

Reviews and Meta-Analysis

Evolution of public participation in the assessment and management of environmental health risks: a brief history of developments in the United States

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Significance for public health

Risk-based decision making is a core feature of government actions aimed at protecting public health from the adverse effects of environmental hazards. In the past, it has often been an expert-driven, mostly obscure process used by federal agencies to justify and defend regulatory decisions made outside the public arena. But the nature of decision making has changed as it has become apparent that environmental health problems are more complicated, controversial, and costly to solve than originally thought. Meaningful public engagement is now an inherent component of all phases of the risk assessment – risk management paradigm because it promotes stakeholder buy in, taps into unique stakeholder knowledge, and promotes the concept of environmental democracy.

Abstract

In the United States, the risk assessment – risk management paradigm that underpins federal decisions about environmental health risks was first established in 1983. In the beginning, the importance of public participation was not explicitly recognized within the paradigm. Over time, however, it has become evident that not only must risk-based decisions be founded on the best available scientific knowledge and understanding, but also that they must take account of the knowledge, values, and preferences of interested and affected parties, including community members, business people, and environmental advocates. This article examines the gradually expanding role of public participation in risk-based decision making in the United States, and traces its evolution from a peripheral issue labeled as an *external pressure* to an integral element of the 21st century risk assessment – risk management paradigm. Today, and into the foreseeable future, public participation and stakeholder involvement are intrinsic features of the emerging American regulatory landscape, which emphasizes collaborative approaches for achieving cooperative and cost-effective solutions to complicated and often controversial environmental health problems.

Introduction

The socially-constructed and culturally-mediated concept of *risk* is used to give meaning to things, forces, or circumstances that are deemed to pose danger to people or what they value.¹⁻³ *Risk assessment* in various forms has been used for centuries by individuals and societies to evaluate particular hazards that they believe to be of special concern.^{2,4} After World War II, many industrialized societies began to

view risk from injurious by-products of technology and economic activity as a noxious quality present to varying degrees in diverse geospatial locations and environmental settings. In today's world, the principal method for describing environmental health risks is through a quantitative, or at least semi-quantitative estimation of the likelihood and severity of harm resulting from exposure to recognized hazards.⁵⁻⁸ Proponents of this approach assert that risk assessment is a valuable decision-making tool for identifying, evaluating, and resolving environmental health problems.^{5,7-10} Critics, on the other hand, tend to see it as an ethically suspect, resource-intensive, elitist, never-ending process used by those in power to maintain the *status quo*.¹¹⁻¹⁷

In the United States, the U.S. Environmental Protection Agency (EPA) is required by federal statutes, such as the Clean Air Act, Safe Drinking Water Act, Toxic Substances Control Act (TSCA), and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to make decisions about safeguarding human health and environmental quality from the harmful effects of environmental hazards. The conceptual framework underpinning these decisions is often referred to as the risk assessment – risk management (RA-RM) paradigm.¹⁸⁻²² The RA-RM paradigm consists of three complementary, sequential, and overlapping components: i) risk-related research to provide necessary scientific information and understanding; ii) risk assessment to organize and analyze available scientific data in order to estimate the likelihood, magnitude, and uncertainty of risks; and iii) risk management to evaluate both facts and values so as to determine which risks are unacceptable and what, if anything, to do about them. A fourth component, risk communication, is often considered part of the RA-RM paradigm, and refers to efforts aimed at explaining risks and risk-related decisions to stakeholders and responding to their questions and concerns.²³

The RA-RM paradigm was established in 1983 through publication of the landmark National Research Council (NRC) report, *Risk Assessment in the Federal Government: Managing the Process*, usually referred to as the *Red Book*.¹⁸ The NRC was established by a charter granted to it by the U.S. Congress in 1863, which calls on this society of distinguished scholars to provide advice to the U.S. government on scientific and technical matters. Since it was first enunciated, the RA-RM paradigm has evolved considerably as new research methods and better scientific data became available, and it became obvious that environmental health risks were more complicated and expensive to solve than initially supposed. At the outset, the process of risk-based decision making was seen as an expert-driven, largely opaque method for justifying decisions by regulatory agencies. Over time, however, it has become apparent that regulatory decisions need to be based on more than just technical expertise – they need to be informed by input from stakeholders and the public in order to improve the quality, legitimacy, and capacity of risk-based decisions.^{19-22,24} The following discussion looks at how public participation in the RA-RM paradigm has

evolved since 1983, where *public participation* is defined to mean organizational processes adopted by the EPA and other regulatory agencies to engage stakeholders, directly affected groups, interested observers, and the general public in decisions about assessment and management of environmental health risks. The goal is to highlight key changes to the RA-RM process and examine important lessons learned.

Public participation in federal environmental decisions

The impetus for public participation and the challenges encountered during implementation occur within the context of risk-based decision making by EPA and its sister regulatory agencies. Although scientific analysis is a necessary component of these decisions, it is not sufficient, by itself, to ensure proper consideration of tradeoffs among risks, costs, and benefits or their appropriate distribution across human populations. There is broad consensus as well as statutory requirements that i) risk-based decisions be founded on the best available scientific evidence and technical judgments, and ii) that they also take into account the knowledge, values, and preferences of interested and affected parties. According to the NRC, it is critical, therefore, to acknowledge that decision making about environmental health risks is inherently a political process, which depends *not only on factual information, but also on values and preferences and on interpretation of factual information.*²⁴

Aside from the statutory requirements, there are continuing debates about why EPA should involve the public as an integral part of the RA-RM paradigm and the costs and benefits of doing so. Those favoring public participation typically base their arguments on normative theories of democracy and collective action or on substantive and instrumental justifications related to improving quality, enhancing legitimacy, and building capacity.^{20,25} Critics, including academics and practitioners concerned about issues of practicality, transaction costs, and efficient decision-making, usually question the basic logic of public involvement in complicated scientific judgments.^{20,24,26-29} They argue on practical grounds that the costs are not justified by the benefits, and that attempts to reach consensus among multiple stakeholders with conflicting values and diverging interests are either unsuccessful or lead to inconsequential results that reflect the lowest common denominator. The reality is that decisions about the desirability of public involvement and the design of appropriate participation processes are value judgments that reflect the political power of certain stakeholders to influence those choices.²⁴

Public participation in environmental decision making at the federal level has been institutionalized since 1946 by the Administrative Procedure Act (APA), which established general procedures to be used by all agencies for developing policy, promulgating rules, notifying the public and other agencies of intended actions, requesting public information, disseminating information to the public, and receiving comments from the public and other agencies (5 U.S.C. §§551-559, 701-706). The APA recognized the right of the public to know about, contribute to, and monitor the actions of federal agencies, and it established the Federal Register as an official mechanism for information dissemination and solicitation. Although the APA did not call for public involvement in the actual decision-making itself, it did create requirements and procedures for public participation in the information gathering and feedback phases of the process.²⁴

More than 20 years later, in 1969, the National Environmental Policy Act (NEPA) required federal agencies to inform one another and the public about the expected environmental, economic, and social ramifications of their proposed actions. Whereas the APA required agencies

to make relevant documents available to the public, the NEPA guaranteed access to public information and the right to be heard before the final decision was made. In 1970, President Richard M. Nixon issued Executive Order 11514 (March 7, 1970, 35 F.R. 4247), which increased the public notice requirements established by NEPA so that federal agencies were required to *Develop procedures to ensure the fullest practicable provision of timely public information and understanding of Federal plans and programs with environmental impact in order to obtain the views of interested parties.*²⁴

The 1970s saw increased support for public participation in environmental assessment and decision making. The Federal Advisory Committee Act (FACA) of 1972 mandated standards and procedures to assure that federal advisory committees served public rather than private interests, and required that committee composition fairly balance competing viewpoints and biases. In 1978, the Council on Environmental Quality (CEQ) expanded NEPA requirements by compelling federal agencies to ascertain which issues the public believed were important as part of the initial scoping process for environmental impact assessments.²⁴

Today, federal agencies have significant latitude in determining who to involve in environmental decision making, when they are involved, the type and intensity of involvement, the influence of public participation on the final decision, and the goals of the participation process. Officially sanctioned processes and procedures for public participation typically aim to achieve one or more of six main objectives: i) improve the quality of decision output; ii) represent values and preferences in proportion to their prevalence in the affected population; iii) encourage competition of arguments with respect to criteria of truth, normative validity, and truthfulness; iv) use common sense as the final arbiter in disputes, *e.g.*, the jury model; v) empower less privileged groups and individuals; and vi) demonstrate the variability, plurality, and legitimacy of dissent.^{24,30} Nevertheless, concerns remain that public participation might damage the decision-making process through unintended consequences and increased transaction costs. Criticisms generally fall into four main categories: i) public participation may descend into political manipulation; ii) public participation may impair decision quality, particularly the use of scientific evidence; iii) public participation does not necessarily guarantee fairness and equity; and iv) public participation may produce trivial or undesirable results at substantial costs.^{24,31-33} So, while there is general agreement that people whose lives are affected should have a say in environmental health decisions, there is still considerable debate about how best to integrate values and judgment into the science-based process of assessing and managing risks.

Public participation in the assessment and management of risk

Since publication of the NRC's *Red Book* in 1983,¹⁸ four major trends in the evolution of the RA-RM paradigm are evident. First, a consensus has emerged that it is important at the outset to develop a shared understanding of the context, formulation, and scope of the problem being addressed, including concurrence among participants about a suitable risk management approach.^{21,24} Second, it is now widely accepted that socioeconomically and politically disadvantaged communities, many of whom are ethnic and racial minorities, are likely to be more vulnerable to the adverse effects of environmental stressors because they tend to be both more exposed and more susceptible than the general population.³⁴⁻³⁸ Third, there is broad-based agreement among both experts and stakeholders that the domain of risk assessment must expand beyond single chemicals, individual emission

sources, and specific exposure pathways and routes to encompass combined health effects from exposures to multiple chemical and non-chemical stressors via all relevant modes of exposure.^{21,39-45} And fourth, public participation is now an explicit and intrinsic part of EPA's process for assessing and managing environmental health risks.^{18-22,46-49} The progression of public participation in the RA-RM paradigm can be traced through a series of influential public-sector reports that document its increasingly pivotal role over the past 30 years.

In the NRC's *Red Book*,¹⁸ the emphasis was on establishing the basic four-step framework (*i.e.*, hazard identification, dose-response assessment, exposure assessment, risk characterization) for risk assessment and clarifying the interconnected and mutually supportive relationships among scientific research, risk assessment and risk management in the decision-making process. As shown in Figure 1, the NRC did not include public participation as an explicit component of the RA-RM paradigm. The report deemed *public concern* to be an external pressure and recommended that *detailed guidelines setting forth the scientific and policy bases of risk assessment could improve public understanding and help dispel the impression that government actions are based on tenuous and inadequate reasoning*. The NRC noted that public perceptions of risk and risk-based decisions could be inaccurate and inappropriate if government agencies do not provide suitable and timely information to the interested parties. The NRC further recommended that *before an agency decides whether a substance should or should not be regulated as a health hazard, a detailed and comprehensive written risk assessment should be prepared and made publicly available. This written assessment should clearly distinguish between the scientific basis and the policy basis for the agency's conclusions*. They went on to say that *the written assessment should be made accessible to the public at a time and in a form that facilitates public participation in any attendant risk management decision*. This is the first mention by the NRC of the need for public participation in the RA-RM paradigm.

Eleven years later in 1994, the NRC published a reappraisal of the RA-RM paradigm, titled *Science and Judgment in Risk Assessment*.¹⁹ Although the report focused primarily on risk assessment practices and strategies for improving them, it noted that the RA-RM paradigm had come under increasing criticism pertaining to both the conduct of risk assessments and the relationship between risk assessment and risk management. The committee affirmed that social and cultural factors were important and might alter risk management priorities when taken into account. They also observed that people's perceptions of environmental health risks do not necessarily match those of technical experts, and that public opinion about the need for regulations is influenced by factors such as trust in government, experience with expert judgments, and attitudes about social justice. Among the committee's recommendations was for EPA to *fully communicate to the public each risk estimate, the uncertainty in the risk estimates, and the degree of protection*. However, no changes related to public participation in the RA-RM paradigm were proposed.

The NRC report *Understanding Risk: Informing Decisions in a Democratic Society* was released in 1996.²⁰ In it the NRC proposed reinterpreting risk characterization as a combination of analytical and deliberative processes that would increase the likelihood of achieving sound and acceptable risk-based decisions (Figure 2). The committee identified broad public participation by interested and affected parties as one of the essential aspects of this change, and listed three fundamental reasons for involving the public in the RA-RM paradigm; i) it is consistent with the principle that government should obtain the consent of the governed; ii) risk-related wisdom is not limited to scientific specialists and public officials, which suggests that participation by diverse groups and individuals will interject new information and practical insights into the decision-making process; and iii) meaningful participation by a broad-based constituency is likely to increase acceptance and build trust in risk-related decisions. The committee felt that

deliberations about risk characterization should occur prior to any agency proposals or actions, and that they should be aimed at improving mutual understanding of risk situations through collaborative exchanges in which public officials, risk experts, and key stakeholders share information and ideas while interacting as equals.

In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM) published its report *Framework for Environmental Health Risk Management*,²² which introduced a new conceptual process for managing environmental health risks. The commission defined a six-stage procedure for making good risk management decisions: i) define the problem; ii) analyze risks associated with the problem in context; iii) examine options for addressing the risks; iv) make decisions about which options to implement; v) take action to implement the decisions; and vi) conduct an evaluation of the actions. All six phases were to be conducted in collaboration with stakeholders as active partners so that different technical perspectives, public values and perceptions, and community ethics are

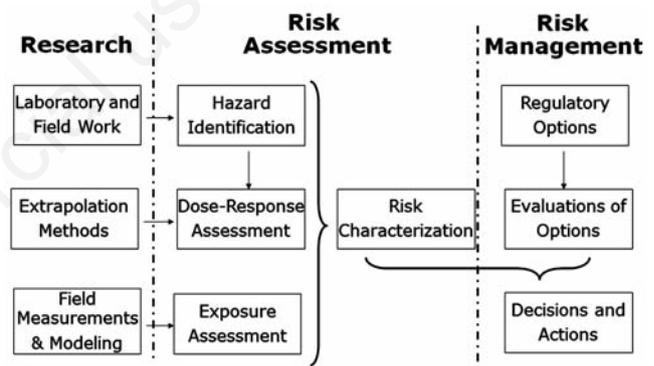


Figure 1. The risk assessment-risk management paradigm established in the 1983 NRC report. Reproduced with permission from *Risk assessment in the federal government: managing the process*, 1983, by the National Academy of Sciences, courtesy of the National Academies Press, Washington D.C.¹⁸

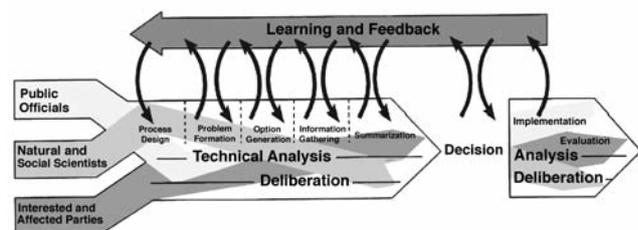


Figure 2. The conceptual framework for risk-based decision making proposed in the 1996 NRC report. Reproduced with permission from *Understanding Risk: Informing Decisions in a Democratic Society*, 1996, by the National Academy of Sciences, courtesy of the National Academies Press, Washington D.C.²⁰

considered (Figure 3). Recommendations were made to establish a process for engaging stakeholders, and a set of guidelines for stakeholder involvement was proposed (Table 1). The PCCRARM listed seven benefits of involving stakeholders in the risk management process: supports democratic decision-making; ensures that public values are considered; develops the understanding needed to make better decisions; improves the knowledge base for decision-making; reduces overall time and expense of decision-making; improves the credibility of agencies responsible for managing risks; and fosters risk management decisions that are better accepted and more readily implemented.²²

The NRC's *Science and Decisions: Advancing Risk Assessment*,²¹ also known as the *Silver Book*, was published in 2009. It provided a scientific and technical review of current risk-analysis concepts and practices at the EPA and offered recommendations for practical improvements. The committee proposed that the RA-RM paradigm first established in 1983 be modified to include three distinct phases: phase 1, problem formulation and scoping; phase 2, planning and conduct of risk assessment; phase 3, risk management (Figure 4). Formal provisions were to be made for internal and external stakeholder involvement in all three phases because the committee *recognized that greater stakeholder involvement is necessary to ensure that the process is transparent and the risk-based decision-making proceeds effectively, efficiently, and credibly*. The NRC recommended that *EPA should establish a formal process for stakeholder involvement in the framework for risk-based decision-making with time limits to ensure that decision-making schedules are met and with incentives to allow for balanced participation of stakeholders, including impacted communities and less advantaged stakeholders*.²¹ The NRC committee observed that without meaningful stakeholder involvement, there is no way to assure that risk-based decision-making will be satisfactory and, in fact, that decisions will be unavoidably incomplete in the absence of such involvement. They went on to point out that the box representing stakeholder involvement at the bottom of Figure 4 spans all three phases of the RA-RM paradigm, and that the two-headed arrows are meant to represent the necessity of two-way communication. The committee opined that *adequate stakeholder involvement and communication among those involved in the policy and technical evaluations are difficult to achieve, but they are necessary for success. It is time that formal processes be established to ensure implementation of effective stakeholder participation in all stages of risk assessment*.²¹

Looking ahead at public participation in risk-based decisions

Over the past three decades, the role of public participation has expanded from being only a peripheral concern labeled as an *external pressure* in the 1983 *Red Book*,¹⁸ to being formally incorporated into the RA-RM paradigm in the 2009 *Silver Book*.²¹ It is now the NRC's position that stakeholder involvement needs to be an integral part of all phases of risk-based decision making, including problem formulation and scoping, planning and conduct of risk assessments, and decisions about risk management options. Most observers and participants agree

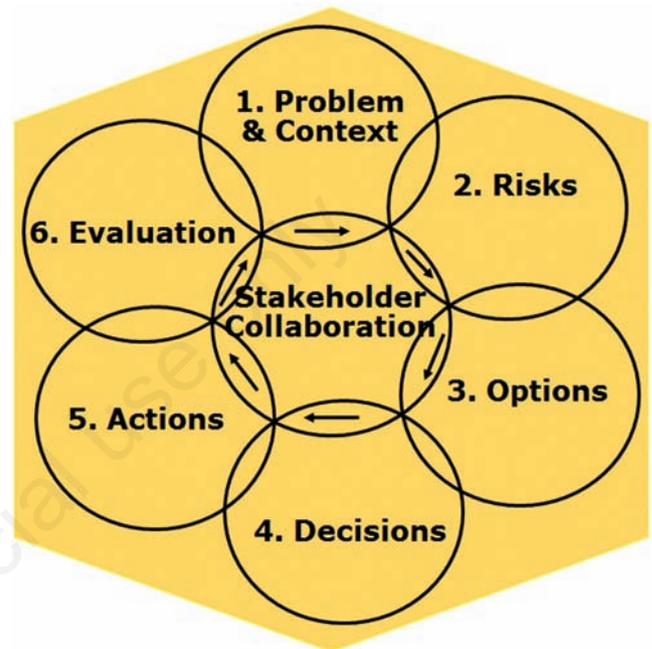


Figure 3. The framework for risk management proposed in the 1997 report by the Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM), *Framework for Environmental Health Risk Management*.²²

Table 1. Proposed guidelines for stakeholder involvement in risk management decisions from the 1997 report, by the Presidential/Congressional Commission on Risk Assessment and Risk Management.²²

1	Regulatory agencies or other organizations considering stakeholder involvement should be clear about the extent to which they are willing or able to respond to stakeholder involvement before they undertake such efforts. If a decision is not negotiable, don't waste stakeholders' time
2	The goals of stakeholder involvement should be clarified at the outset and stakeholders should be involved early in the decision-making process. Don't make saving money the sole criterion for success or expect stakeholder involvement to end controversy
3	Stakeholder involvement efforts should attempt to engage all potentially affected parties and solicit a diversity of perspectives. It may be necessary to provide appropriate incentives to encourage stakeholder participation
4	Stakeholders must be willing to negotiate and should be flexible. They must be prepared to listen and to learn from diverse viewpoints. Where possible, empower stakeholders to make decisions, including providing them with the opportunity to obtain technical assistance
5	Stakeholders should be given credit for their roles in a decision, and how stakeholder input was used should be explained. If stakeholder suggestions were not used, explain why
6	Stakeholder involvement should be made part of a regulatory agency's mission by: <ul style="list-style-type: none"> Creating an office that supports stakeholder processes Seeking guidance from experts in stakeholder processes Training risk managers to take part in stakeholder involvement efforts Building on experiences of other agencies and on community partnerships Emphasizing that stakeholder involvement is a learning process
7	The nature, extent, and complexity of stakeholder involvement should be appropriate to the scope and impact of a decision and the potential of the decision to generate controversy

that affected parties, including members of impacted communities, representatives of NGOs, business people, and interested citizens, should join with regulatory officials to evaluate threats from environmental hazards, make mutually acceptable risk management decisions and jointly solve environmental problems. While the costs and benefits of involving stakeholders in the decision-making process vary according to situations and circumstances, it has become evident that public participation offers three major benefits: i) it promotes stakeholder buy in, which is vital for ensuring public acceptance of risk-based decisions; ii) it taps into unique stakeholder knowledge of the local situation, which can complement specialized knowledge of scientists and risk assessors; and iii) it promotes the concept of environmental

democracy, an important social value, by treating stakeholders as equals in decision-making.^{20-22,24}

Public participation in risk-based decision making is not a political-correct fad that will fade as new issues and ideas become fashionable. The idea of meaningfully involving interested and affected parties in all aspects of environmental health decisions is indorsed by the NRC^{20,21,24} and incorporated into official EPA policy.⁴⁶⁻⁴⁸ Moreover, environmental policy in the United States continues to undergo a transition from the partially successful but increasingly outdated pollution control strategies of the 20th century to new and innovative 21st century approaches that offer greater environmental improvements at less cost (Table 2).⁴⁹⁻⁵² Stakeholder involvement in collaborative coalitions and

Table 2. Comparison of important characteristics of the old 20th century and the new 21st century systems for protection of environmental health in the U.S.⁴⁹

Key characteristics of the regulatory system	Traditional, 20 th Century regulatory system (adversarial relationships)	New, 21 st Century regulatory system (cooperative solutions)
Philosophy	Regulators <i>vs.</i> industry	Collaborative partnerships
Strategy	Command-and-control policies	Cooperative, voluntary agreements
Approach	Rigid, prescriptive rules	Flexible, easy-to-adjust rules
Scope	Narrow, media-based statutes	Holistic, multi-media approaches
Standard setting	Means (process-based) standards	Outcome (results-based) standards
Geospatial scale	One-size-fits-all regulations	Place-Based (customized) regulations
Pollution control	End-of-pipe controls	Focus on pollution prevention first
Market perspective	Limited use of market mechanisms	Expanded use of market mechanisms
Risk-based choices	Narrow, opaque, expert-driven	Broader, transparent, collaborative
Public Participation	<i>Pro forma</i> consultation	Meaningful involvement in all phases

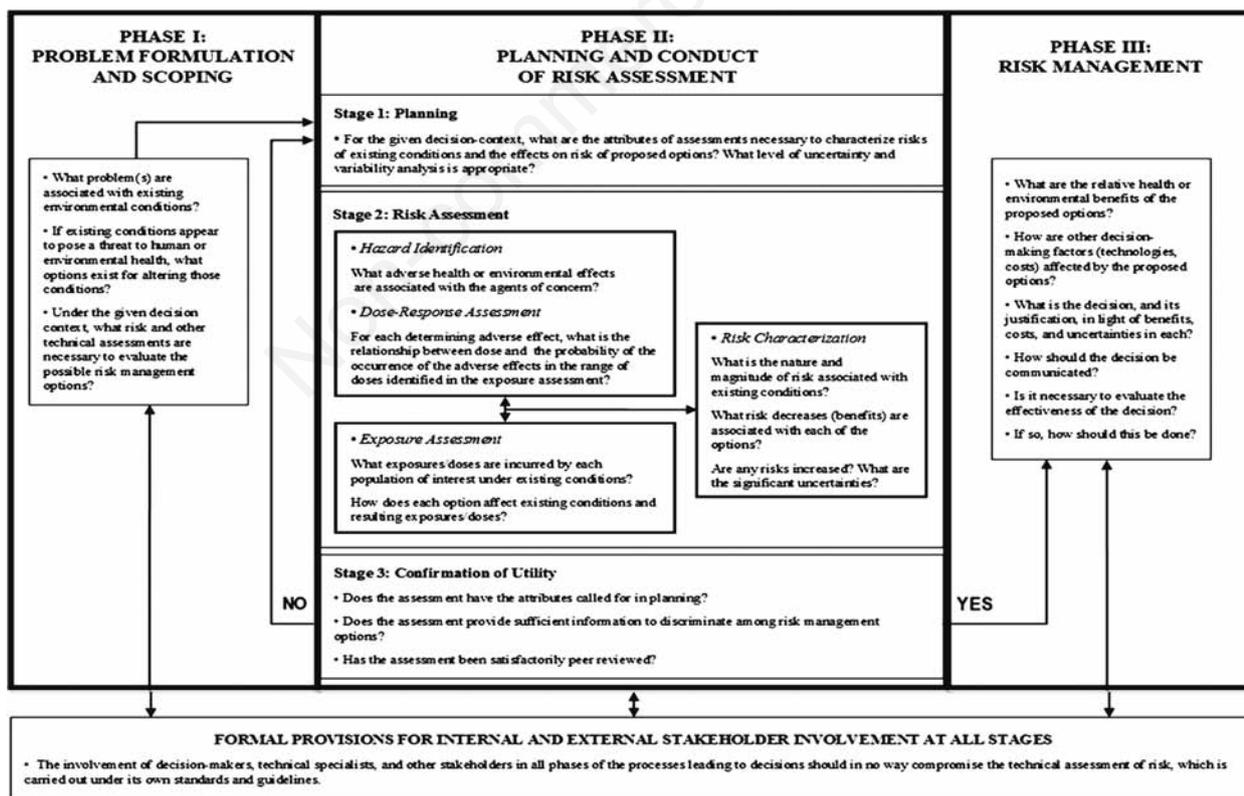


Figure 4. The framework for risk-based decision making proposed by the NRC in its 2009 report. Reproduced with permission from Science and Decisions: Advancing Risk Assessment, 2009, by the National Academy of Sciences, courtesy of the National Academies Press, Washington D.C.²¹

partnerships aimed at finding cooperative resolutions to complex and contentious environmental health problems is a key element of the new 21st century regulatory strategy. Public participation and stakeholder involvement are central to this emerging policy landscape, which emphasizes finding common ground among diverse stakeholders in order to achieve cooperative and cost-effective solutions.

On January 21, 2009, President Barack H. Obama issued a memorandum on transparency and open government, in which he said: *My Administration is committed to creating an unprecedented level of openness in government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration.*⁵³ In the memorandum he enunciated three principles: i) *Government should be transparent.* Transparency promotes accountability and provides information for citizens about what their Government is doing. ii) *Government should be participatory.* Public engagement enhances the Government's effectiveness and improves the quality of its decisions. Knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge. iii) *Government should be collaborative.* Collaboration actively engages Americans in the work of their Government.⁵³

Looking ahead, it seems clear that public participation will remain a vital and intrinsic feature of the RA-RM paradigm for the foreseeable future. Both advocates and critics alike agree that risk-based decisions should not be based solely on scientific and technical expertise, but ought to be refined and enhanced through stakeholder involvement and public participation. To the extent that interested and affected parties are involved meaningfully in risk-based decision making, both the process and the product are improved substantially.

Lessons learned and questions raised

What lessons can we draw from the U.S. experience with public participation in the RA-RM paradigm? First, it is apparent that a private, nonprofit, self-perpetuating society of distinguished scholars, like the National Academy of Sciences (NAS), whose function is to provide independent advice to the federal government on scientific and technical matters, can serve a pivotal role in evaluating the RA-RM paradigm and recommending needed modifications.^{18,19,21} The scientific stature and respect accorded the NAS ensures that its recommendations are publicized and taken seriously; often acting as catalysts for action.²¹ Second, as experience is gained with ever more complex and costly-to-solve environmental health risks, it often becomes necessary to adapt and modify various aspects of the RA-RM paradigm to accommodate newly recognized and/or recently redefined problems.^{39,44,54,55} Third, a general consensus has emerged that public participation is usually desirable and that it constitutes a worthwhile goal; sentiments which have caused it to be incorporated formally into the RA-RM paradigm.^{24,46,47,56,57} Fourth, although participation is embraced in principle, in practice questions remain about appropriate procedures and processes for successful implementation.^{25-33,56,57} And fifth, evolution of the RA-RM paradigm, including the expanding role of public participation, tends to reflect adjustments and alterations in environmental health policy as the U.S. transitions from a more adversarial pollution control system to one that is more of a collaborative partnership among government, industry, and stakeholders.^{39,49-52,58}

But the escalating role of public participation in the RA-RM paradigm raises at least as many questions as it answers.^{26-33,56,57} Among the more important are the following: i) Do present-day methods for risk assessment and risk management include adequate mechanisms for involving the public meaningfully in risk-based decision making? ii) To what extent are different forms and degrees of public participa-

tion applicable to specific risk-based situations and circumstances? iii) What are the relative transaction costs and opportunity costs associated with different forms of public involvement? iv) Are there practical limits to the value of public participation for risk-based decision making and, if so, what are they? v) How do the political and policy contexts within which the RA-RM paradigm is rooted affect the form and function of public participation? vi) How do social mores and cultural values affect the conceptual configuration of the RA-RM paradigm and the role of public participation within that framework? vii) Does increasing public involvement in risk-based decisions make them more likely to be accepted by the general public as well as affected communities and populations? viii) Does public participation (in whatever guise) as part of the RA-RM paradigm lead to *better* risk-based decisions – where *better* means more effective, efficient, and equitable?

Ultimately, targeted research is needed to answer these and related questions so that we can make informed choices about adjustments to the RA-RM process that will encourage improved decisions about protecting environmental quality and safeguarding human health.

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