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The Strengths of the Ecological Risk Assessment Process: Linking Science to Decision Making

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This is 1 of 4 papers from the US Environmental Protection Agency Science Advisory Board's Ecological Processes and Effects Committee workshop on the current and future practice of ecological risk assessment. The workshop was held in Washington, DC in February 2006.

ABSTRACT

Twenty-five years ago, ecological assessments were being performed by different organizations, using different principles and methods, with little or no communication between different groups and no means for reconciling conflicts and inconsistencies between assessment methodologies. The recognition by practitioners of environmental assessment of the need for a unifying conceptual framework stimulated the development of today's Framework and Guidelines for Ecological Risk Assessment (ERA). This paper discusses the success of ERA as a process for linking environmental science to decision making, using 3 recently published case studies involving establishment of baseline ecological risks at a contaminated site, probabilistic assessment of regional risks of pesticide use, and regulation of pharmaceutical product manufacture. Some promising future directions in ERA are briefly discussed, and 3 critical challenges to future success are identified.

Keywords: Ecological risk assessment   Ecology   Environmental regulation   Environmental restoration

INTRODUCTION: THE ORIGIN OF ECOLOGICAL RISK ASSESSMENT

The easiest way to see how far ecological risk assessment (ERA) has come is to look at where it's been. Twenty-five years ago, the term "ecological risk assessment" had not been invented. Ecological assessments were being performed by different organizations, using different principles and methods, with little or no communication between different groups and no means for reconciling conflicts and inconsistencies between assessment methodologies. Within the US Environmental Protection Agency (USEPA), independent ecological assessments were being performed to support implementation of the Clean Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act. Outside the USEPA, different groups of scientists working for other agencies were performing environmental studies related to environmental impact statements for power plants, introductions of invasive species, marine pollution, and protection of endangered species. No unifying framework for promoting the consistency of these various activities existed, and skeptics argued that ecological assessments were so diverse that no such framework could ever be developed.

Suter et al. (2003) summarized the history of the development of a unified approach to ERA, beginning with the initiation of the USEPA's 1st funded project on ERA in 1981. By that time, ecologists inside and outside the USEPA realized that to be accepted as contributors to environmental decision making, ecologists, environmental toxicologists, and other environmental scientists had to get their act together. To earn the respect of the engineers and health scientists who dominated the USEPA, other agencies, and the environmental departments of major corporations, they would have to develop a unified conceptual approach to environmental assessment analogous to the framework that was at that time coalescing for human health risk assessment (NRC 1983).

A coherent assessment framework would facilitate cooperation and collaboration between different assessment-related disciplines, so that, for example, laboratory studies of effects of toxic chemicals could be integrated with field studies of ecological effects of pollutant discharges. Standardized tools and techniques could be developed and used by all of the organizations involved in environmental assessment and management. In addition to improving the science of ecological assessment, a unified framework would increase the consistency and transparency of ERAs, thereby increasing the likelihood that assessment results would be understood and used by agencies and corporate managers. Ecological assessors would be able to dispel the then-common perception that "ecological risk assessment is impossible" and gain a seat at the environmental decision-making table.

Fortunately, the effort to develop consistent principles and procedures for ERA was supported by senior USEPA policy makers, most notably William Ruckelshaus, who became Administrator of the USEPA in 1983. Throughout the 1980s, the USEPA supported research programs on risk assessment methods through a collaborative effort involving the USEPA research labs, academic researchers, and the US Department of Energy's Oak Ridge National Laboratory. A core team of scientists drawn from the USEPA's program offices, under the sponsorship of the Risk Assessment Forum, convened workshops and commissioned white papers on ERA.

This effort bore fruit in the 1990s. The Framework for Ecological Risk Assessment was published in 1992 (USEPA 1992) and the Risk Assessment Forum Guidelines for Ecological Risk Assessment were published in 1998 (USEPA 1998). Program-specific ERA procedures consistent with the Framework and Guidelines were developed by the Office of

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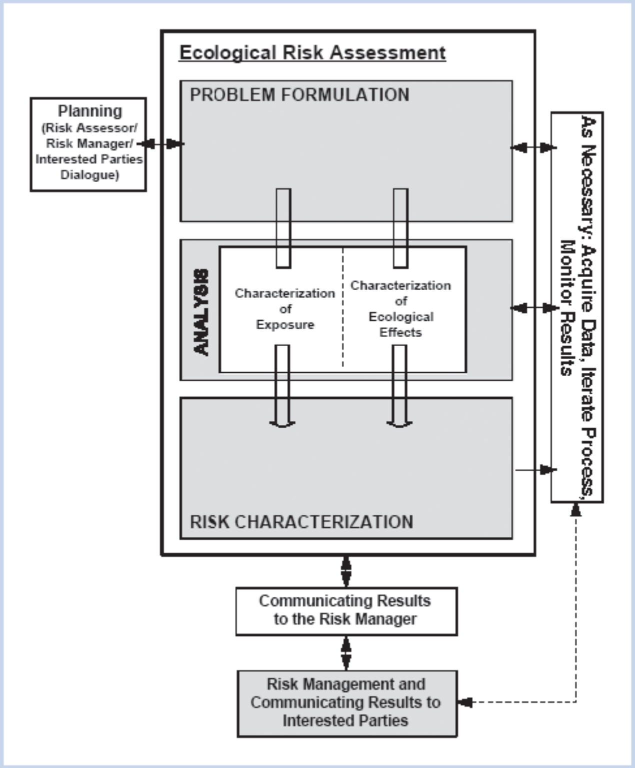

Figure 1. The framework for ecological risk assessment.

Toxic Substances, the Office of Pesticide Programs, the Office of Water, and the Superfund office.

THE FRAMEWORK FOR ERA

The key to success was the realization by the architects of ERA that risk assessment is a process and not a specific set of data collection techniques or analytical methods. The Framework figure (Figure 1) is now so widely known and copied that many who are new to ERA do not recognize its significance. The idea that the complex linkages between science and environmental decision making could be captured in a simple diagram with 3 boxes was considered revolutionary at the time, and is a major accomplishment of which the developers should be justly proud. In many ways, the Framework for ERA goes well beyond the health risk assessment framework in recognizing the central role of communication between science and management in ensuring that assessments address issues that are important to decision making and that decision makers (including public stakeholders) understand the implications of the assessment results.

The problem formulation component, for example, was a key innovation that is absent from the human health risk assessment framework. The central insight underlying this problem formulation is that the scope and content of an ERA depend on the problem in hand, and must be discussed with risk managers and other interested stakeholders before the process even begins. The Guidelines (USEPA 1998) describe a formal process for identifying and considering relevant issues, defining data needs, and developing a conceptual model that communicates the content of the assessment to interested parties and lays the foundation for data collection and analysis.

The analysis component is another key innovation because enclosing "characterization of exposure" and "characterization of ecological effects" in a single box recognizes the close interaction between chemists, toxicologists, and ecologists that is required to produce a coherent risk assessment. The data and models used for exposure assessment depend in part on the types of effects that are expected and are most relevant for decision making; the data and models used for effects assessment depend in part on the expected spatial and temporal exposure patterns. Together, exposure and effects assessment provide the scientific foundation for the risk assessment.

Risk characterization is a key component of the process, and in many ways the most complex and difficult. Without a good risk characterization, all of the time and effort devoted to an assessment may be wasted. From a technical perspective, risk characterization involves synthesis of data on exposures and effects that may involve a wide variety of quantitative techniques. Equally important, risk characterization includes interpreting the significance of the assessment findings and documenting the assessment results in a form that can be communicated to risk managers and the public.

ECOLOGICAL RISK ASSESSMENT TODAY

The Guidelines have been in place for nearly a decade and the success of ERA has far surpassed the original goals of the scientists who initiated this effort 25 y ago. Numerous agency-wide, program-specific documents are on the shelf, and the USEPA's framework has been widely imitated outside the United States. The USEPA continues to refine and expand on specific topic areas covered by the guidelines, and program offices such as the Office of Pesticide Programs are refining and improving the scientific content of their ERA procedures.

Peer-reviewed articles documenting ERA methods and results appear regularly in *Environmental Toxicology and Chemistry*, *Integrated Environmental Assessment and Management*, *Human and Ecological Risk Assessment*, and *Environmental Science and Technology*. The 1st textbook on ERA is now into its 2nd edition (Suter 2007).

Most important, recognition that assessments performed by different organizations with different regulatory mandates share common scientific principles has led to the development of new scientific tools that can be applied in a consistent way to many types of assessment problems. The following examples (out of many that could be discussed) exemplify the enormous scientific advances in ERA that have occurred since 1981.

The Clinch River remedial investigation

The Clinch River remedial investigation (RI) characterized the nature and extent of contamination in the Clinch River, Watts Bar Reservoir, Tennessee, USA, and tributaries to these 2 reservoirs and estimated the associated baseline ecological risks (Adams et al. 1999; Baron et al. 1999; Cook et al. 1999; Halbrook et al. 1999; Jones et al. 1999; Sample and Suter 1999; Suter et al. 1999).This study was performed to support the environmental restoration program for the US Department of Energy's Oak Ridge Reservation, conducted in accordance with the requirements of the Comprehensive Environmental Response, Compensation, and Liability Act (better known as the Superfund Act).

The ERA performed to support the Clinch River RI employed a complex set of field and laboratory studies, including contaminant mapping, environmental fate modeling, community surveys, body burden measurements, biomarkers, single chemical toxicity tests, and ambient media toxicity tests. Through the USEPA Framework, the assessment team was able to organize the results of these diverse studies and develop defensible conclusions concerning risks posed to terrestrial and aquatic biota from chemicals derived from the Department of Energy's Oak Ridge facilities. Site characterization studies detected nearly 30 inorganic and organic chemicals that could be posing significant risks to fish, wildlife, or benthic invertebrates. The assessment team was faced with the task of identifying specific habitats and river reaches that might have been affected by these chemicals, the types of organisms within each habitat and reach that could have been affected, and the chemicals most likely responsible for any observed effects. Such a study would have been unthinkable in 1981.

The fish community component of the assessment (Suter et al. 1999) provides an excellent example of the way in which multiple lines of evidence integrated using the USEPA Framework can be used to assess ecological risks. The assessment endpoint chosen for the fish community was "reduction in species richness or abundance or increased frequency of gross pathologies in fish communities resulting from toxicity." This specification of the assessment endpoint is important because it implies that the scale of the assessment is the fish community of the receiving system. Mere demonstration of the presence of hazardous chemicals in water or sediment samples would be insufficient to demonstrate a risk significant enough to require remedial action. Effects would have to be observed at the scale of the reservoir and its tributaries, and a determination made that these effects were caused by toxic chemical releases from the reservation.

Available measures of exposure included measurements of chemical concentrations in sediment, water, and fish tissue from numerous sampling stations in the Clinch River, Watts Bar Reservoir, and tributary streams originating on or passing through the Oak Ridge Reservation. Available measures of effects included water-quality criteria and other literature-derived toxicity benchmarks, ambient toxicity tests performed using several species of fish, histopathological and reproductive bioindicators in fish collected from exposed habitats, and fish community survey data.

Using this information, the assessment team developed a systematic approach to assessing risks to fish communities at the subreach, tributary, and reservoir scales. As documented by Suter et al. (1999), the team used single-chemical toxicity information from criteria documents and the scientific literature to screen out chemicals present in low enough concentrations that they were extremely unlikely to have caused any effects. These same benchmarks were used identify locations that might have been affected by the cumulative effects of multiple chemicals present in surface water, and to identify the specific chemicals that would most likely have been responsible for these effects.

In addition, the team compared cumulative distributions of exposure concentrations in each study reach to cumulative distributions of effects concentrations measured in laboratory studies. This approach, which is similar in concept to the species sensitivity distribution approach used in the following case study (Solomon et al 1996), enabled the team to conclude that infrequent high-exposure events were more important than long-term chronic exposures as stressors on the fish communities present in Poplar Creek Embayment and in the Clinch River immediately downstream. Ambient toxicity tests performed using water collected from several sites within Poplar Creek confirmed the presence of surface water toxicity in Poplar Creek Embayment.

Fish community survey data were analyzed at 2 spatial scales. First, data collected by the Tennessee Valley Authority were used to compare Watts Bar Reservoir to other reservoirs in the Tennessee Valley Authority system. This analysis showed the Watts Bar fish community as a whole is similar to fish communities in adjoining reservoirs and exhibited no anomalies that might be related to site-derived chemicals. Second, fish surveys conducted to support the Clinch River RI were used to examine effects at the local scale. This analysis showed that a depauperate fish community was present in Poplar Creek embayment.

The consistency of the various lines of evidence was evaluating using weight-of-evidence rules that assigned each type of evidence a score of (+), (–), or (±) depending on whether it was consistent with the hypothesis that significant risks were present, inconsistent with that hypothesis, or ambiguous. The weight-of-evidence evaluation showed that, with respect to all but one study reach, the available evidence indicated an absence of significant risks attributable to site-related chemicals. However, most lines of evidence indicated the presence of significant risks in Poplar Creek Embayment. A parallel assessment of risks to aquatic invertebrates (Jones et al. 1999) also found significant ecological risks at this location. All of the multiple lines of evidence were needed to convince the responsible parties that significant risks were present at this location.

Based on the results of human health and ERAs, no remediation was required in Watts Bar Reservoir (USEPA 1995). The USEPA determined that aggressive remediation (i.e., dredging) of sediments in Poplar Creek Embayment would be impractical and ecologically destructive, therefore, the remedy selected for this site was limited to institutional controls and consumption advisories intended to minimize human health risks (USEPA 1997).

In addition to providing defensible conclusions regarding the need for remediation to reduce risks to aquatic biota due to historic releases from the Oak Ridge Reservation, the Clinch River study demonstrated the value of using multiple lines of evidence from multiple scales of organization to evaluate the magnitude, significance, and spatial scale of ecological risks.

Ecological risk assessment of atrazine in North American surface waters

This regional-scale assessment was performed as part of a "special review" of atrazine performed under FIFRA. The legal authority for FIFRA assessments in completely different from the authority for Superfund assessments, and the USEPA program offices are independent. Technical staffs are independent, and in past years there might have been no connections whatsoever between a pesticide assessment and a contaminated site assessment.

Yet, there are many common features. Perhaps the most important of these features is that the scale of the atrazine assessment, which was defined by the USEPA to be the entire midwestern Corn Belt, was so large as to preclude the use of a strictly toxicity-based assessment approach. The toxicity-based approach normally used by the USEPA's Office of Pesticide Programs, as documented by Urban and Cook (1986), is a tiered hazard assessment approach. At the lowest tier, measured or modeled environmental concentrations are compared to standard toxicological endpoints such as LC50s for a relatively small number of indicator species. If lower-tier data suggest the possibility of effects on nontarget organisms exposed in the field, then additional laboratory or field tests might be required. Although refined versions of this scheme are still used by the USEPA today as part of the registration process for new pesticides, the tiered testing approach was obviously inadequate for the atrazine special review.

The special review required assessments of risks across a complex landscape in which concentrations of atrazine would vary in time and space. Concentrations in streams immediately adjacent to fields where atrazine was applied would be expected to experience brief, high-intensity pulses of atrazine, whereas downstream rivers receiving drainage from large agricultural areas would experience prolonged, low-intensity exposures. The assessment also had to consider potential effects of atrazine exposure on a wide variety of organisms. In addition to direct effects of exposure, which were expected to be limited to plants, the assessment had to consider indirect effects due to atrazine-related reductions in primary production.

The atrazine assessment was conducted using procedures prescribed in the Framework for Ecological Risk Assessment (USEPA 1992) and the Report of the Aquatic Risk Assessment Mitigation Dialog Group (ARAMDG 1994). The ARAMDG was a multi-stakeholder scientific group established by the USEPA specifically to improve the science underlying risk assessments for pesticides and to make pesticide risk assessments consistent with the recently published Framework. One specific and very important recommendation from the ARAMDG was to utilize probabilistic methods in both the exposure and the effects components of the risk assessment. The atrazine assessment was one of the 1st ERAs to characterize both exposures and effects using probabilistic methods.

The assessment endpoints chosen for the atrazine assessment included primary productivity, the sustainability of aquatic macrophyte community structure, and long-term viability of fish populations. The ecosystems at risk were considered to be streams, rivers, and reservoirs of the midwestern corn-growing regions of North America. The most susceptible organisms were considered to be phytoplankton, periphyton, and macrophytes. However, aquatic animals could be indirectly affected because of reduced food supply or changes in physical habitat (reduction or elimination of macrophyte beds).

The exposure assessment used measured concentrations of atrazine in surface water. Data sets from Ohio, Iowa, Illinois, and Nebraska, were used to develop the exposure estimates. These data sets represented a range of watershed sizes, selected because frequencies of monitoring were sufficient to characterize pesticide concentration distributions during storm events. The raw concentration measurements were used to compute probability distributions for instantaneous exposures, 4-d average exposures, and 21-d average exposures. The more limited data available for atrazine in reservoirs were used to compute probability distributions for point measurements of atrazine, by season.

The effects assessment used acute and chronic toxicity test data for 85 freshwater species and 47 saltwater species. The data were segregated by major taxonomic groups (phytoplankton, aquatic macrophytes, benthos, zooplankton, and fish). For each taxonomic group, and for both acute and chronic endpoints, the test results were used to compute cumulative frequency distributions of effects concentrations. In interpreting these sensitivity distributions, an assumption was made that the tested species constitute a representative sample of all of the species within that taxonomic group present in a typical aquatic community. Under this assumption, the frequency distributions can be used to calculate, for any concentration of atrazine, the fraction of species for which chronic or acute effects would be expected to occur.

For risk characterization, overlaps between exposure concentrations and sensitivity distributions were calculated. Distributions of species sensitivity were compared with distributions of exposure concentrations for a number of sites on major rivers, streams, and reservoirs in the United States and Canada. In almost all cases, a negligible overlap of distributions was found for both acute and chronic effects, indicating that under most circumstances risks due atrazine exposure should be negligible. Potentially significant risks were found only for a relatively small subset of small streams and reservoirs located in watersheds with high pesticide use.

Although the atrazine risk assessment is well-known primarily as the 1st large-scale probabilistic risk assessment performed for a pesticide, this assessment, like the Clinch River assessment also demonstrates the importance of examining multiple lines of evidence. Conclusions drawn from the species sensitivity distribution approach regarding concentrations that could potentially affect aquatic communities were compared to concentrations observed to cause effects in microcosm and mesocosm studies. The predictions and observations were consistent, demonstrating that the species sensitivity distribution approach was a reasonable way to characterize ecological risks of atrazine exposure.

Based on the Solomon et al. (1996) and other studies addressing human health and ecological risks of atrazine, USEPA (2003) approved atrazine for reregistration, but required the registrant to establish a watershed monitoring program involving 40 potentially vulnerable watersheds in 10 states. Additional management actions to reduce atrazine inputs to surface water will be required if the measured concentrations exceed levels shown to adversely affect aquatic communities.

Environmental risk assessment of 6 human pharmaceuticals

Ferrari et al. (2004) documented a study performed to test a procedure proposed by the European Medicines Evaluation Agency (EMEA) for conducting ERAs for pharmaceutical products present in wastewater treatment plant effluent (EMEA 2001). This study is an example of the convergence in assessment methods between North America and Europe that has occurred over the past 25 y. The draft EMEA procedure, like assessment procedures used for chemical evaluation in the United States and Canada, utilizes multiple sequential tiers of testing and assessment. The lowest tier (tier 1) utilizes only information on use levels, wastewater treatment efficiency, wastewater discharge volume, and receiving stream dilution. If the predicted environmental concentration following dilution, termed the "predicted environmental concentration" (PEC), exceeds a de minimis value of 10 ng/L, then the assessment proceeds to a 2nd tier. In tier 2, acute toxicity test data for the substance in question are used to calculate a predicted no-effect concentration (PNEC). If the PEC from tier 1 exceeds the PNEC, then the assessment proceeds to higher tiers.

The lower tiers of EMEA procedure are intended to be conservative, i.e., they should overestimate rather than underestimate the ecological risks posed by pharmaceutical products. Ferrari et al. (2004) used available data on measured concentrations of 6 pharmaceutical products in rivers in France and Germany, together with chronic effects data available for these same 6 products, to test the conservatism of the draft EMEA procedure.

The assessment endpoints, measures of exposure and measures of effects for this assessment were, of necessity, much less complex than the equivalent endpoints and measures for the Clinch River and atrazine ERAs. When the decision to be made concerns pharmaceutical products or manufactured chemicals that are not released directly to the environment, relatively simplistic estimates of exposures and effects are the only kinds of estimates that are possible. Even with the limited data available, however, Ferrari et al. (2004) were able to find a potentially significant flaw in the EMEA risk assessment procedure.

The authors used available data to address the following 2 questions: 1) Would the simplistic exposure model and trigger concentration used in tier 1 of the EMEA procedure correctly identify pharmaceutical products that might pose significant ecological risks? 2) Would the acute toxicity data used in tier 2 of the EMEA procedure correctly identify pharmaceutical products for which chronic exposure might pose significant ecological risks?

Answering the 1st question involved 2 steps. In the 1st step, PECs for 6 widely used pharmaceuticals were compared to measured concentrations in French and German wastewater treatment effluents and surface waters. In all cases, the wastewater PECs were substantially higher than the measured concentrations in wastewater treatment effluents. However, in some cases measured concentrations in surface water exceeded the surface-water PECs, indicating a need for more comprehensive data on sources of pharmaceuticals and more refined modeling of environmental fate processes for pharmaceuticals. However, for practical assessment purposes, these deficiencies were irrelevant because in all cases both the predicted and measured concentrations exceeded the 10 ng/L cutoff value by more than an order of magnitude. In the 2nd step, the protective nature of the10 ng/L cutoff value was tested using acute and chronic toxicity test data for the 6 pharmaceuticals. A total of 53 acute EC50s (15 test species) and 41 chronic NOECs (9 test species) were available. These values were used to construct species sensitivity distributions for acute effects and for chronic effects. As in the atrazine study, it was assumed that the tested species are representative of all potentially exposed species. The 5th percentiles of these distributions were chosen as the threshold for ecologically significant effects (i.e., predicted effects on more than 5% of species would be considered ecologically significant) and were compared to the 10 ng/L cutoff value. For both acute and chronic effects, the 5th percentile values were at least an order of magnitude higher than the cutoff value, indicating that a 10 ng/L cutoff should identify all potentially significant pharmaceutical exposures.

As a final test, the protective nature of the acute toxicity tests used in tier 2 of the EMEA procedure was evaluated by comparing PNEC values calculated using acute EC50s to PNEC values calculated using chronic test data. The authors found that, due to the highly variable toxicity of pharmaceutical compounds to different classes of organisms, the risks posed by some of the compounds evaluated were significantly underestimated using the EMEA tier 2 procedure.

One important reason for the failure of the proposed procedure, according to the authors, is that pharmaceutical products, unlike general industrial chemicals, are specifically designed to have biological effects, and these effects vary greatly among pharmaceuticals because of their greatly differing modes of action. Assumptions typically used in regulatory assessment schemes, e.g., estimating chronic effects thresholds through application of a safety factor (typically a factor of 1000) to acute EC50s or LC50s, may not be adequate for predicting chronic effects of pharmaceuticals.

Ferrari et al. (2004) concluded that the draft EMEA procedure was inadequate and should be refined to rely more heavily on chronic effects studies and to take greater account of the specific modes of action of pharmaceuticals.

The Ferrari et al. (2004) study, unlike the Clinch River or atrazine studies, was not performed to support a specific regulatory decision. However, the draft EMEA procedure has been modified to include a requirement for chronic toxicity testing in tier 2.

FUTURE DIRECTIONS IN ERA

The environmental problems at hand when ERA first began to emerge were primarily regulatory in nature: Chemical manufacturing, pesticide registration, pollutant emissions, and hazardous waste site cleanup. The environmental problems of the 21st century provide opportunities to expand the scope of ERA to support a wider array of environmental decisions. Two examples are briefly described below.

Environmental restoration

Beyond preventing damage to the environment, ERA can play an important role in reversing historical environmental degradation. As exemplified by the Clinch River RI, field study methods and weight-of-evidence techniques can be used at contaminated sites to assess whether local populations and communities have been adversely affected by site-related chemicals. Methods are also available for assessing whether pollutant discharges have adversely affected the biological integrity of surface waters (Barbour et al. 1999, Karr and Chu 1999). Many of these same methods can be used to reverse this assessment process by identifying the causes of observed biological degradation (USEPA 2000, Suter et al. 2002). Once the causes have been identified, management actions to reverse the degradation can be developed.

Linking ERA to adaptive management (Holling 1978) could be an especially valuable approach at many sites. A review committee of the National Research Council recently concluded that the only way to restore large, complex sites is through the use of adaptive management (NRC 2005). At such sites, it simply is impossible to specify a "final" remedy through the conventional Remedial Investigation/Feasibility Study process. An adaptive approach to site restoration would involve a cyclical process of study, remedial design, implementation, performance monitoring, and redesign that views the restoration process itself as a management experiment (Gustavson et al. 2007). The ERA can contribute to this process by providing 1) diagnostic procedures that can be used to identify the stressors contributing to biological impairment and 2) biological performance goals that can be used to measure restoration success.

Regional environmental management

Managing the environment to ensure long-term sustainability clearly involves much more than simply regulating pollutants and cleaning up contaminated sites. Ideally, the focus of management should involve entire watersheds (and airsheds), including urban, suburban, agricultural, and forested landscapes. Assessments at this level almost of necessity involve establishment of biological integrity goals for both aquatic and terrestrial ecosystems and consideration of multiple chemical and nonchemical stressors. The USEPA has already taken important steps in this direction, through a series of watershed-level risk assessment case studies (Cormier et al. 2000; Norton et al. 2000; Serveiss 2002). Other investigators have developed regional-scale assessment approaches as well (Landis et al. 2005). Databases and quantitative methods for use in these assessments are expanding rapidly, however, almost by definition, regional-scale management involves multiple political jurisdictions and stakeholder groups (Serveiss 2002). The principal barrier to more extensive application of regional-scale assessment methods appears to be the institutional complexity of regional environmental management problems.

CRITICAL CHALLENGES AND THREATS

The purpose of this paper is to highlight the successes of the ERA process, not to argue that ERA is perfect. Uncertainties in the available scientific information will always exist, and will translate directly into uncertainties in ERAs. Scientific uncertainty is not, however, the most important challenge for ERA. As discussed below, the greatest threats to ERA relate more to institutions and people than to scientific uncertainty.

Science-lag

Van Straalen (2003) argued the ecotoxicology is beginning to merge with ecology to become a more integrative discipline which he termed "stress ecology." This evolution provides a concrete example of the continuous advancement of the scientific disciplines underlying ERA. New tools such as genomic analysis and geographic information systems, originally developed for purposes unrelated to risk assessment, are now available for use in ERAs. This means that an ERA that is state-of-the-science today may be obsolete tomorrow. The ERA must be viewed not as a static set of procedures but as a dynamic discipline that evolves as environmental science evolves. For regulatory and resource management agencies, this means that all risk assessment procedures should be regularly reviewed and revised as necessary to keep up with scientific advances.

Unrecognized value judgments

Risk assessment is performed in a social context (Shrader-Frechette 1985). Assumptions and degrees of conservatism differ depending on stakeholder perceptions, and assessors working for different constituent groups may be expected to have different perspectives. This implies that no risk assessment is entirely objective, although assessors should be striving to minimize subjectivity and to explicitly state biases, where they exist. One of the fundamental principles of risk assessment is that value judgments must never be disguised as scientific judgments (NRC 1983); to do so compromises the integrity and credibility of ERA.

Mediocrity-creep

Maintaining quality is the biggest challenge of all. Detractors of risk assessment (e.g., Tannenbaum 2005) are fond of pointing out the superficial nature of many assessments. The availability of screening benchmark databases and user-friendly modeling software makes it easy for anyone, with minimal training and little or no data, to perform a "risk assessment." Because of inevitable limits on budgets and time, the temptation to cut corners will always be present. Consultants who promise to do the job for less are always waiting right outside the project manager's door. The only way to prevent mediocrity-creep is to establish and maintain rigorous standards both for the training of risk assessors and for the quality of assessment products.

CONCLUSION: ERA AS TRANS-SCIENCE

Everyone should understand that ERA involves multiple, conflicting goals:

- Ensure that the assessment addresses management needs,
- Maintain the distinction between management and science,
- Use the best available science,
- Use all available and relevant science,
- Ensure that the assessment process is transparent, and
- Ensure that the methods and results are comprehensible to decision makers and stakeholders.

These goals clearly transcend science and ERA is not a conventional scientific discipline like chemistry, toxicology, or ecology. Ecological risk assessment is best viewed as a bridge between science and management. Ecological risk assessment should serve as a systematic approach to organizing scientific information to support environmental decision making. It should also serve as a source of analytical tools applicable to a wide array of environmental problems, and be a stimulus for development of even better tools to improve future environmental decisions.

I believe that, although imperfect, ERA is currently providing all of these functions in a way that even the most optimistic assessment scientists could not have envisioned in 1981. The challenge to assessors today is to ensure even greater success in the future.

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