

The Use of Risk Assessment in Environmental Law

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INTRODUCTION

Lawyers will spend more of their time in the future coping and living with risk assessment, particularly when representing clients in matters that fall within the jurisdiction of the Environmental Protection Agency ("EPA"). Environmental lawyers must deal with risk assessment in three major areas. The first is regulatory decisionmaking. The second is related to toxic substance exposure (tort litigation). Insurers are also involved in this area to the extent that they insure environmental risks. The third area is in activity-related risk management, found primarily in the private sector. Following a brief discussion of the elements of risk assessment, this paper will discuss the role risk assessment plays in these three areas of environmental legal practice.

I. THE ELEMENTS AND LIMITATIONS OF RISK ASSESSMENT METHODOLOGY

The elements of risk assessment are (1) hazard identification, (2) dose-response assessment, (3) exposure assessment and (4) risk characterization. Each of these four elements contains the potential for error, regardless of the context of application. Also, both mathematical models and cross-media extrapolations, whose use has increased over the last twenty years, have the potential for introducing bias into risk assessments and magnifying underlying errors of assumption.

There is disagreement among risk assessment professionals about the appropriate use of various methodologies in most of the common exposure scenarios. There is also disagreement about the use of conservative or realistic assumptions. There has been much scientific debate concerning how the relationship among uncertainties of risk assessment, opposition to regulation

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by industry and the sheer numbers of potentially hazardous chemicals has clouded the prospects for an orderly and comprehensive approach to the regulatory control of the environment.

In addition, risk assessment methodology is frequently treated as though it were a scientific discipline when the reality is that it has merely attained a certain degree of acceptance coupled with a veneer of scientific plausibility. With these introductory thoughts in mind, we can begin to examine particular ways in which risk assessment methodology is used by regulatory agencies.

II. REGULATORY AGENCY USE OF RISK ASSESSMENT

Regulatory agencies use risk assessment methodology in two major ways. The first use is to determine the likelihood and consequences of a potentially harmful hypothetical event, such as a highway bridge failure or aircraft structural failure. Structural engineers have assessed and managed these risks for generations. During the early 1970's, the Nuclear Regulatory Commission developed regulations governing the design of nuclear power plants that included elaborate risk assessment methodologies premised on civil engineering principals. Soon, I predict, chemical-release injury-event prediction will occur as a spin-off of the implementation of the Emergency Planning and Community Right-To-Know Act of 1986,¹ because of the mass of plant-specific hazardous chemical and release information that the statute requires to be made available to the public.

Historically, as these uses of risk assessment have developed, qualitative and rudimentary quantitative techniques were relied upon. In the 1970's, however, we saw the rapid development of what has been called probabilistic risk analysis ("PRA") which involves the use of statistical techniques to quantify risks. The broad use of PRA in the regulatory context parallels the rapid deployment of computer technology. The most obvious example of the early regulatory use of PRA is the Nuclear Regulatory Commission's "fault tree" approach to accident prediction at nuclear power plants.

Probabilistic risk analysis has been criticized for producing wide differences in results when one applies different analytical assumptions to the same accident scenario. It is particularly prone to methodological bias that favors a desired result and is also very

1. 42 U.S.C. §§ 11001-11050 (Supp. IV 1986).

expensive. It is important, however, because we will begin to see a transmutation of this methodology for use in predicting toxic accidents at individual facilities as the Emergency Planning and Community Right-To-Know Act of 1986² and state laws such as California's Proposition 65³ are implemented.

The second major regulatory use of risk assessment involves estimating the probable consequences of anticipated or known occurrences to individuals or groups. This type of risk assessment is by and large the kind that EPA uses in administering the Toxic Substances Control Act,⁴ the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"),⁵ and several of the other statutes for which it is responsible.

One prefatory comment is needed prior to addressing specific examples of this type of risk assessment. The difference between individual risk (i.e., if I am exposed to substance x, at what level of greater risk am I that I will develop cancer) and population risk (i.e., if 10,000 people are exposed to 10 ppm of substance x, how many excess cancers can be anticipated in that population) can be significant, and the statutory context in which one or the other of these is assessed can radically affect the results. An example to illustrate this point is a proposed risk analysis done by EPA on formaldehyde a few years ago, under the Toxic Substances Control Act.⁶ The EPA used four different models to look at what the individual and population risk factors would be for exposure to formaldehyde in various workplace environments in which that chemical is used. The four different models produced very different risk numbers. EPA concluded that none of the numbers posed a significant risk of serious harm to any individual, but did conclude that the numbers showed a significant risk of widespread harm to the exposed population of workers in the textile industry. Stated another way, the risk assessment concluded that no single individual exposed to the highest exposure level assumed for formaldehyde was significantly more likely to contract the types of cancer associated with formaldehyde than if the individual were not so exposed. Yet since the models also yielded

2. *Id.*

3. The Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH AND SAFETY CODE § 25249.5 (West 1989) is informally known as Proposition 65.

4. 15 U.S.C. §§ 2601-2629 (1982 & Supp. IV 1986).

5. 7 U.S.C. §§ 136-136y (1982 & Supp. IV 1986).

6. 15 U.S.C. §§ 2601-2629.

data showing two or three excess cancers in a worker population of 100,000 workers exposed to low levels of formaldehyde, EPA provisionally concluded that action was required.

EPA did not act on that proposed rule making, because the Toxic Substances Control Act requires EPA to defer to the Occupational Safety and Health Administration⁷ ("OSHA") in connection with workplace hazards. EPA's analysis is largely an artifact of the statutory language of Section 7 of the Toxic Substances Control Act, which compels EPA to consider both significant and widespread harm.⁸

III. EXAMPLES OF REGULATORY AGENCY USE OF RISK ASSESSMENT

Several current statutory schemes serve as examples of the application of risk assessment methodology to regulatory decisions. The statutory regime in which risks are assessed most conservatively is the Federal Food, Drug and Cosmetic Act ("FFDCA").⁹ When the Food and Drug Administration ("FDA") is licensing food additives, essentially no quantitative risk analysis is permitted if the available toxicological evidence demonstrates the formation of tumors in mammals. The "Delaney Clause"¹⁰ says that if there is any evidence that tumors form following ingestion of a substance that would be a food additive, nothing further need be done, because that substance cannot be used as a food additive.

The Delaney Clause does not apply to pesticide additives, which are residues of pesticides on agricultural commodities, because of the language of the applicable FFDCA provision, and because there is a peculiarity in Section 408 of the FFDCA under which pesticide additives are within EPA's administration rather than the FDA's.¹¹ Other pesticide risks are regulated under FIFRA,¹² and there is no Delaney provision in that statute.

The Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA")¹³ involves risk assessment in a number of different ways. First, EPA has to do a risk assessment

7. Occupational Safety and Health Act, 29 U.S.C. §§ 651-678 (1982 & Supp. IV 1986).

8. 15 U.S.C. § 2606 (1982).

9. 21 U.S.C. §§ 301-392 (1982 & Supp. IV 1986).

10. 21 U.S.C. § 348(c)(3)(A) (1982) ("provided" clause).

11. 21 U.S.C. § 346(a) (1982 & Supp. IV 1986).

12. 7 U.S.C. § 136(a) (1982 & Supp. IV 1986).

13. 42 U.S.C. §§ 9601-9675 (1982 & Supp. IV 1986).

as the basis for listing a site on the National Priorities List.¹⁴ For this purpose EPA has used a rather crude model called the Hazard Ranking System,¹⁵ which deals conservatively with data gaps because it allows the field codes to score a site high in the absence of contrary data. EPA is currently wrestling with the problem of revising the hazard ranking system so as to be able to make more useful and discriminating risk assessments. Second, EPA was required by the 1986 Superfund Amendments and Reauthorization Act ("SARA")¹⁶ to collaborate with the Agency for Toxic Substances and Disease Registry ("ATSDR").¹⁷ ATSDR is required to undertake what is best described as a "seat of the pants" epidemiological assessment of sites on the National Priorities List.

A second use of risk assessment methodology under CERCLA is in the development of toxicity criteria. These are required by the SARA Amendments to be established for the chemicals frequently occurring at waste sites that have the greatest potential for human health risk,¹⁸ and are intended to be used in the priority ranking of sites for remedial action expenditures. EPA is to undertake risk assessments to determine which chemicals are of the greatest health concern. These risk assessments will have a clear economic impact on potentially responsible parties ("PRPs"), the entities which have to pay the bills for cleaning up most Superfund sites.

Finally, risk assessment is involved in remedy selection under CERCLA. There was concern in Congress that EPA over-emphasized risk extrapolation models prior to its adoption of the 1985 revisions to the National Contingency Plan ("NCP"),¹⁹ which tied the "how clean is clean" decision to non-CERCLA regulatory standards, such as federal drinking water standards. The SARA Amendments embraced those changes.²⁰ Both the 1985 NCP revision and SARA embrace the concept of "applicable or relevant and appropriate requirements" ("ARARs") to govern the allocable level of residual pollution following a site clean-up. Nevertheless, even though these developments represent some

14. 42 U.S.C. § 9605(a)(8)(A) (1982 & Supp. IV 1986).

15. See 40 C.F.R. § 300.66 (1988) and Appendix A to Part 300.

16. Pub. L. No. 99-499, 100 Stat. 1613 (codified as amended in scattered sections of 10 U.S.C., 26 U.S.C., 33 U.S.C. and 42 U.S.C.).

17. See 42 U.S.C. § 9605 (1982 & Supp. IV 1986).

18. See 42 U.S.C. § 9605(c) (1982 & Supp. IV 1986).

19. 40 C.F.R. § 300 (1988).

20. 42 U.S.C. § 9621 (Supp. IV 1986).

deemphasis on site-specific risk assessment, risk assessment continues to be a cornerstone of EPA's selection of remedy approach. There is no useful statutory guidance in CERCLA for much of this activity, other than the Section 104 cost-effectiveness criterion,²¹ and the limited guidance inherent in the Section 12 requirement²² that EPA select residual contamination levels that reflect applicable or relevant and appropriate requirements. Since few such requirements will be applicable, the extent to which a given requirement is appropriate will involve a determination that the risks are reasonably similar to those presented by the Superfund site.

The ARAR concept can produce a clash of risk assessment methodologies, since it requires EPA to look at various regulatory standards which will usually not be applicable, thus requiring the agency to determine which ones are relevant and appropriate for CERCLA remedial purposes. There are different statutory bases for establishing acceptable standards. FIFRA,²³ the Resource Conservation and Recovery Act,²⁴ the Federal Food, Drug and Cosmetic Act,²⁵ the Safe Drinking Water Act,²⁶ the Clean Water Act,²⁷ and the Clean Air Act,²⁸ each have their own statutory risk management criteria, and thus different frameworks within which EPA is constrained in determining how to assess risks. The numbers that pop out of a risk assessment under those statutes are going to differ one from the other, and EPA has to do a comparative analysis at each Superfund site in order to determine which of these particular standards is relevant. This is a risk assessment in and of itself.

Before concluding the discussion of CERCLA, there must be a separate mention of ATSDR. Practicing attorneys have recently recognized a connection between the requirements of CERCLA and tort law. A practicing attorney, in an article appearing in BNA's *Toxics Law Reporter*, hypothesized that, "SARA will generate vital scientific information for victims and will do so, in part,

21. 42 U.S.C. § 9604 (1982 & Supp. IV 1986).

22. 42 U.S.C. § 9621 (Supp. IV 1986).

23. 7 U.S.C. § 136 (1982 & Supp. IV 1986).

24. 42 U.S.C. §§ 6901-6991i (1982 & Supp. IV 1986).

25. 21 U.S.C. §§ 301-392 (1982 & Supp. IV 1986).

26. 42 U.S.C. § 300(f) (1982 & Supp. IV 1986).

27. 33 U.S.C. §§ 1251-1376 (1982 & Supp. IV 1986).

28. 42 U.S.C. §§ 7401-7642 (1982 & Supp. IV 1986).

at the expense of the potentially responsible part[ies]."²⁹ The author was referring to the fact that SARA provides for health studies for those who work or live near any potentially hazardous site, whether listed on the National Priorities List or not.³⁰

The trouble with the ATSDR studies is that, since they will be inherently screening level epidemiological studies, they may in fact produce more "noise" than really useful scientific information. This view is shared by a number of epidemiologists. Recently, Leon Gordis, the respected Rutgers University epidemiologist, expressed such concerns during his remarks at a symposium on environmental liability sponsored by The University of Houston Law Center.³¹

A different use of risk assessment in a regulatory context is found in the Clean Air Act's provisions relating to hazardous air pollutants. The statute calls for risk assessment in the context of generic, rather than site-specific, standard setting. Section 112 of the Clean Air Act requires EPA to set emission standards for toxic air pollutants "at the level, which in [EPA's] judgment, provides an ample margin of safety to protect the public health."³² Over the years, EPA has not set many standards under Section 112, and, as it has come under pressure recently to begin to address a broad list of pollutants, it has attempted to set standards that are sensitive to the costs of their application. A recent decision of the United States Court of Appeals for the District of Columbia Circuit, which struck down EPA's vinyl chloride hazardous emission standards, severely limited EPA's consideration of costs in establishing emission standards for hazardous air pollutants.³³ The Court held that Section 112 requires the establishment of standards based only on health risks. Costs should only be factored into the decisionmaking process of EPA when a margin of safety is chosen.

There are a number of legislative proposals currently pending before Congress that would require risk-based airborne contaminant-dispersion modeling at individual plant sites for purposes of

29. Kanner, *Superfund and the Future of Toxic Tort Litigation*, 2 TOXICS LAW REPORTER 671, 672 (1987).

30. *Id.*

31. His comments were published as Gordis, *Epidemiologic Approaches for Studying Human Diseases in Relation to Hazardous Waste Disposal Sites*, 25 HOUS. L. REV. 837 (1988).

32. 42 U.S.C. § 7412(b)(1)(B) (1982).

33. NRDC v. Thomas, 804 F.2d 710 (D.C. Cir. 1986); see also NRDC v. Thomas, 824 F.2d 1146 (D.C. Cir. 1987).

emergency preparedness under the Emergency Planning and Community Right-To-Know Act,³⁴ and similar requirements are being considered independently by local or state emergency preparedness agencies. Senate Bill 1894, one of the leading Clean Air Act reauthorization bills in the 100th Congress, contained elaborate provisions along these lines. That bill also proposed to change the basis for setting standards under Section 112 from a risk assessment basis to a technology standard basis, taking an approach similar to that of the Clean Water Act, on the premise that the risk-based scheme under the present Section 112 is not workable.

Municipal resource recovery facilities and other actual or potential emitters of toxic air pollutants face particular problems with dispersion modes, and other transport/exposure models, which form the basis for health risk assessments from these facilities. These models are generally crude and difficult to deal with because they are mathematical models, totally dependent on assumptions. In litigating a case that involves dispersion modelling, the nuances of model success or failure can be difficult to get across to the court. Dispersion models inherently contain quite a potential for error. The misconception that they are scientific and empirical makes attacking these models a particularly delicate matter.

IV. RISK ASSESSMENT IN TORT LITIGATION

The use of risk assessment methodology in the context of tort litigation is a relatively recent phenomenon. It is increasingly employed in long latency period cases where the plaintiff can demonstrate exposure to a substance that can cause morbidity, but where the plaintiff is not then sick. Use of risk assessment in tort cases is most prevalent, of course, in jurisdictions where the courts have allowed toxic tort plaintiffs to recover for enhanced

34. 42 U.S.C. §§ 11001-11050.

risk of illness.³⁵ Most state courts, to date, have had a lot of trouble with this type of relief.³⁶

In *Ayers v. Jackson Township*,³⁷ the New Jersey Supreme Court recently explored the issue in thoughtful detail, ultimately concluding that an inability on the part of the plaintiffs' expert to quantify the enhanced risk was a barrier to recovery in that case. The court did, however, allow damages for medical surveillance and allowed the plaintiffs to split their cause of action and come back for further relief if it turned out that any of them ultimately became sick in the manner predicted.³⁸

Risk assessment can also be relevant to tort cases where the plaintiff has unquestionably suffered damages that may or may not have been caused by the substance to which the plaintiff claims to have been exposed. Such cases involve the question of what is the likelihood that A rather than B, or some other event, caused the plaintiff's injury, given the known universe of facts.

Defendants in toxic tort cases of either type face an unquantifiable risk that is quite unrelated to real risk. The risk is that a defendant might win its case on the merits but still be penalized. In such a case, a jury faced with compelling evidence of a negligible real risk to the plaintiffs might award only token compensatory damages, but nevertheless award millions of dollars in punitive damages. The possibility that a jury will award "insult damages" despite finding that little or no potential exists for real harm from exposure to minute amounts of an allegedly hazardous substance presents a risk to defendants that cannot be anticipated by any quantifiable, empirical methods.

35. For cases recognizing the enhanced risk cause of action but requiring that proof of future injury be reasonably certain, see *Hagerty v. L & L Marine Services*, 788 F.2d 315 (5th Cir. 1986); *Wilson v. Johns-Manville Sales Corp.*, 684 F.2d 111 (D.C. Cir. 1982); *Sterling v. Velsicol Chemical Corp.*, 647 F. Supp. 303 (W.D. Tenn. 1986); *Lorenc v. Chemirad Corp.*, 37 N.J. 56 (1962); *Devlin v. Johns-Manville Corp.*, 202 N.J. Super. 556 (Law Div. 1985). For cases only permitting recovery where the plaintiff exhibited some present manifestation of the disease, see *Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394 (5th Cir. 1986), *cert. denied*, 478 U.S. 1022 (1986); *Brafford v. Susquehanna Corp.*, 586 F. Supp. 14 (D. Colo. 1984).

36. See, e.g., *Morrissy v. Eli Lilly & Co.*, 76 Ill. App.3d 753, 394 N.E.2d 1369 (Ill. App. Ct. 1979).

37. 106 N.J. 557, 525 A.2d 287 (1987).

38. *Id.*

V. ANTICIPATORY RISK ASSESSMENT

The third major area in which lawyers often encounter and use risk assessment is in corporate risk management. In part, this activity has been required in recent years by the insurance industry's decision that the potential for claims that is inherent in insuring environmental risks outweighs the monetary gains to the insurance companies from the premiums. This, coupled with legitimate concerns that hazardous substance-related liabilities can exceed insurance, has caused corporations engaging in risk-producing activities to do their risk evaluation in a much more sophisticated way than they have before. This is particularly the case with new product marketing, when companies try to ascertain their long-term risks from new products or from continuing uses of existing products. These assessments go above and beyond the formalized risk assessments that are done under the government's product regulation statutes.

Another type of anticipatory risk analysis occurs in the context of large corporate or real property transactions. Where there is a purchase of a corporation or the assets of a corporation, or where a company is doing an in-house assessment of future liability as part of long-range strategic planning, program managers, aided by risk assessment professionals and lawyers, employ risk assessment methodologies to evaluate the potential environmental liabilities of an acquisition target or their own company.

This activity involves efforts to quantify environmental liabilities, only some of which have been identified, that may be significant to management, lenders, shareholders or buyers. The following scenario illustrates the importance of risk assessment in this context. Suppose that I represent a buyer or a lender. I know that Corporation X, the acquisition target, generated and sent off-site large amounts of trichlorethylene (TCE) for a known period of twenty years, but the corporation has no records as to where the TCE went. The company is not presently on any PRP list maintained by a state agency or EPA, but we know that it is likely to be a PRP in the future. The lender or buyer conducts an environmental assessment because it needs to place a value on the risk that it will become a PRP in the future.

Underground storage tanks pose a similar problem. Where there are large numbers of them, and it is not possible to test every one, mathematical probabilities must be resorted to in order to estimate the number of potential leakers and the remedial

cost attached to them. Where there are very large numbers of tanks that are dispersed geographically, differences in local geological conditions and soil types complicate the risk assessment picture.

VI. THE PITFALLS OF RISK ASSESSMENT

There are a number of factual and evidentiary issues inherent in any risk assessment scenario. One overriding concern in litigation is that great care must be taken to explain risk assessment in terms understandable to lay people. Litigation attorneys must have a firm grasp of the details of risk assessment methodology in order to be able to clearly communicate the issues to judges, juries and agency managers. The following is a brief check-list of the topics to be considered in evaluating any risk assessment.

Lawyers must first evaluate the adequacy of the data. Lawyers are usually involved in situations in which a risk assessment affects the client's interest. Lawyers must be able to work with risk assessment experts. When experts are not available, the lawyer must try to deal with data gaps and other data problems. This is essential because the reliability of risk assessment results depends on the data. For example, in the groundwater contamination context it is important to know whether there are sufficient monitoring wells placed in the right location, whether they are properly screened to correctly predict the groundwater rate and direction of movement, and whether the correct aquifer or the correct area within the aquifer has been sampled for the contaminants alleged to be the source of exposure or other concerns.

Lawyers may also have to challenge, or deal with challenges to, the assumptions that are made by risk assessors in the absence of adequate data. For example, it is important to know whether worst-case assumptions are being made, and what the underlying parameters of those assumptions are. Once identified, the assumptions must be evaluated for their relevance to the situation at issue. Exposure assumptions are very important, particularly in hydrogeological modelling and dispersion modelling scenarios.

One must always probe for biases such as selection bias in the design of an epidemiological study, the use of an improper control group, biases in a toxicological study or in the placement of monitoring wells. Biases in study design may be accidental and not necessarily related to intent on the part of the designer of the study. These biases can creep into the risk assessment unnoticed

by its conductors. A classic, and obvious, example of a bias in an epidemiological study seeking to evaluate the relationship between airborne exposure to asbestos and lung cancer would be a failure to ask the subjects about their cigarette smoking habits.

There are other types of error in study design. For example, there may have been too few animals used in a toxicological study to yield statistically significant results, or a failure to insulate the animals from other causes of mortality or morbidity. Over-susceptible or overly-resistant strains of animals may have been used. There may have been poor screening of monitoring wells, or the use of the wrong casing materials.

Another area of potential concern is the possibility that key data has been wrongly or poorly manipulated. There may, for example, have been an improper application of the statistical methodology where the data was limited. Risk assessment involves the application of statistics in many contexts. Moreover, there are often acceptable alternative approaches to the data. The data could reasonably have been looked at in a different way, and if viewed differently there might be a change in the result, or in an expert's opinion.

Another statistical issue involves the confidence intervals applicable to the statistical results, which are related to the use of norms. Federal government agencies use norms all the time. The Office of Science and Technology cancer principles, as well as EPA's 1986 cross media guidelines, are relied upon heavily, essentially being regarded as binding by government decision-makers. One must understand that fact when dealing with federal regulatory risk assessment, understand the limitations and the assumptions behind the guidelines, and work with them. Norms sometimes mask the existence of conflicts of opinions within the scientific community.

Increasingly, risk assessment involves the use of mathematical models. Whether a given model is appropriate to the situation, what assumptions are inherent in its architecture, and the degree of conservatism in those assumptions are all important areas of inquiry whenever such models are employed. It is also important to understand the role that peer review has in acceptance of models and other risk assessment methodologies by the scientific community and by regulatory agencies. Particularly in the case of atmospheric dispersion models, the acceptance of the model as a regulatory model or as a screening model must be ascertained,

whether the model is being used against or in support of your client's position.

Finally, models and some of the other risk assessment methodologies pose unique evidentiary problems because the standards for admissibility vary. One standard, derived from *Frye v. United States*,³⁹ is employed to one degree or another by federal courts, and there are a number of different state law standards. Admissibility is frequently a problem for both the person trying to get a model introduced into evidence and the person trying to keep it out.

VII. CONCLUSION: CURRENT RISK ASSESSMENT POLICY ISSUES

In these final paragraphs, I want to highlight five regulatory and policy issues that are currently being debated in regulatory and scientific forums, some of which make the life of environmental lawyers more complex than necessary.

First, federal regulatory risk assessment is rampant with inter-agency inconsistencies. For example, the Occupational Safety and Health Administration and EPA both approach worker exposure using risk assessment methodology. However, risks to the same workers can be evaluated quite differently under each of these statutory schemes. Because of differences in the statutory language, very different risk assumptions can be made concerning, and different standards applied to, the same workers exposed to the same chemicals in essentially the same exposure scenarios. We need to understand how those differences come about when we are confronted with those standards in another context, such as tort litigation, as well as in a regulatory context.

Second, there are also intra-agency inconsistencies. EPA has looked at the same risks differently over time. One example has been the EPA's recent revision of the risk assessment for dioxin. Possessed of new data, or a different approach to the same data, EPA decided that dioxins in soil are not as risky as its official view previously held them to be. Also, there are sometimes differences between regions or among programs within EPA. For example, the EPA's approach to PCB risk assessments has had different regions looking at risks from PCBs in significantly different ways. There were widely differing risks being predicted from similar ex-

39. 293 F. 1013 (D.C. Cir. 1923).

posure scenarios. The EPA has not denied that such differences exist, and that they will probably continue to exist.

A third issue of current prominence is the need to develop a useful, meaningful perspective on risks, and to provide better means for comparing risks. Legislators, administrators and lawyers must all grapple with this problem.

The fourth issue is the need to standardize, or at least develop a workable validation system for, risk assessment methodologies and risk assessment procedures used within the same context. There is some attempt at this being made under the Clean Air Act in EPA protocols for approving dispersion models, although EPA has not yet really tried to standardize models, but rather accepts a wide range of models that will provide different levels of predictability when applied to similar events.

Finally, there are significant problems of quantification. At bottom, many risk assessment methodologies attempt to quantify the ultimate risk, and the starkest examples of such quantification problems are found in how government agencies value human lives. What is a life worth? What is a shortened lifetime worth? There are wide differences of opinion about these questions, differences which approach the metaphysical. What a life is worth depends on which risk assessment methodology is applied, by which agency, and at what time it was done in the agency's regulatory history. Quantification, moreover, is particularly difficult where the framework within which risk assessment is done requires a risk benefit, cost benefit, or some other approach that requires easily calculated units of cost or benefit to be weighed against a health or environmental risk.

In conclusion, risk assessment, with all of its glitches and uncertainties, is increasingly becoming a fact of environmental regulatory life and a tool in corporate risk management. It has begun to find its way into the courthouse as well. The fact that lawyers have an obligation to their clients to keep abreast of technological change requires that attention be paid to the methodologies and legal consequences of risk assessment.