Risk Assessment in Environmental Policy-Making

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Environmental policy-making has become more dependent on formal, quantitative risk assessment because of increasing attention to the prevention of human health damage from toxic chemicals. Risk assessment helps set priorities for regulation of the very large numbers of chemicals that are of potential concern and helps direct limited social and government resources against the most significant risks. Although the scientific basis for risk assessment is often uncertain and the public and its representatives have often been confused by its use in regulatory decisions, the U.S. Environmental Protection Agency currently uses a variety of risk assessment techniques to set priorities, tailor regulations, and make decisions at particular sites. The Environmental Protection Agency also attempts to make the practice of risk assessment more consistent throughout the agency and to improve public understanding of the meaning of risk assessment and risk management.

THE U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA) must analyze the magnitude of the risks of environmental damage it intends to reduce in order to use its own and society's resources to maximum effect. Although quantitative risk assessment has become an important part of this analysis, its use as a basis for implementing environmental policy remains controversial. This is so because quantitative risk assessment is the product of what former EPA administrator William Ruckelshaus has called "a shotgun wedding between science and the law" (*1*, p. 1026). The method attempts to use scientific evidence and techniques in the context of legal and administrative procedure, and in so doing fails to fully satisfy either the people who advocate, draft, and administer environmental law or members of the scientific community (*2*).

The EPA persists in placing itself on this uncomfortable middle ground because its mission often requires it to act in the absence of full knowledge about risks, and because limited resources mean that it cannot act in every situation where risk may exist. Quantitative risk assessment is a valuable tool for reconciling these conflicting demands (*3*). It helps EPA to (i) set priorities, (ii) adjust national regulations to the degree and distribution of the risk to be controlled, and (iii) make site-specific decisions by considering the nature of the pollutant, the sensitivity of the environmental setting, and the availability of control techniques. (Although EPA uses quantitative and semiquantitative tools to assess the impact of pollution whenever possible, for example, on ecological systems or on resources of economic value, such tools have been most highly developed for application to human health risk. "Risk assessment," as used in this article, refers to the techniques used to generate estimates of human health risk.)

The Performance of Risk Assessment at EPA

Risk assessment at EPA proceeds in four steps: (i) hazard assessment, (ii) dose-response assessment, (iii) exposure assessment, and (iv) risk characterization. Hazard assessment examines the evidence that associates exposure to an agent with its toxicity and produces a qualitative judgment about the strength of that evidence, whether it is derived from human epidemiology or extrapolated from laboratory animal data. Dose-response assessment examines the quantitative relation between the experimentally administered dose level of a toxicant and the incidence or severity or both of a response in test animals, and draws inferences for humans. The presumed human dosages and incidences in human populations may also be used in cases where epidemiological studies are available.

Exposure assessment identifies populations exposed to the toxicant, describes their composition and size, and examines the routes, magnitudes, frequencies, and durations of such exposures. Risk characterization presents the policy-maker with a synopsis of all the information that contributes to a conclusion about the nature of the risk and evaluates the magnitudes of the uncertainties involved and the major assumptions that were used.

This last element is particularly important in understanding what risk assessment can and cannot do. The National Research Council (NRC) has pointed out that in any risk assessment "a number of decision points occur where risk to human health can only be inferred. . . . Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges" (*4*, p. 3). The NRC also noted that much of the controversy that surrounds the use of risk as a guide to making regulations may arise from the confusion between risk assessment, a largely scientific enterprise that may involve science policy decisions, and risk management, which is the process by which a regulatory agency decides what to do about the results of a risk assessment. A risk management decision may involve economic, social, and political considerations and is subject to the constraints of particular statutes, which differ in the way they allow risk to be considered. The NRC recommended that risk assessment and risk management activities be clearly distinguished and separated institutionally in regulatory agencies. This separation has been accepted as a principle by EPA (*5*).

It is not easy to sustain. There is, after all, no natural "bright line" between the policy considerations inherent in risk management and those inherent in risk assessment. EPA has attempted to reduce possible confusion by dealing consistently and openly with the

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assumptions and extrapolations that are required to bridge the gap between scientific findings and the risk assessments derived from them. This is done through the publication of guidelines for the assessment of different health end points (*6–8*), for the effects of chemical mixtures (*9*), and for exposure assessments (*10*). These guidelines represent the formal consensus of scientists throughout EPA and in EPA's Science Advisory Board about what has and has not been determined scientifically about different aspects of risk assessment, and about procedures and judgments to be used in moving from these findings to an actual risk assessment.

An illustration of what guidelines do may be taken from the *Guidelines for Carcinogen Assessment* (*6*). This document classifies evidence about the potential human carcinogenicity of a substance into five groups, which are "sufficient evidence," "limited evidence," "inadequate evidence," "no data," and "no evidence," and provides rules for placing different kinds of findings in each class. For example, these guidelines accept mouse liver tumors as "sufficient" evidence of human carcinogenicity even when such tumors occur in strains with high background incidence and when they constitute the only tumor response to an agent, provided other criteria of "sufficient" evidence are met. Similar guidance is given on the choice of mathematical models for extrapolation to low doses; in the absence of evidence to the contrary, the linearized multistage procedure is preferred. Interspecies extrapolation on the basis of surface area is the recommended method.

The guidelines are thus a means of provisionally "resolving" open scientific controversies so that EPA can make the decisions required by administrative efficiency and the mandates of its legislation. They are conceived to be working documents, subject to change when new knowledge warrants, through the same formal, open process involved in drafting them.

The risk assessment guidelines foster a consistent approach across programs within EPA, establish a standard for quality of work and comparison of studies, and help inform the public about how scientific judgments and assumptions have been incorporated into risk assessments. Making decisions about risk in the absence of guidelines may lead to idiosyncratic decisions that cannot easily be explained or defended and that are subject both to accusations of capriciousness and to real or perceived manipulation in the service of political expediency. In addition, by focusing attention on areas that require judgments to be made, the guidelines help to show where additional research and analysis might make important contributions to understanding how pollutants cause adverse health effects.

The science community at large was solicited formally and informally to participate in development of these guidelines, but that does not mean that the guidelines as published represent a perfect consensus. Some scientists would make different judgments, and others would reject the premise that the state of science supports such judgments at all. Wilkinson (*11*, p. 10) epitomizes this caveat as follows:

> The fundamental problem facing toxicologists and regulators alike is that the chronic health effects of chemicals cannot be verified by direct experimentation. Consequently, . . . risk assessment invariably requires the extrapolation of data obtained under one set of laboratory conditions to those likely to be encountered under another totally different set of conditions. . . . It is disconcerting to realize that the science of toxicology simply cannot provide unequivocal answers to many of the questions being asked by the public and demanded by the regulatory process.

Risk assessments governed by guidelines only provide for consistency and orderly decision-making. They do not give certainty in the scientific sense, nor can they be used to establish precise numbers of persons who will be stricken with some disease. Quantification is useful in risk assessment to approximate the magnitude of an effect, to set priorities, or to make comparisons. Such comparisons are necessary, for example, when two alternative regulatory options have significantly different consequences in terms of risk, or when options with similar risk reduction possibilities vary widely in terms of administrative feasibility or economic impact.

The Use of Risk Information

Setting priorities. In environmental protection all the beneficial actions that might be taken cannot be performed simultaneously. EPA should act to reduce as much risk as possible, as fast as possible, giving due weight to its mandatory duties under statute and to the fact that the public it serves is concerned about some kinds of risk more than other kinds (*12*).

Although priority setting is vital to sensible environmental policy-making, limitations abound in practice. EPA administers all or part of some dozen different and independent statutes, each of which considers risk in a different way (*13*). Most of these statutes contain stringent deadlines for action and are supported by constituencies that zealously monitor their timely implementation. It is not surprising, therefore, that EPA has had great difficulty in setting explicit risk-based priorities, especially for the agency as a whole, across program lines. In general, the operational priorities of agencies in a democratic government arise from politics, especially the politics of the budgetary process, a not entirely rational enterprise.

But EPA has in recent years persevered in the development of risk-based approaches to set priorities for actions within its control and in hope of influencing the discussions from which externally imposed priorities emerge. For example, its Integrated Environmental Management Program has developed an approach that enables risk-based priorities to be set among the pollution problems that affect a particular geographic area. Exposures through all media (for example, air, drinking water, or food) from all significant toxic chemical sources in the area are modeled and the associated risks are estimated. The risks from various control options are also estimated. Through additional modeling it is then possible to arrive at the most efficient way of reducing total risk for any desired expenditure (*14*). A similar approach can be used to set priorities for dealing with major environmental problems that have cross-media consequences (the disposal of sewage sludge, for example). On a broader scale, EPA has recently completed the first comprehensive examination of the environmental problems its programs seek to control. The problems are ranked in terms of how heavily they bear against human health, ecological, economic, and general welfare values (*15*).

Design of regulations. By far the most common use of risk assessment at EPA has been in the design of regulations. Risk assessments contribute to the design of regulations in two ways. The first is to select targets for regulation and to decide how stringently to control the various sources that contribute to a particular problem. A given pollutant may be released by diverse sources that are unequally amenable to control. It may produce its adverse effect through transport by different media into locations of differing environmental sensitivity. It may impose widely differing risks, or none at all, depending on these factors. Risk assessments may help tailor regulations to varying risks and direct administrative attention to the most severe ones. This is done so that regulations can be instituted efficiently with respect to government and private resources and with a minimum of social and economic disruption.

The second use of risk assessment in regulatory design is to inform policy-makers of the implications of various levels of control so that they can decide what actions provide "safety"; that is, what degree of residual risk to accept in particular circumstances. We

present an example of each: for partitioning risk, the emergency suspension of major uses of the pesticide ethylene dibromide (EDB); and for establishing control levels, the regulation of radon from uranium mill tailings.

Between 1977 and 1983 EPA had accumulated substantial evidence that EDB was a potent carcinogen in laboratory animals. EDB had been shown to be carcinogenic in two species (rats and mice), in both sexes, and through three routes of administration (gavage, inhalation, and skin painting) (*16–18*). EPA had also gathered evidence that dietary exposure to EDB through fruits and uncooked grain products was extensive and that when these exposures were modeled with the "one-hit model" which was then standard at EPA, quite high risks were estimated for both workers and the general public (*16*). Criticisms that this model was too simplistic led EPA to reestimate the risk from dietary exposure in 1983 (*17*) with a new model that allowed calculation of differential risks for less than lifetime exposure for different age groups. This model was still "conservative," in accordance with EPA policy, in that it assumed low-dose linearity, and represented a "plausible upper bound"; that is, the number of cases it predicted were unlikely to be higher and probably were lower. Even with this caveat, the results were disturbing. An animal carcinogen was widely distributed in the national food supply, and the potential risks from this, should nothing be done, were substantial. [Note that although EPA had not published its final guidelines on carcinogen risk assessment at this time, the EDB risk assessment was performed under a previous, and quite similar, set of assumptions (*19*).]

In 1983, evidence from ground water–monitoring studies showed that EDB was contaminating this source of drinking water. Since a major use of EDB-based pesticides was as a soil fumigant, this was serious news. In the fall of 1983 EPA issued an emergency suspension of that use. At the same time EPA began a process to cancel the use of EDB as a grain and fruit fumigant as well, a process that would have eliminated the use of EDB for these purposes by 1986 should health risks be found to warrant it. EPA did not immediately suspend these uses despite the carcinogenic potential because EPA management did not believe enough was known at the time about the risks from residues on food, the risks from substitute fumigants, or the risks from leaving crops and foodstuffs unprotected. (Consideration of these factors, as well as the economic costs of prohibiting a pesticide usage, is mandated by the statute under which EPA must act in such cases.) It decided to await the results of studies then in progress.

Shortly thereafter, EPA learned that food residues of EDB were higher and more widely distributed among grain and fruit products than previous EPA estimates had suggested. Also at about this time, the risk management situation changed markedly. EDB became a matter of intense public interest and discussion and led to demands for federal action and initiatives by state governments.

States began adopting "safety" standards for EDB in food that, in the absence of information, were typically set around the level of detection. The adoption of differing standards in different areas threatened a substantial disruption of the national food distribution system. The stringency of these standards might have led to the destruction of a significant proportion of the national grain-based food supply with a public health benefit that, while uncertain, was probably small.

The challenge to EPA was to craft a regulatory policy that would respond to the public demands for action without major economic and social dislocations, before it possessed certainty about whether the substitute fumigants were better or worse than EDB with regard to risk. After satisfying itself on the basis of the information available that substitutes were no worse than EDB, EPA immediately suspended almost all uses of EDB so that it would eventually be purged from the food chain, and established "levels of concern" based on risk assessment so that the public would have a clear guide to what food presented acceptable risks and what had to be destroyed.

In this regulatory enterprise, risk assessment was used first to adjust the remedy to the severity of different aspects of the problem. EPA first focused attention on dietary risks from soil fumigation and from grain and milling machinery (spot) fumigation, because these presented the highest total population risk with lifetime exposures expected to yield a risk range of from 10^{-4} to 10^{-6}. Soil fumigation also presented the additional concern about ground water contamination. The risks to workers associated with spot and soil fumigation was also extremely high (10^{-2}). If EPA had proposed canceling these uses in the normal way authorized by the relevant statute, it might have taken 2 years or longer for administrative processes and appeals to be completed. The risks were deemed high enough to make such a delay undesirable. In October 1983 EPA used its emergency suspension authority to stop soil fumigation with EDB and 4 months later did the same for grain and milling machinery fumigation. EPA also served notice (*20*) of its intent to cancel most other uses of the pesticide. The risks from these sources, however, when compared to the benefits from continued short-term use pending the development of substitutes, were not considered high enough to require immediate suspension.

Through a major public information effort (*21*) EPA was able to show that while the risks warranted the removal of the fungicide from further use, they did not warrant the indiscriminate destruction of food contaminated at very low levels. Further, risk assessment was used to focus the attention of EPA on the worst sources of exposure first, that is, on ground water before grainstuffs, on grainstuffs before citrus, and on citrus before mangoes. This enabled EDB to be removed in an orderly way without straining the resources of state or federal agencies and without undue economic impact.

The second major use of risk in designing regulations, the establishment of the appropriate level of control, is demonstrated in the decision EPA made in 1983 on the control of radon from licensed uranium mill tailings (*22*). Such tailings release radon gas, which can lead to cancer if inhaled. The reduction of radon emissions is relatively simple; the tailings are covered with earth and due provision is made for keeping this barrier from eroding over time. Obviously, thicker barriers give greater protection and cost more to build than thin ones. Important guidance on selecting the appropriate barrier was provided by estimates of residual risk from the alternative options.

EPA estimated that the plausible upper bound for the base case, that is, the uncontrolled situation, was 600 excess cancer deaths over the next 100 years, or 6 per year. EPA eventually selected an option that would typically lead to about 2.4 meters of cover. It estimated that this would avoid 95 percent of the estimated base risk (about 570 "deaths" over the next century) at an estimated cost to industry of about $500 million. EPA rejected another option that involved an earth cover twice as thick that would have cost $750 million and might have avoided 99.5 percent of the risk (about 597 "deaths"). Given the uncertainties involved, these numbers are indistinguishable; they cannot be said to represent differing "counts" of cancer deaths. The point of the analysis is that the extra $250 million probably buys nothing at all, and perhaps even has adverse effects when incremental risks involved in increasing the depth of the earth cover, such as those from additional traffic, construction injury, and flying dust, are considered.

In these two examples, people who hold a different set of values might have chosen different actions based on the same evidence. They might have decided that immediately eliminating EDB from the diet warranted major disruptions of the food supply and large-

scale destruction of foods, or conversely, that EDB should continue to be used at least until evidence on risk from substitutes was better understood. They might have decided that the possible consequences of uncontrolled risks from tailing piles were not worth $500 million to avoid, or that a more protective standard should have been chosen. Such values cannot be argued except through the political process. What can be argued, and what we do argue here, is that the political process itself relies for its proper operation on communicating to the public the risk basis of the decision. Risk-based regulatory policy-making allows one to do this clearly and in an orderly fashion.

Site-specific risk assessment. As might be expected, the Superfund program is the source of most of the demand for the use of site-specific risk assessments. Potential sites must be characterized to determine eligibility for Superfund cleanups and once on the priority list the extent and scope of the problem must be determined and remedies must be selected. This is so because actual and potential exposure of people and natural resources to pollutants from abandoned waste dumps depends on location; populations around sites, contaminants, and exposure pathways vary, and site characteristics affect the success of alternative engineering intervention strategies.

Placement on the list is accomplished through use of the Hazard Ranking System, which is being revised under the Superfund Amendments and Reauthorization Act to incorporate a more robust risk basis. The National Contingency Plan, which governs the criteria for selection of remedies, includes a Public Health Evaluation to assess the existing risk in the absence of any remedial action. Finally, assessment of estimated residual risk under different cleanup options is undertaken to meet the statutory requirements for cost-effectiveness, permanence, and "fund balancing," the latter referring to the balance of benefits from more protective solutions with the urgency of the need to devote resources to other sites (*23*).

The importance of these risk assessment tasks is matched only by their complexity. Although EPA has been improving the necessary risk assessments, the agency has thus far been forced to rely mainly on highly conservative exposure scenarios and protective, technology-based practices in its cleanups. Thus site-specific risk assessments to guide the Superfund program have been accepted in principle but remain to be fully implemented.

The Evaluation of the Use of Risk Assessment

Priority-setting, regulatory design, and site-specific control decisions could be made without a risk-based approach. If historical evidence is any guide, priorities would be set by individual programs, each one focused on a particular environmental medium or aspect of an environmental problem, for example, air pollution, water pollution, or pesticides. Priorities would be compared and assessed by such measures as "tons removed," or by administrative achievements, such as "permits issued" and "construction or remedial actions completed." Resources would be allocated among environmental problems on the basis of historical accident and political influences, and the level of control imposed would be determined by broader political forces that are generally untutored by explicit consideration of what the programs actually did for human health or the environment.

This method of setting priorities was adequate when only a small number of pollutants were of concern, most of which were characteristic of one particular medium, and, of course, substantial environmental progress has been made under it. But such a method provides no way of coping with the negative and even perverse effects that result from the transfer of pollutants between media (*24*). For example, the removal of pollutants from waste water produces sludge that must either be disposed of on land, incinerated, or dumped at sea. None of these procedures are without risk to human health or the environment. When hundreds of toxic chemicals must be regulated, most of which travel freely between media, setting priorities on any other basis than the reduction of risk quickly descends into confusion. Furthermore, such an approach is ill-suited for dealing with new problems. Unless a systematic assessment of opportunities to reduce risk is imposed, the natural tendency is to continue existing reduction programs against existing targets, with ever diminishing returns, while virtually ignoring other, possibly larger, risks.

The alternative to a risk basis in designing regulations is to require the installation of a particular technology. Historically the EPA programs that have followed this approach have sought to mandate technologies that remove the greatest possible amount of pollution without causing widespread economic hardship to individual firms. This is the so-called best available technology (BAT) approach. But the BAT approach is "best" only from the standpoint of removal from a single medium. Ordinarily BAT approaches make no serious attempt to deal with transfer of risk to other media. Also, a BAT approach implies universal application across all facilities, perhaps at substantial cost, whether they produce any dangerous pollution or not. Of course, in a relatively uncontrolled situation a BAT approach may be necessary. This was the case in 1972 when the Clean Water Act mandated primary treatment for all sewage that entered surface waters. The risk reduction potential and the net benefits were so substantial that formal risk assessment was unnecessary. But it does not follow from such experiences that environmental policy should be based on the continuous redefinition of what "best" technology is so as to make uniform controls increasingly more stringent. Given the immense task of protecting the environment on a limited public and social budget and given the large number of important problems that receive little attention, the waste of resources inherent in any strict BAT approach would seem unwise.

For site-specific decisions the alternatives to a risk-based approach are either universal application of BAT (with all its problems) or mandating controls sufficient to reduce pollutants to some "safe" level. This latter approach assumes that there is a level of exposure or threshold that is too low to cause any biological effect. Where this assumption cannot be justified, as may be the case with carcinogens, it cannot be used. The recourse in such cases, of which abandoned toxic waste sites are the most familiar example, is to use an absolute approach, such as destroying or removing the offending material to the level of detection or to background. This eliminates the risk in one location but may create a mass of toxic material that must be deposited somewhere else, where it will inevitably pose some risk to some other population.

The discussion thus far suggests that risk assessment, despite its limitations, has substantial utility in making decisions about the environment, especially when the problems with the alternatives are taken into account. Even that measured endorsement is controversial. One common criticism is that EPA's risk assessments typically overestimate risk, lead to excessive control, and engender unjustified public concern. The basis of this criticism is that the models used and the science policy judgments built into the assessment procedures are inappropriately "conservative"; that is, they have an unwarranted and excessive health-protective bias that leads to controls where none are justified and to excessively stringent controls elsewhere. Such critics also fault EPA for taking action based on incomplete or faulty data or on inappropriate models. It should be noted that the courts have generally sustained the judgments of EPA on risk, provided care has been taken to consider the relevant evidence (*2*).

The opposite conclusion is also common, that decisions informed by risk assessments tend to be insufficiently protective; in other words, what risk assessment shows is but the tip of the iceberg. Those critics claim that the scientific basis for risk assessment is not advanced enough for consideration of the synergistic effects of pollutants, all of the potential adverse health effects, or more than a small fraction of the large number of pollutants that might pose some risk. The risk-based approach is also faulted because it can slow the pace of control. The alternative usually suggested is to press control of all pollutants in all circumstances to the limits of technology and hope that when industry is pressed in this way it will respond with more effective technology.

In that these contradictory criticisms reflect technical problems, we may look forward to at least a partial solution through advances in modeling, in toxicology, and, most important, in the ability to gather, assess, manipulate, and communicate increasingly more complex bodies of information. The use of risk assessment, despite its shortcomings, to make important decisions represents the major incentive to address these issues and to increase the resources devoted to the task. EPA itself is investing heavily in risk assessment research and in the distribution of its databases to increase access to information about risk and exposure assessment methods and data.

But the objections to the expanded and more public use of risk assessment also has a political, even a moral, dimension. Risk-based approaches confront people with the fact that they are inevitably, as a consequence of their membership in an industrial society, exposed to risks. Public officials are understandably uncomfortable with bearing such news, and most people are not comfortable with receiving it. Recent studies suggest, however, that communicating risk has become important to policy-makers at the national level (*25*).

Confronting risk in this way also raises disturbing questions about what kind of society we want to have and about the distribution of risk among different areas and social sectors. Such questions are as vexing ethically and as politically sensitive as the more familiar ones about the distribution of income and opportunities among our people. Much of the heat generated by the risk assessment policies described here derives from the association, perhaps barely sensed by most, between such policies and the profound issues that arise from our conflicting desires for prosperity, justice, equity, and environmental quality.

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