

INTRODUCTION ON SPECIAL ISSUE: REGULATION AND LEGISLATION

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This Issue is the second in a series of Special Issues addressing the Regulatory, Legislative, and Risk Management aspects of hazardous materials. The first Special Issue, published in *Journal of Hazardous Materials*, 10 (July 1985) 163-458, concentrated on Risk Assessment and Risk Management specifically addressing three principal areas:

- (1) Epidemiology and dose response studies
- (2) The (sometimes) diverse positions of different groups on the causes of induced cancer; and
- (3) Approaches and methodologies for assessing and managing risks.

The theme of the July 1985 Special Issue suggested that in the last few decades, we have become increasingly reliant on chemical and industrial processes and products. Prior to 1970, there was little control on releases of hazardous materials into the workplace, air, water, and land. Today, although we have government agencies to monitor and check dangerous exposure, the task they face is formidable. Indeed, we are only now finding that many of the hazardous substances in place in society can cause severe health problems, including birth defects and, most notably, cancer.

Some researchers have found increases in the incidences and deaths of workers from various types of cancers associated with workplace exposure. It is not yet clear whether the widespread use of toxic materials has led to a generalized increase in the cancer incidence. Because the production of such substances increased markedly only in the last decade, we may not know the full influence of their ubiquity until the turn of the century.

Epidemiological studies will play the major role in ultimately linking the substances to the disease. Although it is unequivocally useful for such retrospective conclusions, epidemiology must not be relied upon for prospective policymaking. Laboratory studies, have been useful for deciding which chemicals pose a potential threat to humans. Decisions on whether to introduce substances into commerce must be based on the results of such laboratory studies and on research efforts like those described here.

We can learn a great deal about the processes of toxic species in the air, land, and water through assessment studies and environmental modeling. We can get more information on the problems we face in using hazardous substances

on human health by using laboratory data and dose-response modeling techniques. How to best perform these studies, including those of this issue, is still evolving; how to wisely interpret their results to save lives is the challenge of our decade.

The current special issue concentrates on a regulatory and legislative theme and addresses it from a number of different perspectives. This multiple perspective can be well demonstrated by the diverse academic disciplines represented by the authors and co-authors. The authors and co-authors in the second special issue have the following collective training:

- chemical engineering
- chemistry
- economics
- epidemiology
- industrial engineering
- law
- materials science
- medicine
- nuclear science
- operations research
- physical chemistry
- political science
- policy science
- public administration
- safety

Many of the authors and co-authors are degreed in multiple disciplines and are employed by universities, private and public research foundations, law firms, private industry and government agencies.

While the theme of this second special issue is well focused, the approach in each of the papers is varied.

One paper (Colen) examines the legal and regulatory constraints associated with transporting hazardous and radioactive materials across federal, state, regional, and local jurisdictions. This paper cites case law as well as administrative rulings and very clearly demonstrates the multi-faceted constraints on transporting such materials and the fact that the federal government has failed to solve the dilemma of multiple attempts by jurisdictions to simultaneously regulate the same thing.

A second paper by the same author (Colen) concerns the nature of the burden of plaintiff proving causation in a toxic tort lawsuit and correlates the techniques available to the defendant to defeat that proof of causation. Causation is shown to be comprised of two components: cause-in-fact, and proximate or legal cause. Of these, Colen demonstrates that cause-in-fact is far more critical to the defendant in toxic tort litigation. The use of data based upon animal studies is found to be particularly susceptible to challenge.

Ricci et al. show that the consistency, effectiveness, and benefits of regulatory programs will be enhanced if a national approach can be made available to agencies for establishing *de minimis* risk levels. The development of a formal *de minimis* approach requires resolution of several legal and technical issues and in their paper, Ricci et al. provide conceptual and legal rationales for a *de minimis* policy to determine plausible risk bounds for chronic health risks.

In their paper, Paté-Cornell et al. discuss the recent evolution of risk regulation in general by assessing the state-of-the-art probabilistic risk assessments (PRAs) in the chemical industry. They examine the current use of the results by the industry and the regulatory agencies. They consider PRA methodology, treatment of uncertainties, safety goals, and the notion of coherence of standards.

Heising proposes the use of PRAs in supporting regulatory decisions. Her paper draws particular attention to how human error should be treated in PRAs.

Wolf et al. present two case studies that highlight the interaction that can occur among members of the class of chlorinated solvents when one of them is regulated. Such interactions occur in the production, use, and regulation of the solvents. These interrelationships can lead to unexpected and unaccepted consequences and market dislocations when one of the members of the class is regulated.

Vinyl chloride and dichloroethylene have been found at sites where the widely used chlorinated solvents – TCA, PERC, and TCE – have been released into the soil and groundwater. Wolf et al. state that vinyl chloride has also been detected in the gas streams emitted from sanitary landfills. Both vinyl chloride and dichloroethylene are used only as intermediates in the production of other chemicals so it is unlikely that either chemical was disposed of or used in the vicinity of the sites of detection.

They note that a number of investigators have demonstrated that VC and DCE are formed in the laboratory through anaerobic transformation of TCE or PERC by microorganisms. This mechanism is a possible explanation for the origin of VC and DCE. Wolf et al. assert that more research is required for verification of this formation mechanism.

Lipsett examines the principles of caused inference in epidemiology and contrasts it with principles in tort law. He finds that the outcome of litigation involving allegations of disease caused by exposure to toxic substances can be determined by epidemiological evidence. Reliance on such evidence to establish causation is a relatively recent phenomenon that courts have, with some reluctance, allowed to encroach upon the domain of the physician expert witness. This article discusses the nature of epidemiological evidence, including the process of causal inference from epidemiological studies. Causal inference is a matter of judgment involving practical application of general criteria, including the existence of an appropriate chronology, a biological gradient, biological plausibility, the evidence, consistency with other epidemiological evidence, the quality of the studies at issue, and the exclusion of alternative

causal explanations. Limitations of such studies are discussed with particular reference to the context of litigation and compensation for disease. Procedural issues in litigation, such as the exclusionary hearsay rule and the lack of an evidentiary standard to apply to epidemiological studies, have engendered inconsistency in courts' treatment of epidemiological evidence. While in some cases the role of epidemiological investigations has been dispositive, in most lawsuits such studies are of limited utility.

Rodgers' paper describes four types of uncertainty confronted by decision-makers undertaking risk assessments. It then discusses individual and institutional responses to uncertainty; these include both formal attempts to acquire more information, and more pragmatic responses to salient consideration. Then, it presents judicial reviews as a sorting or culling mechanism to distinguish acceptable from unacceptable agency responses to uncertainty.

Rosenberg finds that joint and several liability can be an effective instrument for regulating the risk of and compensating the losses from toxic torts. Upon close analysis, efficiency and fairness concerns about the rule's potential to impose disproportionate liability upon wealthier firms do not support current reform efforts to replace or supplement joint and several liability with one of the judicial allocation methods – either apportioned liability or contribution. Under the negligence standard, the threat of disproportionate liability serves only to reinforce a firm's incentives to act non-negligently and avoid all liability. As such, when the negligence standard applies, efficiency and fairness norms will be satisfied regardless of whether or by what formula liability is apportioned.

Inhaber's paper examines the storage, either temporary or permanent, of high-level nuclear wastes in the form of spent fuel from reactors and concentrates on the specific issue of Monitored Retrievable Storage (MRS). Originally only a little-known provision of the Nuclear Waste Policy Act (NWPA), it became a major issue in Tennessee. One town, Oak Ridge, was the first community in the United States to vote officially to accept high-level wastes under any conditions. His paper outlines some of the debates and the considerations going into this decision, from a social viewpoint.

Solomon's paper contrasts the current view of risk management held by local government officials with those views held by both State level and Federal level government officials. While generalization is itself risky, all of his observations point toward the conclusion that relative to State and Federal officials, local government officials have little understanding of, hence little concern for, the quantity of risk posed for citizens by various hazards. To the extent that it seems desirable to place risk-management type decisions in the hands of local government officials, then some capacity for risk quantification, hence comparison, must be developed.

The findings presented in Solomon's paper are drawn from both generalized surveys of local and state decisionmakers and analysis of specific case studies. These case studies include the decisions to: remove asbestos from schools; close down a copper smelting facility in Tacoma, Washington; shut off contaminated drinking wells; cite hazardous waste facilities; and store hazardous chemicals.