

# Ecological Risk Assessment in the United States Environmental Protection Agency: A Historical Overview

Glenn W Suter II\*

*Office of Research and Development, US Environmental Protection Agency, Cincinnati, Ohio 45268*

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## EDITOR'S NOTE:

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## ABSTRACT

Risk assessment originated with the insurance industry and spread to the estimation of risks to people and property in other contexts, including the regulation of environmental contamination. Ecological assessment became an important component of environmental management in the United States with the legal mandate for environmental impact assessment in 1970. Risk assessment and ecological assessment merged in the 1980s to form ecological risk assessment (ERA). Since then, ERA has been institutionalized with the development of the US Environmental Protection Agency's (hereafter, USEPA or Agency) framework and guidance documents. Ecological risk assessment has been adapted by the Agency's program offices to fit their legal and policy contexts. The future of ERA will inevitably include the incorporation of more complex and demanding methods. However, the biggest challenge for future risk assessors will be to make ecological risks more compelling to decision makers.

**Keywords:** History Ecological risk assessment US Environmental Protection Agency

## RISK ASSESSMENT HISTORY

As with other human enterprises, ecological risk assessment (ERA) should be understood as a product of its history. In particular, the current practice of ERA results from blending 2 historical streams: Risk assessment and ecological assessment. This account addresses the history of ERA in the context of its institution of origin, the US Environmental Protection Agency (hereafter USEPA or Agency). It provides background information that informed the Science Advisory Board's review of the use of ERA by the USEPA (Dale et al. 2008).

Risk assessment began with the insurance of merchant ships in England and the Netherlands in the 17th century (Bernstein 1996). To this day, most risk assessors work in the insurance and financial industries. Risk assessment in this context includes a variety of techniques: Statistical analysis of past frequencies of events, trend analysis, mechanistic modeling, and professional judgment to estimate how proposed actions, individual events, and poorly defined trends will affect the future. From the insurance context, risk assessment spread to the assessment of risks to the safety of people and property, health risk assessment (e.g., drugs, devices, and chemicals) and engineering risk assessment (e.g., reactor and aircraft safety).

Risk assessment in the environmental context developed first in the United States in the 1970s as a response to the enactment of a series of environmental laws: The Clean Air Act of 1970, the Federal Insecticide, Fungicide, and Rodenticide Act of 1972, the Safe Drinking Water Act of 1974, the Toxic Substances Control Act of 1976, and the Clean Water Act of 1977. The enforcement of these regulatory statutes was assigned to the newly created USEPA. Those laws explicitly or

implicitly called for the assessment of risks to public health and the environment as a basis for regulatory decision making. However, risk assessment was variously interpreted by the offices of the USEPA and other regulatory agencies that enforce regulatory statutes. Because of the controversy that the risk assessments engendered, in 1981 the US National Academy of Sciences was commissioned to review the "institutional means of assessment of risks to public health" (NRC 1983). The product, known as the Red Book (NRC 1983), provides a framework for human health risk assessment that included hazard identification, dose-response assessment, exposure assessment, and risk characterization. Risk assessment was to be informed by research and was to inform a risk management process that would identify options for addressing risks and choosing among the options based on health risk plus economic, social, and political considerations. The Red Book continues to provide the fundamental framework for health risk assessment in the US Federal Government.

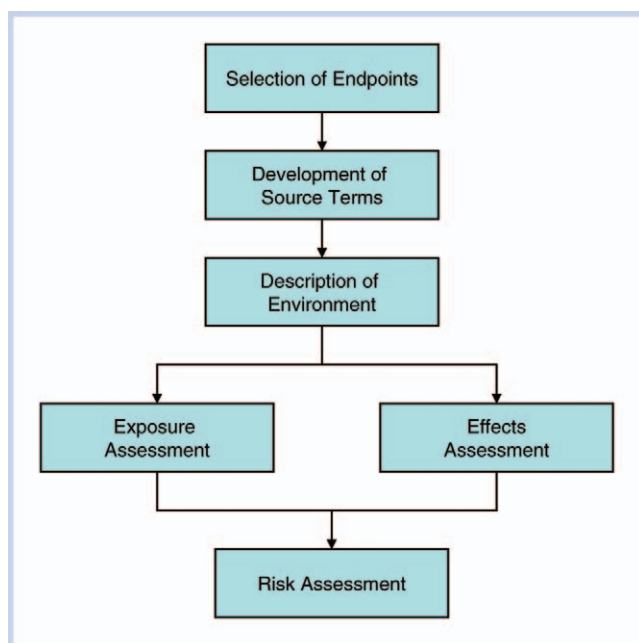
## ECOLOGICAL ASSESSMENT PRIOR TO ECOLOGICAL RISK ASSESSMENT

Prior to the development of ERA, the USEPA assessed anthropogenic effects on nonhuman organisms and ecosystems primarily through 3 ecological assessment approaches: Environmental impact assessment, hazard assessment, and the development and application of criteria values.

The National Environmental Policy Act of 1969 required that the US Federal Government prepare an environmental impact statement of all major federal actions with the potential to significantly affect the quality of the environment. About 10000 preliminary screening documents (Environmental Assessments) and about 500 full Environmental Impact statements are produced annually. These documents

\* To whom correspondence may be addressed: suter.glenn@epa.gov

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**Figure 1.** The first framework for ecological risk assessment (Barnthouse and Suter 1986). It illustrates the early concern of ecological risk assessors with defining the assessment problem by selecting endpoints and characterizing the sources and receiving environment.

tend to be descriptive and, because of the history of litigation, they tend to be focused on compliance with the procedural requirements. However, some impact assessments have included highly refined and quantitative analyses that have been influential in environmental decision making. Because they frequently address construction and resource extraction activities, impact assessments focus on physical disturbances such as highway construction that destroy ecosystems and the killing of organisms as in tree harvesting and fish entrainment by power plants. The USEPA's regulatory activities, which are more toxicologically oriented, are exempt from the requirement for impact assessment. However, the USEPA may review impact assessments performed by other agencies.

While the USEPA and other organizations were developing environmental risk assessment to deal with toxicological risks to humans, a separate approach was developed for ecological assessment of toxic chemicals. A series of workshops generated the hazard assessment paradigm (Cairns et al. 1979). This paradigm focused on the aquatic environment and emphasized 3 concepts. First, the hazard posed by a chemical is a function of the magnitude of the exposure concentration relative to the toxicologically effective concentration. Second, toxicity tests and studies of environmental transport and fate properties should be performed in tiers, beginning with simple and inexpensive studies. Third, as more tiers of testing are performed, uncertainty will decline and the relative magnitudes of exposure and effective concentrations will become clear. These concepts have been very influential in the development of subsequent risk assessment methodology, particularly with respect to the assessment of pesticides and toxic substances (Urban and Cook 1986).

The Clean Water Act's mandate to protect the biological integrity of the United States' waters inspired its own ecological assessment and management approach. It has been expressed primarily in the development and enforcement of criteria and standards for the protection of aquatic life. Water quality criteria were initially developed by reviewing the aquatic

toxicity literature for each chemical and applying expert judgment (NAS/NAE 1972; USEPA 1976). However, the USEPA eventually developed a formal, quantitative method for estimating criteria (Stephan et al. 1985). The realization that single-chemical criteria do not address combined toxic effects or local water chemistry led to the development of biocriteria based on effluent toxicity tests and ambient water and sediment toxicity tests (USEPA 1991b; Grothe et al. 1996). Finally, to incorporate effects of agents other than chemicals or chemical effluents, biocriteria were developed based on biological surveys of aquatic or benthic communities (Davies 1991; USEPA 1996). These 3 approaches are independently applicable. That is, a water body may be declared to be impaired based on any one of the 3.

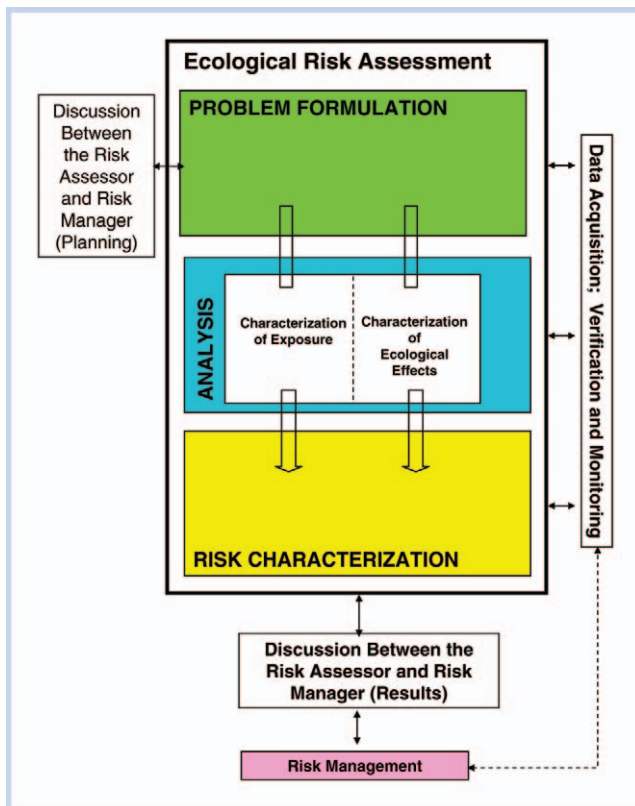
### THE BIRTH OF ECOLOGICAL RISK ASSESSMENT

In 1981, the USEPA commissioned the Environmental Sciences Division of Oak Ridge National Laboratory (ORNL) to develop methods for ERA and apply them to synthetic fuels technologies. The USEPA provided no guidance concerning the nature of an appropriate ERA methodology, except that it should be analogous to human health risk assessment. Hence, the ORNL investigators developed methods to calculate ecological risks equivalent to probabilities of cancer. Specifically, the ORNL investigators developed methods for estimating the probabilities of effects of clearly defined assessment endpoints at relevant levels of biological organization. Their methods were published (Barnthouse et al. 1982), applied (Suter et al. 1984; Barnthouse et al. 1985), and then published as a manual after a USEPA peer-review workshop (Barnthouse and Suter 1986). That manual was expanded into 2 books: A general ERA text (Suter 1993) and a text on the use of ecosystem models in ERA (Bartell et al. 1992).

When the Red Book was published in 1983, the ORNL team developed an equivalent framework for ERA (Figure 1). The ORNL ERA framework differed from the Red Book framework in having 3 preliminary steps that differed from the hazard identification step in the Red Book framework. The first, defining the endpoints, was necessitated by the diversity of ecological entities and attributes that might be at risk (Suter 1989). The second, development of source terms, was neglected by the Red Book, which focused on human exposure processes. However, the synthetic fuels case studies clarified the importance of determining where, when, and how pollutants are released to the environment. The third, description of the environment, was necessitated by the recognition that ecological risks are determined by the environmental context. The ORNL ERA framework linked these pre-analytical steps to the assessments of both exposure and effects.

### ECOLOGICAL RISK ASSESSMENT FOR CONTAMINATED SITES

While other USEPA programs continued to use hazard assessment and criteria setting as their ecological assessment approaches through the 1980s, the passage of the Superfund legislation in 1980 led to early adoption of the ERA paradigm as USEPA policy. As a result, the assessment of contaminated sites dominated the development of ERA in the late 1980s and through the 1990s. In 1989, the USEPA published a field and laboratory methods document and an ERA guidance document (USEPA 1989a; Warren-Hicks et al. 1989). The guidance document was rather general and has been replaced by more detailed documents for the ERA process (Spranger and Charters 1997) and for specific activities



**Figure 2.** The USEPA's framework for ERA, which is the standard for practice in the Agency and has served as a model for other organizations and nations (Norton et al. 1992; USEPA 1992a).

(e.g., Environmental Response Team 1994, 1995, 1996). The responsible parties, their contractors, and the USEPA's contractors produced many publications on ERA for the Superfund including guidance documents (Wentzel et al. 1996) and a text (Suter et al. 2000).

### THE USEPA'S GUIDELINES FOR ERA

In the late 1980s, the USEPA began to work toward Agency-wide guidance for ERA. Between 1987 and 1990, the USEPA and others conducted a series of literature reviews, colloquia, and workshops to gather information (Norton et al. 1988; USEPA 1989b, 1991a). A 1991 NRC workshop and a peer-review workshop encouraged the USEPA to complete a single framework for all of the Agency's ERAs (NRC 1993; USEPA 1992b). The framework document was quickly published (Norton et al. 1992; USEPA 1992a).

The new ERA framework identified the components of the process and their relationships to each other. Its primary innovation was the identification of planning and problem formulation steps (Figure 2). Planning included interactions of the assessors with decision makers and stakeholders to determine the scope and goals of the ERA. Problem formulation replaced the hazard evaluation from the Red Book and the 3 preliminary steps of the ORNL framework with a set of 3 interacting tasks: Endpoint selection; development of a conceptual model that describes how a source could cause the endpoint effects; and development of an analysis plan that lays out procedures for data collection, analysis, and modeling. The new ERA framework also differed from the Red Book and prior USEPA risk assessment guidance by including risks from nonchemical stressors such as heat, silt, and habitat loss.

The USEPA's next goal was to develop guidelines that explained how to perform the process outlined in the new ERA framework. The 1st step towards that goal was the development of a set of case studies that applied the framework to various ecological assessment problems (USEPA 1993, 1994a). The case studies demonstrated that the new ERA framework could be applied to the range of assessment needs. The 2nd step was to commission a set of issue papers addressing the state of science and practice with respect to each component of the framework (USEPA 1994b). At the same time, the USEPA published a review of its policies and practices related to managing ecological risks (Troyer and Brody 1994). Those activities provided the basis for the guidelines (USEPA 1998). The guidelines left the framework essentially unchanged but put more emphasis on the planning step, prior to problem formulation, and provided much more technical guidance.

Following the publication of the guidelines for ERA, the USEPA conducted a colloquium to determine next steps. The resulting consensus was that certain difficult issues should be addressed in supplements to the guidelines. One supplement, which clarifies some issues related to ecological assessment endpoints and identifies endpoints that are generally acceptable to the Agency, has been published (USEPA 2003) and explained in the open literature (Suter et al. 2004, 2005). More supplements are planned.

### ECOLOGICAL RISK ASSESSMENT IN THE USEPA'S PROGRAMS

The USEPA's ERA framework and guidelines have influenced assessment practices in the Agency's programs for air, water, toxics, and contaminated sites. However, the results of that influence have been quite variable because of the provisions of the applicable laws and regulations and because of the influences of past practices.

Because pesticides are toxic by design and are deliberately released to the environment, they have been more strictly regulated than other chemicals. As a result, more data are available for ERAs of pesticides than for any other toxicant. Because of the robust data, the USEPA and others have proposed and employed more complex methods for assessing pesticide exposure. Methods to make pesticide assessments more probabilistic and realistic were developed by 2 organizations that included scientists from the USEPA, industry and academia, the Aquatic Risk Assessment and Mitigation Dialog Group (Baker et al. 1994), and the Avian Effects Dialog Group (1994). In 1996, Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel directed the Office of Pesticide Programs to develop probabilistic methods for ERA. The terrestrial and aquatic workgroups organized by the Office of Pesticide Programs to develop those methods included industry and academic scientists from multiple nations. The resulting methodologies were extensions of the results from the prior dialog groups (ECOFRAM Aquatic Workgroup 1999; ECOFRAM Terrestrial Workgroup 1999). The methodologies have been applied to numerous ERAs, principally by Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) members funded by industry, including Giddings et al. (2000, 2001), Giesy et al. (1999, 2000), Hall et al. (1999, 2000), Hendley et al. (2001), Klaine et al. (1996), Maund et al. (2001), Solomon et al. (1996), Solomon, Giddings, et al. (2001), and Solomon, Giesy, et al. (2001). The Office of Pesticide Programs has been working on its own versions of the ECOFRAM methods and has reviewed the manufacturer's probabilistic assessments in the course of pesticide registrations.

As discussed previously, ecological analyses for the Clean Water Act have consisted primarily of developing and applying water quality criteria including both chemical criteria and biocriteria. The 1985 guidelines for chemical criteria were quite algorithmic (Stephan et al. 1985). Much of the effort since has been devoted to adding flexibility to address local conditions and to incorporate nonstandard data. Currently, the USEPA, with input from other agencies, is revising the 1985 guidelines to incorporate the latest science and the ERA guidelines. In particular, the new approach requires a problem formulation to determine what endpoints, routes or exposure, and spatial areas will be included.

Secondary air quality standards are developed under the Clean Air Act to protect public welfare including ecological resources. The assessments to derive those standards do not follow the USEPA's ERA framework or any other standard procedure, but they do employ a risk-based approach. The air quality criteria document for ozone is an excellent, recent example (USEPA 2006).

### EXTENDING ERA

The ERA paradigm has been extended in various ways including applications outside the USEPA's regulatory mandate and at larger spatial scales. In particular, in the 1990s, a USEPA program demonstrated ERA's application to watersheds (Cormier et al. 2000; Norton et al. 2000; Serveiss et al. 2000; Diamond and Serveiss 2001; Diamond et al. 2002; Serveiss 2002). These assessments differed from prior ERAs in that they defined goals and described or prioritize risks to a regional resource rather than informing a decision concerning an environmental management action. Such qualitative and decision independent assessments typify regional scale ERAs (Landis 2005). While they are not influential in the sense that they do not drive a decision, such assessments may serve to mobilize a community or develop a consensus among stakeholders concerning goals and priorities. The USEPA's watershed ERA program also clarified the need to develop guidance for determining the cause of observed ecological impairments (USEPA 2000).

### CONCLUSIONS

ERA has a well-developed framework and guidelines, and its use has become established in the USEPA by policy and in practice. Although its implementation by the various programs and region offices has differed in response to legal mandates and other constraints, it is characterized by performance of a problem formulation, including identification of assessment endpoints, analysis of exposure and exposure-response relationships, characterization of risk including determination of the nature and likelihood of effects, and communication with the decision maker. As implemented in each of those contexts, ERA has met the expressed needs of decision makers and withstood legal challenges.

Although it has been successful, ERA has been challenged on political and technical grounds. Environmental advocates often challenge risk assessment in general as a pretext for delaying or avoiding proper action by regulators to protect or restore the environment. Advocates for industry and academic scientists often challenge ERA for not adequately considering particular technical issues or not using state-of-the-science techniques. These include quantitative uncertainty analysis, spatially explicit analysis, assessment of effects at multiple levels of organization, and analysis of the weight of evidence. Clearly, these 2 critiques are contradictory: More analysis

using more complex methods will further delay decisions and decrease the number of decisions that can be supported by assessment, given limited resources. However, those fewer and slower management decisions might be better informed.

The most important critique of ERA is its relative lack of influence in USEPA decision making. Although ecological receptors are commonly more sensitive and more exposed than humans, human health risks dominate rule making, remedial actions, and other regulatory decisions. In part this is an inevitable result of the species making the decisions. Even environmental advocacy groups are primarily human health advocates. Hence, the future success of ERA will depend more on making it more compelling to decision makers than on making it more technically sophisticated.

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