Science, Risk, and Risk Assessment and Their Role(s) Supporting Environmental Risk Management

Robert G. Hetes
U.S. Environmental Protection Agency
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC

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Abstract: The U.S. Environmental Protection Agency (EPA) fulfills its mission of protecting public health and the environment by, among other things, developing and enforcing regulations that implement environmental laws enacted by Congress. Ensuring that its regulations have a sound analytical foundation reduces both controversy and, to some extent, court challenges and increases the likelihood of compliance by the regulated community, which is key to achieving real environmental improvement. Given the complexity of the nature of the environment, risk, and environmental risk, it is not feasible currently to measure or assess risks fully. The environment, risk and environmental risk are case-specific and too complex to capture fully. EPA uses risk assessment as a key source of scientific information for making good, sound decisions about managing risks to human health and the environment. Risk assessment is a necessary tool used to inform decisions where direct measurements are not possible. While risk assessment involves science and is a scientific activity, it is best described as "trans-scientific", and normative aspects and judgment are inherent. EPA has instituted numerous processes and systems to make risk assessments tractable and feasible, while insuring their overall quality. This presentation will review risk assessment, and its role in risk management decisions, with emphasis on science and policy influences on procedures for conducting such assessments and making such decisions, and vice versa.

Disclaimer: *The views expressed in this paper are solely those of the author and do not necessarily reflect the views of the Agency.*

Quality Decisions Needed to Meet Mission of Environmental Protection

The mission of the U.S. Environmental Protection Agency (EPA) is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends. EPA fulfills this mission by, among other things, developing and enforcing regulations that implement environmental laws enacted by Congress (EPA, 2004). Inferred is the fact that successful environmental problem-solving must encompass not only “what must be done” (setting a standard or risk management objective), but equally “how it shall be accomplished” (implementation and enforcement). Determining environmental standards, policies, guidelines, regulations, and actions requires making decisions considering this full spectrum. The quality of any decision and resulting action determines how well environmental programs actually work and the extent to which they achieve the health and environmental goals (EPA, 2001). There are many factors which impact the quality and success of any decision/action, and many of these are competing or contradictory forces such as

Legally defensible	<<<<<<<<<	>>>>>>>>>>	Clear and concise
Comprehensive	<<<<<<<<<	>>>>>>>>>>	Simple
Flexible	<<<<<<<<<	>>>>>>>>>>	Easy to implement
Sound analysis (Scientific and economic)	<<<<<<<<<	>>>>>>>>>>	Timely and inexpensive

The quality and/or acceptability of any decision is one which effectively balances these factors.

Determining environmental standards, policies, guidelines, regulations, and actions requires making decisions which are often contentious. Setting an environmental standard that is too lax may threaten public health or the environment, while a standard that is unnecessarily stringent may impose a significant marginal economic cost for small marginal gain. Environmental decisions are often time-sensitive, for example when public health is known or suspected to be at risk. The decisions must frequently be made with incomplete or imperfect information and many times under the additional pressure of heightened public scrutiny and concern. And, once made, the decisions are often challenged in court and subject to high levels of public and scientific scrutiny (EPA, 2004). As a result, making such decisions requires

- Rational support for answers to key questions
- Decisions based on current state of knowledge – certainty is not necessary
- Use means which are appropriate
- Estimate of confidence in decision

There are often conflicting interests than can have a bearing on environmental decisions, and as a result, it is well recognized that it is important to consider (and in some cases even mandated) a broad range of factors when making decisions about risk management including:

- Risk – nature, magnitude, severity, and likelihood of adverse outcomes/effects
- Economic factors — costs and benefits of risks and risk mitigation alternatives.
- Laws and legal decisions — framework that prohibits or requires some actions.
- Social factors — attributes of individuals or populations that may affect

their susceptibility to risks from a particular stressor.

- Technological factors — feasibility, impact, and range of risk management options

Role of Science

The credibility of EPA decisions depends on the science and analysis underlying those regulations. Ensuring that our regulations have a sound analytical foundation reduces both controversy and, to some extent, court challenges. It also increases the likelihood of compliance by the regulated community, which is key to achieving real environmental improvement (EPA, 2001) as well as public confidence.

As highlighted above, science is one factor of many which contribute to an overall decision. In reality, most decisions are based on a balance of many factors, and in some cases may even be influenced or determined by factors other than science (e.g., economic, political). Decisions influenced or directed by factors other than science is legitimate. However, there is a tendency for decision-makers to look to science to support or justify their positions ("the science made me do it"). Science is often viewed as objective, value-neutral, and concrete, and many feel that if science can support a decision it will be non-controversial and acceptable to the broadest range of stakeholders. Highlighting the fact that a decision was based on factors other than science highlights the underlying values supporting that decision. As a result, this may provide a motivation to influence or undermine the science to provide a supporting rationale. The distinction between science-informed decisions versus science-based decisions is critical. Quality and defensible decisions are those which are rational, where science is used to informed. Decisions supported by rationale alone are subject to criticism and challenge. To maintain the quality of environmental decisions we must ensure a science-informed focus, and the rest of this paper will provide an overview of how EPA approaches this.

Risk Assessment as Key Source of Scientific Information

As described in the *Risk Assessment Principles and Practices* staff paper (EPA, 2004), risk assessment is a key source of scientific information for making good, sound decisions about managing risks to human health and the environment. EPA conducts risk assessment to provide the best possible scientific characterization of risks based on a rigorous analysis of available information and knowledge — that is, a description of the nature and magnitude of the risk, an interpretation of the adversity of the risk, a summary of the confidence or reliability of the information available to describe the risk, areas where information is uncertain or lacking completely, and documentation of all of the evidence supporting the characterization of the risk. Risk assessment, therefore, informs decision makers about the science implications of the risk in question (EPA, 2004). The primary purpose of a risk assessment is not to make or recommend any particular decisions; rather, it gives the risk manager information to consider along with other pertinent information. To better understand the role of science in EPA, as manifested through risk assessment, I will focus on defining risk and risk assessment, the role of policy and judgment, and procedures or practices EPA uses to provide the highest quality information to decision-makers.

What is Risk?

Risk is an inherent consequence of life, and it is not possible to avoid or eliminate risk. Risk is a very elusive and often contentious concept, but in general, is a concept that denotes a potential negative impact or outcome that may arise from some present or future process. The definitions of risk depend on specific contexts or applications, and there are multiple dimensions to risk ranging from the tangible/quantitative to the psychological/emotional. For our purposes I will focus on Garrick and Kaplan, (1981) which described risk as consisting of three components: (1) outcome(s), (2) likelihood, and (3) severity. Most importantly it is the complete range of possible outcomes, their severity, and likelihood; and not just the actual outcomes which have occur or will actually occur. Another critical dimension of risk is uncertainty – the fact that outcomes are uncertain makes them risk, and unavoidable. These concepts are illustrated (highlighted) in the following quote

> "Reports that say that something hasn't happened are always interesting to me, because as we know, there are **known knowns**; there are **things we know we know**. We also know there are **known unknowns**; that is to say we know there are some things we do not know. But there are also **unknown unknowns** -- the ones we don't know we don't know. And if one looks throughout the history of our country and other free countries, it is the latter category that tend to be the difficult ones."
> Donald Rumsfeld, DoD News Briefing – February 12, 2002.

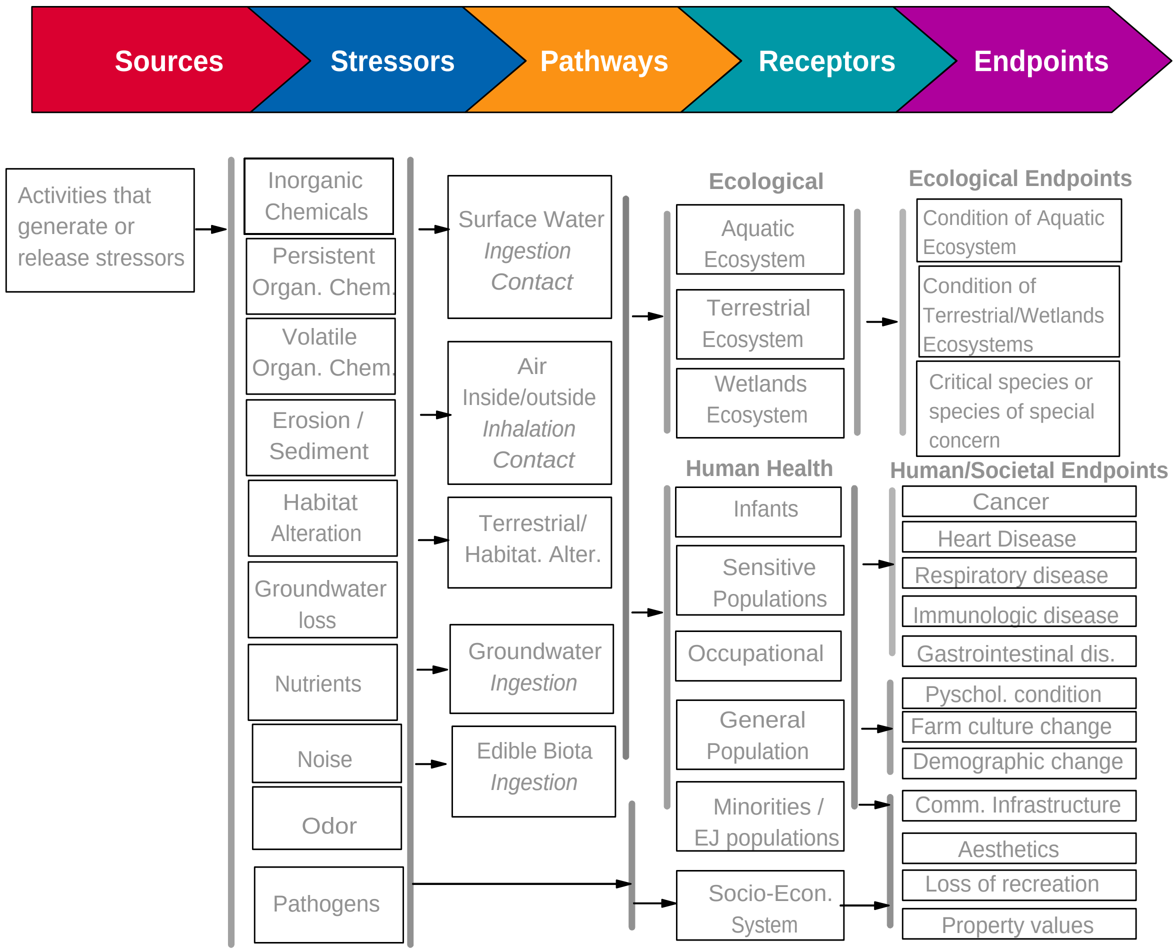
What is environmental risk?

If risk generally is the potential negative outcomes arising from current or future processes, what does this mean when we consider environmental risk. The environment is a complex and interconnected web of organisms, systems and processes at various levels of organization. Environmental risks can be described as the stressors (natural or anthropogenic) which negatively impact these systems. Inherent in the environment being a complex web of interdependent systems, any perturbation (stressor) can have a multitude of potential outcomes highlighting the range of possible outcomes aspect in the definition of risk. The figure below presents a general conceptual model of the theoretical pathways and routes of exposure between stressors (and sources of stressors) and effects (endpoints) for human and ecological receptors. Further complicating assessing environmental risks is that not only can there be a wide range of impacts associated with stressors in the environment, but that environmental releases, fate and transport (environmental concentrations), exposures (contact), and biological responses will tend to vary both spatially and temporally.

While the phrasing is different, and while different legal cases and interpretations certainly influence how these phrases are put into practice, EPA offices are faced with qualitatively similar mandates that point to at least some level of comparability between assessments. One way to state a general risk goal under these diverse mandates is to *protect an appropriate fraction of the population from exposures that produce unacceptable risk (of adverse effects), and to do so with some appropriate degree of confidence*. The basic attributes of any risk-based goal can be described as:

· Who are we protecting? – e.g., sensitive individuals, individuals, populations, communities

· What are we protecting them from? adverse effects – continuum of responses – perturbation of compensatory processes –> clinical signs – >



Generic Conceptual Model

disease

· What constitutes an appropriate degree of confidence in that protection?

The Need for Risk Assessment

Given the complexity of the nature of the environment, risk, and environmental risk, it is not feasible to measure or assess risks fully. As stated above, the natural environment is a complex web of systems at various levels of organization. The makeup of the environment and the mix of stressors (in both composition and magnitude) varies dramatically over time and space, and that the environment is comprised of interconnected systems which are not distinct.. As a result, it is not feasible to directly isolate or measure impacts with respect to any past or ongoing stressors, as well as in making predictions of future condition.

Any full analysis of risks must consider the entirety of the system and thus is interdisciplinary and draws on diverse fields such as biology, toxicology, ecology, engineering, geology, statistics, and even social sciences to create a rational framework for evaluating environmental hazards. The most powerful method of science – experimental observation – is inapplicable to the estimation of overall risk in exactly those instances where public policy most demands assessment of risk (Weinberg, 1981).

Risk assessment is used to address such situations and are produced for a particular purpose, to support the decision-making process. While risk assessment involves science and is a scientific activity, it is not science per se. Risk assessment focuses on questions which can be asked within the framework of science, but which are beyond the capacity of science to answer (through focused observational experimentation) and is thus "trans-scientific" (Cumming, 1981).

How to make risk assessment tractable and feasible?

The environment, risk and environmental risk are case-specific and too complex to capture fully. Any thorough assessment would be extremely resource intensive, and mostly infeasible, especially given the number of decisions and assessments. Therefore, there is a push toward reducing the resources demands of any assessment without compromising the overall quality of the assessment. As a result, in a general sense, the Agency has pursued the use of defaults, guidelines, and shared tools to reduce the resource requirements of assessments.

Defaults – given the inherent nature of uncertainties and data gaps, default assumptions are used to address these uncertainties. A default assumption is "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary (NRC, 1983). While often controversial in how they are developed and applied, the scientific community has long supported EPA's use of defaults as a reasonable way to deal with uncertainty (NRC, 1994).

Guidelines – Developed to help guide EPA scientists in assessing risks and to inform decision makers and the general public about those procedures. Specific guidelines cover various aspects of risk assessment (e.g., Carcinogen, Exposure, Neurotoxicity, Ecological) and are revised or new ones developed as experience and scientific understanding evolve.

Tools – Models, databases, and analytical frameworks to support or guide specific analyses.

While such approaches certainly promote efficiency and consistency, it can be viewed that this enforced procedural consistency has been substituted for serious evaluation of the consistency and overall desirability of the uncertain range of risk outcomes (Hattis and Anderson, 1999). It should also be noted, that these approaches each represent a simplification of the assessment. As a result, choices are made to simplify the problem, either in reducing the scope or the degree to which natural processes are fully captured.

An additional approach EPA pursues in making risk assessments tractable and feasible is the iterative approach to risk assessment. Risk assessments can be very complex and resource intensive, and may vary in terms of complexity and rigor. This is ultimately a balance of cost (resources) and uncertainty. The more complete or rigorous an assessment is the lower the uncertainty but the greater the cost, and vice versa the lower the rigor the lower the cost but the greater the uncertainty. The risk assessments are often geared toward the decision and the needs of the decision maker.

Judgment and normative values, and policy are unavoidable

While many science as objective and value neutral, in fact judgment is inherent and unavoidable both in conducting experimental observations and in the interpretation of those observations. For example, judgment is critical and unavoidable in stating a hypothesis, study design, sampling strategy, and statistical analysis. Furthermore, implicit in scientific inference is the role of professional judgment (Cranor, 2006). This is especially true or exacerbated in risk assessment which essentially consists of integrating vast amounts of data and evidence across multiple disciplines, which are not subject to verification through empirical observation.

Risk assessments are intended to support decisions which are influenced by statute, values, and policy; and therefore, to effectively support decision makers must address or account for these. Any decision on scope, underlying assumptions, analytical approaches, or how one responds to uncertainty is a decision informed by policy, judgment and statute. Each of these often has associated normative foundations which are then integrated into the assessment and in the end indistinguishable from the pure science. There are some who suggest that analysis should be value free or objective, without normative foundations. However, it should be noted that such an approach is itself value-laden decision. For if one were to focus on the "best" (e.g., maximum likelihood) estimate of an average person that is essentially focused on protecting the "average" individual and allows greater risk and harm to those more susceptible, or against risks which have not yet been conclusively proven.

As noted above, given the inherent nature of uncertainty and data gaps, it has become accepted practice to use defaults to address these uncertainties. The use of default options have long been supported (e.g., NRC, 1983 and 1994) though they noted that the principles for choosing defaults goes beyond science and inevitably involves policy choices. These defaults can be incorporated into or serve as the foundation for general EPA guidelines (e.g., linear low-dose extrapolation) or specific assessments (e.g., exposure or parameter values). EPA in general, uses defaults that are conservative (i.e., they represent a choice that, although scientifically plausible given existing uncertainty, is more likely to result in overestimating rather than underestimating risk). EPA believes this conservative bias is aligned with their mission of protecting public health and the environment (EPA, 2004). It should be noted that conservatism may have different meanings in differing contexts, and only reflects the type of decisions errors one is minimizing. For example, in cost-benefit analysis "conservative" estimate of benefits are generally those which are not likely to be overestimates.

The use of conservative defaults has long been the basis for criticism levied at EPA risk assessment practices. These critics contend that EPA has so overemphasized the principle of conservatism that most risk estimates are alarmingly false, meaningless, and unscientific. First, it should be noted that the use of "conservative" defaults do not render the process or results non-scientific. Given that risk assessments inevitably involve varying degrees of scientific uncertainty, although science remains a necessary element of risk management decisions, it may be insufficient in the regulatory process. As uncertainty increases, it is unavoidable that risk management decisions become more conservative in nature and this is not necessarily unscientific (Rogers, 2000). Others have suggested that if anything, the claims of these critics (of conservatism) tend to be more reflexive, undocumented by evidence, and exaggerated than are EPA's risk estimates themselves (Finkel, 1989). "(S)ome of the intensity marking this debate is due to a variety of mis-impressions about what conservatism is and what its ramifications are." (NRC, 1994)

Regardless of one's position, judgment and values are inherent and unavoidable in risk assessment. Therefore, at best one must be transparent.

Statutory Influences in Risk Assessment

As noted in the EPA Staff Paper (EPA, 2004), despite standardized guidelines and methodologies, apparent inconsistencies in risk assessment practices across the Agency may stem from differences found in the statutory language. Such language on risk and protection varies, opening the way for subtle differences in interpretation (e.g., margin of safety, protect public welfare, unreasonable risk, protect sensitive resources, reduce overall risks, function without adverse effects). Examples among major program offices illustrates some of the differences:

- ...to assure chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment (OPPTS; TSCA §2(b)(3))
- ...function without unreasonable and adverse effects on human health and the environment (OPPTS; FIFRA §3)
- ...necessary to protect human health and the environment (OSWER; RCRA §3005 as amended)
- ...provide the basis for the development of protective exposure levels (OSWER; NCP §300.430(d))
- ...adequate to protect public health and the environment from any reasonably anticipated adverse effects (OW; CWA §405(d)(2)(D))

Even the statutory language used for different statutes administered within one major office, OAR, shows differences:

- ...protect public health with an adequate margin of safety (OAR; CAA §109)
- ...provide an ample margin of safety to protect public health or to prevent an adverse environmental effect (OAR; CAA §112(f))
- ...protect the public welfare from any known or anticipated adverse effects (OAR; CAA §109)
- ...(not) cause or contribute to an unreasonable risk to public health, welfare, or safety (OAR; CAA §202(a)(4))
- ...protect sensitive and critically sensitive aquatic and terrestrial resources

(OAR; CAAA §404 (Appendix B))

- ...reduce overall risks to human health and the environment (OAR; Title VI of CAA)
- ...actions to mitigate environmental and health risks (OAR; SARA Title IV)

In addition to the variability of the language found in the various statutes EPA administers, the purpose and scope of a risk assessment can differ. As a result, it is not surprising then that differences in terms can lead to subtle and maybe significant differences in risk assessment practices across the EPA.

Limits of Risk Assessment

As outlined above, risk assessment represents the key source of scientific information in making decisions about managing risks to human health and the environment. Risk assessment is a necessary tool used to inform decisions where direct measurements are not possible. However, one must also be aware of the nature of risk assessment so as not to place undue and unreasonable demands. While risk assessment is the key source of scientific information, it is not a science. Risk assessments are only an approximate, incomplete, and unverifiable description of reality. While risk estimates are not absolute predictors of risk or description of truth they can provide useful information to decision-makers. After all, "all models are wrong, some are useful."

Uncertainty is inherent and unavoidable in risk assessment, and this does impugn the integrity and/or the utility of any risk assessment its results. While uncertainty greatly impacts the ability to develop environmental policy and regulation, it does not necessarily prevent action. Risk management is characterized by decisions and actions in the face uncertainty, and public health in general requires such actions. The courts have long deferred to Agency's discretion in responding to uncertainty so the presence of uncertainty does not challenge specific decisions, rules or regulations.

Insuring Quality Science Supporting EPA Decisions

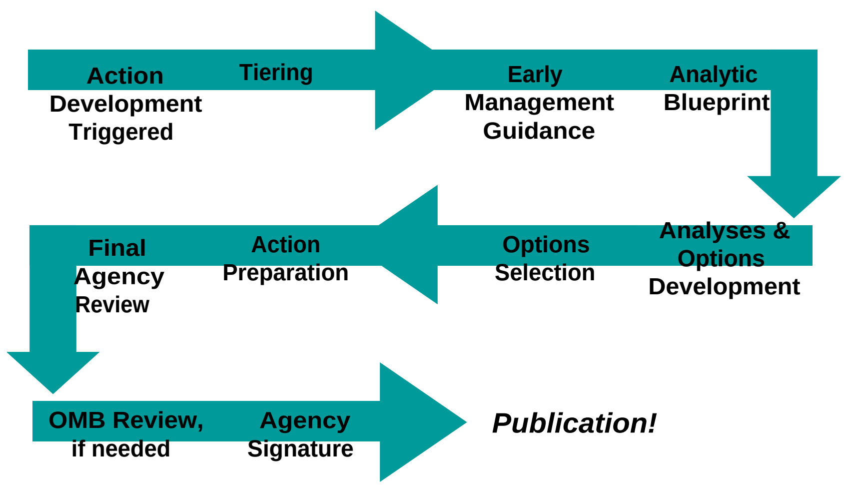
Given all of the limitations of risk assessment -- the need to balance resources with detailed analysis, implicit normative aspects, uncertainty, and context-specific nature of these assessments – how can we insure that they are of the highest quality? The EPA has an ongoing commitment to ensure the quality of information used to support Agency decisions and actions. Such efforts are achieved through existing policies, systems and programs which are broadly discussed in the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA Information Quality Guidelines) (EPA, 2002). The quality of science and analysis that underlie EPA regulations is vital to the credibility of EPA decisions and ultimately our effectiveness in protecting human health and the environment (EPA, 2001). In April of 2001, Administrator Whitman, EPA requested that the Agency reexamine it's regulatory process and identify ways to strengthen and improve the quality of supporting scientific, economic, and policy analysis. In general, the Task Force (EPA, 2001) found that existing system for developing regulations is well designed, but that certain areas need improvement.   Task force recommendations include

- reaffirm the Action Development Process
- reaffirm the need for Analytical Blueprints
- reaffirm need for Agency involvement in the Options Selection process

Action Development Process (ADP) (EPA, 2004b)

EPA publishes hundreds of actions a year that define the technical and operational details of environmental programs. Some actions are fairly narrow and routine, while others may be broad and complex, but all must be of consistently high quality. The ADP is a method for producing quality actions and ensures that we use quality information to support our actions and ensures that scientific, economic, and policy issues are adequately addressed at the right stages in action development.. Quality actions have common characteristics, they:

- Achieve environmental objectives cost-effectively;
- Are consistent with legal requirements, executive orders, directives, Agency guidance, and national policies;
- Reflect EPA-wide involvement when necessary, in particular, involvement of offices with cross-cutting responsibilities;
- Reflect appropriate consideration of the views outside EPA;
- Consider multimedia effects;
- Consider pollution prevention principles and innovative alternatives during the investigative and development process;
- Are based on sound economic, scientific, legal, policy, and technical analyses;
- Can be efficiently implemented and effectively enforced;
- Are clear, concise and written in plain language; and
- Are timely.



At each step in the ADP (depicted here), the soundness of any scientific analysis or information is reviewed and assessed. Given that resources are not always available to maximize all of the characteristics of quality actions. As a result, decisions are often made to focus an assessment to insure that it is practical, feasible and useful. Science considerations play a prominent role in such discussions which occur during:

Early Management Guidance - Purpose to establish priorities and expectations early

- Identify major policy, economic and scientific issues to consider

Analytical Blueprint

- Identify information and scientific analyses that would help inform the decision
- Identify resources and schedule for completing work
- Serves as up-front agreement on technical approach
- Addresses statutory and executive orders

General Assessment Factors (EPA, 2003)

EPA relies on information integrated across a broad range of disciplines to develop an overall assessment. This weight-of-evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together. Integrating a body of evidence depend on the type of decision or action being undertaken. While there may be specific guidance on how weight-of-evidence is approached for specific applications (e.g., carcinogenicity) there is still a need to guide such a process more generally for different uses, which are provided in the General Assessment Factors. When evaluating the quality and relevance of scientific and technical information, the considerations that the Agency typically takes into account can be characterized by five general assessment factors:

Soundness *- The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.*

Applicability and Utility *- The extent to which the information is relevant for the Agency's intended use.*

Clarity and Completeness *- The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.*

Uncertainty and Variability *- The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.*

Evaluation and Review *- The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.*

These assessment factors reflect the most salient features of EPA's existing information quality policies and guidelines. Whether the information consists of scientific theories, computer codes for modeling environmental systems, environmental monitoring data, economic analyses, social survey or demographic data, chemical toxicity testing, environmental fate and transport predictions or a human health risk assessment, EPA generally evaluates information by weighing considerations that fit within these five assessment factors. Thus, these factors encompass considerations that are weighed in the process of evaluating the quality and relevance of information. The appropriate level of quality for any particular information product is necessarily related to how and in what context the information is to be used

Peer Review (EPA, 2006)

Strong, independent science is of paramount importance to quality of EPA policies and actions, and the credibility of those actions. One important way to ensure decisions are based on defensible science is to have an open and transparent peer review process. Consistently Agency -wide implementation of peer review has been an EPA priority for many years. EPA issued its first Peer Review Policy in 1993, it s first Peer Review Handbook in 1998 which was updated in 2000 based on feedback from EPA's science community. In response to OMB's 2004 "Final Information Quality Bulletin for Peer Review", EPA again revised its Peer Review Policy and Handbook accordingly. This policy encourages and expects peer review of all scientific and technical information that is intended to inform or support Agency decisions. For any particular product, such a peer review may be **internal** (reviewers are independent experts from inside EPA) and/or **external** (reviewers are independent experts from outside the EPA). The policy also notes that for influential scientific information, including highly influential scientific assessments, peer review is expected, and that external peer review is the preferred approach of choice.

Where can/does it go wrong?

The EPA has developed numerous systems, procedures, and processes to ensure that the highest quality science is used to support EPA decisions. Despite these, there are often concerns, real or perceived, that science is improperly used or characterized to support specific decisions. Not to say that these have or do occur, to spark discussion I have outlined a few points which may be susceptible to or lead to improper use or characterization of science.

Project scoping (early guidance) - As risk assessments are intended to meet specific purposes, supporting specific decisions, it is critical that proper input and direction be obtained from the decision-maker as to what is important to the decision, to identify specific issues and technical approach. However, the potential exists to use this phase to define a desired outcome rather than issues and technical approach. Also the potential exists to selectively define the problem to meet a predetermined outcome or action.

Inappropriate demand for certainty - Risk assessment uses a systematic approach to estimating or characterizing an (albeit incomplete) "illustration of the world". Uncertainty, defined as a lack of precise knowledge as to what the truth is (qualitative or quantitative) is inherent in this illustration. As such, it cannot demand the certainty and completeness of science.

Inappropriate targeting of specific uncertain elements - Risk assessments are very complex and require the integration of information across a broad range of disciplines, and often consist of numerous components each with models and multiple parameters. Uncertainty is inherent and unavoidable in the overall assessment as well as in each component. The uncertainties for any component, model, or parameter can be focused on to impugn the integrity of the overall assessment or to initiate a detailed and protracted debate. Such efforts may focus on (albeit uncertain) elements which may have little or no impact on the overall assessment or the decision.

Limited resources - Risk assessments are highly complex and thorough assessments are resource intensive, and it is not possible to conduct such assessment for every application. As described above, the EPA attempts to balance the resource demands to the needs of the decision to ensure the assessment is reasonable and appropriate for a specific decision which may impact the overall uncertainty in any assessment. Furthermore, it is not uncommon for review of risk assessments by outside parties to consume more resources in reviewing those assessments than were expended in the conduct of the assessment in the first place. As a result, specific uncertainties can be highlighted (in support of the previous two bullets).

Misuse of process / administrative requirements - There are numerous administrative demands and burdens outlining the conduct and use of risk assessments. Many of these (e.g., Circular A-4 requirement for full probabilistic analysis) may pose undue or unreasonable demands on specific assessments which are either not possible given the current state of knowledge or infeasible given finite resources. As a result, it is not possible to meet all requirements to their fullest extent for all assessments. While not fully meeting all requirements does not necessarily impugn the overall integrity or utility of a particular assessment, it does make these assessments susceptible to challenge. Specific controversial assessments may be challenged or targeted through selective enforcement of requirements.

Who decides on quality of science and when? – The ADP delineates who evaluates the quality of science and when, though it is less clear for external review. OMB has a clear role in reviewing Agency actions and supporting analysis though there are several avenues such evaluation may occur. Review of Agency regulatory packages is the most prominent, however, additional review may occur via other authorities such as their general Information Quality Guidelines, those specific to Peer Review, and most recently the Good Guidance Practice. Given the ambiguity of many provisions or definitions, they have wide flexibility to identify specific products at varying steps in the process. Additionally, much of their review may not be publicly transparent.

Differentiating science from policy - As described above, risk assessments are intended to support decisions not purport “truth”and is considered a “trans-science” activity. As a result, judgment and normative aspects are inherent in any risk assessment, and science is not easily discretely defined. Being relative indistinguishable from policy it makes risk assessment susceptible to challenge under rubric of policy and law, and the processes for resolving such matters which are more subjective than typical rules of science. As a result, it may be difficult to challenge the use of science as rationale (policy interpretations) as opposed to preferred approach of using science in a rational process for decisions.

What can we do to improve/maintain role of science?

Environmental decision-making and risk assessment are not scientific but rather utilize and rely on science as their foundations. These activities can bet be described as a weight of evidence provided by all available scientific data, and other relevant information and considerations. Since risk assessment and environmental decisions are complex and rely on multiple disciplines, the weight-of-evidence judgment requires combined input of these relevant disciplines (e.g., toxicology, biology, chemistry, epidemiology, statistics, engineering). While views of the "state of the world" may change significantly when other data are brought into consideration, the overall decision is based on the totality of the evidence and no single study, whether positive or negative, drives the overall weight-of-evidence judgment. Judgment on the weight of evidence involves consideration of the quality and adequacy of the available data and consistency across lines of evidence.

Weight of evidence (WOE) is a commonly accepted but elusive concept. WOE is a common term in the scientific and policy-making literature but its definition is unclear, and defies categorization, and variably applied. Clearer and more transparent definitions of what is meant by "weight of evidence" and how it is used will enhance the quality of risk assessments used to protect and improve public health and the environment (Weed, 2005). Having a formal definition can lead to a more formal description of the process as well and clearly delineate scientific evidence and how it is used. Crawford-Brown (2005) has proposed such a framework defining the concept of "sound science" as a dialogical process rooted in rational exploration of the evidence. This focus on rationality if formalized could greatly reduce the desire or ability to use science as rationale, thereby maintaining its integrity and minimize the potential, perceived or real, to manipulate science.

Should such a framework be agreed upon and defined, the next step would be to formalize the process. With formal schemes in place, there is a basis upon which to evaluate science, and more importantly evaluate how science is used. Finally, transparency is the foundation of a democratic society and it is critical to ensure quality decisions and public confidence. Related to transparency is accountability to the process and the decisions.

A related point is the acknowledgment that uncertainty is inherent and unavoidable, and that decisions are made in light of such uncertainty. As a result, we cannot expect perfect decisions but rather hope for the "best" decisions under the current state of knowledge. The courts have continuously deferred to Agencies and provide them the flexibility to act appropriately given attendant uncertainties. If we had complete information or "truth" about the state of our world we would make an optimal choice which maximizes the benefits of a risk reduction or control mitigation measure relative to the cost (impact) of that measure. However, given the inherent uncertainty, a chance that the wrong decision will be made is unavoidable. Such an acknowledgment on the part of the decision makers and especially the public may minimize the need for definitive answers and misuse or mischaracterization of science to support any specific decision. While this will not alleviate the pressures to hide political decisions as scientific, it will hopefully be major step forward.

References

Cranor, C., 2006. Toxic Torts: Science, Law and the Possibility of Justice
Crawford-Brown, D., 2005. The Concept of "Sound Science" in Risk Management Decisions, *Risk Management: An International Journal*, January 2005, 7(3): 7-20

Cumming, R.H., 1981. Is Risk Assessment a Science?, *Risk Analysis*, 1(1): 1-3.

EPA, 2001. *Improving EPA Regulations*, Task Force Report, Washington, DC.

EPA, 2003. *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, Science Policy Council, Washington, DC. EPA 100/B-03/001

EPA, 2004 *Risk Assessment Principles and Practices*, Office of Science Advisor, Washington, DC., EPA/100/B-04/001, March 2004

EPA, 2004b. *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions*, OPEI Regulatory Development Series, Washington, DC., June 30, 2004.

EPA, 2006. *Peer Review Handbook*, 3rd Edition, Science Policy Council, Washington, DC, EPA/100/B-06/002

Weed, D.L, 2005. Weight of evidence: A review of concept and methods, *Risk Analysis*, 25: 1545-1557.

Weinberg, A.M., 1981. Reflections on Risk Assessment, *Risk Analysis*, 1(1):5-7.