# TOXIC EFFLUENTS: A SIMPLIFIED PROCEDURE FOR ASSESSING HUMAN HEALTH RISKS

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## ABSTRACT

This paper presents a simplified methodology for assessing the chronic health risks caused by discharge of toxic pollutants to surface water bodies. The methodology has been incorporated into a microcomputer program (WTRISK) and includes simplified transport models for atmospheric, overland, and surface water media, as well as procedures for calculating exposure rates through alternative pathways and the consequent chronic health risks. The program can be used to make preliminary calculations of potential risks and to estimate the uncertainties in the results. With this information, the risk analyst can evaluate discharge problems and determine where additional data or more detailed analysis are required. The approach has been applied to a case study where an effluent containing selenium was discharged from an existing coal-fired power plant. The analysis found that incremental exposure rates and health risks are negligible and that the simplified approach can be used to assess the bounds on potential risks.

KEY WORDS: Risk analysis, Chronic health risk, Environmental transport Risk assessment, Toxic chemicals, Selenium, Coal fired power plant,

## BACKGROUND

The health risks associated with the discharge of toxic pollutants from industrial sources have become the subject of growing concern within industry and government agencies at the federal and state level. Federal legislation to regulate these emissions includes the Clean Air Act, Clean Water Act, and the Resource Conservation and Recovery Act of 1976. In the context of deriving specific environmental regulations, government agencies and industries have recognized the need for a relatively simple approach to calculating the health risks of toxic discharges into the air.

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Although researchers have developed many specific computer models for risk assessment, most of these models are not suitable for first order or preliminary analysis. Currently available codes are generally complex, data-intensive, and expensive to run. They cannot be easily transferred between computer systems or used by people, other than their developers, without lengthy preparation and instruction. Moreover, because they are expensive and difficult to use, these codes may not be suitable for the large-scale sensitivity analyses needed in the initial phases of a study when specific costs and benefits have not been established (Ricci, 1985).

Recognizing the need for a simplified, integrated approach to health risk assessment, the Electric Power Research Institute (EPRI) began supporting the Rand Corporation in the development of such a tool. The goal was to develop a computer model that could be easily applied to a wide variety of effluent discharge problems. The approach considers the chronic health risks associated with toxic emissions to all environmental media, but is directed primarily toward discharges to surface water and associated exposure pathways. Moreover, it is oriented toward the needs of the potential user, easily transferred to other locations and computer systems, and it incorporates existing models whenever possible.

Although developed primarily for the electric utility industry, the program can be used in those situations involving discharges from either a point source or a limited area. It has been applied to two hypothetical case studies and one actual case study of arsenic and selenium discharges from coal-fired power plants. These studies have helped to improve the models and have demonstrated how the approach can be applied to actual situations. The overall approach and details of the computer program and case studies are described fully in Bolten et al. (1983, 1985).

The methodology of the program should be used in preliminary analysis, where its convenience and low cost facilitates rapid and extensive sensitivity analysis. Using the model, the analyst can estimate upper and lower bounds for pollutant concentrations and the consequent exposure rates. These results and others can be used to improve understanding and definition of the problem, eliminate unimportant pathways, and isolate those areas where additional, more intensive research is necessary. Specifically, the models could be used to (1) prepare for regulatory and licensing proceedings, (2) support site selection, (3) prepare environmental impact reports, (4) facilitate long-term environmental planning, (5) study the effect of alternative regulatory formulations, and (6) respond to public concerns about current or future issues.

## DESCRIPTION OF THE APPROACH

Risk calculations should be performed within a well-understood context. More specifically, one must first define the existing or base case situation, to serve as a reference for all subsequent risk calculations. Within this context, background pollutant concentrations, exposure rates, and health risks should be determined. With these results, the marginal changes in pollutant concentrations, exposure rates, and chronic health risks for all alternative discharge rates and concentrations can be calculated and compared.

### Risk Assessment Framework

As shown in Figure 1, the general risk assessment framework consists of five distinct stages: (1) plant emissions, (2) environmental transport, (3) exposure analysis, (4) toxicology and pharmacokinetics, and (5) dose-

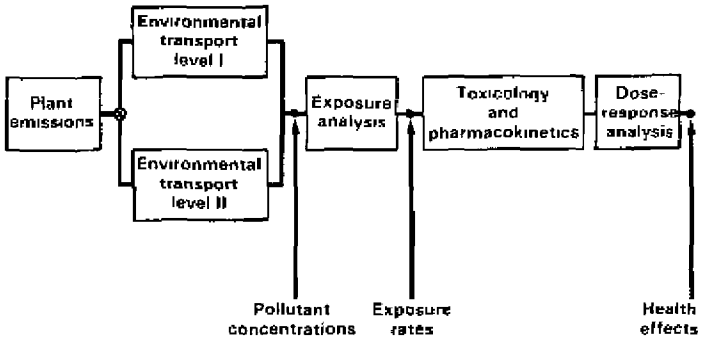


Figure 1

General Analysis Framework

response analysis. To assess the risk associated with emission of a toxic pollutant from a specific source, models, measured data, or a combination of both are used at each stage of the analysis. The framework is designed to permit use of alternative models at the different stages of the analysis, depending on the problem and the specific constraints of the situation. In this paper, we are most concerned with the two alternative levels available in the environmental transport analysis--levels I and II.

Levels of Analysis

The environmental transport analysis takes the rate and concentration of the discharge from the source to each environmental medium and calculates the distribution of pollutant in the environment surrounding the source. As shown in Fig. 1, these calculations can be performed at either of two levels. The Level I calculations use simplified transport models. These models can be set up and operated by people with a basic understanding of transport processes and a knowledge of the particular problem. The models require limited amounts of aggregated data and can be run quickly and cheaply. They are designed to be used with extensive sensitivity analysis of key parameters.

The assumptions and simplifications made in these models may cause them to be less realistic and could lead to significant errors if they are not used correctly. The analyst should be aware of the limitations of the models and data and must realize that these simplified calculations are best used in sensitivity analysis for the purpose of (1) defining the problem, (2) generating upper and lower bounds on results, and (3) investigating the sensitivity of results to variations in inputs and model parameters.

The Level II calculations use the more traditional complex environmental transport models, such as EXAMS, ARM, SERATRA, ISC, and others (Bolten et al., 1983; Onishi et al., 1982). These models, although they may produce more realistic results in specific cases, cannot be run easily and cheaply. They are complex and require specialized knowledge and significant effort for operation on a computer system. They also have extensive data requirements that must be met if the models are to be used to their full advantage. Because of the costs and difficulty of using

these Level II models, they are not suitable for extensive sensitivity analysis, particularly at the beginning of a study.

The results of either level of environmental transport analysis will be the distribution of pollutant concentrations in the environment around the source. These concentrations can then be used in the exposure analysis to calculate population exposure rates as a function of exposure pathway, location, and other characteristics. The toxicological and pharmacokinetic analysis of the pollutant should be considered to develop the appropriate health effects from the population data and the calculated exposure rates. Although this approach would normally involve the use of dose-response relationships, in many cases health data or pollutant characteristics may not suffice for this type of analysis and other approaches become necessary.

In addressing a discharge problem, the analyst should follow a specific strategy. The first step is to define the situation, including those factors and alternatives that will be modeled, given the problem and the objectives of the analysis. After collecting relevant data, the Level I transport models should be used to calculate pollutant concentrations, exposure rates, and health risks for the nominal situation and alternatives. This step of the analysis can help the analyst to define the problem more clearly and determine data requirements more precisely. Next, the Level I models should be used in extensive sensitivity analysis involving all stages of the risk assessment process. The results of this step are upper and lower bounds on the concentrations, exposure rates, and health risks. These bounds should provide a quantitative description of the relative importance of different environmental and exposure pathways and allow the analyst to bound the problem accurately.

These results may show that there is no emissions problem (i.e., significant health risk) even under worst-case assumptions. However, if the results do indicate a potential problem or are ambiguous, then more intensive analysis with the Level II environmental models is required. In this case, the Level I analysis provides information to improve allocation of resources to the various aspects of the problem. If the upper bounds determined in the Level I analysis indicate that certain pathways or emissions are not important, subsequent work can concentrate on those areas of the analysis where the Level I results show a problem.

WTRISK Model

To facilitate the process of assessing chronic health risks, we have developed a computer program that can be applied to a wide variety of problems. This program, called WTRISK (WaTeR RISK), includes (1) simplified models for transport in the air, overland, and surface waters; (2) exposure models for all significant pathways; and (3) six dose-response functions. The program allows the user to specify a region in terms of geographic or representative areas with appropriate populations separated by age, sex, or other characteristics. Exposure rates can be calculated by population group, location, and specific pathway for up to five pollutant species simultaneously. Although the species must act independently in the transport and exposure calculations, their effects can be aggregated in the dose-response calculations.

Using WTRISK, an analyst can perform Level I investigations of point source or indirect atmospheric emissions and surface water discharges, including the transfer of pollutant between media. Although the program does not incorporate simplified transport models for saturated or unsaturated groundwater, it does provide for the contamination of surface waters from the groundwater. The atmospheric transport component includes

a simple Gaussian plume model and a distributed source model. Surface water transport calculations can be performed for either rivers and streams, or lakes with some thermal stratification. The overland model partitions total pollutant deposition (atmospheric and irrigation) into runoff, infiltration, and retention in surface soil layers.

The exposure analysis section of WTRISK calculates total exposure by intake route for the population surrounding the emission source. The calculation involves summing the exposure from each separate pathway to the three intake modes: inhalation, ingestion, and dermal contact. Inhalation exposure is calculated from the distribution of air pollutant concentrations. Ingestion exposure is determined for consumption of drinking water, atmospheric particulates, aquatic organisms, and animal and vegetable products. Dermal exposure can be calculated for exposure to air pollutants as well as treated or untreated waters.

The health effect calculations use the exposure rate results to estimate the increased risk (over background) of a particular chronic toxic response (or set of responses). To calculate this estimated risk, one must use statistical or statistical-biological models relating the dose presented to a human or test animal to the increased probability of toxic response per unit of exposed population. Because we are concerned with chronic (long-term) rather than acute effects, the code (and its associated methods) are focused on dose-response relationships for chemical carcinogens.[1]

The WTRISK model incorporates six dose-response functions. Parameter values (potency) for these must be supplied to the program, and must be estimated through off-line calculations or obtained from the literature. The six models included in the program are the one-hit, multihit, multistage, Crump, probit, and Weibull models. Because none of these dose-response functions can be said to have a superion molecular and biologic-biochemical basis (Ricci and Molton, 1985), alternative, but biologically plausible, functions should be used whenever possible to provide alternative estimates of the adverse health effects. This is particularly true because some functions generate either high or low response rates for a given dose. Unfortunately, for many of the toxic pollutants, the available data may not be sufficient in quantity or quality to estimate the necessary parameters for some of the more complex models. As a result, the analyst must make use of experience and judgment

Uncertainty Analysis

Quantitative risk assessment deals with, and has long been plagued by uncertainty. An analysis may have little meaning and questionable value in setting or meeting regulations if its results have an uncertainty of several orders of magnitude Unfortunately, this may frequently be the case when determining the chronic health effects of toxic pollutants Even if the overall uncertainty in an analysis cannot be reduced, it is incumbent on the analyst to obtain and portray some measure of it. If the sources of uncertainty in the results can be determined, it may be

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[1]These models may equally well be used to estimate the prevalence of other chronic diseases such as liver or kidney necrosis, teratogenicity, or fetotoxicity, so long as a threshold is not apparent and the cellular and organism responses are replicated by the dose-response functions chosen (Ricci and Molton, 1985).

possible to improve the analysis in those areas.

The WTRISK program can be used to assess how errors in the input and parameter values required by the various models contribute to the overall uncertainty in results--the health risk. A number of theoretical approaches have been applied to the problem of quantifying uncertainty associated with input and parameter values. Although Cox and Baybutt (1981) address five alternative methods, several others have been discussed in the literature. Eight methods, including (1) analytic techniques, (2) Monte Carlo simulation, (3) response surface analysis, (4) differential sensitivity analysis, (5) confidence intervals, (6) extreme values, (7) linear propagation of errors, and (8) simple sensitivity analysis have been considered in our work (Bolten et al., 1983). Not all of these approaches are useful for the complex problem of risk assessment, and each has relative advantages and disadvantages.

Of these alternatives, five could reasonably be used in risk assessment. These are (1) response surface analysis, (2) differential sensitivity analysis, (3) extreme values, (4) linear propagation of errors, and (5) simple sensitivity analysis. If an analysis is constrained by limited resources, a simple sensitivity analysis is reasonable. In this approach, the analyst makes three point estimates of each parameter (a "best" estimate, a low, and a high value) rather than using a distribution of values. During the investigation, the analyst can observe how changes in the values of each parameter (between the low, best, and high estimates), one at a time, affect the results. For the more sensitive parameters (i.e., those that have greater influence on the net risk), simultaneous changes in two or three parameters can be made. Thus, sensitivity analysis can be considered as informal uncertainty analysis.

It would be much too laborious, in most cases, to perform sensitivity analysis on each parameter or pairs, given their number. To reduce the number of perturbations, the analyst should use the models and data to establish which (among all parameters) meet two conditions: (1) they might significantly affect the results, and (2) their values are not well established and have large uncertainty. These selected parameters can then be perturbed.

## APPLICATION TO A CASE STUDY

To demonstrate how the overall risk analysis framework and the WTRISK program could be used, we have applied them to two simplified, illustrative case studies and to one actual case study. The simplified studies, described in Bolten et al. (1983, 1985), considered a hypothetical coal-fired power plant of 500 MWe generating capacity sited near rivers in Washington and Nebraska. These studies looked at discharges of arsenic and selenium into the air, surface water, and groundwater. The actual case study, discussed in Bolten and Resetar (to be published), considers the discharges of selenium into surface waters by a coal-fired power plant in Pennsylvania. The utility (Pennsylvania Power and Light Company) that operates this power plant (the Montour Steam Electric Station) is currently undergoing permit review for the surface water discharges.

The analysis was, by design, limited to the chronic health risks associated with selenium discharged from the waste treatment basin at the Montour plant. The plant, located north of the junction of the West and North Branches of the Susquehanna River, discharges into the Chillisquaque Creek, which subsequently flows into the Susquehanna. Exposure pathways considered in the analysis included the consumption of treated drinking

water and fish obtained from the Susquehanna. These two pathways are used by the Environmental Protection Agency in its determination of the water quality criterion for selenium (EPA, 1980a).

Approach

Once the basic problem had been defined and initial bounds were placed on the analysis, the approach used in the Montour case study followed the general procedure developed in the previous two hypothetical cases. The steps in this analysis were as follows:

- Describe Montour water systems, calculate from mass balance analysis the selenium discharge rates, and compare these calculated rates with discharge concentration measurements.
- Specify the base case (nominal discharge rate) and alternatives to be considered.
- Determine the hydrologic characteristics of the affected surface waterways (Chillisquaque Creek and Susquehanna River) and find background selenium concentrations.
- Specify the exposure pathways and collect appropriate data.
- Identify the exposed population for each pathway.
- Define the health effects analysis and method of calculation.
- Use WTRISK (including Level I transport models) to calculate selenium concentrations, exposure rates, and health effects for the base case and its alternatives.
- Perform sensitivity analysis for the transport, exposure, and health effects calculations.
- Refine or revise the analysis as necessary on the basis of all results, including the sensitivity analyses.

Assumptions

The analysis was based on a number of assumptions that simplified the calculations. The primary assumptions, most of which were supported by preliminary analysis, include:

- There is no significant contribution to surface waters from plant selenium emissions in stack discharge or leaching from disposal ponds and landfills.
- Processes removing selenium from surface waters or changing its chemical form can be approximated by first order relationships.
- The exposed population includes only those people who regularly consume either drinking water or fish obtained from the Susquehanna or Chillisquaque downstream from the discharge point.
- The health effect of concern was selenosis rather than cancer.

Because no dose-response potencies have been estimated for selenosis, the health effects calculations were based on the threshold ingestion rate approach described in the Environmental Protection Agency water quality criteria document for selenium (EPA, 1980a). Using literature data, we modeled the distribution of selenium consumption in the population with a log normal probability distribution function. The fraction of the exposed population that might be expected to exceed the selenosis threshold (calculated by the EPA to be 7.0 mg/day), given a particular mean consumption rate and the estimated standard deviation of the distribution, was then calculated. Plant emissions affect the mean consumption rate by shifting the distribution toward higher or lower consumption levels, in turn, changing the number of people that might exceed the threshold. The shifts were also modeled and found not to unduly change the excess risks. The calculated population exposure rates were thus translated into an equivalent chronic health risk. We discuss these results next.

## Results and Sensitivity Analysis

In the analysis, the transport calculations were separated from the exposure and health effects work. This permitted the identification of those parameters that affect each aspect of the calculations, as well as the overall risk estimates. The results of the sensitivity studies of selenium transport were used as inputs to the sensitivity analysis of exposure rates and health effects, along with variations in the exposure and health effects parameters. In general, the primary parameters in the analysis were the (1) river flow rates, (2) effectiveness of drinking water treatment processes, (3) ingestion threshold for selenosis, and (4) background level of selenium in the general diet.

The results of the basic calculations and sensitivity analysis of selenium concentrations along the Susquehanna River are summarized in Table 1. These results show that selenium concentrations were not increased significantly in the Susquehanna, the only waterway that both receives plant discharges and affects population exposure to selenium. With long-term mean flow rates (the flows most significantly affecting chronic health risk), selenium concentration increases were negligible. Even under worst-case assumptions (an upper bound), average selenium concentrations along the river increased by less than 10 percent and remained well below the primary drinking water quality standard of 0.010 mg/l. This criterion is based on animal data; the Lowest Observed Effect Level (LOEL) is derived from rat studies.

Table 1

SELENIUM CONCENTRATIONS IN THE SUSQUEHANNA RIVER
(mg/l)

| Case Description | | | Mean Selenium Concentration | | |
|---|---|---|---|---|---|
| Discharge Rate[a] | Removal Rate[b] | River Flow | Chillisquaque Inflow | Harrisburg | Maryland Border |
| Background Concentration | | | 0.00200 | 0.00200 | 0.00200 |
| Permit | Nominal | Mean | 0.00201 | 0.00200 | 0.00200 |
| Permit | None | Mean | 0.00201 | 0.00200 | 0.00200 |
| Permit | None | Minimum[c] | 0.00228 | 0.00209 | 0.00208 |
| Nominal | Nominal | Mean | 0.00202 | 0.00200 | 0.00200 |
| Nominal | None | Mean | 0.00202 | 0.00201 | 0.00201 |
| Nominal | None | Minimum[c] | 0.00252 | 0.00216 | 0.00214 |

NOTES: [a] Selenium concentrations in plant discharge: Permit level--0.010 mg/l; Nominal discharge--0.017 mg/l
[b] Nominal removal rate coefficient--8.02 x 10(-7)
[c] Worst-case conditions (upper bounds)

Similarly, exposure rates for the 727,000 people in the affected population increased insignificantly over background levels. Background and total selenium exposure rates for the basic analysis and sensitivity cases are summarized in Table 2. As shown in the table, the increase in the worst case was less than 0.15 percent of background exposure levels. In the nominal case, using mean flow rates, the increase was less than 0.002 percent of background exposure.

The health effects associated with these exposure rates depended

strongly on both the assumed threshold level and the background consumption rate for selenium. In spite of this dependence, in the analysis of the worst case, the individual lifetime health risk was less than 10(-6), a standard of acceptability often applied in risk assessment and environmental standard-setting approaches (EPA, 1980b). Table 3, which summarizes the results of the health risk calculations, shows the number of people in the exposed population of 727,000 that could be expected to exceed the EPA selenosis threshold of 7.0 mg/day. The table presents the results for both the nominal background exposure rate and for a high background rate used in the sensitivity analysis.

Table 2

SELENIUM EXPOSURE RATES FOR REGIONAL POPULATION
(mg/day)

| Case Description | | | Mean Population |
|---|---|---|---|
| Discharge Rate | Removal Rate | River Flow | Exposure Rate[a] |
| EPA selenosis threshold | | | 7 000000 |
| Background exposure rate | | | 0.129317 |
| Permit | Nominal | Mean | 0.129320 |
| Permit | None | Mean | 0.129321 |
| Permit | None | Minimum | 0.129419 |
| Nominal | None | Mean | 0.129324 |
| Nominal | None | Minimum | 0.129509 |

NOTE: [a] Exposure rates are expressed to six digits only to show the variation between cases. Actual selenium background exposure rates may differ from calculated values by as much as fifty percent, although the increments associated with plant discharges should not change.

## CONCLUSIONS

The potential user of WTRISK or other risk assessment methods should recognize risk analysis is not an exact science that can develop accurate and precise risk estimates. Instead, risk analysis is a quasi- science that can (1) roughly approximate the relative risks of alternative designs, (2) determine the relative sensitivities of calculated risks to uncertainties in input data, and (3) identify weaknesses in the original assumptions. Our risk assessment methodology is based on a particular set of assumptions and is thus subject to limitations and potential problems.

No risk analysis framework or methodology should be used without a thorough understanding of the various models and data, their scientific basis, and their limitations. No one can construct a foolproof package of models that can be properly used by someone unfamiliar with the basic problem and general situation. "Cookbook" risk analysis must not be done. The analyst must have access to adequate information about (1) all models used in the analysis; (2) the operation and characteristics of the emission source and its waste streams; (3) the relevant characteristics of the regional geography, geology, hydrology, meteorology, and agricultural production (if relevant); (4) regional population; and (5) the behavior and chronic health effects of the pollutant. This is basic information, although the level of detail required will vary significantly between problems.

Table 3

HEALTH EFFECTS: NUMBER OF INDIVIDUALS AT LIKELY RISK

| Case Description | | | Expected Number |
|---|---|---|---|
| Discharge Rate | Removal Rate | River Flow | Exceeding Threshold |
| Threshold Level = 7.0 mg/day | | | |
| Background exposure--0.129317 mg/day | | | 0.0281 |
| Permit | Nominal | Mean | 0.0281 |
| Permit | None | Mean | 0.0281 |
| Permit | None | Minimum | 0.0282 |
| Nominal | None | Mean | 0.0281 |
| Nominal | None | Minimum | 0.0284 |
| Background exposure--0.256470 mg/day | | | 3.3650 |
| Permit | Nominal | Mean | 3.3653 |
| Permit | None | Mean | 3.3653 |
| Permit | None | Minimum | 3.3737 |
| Nominal | None | Mean | 3.3655 |
| Nominal | None | Minimum | 3.3813 |

The simplified approach described in this paper and implemented in the WTRISK program is designed to make the process of data collection and analysis as simple and understandable as possible. The user must always remember his responsibility to use this and other tools in a reasonable and appropriate manner, recognizing the limitations and uncertainties that will be present in his results.

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# DEALING WITH UNCERTAINTY ABOUT RISK IN RISK MANAGEMENT

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## ABSTRACT

Conservative assumptions in risk analysis are shown to be protective of human health when the social costs of misestimation are highly asymmetrical, when risk management actions do not incur significant opportunity costs, when risk management actions do not lead to the substitution of significant new risks, and when risk managers do not compensate for perceived conservatisms when setting standards or making other risk management decisions. An issue central to the effect of systematically conservative assumptions is the ability of risk analyses to distinguish large risk from small risk; here it is argued that conservative assessments can fail to make adequate distinctions. The influence of these factors on the protectiveness of conservative analytical methods is examined.

KEY WORDS: risk, uncertainty, conservatism

> Science tells us what we can know, but what we can know is little, and if we forget how much we cannot know we become insensitive to many things of great importance. Theology, on the other hand, induces a dogmatic belief that we have knowledge where in fact we have ignorance, and by doing so generates a kind of impertinent insolence towards the universe. Uncertainty, in the presence of vivid hopes and fears, is painful, but must be endured if we wish to live without the support of comforting fairy tales.
>
> Bertrand Russell, in the Introduction to A History of Western Philosophy, 1945

## INTRODUCTION

Until the last fifteen or so years, efforts to improve health and safety were directed primarily at risks of relatively certain magnitude. The social harm from accidents and diseases such as polio were all too easy to measure. Risks were managed by learning from past mistakes; this is still an essential part of good risk management. But trial and error management is particularly ill suited for many risks of current concern, for example, risks with long latency periods or catastrophic potential.

We now seek better ways to manage risks prospectively, methods which avoid the human costs of a trial and error approach.

Where past experience is not a guide, risk management is more difficult. We have been struggling with several such cases for the past decade: nuclear power, chemical carcinogens, and more recently, biotechnologies. Here, one approach to uncertainty about such risks has been to try to reduce it through research. Substantial resources have been expended to understand these risks, and risk management has been improved by such studies. Despite much effort to estimate risk, where direct human evidence is not available, large uncertainties about risk remain. Research may eventually resolve many questions that now trouble us, and in some cases postponing a decision for research may avoid uncertainty. But many risks are likely to remain uncertain for the foreseeable future.

Estimating the magnitude of risks that cannot be measured directly frequently requires the use of assumptions that cannot be tested empirically. Not only are such risks uncertain, but often the uncertainty cannot be characterized probabilistically. Probability distributions are useful for describing some uncertainties, but this is often not feasible in risk assessment. Often there is no reasonable method even to assign weights to the plausibility of alternative assumptions. Methods have been developed to elicit subjective descriptions of uncertainty; this raises the question of whose estimates to accept.

Recognition of these uncertainties has at times led to the view that risk assessment is a dubious enterprise, too uncertain to be relied upon for risk management decisions. But low level risks are inherently uncertain regardless of the approach taken to their study. This uncertainty is simply more apparent under some approaches to social risk management than others. Given the discomfort that uncertainty causes, it is tempting in some cases to overstate what risk assessment can tell us. The limits to science are imprecise, as are the distinctions between that which is known and that which can reasonably be assumed. For this reason, a technically accurate description of uncertainties is now considered essential in risk assessment.

Risk assessors bridge gaps in knowledge with assumptions. Often there are many alternative assumptions, each scientifically plausible, with no reasonable basis for choosing among them. For example, an analyst must select a dose-response model for extrapolation to low dose risk. Here the recent tradition endorses conservatism in risk estimation as protective of public health. I argue here that conservatism, defined here to refer to the systematic selection of assumptions leading to high risk estimates, is not protective of human health in most situations.

## RISK VERSUS UNCERTAINTY

Risk, as generally used by health and safety risk analysts, measures probability and severity of loss or injury. Uncertainty, using the dictionary definition that best describes its use in the risk field, refers to a lack of definite knowledge, a lack of sureness; doubt is the closest synonym. At times, these definitions are confused. Risk and uncertainty are related to the extent that both preclude knowledge of future states, and that both are often described by use of probabilities. But it is important to distinguish whether a lack of predictability arises from insufficient knowledge (uncertainty) or from a well understood probabilistic process (risk). The risk associated with a bet on a fair coin toss is precisely known; the risk has no uncertainty,

although the outcome of the toss is uncertain. Conversely, the outcome of the administration of an experimental drug is also uncertain, but in such a case the inability to predict may be due more to a lack of information than to what also may be an inherently probabilistic process. The predictability of the result of a large number of trials helps to make the distinction between risk and uncertainty clearer -- for a fair coin toss, we can predict that about half of the results will be heads. For an experimental drug given to a large population, the number of people adversely affected may not be predictable except to within a broad range.

In the case of an experimental drug, the estimated probability that an average individual will experience an adverse effect (or equivalently, the number of people in an exposed population experiencing an adverse effect) might be described by use of a probability distribution. A probability distribution applied to a probability is known as a second story probability (such a distribution describes the relative likelihood that the probability of an adverse effect is a particular value).

Decision analysts and theorists of subjective probability frequently note that the second story probability representation is unnecessarily complex; that such measures can be mathematically collapsed into a single probability. That is, the probability of a probability is a probability. For individual decision making, it may be immaterial what combination of probabilistic processes and information gaps give rise to an estimate of the likelihood of some outcome; it is sufficient to describe the likelihood of an outcome by a probability. However, in the case of social risk management by a regulatory agency, it is often useful to distinguish between risk and uncertainty.

## RISK ASSESSMENT POLICY

The recent National Academy of Sciences report Risk Assessment in the Federal Government: Managing the Process (National Research Council 1983) endorsed the concept that scientific questions about the degree of risk posed by some exposure or activity should be separated, to the extent feasible, from the policy questions of what risk management steps should be taken. This report clearly describes how science and policy cannot be entirely separated, and noted that many seemingly scientific issues such as the assumptions made in a risk assessment have direct relevance to management decisions. As seen by the committee which wrote this report:

> The goal of risk assessment is to describe, as accurately as possible, the possible health consequences of changes in human exposure to a hazardous substance; the need for accuracy implies that the best available scientific knowledge, supplemented as necessary by assumptions that are consistent with science, will be applied.

The difficulty arises when there is no scientific basis to select among alternative assumptions. The NAS Committee did not offer a general recommendation for choosing assumptions when this occurs, however it did note that in such cases, it may be appropriate to select the most conservative assumptions (i.e., those leading to the highest estimate of risk).

Carcinogenic risks and their assessment were chosen to illustrate many points in the NAS report cited above, primarily because the approach to these risks has become more standardized than has the estimation of other risks. Assumptions generally thought to be conservative are used by agencies in evaluating potential carcinogens. For example, conservative

risk assessment assumptions are used by EPA's Carcinogen Assessment Group to estimate a plausible upper bound for risk; the plausible lower bound is taken to be zero risk except where direct human evidence indicates otherwise. These upper bound risk estimates are based on data from the most sensitive sex, strain, and species of test animal; for the cancer tumor type (often including benign tumors) and site which maximize the estimated potency; transfer of animal results to humans based on the ratio of surface areas, an approach more conservative then scaling by weight; and extrapolation to low dose is based on a dose-response model that exhibits linearity at low doses. The sensitive sex, strain, and species selection is at times justified on the grounds that humans are genetically diverse, widely varying in existing health status, and exposed to many other potentially harmful agents. A recent article (Anderson et al, 1983) provides a good description of carcinogenic risk assessment at the EPA.

## IS CONSERVATISM PROTECTIVE?

Does reliance on assumptions producing upper bound risk estimates protect health? The question is analytically tractable. Not surprisingly, its answer depends what assumptions are made. For some seemingly reasonable analytical assumptions, conservatism is protective; for other assumptions, also reasonable, conservatism is not.

Certainly the perception of many risk analysts is that conservative risk assessment assumptions are protective. High risk estimates are associated with stringent standards. An analyst's own sense of responsibility encourages conservatism. Although the social costs of false alarms are acknowledged, to give a false assurance of safety is believed to be far worse. The relative social cost of risk underestimation is taken to outweigh that from overestimation. An analytical case for conservatism is made by Talbot Page (Page,1978), who argues that the appropriate response to uncertain environmental risks is to balance the social costs of false negatives (substances or activities incorrectly thought to be safe) with the costs of false positives (things incorrectly believed to be hazardous). His analysis indicates that the use of this expectation rule seems clearly preferable to approaches aimed exclusively at avoiding either type of risk misclassification (i.e. false positives or false negatives). Page notes that "Application of this approach requires four pieces of information: the cost of a false negative; the cost of a false positive; and the probability of each." Given the difficulty in knowing the probabilities of false positives and negatives, he argues that:

> when the potential adverse effects of an environmental risk are many times greater than the potential benefits, a proper standard of proof of danger under the expected cost minimization criterion may be that there is only 'at least a reasonable doubt' that the adverse effect will occur, rather than requiring a greater probability, such as 'more likely than not,' that the effect will occur. Simple rules of thumb embodied in legal and regulatory institutions may come closer to expected cost minimization than elaborate attempts at quantification.

The interesting feature of Page's analysis is his lack of aversion to uncertainty; uncertain risks are judged on their expectation to the extent it can be estimated and characterized. The rather stringent proposed rule, "at least a reasonable doubt" is consistent with Page's analysis in which it is argued that for most environmental risks, the relative social costs of a false negative (leading to a failure to regulate a hazardous substance) greatly exceed the costs of regulating a safe substance. Among

the common characteristics of environmental risk, Page lists modest benefits and catastrophic costs. For substances like food color additives or fluorocarbon propellants, where benefits are easy to forgo or where safer substitutes exist, the "at least a reasonable doubt" rule is appropriate from a cost-benefit viewpoint.

But to find that analytical conservatism is protective requires three premises: (1) that the disparity in social costs between false negatives and false positives is great, (2) that risk management decisions are insensitive to resource constraints and do not incur significant opportunity costs, and (3) that activities or agents identified as hazardous (whether true positives or false positives) can be eliminated without the creation of significant new risks. The potential protectiveness of conservatism also depends on whether risk managers compensate for conservatism in standard setting.

## THE SOCIAL COSTS OF ERROR

In his analysis, Page described dichotomous risk decisions and classifications. Substances were carcinogenic or not; when they were misclassified, the resultant errors were false positives or negatives. This representation is a useful way to illustrate how it is socially desirable to balance the costs of errors in managing uncertain risks, and this was Page's objective.

Actual problems are generally not so black-or-white. Current issues often are with a substance's degree of carcinogenic potency, and with the establishment of exposure limits. Under this view, risks and risk management alternatives are continuously variable rather than discrete. It is actually easier to make the case for controlling risk under this continuous perspective, because it is generally harder to justify the ban of a hazardous substance on cost-benefit grounds than it is to justify a marginal reduction. This follows from the common assumption that health benefits are constant per unit of reduced exposure but that as use goes to zero, progressively more valuable social benefits are forgone.

If potency and exposure are variable, the harm from risk assessment errors is less than if they are discrete. A shift in analytic assumptions, for example to the average carcinogenic potency exhibited in several species rather than potency in the most sensitive species, could result in a less stringent standard. But this seems unlikely to lead to a public health disaster or excessive individual risk that one associates with the failure to recognize and control a potent carcinogen. Some risks, such as from biotechnologies or from climatic change do not necessarily follow this characterization. Consider basing exposure standards on assessed risk, using cost effectiveness criteria that appropriately reflect social cost. For exposures at the standard, marginal costs and risks are presumed to be equal. For slightly misplaced standards, due perhaps to small errors in assessing risk, the costs of over (or under) exposure will largely be offset by reduced (or increased) costs of risk control. These costs due to small inaccuracies in the estimation of risk are roughly symmetrical; for large errors,the costs of excessive public health risk and unnecessary regulation will vary.

The social costs from errors in risk estimation would be minimized if mean value estimates were used. Mean value risk estimates reflect the weighted average of all possible risk values. Conservative analysis and upper-confidence-bound estimates lead to overinvestment in risk control, but also to lower risk. At least this is the first-order effect.

## RESOURCE CONSTRAINTS AND RISK MANAGEMENT

Are national health and safety expenditures limited in the aggregate, or are they variable, depending on the outcome of many independent risk management decisions? If risk reduction expenditures are not limited in the aggregate, but are determined on a case-by-case basis, then it is appropriate to consider whether conservatism is protective by considering specific cases. However, if the fraction of GNP allocated for risk reduction is politically constrained, or if some other factor constrains risk management spending in the aggregate, then the collective effect of risk management decisions is the appropriate basis for evaluating whether conservatism serves a useful purpose.

Because risk analysts and agency standard setters generally focus on one risk at a time, this single risk focus is a natural frame of reference. From the perspective of a single risk management decision, analytical conservatism is protective, but at a price. A conservative risk estimate produces lower risk exposures. Here, the potential costs of large errors seem to be asymmetrical to the regulator. Risk reduction costs appear to be bounded, while the consequences of uncertain risk exposures are potentially much greater than these control costs.

An additional factor encouraging conservatism is how decisions might be judged in hindsight. An overcontrolled risk will probably drop from sight once a decision is implemented and control investments made. But an undercontrolled risk, possibly discovered through the identification of victims, is far more disturbing for a regulatory agency.

If risk reductions are limited by resource scarcity, however, the logical objective is to allocate the scarce resource in a way which maximizes social benefits. Opportunity costs, of little concern for a single risk, become important under this viewpoint. Money or regulatory attention spent on one risk is not available for another, so it is important not to waste resources on trivial risks. In this case, conservatism is counterproductive, and risks are increased if resources are shifted from significant risks to small, exaggerated risks. Under this fixed allocation or zero sum case, risk reductions are maximized when the cheapest and easiest risk reductions are given highest priority. Here, conservative estimates shift resources to uncertain risks, increasing expected health consequences.

Which perspective on regulatory resources is correct? Both have their merits. Regulatory agencies actions may be limited by the availability of scientific or administrative resources within their own staffs. But risk management responsibility assigned to the agencies by Congress is fragmented, and suggests nothing in the way of an overall ceiling on risk spending. The bulk of control costs come from producers, not regulatory agencies, so agency budgets are not a direct constraint. But while these expenditures appear to be variable and flexible, dependent on the perceived appropriate action in each case, there may be a political feedback from the regulated parties that limits the amount of money an agency can require to spend. A subtler consideration is that, to the extent that the public finds uncertain risks discomforting, greater expenditures for risk control may be politically feasible if funds are directed to deal with uncertain (and unpopular) risks.

## RISK TRANSFERS

Often a regulatory action that reduces one risk will increase another

(Whipple 1985). This is especially prevalent when the particular benefit being obtained is considered essential but all methods for achieving the benefit carry risks. The important issue here is the recognition that the appropriate measure for analysis of a risk-reducing action is the net risk reduction. From this perspective, uneven conservatism in risk assessment can have a perverse effect by leading to the substitution of large risk for a small one. The cyclamate ban, leading to greater use of saccharine, may be a case in which this occurred. (Risks from both substances are significantly uncertain.) Electricity production is also a good example, because utilities are obligated to provide service. A restriction on coal use can lead to greater oil use; regulatory restrictions on nuclear power can lead to increased use of coal.

In some cases, for example, those involving carcinogens, it may be possible to compare risks with common conservative assumptions and arrive at a reasonable relative ranking. But for dissimilar technologies such as coal and nuclear electricity, the comparison of conservative risk estimates does not include conservatisms common to both estimates. In these cases, conservatism is less useful and less protective than are central estimates or risk.

## DO STANDARD SETTERS COMPENSATE FOR CONSERVATIVE RISK ANALYSIS?

Regulatory decision makers may consider the details of the evidence supporting a risk estimate and compensate for perceived biases in analysis. If this is the case, and appropriate adjustments are made, then standards will be the same no matter what risk assessment assumptions are made. In this case, conservative analysis would not lead to more or less stringent standards than would best estimates. It is likely that conservatively estimated risks are discounted in some cases but not in others and it is unlikely that adjustments could be made appropriately and consistently.

In the previous discussion of resource constraints, it was assumed that conservative estimates lead to stringent criteria But it is apparent that conservatism in risk management need not be achieved through conservative risk assessment assumptions. One could use stringent criteria for allowable risk, and less conservative assumptions for estimating risk, and end up with the current levels of protection.

If greater use were made of this flexibility to vary risk criteria in response to conservatisms in risk assessment, an attractive approach would be to select risk assessment assumptions based on their discriminatory power. Relative risk estimates based on overly conservative assumptions may not distinguish important differences between risk. For example, an increase in benign liver tumors and decrease in leukemias and mammary gland fibroadenomas has been observed in response to test chemicals in the Fischer 344 rat (Haseman 1983). Under present assessment methods, a carcinogen that increases benign tumors at one site but reduces malignant tumors at other sites might have the same assessed risk as one that increases the overall burden of malignant tumors.

## CONSERVATISM IN RISK ASSESSMENT: COMMENTS

Even if efforts to be less conservative in risk assessment are accepted, there will be cases where no method for choosing between

alternative assumptions is available. About the best that risk analysis can provide when this happens is a collection of estimates based on a range of plausible models. Granger Morgan and his colleages have taken this approach to describe the estimated health effects from sulfur air pollution (Morgan et al,1984).

If less conservative assumptions are adopted for carcinogens, understanding the implications for human health of alternative animal bioassay results takes on added importance. There would be apparent value in conducting a wide variety of animal tests with known human carcinogens as a means of calibrating these experiments. A second consideration, suggested by animal test results (Haseman '983), is whether certain carcinogens redistribute the tumor burden, whereas others increase total tumor incidence. If this turns out to be the case, it would be beneficial to health to discriminate between the two types of effect. Conservative assumptions about risk are thought to provide protection against uncertainty in risk, although sometimes at an added cost. Much impetus for analytical conservatism comes from the perception that this practice is protective of health. This is the perspective when risks are viewed singly. But conservatism may not protect if reduced exposures to uncertain risks is achieved at the expense of increased exposures to known risks.

Considering the many ways in which a conservative analysis can fail to protect, intentional use of conservative risk estimates is not beneficial to public health. In addition to misallocating scarce resources, conservatism can lead to unwise risk transfers and encourage risk regulators to compensate for perceived conservatisms. When this happens, risk regulation becomes less predictable and more arbitrary.

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# DEALING WITH UNCERTAINTY IN RISK REGULATION

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ABSTRACT

The uncertainties in risk analysis are inevitable and cannot be reduced to zero. They arise from the incompleteness of the system modeling, the simplification of sub-system interactions, database errors, the variety of failure initiators, the range of failure consequences, and the prediction of public and individual exposures and doses. The composite uncertainty in the quantification of a single risk makes choosing regulatory criteria difficult. However, alternative systems for providing a specific end function generally have similar types and magnitudes of uncertainty, and a comparison of their mean values of quantitative public risk may disclose their relative risks adequately for regulatory purposes.

KEY WORDS: Uncertainty, risk, regulation

The use of the regulatory process to establish boundaries on public risks is usually presumed to be based on a valid perception of these risks, and of their relative importance in the spectrum of public exposure to all risks.

Let me specify what I mean by risk. Risk is a measure of the potential exposure to a loss arising from the by-products of an activity, with the usual descriptives of what, where, when, who, and how much. The ambiguities associated with this simple definition arise from the variety of the losses that may be incurred (life, life expectancy, financial, property, environmental, etc.), the time periods used for the probability statement (exposure time, latency period, lifetime, annual, etc.), the population exposed (individual, group, regional, national, age sector, etc.), and the quality of the estimate. The calculation of risk involves the product of three separate factors, (1) the probability of an initiating event, (2) the magnitude of the loss-creating outcome, and (3) the resulting size of the loss.

The average person is not likely to develop a balanced perspective of life's spectrum of risks, or of the associated benefits of life's activities. Although risks are real, and often quantifiable in the aggregate -- as with physical accidents -- individual perceptions and attitudes usually are not derived from these realities. Thus, public concern with issues of risk may result in powerful popular movements, but these are rarely a useful guide for the most effective allocation of national resources to increase public health and safety. Providing a

better and less subjective guide for this purpose is the objective of risk analysis and regulation.

The regulatory process obviously deals with future events, and thus suffers from the well-known limitations of any prediction. Ideally, risk regulation should be based on a statistically significant history of similar risk events which are reasonably measurable and which disclose the relevant cause-effect relationships. Unfortunately, such a professionally satisfying analytical basis seldom exists, and most risk regulation is unavoidably embedded in large uncertainties. Even when a reasonably verifiable basis exists -- such as with smoking, drunk driving, auto seat belts -- the predicted outcomes of proposed regulatory actions are sufficiently uncertain as to provoke much public argument.

The uncertainties in risk analysis are inevitable and can never be reduced to zero. Consider any system intended by man or nature to function safely under normal conditions. For obvious reasons, the actual operating conditions will vary about the norm in some statistical fashion, and for this discussion assume the usual bell-shaped probability distribution of such conditions. So, the stresses on the system produced during operation will sometimes be below the norm and sometimes above. To operate safely most of the time the system is designed to withstand a stress considerably above the normal operating point, thus providing a "safety factor". The actual ability of the system to withstand stress varies with time about the design level in some statistical fashion due to the usual uncontrollable elements - material variations, aging processes, assembly tolerances, etc. Again, assume a bell-shaped probability distribution for the system strength. We thus have an analytical situation in which the upper tail of the operating stress distribution overlaps the lower tail of the system strength distribution. This overlap area is the failure zone.

It is clear that as long as the tails of the probability distributions extend sufficiently, the overlap failure zone will always exist. Narrowing the probability distributions by (1) greater effort to minimize variations from normal operation, and (2) to strive for "zero defects" in the system, will certainly decrease the probability overlap and thus the frequency of failure, but can never remove the failure zone. In a schematic sense, this explains why "zero risk" is not a rational objective. In a pragmatic sense, this explains why we will always have to deal with uncertainties in projecting future probabilities.

Thus the policy issue is not whether regulation of risk should be withheld until everything is predictable, - an impractical goal - but rather, when the body of evidence is sufficiently strong to clearly justify some regulation, how should the many pervasive uncertainties be taken into consideration.

In this regard, we should recognize that regulations operate at two extremes of public risk. The first is the great body of public exposures which are commonly assumed to be safe (e.g. natural foods) and are occasionally found to represent a hazard requiring regulatory constraints (e.g. aflatoxin in peanut butter). The second is the growing body of public exposures which are commonly assumed to be hazardous, and require regulatory permission for use (e.g., man-made drugs and pesticides). Constraint and permission are thus the two sides of the regulatory coin, but their implementations are quite different. The first is safe until proven guilty, the second is guilty until proven safe. Constraint requires the regulatory agency to prove the risk, whereas permission requires the producer to prove the safety, both beyond a reasonable doubt.

The treatment of uncertainty is thus also implemented at the extremes. In the case of the commonly safe exposures, constraint is absent until the risks are well established, i.e., the uncertainty in risk quantification may be small (e.g., tobacco). For the commonly hazardous group, permission is withheld if there exists any indication of risk, i.e., the uncertainty in risk quantification may be large (e.g., PCB's, dioxin, etc.).

In any risk analysis, the uncertainties arise in each one of the basic components of the analysis. The first is the completeness of the model used to represent the system. The core structure of any model consists of the "?" whose role and system behavior are assumed to be well understood. These are interwoven with the "known-unknowns" whose existence is recognized but whose behavior is not well understood. Omitted from the models are the "unknown-unknowns", elements which are not recognized as being involved, but nevertheless may become important factors in a failure sequence.

The second uncertainty arises from the inadequacy of the model's prediction of system behavior. The dynamics of the relationships among the many model elements is rarely simple, but it becomes impractical to include higher-order effects and probability distributions in a complicated system analysis. As a result, the best one can expect is an approximate quantitative mean value prediction, and a crude estimate of a resulting band of uncertainty. The third uncertainty arises from errors in the data base used in the model calculations. In most issues of public risk, the data is likely to be of dubious accuracy or incomplete or difficult to separate from secondary variables. In most models, quantitative outcomes can be very sensitive to small changes in some of the relevant data, so the selection of a data base can often determine the outcome of the model.

The above three sources of modeling uncertainty relate to the methodology of analysis. As a practical matter, the quantitative assessment of a public risk involves a sequence of several relatively independent models. The initial model commonly attempts to predict the probability distribution of failure of a system during normal operation - e.g. the collapse of a bridge or a dam, the explosion of a steamboiler, the blowout of an auto tire, the nuclear core-melt, etc. Such failures may have many diverse causes such as corrosion processes, or poor maintenance, or a stressful concentration of several independent events. A rare-event input model attempts to predict the probability distribution of failure initiators arising from unusual natural phenomena such as earthquakes, lightning, hurricanes, tornadoes, and the thousand-year flood; and from man-made events such as fires, bombs, sabotage, etc. A third model estimates the magnitude of the physical consequences of the failures - for example, the amount of water released by a dam failure, or the chemicals released in a plant explosion. A fourth model is concerned with the size of the public exposure to these physical consequences - how many people are involved, and can they be evacuated or protected? A fifth model covers the individual dose exposure - wet feet to drowning; or lung irritation to asphyxiation.

This is a typical list of the models needed to predict physical or physiologic failure probabilities and uncertainties. There is also a non-technical domain of economic, sociologic, and political factors that always encompasses the regulatory process. Such factors generally are not as susceptible to quantified analysis as are the technical factors listed above, although they may be pragmatically of comparable or greater importance. It is obvious that in many cases, the quantification of risk

is often overwhelmed by the composite magnitude of the uncertainties. It is important, therefore, to review the value of risk quantification under such circumstances, to establish its area of usefulness

We should recall that the prime criterion in the choice of a technical system (physical or physiologic) is the successful accomplishment of an end objective. For example, the need for a river crossing leads to a choice of a bridge or a ferry. Or, more commonly, cure of a disease leads to a choice among medical treatments or drugs. In every case, the chosen mode is designed to work, not fail. From this positive perspective, risk quantification serves two functions: first it assists in the disclosure of the comparative risks among available alternatives; second, for any chosen mode, it assists in the comparison of design alternatives within that mode. In either case, it is the comparative risk analysis which makes risk quantification useful. The process raises the probability of successful achievement of the end function, and reduces the public risks from a potential failure of the chosen mode.

The novel contribution of modern risk analysis, based on quantification of system event probabilities and their consequences, is best understood by considering the accepted approaches to risk prior to the middle of this century. Civil engineering structures -- buildings, bridges, dams, etc. -- are classic examples. The historical design objective was to avoid failure of the structure, defined as collapse under expected usage. To provide such assurance, the designers applied a traditional "safety factor." For example, if a rope was tested to hold 100 pounds, a safety factor of 10 would be provided if the maximum load did not exceed 10 pounds. In practice, these safety factors traditionally ranged from a low of 3 to as much as 40, depending on the designers' judgment and the tradition for each type of usage, i.e., steady state, cyclic stress, shock, corrosion, etc. Thus, the safety factor supplied a design umbrella large enough to cover all the areas of the designers' known range of ignorance, i.e., the "known unknowns." The system worked reasonably well, although an occasional structure collapsed because of an "unknown unknown"; for example, the Tacoma bridge collapse caused by unanticipated wind-induced oscillations; or the sinking of the "unsinkable" Titanic by iceberg collision.

The safety factor design approach was socially acceptable at that time. The engineering profession said, "trust us," and the public did. There were no probabilistic risk assessments involving off-design failure analyses, no environmental impact statements, nor any of the other modern trappings of project reviews. The designers' judgment on the choice of safety factors integrated all uncertainties without an explicit justification of the choices. The public risk was implicitly covered by the presumption of safety arising from the design objective of avoiding failure, but risk was never explicitly estimated. When the unforeseen occasionally occurred, it was usually accepted as an "act of God."

The historical approach to the risk management of a short-lived replaceable product which permitted rapid feedback was one of empirical "trial and error," as, for example, with modern autos and modern airplanes. Operating experience was fed back to guide improvements, a process that continues today. The traditional "safety factor" was less important in such product designs, because the feedback process was sufficiently rapid (a few years) to permit improvements needed for achieving a performance target. The collective public risk was initially low, because only a few individuals were involved in the early developmental stages, although individual risks were high.

It should be recognized that the "safety factor" and "trial and error" methodologies continue to be pragmatically useful, and are only slowly being supplemented by modern risk assessment approaches in a limited number of publicly pervasive systems. The public penetration of large-scale technologies has become much more rapid than decades ago, so the "safety factor" and "trial and error" method can be very costly both in public health and cost. This is particularly evident with low-level effects which can develop in a large population. Further, some large-scale systems involve so many interdependent components, that the compounding of individual safety factors would make the system inoperable (e.g. air transport). Finally, very rare but high consequence events may require decades or centuries to provide the feedback information for guiding decisions, and each such occurrence may be undesirably costly to public health and safety. It is these considerations that have encouraged the development of modern risk assessment approaches which try to estimate the probability and magnitude of future events. Such risk assessments disclose the system interactions, sequences, and individual component failure probabilities that produce the final estimate of the probability distribution of a public risk. The assessments thus provide a guide to reiteratively altering the system to reduce the public risk. A notable example is the Probabilistic Risk Assessment (PRA) now common in nuclear plant engineering. Thus risk assessment is a powerful tool for reducing the central value (mean) of the probability distribution of a public risk, but it has little influence on reducing the uncertainties. In fact, risk assessment tends to make the uncertainties more evident by disclosing the sensitivity of the mean value to small variations in the database or the model

Recognizing the technical merit of an analytical projection of future probabilities, the handling of the uncertainties surrounding such projections is a major obstacle to regulations. It is particularly so when the quantification of an isolated single risk is being sought. For some time, many of us have emphasized that the well known Probabilistic Risk Assessment (PRA) of nuclear plants is useful primarily as a guide to comparative analysis of alternative engineering modifications. Extension of the PRA to a quantification of public risk in an absolute sense is very dubious, for the reasons I've already given.

However, if the objective is a comparison of the relative public risk of alternative electricity generation systems (coal, oil, gas and nuclear), such a comparative quantification has usefulness in managerial and regulatory decision making. Because alternative systems for providing a specific end function may have many common modes of uncertainty, or similar magnitudes of uncertainties, in such a comparative framework the central values (the mean) of quantitative public risk estimates may correctly disclose the relative risks of alternative choices, even if the absolute scale remains uncertain.

It has become very evident that the uncertainties surrounding individual projected public risk estimates will always be large. These uncertainties can be disregarded only when the public risk quantification is so low, that even the upper bound of the uncertainty estimate is below a "de minimis" level (e.g. the aflatoxin constraint in food). For larger risks only the comparative risk analysis of alternatives is meaningful.

It should be emphasized that foreclosure of any technical option forces the acceptance of an alternative. The resulting transfer of public risk to that of an alternative should not be disregarded. Our current example is the nuclear power regulatory debate, presently being conducted without a balanced comparison with the risks of the fossil fuel options.

Eventually, a comparative risk analysis of all electricity alternatives must become the basis of a rational regulatory policy. In general, while much may eventually be accomplished to reduce the uncertainties in public risk analysis, the emphasis should be on the use of comparative risk analysis as a means of reducing the influence of uncertainties on the choice among alternatives for providing an end-function.