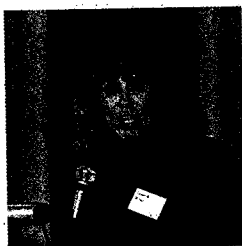




Risk in Perspective

Managing Risk Tradeoffs

"The elements of risk assessment that have been defined by the National Academy of Sciences can be applied to microbial contaminants."



Joan B. Rose, Ph.D.
University of South Florida

On March 30-31, 1995, over 400 individuals from government, business, academia, the media, and non-profit organizations convened at the Hotel Washington to discuss a "sleeper" issue in regulatory reform. How should regulators charged with protecting the public from dangers to health, safety and the environment recognize and weigh dangers that might be caused by their own actions?

Historically, regulators have concentrated on reducing the immediate "target risks" of concern to Congress and the public, but it is becoming increasingly apparent that the "countervailing risks" induced by regulation should not be ignored. Regulators are like doctors: they have a responsibility to disclose and consider any side effects that may result from treatment as well as the treatment's anticipated effectiveness against the patient's ailment.

The symposium "Weighing the Risks," sponsored by the Harvard Center for Risk Analysis, was dedicated to stimulating awareness of the "risk-tradeoff" issues. This theme was highlighted in five well-defined case studies: drinking water, pesticide products, the reformulation of gasoline, hazardous waste sites, and pollution prevention. In the last session of the symposium, speakers addressed how risk tradeoffs should be addressed in legislation, administrative policies, and judicial review.

The meeting was held in the context of intense congressional interest in the need for better risk analysis and regulatory reform. Of particular interest to the symposium was an explicit provision in H.R. 1022 (passed by the House of Representatives) calling for a statement of any "significant substitution risks" that may result from a regulator's actions.

In this issue of RISK IN PERSPECTIVE, we highlight the points of view raised at the symposium for the benefit of those who were not in attendance. Many points of view were expressed, not only by the invited speakers, but

also through spontaneous remarks from individuals in the audience. We cannot possibly cover all the viewpoints expressed during the two days and thus this piece is a synopsis based on the symposium transcript.

Case Study One: Drinking Water

Beginning in the early 1900's, communities in the United States began to use chlorine to disinfect their drinking water supplies. This chlorination process proved to be quite effective in preventing waterborne diseases ranging from chronic diarrhea to typhoid fever. Today, chlorination of drinking water is considered one of the most dramatic success stories in the field of public health.

It is becoming apparent, however, that chlorination is not free of countervailing risks. The addition of chlorine to water supplies can cause the formation of a variety of chemical byproducts, especially chlorinated hydrocarbons (trihalomethanes). The levels of trihalomethanes in treated water are not acutely toxic to people, but the possibility that these compounds could cause long-term, chronic effects, including cancer, is now a subject of intensive research by toxicologists and epidemiologists.

The policymaker responsible for assuring safe drinking water faces a dilemma: How should the well-known and acute risks of waterborne microbial disease be weighed against the uncertain but potentially serious long-term health risks created by the byproducts of chlorination? The U.S. EPA and regulatory authorities throughout the world are now struggling with this dilemma.

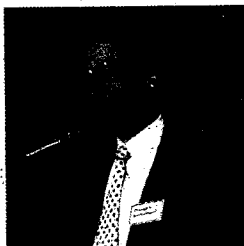
Dr. Joan B. Rose, a microbiologist from the University of South Florida, urged the scientific community to develop better methods and data on the risks of microbial disease that can be used by regulatory authorities. She emphasized that scientists are only beginning to recognize the full range of viruses and protozoa that people are consuming in their

"Use of comparative risk tools is only rational if the result will be that the risks that are identified can be reduced. Analysis should lead to action."



Lynn Goldman, M.D.
U.S. Environmental Protection Agency

"More public understanding of the various public health benefits of MTBE would be appropriate."



Daniel S. Greenbaum
Health Effects Institute

drinking water. The segments of the population that are most likely to be adversely affected are the sensitive and vulnerable groups: infants, the aged, pregnant women in some cases, and the immunosuppressed. Since as many as one out of every four Americans may fall into a vulnerable segment of the population, there is a strong public health rationale for better understanding the microbiology of waterborne diseases.

Dr. Gail Charnley, a toxicologist and Executive Director of the Congressional Commission on Risk Assessment and Risk Management, described the basis for health concerns about prolonged exposure to trihalomethanes in drinking water. Epidemiologic studies have reported associations with certain types of cancer but the causative roles of chlorination and various confounding variables are not fully understood. Some of the trihalomethanes have been shown to cause cancer in high-dose rodent tests but it is not known whether those compounds are metabolized similarly by rodents and humans. Dr. Charnley emphasized not only the limited knowledge about cancer risks but also the paucity of evidence on other health endpoints such as reproductive and developmental toxicity. From a risk assessment perspective, she highlighted the complications posed by ingestion of a complex mixture of chemicals rather than a single compound.

Dr. Thomas Burke, a faculty member at the Johns Hopkins University School of Public Health and Hygiene and former state regulator from New Jersey, confronted the dilemma faced by regulatory authorities. To the Governor of New Jersey, he would emphasize that both risks are probably small. But since chlorination presents risks as well as benefits, both microbiological and chemical risks can be addressed by carefully choosing and protecting the sources of water used for drinking water supplies.

Case Study Two: Pesticide Products

Congress has charged the EPA with the responsibility to regulate pesticide use to prevent any "unreasonable risks" to public health and the environment. While EPA's mandate from Congress would seem to authorize risk-tradeoff analysis of pest control, the symposium revealed a variety of obstacles to optimal regulation of pesticide products. Complications arise when the risks of one method of pest control are compared to the risks of a competing method.

Dr. George M. Gray, a toxicologist at the Harvard Center for Risk Analysis, argued that the government's standard approaches to risk assessment may produce misleading comparisons of risks. When one pesticide product is

compared to another, strictly numerical comparisons of risk may conceal differences in the quality and weight of evidence about the two products. For example, the default assumption that carcinogens have no safe level of exposure may be biologically less plausible for one pesticide product than for a competing product. In order to perform valid analysis of risk tradeoffs, agencies need to present a variety of risk estimates for each compound, including indications of the relative plausibility of the various estimates.

Dr. William Pease, an Environmental Scientist at the University of California at Berkeley, highlighted several barriers to resolution of risk-tradeoff issues and suggested that sweeping legislative mandates, such as H.R. 1022, will not prove to be workable. The current regulatory approach focuses on registration of chemical methods of pest control, a process that is not very conducive to considering the relative risks of non-chemical methods of pest control. In fact, manufacturers seeking approval of their products may resist explicit comparisons of the risks of their products to the risks of competitive products. When comparisons are made, numerous attributes must be compared such as worker safety, dietary risk, groundwater threats, and ecological impacts. Yet Congress is not considering steps that would create better incentives for data collection on each of these attributes.

Dr. Lynn Goldman, Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, reported that the agency's pesticide office has found relative risk analysis useful to help set regulatory priorities. A greater emphasis on the use of these tools will require the collection of more information about hazards and exposures. While these tools are useful in screening, they are not and cannot be used to dictate final risk management actions.

Case Study Three: Reformulating Gasoline

In the 1990 Clean Air Act Amendments, Congress required EPA to issue regulations that would stimulate the availability of cleaner gasoline for use in motor vehicles. The aim of these rules was to reduce pollution from the combustion of gasoline, including the release of carbon monoxide, volatile organic compounds (that contribute to smog), and carcinogenic chemicals such as benzene and butadiene.

In response to EPA's rules, gasolines in many regions of the country have been reformulated with oxygenates such as MTBE. Since this refined gasoline product was introduced in the state of Alaska in 1992, health concerns about MTBE have been raised, ranging from symptoms

of nausea among exposed citizens to cancer based on data from high-dose rodent tests.

Ms. Margo Oge, Director, Office of Mobile Sources, U.S. Environmental Protection Agency, emphasized that the EPA programs to promote cleaner fuels should be evaluated in terms of relative benefit and risk. The public objections that have been raised about reformulated gasoline are not based solely on health concerns; they include other concerns, such as increases in fuel prices, perceived declines in engine fuel economy, and objections to the role of government in the private lives of citizens. She acknowledged that government needs to do a better job of educating the public about the issues associated with reformulated gasoline.

Mr. Daniel Greenbaum, President of the Health Effects Institute and former state regulator in Massachusetts, noted that HEI is undertaking a careful review of the health effects information on MTBE. Greenbaum sensed more public scrutiny of the possible health risks of this new additive than appreciation of the risks from carbon monoxide, smog, and toxins that are reduced by use of MTBE. He also observed that while some questions have been raised about MTBE, more studies have been conducted of MTBE than other oxygenates such as ETBE and ethanol.

Mr. Fred Anderson, an attorney at Cadwalader, Wickersham, and Taft, commented that the reformulated gasoline rule might have stronger public support if it had been adopted pursuant to a broad-based risk-benefit law such as H.R. 1022. Under such a law, EPA would have generated the risk-benefit justification for MTBE prior to adopting a rule. Such analyses would have provided environmental advocates and state/local officials with the information that the public is now asking for.

Case Study Four: Hazardous Waste Cleanup

In 1980, the United States Congress passed the "Superfund" law aimed at cleaning up abandoned hazardous waste sites in the United States. While the goal of the law is to protect public health and the environment, it is now apparent that some remediation activities may create dangers to human health, safety and the environment. As Congress considers reauthorization of the Superfund program, thought needs to be given to whether EPA's current policies give proper weight to the countervailing risks of various cleanup strategies.

J. Paul Leigh, Professor of Economics at San Jose State University, presented quantitative estimates of the fatal injury risks to workers who remediate hazardous waste sites. While no direct data are available, Leigh used infor-

mation on the safety of specific occupations that correspond closely to the types of excavation and construction activities that occur in cleanup projects. Leigh concluded that the fatality risks to the average cleanup worker are considerably larger than the cancer risks to individual residents that might result from exposures to unremediated sites.

Curtis Travis, Director of the Center for Risk Management, Oak Ridge National Laboratory, described several case studies of actual site cleanups where target risks and countervailing risks have been estimated. A key finding is that worker fatality risks tend to increase as the desired levels of cleanup increase, since more soil excavation, solidification, and transportation is required to make the site cleaner. In contrast, the baseline risks at unremediated sites are often small because of the small numbers of people who live near sites. In future decisions, Travis recommended that more systematic attention be given to tradeoffs between the desire for risk reduction at sites and the risks and costs that are posed by remedial alternatives.

Alan Krupnick, Senior Fellow at Resources for the Future, examined the role that countervailing risks play in the current Superfund program. While the current law discourages remedies that entail off-site transport and disposal of hazardous substances, the analysis of risk-risk trade-offs on a site-specific basis is not very systematic or transparent. In the official "Records of Decisions" at many sites, the possibility of dangers to remediation workers are not even mentioned. In some cases "off-site" risks may receive too much weight, since the issue is not addressed analytically with a formal methodology.

Case Study Five: Pollution Prevention

A growing consensus supports the prevention of pollution before it occurs rather than being compelled to clean it up at considerable cost after the fact. Prevention is sometimes portrayed as a universal good since both environmental and economic objectives can be advanced. Less attention has been given to the sobering possibility that some pollution prevention activities can themselves create risks to human health, safety, and the environment. If the countervailing risks of pollution prevention are widespread and serious, a risk-analytic approach may be necessary to implement an intelligent pollution-prevention policy.

Lester B. Lave, University Professor and James Higgins Professor of Economics at Carnegie Mellon University, argued that the overall impact of pollution prevention policies may require a complex analysis of direct and

"While cleanups involve real risks to real people, the workers engaged in remediation tasks, the decisions to clean up sites are often driven by hypothetical risks to hypothetical people, people who are not yet living near a site but may move there sometime in the future."



Curtis Travis, Ph.D.
Oak Ridge National Laboratory

"In spite of its complexities and uncertainties risk assessment can play a significant role in moving companies toward more environmentally accepted processes and products."



Carl Mazza, Ph.D.
U.S. Environmental Protection Agency

"The regulated party, or others directly affected, should carry the burden of coming forward with evidence that there was, in fact, an important risk tradeoff that the agency failed to consider."



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100% recycled paper,
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FURTHER READING:

Graham JD, Wiener JB,
editors, *Risk versus Risk:
Tradeoffs in Protecting Health
and the Environment*, Harvard
University Press, 1995. This
book can be ordered by
contacting Harvard University
Press at 1-800-448-2242 or by
facsimile 1-800-962-4983.

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indirect effects on economic activity. For example, when calculating the change in the amount of toxic emissions emitted by a firm or industry, it is important to consider any changes in the type and levels of inputs provided by suppliers to the firm or industry of interest. In the automotive sector, Lave showed that the amounts of toxic emissions by auto manufacturers are small compared to the amounts of emissions from various suppliers of automotive inputs. Another illustration is the recent policy interest in the electric car, a technology that Lave believes will achieve some pollution-prevention goals but at the risk of introducing much larger quantities of lead into the environment (due to the widespread use and disposal of lead-acid batteries).

Carl Mazza, Science Advisor to the EPA's Assistant Administrator of the Office of Air and Radiation, argued that key risk-tradeoff or "substitution risk" issues play an important role in pollution prevention. In the case of stratospheric ozone depleters, the national strategy was to drive users away from chlorofluorocarbons and other ozone depleters while trying to avoid those substitutes that would be unacceptable from a risk perspective. A full-blown risk assessment of substitutes, as required in some legislative proposals, would require considerable data development and is often not practical. Substitution analysis is also complicated by the need to compare diverse endpoints such as carcinogenicity and ozone depletion. Mazza pointed out that risk assessment thinking has an important role to play in "green chemistry," where products are sought that avoid not only direct toxicity problems but problems associated with toxic by-products which require disposal and treatment.

Terry F. Yosie, Executive Vice President at E. Bruce Harrison Company, emphasized that pollution prevention, as currently practiced, is more a market-driven process than a risk-based process. This is unlikely to change since risk is only one of several factors that influence pollution-prevention decisions in the private sector. Risk can play a stronger role in future pollution-prevention decisions if government takes the step of including risk considerations in environmental reporting requirements. For example, EPA's Toxic Release Inventory could be improved by allowing risk to influence who is required to report and what compounds are included in the Inventory.

Implications for Legislation and Judicial Review

If risk-tradeoff analysis is to play a more central role in environmental policies, changes may be necessary in legislation, administrative guidelines, and judicial review practices. These changes will influence when agencies consider

countervailing risks, how seriously they analyze them, and how judges will respond to claims that countervailing risks have been given too little or too much weight in final agency actions.

Edward Warren, Senior Attorney at Kirkland and Ellis, commented that federal courts have indicated increasing receptivity to risk-tradeoff arguments in recent cases including EPA's ban on products containing asbestos and NHTSA's fuel efficiency standards for new cars. But judicial intervention should not be counted as the only, or even the best, strategy for addressing regulatory disputes, since judges are ill-equipped by training and access to information to discern what makes sense. A better approach, argued Warren, would be for Congress to pass broad-based legislation requiring agencies to make a finding that proposed regulations are likely to produce "more good than harm." Courts should then play a limited role in making sure that agencies have taken seriously their responsibility to weigh risk tradeoffs.

Jonathan B. Wiener, Associate Professor, Duke University School of Law and School of the Environment, described the context of risk-tradeoff analysis and offered proposals for incorporating such analysis in national policy. He began by noting that concern for risk tradeoffs has strong intellectual roots in diverse fields such as medicine, economics, and ecology. He then proposed a graphical model for depicting risk tradeoffs, demonstrating the challenge of weighing risk versus risk in the short term and the opportunity to develop "risk-superior" options over the longer term—options that expand society's capacity to reduce multiple risks in concert.

Turning to the role of risk-tradeoff analysis in regulatory reform, Wiener argued that recognition of risk tradeoffs counsels neither less regulation nor more regulation, but rather smarter regulation that addresses both target and countervailing risks. He noted that several bills in Congress address the risk-tradeoff issue, but not in a very systematic or comprehensive manner. Among seven specific recommendations for revising this legislation, Wiener emphasized that Congress should go beyond a requirement that substitution risks be merely stated, and should require that agencies weigh countervailing risks as part of the risk management calculus that they perform and submit to OMB for approval. He also urged that the required risk-tradeoff analysis cover not only newly created risks to human health, as the House bill indicates, but new risks to the environment as well. Finally, Wiener offered suggestions for incorporating risk-tradeoff analysis into decision making in the White House and regulatory agencies.