SPECIAL SECTION
Perspectives of the Scientific Community on the Status of Ecological Risk Assessment

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DEBATE ABSTRACT / Views from a wide variety of practicing environmental professionals on the current status of ecological risk assessment (ERA) indicate consensus and divergence of opinion on the utility and practice of risk assessment. Central to the debate were the issues of whether ERA appropriately incorporates ecological and scientific principle into its conceptual paradigm. Advocates argue that ERA effectively does both, noting that much of the fault detractors find with the process has more to do with its practice than its purpose. Critics argue that failure to validate ERA predictions and the tendency to over-simplify ecological principles compromise the integrity of ERA and may lead to misleading advice on the appropriate responses to environmental problems. All authors felt that many improvements could be made, including validation, better definition of the ecological questions and boundaries of ERA, improved harmonization of selected methods, and improvements in the knowledge base. Despite identified deficiencies, most authors felt that ERA was a useful process undergoing evolutionary changes that will inevitably determine the range of environmental problems to which it can be appropriately applied. The views expressed give ERA a cautious vote of approval and highlight many of the critical strengths and weaknesses in one of our most important environmental assessment tools.

Charlatan or Sage? A Dichotomy of Views on Ecological Risk Assessment

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Global climate change, reductions in biodiversity, and the potential implications of pesticide and toxic chemical releases have all raised public awareness of ecological issues in the last decade. Established toxicology, ecology, and fisheries journals have devoted increasing space to discussion of impact related issues. No less spectacular has been the profusion of new journals dedicated to various aspects of assessing the impacts of anthropogenic activities on the environment. These include *Environmental Modeling & Assessment, Human and Ecological Risk Assessment, Ecotoxicology,* and the *Journal of Aquatic Ecosystem Stress and Recovery.* Central to many of these journals, their readers, and their authors are issues relating to the use, abuse, and development of the practice of ecological risk assessment.

The respectability and fashion of risk assessment as a means for evaluating scientific information on the potential adverse environmental effects of physical and chemical stressors was sanctified in 1992 with the release of the Framework for Ecological Risk Assessment by the US Environmental Protection Agency (US EPA 1992). Broadly speaking, ecological risk assessment can be viewed as an exercise in environmental problem solving. It is a systematic means of assessing the state of ecological resources and determining remediative priorities for the myriad of potential ecological problems human action has caused. More precisely, ecological risk assessment is defined as the use of available toxicological and ecological information to estimate the probability of an unwanted ecological event occurring (Wilson and Crouch 1987).

Regulatory and scientific interests have both played important roles in the development of risk assessment techniques. Regulatory interest has focused on legal issues surrounding the need to complete assessments and the design of management protocols. Science has defined the kinetics and potential impact of stressors

KEY WORDS: Ecological risk assessment; Ecology; Probability

[1]Managed by Lockheed Martin Energy Research Corporation for the US Department of Energy under contract number DE-AC05-960R22464.

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through the completion of hazard, effects, and exposure assessments. Regulatory interest, resulting in legislation, has forced decisions on the use and disposal of contaminants. Accordingly, as Bartell and others (1992) have argued, it is prudent to develop and evaluate scientifically defensible methods that can be employed by environmental decision makers and regulators. Undoubtedly, a general framework for ecological risk assessment would have heuristic value, despite the unique scientific questions and regulatory issues likely to be raised in each case.

To its advocates risk assessment is a rigorous form of assessment that uses formal quantitative techniques to estimate probabilities of effects on well-defined endpoints, estimate uncertainties, and partition the analysis of risks from discussions concerning their significance, or choice, of appropriate remediative action (Suter 1993). To its detractors, however, risk assessment is little more than a jumble of technical jargon designed to expedite the degradation of natural environments. Slightly less extreme views characterize it as a means of facilitating the acceptance of the views of the technical elite by the public under the guise of scientific objectivity (Lackey 1994). Clearly, there is much that divides the two views of risk assessment. This, in part, may reflect the fact that scientists and analysts are not effectively conveying ecological options to decision makers or the public. Confusion leads to mistrust, and mistrust to ridicule. If risk assessment techniques are ultimately to be successful and contribute to the continued refinement of environmental guidelines, then scientifically credible methods must be developed and debated. The rate at which the methodology is developing, and discussions concerning the utility of its application within the wider context of social decision making, suggest there is need and merit in critically assessing the current state of the art in ecological risk assessment.

Permeating much of the discussion on risk assessment is the technocratic view of objectivity. This views risk assessment as objective in the sense that different risks may be evaluated using a standard approach. Furthermore, it claims that, at least at the stage of calculating the probabilities associated with hazards and their effects, risk assessment is completely objective, neutral, and value free. Many, however, still view risk analyses as being value laden (Shrader-Frechette 1991). Assessors must make value judgements about which data to collect, how to simplify available facts into simple models, how to extrapolate because of unknowns, how to select the statistical tests to be used, how to select sample size, and which exposure–response model to employ.

Even within the scientific community there is discussion concerning the confidence that can be placed in obtained estimates. Incomplete understanding of ecological systems combined with the uniqueness of individual systems (Loucks 1985) implies much uncertainty. If, however, the ultimate goal of risk assessment is predictability, then there must be a good understanding of all possible ecological outcomes and probabilities associated with any perturbation. Although practitioners are quick to claim that an important feature of risk analysis is the explicit consideration of uncertainties in the analyses, questions remain about how the unknown can be adequately expressed as a probability in the final estimate of effect. Calow (1994) maintains that we still do not know enough about ecological systems to be able to identify what it is we want to protect about them and hence, what we should be measuring. Ludwig and others (1993) point out that scientific understanding is hampered by lack of controls and replicates to the point where each new problem involves learning about a new system.

We are left, then, to question a central tenet of ecological risk assessment: probability. Probability is typically defined as the portion of times a given outcome is observed in a series of identical, repeatable experiments. Without probability, the distinction between risk assessment and other assessment methods (e.g., environmental impact assessment) becomes murky. Without clear knowledge of what we should measure, how do we select or define endpoints? And without endpoints, or replication, how do we define probability? The fact that available data indicate a low frequency of observed effects does not prove a low probability of occurrence if each observation cannot be viewed as the product of an identical, repeatable experiment. Without repeatability, the statistical foundations of risk assessment appear weak and the scientific foundations are almost certainly questionable. Protocols whose results cannot be readily replicated will inevitably labor under the same suspicions as the alchemists of old.

The above observations raise the obvious questions as to what lack of knowledge about ecological systems and lack of replications imply for ecological risk assessment. Since much of the information incorporated into assessments is demonstrably not of acceptable probabilistic character, is ecological risk assessment abusing statistics with wanton disregard for the principles and assumptions of the practice? Furthermore, can the problem be remedied, given the definitional impossibility of duplication in ecological systems? If not, do we condemn the practice of risk assessment as a charlatan pseudoscience intent more on the enunciation of frameworks than on improving scientific practice? Or do we regard ecological risk assessment as delivering the tools necessary to describe, priorize, and ultimately address the many complicated environmental issues that lie before us?

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Science and Subjectivity in the Practice of Ecological Risk Assessment

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As highlighted in the introduction to this debate, much of the disagreement surrounding risk assessment depends on whether it is viewed as inherently an objective or a subjective process. Objective means settling issues using scientific procedures of critical analysis and carefully controlled observation, and subjective means settling issues by an appeal to human values. However, it is our main thesis that presenting the debate as polarized between these extremes obscures the potential value that both objectivity and subjectivity can add to the risk assessment process. In particular, this paper focuses on the following points: (1) risk assessment, as a procedure, can be defined unambiguously and objectively; (2) scientific procedures can be used to provide the information and understanding (criteria) needed to carry out risk assessment if it is known a priori what is being protected; (3) defining what it is that we want to protect may not (and perhaps should not) be entirely, or even mainly, something that can be decided on the basis of scientific criteria especially as far as ecological systems are concerned; and (4) risk assessment represents the application of science in situations where there is much uncertainty. Estimating the statistical confidence with which effects can be detected (given fixed experimental designs) can be a substantial aid to the risk assessment.

KEY WORDS: Extrapolation; Risk quotients; Ecosystem health; Ecosystem service; Statistical errors

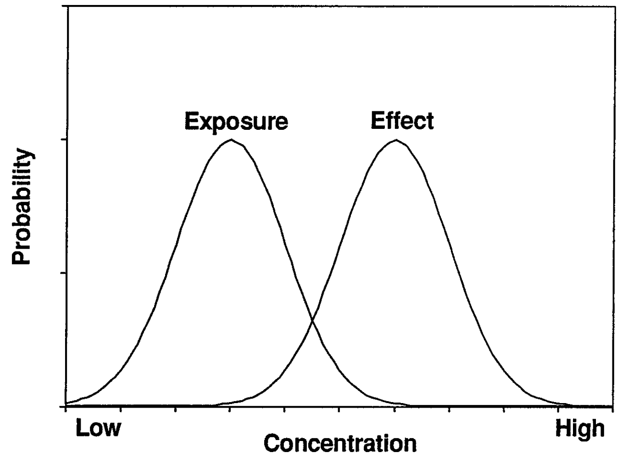

Figure 1. Risk assessment of chemicals compares likely exposure and effect distributions. The variability in each derives from biological sources (effects) and the physico-chemical complexity of the environment (exposure). Though both are represented as symmetrical distributions, they need not be so. A probability of effect is computed from the extent of overlap between the two distributions.

Defining Risk Assessment Objectively

Risk is defined as the likelihood that the potential to cause harm inherent in some substance, process, or activity is realized in some "real-world" situation. As far as commercial chemicals and pesticides go, estimating risk involves combining an understanding of their potential to cause harm to a target (hazard identification) with an understanding of the likelihood and extent of that harm being realized (fate and exposure). The elements in this kind of risk assessment are illustrated in Figure 1. The goal of risk assessment in this context is to determine those situations in which the likely exposure concentration overlaps with the concentrations likely to cause biological effects.

Clearly, the most important requirement for a risk assessment is knowing what it is that we want to protect and hence calculate a risk for, i.e., that we have a clearly defined target and clearly defined features of the target that we want to keep in some preferred state (Calow 1994). Harm is defined in terms of a shift away from the preferred state. For humans, the preferred state is straightforwardly quantified in terms of morbidity and mortality.

The situation is much less straightforward for ecological systems because of the amount of uncertainty associated with the selection of preferred states. In predicting the nature and extent of harm to ecosystems, uncertainties arise from errors, ignorance, and the stochastic nature of natural systems. Risk assessments attempt to quantify these uncertainties, either from first principles or from observation, and package them into probability statements of effect. Commonly a few, or possibly none, of the uncertainty elements can be specified, and they remain more or less hidden in the risk assessment. Consequently, risk assessments are often expressed in terms of risk quotients. These give only general indications of the extent to which ecological harm is likely to occur as most of the uncertainty remains concealed.

Difficulties of Defining Targets for Ecological Systems

For individual organisms it is relatively straightforward to define optimum states. Organisms exist as recognizably organized and coherent systems, are persistent, and have specific properties and processes that contribute to this organization. Because individual organisms generally act as the units of natural selection and are composed of cooperating biochemical, physiological, and behavioral systems that have evolved homeostatic control, differences in fitness among organisms can be used as criteria for defining optimum states (Sibly and Calow 1986). The criteria used for assessing risks to individuals (e.g., humans) from commercial chemicals are survival (an important component of Darwinian fitness) and the properties and processes that contribute to it. Emphasis is thus appropriately placed on the effects of chemicals on individual performance or health. Identifying risk assessment criteria is less straightforward for ecological systems for they are less obviously organized and coherent, cannot generally be considered as units of selection, and cannot unambiguously be described by terms such as ''health'' (Forbes and Forbes 1994, Calow 1995). As Suter (1993) and others have pointed out, ecosystems do not necessarily have clear boundaries, they do not have consistent structures from one individual example to the next, they do not develop in a consistent and predictable manner, and they do not have mechanisms like the neural and hormonal systems of organisms to maintain homeostasis. In short, ecosystems are not superorganisms. Furthermore, the relationship between ecosystem processes and the organisms of which they are composed remains unclear, although several testable hypotheses have been proposed (Lawton 1994).

Despite the difficulties in identifying appropriate ecosystem targets, in practice ecological risk is often defined in terms of the probability of: (1) mortality/morbidity in a fraction of a population; (2) extinction of a species or fraction of a species; or (3) loss of a certain fraction of ecosystem process and/or ''service.'' There are two possible views on the extent to which these targets can be defined objectively: the ecosystem health and the ecosystem services paradigms. In the ecosystem health paradigm, ecological systems have a coherence and integrity that depend upon certain states. It is for ecology to define these states and for ecological risk assessment to be expressed in terms of them (Calow 1995, cf. Rapport 1989). In the ecosystem service paradigm, ecological systems do not have intrinsic coherence (Calow 1995) but what human society gets from them does depend on their structure and function (Ehrlich and Wilson 1991). The ecosystem health paradigm requires that ecology and ecologists play a dominant role in not only carrying out risk assessments but in defining the criteria by which risks are evaluated. The ecosystem service paradigm suggests that social needs and values are as important as scientific ones and so emphasizes the need for interaction between scientists and society at large in defining ecological risk criteria.

Whereas both of these positions may be valid in different circumstances, deciding which of them is more useful for any given risk assessment will depend, among other things, on the ecological level being addressed. Thus, if the requirement is to protect particular populations, the criterion of persistence is important, and the critical variables and the values that they must take for long-term stability are defined by the theory of population dynamics. On the other hand, deciding which species should be protected and what levels of ecosystem processing are desirable may not be so decisively defined even if we understood enough about the structure and functioning of ecosystems and the relationship between the two. The reason is that, as discussed above, ecosystems do not operate as unitary wholes but rather as dynamic collections of species populations without goal states, except insofar as they are defined in terms of our human needs and desires.

Ecological Risk Assessment Is Pragmatic

There are two major areas of ecological uncertainty in the practice of risk assessment as presently conducted. The first is the uncertainty in predicting effects on organisms in field situations from their responses in controlled laboratory test systems. The second is the uncertainty about the roles of different species in ecosystems and the point at which damage to individual species or populations can be considered as damage to the community or ecosystem. Given targets, a risk assessment can be carried out objectively on the basis of scientifically defined criteria and procedures. If we know what population, species, combination of species, or ecosystem process we want to protect, then in principle we can use the scientific method to define which variables are important and within which limits they should be maintained. However, uncertainties arise out of our rudimentary understanding of ecological structures and processes and the extent to which appropriate states can, and indeed should, be defined in ecological terms.

Accordingly, the current approach to ecological risk assessment is to define circumstances likely to be generally protective for an ecosystem based on generalized ecological responses such as survivorship and fecundity in representative systems. The most common approach involves applying arbitrary uncertainty factors to the lowest observed effect concentrations [to calculate predicted no-effect concentrations (PNECs)] and using worst-case assumptions to estimate predicted environmental concentrations (PECs). A risk assessment is then carried out by dividing PEC by PNEC. A ratio of less than 1 does not give a precise probability of effect, only an indication that the likelihood of effect is very low. The approach, therefore, masks some of the uncertainty.

Another approach for extrapolating effects of chemicals from laboratory test systems to field situations is to fit toxicity data for a few (e.g., 3–11) laboratory test species to an assumed distribution function (e.g., lognormal, log-logistic, or log-triangular) and use the resulting curve to estimate the chemical concentration at which most (usually 95%) of the species in an ecosystem will be protected (Stephan and others 1985, Aldenberg and Slob 1991, Wagner and Loekke 1991). In other words, it provides the basis of a probabilistic risk statement and gives the impression of uncovering some of the uncertainty. However, like the quotient approach, the distribution-based extrapolation models involve a number of, as yet, untested assumptions such as that the sensitivities of laboratory test species provide an unbiased measure of the sensitivity distribution of species in natural communities, that species interactions can be ignored, and that protecting species composition protects ecosystem processes. Comparison of the predictions of the distribution-based extrapolation models with those derived from employing arbitrary uncertainty factors indicates that the former do not appear to result in significantly improved risk assessments (Forbes and Forbes 1994).

Avoiding False Negatives as Well as False Positives

The design and analysis of scientific experiments has traditionally focused on minimizing the incidence of false positives (i.e., of concluding that there is an effect when, in fact, there is none; in statistical terminology, of making a type I error). Thus significance criteria are typically set very low and a relatively large effect is required before it can be detected statistically. However, to maximize the probability of protecting the environment, it is more appropriate to guard against false negatives (i.e., concluding that there is no effect when, in fact, there is; making a type II error). Experimental designs and statistical analyses need to be adjusted accordingly when minimizing the probabilities of false negatives (Forbes and Forbes 1994). An extreme version of this strategy suggests that in environmental protection decisions the precautionary principle should replace risk assessment altogether (Wynne and Mayer 1993). This is both unrealistic and unnecessary. Precaution can be used in the application of risk assessment, for example, in establishing levels of statistical significance to take account of type II errors. Improving the statistical power of test designs to detect existing effects so that both type I and type II error rates are minimized can greatly strengthen the risk assessment process (Cranor 1993).

The Present System of Ecological Risk Assessment Is Not Satisfactory

Perhaps the biggest weakness, then, in the present practice of risk assessment is in defining the critical questions that need to be addressed. Part of this is a challenge for science to define natural systems and their natural states, but part is a more general challenge of defining what it is about these natural systems that we value. We need more explicit interaction between scientists and society to clarify these questions (Calow 1997). Once the questions are refined, scientists ought to be able to develop risk assessment procedures that are both rigorous and transparent. However, this will not be achieved by measuring as many variables in as many ecosystems as we can, but rather by defining clear hypotheses that can be tested rigorously in well-designed research programs. Although ecosystems in their entirety may be unique and hence unrepeatable in space and time, many of their component parts can be replicated and can, therefore, lend themselves to experimentation and statistical analysis. Given our present lack of knowledge, it would be wise to develop flexible risk assessment approaches that are responsive to new information. As we learn more about ecosystems and about what we want and/or need to protect, both scientific objectivity and informed value judgements have key roles to play in improving the practice of ecological risk assessment.

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Ecological Risk Assessment: Use, Abuse, and Alternatives

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Debates over the role of ecological risk assessment should start with agreement on a definition. Much of the confusion and divisiveness over risk assessment applied to ecological problems is caused by using the same terms but attributing different meanings to them. Indeed, in the classical applications of risk analysis (automobile, life, and health insurance; industrial failures; natural disasters; accident prevention; etc.), the definition, if not the practice, of risk assessment is different from that typically used in ecological risk assessment. The concept of ecological risk assessment I refer to here is best defined along the lines of ''. . . a way of examining risks so that they may be better avoided, reduced, or otherwise managed'' (Wilson and Crouch 1987); ''. . . a process to evaluate the likelihood of undesirable effects on ecological receptors from exposure to one or more stressors . . . '' (Regens 1995); and ''. . . a series of questions directed to the available data to analyze the expected risk'' (Patton 1995). There are many other risk assessment concepts, but these are beyond the discussion here: human health risk assessment, comparative risk assessment, engineering risk assessment, environmental risk assessment, risk communication, risk regulation, risk reduction, risk allocation or justice issues, and a suite of decision making paradigms.

Opinions on the use of ecological risk assessment in public policy analysis are diverse; they range from positive: ''. . . scientifically credible evaluation of the ecological effects of human activities'' (Suter 1993) to sceptical: ''. . . one more hurdle on the road to a permit'' (Webster and Connett 1990) to dismissive: ''. . . risk assessment is a sham . . .'' (Merrell 1995). The middle ground is populated by a disjointed array of

KEY WORDS: Ecological risk assessment; Risk decision making; Risk management; Ecological consequence assessment

[1]The views expressed here do not necessarily reflect those of the US Environmental Protection Agency or any other organization.

opinions because the debate over the proper role of ecological risk assessment defies the simplistic categorization of right versus left, conservative versus liberal, technocratic versus democratic, and green versus balanced use. Neither the debate nor the tool is new, but the intensity of the debate has increased as ecological risk assessment has become the policy tool of choice in some organizations (Lipton and others 1993, Lackey 1994, 1995, Regens 1995).

Some critics contend that risk assessment is ''. . . deeply flawed and subject to abuse'' (Montague 1995). Its use to help resolve public policy on human health issues is equivalent to ''premeditated murder'' (Merrell 1995). Some people will die or suffer disease by a policy decision when society makes a decision as to how many deaths will be tolerated for the benefits obtained. When used in making policy on ecological issues, the users of risk assessment have accepted a form of ecological triage, administratively deciding which individuals, populations, or species will live and which will die (Montague 1995).

Another type of criticism is the contention that ecological risk assessment as currently practiced is nothing more than ''the paradigm of human health risk assessment, laying on an underlying, unsophisticated, ecological veneer'' (Karr 1995). While not morally repugnant to such critics, many current applications of ecological risk assessment are inappropriate. Further, such a position questions the assertion that ecological ''health'' is analogous to human ''health'' and, thus, that the approaches and tools of human health risk assessment can be easily adapted to ecological problems (Menzie 1995).

Ecological risk assessment is not without strong supporters (Suter 1993). Generally, supporters tend to come from regulatory agencies and much of the regulated community. Some governmental agencies are strongly supportive, to the point of implementing policies and guidelines (Patton 1995). Much of the scientific and engineering infrastructure has embraced the approach. ''How-to'' training courses and symposia are plentiful. Books and technical papers explain in detail the technical intricacies of conducting ecological risk assessments (Suter 1993, Molak 1996).

Other advocates of ecological risk assessment, although far from effusive, acknowledge a useful role: ''Risk assessment is a very flawed tool, but, given the current process of policy formulation, it has a legitimate role to play'' (Funke 1995). In an ideal application, ecological risk assessment ''. . . should be a purely technical analysis driven by scientifically acquired data, and free from social bias'' (Fairbrother and others 1995).

What is the appropriate use of ecological risk assessment? When is its use inappropriate? How is it misused? What are the alternatives? Is it underused, and would its increased use bring rationality to public policy? I will argue here that ecological risk assessment: (1) has a legitimate, appropriate, but limited role in science, policy analysis, and policy implementation; (2) is often misused, and in some circumstances abused, both naively or intentionally; and (3) is not the only approach and others should be seriously evaluated.

Appropriate Use

Risk assessment has been used effectively in many fields as an aid in decision making. It is used to estimate the likelihood of an event (i.e., automobile fatality, flood, nuclear accident, etc.), clearly recognized as adverse. Its typical use in decision making with regard to ecological issues is similar: estimating the likelihood of a certain, defined event occurring (e.g., what are likely mortality consequences to biota of the use of a particular chemical?). The key requirement is that the consequence be adverse by definition, which enables the analyst to conduct the risk assessment (Bartell and others 1992, Lackey 1994, 1996a). In classical risk assessment the adverse consequence is easy to identify: a nuclear accident is universally accepted as adverse, as is an automobile crash, a skiing accident, a heart attack, or an airplane crash. The analog in ecological risk assessment is less clear.

To be technically tractable and credible, the risk problem must be defined in fairly narrow terms. Even when defined in fairly narrow terms, the analysis may be technically complex and require sophisticated scientific information. Often the narrowing results from legislative policy mandate [e.g., Comprehensive Environmental Response, Compensation, and Liability Act and its implementation (Lipton and others 1993, Friant and others 1995)]. The risk problem then becomes relatively simple analytically [e.g., one or a few chemicals are the stressor causing effects on a few biological components; the effects, if present, are adverse by definition (Regens 1995)]. Simplification, of course, begs the question of whether analysis leads to good policy options, but it does give the analyst a toe hold on what is desired or adverse (Friant and others 1995). Another way to state this perspective is that risk assessments assume a definition of health conditions. (Funke 1995).

Although beyond the scope of the debate here, an obvious potential role of risk assessment is to help allocate scarce resources. Risks need to be managed in our personal lives, companies, and government. How does one compare risks? Potentially, risk assessment offers an approach for comparing, rather than measuring, individual risks. Such an approach has been used by the EPA Science Advisory Board (US EPA 1990). The four ecological problems with highest risk were habitat alteration, decrease in biological diversity, stratospheric ozone depletion, and global climate change. Risks such as herbicides, pesticides, toxic chemicals, and acid deposition were medium-risk problems. Oil spills, groundwater pollution, radionuclides, acid runoff, and thermal pollution were relatively low-risk problems. An obvious use of risk assessment would be as one tool to help allocate research and regulatory efforts from lower to higher risk problems. Risk, of course, is only one factor in allocating resources, so ecological risk assessment should be only one element in the decision-making process.

Whether ecological risk assessment is used to address relatively narrow, technical questions [e.g., toxicological effects of a chemical on a particular biotic component (Friant and others 1995)] or to allocate scarce government resources (i.e., comparative risk assessment), it is critical to recognize that risk assessment is merely a tool in the decision-making process. At best, and if used properly, it is a tool that can assist in presenting the likely consequences of various decision alternatives (Woodhouse 1995).

Abuse

Concerns about abuse in ecological risk assessment often revolve around the contention that the tool can be used to support a predetermined policy position (Merrell 1995). The metaphor often used to illustrate this concern is that of the tortured prisoner. A tortured prisoner will confess to any crime; the confessions are only limited by the creativity and persistence of the prison guards. The allegation about risk assessment and its practitioners is: given enough creativity, virtually any policy position can be supported by risk assessment. The most common allegation is that the policy questions are formulated in a way that will produce virtually any result and that the result has the aura of scientific acceptability (Montague 1995). Those who know the most about how to manipulate the procedures control the discourse, the questions asked, and how they are answered (Funke 1995, O'Brien 1995).

Another potential abuse is that technocrats and politicians will define risk problems in ways that can be solved technically but have little real relevance to the public policy issue. The metaphor often used is that of a risk assessor looking for his lost keys under the street lamp. Although the keys were most likely lost far from the street light, the risk assessor laments that he has little chance of finding the keys in the dark so why waste time looking there. Although this makes a humorous story, ecology is complex and our understanding is limited. There is a strong tendency to define problems in ways that we can handle scientifically, even though the formulation may be policy irrelevant (O'Brien 1995).

A potential abuse of ecological risk assessment is to apply the same analytical tool to every problem: if your only tool is a hammer, every problem must be a nail. If every ecological policy problem is viewed from a risk perspective, then it is not surprising that technocrats will try to force a fit. The useful role of ecological risk assessment is to help solve fairly narrow, well-defined technical questions, not to answer larger, more complex public policy questions.

One of the most serious types of misuse by technocrats is to substitute their values and priorities for those of the public or their elected representatives (Webster and Connett 1990, Menzie 1995). In philosophical terms, this is illustrated by shifting the scientific ''is'' to the political ''ought.'' In science there are no ''oughts.'' Animals, plants, and ecosystems are neither good nor bad, better or worse, or healthy or sick unless a value criterion is applied. ''Risk'' has no definition in ecology unless someone defines what is adverse (or healthy). Whether the introduction of wheat, horses, or zebra mussels to North America is good or bad depends on the value criteria applied, not the personal opinions of scientists and risk assessors.

Alternatives

One obvious alternative to ecological risk assessment is a modification to drop the idea of risk. Some have referred to this as benefits analysis, where the desired benefits are selected by the political process (Principe 1995). Others refer to consequence analysis, which simply assesses ecological consequences without defining good or bad, adverse, ecological health, or risk (Lackey 1996b). Eliminating the concept of risk in ecological policy problems reduces the number of value-based choices scientists and assessors must make; thus more choices are reserved for democratic processes through accountable decision makers. In some cases it may be that analysts are actually conducting something closer to ecological consequence analysis than ecological risk analysis.

Another, related approach is ''ecological alternatives assessment'' (O'Brien 1995, Pagel 1995). Alternatives assessment steps back even further from risk assessment and focuses on the questions being asked. Critical public policy questions would not be buried in technical analysis. As with other analytical tools, whoever controls the questions asked in risk assessment constrains the policy options under consideration (Funke 1995).

The old concept of benefit–cost analysis, which suffered, justifiably, many of the same criticisms now leveled against ecological risk assessment (Schrecker 1991), is potentially a viable alternative to ecological risk assessment. Benefit–cost analysis is much closer to a decision-making framework than is risk assessment. Although, it is an illusion that public policy questions can be reduced to a single metric of value (money), the basic concept of trade-offs has appeal. Although fraught with analytical difficulty, benefit–cost analysis is closer to the kind of information decision makers actually need from technocrats, but it is subject to the same distortion by improper use of personal values as is ecological risk assessment.

Conclusion

Over the past few decades there has been a diverse array of tools and paradigms offered as the solution to ecological policy and decision-making problems. Is ecological risk assessment just another tool that will follow the fate of computer-based modeling, geographic information analysis, management by objectives, total quality management, management reengineering, Delphi, and organizational reinvention? Each burst on the scene and was advocated by some with near religious zeal, only to fall from favor in lieu of and be replaced by another, newer tool. Each did eventually assume a useful role as a tool appropriate for some problems under some circumstances but not as an overall panacea (Lackey 1996a,b).

Ecological risk assessment is a tool that might help resolve some kinds of public policy questions, although policy questions must be fairly narrowly defined and explicitly described to be analytically tractable. This does not mean that they are simple problems, merely analytically tractable. The most common use of ecological risk assessment will continue to be with questions where the definition of ecological adversity is provided by legislation, policy, or arbitrarily assumed by the analyst. Its potential for addressing more complex, and relevant, ecological policy questions has yet to be fully evaluated.

A serious allegation is that ecological risk assessment (along with many other technocratic tools) provides a route to subvert the democratic process (e.g., how does the public decide which ecological changes are adverse and which are beneficial?). The very nature of the process requires the analyst to make many value-based decisions, hence the charge that the process is elitist by its very nature (O'Brien 1995). In fact, the decision to use risk assessment is a heavily value-laden decision. Technical expertise cannot substitute for values and priorities in ecological risk assessment; these are issues of policy, not science.

Ecological systems are complicated and the ecological consequences of decisions are often difficult for the ecologist to grasp, much less those without this expertise. Furthermore, analysts and scientists involved in ecological risk assessment are using a tool that most of the public does not comprehend; thus the danger of misuse through miscommunication, unintentional or otherwise, is great. There is no scientific or ecological imperative in risk assessment; it is only a tool to help those charged with making decisions evaluate options.

Those of us involved in ecological research and assessment should remember that risk assessment is the latest of a large number of tools and approaches that have played on the scientific and management stage with great fanfare. These tools and approaches have each evolved to be useful in certain, clearly defined circumstances. Ecological risk assessment is undergoing a similar transformation.

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Ecological Risk Assessment: An Input for Decision-Making

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In the European Union (EU), ecological risk assessment (ERA) is a well-developed tool used primarily as an input into the decision-making process governing chemical regulation. It is entrenched in legislation pertaining to new and existing chemicals, including pesticides. It is applied in waste management and water quality control decisions. In short, ERA is an important element in the environmental decision-making processes. For critical environmental decisions, however, the need to compare risks and benefits requires ERA be only one of many elements considered in the decision-making process. Legislative, political, and social factors; research uncertainties, and the technical feasibility of options for risk reduction (Carnegie Commission 1993) must also be considered before a final decision is reached. Whether ecological risks will ultimately gain priority over other aspects of the decision-making process cannot be said at this point. Nevertheless, it is clear that the most important development in environmental decision making in the last decade has been the inclusion of ERA by regulatory managers in decision making.

KEY WORDS: Ecological risk assessment; Generic ERA; EUSES model

ERA: A Drama-Driven Emergence

Although regulatory and scientific interests have played important roles in the development of ERA, neither drove its emergence. Instead, accidents and growing public awareness of environmental problems provided the impetus to both science and regulation in the development of ERA. Well-known examples from Europe include: sharp declines in bird populations caused by persistent organic pollutants (including pesticides), surface waters covered with foam (nondegradable detergents), calamities in Seveso, Italy (dioxins), and massive fish kills in the river Rhine (endosulfan and organophosphate pesticides). These events triggered the development of legislation on pesticides, end-of-pipe emission standards, requirements for the rapid primary degradation of detergents, and international environmental treaties for the Rhine and North Sea, respectively.

ERA was thus born in an era of rapid industrialization, where the effects of pollution could not remain unnoticed. The public could see, smell, taste, hear, and sometimes feel the pollution. The resulting public and political awareness of environmental degradation and its possible consequences created the need for legislation and international cooperation out of which ERA grew. ERA was, accordingly, a drama-driven process that evolved as a reactive solution to obvious pollution problems. Now, however, ERA is used in a proactive manner to prevent the unacceptable ecological effects

Table 1. Changing perceptions of health and environmental problems and their solution

1970	1995
Perceptions	
Sectoral (air, surface, water) problems paramount	Multiple media problems in soil, sediments and ground water
Local pollution issues	Diffuse pollution issues
Limited economic damage caused by pollution	Economic losses from pollution known to be large
Limited environmental responsibility on the part of industry	Environmental responsibility a leading industrial principle
Solutions	
Protection of human health and well-being	Protection of ecosystem health, human health, economic well-being
Use of end-of-pipe technologies	Use of integrated approaches to pollution prevention, remediation
Pollution prevention a threat to economic welfare	Pollution prevention a premise and opportunity for economic growth
Use of legislation and regulation to control pollution	Use of fiscal incentives and negotiated agreements
ERA framework absent	ERA part of legislation

associated with the production, use, and disposal of chemicals.

Further Development of ERA

The occurrence of accidents and incidents is unpredictable. That ERA developed in response to the societal and political needs triggered by such events is natural. In the 1960s and 1970s, industry's response to requests to reduce pollution stress was defensive. The need for environmental legislation was often denied. Questions were raised about the need to protect species and ecosystems, and cleaner production was portrayed as a threat to economic growth.

Viewpoints, however, have changed dramatically. Table 1 details some of the perceptual changes that have occurred over the last 25 years. Industry has become more proactive. Initiatives are now taken to meet perceived consumer environmental needs. Heightened environmental consciousness suggests the inclusion of pollution prevention measures in process optimization helps, rather than hinders, corporate profitability. As a result, ERA and LCA (life-cycle assessment) have become important instruments in the development and evaluation of chemical products and processes.

In part the changes in societal views are reflected in the numerous developments with respect to ERA that have occurred within the OECD and the EU. In the EU, legislative instruments for new chemicals (the seventh amendment to Directive 67/548/EEC), existing chemicals (EC Council Regulation 793/93), plant protection products, i.e., agricultural pesticides (914/414/EEC) and biocides (in preparation), have been developed [see Vermeire and Van Der Zandt (1995) for a description of these frameworks]. In Europe ERA was, and is, a pragmatic response to the need to mitigate and control the most obvious impacts of pollution. It is important to realize that ERA procedures have evolved from long discussions between the chemical industry, member states, and the European Commission. ERA has evolved from communication and perhaps is communication.

ERA and Science Policy Decisions

Calow (1994) stated that we still do not know enough about ecological systems to be able to identify what it is we want to protect about them and, hence, what we should be measuring. While correct from a scientific viewpoint, from a risk management point of view the statement is naive. It is not ecotoxicologists who should be determining the targets and extent of protection. Both are matters for policy. Scientists have played, and should continue to play, a crucial role in the development and improvement of ERA techniques. However, as the developments of the last decades have shown, it is societal views that provide the crucial force behind the development of environmental protection measures, not scientific investigation. Further research directed toward elucidating what needs to be protected is not the issue, especially when world-wide biodiversity is expected to decrease by approximately 25% in the next few decades (McNeely 1990). What is important is that ERA is a risk management tool. Our efforts should be concentrated on making it acceptable to those who apply it now, rather than deferring to the need for yet more knowledge. Making ERA acceptable to an international community of academia, industry, and regulatory bodies will require a combination of both political and science policy decisions (Milloy and others 1994). For example:

1. Determination of appropriate ERA protocols requires scientific input. Ultimately, however, the selection of methodologies will involve a political decision on the acceptable trade-off between scientific precision, industry cost, and realistic time frames.

2. Although measurement endpoints require scientific input, decisions about valued ecosystem components and assessment endpoints depend critically on risk managers, politicians, and society. In the end

decisions regarding assessment endpoints define the measurement endpoints employed in an ERA.

3. Although various methods for exposure and effects assessments exist, all invariably contain explicit and implicit science-based policy choices pertaining to technique and interpretation (Commission of the European Communities 1996). In the end the nature of the ERA methodology relies on decisions taken by risk managers. Risk assessors, therefore, have an important role in communicating the uncertainties inherent in their own policy-based methodology choices to risk managers.

4. While the outcome of an ERA may be quantified, the categorization of the outcome as a low, medium, or high risk is ultimately a matter for societal debate. This is a dynamic process and views may change over time (see Table 1).

Generic Nature of ERA in the EU

The cumulative effect of social and political choice on ERA is not necessarily detrimental to its practice. A glance at the EU guidance documents for risk assessment (Commission of the European Communities 1996) indicates it is comprised of the following elements: a standardized minimum data set (the so-called base set) that contains both short-term toxicity and ecotoxicity data, basic physicochemical data, use information, and import / production data. A standardized realistic worst-case emission scenario is used by applying emission scenarios for use categories based on use-specific emission patterns and emission factors. Predicted environmental concentrations (PECs) are determined for local and regional situations using multimedia exposure models. These models operate by simplifying environmental media—air, water, soil, sediment, and biota—into homogeneous compartments and then tracking movement, degradation, and accumulation of chemicals from compartment to compartment. Geographic, hydrological, and climatic variability are excluded from the models as standardized environments are used for all exposure calculations. All factors and methodologies are clearly described. Estimation methodologies and a critical assessment of their limitations are given for physicochemical parameters, (bio)degradation, sorption, and (eco)toxicity data. The model also contains modules for characterizing the risks of occupational, consumption, and indirect environmental (via drinking water, fish, plants, milk, and meat) exposure.

The shortcomings of this generic approach for ERA are obvious. It has almost nothing to do with ecology. Numerous assumptions and arbitrary decisions are made to arrive at a risk characterization for both humans and ecosystems. These include assumptions concerning equilibrium partitioning, instantaneous mixing in the compartments of the exposure model, simplistic representations of aquatic and terrestrial ecosystems, and consideration of only a few biomagnification routes. Despite the uncertainties introduced with these assumptions, the greatest uncertainties are probably not related to what we do not know about ecology, but to what we do not know about emission and fate processes. For example, little is known about actual chemical use patterns or their compartmentalization or speciation after release. Product registers can only partly overcome this problem. For all practical purposes, the enormous variations in climatic (e.g., temperature and precipitation), hydrologic, and geographic (e.g., soil type) conditions and techniques used to reduce emissions necessitate the use of average values in the completion of ERAs. Under these conditions ERA methods can do little but focus on the generic assessment of risk. While such assessments may not be suited to site-specific problems, the process is more easily adapted to the environmental, scientific, and political conditions found in other regions or nations. Site-specific assessments require the development of more sophisticated models, increased data detail, and greater costs. Their results lack generality and cannot easily be adapted to conditions found outside the bounds of the problem and site for which they were developed.

As Aristotle pointed out, "It is the mark of an instructed mind to rest easy with the degree of precision which the nature of the subject permits and not to seek an exactness where only an approximation of the truth is possible." As long as ERA is carried out in a standardized manner, it is possible to compare the generic risks of many chemicals and their substitutes. With generic ERA it is also possible to predict the environmental impact of proposed risk-reduction measures. Even in situations where risks cannot be precisely determined, because of the inability to include all site-specific factors, generic ERA approaches allow gross comparative risks to be quantified. In doing so, generic approaches make a valuable and pragmatic contribution to aiding risk managers and society in controlling the impacts of chemical use.

A European uniform system for the evaluation of substances (EUSES model) has been developed for the evaluation of new and existing chemicals. EUSES is a simple, straightforward, and transparent set of risk assessment methodologies that recognizes the availability of limited data sets, the accuracy and variability of the data, and the uncertainties associated with many of the methodological assumptions. The advantages of a standardized approach for risk assessment, both ecological and human, are threefold:

1. Risk assessments are accompanied by complete transparency of methods, assumptions and uncertainties. Assessments become predictable and their acceptance will increase, leading to increased cooperation and sharing of the burden.

2. Conditions are created for regular methodological improvements and adaptations on the basis of both scientific and legislative developments.

3. Time and money can be more effectively spent on priority chemicals for which in-depth ERA and expert judgement are required.

ERA and Capacity Building

ERA is becoming an increasingly important issue, particularly in view of the rapid industrialization of many national economies. Rapid growth is often accompanied by increasing levels of pollution. Without proper regulation of production and consumption patterns, rapid growth is likely to have large environmental impacts. Lessons from the ''do-nothing'' decades of the past have taught developed countries that pollution prevention is cheaper than cleanup. The high costs involved in cleanup operations (e.g., polluted soils, aquatic sediments, or dump sites) provide painful reminders of the past when dilution, adsorption, or leaching were used as an excuse for not taking preventive measures. The ''out-of-sight, out-of-mind'' policy led to severe environmental deterioration. Despite available financial resources, restoration is out of the question in many instances. Strengthening the capabilities and capacities of less-developed nations for risk assessment is, therefore, a necessary prerequisite to their avoiding a similar fate. To teach them not do to what we have done is probably our greatest challenge in the area of chemicals control. For example, Agenda 21 from the 1992 United Nations Conference on Environment and Development (UNCED) places great emphasis on the environmentally sound management of chemicals (United Nations 1992). ERA promises to allow us to put action behind those words. However, to properly accomplish the task, risk assessment must continue to evolve. In that regard, among the important developments for the future of ERA will be the following:

1. Periodic updating of guidance documents due to the rapid development of risk assessment theory and methods. It is essential that this proceeds as a result of adequate communication between industry, national governments, and international bodies, such as the European Commission. Significant contributions from the scientific community in this process will remain essential.

2. Priority should be placed on refining the ERA modules or data and/or estimates with the largest associated uncertainties. This assumes that uncertainty can be reduced through additional research.

3. Currently only a few endpoints and exposure routes are considered within the context of ERA. Further development, refinements and validation of models and modules for assessing additional endpoints and exposure routes is accordingly necessary.

4. The emission and exposure of chemicals throughout their life cycles needs further attention. Industry should play an important role here, as their responsibility should not stop once a chemical is sold or exported.

5. Cost-effective approaches to expediting the risk assessment process are necessary as many existing chemicals have yet to be assessed for their ecological risks. The clustering of chemicals on the basis of modes of toxic action, use pattern, etc., may provide promising avenues of investigation. Furthermore, the development of structure–activity relationships (SARs) and quantitative structure–activity relationships (QSARs) to overcome data gap problems remains essential.

6. To harmonize the generic risk assessment of chemicals, international agreement must be reached on base-set requirements for new chemicals, existing chemicals, pesticides, and biocides. The worldwide acceptance of the OECD minimum premarketing data set for new chemicals is an essential step.

Despite the need for change, risk assessment is clearly a valuable methodology. It delivers the tools necessary to describe, priorize, and pragmatically address the complicated environmental issues that lie ahead. With appropriate international coordination, generic approaches to risk assessment, transferable to the rapidly developing Third World nations, can help avoid the concomitant increases in pollution stress invariably associated with economic activity.

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Truth and Validation in Ecological Risk Assessment

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Extensive use has been made of the term ''ecological risk assessment'' in recent years. It has a comforting kind of ring to it and permits politicians and environmental managers to persuade a sceptical and often suspicious public that some major project or another has been scientifically assessed and judged to have minimal, little, or no risk. It is rare for an ecological risk assessment to be undertaken to disprove the null hypothesis, since neither industry nor government generally wants to prove that significant risks exist. The norm for ecological risk assessments is rather to attempt to prove the null hypothesis, that is, to prove no risk. Risk assessments are thus fraught with type II errors (accepting as true a false null hypothesis) while spending the majority of their efforts in minimizing type I errors (rejecting a true null hypothesis). This problem is a very serious statistical one by itself, even when only working with single-species toxicity testing (Holdway 1992), much less when involving the enormous difficulties of measuring and predicting the behavior of complex ecosystems.

In the introductory paper for this debate, the point is made that a central tenet of ecological risk assessment is probability, defined as the portion of times a given event is observed in a series of identical, repeatable experiments (Power and Adams 1997). Since major projects that require ecological risk assessments are rarely if ever completely replicated elsewhere, and since individual ecosystems are generally unique, this aspect of repeatability is obviously going to be compromised. However, if empirical evidence is gathered in sufficient quantity to address appropriately constructed critical questions, then it should be possible to construct a body of information that would support or disprove any significant predictions made by ecological risk assessments. Given that we have had qualitative environmental impact statements for some 30 years or more, semiquantitative ecological risk assessments for roughly 10–15 years, and involved some thousands of projects worldwide, there should be an enormous literature containing the follow-up validation and monitoring data for each of these assessments, providing a large empirical data set for assessing the strengths and failings of each type of impact / hazard / risk assessment. This should be the case, but few if any validation follow-up studies have been conducted.

KEY WORDS: Ecological risk assessment; Validation; Hazard assessments; Quantitative modeling

The Validation Requirement

The vast majority of projects have completed the impact / hazard / risk assessment as a stand-alone effort for project approval, usually without an ongoing pre- or postoperational monitoring program. When monitoring has been required, there has generally been no requirement for monitoring information to be correlated with preproject predictions. There is thus no significant body of information available to determine the accuracy of impact predictions, irrespective of whether or not the predictions were qualitative, semiquantitative, or quantitative. Were the required environmental regulations sufficient to prevent significant measurable damage to the environmental attributes of value in question? If not, how substantial was the actual measured damage and what factors were the likely causes of the observed effects? If wrong, why were the predictions wrong? Where is the literature providing the data to permit empirical predictive modeling of ecosystem risks? Only when a detailed and appropriately planned validation program that addresses the critical predictions for a large number of major ecological risk assessments is undertaken will we begin to get an idea of how well our pseudoquantitative (many would argue pseudoscientific) ecological risk assessments are actually doing in predicting the occurrence or absence of impacts.

One major weakness that exists in any sort of ecological risk assessment is the lack of prediction validation. Another weakness lies in the simplistic assumptions and gross oversimplifications required to create the present generation of ecological risk assessment models. These assumptions generally include some or all of: (1) single species acute toxicity tests that are used to represent population impacts; (2) prediction of community effects using data from experiments utilizing inappropriate time and spatial scales; (3) use of single-substance toxicity tests to address complex mixture toxicity; (4) assumptions of simple additive effects in complex mixtures of toxicants; (5) assumptions regarding the importance of indirect effects and abiotic modifying factors; and (6) lack of appropriate data to permit the separation of altered habitat from altered chemical status, just to name a few.

Quantitative Modeling Weaknesses

What is even more insidious is the move towards models that are extremely user friendly and that do not explicitly reveal the major assumptions being made unless one takes the time and effort to read the appendices [e.g., the Dutch soil ecological risk assessment model (Denneman and van den Berg 1993)]. Here we have the problem of a semiquantitative (at best) model, full of critical and often highly simplistic assumptions, being disguised to appear far more authoritative and accurate (e.g., two- to three-place decimal threshold values) than is the case in reality. The old adage ''garbage in–garbage out'' is as true today as it was when the expression was coined. The only difference is that today's garbage often appears more palatable because of attractive packaging.

I believe the move towards quantitative ecological risk assessments stems from the desire of industry and government to provide a legal and management framework that will produce unambiguous, legally defensible assessments divorced from subjective scientific judgements. This, of course, is based on the erroneous belief that good science is always nonjudgemental and quantitative in nature. Nothing could be further from the truth. Science and scientists are products of society. The inherent biases and beliefs of the time will permeate and direct scientific endeavor and output. The self-correcting nature of science means, however, that such biases and any mistaken directions or hypotheses will not stand the test of time. Eventually they will be replaced by new ''politically correct'' hypotheses. Thus the movement towards quantitative ecological risk assessment does not mean that previous approaches are necessarily wrong, only that they have lost favor with the powers that direct funding in these areas, i.e., governments and industry. They are no longer accepted as conventional wisdom.

The numbers produced by most quantitative ecological risk assessments are generally unvalidated and in many cases highly misleading. How can one put a probability of occurrence on nonreplicated and unique events for which one does not understand the complex causal mechanisms involved (e.g., possible indirect effects of a toxicant on population and community structure) or even the final endpoints or parameters that are important? Is a change of species within a given level of productivity important? Is it possible to realistically quantitate the ecological relevance of such a change? How does one interpret the ecological meaning of a multitude of such changes on multiple trophic levels within an ecosystem? Munkittrick and McCarty (1995) argue that the differences in spatial and time scales between population and community changes and single species effects make single-species toxicity test results of very doubtful value for predicting impacts at higher levels of biological organization, a view shared by others (Adams and others 1997, Depledge and Fossi 1994). Certainly, we can define specific arbitrary objectives to be adhered to (e.g., a ≤10% loss of species richness, ≤10% acute mortality, ≤20% decline in population, etc.), but we are still no closer to understanding what the generic meaning is (if any) of such changes to the function of ecosystems as a whole.

Truth in Hazard Assessments

Regulators and politicians want to simplify biological and ecological processes to single numbers for the sake of management. Such simplifications may be completely irrational and meaningless both ecologically and statistically. Nevertheless, they may be promoted by scientists as politically viable options. Are we not then simply producing politically correct science rather than ecologically relevant science? We should not encourage our regulators and politicians to believe that we know the answers to questions that have not even been appropriately conceived much less answered. Who can really tell what a 5% or 20% loss of one species means to the ultimate productivity and stability of an ecosystem? It may be irrelevant, but it might also be highly important. If a professional judgement is called for, I would rather that judgement be made by an experienced ecotoxicologist sufficiently convinced of his or her beliefs to openly author the opinion. The idea that some simplistic computer program can be run anonymously to produce a numerical result for regulatory purposes, without understanding model limitations and assumptions and without the personal credibility of a named professional being on the line, is very disturbing.

It is certainly possible to predict chemical transport and fate using reasonably validated models that provide for estimates of error (Suter 1995, Rand 1995). Biological exposure to chemicals can even, on occasion, be estimated using calibrated biomarkers (referred to as bioindicators by McCarty and Munkittrick 1996), although they do not generally represent very useful tools for risk assessment (Holdway 1996). However, it is not the environmental chemistry that provides the greatest challenge for ecological risk assessment. It is the ecological and biological aspects of ecological risk assessment that can not be easily modeled. Many of the new and generally highly simplistic computer models imply this is not the case. Who needs to know about energy flow, trophic status, habitat alteration, abiotic or biotic modifying factors, and all the unknown variables involved in understanding ecosystems. Simply enter your eight or ten literature LC_{50}s and watch the computer provide ''unambiguous environmental regulation'' by generating to three significant digits ''safe'' exposure concentrations. Yet we only know the names of 10% of the organisms present in some ecosystems and have little information on their relative abundance (e.g., the present situation for inshore Australian marine ecosystems).

Detailed ecological information, i.e., population and community level information, is generally difficult to obtain, can delay potential projects by months to years, and costs significantly more money while not necessarily providing unambiguous answers. This is not the type of information generally sought by either project proponents or regulators. Quantitative ecological risk assessment marks the beginning of a new era in environmental regulation: the ''ecotoxicologist on a disc'' era. Since the general move of ecological risk assessment in the future will be towards the use of more user-friendly, mathematically complex computer models, the average risk assessor will soon be little more than a computer keyboard operator / clerical administrator.

I do not believe we should excessively simplify ecological science in order to cater to the needs of regulators, lawyers, and politicians. The fact remains that few if any of our ecological risk assessment predictions are being validated today. Consequently, how can we have any statistical or ecological confidence in the predictions or the methods generating them? How is it possible for the probabilities to be accurate if we have no understanding of how often we have failed to determine impacts or have succeeded in predicting effects? Without a comprehensive retrospective investigation of the past predictions and ultimate outcomes within a variety of time scales, we are simply not able to provide meaningful probability-based quantitative ecological risk assessments.

Conclusions

What is the solution to ecological risk assessment? In my opinion, the best solution we can presently offer is to undertake semiquantitative hazard assessments that evaluate the potential of deleterious effects occurring in an ecosystem given the presence of defined toxic agents or pollutants. Such assessments require extensive use of expert judgement, often from a number of experts representing various environmental disciplines and will be open to alternate interpretation. The application of significant safety or uncertainty factors to all toxicity threshold numbers will be required both to protect the ecosystems being assessed from type II errors, resulting from our lack of understanding of indirect population and community effects and ecosystem dynamics, and to provide conservative overall margins of error. Furthermore, all assessments of significance should be followed up with appropriately designed environmental monitoring programs to test the truth of environmental risk (hazard) assessment predictions.

A concerted international effort needs to be made to collect and collate impact or risk assessments containing explicit predictions relating to significant projects that have proceeded and for which biological / ecological monitoring programs were put in place. These data need to be analyzed and evaluated to determine the types of predictions made and their relative accuracy. Only when a significant data base has been created can we hope to have biological and mathematical modelers attempt to estimate the occurrence probabilities of various ecological impact categories.

It is quite likely that some types of hazards are far more amenable to accurate prediction than others and that the approach eventually adopted by diligent environmental regulators will, of necessity, be site or project-type specific. These are no easy short cuts in ecological risk assessment, only simple questions requiring difficult and often complex answers. It is our responsibility to ensure that regulators and politicians understand both the complexity and uncertainty of any answers that are provided for the ecological risk questions they have asked. To do anything less is to greatly mislead the public and risk undermining the public's overall confidence in the use of science to address important questions.

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Controversies in Ecological Risk Assessment: Assessment Scientists Respond

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The following are responses by two scientists engaged in the practice of ecological risk assessment (ERA) to some recent criticisms of the field. In our opinion, many of the critics are setting up and knocking down straw men for purposes of advocacy. Some are attempting to hold ERA to standards of certainty that are impossible to meet, and others simply mistake the values of particular agencies and organizations that use ERA for an inherent feature of the practice. A complete rebuttal would require far more space than is allowed. We believe, however, that the following points are particularly important.

KEY WORDS: Ecological risk assessment; Probability; Values; Burden of proof; Benefits assessment; Alternatives; Risk management

False Dichotomies

Most of the critics formulate their argument in terms of a dichotomy, ERA versus something else. However, they do not agree on what the alternative is, and some do not even propose an alternative. We believe that a fundamental dichotomy underlying many of the criticisms is between those who would impose a burden of proof on ERA and those who estimate effects using the ERA paradigm.

Advocates of strict environmental regulation take the position that safety should be proven before actions are allowed. This position has been termed the ''precautionary principle'' (MacGarvin 1994). Critics who assume this position attack ERA because it makes judgements about effects of actions and their potential acceptability without sufficient information to prove safety. For example, Pagel, who takes as his slogan ''knowledgeable trespass or none at all,'' points out the infinite complexity of ecological systems, and invokes the chaos theory cliche of a flap of a butterfly's wing causing a storm to argue that ERA does not and can not demonstrate safety (Pagel 1995).

Opponents of strict regulation take the position that unacceptable injury should be proven before actions are restricted. This position is frequently described as ''good science'' because it demands the same high standard of proof for anthropogenic effects that are required for proving a hypothesis in pure science (Suter 1996). That is, it requires rejecting the hypothesis of no effect with 95% confidence.

ERA does not demand that all actions be proven harmless with high confidence, and it does not require that effects be demonstrated with 95% confidence. Rather it uses a variety of quantitative and logical techniques to analyze the evidence and reach a judgement based on the weight of evidence (Suter 1993, Suter and Loar 1992, US EPA 1992). The weight of evidence standard is unacceptable to those who require proof. For example, Cooper (1995) advocated good science and rejected the weight of evidence standard as being used by lawyers with no interest in the truth. Cooper misunderstands the legal system. It is judges and juries who weigh evidence and they do seek the truth.

We argue that the weight of evidence standard is, in most cases, the appropriate standard for risk assessors. A central tenet of risk assessment is that the assessor is a technical consultant to the risk manager. The risk manager is the individual responsible for making the decision, including deciding what degree of confidence is needed concerning safety. For a risk assessor to require either proof of safety or proof of harm would be to drastically bias the analysis. Such biases are appropriate only when mandated by law or regulation as in the US Federal Insecticide, Fungicide, and Rodenticide Act.

The Role of Values

A variety of criticisms of ERA relate to the role of values. The most easily dismissed criticisms are the calls for risk assessors to adopt a particular set of values advocated by the critic. Most risk assessors realize that if they adopt an advocacy position and design their assessments to support that position, they will lose their credibility. Assessors are advised by some critics to ''retain emotion'' and ''treat the earth as their child'' (O'Brien 1995), reject humanistic values (Pagel 1995), and take a consciously spiritual approach to their work (Hayakawa 1995). If they did so, they would open themselves to charges such as those of US Congressional Representative H. Chenoweth that environmental protection violates the antiestablishment clause of the US Constitution because it is based on a religion which places the interests of trees before humans (cited in *The Washington Post*, 5 February 1996, p. A19). Risk assessors are not elected or appointed, so their values have no particular standing in a democracy. Like any citizen they may vote, write letters, etc., but they may not use their positions as scientific experts to make public policy by biasing their analyses.

A more subtle argument involving values is that many of the decisions made by risk assessors are value-laden, so they are making unconscious value judgements and therefore they are functioning as risk managers (Crawford-Brown 1995). Specifically, Crawford-Brown (1995) argues that risk assessors should consider what should be valued and why we should value it. That is clearly a risk management decision, and in the conventional ERA paradigm it is described as such (US EPA 1992). The risk manager is included in the problem formulation process, the planning phase of the risk assessment, specifically so that value-laden decisions about how to perform the assessment are made by the individuals who have the authority to address them.

An even more subtle argument is that there is no clear distinction between facts and values, and therefore the division of risk assessment from risk management is artificial and untenable (Schrader-Frechette 1985, Schrader-Frechette and McCoy 1994). To those who make this philosophical argument, even decisions about model forms or experimental methods are value judgements. However, in practice these are a very different sort of value judgement than deciding whether to allow the northern spotted owl to go extinct in order to preserve the jobs of loggers. It is not necessary to distinguish value judgements from facts, or to keep scientists from making any value judgements. Rather, one must distinguish value judgements that the public would recognize as such, and would not want to leave to scientists, from those that a scientist can make with a clear conscience. The distinction is difficult in the abstract, but we have found it to be relatively simple in practice. For example, the choice of an area or transect method for vegetation surveys may be made on the basis of efficiency of effort. That choice is value laden in the sense that efficiency is a value not a fact. However, no remedial project manager or citizens advisory council wants the choice of sampling methods left to them so that they can choose on some basis other than efficiency. Rather, they want to decide whether vegetation will be assessed and what types of changes in vegetation are potentially significant.

Probability and Risk

The relationship between uncertainty, probability, and risk is another source of controversy. The editors of this forum present the argument that the scientific foundations of ERA and presumably all other risk assessments are weak because risk incorporates the concept of probability but does not define it on the basis of observed frequencies from ''identical repeatable experiments'' (Power and Adams 1997). This is an extremely narrow definition of probability that is not in concordance with most concepts of risk (Morgan and others 1985, Suter 1990). It ignores most of frequentist statistics and all of Bayesian statistics and other nonfrequentist methods of deriving probabilities. It is impossible or ethically unacceptable to base most risk assessments on the frequency of outcomes in identical repeated experiments (e.g., create identical waste sites or crash identical tankers). Therefore, if we take the arguments presented by Power and Adams (1997) to heart, we must either restrict ourselves to the few cases where we can subject replicates of all of the systems that are at risk to the agent of interest or ignore the uncertainties and pretend that we know the answers with certainty. We argue that risk assessors must acknowledge that, because hazards have uncertain consequences that must be estimated, they cannot limit themselves to a concept of probability that is irrelevant to the problem.

ERA versus Alternatives Assessment

The consideration of alternative options provides a basis for choosing the best action rather than determining whether the proposed action is acceptable (O'Brien 1995, Pagel 1995). However, Pagel (1995) and O'Brien (1995) are mistaken in suggesting that ERA is not or cannot be comparative. For example, ERA is commonly used as one of several means of comparing alternative remedial choices: which sites carry greater potential ecological risks, or which proposed remedial actions are associated with risks of greater geographic extent and duration than other scenarios, including the no-action case. ERA's estimates of effects on well-defined assessment endpoints are a much simpler basis for comparison than criteria that cross endpoint and scale (Suter and others 1995). In addition, both federal and state agencies in the United States are beginning to use comparative risk assessment methods to prioritize their environmental programs.

ERA Versus Benefits Assessment

Benefits assessment is advocated as preferable to risk assessment in ''large ecological units'' (Principe 1995) or in evaluations of ecological alternatives (O'Brien 1995). We agree that benefits should be considered prior to decision making, but not because of a limitation specific to ERA at large scales (see below). It is somewhat ironic to practitioners of retrospective (remedial) ERA that advocates for the environment promote benefits assessment, with roots in utilitarian cost–benefit analysis (Principe 1995). Historically, National Environmental Policy Act (NEPA)-driven environmental impact assessment, to which ERA owes a philosophical and methodological debt, arose because promoters of federal projects touted benefits but often overlooked environmental, health, or social risks. Advocates of projects seldom ignore benefits, including those that accrued to ecological systems. Finally, one of the major functions of retrospective ERA is to direct the remediation and restoration of damaged ecosystems, the very ecological relief that critics such as O'Brien (1995) seek.

ERA Versus Management of Hazards

An alternative approach to the risk paradigm for environmental problem solving is to shift the relative emphasis from assessment to management (Woodhouse 1995). We might call this the natural disaster paradigm, where predictions are perceived to have limited utility for reducing adverse consequences. With a risk management emphasis, experts can deal with environmental uncertainties through ''intelligent trial and error'' (Woodhouse 1995). This choice is dominant when the political and economic stakes are high (e.g., containment for biotechnology or double-hulled tankers for petroleum transport) and when the cost of ERA is high because the knowledge base does not permit much extrapolation from case to case. In this management-heavy scenario, risk assessors are relegated to the postdecision position of characterizing undesirable side effects and estimating effectiveness of an action (Woodhouse 1995). We argue that management actions should not be selected by exclusively political means. Rather, risks should be estimated so that managers can select trials on the basis of estimated risk, leading to fewer errors.

Not Enough Is Known

It is argued that ecological risks, particularly at large geographic scales or at higher levels of organization, are difficult to quantify (Regens 1995), to characterize generally (Principe 1995), or to predict at all (Pagel 1995). However, some ecosystem level responses such as the degree of eutrophication induced by a phosphorus source are routinely predicted with reasonable confidence. Even relatively simple toxicity tests can be used to predict which effluents will change community composition (Dickson and others 1992). Further, most of the risk assessments that are currently performed are for contaminated sites where effects can be measured by various biological survey techniques, supplemented by measures of ambient exposure and tests of ambient toxicity. ERA may be unable to quantify the value-laden concept of ecosystem health (Regens 1995), but we are often able to estimate aspects of ecosystem condition.

It is surprising that these indictments of the knowledge base lead to condemnations of ERA rather than to arguments for research. If asked where most ERAs could be improved (aside from assuring basic competence), we would point to failures to obtain site-specific information. For example, ERA practitioners substitute data on estuarine benthic organisms for freshwater, total concentrations of contaminants in soil for bioavailable concentrations, or generic soil-to-plant uptake factors for site-specific factors. ERA should be held to a best-available knowledge standard, and society should reasonably expect that standard to improve with time.

Conclusions

ERA is not a perfect basis for environmental management, nor does it claim to be a complete basis. It is simply a conceptual paradigm for providing timely technical consultancy to environmental decision makers without hiding uncertainties or introducing the analyst's values. By distinguishing risk management from risk assessment and assigning them proper roles, ERA does not completely eliminate the blurring of facts and values, but it is a considerable improvement over purely technocratic or purely political approaches. ERA's insistence on pursuing estimation under uncertainty will not satisfy those who demand proof of safety or of injury, but it is preferable to paralysis or decisions based purely on political pressures. ERA acknowledges and estimates uncertainty even when the bases for quantification are incomplete because ignoring uncertainty can result in worse predictions. Knowledge is never adequate, and the world will not stop while adequate knowledge is sought.

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Ecological Risk Assessment: Progressing Through Experience or Stalling in Debate

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It is déjà vu all over again. The validity and efficacy of ecological risk assessment (ERA) have been recently questioned in discussions in a special issue of *Human and Ecological Risk Assessment* [Vol. 1(4), October 1995]. Proponents and opponents of the process have rendered their opinions and positions in various symposia and workshops, as well as in the popular and technical literature. To the extent that such deliberations improve and advance the concepts and methods that form the foundation of ERA, these kinds of activities are useful.

This brief essay attempts merely to point out several perceived strengths and limitations of ecological risk assessment gleaned from assessment experience. The intent is not to fuel unproductive debate but to suggest that ecological risk assessment follows simply, yet importantly, as a conceptual and methodological extension of traditional environmental assessments (i.e., NEPA environmental impact assessments). Throughout this entire discussion, however, we should not lose sight of the ultimate objective, to provide scientifically defensible quantitative ecological and environmental inputs to

KEY WORDS: Ecological risk assessment; Environmental decision making; Levels of organization; Baseline environmental model

informed decision making, independent of terminology, the creation of new disciplines, and unproductive debate.

Perceived Strengths

With a recognition and emphasis on an honest accounting of uncertainty, ecological risk assessment provides an opportunity and offers regulatory incentive to attack the complexities of real-world environmental problem solving and decision making. Ecological risk assessment opens the door for sophisticated applications of systems analysis and ecological modeling, in part, because the foci of ERA are precisely those middle-number ecological systems that defy simple analytical or brute-force statistical description (Allen and Starr 1982, Weinberg 1975). The cleverness comes in using the ERA process to identify the critical simplifications that translate seemingly intractable environmental problems into tractable ones, using available ecological methods and models (i.e., knowledge).

Ecological risk assessment provides at least one operational advance over traditional NEPA-driven assessments, namely, the explicit consideration of uncertainty. This uncertainty results from: the imperfect characterization of ecological disturbances (e.g., toxic chemicals, habitat alteration, exotic species introductions), an incomplete understanding of ecological responses to disturbance, typically sparse site-specific data, measured spatial and temporal variability, often inadequate sampling design, and errors in sample collection and processing. Uncertainties were, of course, always present in the traditional NEPA assessment process. However, the nature of the assessment and the prescribed reporting format for a NEPA environmental impact statement minimized the explicit examination of uncertainties and consigned their presentation and evaluation to easily ignored appendices. In ERA, explicit consideration of uncertainty includes identifying, quantifying, and propagating uncertainties through the analysis and reporting their consequences for risk estimates. This aspect of risk assessment might in itself justify the effort and validate the process of ERA.

A related strength of ecological risk assessment is that it is, in a sense, self-diagnostic. That is, uncertainties can be exploited using methods of sensitivity and / or uncertainty analysis to identify the key contributors to estimated risk. Limited resources can then be efficiently allocated to provide the greatest reduction in assessment uncertainty per unit investment of time and money. This procedure can be repeated until a risk management decision becomes evident or until it is recognized that uncertainties cannot be reduced further without substantial investment in acquiring new knowledge.

Insistence on a probabilistic context for ERA provides the opportunity and capability to introduce ecological risks on quantitative scales commensurate with other components of comprehensive environmental assessments, particularly those involving economics and engineering. In fact, the continued evolution and increased sophistication of ecological risk assessment might benefit from an infusion of the more rigorous mathematical and statistical formulations of risk existing in engineering disciplines (e.g. Haimes and Stakhiv 1989, 1990).

A probabilistic framework for ecological risk also affords an opportunity for ecological assessment to enter formally into decision analysis, including consideration of risks, benefits, and costs. Risk assessment can be broadly viewed as decision making under uncertainty (Rubenstein 1975). Formal decision models can then be used in examining the implications of selecting among decision alternatives. For example, in risk-based remediation, the economic consequences and effectiveness of different cleanup technologies for reducing risk could be described quantitatively and informed choices subsequently made. As a result, risk assessment derives its significance in the context of decision making (Kaplan and Garrick 1981).

Perceived Limitations

Ecological risk assessment, as currently conceived and practiced, is not the final solution for environmental problem solving. Increasing the effectiveness of ERA will require successfully addressing several limitations in the current assessment process. These limitations include the imprecise nature of environmental legislation, incomplete communication of the regulatory decision-making process, oversimplified ecological concepts, assessment methods of unknown performance, and an accumulation of jargon that unfortunately disconnects ERA from the risk assessment methods more formally established in other fields (e.g., Helton 1993, Kaplan and Garrick 1981). This brief exposition, however, cannot address all of these stated concerns.

Practicing the current paradigm (i.e., US EPA 1992) is made difficult by the absence of a clearly stated environmental baseline or a heuristic for defining or selecting the baseline. This difficulty arises in part from the many unspecified notional reference environments and different underlying human environment models that influence the ecological characteristics used to define or identify references for ERA (e.g., Holling 1986). Human perceptions of the natural world will influence the definition of reference environments, the selection of endpoints, and consequently, the effectiveness of any assessment. In the context of current environmental regulation, some constant environment and a corresponding desire for maintaining the ecological status quo seem to characterize the implicit model. However, ecological risks cannot be easily or convincingly assessed in relation to such a static model of nature. The significance of decreased productivity or extinction cannot be judged on purely ecological grounds. In adopting the status quo as the frame of reference, ecological entities are not accorded an inherent ecological value. Instead, value accrues only when ecological entities are identified as resources.

Several limitations were identified above as components of uncertainty in assessments. In a very pragmatic sense, many of these uncertainties prove difficult, or nearly impossible, to quantify given commonly encountered budget and / or time limitations. There is a corresponding concern that uncertainty in ERA can paralyze the decision-making process or be used as an excuse for indecision.

ERA can benefit from continued efforts to interject modern quantitative ecology to the risk assessment process. Progress in ERA has been curtailed by unprofitable debates concerning, for example, simple versus complex models, population versus ecosystem effects, ecology versus toxicology. Consider, for example, ''levels of organization'' in ERA. This reflects a lack of ecological sophistication in concept and method. Each level in fact corresponds to a particular ecological point of view (i.e., model) for describing the same natural world. These levels have been used to construct oversimplified nested models of nature: landscapes that encompass ecosystems consisting of communities made of populations of individuals. Independent of the arguable utility of this simplistic model, the advances in ecological understanding achieved through decades of basic study of each different level offer unique and potentially powerful concepts and measurements that should be incorporated into the development and application of ecological risk assessment. Moreover, competent attempts at integrating across levels (e.g., Allen and Starr 1982, Allen and others 1984, Holling 1986, O'Neill and others 1986, King 1991) should be explored for their relevance in assessing ecological risks.

One of the dangers implied in the current state of affairs is that ERA might increase in rigor and sophistication, but decrease in relevance. The continued refinement and improvement of concepts and methods used to assess ecological risks is necessary and justifiable for complying with legislation designed to protect the environment from the impacts of toxic chemicals. However, capabilities for assessing ecological risks will be developed fully and applied with the greatest societal benefit only when ERA becomes an integrated component of an overall rational plan for environmental management.

Conclusions

One challenge in realizing the potential of ecological risk assessment lies in interjecting modern ecology and the environmental sciences into the decision-making process and regulatory arena. Here ecological principles are often poorly understood or poorly communicated, and social, economic, and political considerations enter unequally into environmental decision making. To contribute effectively, ecological risk assessors must focus their capabilities and resources on ecological entities that are defensible from a scientific viewpoint and of vital interest to stakeholders and decision makers alike. Successful application of ERA demands the best from science and the best from decision makers.

ERA represents an important next step in a continuing journey from NEPA toward increasingly scientifically defensible environmental decision making. Ecological risk assessment is neither sage nor charlatan. It is simply a process. The effectiveness of this process in advancing the art and science of assessing environmental impacts depends in large part on the capabilities, training, intentions, and integrity of its practitioners. Ecological risk assessment should not become merely a new name for traditional environmental impact assessment. Ecological risk assessment should neither be oversold nor undersold. It is not an environmental panacea or a regulatory silver bullet. Ecological risk assessment cannot transform an absence of information and understanding into informed decision making. However, ecological risk assessment can force the explicit identification, consideration, and incorporation of uncertainties into the assessment process. Used with technical competence and integrity, ERA interjects an honest use of typically sparse information and incomplete ecological understanding into environmental decision making.

Presumably, increased capabilities in assessing ecological risks will result from emphasizing strengths and surmounting limitations. Such progress will likely ensue in proportion to actual assessment experience, rather than as the result of debate. Keep talking, but more importantly, get to work.

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Assessing the Current Status of Ecological Risk Assessment

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Risk assessment has developed from the specifics of using available toxicological and ecological information to estimate the probabilities associated with unwanted environmental outcomes (Wilson and Crouch 1987) to become an important environmental policy instrument. As Bartell (1997) has noted, risk assessment represents an important step in the journey from broadly based, descriptive environmental impact assessments toward increasing the scientific defensibility of environmental decision-making. Lackey (1997) concludes that much of the excitement surrounding risk assessment stems from the fact that it is the most recent in a succession of tools aimed at scientific environmental management. It seems appropriate, therefore, to have sought current views on risk assessment from ecotoxicologists, risk assessors, and environmental regulators on the acceptability and utility of ecological risk assessment as a tool for describing, ranking, and addressing the complicated environmental issues that lie before us.

Views about the details of risk assessment necessarily differ, but as the debate has shown, there is wide agreement on the need to apply available scientific tools to the problem of minimizing the environmental consequences of human action. A point–counterpoint summary of the views expressed by the discussants on a common set of risk assessment issues is presented in the ecological risk assessment issues matrix of Table 1. The matrix focuses on 12 issues raised in common by the discussants and gives a synthesis of their respective views on risk assessment. Issues other than those detailed in the matrix were discussed by authors, but not by a sufficient number to warrant their inclusion in Table 1. From among the issues raised, we have chosen the subset representing the greatest extent of disagreement as the focus of our own discussion. These issues are also those that we believe will be most pertinent to determining the future success or failure of ERA as an environmental decision-making tool. Included in the selected list of critical issues are validation, sources of ambiguity, limitations, ecology, appropriate use, and most pressing demands.

KEY WORDS: Ecological risk assessment; Validation; Ecology; Limitations

[3]Managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

Validation

The traditional application of ERA has been predictive in nature and focused on the localized effects of a particular stressor (Suter 1993). In that sense ERA is a logical extension of descriptive environmental impacts assessments (EIAs). Despite the long history of interest in predicting the effects of action, Holdway (1997) notes the paucity of information available to determine the predictive accuracy of assessment methodologies. Given the predilection for modeling (Holdway 1997, Van Leeuwen 1997), the result is curious, because the

Table 1. Ecological risk assessment issues matrix

Issue	Calow and Forbes	Holdway	van Leeuwen	Lackey	Bartell	Suter and Efroymson
Validation	Many assumptions remain untested	ERA predictions not validated		Evaluation of ERA applicability incomplete	Many assessment methods are of unknown value	
Objectivity versus subjectivity	ERA objectively definable	ERA necessarily subjective	Subjective choice used as required but ERAs transparent and defined	Subjective in the sense that value criteria used to bound ERAs	Subjective because human values influence baseline definitions	Objective, but subjective probabilities allowed
Management or science	Both but more interaction required	ERA driven by management not science	ERA is a pragmatic pollution management process reliant on science	ERA is a decision-making and resource allocation tool	Science deriving significance in the context of decision-making	ERA is science and provides a basis for management
Quantitative methods	Selected methods often mask uncertainty	Too reliant on unvalidated models and parameters	Must develop "generic" approaches using "average" values		Help identify estimate, propagate uncertainties in all analyses	When used must be accompanied by uncertainty analysis
Sources of ambiguity	Difficulties with defining ERA problem boundaries	Implications of toxicity tests for ecosystems unknown	Generic approach removes ambiguity, makes ERA methods transparent	Terminology related	Incomplete communication of the regulatory decision process	
Alternative approaches		Semiquantitative hazard assessment by experts	SARS and QSARs to overcome data gaps	Benefits or consequence analysis	Traditional EIS possible but less desirable	No alternative is as appropriate as ERA
Consistency of view	Two paradigms: ecosystem health ecosystem services	Required only to ease regulatory processes	Emphasis on issues varies with time	Many diverse views exist		
Appropriate use	At population and community levels when uncertainty prevails	As currently defined, never	Generic ERA best and adaptable to many problems	As an aid to decision making for narrowly defined issues	To formally infuse ecological assessment into decision making	For choosing between alternative actions
Limitations	Not valid for ecosystems	Imposed by numerous assumptions	Little known about patterns of chemical use and dispersal	Cannot address large, complex public policy issues	Jargon and the imprecise nature of environmental legislation	
Value criteria	Specified a priori by both science and the public	Injected by modelers and the politically correct	Bounded by political and social factors	Must be defined by both science and the public	Required to judge ecological significance	A function of risk management
Ecology	Ecology concerns dominate under the ecosystem health paradigm	Ecological complexity not reflected by ERA	ERA has little to do with ecology		Ecological concepts often oversimplified in ERA	Site-specific ecological detail included
Most pressing demand	Defining the questions to be asked	Validation	Improved methodological harmonization and communication	Further definition of when and where ERA is appropriate	Lack of clearly stated environmental baselines	Improvement of the knowledge base
Summary assessment	In ERA the questions are not clearly defined	ERA is a misleading short cut	ERA is a pragmatic decision-making tool for environmental regulation	ERA is appropriate in limited circumstances for environmental management	ERA is a conceptual and methodological extension of traditional EIS	ERA is a conceptual paradigm providing timely advice to environmental decision makers

modeling literature itself has been quite clear on the need for validation. There is no assurance that models that provide the best fit to available sample data will be the best predictors of future behavior. As a consequence, the statistical literature requires the validation of model predictive accuracy and bias in all circumstances (Montgomery and Peck 1982). Insofar as models of ecological systems offer the potential for understanding the consequences of human action, thereby allowing us to minimize the consequences of our actions, the importance of predictive validation cannot be understated (Power 1993).

In addition to concerns about validation, Holdway (1997) argues that ERA predictions are likely to be misleading given our incomplete understanding of the complex causal mechanisms governing ecological interactions. Lackey (1997) is less sanguine, noting that the potential for ERA to address complex ecological policy questions has yet to be fully evaluated. Calow and Forbes (1997) and Bartell (1997) caution that many of the assumptions and techniques used in ERA remain untested and of unknown value. Although advocates of ERA have made much of its scientific basis, they remain ominously silent on the issue of validation. The ERA paradigm does not explicitly highlight the need for validation. Instead, practitioners are assumed to foresee the need. The evidence, however, suggests that they do not. The fact that there is no validation is often excused by ERA supporters on the grounds that it is the practice, and not the paradigm, that is at fault on the validation score. It is not sufficient to impute that it is the practice, rather than the paradigm, that is flawed when the latter justifies the former.

In its defense Bartell (1997) suggests ERA would benefit from an infusion of the rigorous mathematical and statistical formulations of risk extant in the engineering disciplines. Among the rigors infused must be an explicit requirement for the conduct of validation studies. The methodologies used as part of ERA are surrogates for actual experience or experimentation with a specific ecosystem. Thus it is important to establish the credibility of employed techniques to ensure that assessors, regulators, and the public have sufficient confidence in the predictions generated by ERAs (Van Horn 1971). Having the benefit of the EIA experience, ERA should not repeat the mistake of its predecessor in failing to validate its methods and predictions. Science demands that predictive claims be substantiated, and ERA cannot legitimately claim a scientific basis without living up to that same standard. Clearly an important future challenge for ERA will be to install confidence in both the paradigm and the techniques coopted by its application.

Sources of Ambiguity

To some extent the validation issue is confounded by the ambiguities extant in procedural applications of ERA. While Suter and Efroymson (1997) admit particular applications of the ERA paradigm have led many to confuse a feature of ERA practice with ERA, or mix values with facts, they find such distinctions easily made in practice. Others would disagree. Lackey (1997) points to a diffuse set of similar paradigms and terminology as being one source of ambiguity about the nature and practice of risk assessment. Bartell (1997) adds incomplete communication between regulatory decision makers and risk assessors and the imprecise nature of environmental legislation to the list of ambiguities hampering our ability to define decision alternatives and the best means of selecting among them. Calow and Forbes (1997) reiterate the claim in ecological terms, noting the difficulties with defining ERA problem boundaries and determining what it is about the environment we actually want to protect.

The list of factors contributing to misunderstandings about ERA suggests more than mere confusion over the particulars of its practice. They are fundamental expositional or practical weaknesses of the paradigm which, more than anything, underpin the dichotomy of views expressed by Holdway (1997) on the one hand, and Suter and Efroymson (1997) on the other hand. Although one can sympathize with the appeal to refine ERA through experience, rather than debate (Bartell 1997), with limited resources we must be cognizant of the need to think before we act. Far from being an appeal to act only when sufficient information is available, this is an appeal to wisely use what information is available. For complex, intractable environmental problems constructive debate is surely as legitimate a tool of action as toxicity testing.

The lack of a coherent view on the extent and nature of ERA presents obvious problems for validation. Validating predictions of questionable value is undoubtedly a vain use of limited scientific resources. The generic European approach (Van Leeuwen 1997) attempts to remove much of the ambiguity associated with mandate and boundary issues by standardizing ERA within a computerized modeling environment. Although clearly transparent, the approach does not overcome the technical issues involved in extrapolating laboratory toxicity test results to the complexities of the environment (Holdway 1997). This suggests that the lack of predictive validation is itself one of the largest sources of ambiguity in ERA. Without the ability conferred by validation to quantitative arbitrate between competing methods, methodological choice is left to the subjective selection of the assessor and rancorous, unproductive debate ensues.

Limitations

Limitations arising from the numerous assumptions and imprecise nature of much of the knowledge base pertaining to the application of ERA were generally recognized by the discussants. As a result, emphasis was placed on attempts to increase the scientific credibility of ERA by addressing identified limitations and reducing ambiguities to the maximum extent possible. Several authors argued that a major limitation of ERA was the generic assessment approaches that have been developed without focusing on clearly defined problems or target areas with well defined features. Van Leeuwen (1997) believes that ERA has been mainly geared to function in a generic assessment mode. Lackey (1997), Calow and Forbes (1997), and Bartell (1997), however, advocate the use of ERA for addressing well-defined technical questions, including establishment of environmental baseline conditions, rather than as a means of addressing complex public policy questions. Defining clear hypotheses that can be rigorously tested in well-designed research programs should be the basis of scientifically credible ERA programs. When used in generic assessments, ERA is too easily adapted to environmental, scientific, and political conditions and becomes more an instrument of environmental policy than science.

Generic approaches have little to do with ecology and are fraught with numerous assumptions and value judgements (Van Leeuwen 1997). Site-specific assessments require the development of sophisticated models, use large amounts of data, and involve high costs. There are, therefore, disadvantages in using ERA on both a generic and site-specific basis. Defining an ERA problem on a narrow scale makes its solution less transferable, but it also makes the assessment more ecologically relevant by requiring fewer assumptions and / or scientific judgements. Because the nature of the ERA process invariably requires the analyst to make many value-based decisions, even in the most focused of studies, limiting application to focused and well-defined issues will help reduce the dependence of ERA on assumptions and value judgements and increase its scientific credibility.

Another major concern addressed in this series of papers is that ERA is typically fraught with type II errors or that it strives to prove the null hypothesis of no risk. This problem is a serious statistical one when working only with single-species toxicity tests (Holdway 1997). When the difficulties of measuring and predicting the behavior of complex ecosystems are included, it becomes an even more serious statistical problem. To maximize the probability of protecting the environment, experimental designs and statistical analysis must be adjusted to minimize the probabilities of false negatives (Forbes and Forbes 1994). Improving the statistical power of test designs to detect existing effects and minimize type I and II errors can only strengthen the risk assessment process (Cranor 1993).

Ecology

One of the major concerns voiced by several authors was the general lack of ecological realism and sophistication in the conception and practice of ERA. Of necessity, ecosystem models must be relatively simple in design, yet in ERA many models have been oversimplified (Bartell 1997, Holdway 1997). Calow (1994) stated that we still do not know enough about ecological systems to be able to identify what it is we want to protect and, hence, what we should be measuring. Holdway (1997) believes that as a result ecological science has been oversimplified in order to cater to the needs of legislators, politicians, and attorneys. In support of this position, Lackey (1997) points out that a serious misuse of the ERA process has been to substitute political values and priorities for those of public concern, thus shifting the emphasis of ERA from the scientific to the political arena.

Questions have also been raised relative to the issue of making decisions of ecosystem risk based on generalized ecological responses such as the survivorship and fecundity of representative species. Typically, damage to individual organisms or populations is used to extrapolate to effects at the community or ecosystem level. Because of our rudimentary understanding of ecosystem structure, function, and processes, extrapolating across multiple-trophic levels is a major limitation in ERA. Reasonable attempts should be made at integrating across multiple levels (Bartell 1997) and interpreting the ecological meaning of change at one particular level to effects at multiple trophic levels (Holdway 1997). In the same context, assessing the ecological relevance of some predetermined and arbitrary percentage loss of a species (e.g., 10%) may be somewhat unrealistic because we do not currently understand what a partial species loss, or even a total species loss, ultimately means to the productivity, stability, or fitness of the entire ecosystem.

If the observable loss of a species, or population, is the ecological endpoint on which decisions about ecological harm are based, then the use of an arbitrary percentage loss defeats the predictive purposes of ERA. For example, a 10% loss in a population has to be observed before risk can be assigned. When the risk is known, the harm has already occurred. The assessment, therefore, loses much of its predictive function simply because its conclusions have become largely retrospective in nature. In reality, individual organisms become sublethally stressed and their physiological systems compromised before more serious effects are manifested at the higher levels of biological organization. For example, the biochemical and physiological systems of organisms become compromised before changes in reproductive and population attributes are observed. If ERA is to be truly predictive in nature, assessment approaches must incorporate the ability to address the sublethal changes in organisms that function as early-warning signals or indicators of impending environmental damage. Unfortunately, most ERAs currently fail to meet this crucial need.

Appropriate Use

Views on validation, ambiguities, limitations, and ecology invariably influenced the opinions of authors on where and when ERA should be used. Holdway (1997), having argued that ERA was neither appropriately validated nor ecologically sophisticated, concluded that as currently defined ERA should never be used. In its place semiquantitative hazard assessments that evaluate the potential for deleterious effects occurring in an ecosystem given the presence of defined toxic agents or pollutants were suggested. Lackey (1997), noting the tendency to apply ERA to every environmental problem at hand, called for a clear definition of the circumstances under which ERA should be used as a decision-making tool. Bartell (1997) viewed ERA as a credible means of infusing ecological information into the wider social environmental decision-making process. Calow and Forbes (1997), however, restricted the use of ERA to population and community-level related problems dominated by uncertainty.

Although advocates offer ERA as a panacea for environmental decision making, most authors clearly argued that ERA should be applied only in limited circumstances. The split over circumstances occurred largely between those who viewed ERA as a generic process capable of screening, ranking, and expediting the solution of environmental problems (e.g., Van Leeuwen 1997), and those who viewed ERA as most potentially useful for addressing site-specific decisions (e.g., Bartell 1997, Lackey 1997). Future methodological developments will ultimately determine which view prevails. For example, improved, validated modeling approaches would clearly enhance the effectiveness of ERA as a screening tool, while the infusion of more ecological principles into the practice of ERA is likely to increase the specificity of its conclusions, thereby limiting its use to narrowly defined questions. It is difficult to predict into which role ERA will ultimately evolve. That, in part, will depend on the enthusiasm and efforts of both its detractors and proponents. What is clear, however, is that ERA will not effectively fulfill either role if further conceptual and methodological developments do not occur.

Most Pressing Demands

Despite divergences in opinion regarding the utility of risk assessment, there was a consensus on the need to further develop and refine the approach. The specific recommendations of each author varied. Calow and Forbes (1997) focused on the need to clarify the ecological questions being asked. Van Leeuwen (1997) stressed improvements in the harmonization and communication of methodological developments within the assessment and regulatory communities. Predictive validation and the selection of environmental baselines, however, undoubtedly represent the greatest challenges to ERA. Without confidence in the accuracy of the predictive techniques used and knowledge of the baseline conditions against which to compare predicted changes, ERA cannot hope to either effectively predict the consequences of human action or judge the probable significance of its predictions. And without these abilities, ERA will almost certainly fail to convince its sceptics or live up to its promise of injecting scientifically sound advice into the environmental decision-making process.

Conclusions

The opinions offered by discussants in this debate do not allow us to either condemn risk assessment as a pseudoscience or to treat it as a fully adequate tool for describing, ranking, and addressing complicated environmental problems. ERA has undergone significant change since it first appeared little more than a decade ago. Revision of the US EPA risk assessment guidelines, numerous methodological conferences, and specialty books all point to considerable scientific and regulatory interest in both the practice and development of ERA. Risk assessment will undoubtedly evolve to meet the concerns of its critics on many issues (e.g., validation, improved definition of problem boundaries), but on many issues the concerns of its critics will not easily be met (e.g., demonstration of ecological relevance, extrapolation between levels of biological organization), which will serve to limit the functional role of ERA within the wider activity of environmental decision making and management.

In point of fact there are no methods that evaluate or predict the status of ecological systems that are without limitations. Every approach has its unique set of advantages and limitations. Furthermore, every approach will, to some extent, share characteristics in common with other approaches aimed at a similar, generic objective. We have indicated some of the agreed on strengths and limitations of ERA in relation to the ecological processes we seek to understand and manage. Recognizing the strengths and weaknesses of any paradigm, ERA included, is the best means of attempting to delineate its appropriate use and reinforce its associated scientific credibility. As we learn more about ecosystems and what it is we want or need to protect in them, scientifically credible methods of assessment will have increasingly important roles to play in improving the practice of environmental management. This implies that ERA, as it predecessors have done, will undergo a significant transformation as it establishes its place in the collection of methods we use to provide timely technical advice to environmental decision makers.

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