the

laboratory or with cultured/farm raised organisms may not reflect the health of field populations (field populations may be more stressed due to other stressors or they may have adapted to existing stressors).

- There is a need to augment the current life history information available for non-invertebrates.

- There is a need to conduct research to provide more information for common or important species.

- There is a need for methods to provide a better link between biological levels of organization (e.g., tissue to community).

- Additional basic life history for information, such as home ranges and organism distribution, is needed for many species to improve assessment of exposure to contaminants and ecological risk. There is often a mismatch between available ecological and toxicity information for species at contaminated sites.

- Long term ecological research is needed for some large scale contaminated sites. Post remediation monitoring is needed to improve our understanding of how risk assessments can be enhanced. Criteria must be set for assessing the outcome and success of contaminated site remediation. Exploratory long term ecological research can also be conducted at these sites and adaptive management approaches can be demonstrated.

4.7. Toxicology

- Additional toxicity data should be generated to improve species sensitivity analyses used in ecological risk assessments.

- New biomarker and mechanistic data should be incorporated into ecological risk assessments for product health and safety decision-making. Additional research should be completed to determine whether such data can be used to indicate exposure or risk.

- Since so many sites are driven by PCB contamination, there is a need for methods with lower detection limits for PCBs in water. Major sources are atmospheric not dischargers. There is a need for a national ecological risk assessment for mercury and PCBs since these chemicals are ubiquitous. Risk assessments for mercury have been inaccurate because of inaccurate bioaccumulation factors and also because mercury does not methylate everywhere. (e.g., risk assessments indicate that there should be no bald eagles found anywhere). There is a tendancy among risk assessors to focus on things that can be done for source apportionment (e.g., hit the NPDES dischargers).

- There is a mismatch between ecology and toxicity parameters (LC50s, NOECs). This impedes matching exposure and effects. The following information is needed for consideration in risk assessments: home range, survival rates, reproductive rates (basic life history information), HSIs (hazardous substances information) versus contaminants. Tools to estimate life history are not used as often as warranted. Much of this information is currently available but it is not used.

- Risk assessors are taking attributes of a population and applying them to a feeding class (e.g., carnivorous). Protecting mink or mammalian receptors that eat fish. The assessment endpoint is mammals eating fish.

- There is a need to better communicate why earthworms or midges are important as receptors and indicators.

- It is important to link the nature of a contaminant to the appropriate receptor.

- There is a need for data/metrics on rates for predictions on the appropriate level of biological organization.

- There is a need for conversion of toxicity data into population effects.

- Search for patterns emerging for groups of chemicals or classes of stressors (e.g., use QSAR approaches to estimates of impact of classes of chemicals at different levels)

4.8. Data consistency and quality

- There is a tendancy in ecological risk assessment to work with available data without identifying data gaps. Therefore, decisions are often made with incomplete information. Higher quality decisions will result if problem formulation, identification of testable hypothesis, and design of data collection approaches are completed at the beginning of the assessment process.

- High quality ecological risk assessments may require the collection of new data using more innovative and modern techniques.

- Data quality is driven by costs and needs. Therefore, smaller sites may be more at risk of low quality ecological risk assessments than larger sites.

- It is difficult to define “quality” in this context – poor quality at any level is possible.

- Data quality must be improved so that decisions are legally defensible. One should not rely solely on individual metrics.

4.9. Evaluation of methods

- Through an evaluation process, risk assessors need to first identify sensitive and realistic measurements that can be made. The methods to make such measurements are not always available. It is important to make linkages between sensitive tools for measuring impact and actual effects at an appropriate level (e.g., population or landscape).

- It is necessary to enhance the process of ecological risk assessment by making use of population models. Pre-surveys should be conducted to look at the power of various analyses. Sensitivity analyses are needed.

- It might be possible to provide a menu of optimal tools for use in certain scenarios.

- CENR wrote a document on ecological risk assessment practices across the federal government and found real similarity of principles across agencies. It may be worth updating this

- To avoid fragmented analyses, there is a need to better integrate work that has been conducted in different disciplinary areas (e.g., biology, vs. chemistry, toxicology vs. ecology). For example EPA has developed biological and chemical water quality criteria separately. Expert systems could be developed to enable the integration of specific chemical and biological endpoints and identify classes of chemicals to be assessed.

5. Uncertainty

- Long term monitoring would provide data that would reduce uncertainty and improve decisions about remedy selection and, perhaps, future risk assessments. EPA, in conjunction with other agencies, should evaluate the effects of clean-up on sites remediated 5-20 years ago. This would build a data base that could be used to reduce uncertainty in new sites.

- Probabilistic risk assessments are not very helpful in communicating uncertainty to managers for CERCLA sites. A summary of the sources and size of major uncertainties would be helpful, however, to see patterns emerging across a landscape. This will provide insight into the assessment of cumulative effects. Examples of emerging effects included declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

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- Elements of uncertainty should be identified and incorporated into problem formulation and built into the design of a risk assessment. Uncertainties in an ecological risk assessment should be categorized, and those that profoundly affect results and outcomes should be identified. There is a rich literature on disaggregating analytical variability, stochastic variability, and model variability. It would be useful to consider available tools for use in problem formulation.

- There is a need for a systematic data collection and organization effort to catalog and make available information from past risk assessments in order to reduce the uncertainty of future risk assessments. This effort should provide better metadata and a centralized data repository for: ecological risk assessment data, endangered species information, FIFRA risk assessment information, Superfund risk assessment information, and the peer reviewed literature.

5.1. How to communicate uncertainty

- Risk managers must articulate how much uncertainty they can tolerate. Risk assessments can then be designed to meet their needs, and uncertainty can be communicated in the decision making process.

- Research is needed on how to more effectively communicate uncertainty to risk managers and stakeholders

- It is important to consider uncertainty and probability in risk assessment. Tiered approaches and models have been developed for conducting probabilistic ecological risk assessment and these should be applied in practice. Ecological risk assessors are ahead of their human health risk assessment colleagues in the application of joint probabilities of distributions to assess risk.

- An interagency effort should be undertaken to develop an ecological version of the Integrated Risk Information System (IRIS) that would provide information needed for risk assessments.

5.2. Acceptable levels of uncertainty

- There is a need to reduce uncertainty in ecological risk assessments in order to increase the utility of assessments. Uncertainty in the risk assessment can lead to paralysis of the decision making process.

- Uncertainty can also affect utility of a risk assessment by limiting the ability of risk assessors to extrapolate results to other sites or risk assessments.

- It is important to incorporate considerations of uncertainty into problem formulation and into the design of risk assessments.

- This is case specific, do we want more detail here?

- Worst case scenarios should be discussed as part of uncertainty analysis. Is a 10^{-6} chance of wiping out a population acceptable?

- Perspective of risk managers vs. risk assessors

- Database and repository as a way to reduce uncertainty (analogous to EPA Integrated Risk Information System – IRIS) (I do not recall how this would help in uncertainty reduction)

5.3. Quantifying uncertainty

- A priori identification of the most profound uncertainties is important. Uncertainties should be qualitatively evaluated, dissected and categorized according to type in order to identify those likely to profoundly affect the results and outcomes of the risk assessment.

- A relative assessment of uncertainties in the assessment should be undertaken so the risk assessor can plan around them.

- It is important to identify key variables that can be assessed to help reduce uncertainty.

- Factors of uncertainty should be transparent. Often they are embedded into ecological risk assessment and added afterwards for policy reasons.

- Uncertainty factors should go into the same bin as testable hypotheses. Putting aside screening level assessments, it is not the assessor's job to be conservative, but to capture uncertainty where possible. There are probabilistic methods that can be used for this purpose. The degree of conservatism, or its absence, is up to the risk manager.

- Include explicitly in uncertainty analysis the potential higher-order effects for which there were no data. The same holds true for spatial and temporal scales for which data were not available. The lack of information affects accuracy.

5.4. Separating variability from uncertainty

- Risk assessors should recognize the difference between uncertainty and variability

- Variability is a type of uncertainty

5.5. Perspective of risk managers vs. risk assessors

- It is important to ensure close and frequent communication between risk managers and risk assessors. Both groups need to be involved in problem formulation and the development of testable hypotheses.

- Risk managers and risk assessors address uncertainty differently so it is important to ensure communication between these groups.

- Managers prefer one number, a bright line. Need to find a way to provide manager with something that is more complex than a single number but still useful to the manager. Potential need for some training, an expert system for risk managers to help them understand and incorporate uncertainty into decision-making.

- For decision making in the face of uncertainty, there are really three options:
    - Study Some More
    - Make a Decision and move on, or
    - Make a decision with monitoring and triggers for further action if needed

- There was broad discussion concerning recommending a post audit monitoring program specifically designed to address the impact of contaminated site remedies on the ecosystem (e.g. 5 to 10 years post remedy). Such a program can be used to reduce decision making uncertainties in new sites.

- From both perspective of the environmental community and industry, a positive step forward for ERAs would be to provide a mechanism for managing decision and temporal uncertainty by allowing for a streamlined ERA and remedial decision, and then requiring long term monitoring that could trigger additional work if the expected risk reduction is not achieved

- There are some cases in which a probabilistic risk assessment can be useful in conveying the uncertainty of an ERA. The panel pointed out that unlike the case for HHRA, in which we consider a single species for which lots of data are available, the probabilistic ERA that incorporates the variety of uncertainties associated with ecosystems in many cases does not help management decisions. Of greater value is a clear exposition of the magnitude of the factors driving the ERA uncertainty associated and the sources of the parameters (and assumptions) used therein. In some cases, sensitivity analysis can be more useful.

5.6. Database and repository as a way to reduce uncertainty (analogous to EPA Integrated Risk Information System – IRIS)

- Data for risk assessments should be mined from EPA Superfund Program documents as well as other ecological risk assessment documents.

- There is a need for systematic data collection and organization to support risk assessments. Better metadata are needed. A centralized data repository is needed for: ecological risk assessment data, ES information, FIFRA risk assessment data, Superfund risk assessment data, peer reviewed literature.

- This was discussed in our group and posed as a question to the larger group: should there be an interagency attempt to develop an ecological risk version of IRIS? We did not reach consensus on an answer. (I don't recall that this was discussed under uncertainty; it was discussed more in the context of making the reliable scientific findings available to practitioners.)

- NatureServe has a great deal of species information with good spatial resolution. Another idea was the need for a website or other repository of information that gets truncated in journals or that is otherwise unavailable to practitioners (e.g., state agencies and NGOs without access to all scientific journals).

- Agency risk managers would like a handbook of ecological thresholds. Is that possible with current state of science?

- Need a way to deal with personnel turnover without a loss of information.

6. Decision Making

6.1. Net environmental benefit

- Net environmental benefit analysis is an important tool that can be used more often. For an ERA, a net benefit analysis would compare the incremental positive effects caused by remediation with other effects such as disturbing habitat for threatened and endangered species. There was extensive discussion about when to best incorporate this type of analysis and over what time frame the response is considered. At least two examples were given. A good opportunity for net environmental benefit analysis is evaluating the risk of remedy (or comparing various remedy options) to the ecosystem. An emphasis on incorporating this into the feasibility study, where appropriate, is warranted. This concept is already incorporated into the Guidelines (or guidance?). Development of the process and/or appropriate tools for the spectrum of sites for which these considerations are appropriate is warranted. Another opportunity may be in comparing or prioritizing sites for work.

- From an Agency perspective, decision-making in the presence of uncertainty for contaminated sites is constrained again by the legislative program regulating the site. Where there is uncertainty, Agency decision-makers must select the conservative protective remedy. Additional data can reduce the uncertainty associated with decision making, but there is a financial tradeoff between study cost and remediation cost that needs to be considered. There are sites where no matter how much effort you put into it, the remedy is going to be the same remedy in terms of scale and cost and the study won't change the risk management decision.

6.2. Cost benefit

- Outcome orientation has become more important in risk assessments. Is outcome or the cleanup more important?

- States are "making cookies" doing studies, but not producing the reports that USEPA can use to assess success.

- There is a need to do risk benefit:cost assessment. Valuation of resources and assessment of ecological services is needed. This should be considered from multiple scales/stakeholders (e.g., migratory birds).

- Economists speak of "value of information " – if another dollar is available how should it be spent? This is where we often fail in ecological risk assessment. Prioritizing where to reduce uncertainty could be useful. Listing uncertainties and the consequences of those uncertainties would be useful. Can we use the value of information approaches (if we have additional funds) as a way of setting priorities for reducing exposures?

- Cost-benefit is distinguished from net environmental benefit in that this would be evaluating or structuring the ERA in such a way that the benefits of risk reduction could be compared to the cost of achieving that reduction. This point gets to the OMB guidance's discussion of the tension between the manager's need for a timely, economical, implementable solution and the scientists requirement to use the science to design the best possible answer through research. Cost-benefit analysis would involve much more work than is usually done, and that this analysis would have to be kept separate from the science-based questions asked in risk assessments. The point to consider is not applying analysis as part of the ERA, but to consider providing the ecological tools/indicators that can be later applied by cost/benefit and aid the decision makers

- Additional guidance should be developed for conducting cost-benefit analyses. The SAB is currently providing advice on monetizing benefits, but advice is also needed on how to estimate benefits before they can be monetized

- Benefit/cost assessments are needed. Ecologists and economists do not communicate well because typical monetization methods cannot be used for ecological systems. However, it is important to assess the benefits associates with risk management alternatives. More information is needed for valuation of resources and assessment of ecological services and this information must be provided on multiple scales and from the perspective of multiple stakeholders.

- Net benefit analysis may be a cross-cutting issue linking uncertainty analysis and risk management decisions. Some type of net benefit analysis would be beneficial, but it should not be used to avoid risk assessment.

6.3. Tools

- It is important to explore the use of alternate methods of analyses (e.g., likelihood matrix, Bayesian).

- There is an opportunity to use statistical methods to better inform the ecological risk assessment process (e.g, Type II, Power, sensitivity).

- Risk assessors should take advantage of recent advances in technology and tools for the analysis and interpretation of data. Application of such tools can enhance ecological risk assessments. These tools include: geographic information system mapping technologies, remote sensing technologies, spatial statistics, population and exposure modeling, and improved access to large databases.

6.4. Weight of evidence

- It is important to improve the certainty of ecological risk assessments by using multiple lines of evidence of biological responses. Individual level effect metrics can be protective of populations/communities, but not consistently so (Forbes and Calow). All lines of evidence are not equal in quality and clear guidelines are needed to use them efficiently.

- With regard to feasibility of execution: a low "n" of organisms at a site do not allow for decisions (e.g., minks and kingfishers at the Housatonic River site).

- Weight of evidence-Causal analysis

- Data analysis for examining causality

6.5. Likelihood arrays

- In problem formulation risk assessors should consider the notion of likelihood statements instead of binary (yes/no) statements.

6.6. Decision-making with multiple decision-makers

- Moving from output to outcomes is in EPA's strategic plan and Office of Research and Development research strategy. A feedback loop is a critical issue.

- See Joe Arvai report

7. Management in the Ecological Risk Assessment Context

7.1. Adaptive management

- At long term sites it is better to have an iterative process, try something, see if it works, then try something else.

7.2. Iteration

- The risk assessment process should be made more iterative with peer review.

7.3. Monitoring

- Testing of risk hypotheses (lots of discussion here)

- Focused ecological risk assessment follow-up monitoring, calibration, and corroboration activities should be undertaken to evaluate risk predictions.

- There is a need for post-remediation monitoring, perhaps following the Long Term Ecological Research model for some contaminated sites. Criteria should be established for assessing outcome and success. These sites would be good for conducting exploratory research and adaptive management demonstrations.

- Better interfaces between risk assessment activities and monitoring programs are needed. Monitoring program data should be collected with a purpose. Data collection activities can address risk assessment needs.

- Monitoring programs can incorporate specific projects designed to decrease uncertainty in risk assessments (e.g., monitoring can identify specific measures).

- Monitoring programs need better direction to provide information that can be used to conduct risk assessments. Monitoring programs should be redesigned so they can provide information to help test improved hypotheses. Risk assessors who are working with existing data must influence how new data are collected in monitoring programs.

- A better interface with monitoring programs should be developed so that data could be collected for the purpose of improving risk assessments. Specific monitoring projects could be designed to provide data that could reduce uncertainty in risk assessments.

- Long term monitoring would provide data that would reduce uncertainty and improve decisions about remedy selection and, perhaps, future risk assessments. EPA, in conjunction with other agencies, should evaluate the effects of clean-up on sites remediated 5-20 years ago. This would build a data base that could be used to reduce uncertainty in new sites.

8. Communication

- EPA should develop a checklist that can be used to confirm that the necessary ecological risk assessment steps have been completed and explained.

- See Joe Arvai report

8.1. Involving social scientists

- At large contaminated sites where there is disagreement about the problem formulation it would be useful to include social scientists, and others who have the expertise to address policy questions, on a peer review panel.

8.2. Critical junctures for communication

- Informed consent is needed during problem formulation.

8.3. Who communicates to whom

8.4. Modes of communication (e.g., web-based tools and training modules)

- Practitioners in our group were particularly enthusiastic about web-based tools.

9. Learning from Ecological Risk Assessment Successes and Failures

9.1. Capacity building

- Most ecological risk assessments are carried out at the local level, and often local intellectual capital is not enough to provide adequate problem formulation. It is important to ensure that better training and guidance is available for people who are involved in the actual assessment.

9.2. Standards of practice

- These are needed. They could include a checklist of ecological condition assessments to consider; spatial, temporal scales and biological levels of organization to consider; requirement to assess cumulative risk (the problem is that contaminated sites are treated individually, yet they may all be feeding to the same water body); the need for transparent communication, particularly of uncertainty; discuss political and economic context; identify funding sources for the studies on which analyses were based.

- Inclusion of case studies in this would be beneficial, specifically those demonstrating risk assessments done at appropriate spatial and temporal scales and levels of biological organization and an analysis of the benefit of doing the analysis at the appropriate scale.

- Oregon requires that if bioaccumulation or biomagnification occurs, the risk assessor has to do additional analyses. This is a kind of threshold.

9.3. Case studies

- States want U.S. EPA information on lessons learned.

- A national database of case examples of cleanups is needed with identification of strengths and weaknesses.

- Central data exchanges are improving, Five year Superfund reviews abstract the results and are useful.

- Assemble case studies documenting the value of getting spatial and temporal scales right and market this to risk managers.

- The risk assessment community could benefit by having additional examples or case studies that highlight how the conduct and findings of the ERA did/did not impact the final remedy decision. There are examples where a really a good study and risk assessment can influence the remedy cost in a positive way. The Clark Fork River in Montana is an example where the study and the ERA helped point out opportunities to be protective of human health and the environment, while not having to undertake the costly removal of all contaminated soils/sediments.

9.4. Evaluation (linking risk to performance)

- The timeline for decision making and the timeline needed to see effects in the field are disconnected. This must be addressed in the risk assessment and management.

9.5. Tapping and adapting existing data and methods

- Oregon has a fairly well developed toolbox; these could be evaluated as a "state of the practice" and potentially disseminated. For example, Oregon requires that the assessment be done at the population level, and there is a tool that has a threshold for identifying where one has an 80% chance of affecting 20% or more of the population.

- Consider the range of tools and array them from state of the art to state of the practice. Evaluate the tools and involve the risk manager in assessing what a risk manager understands/needs/wants.

9.6. Cost effectiveness of risk assessment

- There is an issue of technical sophistication vs. utility of the information that sophistication produces. Resources/costs do not always equate to quality and utility.

- There is a research opportunity in evaluating mesocosm studies and their cost/benefit.

9.7. Proactive risk assessment for emergency response

- Use findings from reactive risk assessment to inform proactive risk assessment.

10. Special Issues Concerning Particular Types of Ecological Risk Assessment

10.1. Risk assessment for natural resource management (non-regulatory in the terminology of Barnthouse, meaning not CERCLA, TSCA etc.).

- This should be stated first perhaps, as a 10.1 or 10.2, and then we can draw contrasts.

- **There is need for EPA to clarify what risk assessment means in the context of contaminated sites.** Contaminated sites are those that are regulated under specific programs such as CERCLA, RCRA, or state cleanup programs. Given that contaminated sites are part of a statute-defined process, several panelists and participants noted that there are limits to what "risk assessment" can/cannot evaluate. Risk assessments under CERCLA or RCRA are limited to evaluating releases of hazardous chemicals. As such, the assessment endpoints must reflect the enforcement of the program authority and/or standards set in the law (e.g., ambient water quality criteria). As a result of these regulatory constraints, consideration of ecosystem-level or watershed effects, habitat restoration, and/or the effects from other deleterious substances (e.g., selenium, pesticides, wood wastes) are severely constrained under federal remedial programs. In practice, it is noted that for contaminated sites, true "ecological risk assessment" is not conducted. Rather what is done is **more appropriately termed a "toxicological risk assessment of ecological receptors" or "hazard assessments**".

- For product health and safety decision-making, guidance is needed on the use of models to conduct population level effects assessments, particularly for terrestrial ecological risk assessment.

- Many tools are currently available to conduct accurate screening level risk assessments for product health and safety in a short period of time. Such tools can be applied in risk assessments. There are many sources of information available for conducting these rapid assessments. European Union databases can provide ecotoxicology information. EPA's EPI Suite tool can provide physical and biological parameters to enable a determination of whether a chemical is biodegradable, toxic or bioaccumulative.

- Risk assessments for natural resources protection differ from other kinds of risk assessments. Risk assessments for natural resources protection are more closely tied to a "value" oriented paradigm. Other kinds of risk assessments are conducted from a stressor perspective. In assessments for natural resources protection there is a need to identify the ecological attributes that must be protected and to determine how they can be protected.

- In protecting natural resources it is important to consider "natural change" or change driven through global processes (like climate change). There is a need to know how

such change will influence other changes that might be noted in the system under study.

10.2. Contrasting risk assessments for: product use, contaminated sites, and natural resources management (table of similarities and differences)

- **The risk assessment community could benefit by having additional examples or case studies that highlight how the conduct and findings of the ERA did/did not impact the final remedy decision.** There are examples where a really a good study and risk assessment can influence the remedy cost in a positive way. The Clark Fork River in Montana is an example where the study and the ERA helped point out opportunities to be protective of human health and the environment, while not having to undertake the costly removal of all contaminated soils/sediments**.**

- Ecological epidemiology useful provides tools for assessing ecological risks. Bioassessment guidance has been developed by EPA's Office of Water, Superfund assessments often include observed effects, and pesticide reregistrations include incident reports. Bioassessment can reveal all effects, but they may not be clearly revealed and determining causality is often difficult.

- EPA should develop a checklist that can be used to confirm that the necessary ecological risk assessment steps have been completed and explained.

- A rigorous framework should be developed for considering options for remediating contaminated sites early in the process so that the relevancy of the risk assessment can be enhanced without compromising quality.

10.3 Reactive vs. proactive risk assessments

11. Other

- It is important to look at how good ecological risk assessments are now (with budgets being a constraint). It is important to sell and market ecological risk assessment and determine what the data will tell us at the end of the year. If we don't do the basic ecological risk assessment we should not get more ambitious.

- If a decision maker has a clear idea of desired outcome, then a testable hypothesis may be more appropriate. The yes/no questions of what is acceptable are answered at the management level.

12. Summary Recommendations

- This will need to be revisited once the document is more complete, but the one clear recommendation from our group is the recommendation to use the SAB Ecological

Condition Assessment Framework as a reference checklist during problem formulation. To assess ecological condition, one must consider both pattern and process. A list of factors to consider in evaluating ecological condition is provided in Table ES-1 of an earlier EPEC report entitled "A Framework for Assessing and Reporting on Ecological Condition." The first level of the hierarchy in this table identifies 3 process-related attributes and 3 pattern-related attributes that should be considered.