RISK: Health, Safety & Environment (1990-2002)

Volume 2
Number 2 *RISK: Issues in Health & Safety*

Article 5

March 1991

Regulating Air Toxics in Rhode Island: Policy vs. Technical Decisions

Julie A. Roque

Regulating Air Toxics in Rhode Island: Policy vs. Technical Decisions*

Julie A. Roqué**

Introduction

Approximately 2,000 chemicals are emitted into the air routinely; many are referred to as air toxics.[1] Air toxics are not only wastes, but also compounds that escape from storage facilities, during transport, and from production processes. They include volatile materials, such as gasoline and organic solvents, and metals in gaseous or fine-particulate forms. Some are associated with cancer, as well as acute health effects and other chronic effects such as nervous system and organ damage, teratogenic or reproductive effects.

Until recently, the U.S. Environmental Protection Agency (EPA) delegated the responsibility for managing air toxics to the states. The R.I. Clean Air Act provides that state's Department of Environmental Management (DEM) with the authority to promulgate air quality

* This paper is based upon some of Dr. Roqué's graduate research. During 1986–87, she was responsible for developing the standards for carcinogens discussed here. She would like to thank Barbara Morin of the Rhode Island DEM and Professors Harold Ward, Kim Boekelheide, Nelson Fausto, Robert Kates, and Alan Morrison, her graduate advisors at Brown.

** Dr. Roqué received a B.S. and M.S. in chemistry from the University of California, San Diego, and Brown University, respectively. She also received her Ph.D. from Brown — in an independently designed interdisciplinary program entitled "Environmental Risk Policy."

1 Kean, *Dealing With Toxic Air Pollutants: New Initiatives*, Issues in Science and Technology 19–27 (Summer 1986).

standards and to implement pollution prevention or control programs.

In 1984, DEM proposed the development of an Air Toxics Regulation to control certain industrial emissions. An advisory committee met monthly with officials to review the regulation as it was being written. Notwithstanding the committee's approval, when it went to public hearing in May 1987, the regulation generated over two years of controversy.

This paper will examine the regulation and the processes by which it was derived and resulting controversy was resolved. Ultimately, it will try to show that, had certain questions been initially identified as ones of "policy" rather than "science", much time and effort might have been saved.

The Regulation

Its provisions generally

The Air Toxics Regulation defines Acceptable Ambient Levels (AALs), chemical-specific standards that are used to calculate allowable rates of emissions from major air pollution sources. The AALs are health-based standards in that they are intended to limit ambient concentrations of toxics to levels DEM has deemed "safe"; that is, levels at which exposures to individuals are believed to be below thresholds for noncarcinogenic, adverse health effects, or to result only in "acceptable" additional cancer risks.

Carcinogens

For carcinogens, the regulation has two sets of standards: (1) AALs governing substances posing an additional risk of one in a million for an individual developing a particular type of cancer over a lifetime of exposure (hereinafter 10^{-6} risks), and (2) "AALs with LAER" governing risks of one in one hundred thousand (hereinafter 10^{-5} risks). A permit may be issued for a source if its emissions are not

expected to increase ground level concentrations by more than contemplated by the AAL standards. If the concentrations pose higher risks, DEM can require installation of controls to achieve the "Lowest Achievable Emission Rate" (LAER).

LAER is defined as the most stringent emission limitation imposed by any other state or is considered technologically achievable by a particular industrial category of sources. Permits then may be issued if emissions from sources that have installed LAER meet the 10^{-5} AALs.

Basic policy foundations

It was decided initially that toxic emissions in Rhode Island warranted regulatory action; that DEM would weigh administrative feasibility by regulating 40 substances (not all carcinogens) from only the highest priority users; that the AALs would be health-based; and that DEM would maximize consistency between the AALs and other state and federal standards.

The last was accomplished by using EPA Guidelines[2] that recommend criteria for the selection and interpretation of animal data, a standardized scaling factor based on a surface area basis for conversions of doses across species, and the use of the linearized multistage model for high-to-low dose extrapolation. Many of these propositions are policy based in that they may overlook certain scientific knowledge available for some toxins, in order to simplify the decision process and strike a balance between accuracy and consistency in and between risk assessments. Moreover, they clearly suggest overstating risks and erring on the side of protecting the public health.

Also, under the regulation, risks at or below the 10^{-6} level are considered *de minimis* and are not regulated. Those between 10^{-6} and 10^{-5} are reduced if feasible according to the LAER approach. Sources that poses more than that level of risk may be required to change their

2 U.S. Environmental Protection Agency, Guidelines for Carcinogenic Risk Assessment, 51 Fed. Reg. 33,992–34,003 (1986).

processes or shut down. These choices are clearly ones of policy.

Technical foundations

When AALs for carcinogens were first proposed, it appeared that there were sufficient data available to develop them for 28 compounds. The data for 3 chemicals, however, were later found inadequate for assessment, and another, formaldehyde, posed special problems because of existing high background concentrations.

Fourteen of the remaining twenty-four compounds had been previously evaluated by the Carcinogenic Assessment Group (CAG) at EPA, and their unit risk estimates[3] were used to calculate AALs by assuming a linear dose-response relation. Also, DEM used assessments for perchloroethylene and trichloroethylene generated by the Northeast States for Coordinated Air Use Management (NESCAUM), a coalition of regulators from the New England states plus New York and New Jersey.

Figure 1 shows the steps in calculating AALs for the remaining eight compounds. These methods are in accordance with the EPA Guidelines[4] and had been used by CAG and NESCAUM for the sixteen substances mentioned above.

Although the Guidelines prescribe methods for dealing with the major sources of variations in cancer risk assessments, data are scarce and often are reported in very different forms. Thus, other assumptions had to be incorporated into calculations of the AALs. Informal precedents set by EPA in the development of unit risks or standards for other compounds were relied upon whenever possible. These involved issues such as the minimum number of dose groups in animal bioassays and the use of the 95% lower confidence limit (95% LCL) on the dose

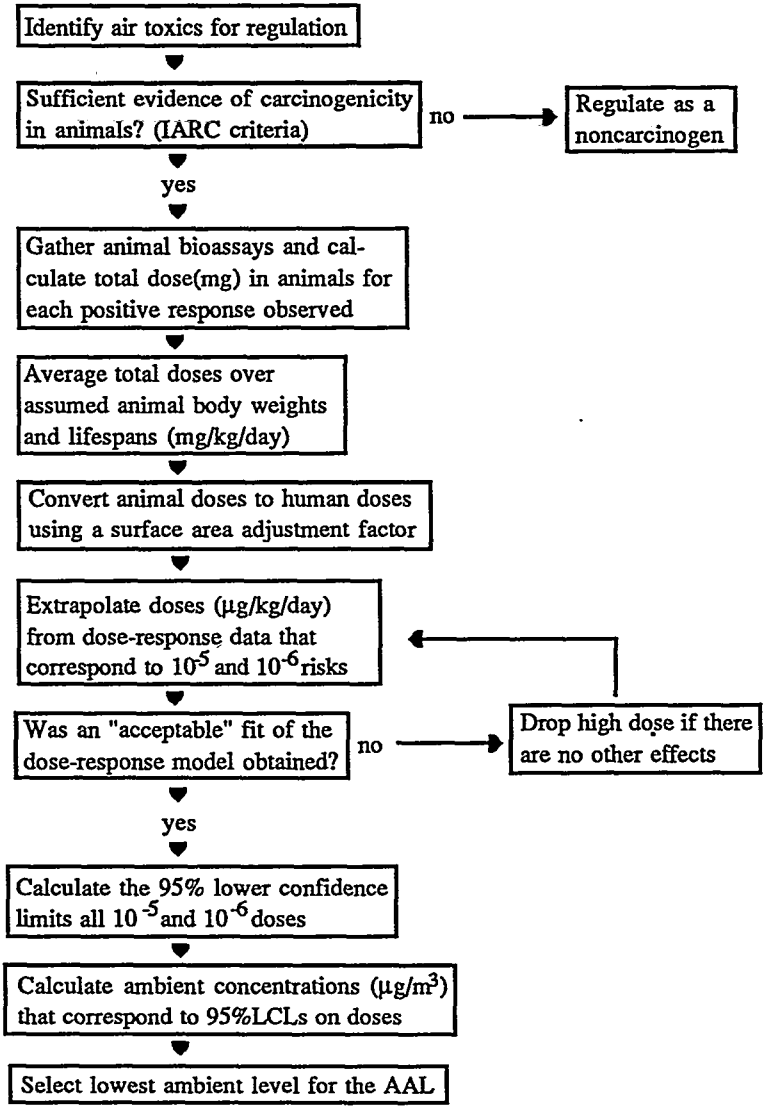
3 Unit risks are the risks associated with inhaling air contaminated with 1 $\mu g/m^3$ of a pollutant over a lifetime.

4 *Supra*, note 2.

corresponding to the levels of risk at which the standards were to be set.

Figure 1

Derivations of the AALs



Opposition

At the public hearing in 1987, the Rhode Island Chamber of Commerce Federation voiced strong opposition, despite having had a technical representative on the advisory committee. It also lodged an unsuccessful attempt to block the regulation, charging that the AALs were "arbitrary and capricious."[5]

After the regulation was promulgated in 1988, the Chamber threatened further legal action. It argued that the methods were overly risk averse, claimed that alternative assumptions in the risk assessments would provide less stringent standards and urged that the AALs should be relaxed.[6]

For example, they criticized the use of a linearized multistage model to extrapolate from high to low doses.[7] They also objected to basing risk estimates only on the most sensitive species and the most pronounced effect reported; converting animal exposures to human

---

5 Rhode Island Chamber of Commerce Federation, Petition to R.I. Superior Court for Temporary Restraining Order Against the R.I. Department of Environmental Management, Division of Air and Hazardous Materials, Regulation 22, Air Toxics (Mar. 1988) (copy of petition available from the Rhode Island Department of Environmental Management, Legal Services, 83 Park Street, Providence, RI 02903).

6 For similar views *see, e.g.*, Nichols & Zeckhauser, *The Perils of Prudence: How Conservative Risk Assessments Distort Regulation*, 10 Regulation 13–24 (Nov./Dec. 1986); Paustenbach, *Health Risk Assessments: Opportunities and Pitfalls*, 14 COLUMBIA J. ENVT'L L. 379–410 (1989); Anderson, *Scientific Developments in Risk Assessment: Legal Implications*, 14 COLUM. J. ENVTL. L. 411–25 (1989).

7 This point is well documented for a number of animal carcinogens where the use of different dose-response relations can alter unit risk values by orders of magnitude. *See, for example:* Schneiderman, *Regulation of Carcinogens in an Imprecise World*, 363 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 217–32 (1981); Van Ryzin, *Quantitative Risk Assessment*, 22 J. OCCUPATIONAL MED. 321–26 (1980); Crump, *Methods for Carcino genic Risk Assessment*, ch. 7 in PRINCIPLES OF HEALTH RISK ASSESSMENT 279–319 (1985); Brown, *Learning About Toxicity in Humans from Studies on Animals*, 13 CHEMTECH 350–58 (1983) and ENVIRON, *Elements of Toxicology and Chemical Risk Assessment* 40 (1986).

doses using factors based on surface area; and using lower 95% confidence limits on doses to calculate the AALs.

Resolution

At the directive of the governor, DEM officials, beginning in 1988, met with Chamber representatives to review the methods by which the AALs were derived. The Chamber finally dropped its threat of legal action in July 1989 after a rigorous, two day meeting attended by it and representatives of statewide health and environmental organizations. The purpose of the meeting was to review the technical details of the AAL calculations and allow a toxicologist hired by the Chamber to question DEM about their methods.

The toxicologist presented only general arguments against the methods used to derive the AALs: why it may not be appropriate to use animal data for calculating human risks; why people may not be as sensitive as the most sensitive animal species; that the linearized multistage model and the 95% LCL can overestimate risks by orders of magnitude; and that, for some compounds, there is evidence to believe that body weight is a more appropriate measure of interspecies variability. Later, the toxicologist questioned how default values for animal and human body weights and other variables were obtained. However, the toxicologist agreed that there are no conclusive answers to such questions.

Ultimately, a number of "points of agreement" were reached concerning the *process* by which future regulations would be developed. These included that DEM would: provide more complete documentation; consider outside peer review of future AALs; consider forming a science panel to advise regulators; and incorporate new scientific information into the derivations of the AALs as the agency finds it appropriate.

However, as mentioned earlier, DEM had made a series of policy

decisions prior to the development of the AALs. Those did not appear to cause significant controversy, although they were perhaps even more influential than issues in dispute. They had been designated as policy choices from the beginning and appeared to leave little room for purely technical criticism. Disputes on scientific issues did not end up being resolved on technical grounds. Had more critical choices been earlier recognized as turning on policy, much debate might have been avoided.

Sensitivity Analyses of Decision Rules

Undertaking a task such as deriving AALs requires choosing among competing decision rules. Some of the rules used by DEM are are set forth below in Table 1 — along with plausible alternatives.

To focus debate on key issues, it is useful to attempt to determine which decision rules play the largest role in the final regulatory determinations. To do this, rules can first be put into two categories: those for which the variations in final risk estimates depend upon particular sets of data and those for which variations are directly proportional to constant ratios.

The data-specific decision rules are: the choice of effect; calculation of AALs based on a single effect; averaging animal doses over their lifetimes; the choice of the dose-response relation; the goodness-of-fit criterion; and the use of the lower confidence limit on dose. The variation in risk estimates attributed to these rules cannot be evaluated without case-by-case calculations and therefore multiple extrapolations were performed for every data set (or combinations of data sets) for each toxic.

The second type of decision rules are: the choice of the interspecies conversion factor; default values for consumption rates, body weights and lifespans in animals; and default values for inhalation rates and body weights in humans. These terms may enter the risk calculations at more than one point, but they are constant and simple proportions can be

formulated.

Table 1

Decision Rules to Derive AALs

Decision	*Choice for AALs*	*Alternatives*
• Choice of effect in animals upon which to base risk estimate	Most pronounced effect observed	Other effects or average of effects
• Calculate the risk of cancer at one site or risk at all sites	Single site	Pool all tumors observed in animals
• Characterization of cumulative animal dose	Total dose averaged over the animals' lifespans — short bioassays not used	Age-specific hazard functions for short-term bioassays
• Default rates for animal consumption & body weights	Mid-range values	Higher & lower values
• Defaults for animal lifespans	Length of observation	Longer spans with correction
• Interspecies conversion	Surface area factor	Body weight or intermediate factor
• Dose-response relation	Linearized	Many other models multistage model
• "Goodness-of-Fit" requirement	95th percentile of chi-sq distribution	No requirement
• Lower confidence limit vs. maximum likelihood estimate of dose	Lower 95% confidence limit on dose	Maximum likelihood estimate
• Human body weight & inhalation rate	70kg person who breathes 20m3 air/day	Higher & lower values

Decision rules that introduce the greatest variation into the AALs can be identified by sensitivity analyses. Such analyses indicate how the AALs would have varied had different decision rules been employed and are easily undertaken — many could be performed on the back of an

envelope. Sensitivity analyses for the rules in Table 1 are summarized in Table 2.

Table 2

Results of Sensitivity Analyses for Decision Rules

Decision Rule	*Factor Changes*
• Choice of effect	1.0 – 50; median = 4.0
• Single vs. pooled effects	0.4 – 1.0*
• Lifetime average exposures	1**
• Animal consumption rates	0.9 – 2.0 (mice)
	1.0 – 2.0 (rats)
	0.9 – 2.0 (overall)
• Animal body weights	0.9 – 1.1 (male rats)
	0.7 – 1.0 (female rats)
	0.8 – 1.5 (mice)
	0.7 – 1.5 (overall)
• Animal lifespans	0.3 – 1.0 (rats)
	0.4 – 1.0 (mice)
	0.3 – 1.0 (overall)
• Interspecies conversion factor (surface area vs. body weight)	1 – 6 (rats)
	1 – 13 (mice)
	1 – 13 (overall)
• Dose-response relation	10^{-35} – 10^{6}
• "Goodness-of-fit"	0.6 – 1.0*
• 95% LCL vs. MLE of dose	1.0 – 1.6
• Human body weight	64 – 1.3
• Human inhalation rate	1.0 – 4***

* The AAL would have differed for just one compound.

** The use of studies based on short-term exposures and averaging exposures over a lifetime could alter risk estimates by factors of .01 – 100. Short-term experiments were not, however, used to derive the AALs.

*** Human inhalation rates may be, in part, dependent upon body weight.

Each range represents the ratios of ambient concentrations that would have been calculated by varying assumptions for each decision

rule, to the AALs that were adopted in the Air Toxics Regulation. A factor change of 0.5, for example, indicates that an AAL that would have been calculated using an alternative decision rule would have been 0.5 x the current value, or twice as stringent. Conversely, a factor change of 2 means the AAL would be twice as high, or half as stringent.

Individually, most decisions are trivial in comparison to the choice of the dose-response relation. Multiplying the extremes of these ranges could provide a "super worst case" measure of the degree by which risk estimates might be over- or understated.[8] Even combined, all of the other decisions do not outweigh the influence of the dose-response model.

The risk tolerance of decision rules

Figure 2, below, sorts decision rules into four categories: risk averse, risk prone, best guess, and "???." Those in the risk averse box are likely to have provided AALs that are more stringent than necessary to achieve the desired risk levels; ones in the risk prone box led to less stringent AALs; and "best guess" decisions are those that are unlikely to over- or understate the "true" risk.

The dose-response relation is placed in a fourth box because there is no evidence supporting the choice of one dose-response model over another for any substance evaluated. Further, the sensitivity calculations indicate that the linearized multistage model may have overestimated the AALs for some compounds, but underestimated them for others. Lacking better chemical-specific information, dose-response decisions cannot categorized as risk averse, risk prone, or best guess.

---

8 Multiplying these factors assumes the "correct" values are the extremes for each. Clearly, the likelihood of such a case is small, if not negligible, and this simplification provides an overestimate. *See* Finkel, *Is Risk Assessment Really Too Conservative?: Revising the Revisionists,* 14 COLUM. J. ENVTL. L. 447 (1989).

Figure 2

Risk Aversity of Risk Assessment Assumptions

" Risk Averse " Choice of effect Interspecies conversion Human inhalation rate 95% LCL vs. MLE	*" Risk Prone "* "Goodness-of fit" Single effect
" Best Guess " Lifetime ave. exposures Animal consumption rates Animal body weights Animal lifespans Human body weight	*" ??? "* Dose-response relation

Some risk adverse rules were stated explicitly when the Air Toxics Regulation was written, e.g., that humans are at least as sensitive as the most sensitive animal species (choice of effect) that the 95% LCL would be used. (The 95% LCL may be considered risk averse 'on the average.' Although it is not risk averse for a single potency assessment, as a lower bound, it is likely to overstate estimates for groups of potencies on the whole.) These could have somewhat significant impacts on the AALs.

However, other rules, whenever adopted, had little influence. Pooling effects; different animal consumption rates, weights or lifespans; human weights; and dropping the goodness-of-fit criterion would have changed the final standards by factors of two or less. And in many cases, these changes would have been lost when the AALs were rounded off to single digits.

The factor changes for high-to-low dose extrapolation demonstrated that the linearized multistage relation is not usually the most risk averse model and, in fact, is risk prone for certain sets of data. Further, the use of other dose-response relations could have decreased some of the AALs (making them more stringent) by factors greater than those by which other AALs would have increased. The sensitivity analyses did not consider the special susceptibility of children to certain toxics which, if taken into account, might indicate that several of these rules are even less risk averse or more risk prone.[9]

Risk Debates

Policy and uncertainty

The choice of different dose-response relations can provide widely varying risk estimates and may change regulatory decisions. In many instances, however, available scientific information is so limited that one cannot approximate the uncertainty associated with an estimate, or even predict whether certain models will over- or understate risks; this was especially true for the air toxics evaluated by DEM.

As noted above, altering most of the other decision rules would not alter the regulatory decisions. Yet, risk controversies often involve lengthy debates about the assumptions that are the most accurate even for those rules.

Some questions could, in theory, be "answered" with sufficient scientific information. The choice of dose-response models is one of those. Table 3 lists other issues facing DEM in regulating carcinogens under the Air Toxics program.

---

9 *See* D. KANE, ENVIRONMENTAL HAZARDS TO YOUNG CHILDREN (1985).

Table 3

Sources of Variation in Risk Estimates

Decision Rule	*Source of variation*
• Drop formaldehyde for practical purposes	policy
• Maximize consistency between AALs and between RI & other states & federal standards by using standardized rules	policy
• Method of regulation	policy
• Develop health-based (vs technology) standards	
• Adopt AALs for both 10^{-6} & 10^{-5} risks (weigh technical feasibility of controls)	
• Regulate 40 toxics from highest priority users (weigh administrative ability)	
• Assess & regulate single effects	policy
• Characterization of animal risk	uncertainty
• Use animal data (assumed relevant)	
• Average dose over lifetimes	
• Default consumption rates, body weights & lifespans	
• Extrapolation from animal to human	uncertainty
• Use most pronounced effect.	
• Surface area interspecies conversion	
• Linearized multistage model	
• "Goodness-of-fit" criterion	
• 95% lower confidence limit on dose	
• Default body weight & inhalation rate for characterization of human risk (portion of the population protected)	policy

Each rule or set of rules is categorized grossly as "policy" or "uncertainty" as indicators of the sources of variation in risk estimates. Rules categorized as "uncertainty" would be redefined or avoided altogether if we had "perfect" information. Thus, rules with sources of variation designated as "uncertainty" are designed to deal with gaps in scientific knowledge. Of course, in the absense of "perfect" scientific

information, the treatment of uncertainty is itself a policy decision — one closely tied to choosing an appropriate level of risk aversion.

"Perfect" scientific information would enable regulators to resolve some controversies, but policy decisions still would remain. In fact, some would become more difficult once we could predict reliably who might be most affected by risk sources. E.g, should the "average" or the most sensitive individual be protected, or how should individual risks be weighed against benefits to society as a whole?

Academic vs. policy science

The distinctions between basic or "academic" science and applied or "policy" science may also exacerbate the tendency to dwell on technical issues. The differences between the two have been explored by authors who agree that both have valid, if different, goals.[10]

The primary goal of academic science is knowledge; this includes developing, usually relatively free of urgent need, further understanding of natural and biological processes that, at least in the near term, may or may not prove socially useful. The goals of policy-driven science are usually to solve pressing problems. Rather than not act at all in the face of potential for large adverse consequences, agencies often use data that would be insufficient by the standards of academic science.

How risk measures are defined also may differ between these two types of science. In academic science, measures often are used to best describe a set of observations; i.e., to be internally valid. Policy research, on the other hand, demands that knowledge be generalized to very different situations than those in which the data may have been collected.

---

10 *See, for example* Ravetz, *Usable Knowledge, Usable Ignorance: Incomplete Science with Policy Implications*, ch. 15 in SUSTAINABLE DEVELOPMENT OF THE BIOSPHERE 415–32 (WILLIAM C. CLARK & R.E. MUNN ed. 1986); and Ravetz, *Uncertainty, Ignorance and Policy*, ch. 7 in SCIENCE FOR PUBLIC POLICY 77–93 (HARVEY BROOKS & CHESTER L. COOPER ed. 1987).

The objectives of risk assessments can determine how scientific information is interpreted and used.[11] Also, in the face of limited resources, regulators often rely on very questionable assumptions to shift the burden of proof onto risk generators. Whether one agrees or not, their choice to do so is clearly not a technical issue.

Conclusion

Rather than argue over explicit policy choices, critics dive into endless technical debates about what are the most "scientifically correct" methods to assess risks. As one author points out: "... in our profoundly numerical contemporary culture, numbers are symbols of precision, accuracy, and objectivity."[12] Even when the variation in risk estimates is characterized, numbers suggest higher levels of accuracy than they really represent.

Regulators are particularly vulnerable to technical attacks because, e.g. allowable rates of discharges are usually set with precision. Yet, investments in new controls are, for the most part, all or nothing, and industries that are just over allowable limits can be required to install pollution controls that may be very expensive for the level of reduction achieved.[13]

Thus, industry may have an incentive to delay. One way to accomplish delay is to argue over endless details.[14] Also, technical arguments are often encouraged and sometimes even required by regulatory and legal institutions for political reasons. The manipulation of technical information to such ends has been explored by others. One

---

11 Russell & Gruber, *Risk Assessment in Environmental Policy-Making*, 236 SCIENCE 286–290 (1987).

12 D. STONE, POLICY PARADOX AND POLITICAL REASON 136 (1988).

13 As a matter of regulatory discretion, however, companies are usually allowed considerable leeway.

14 Moreover, in the case of proposed new facilities, people who oppose them may also have an incentive to delay.

concludes that "Having the balance of scientific evidence on one's side provides strong support and legitimacy for a position."[15] Another observes that "By invoking the authoritative canons of scientific reasoning and method, public authorities and others who have a stake in technical issues seek to demonstrate the rationality of their position and thereby gain political support and acceptance."[16] The result is that quantitative analyses may be granted undeserved prominence in public policy debates, and basic factors driving controversies may be blurred or buried by technical arguments.

Risk management controversies should not be contests over who can produce the most "experts" with the strongest credentials — ones where non-technical interests are often excluded. Regulators can accomplish that end and limit pointless debate by 1) characterizing the variation in risk estimates; 2) providing full presentations of risk calculations, methods and assumptions; and 3) stating policy choices upon which risk assessments are based. Technical criticism appears to dissipate quickly when policy decisions about even legitimate scientific questions are made explicit. The object should not be to eliminate controversy but to force everyone to grapple with tough policy choices that may be concealed in a mass of often irrelevant technical details.

15 Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, 9 SCIENCE, TECHNOLOGY & HUMAN VALUES 54 (1984).

16 Ronald Brickman, as quoted in Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, 9 SCIENCE, TECHNOLOGY & HUMAN VALUES 54 (1984).