We probably all have opinions about the extent to which the government should allow polluters to endanger our health and welfare. We know absolute safety is not possible, but there is no societal consensus that answers the question of how much risk is too much. Moreover, our elected leaders are not ready to make the controversial trade-offs necessary to answer this question. Even if they were, our scientists could not provide them with enough reliable information about the nature and extent of environmental risks for the answers to mean very much. Nonetheless, for more than thirty years environmental laws have required EPA to deliver safety. For almost as long, EPA has responded to the challenge of regulating in the face of uncertainty by basing assessments of environmental risk on reasonable, but unverifiable, assumptions. Scientific progress, however, has begun to undercut this approach. Scientists have been generating too much science for the long-term credibility of the agency’s assumptions about risk, but not enough science to replace those assumptions with reliable information. How then should EPA move forward?

In general, caution is not our collective watchword. Long ago, Alexis de Tocqueville wrote: “The American ... is fond of adventure and, above all, of novelty.” Our heroes still look forward: entrepreneurs and inventors who create what we have barely imagined, athletes who break physical boundaries, and stars of music and film who transcend behavioral conventions. Our own behavior fails to support the theory that a precautionary principle lies at the core of our national character. We eat and drink things that increase our risk of heart disease and cancer. Even with no pressing need to travel, we pack our children into cars and zip around freeways teeming with high-speed vehicles. Many of us still smoke cigarettes. But, as the Royal Swedish Academy of Sciences emphasized by awarding the 2002 Nobel Prize in economics to Daniel Kahneman, people’s preferences in one context do not necessarily reveal their preferences in another. In other words, the fact that we take crazy risks does not mean we think life is cheap. In fact, most of us would probably take more care if we thought our day-to-day behavior would result in actual death or illness, rather than a theoretical increase in risk.

Actual death or illness is, of course, exactly the prospect faced by regulators who make safety decisions that affect entire populations. For example when EPA allows emission of hazardous air pollutants at levels that create a “3 x 10⁻⁴” (or 3 in 10,000) risk of death, the logical expectation is that people will die because of the decision. Simply doing the analysis — or even having the ability to do the analysis — implicates the decisionmaker in the result. Someone who places another “in imminent danger of death or serious bodily injury [from pollution]” risks prosecution for “knowing endangerment” — a felony. The sovereign, of course, cannot be convicted of this crime, but in a discussion about ethics, a regulatory decision that creates unreasonable risks might be analogized to knowing endangerment. Regulatory decisions that are out of step with societal values are legitimately perceived as wrong and, in extreme cases, as outrageous.

To have a credible anti-pollution system, we need a way to face up to the reality of
limited resources — to develop principled ways to determine when other factors should outweigh our desire to protect health and welfare and to decide how safe is safe enough. Environmental policy tends to oscillate between two approaches to making this decision: “technology-based” and “risk-based” regulation. For example, the Clean Air Act Amendments of 1970 required EPA to set risk-based standards to control hazardous air pollutants. The 1990 Clean Air Act Amendments threw out that system and replaced it with a largely technology-based approach. But some senators who voted for the 1990 amendments sought, just a few years later, to force EPA to return to risk-based standards with the failed Comprehensive Regulatory Reform Act of 1995.

Technology-based standards are set at the best levels the regulated community can practically achieve, considering the limits of technology and economic feasibility. Here, for example, is the Ninth Circuit’s explanation of a “top down” approach to setting the quintessential technology-based standard — the Clean Air Act’s requirement for Best Available Control Technology: “The most stringent technology is BACT unless the applicant can show that it is not technically feasible, or if energy, environmental, or economic impacts justify a conclusion that it is not achievable. . . . If the top choice is eliminated, then the next most stringent alternative is considered, and so on. The most effective control option not eliminated is BACT.” Another example is the Maximum Achievable Control Technology requirement for hazardous air pollutants. Congress commanded EPA to set MACT standards for major new sources at least as stringent as “the emission control that is achieved in practice by the best controlled similar source.”

In contrast, regulators set risk-based standards at levels they determine are acceptably safe. Setting these standards generally requires “risk assessments” to (1) identify potential chemical hazards and the nature of the threats they pose, (2) estimate the numbers of bad outcomes, such as illnesses or deaths, that will result from exposures to the chemicals across a range of possible doses, (3) evaluate potential exposures, for example through inhalation, ingestion, and dermal contact, and (4) combine these analyses into “risk characterizations” (for example a “1 x 10⁻⁶” or one-in-a-million risk) that decision-makers can understand and compare. Some risk assessment issues, such as hazard identification and dose-response relationships, are beyond scientists’ current ability to resolve definitively. Resolving others, such as exposure rates, often would require more monitoring than anyone seems willing to do. Thus, risk assessments generally ignore some data gaps and bridge others with estimates and assumptions. Based on these risk assessments, regulators select standards that purport to provide whatever level of protection Congress mandates.

For some chemicals, a pure technology-based standard might be more stringent than a risk-based standard — requiring pollution reduction to continue past a point at which all known risks had been abated. But a technology-based approach might also allow activity to continue that, although subject to state-of-the-art controls, could not meet a reasonable definition of acceptable risk. In contrast, a pure risk-based approach could have drastic results when even the best technologies cannot meet safety goals, potentially requiring wholesale shutdowns of polluting industries. But few real-world regulatory programs are pure examples of either approach since EPA is understandably loath to set either a technology-based standard that has no justification in terms of protecting people or a risk-based standard that cannot be achieved without bankrupting industry. The agency has therefore developed strategies for letting economics influence risk-based decisions while avoiding open consideration of cost, and for allowing technology-based standards to be modified based on risk data.

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More, Not Less, Science Means Better Protection

Twenty years have passed since the National Research Council published Risk Assessment in the Federal Government: Managing the Process — the famous “Red Book.” Much progress has been made on both the bases and processes for risk assessment as practiced by federal agencies, but fundamental insights from the NRC report continue to serve us well. The most significant of these was that the process of risk assessment is simply a tool to organize information for decisionmakers. Although some have made it out to be more than that, risk assessment remains just one source of input among many for use in environmental risk management — which will always be a complex mix of law, science, policy, and judgment.

Having said this, there can never be too much science in the process of environmental decisionmaking. Suggesting that risk-based versus technology-based decisionmaking can be viewed as alternatives ignores the fundamental concern of oversight of environmental decisionmaking. This concern focuses on whether the decisions have been made by caprice rather than by reason. What we all want is reasoned judgment, using all available information, which is communicated in a clear and understandable manner. In the absence of reason and transparency, the observer is free to draw his or her own conclusions regarding the motivation behind the decision. This serves neither the decisionmaker nor the interested parties well, and leads to speculation and post-hoc analysis.

EPA and other federal agencies with similar mandates discharge their duties to protect the environment and public health using risk-based standards, often relying on limited hard facts. Despite this scientific uncertainty, public officials implement environmental laws and are held accountable, which requires filling scientific “holes” with reasoned scientific judgment. Input to decisions based largely on such inference should not be equated with input based on ignorance. While often simplistic and designed to assure that hazard or risk is not underestimated, these inferences, used as “defaults,” represent prevailing scientific thought at the time. Are there scientists who differ with these judgments? Of course. Have some early defaults been modified by emerging science? Certainly. Has scientific progress suggested that this approach led or heavily influenced bad decisionmaking? I think not. Does science in the context of risk assessment lack the theoretical capacity to be a decisionmaking tool? Absolutely not. Can or will risk assessment provide all of the answers? No.

Risk assessment is both a science and an art. It can and will improve with evolving knowledge, better tools and practice. For example, improved approaches to health risk assessment are breaking down the simplistic dichotomy between carcinogens and non-carcinogens. They are better recognizing the distinctions between ambient concentrations of chemicals, exposure, and dose. They are also more fully characterizing the differences among individuals, recognizing the importance of lifestyle, lifestyle, and genetic make-up. Risk assessment tools are evolving to incorporate this new information into the framework of the assessment, leaving behind the concept of one-size-fits-all assessments.

It is naive to think that environmental decisionmakers will abandon risk-based decisionmaking because of its complexity or because of shortcomings in previous decisions made in the absence of better knowledge. It is also unrealistic to think that science will be traded for “precaution.” Instead, the prevailing trend is toward risk-benefit or cost-benefit analysis to assist in informing risk reduction decisions. This trend will put additional demands on the process of risk assessment but, given recent advances in both knowledge and approach, the future looks promising.

That having been said, how does the use of available technology fit into the picture? Ideally, one would argue that environmental decisionmaking should be a combination of risk-based and technology-based drivers. Letting available technology alone drive decisions in the face of incomplete knowledge about risks has significant downsides, not the least of which are poor accountability for the decisionmaker and the potential to freeze technology. Who could argue for a decision to reduce emissions or exposures simply to that level achievable with the best available technology? Besides, once put in place, what is the incentive for improving the technology?

Neither wholly technology-based nor simply precautionary approaches will provide us with a rational regulatory system. What is needed is a system that encourages the use of the available science and reasonable scientific judgment, and relies on available technologies to the extent that they are economically feasible. In addition, such a system should be both science- and technology-forcing to assure that better information will be available to fine tune future decisionmaking.

More, not less, science is required. In order to serve a rational regulatory system, risk assessment will need to continue to evolve, and to focus on the problems and questions faced by decisionmakers. Decisionmakers will need to be more transparent about the bases for their decisions and will have to find innovative approaches to encourage the development of both science and technologies for their future use. More, not less, science in environmental law and decisionmaking will provide stronger, more cost-effective and practical solutions to public health and environmental protection.

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A major concern with the cost-benefit approach to risk-based standard setting is summed up in the question, "Whose costs and whose benefits?"

In a 2001 book, *Chronicles from the Environmental Justice Frontline*, J. Timmons Roberts and Melissa M. Toffolon-Weiss explore the history of the predominately African-American communities living on the fence line of refineries and chemical plants in the part of Louisiana known alternatively as "the industrial corridor" or "cancer alley." Following the civil war, many freed slaves had built small communities on the margins of former plantations near the Mississippi River. These same plantation lands were ideal locations for large facilities during the industrialization after 1940. During this period, Louisiana African-Americans were largely excluded from voting and thus had little ability to protect the rural character of their communities. As a result, huge plants now loom over many of these communities. Residents of these predominately lower-income and African-American communities learn to "shelter in place" from the risks of explosions, fires, and chemical releases that — to at least some extent — are inherent to the enterprise. It seems unlikely that the government would permit such operations as close to the residences of non-acquiescent upper income white communities, regardless of cost-benefit ratios.

As a society, we accept some distributional disparities as the price of an efficient market system. Our system’s unequal distribution of money helps motivate a productive work force, rewarding workers who perform jobs that society values highly (such as filing lawsuits) over those who select occupations the invisible hand deems less important (such as teaching grade school). But recognizing that society distributes economic benefits according to race as well as economic efficiency, even those of us most impressed with the invisible hand’s efficacy might think twice before incorporating such unfairness into a system for distributing safety.

An economist’s answer to this environmental justice concern might be that racial inequities have no economic benefit, are not an inherent part of cost-benefit analyses, and thus should be addressed by other laws rather than by economically inefficient standard-setting. An economist might therefore argue for building the most efficient regulatory system practical and designing a separate system to avoid or compensate for environmental injustice. But each additional system required to prevent a cost-benefit approach from generating unacceptable impacts increases the undertaking’s complexity, making the pure cost-benefit approach less attractive. Moreover, it would take a leap of faith to embrace a standard-setting mechanism with the potential to magnify distributional inequities based on a mere assumption that the political system will provide solutions to the resulting problems. The need to overcome society’s legacy of racism is too deep and central a concern to be swept aside in the name of efficiency.

Why, then, not rely on uniform risk-based standards to offer the same minimum level of protection to all Americans? The most common criticism of risk-based regulation is that it does not work. For example, when Congress required EPA to set risk-based standards for hazardous air pollutants, the agency froze up — issuing standards for only 7 pollutants, compared with the 189 that Congress later listed for regulatory action in the 1990 Clean Air Act Amendments. EPA has still issued only 6 risk-based National Ambient Air Quality Standards, and continues to freeze up when forced to face
unregulated risks from ambient pollutants. Attempts to achieve ambient air standards by imposing facility-specific requirements in “State Implementation Plans” are widely perceived to have been ineffective.

In contrast, technology-based standards — however inefficient — have delivered results. EPA revitalized the Clean Water Act when it adopted a technology-based approach for priority pollutants to supplement standards designed to protect designated uses of streams. Indeed, the Clean Water Act’s relative success with technology-based regulation helped inspire Congress to throw out its risk-based approach to regulation of hazardous air pollutants in 1990 and require EPA to set technology-based standards.

One reason for the risk-based system’s reputation for impracticality is that Congress tends to express mandates for risk-based standard setting in impractical terms, such as the demand for “an adequate margin of safety” regardless of economic considerations. But without considering trade-offs, including costs, EPA has no rational basis for setting an adequate margin of safety at anything other than zero or trivial risk. Of course, risk-based standards can also be geared toward goals that are more achievable than risk elimination. For example, some proponents of risk-based standard setting argue for the use of cost-benefit analyses to set standards at a point where the marginal benefit of further risk reduction equals the marginal cost of pollution control. But this brings us back to the problem of unequal distribution of costs and benefits. Even if we solved that difficult problem, we would need to face the question of how to determine economic values for life and health, which most of us probably consider to be priceless. Not surprisingly, therefore, overt use of cost-benefit analysis in the standard-setting process is the exception rather than the rule at EPA. Instead, the agency often tries to divine levels of risk that are, in and of themselves, “acceptable.”

A reasonable starting point for determining an acceptable level of risk is the point at which risks become too trivial to worry about, that is “de minimis.” Historically (and arbitrarily) the magic number for a de minimis risk has been $1 \times 10^{-6}$ — representing one excess bad outcome in a population of a million people. This one-in-a-million risk sounds so safe that Congress included it in the 1990 Clean Air Act Amendments, although only as a stopgap behind a requirement for state-of-the-art controls. One-in-a-million risk probably would be a good candidate for a uniform “acceptable risk” standard, except it can be expensive and sometimes impractical to achieve. The regulatory challenge, therefore, has been to move acceptable levels of risk past the de minimis level without explicitly undertaking the controversial task of weighing costs and benefits.

Arguing that a single risk target implies an unrealistic degree of scientific precision, EPA moved during the 1980s toward use of an “acceptable risk” range for Superfund cleanups. But instead of putting the $1 \times 10^{-6}$ de minimis level in the middle of the range, the agency, set the range of acceptable risks at $1 \times 10^{-6}$ to $1 \times 10^{-4}$ — 1 in 1 million to 1 in 10 thousand. In other words, rather than bracketing the traditional, de minimis level, EPA’s range allows adjustment to that level only to increase risk. EPA, however, cautioned that $1 \times 10^{-6}$ (the most protective end of the range) remained the starting point for analysis. Nonetheless, the agency selected the least protective end of its acceptable risk range ($1 \times 10^{-4}$) as the “presumptively safe” level for use in decisions about hazardous air pollutants. Emboldened, perhaps, by its success in expanding the concept of acceptable risk, EPA went on to assert that a $3 \times 10^{-4}$ risk (1 in 3,333) is “essentially equivalent” to its $1 \times 10^{-4}$ (1 in 10,000) presumptively-safe level. Both of these expressions of risk end in “10^-4,” but when EPA changes the multiplier from “1” to “3,” it triples the risk. EPA’s assertion that it can provide “essentially equivalent” protection while changing this multiplier raises the question of whether a $9 \times 10^{-4}$ risk (1 in 1,111) might also qualify as “presumptively safe.”

The U.S. Nuclear Regulatory Commission and U.S. Department of Energy have gone even further, accepting risks as high as $2 \times 10^{-3}$. In other words, NRC and DOE
have determined that radioactive risks are sufficiently low when members of the surrounding community are expected to suffer 1 excess cancer per 500 exposed individuals. If, a 1 in 500 or 1 in 3,333 risk really qualified as acceptable, however, EPA would be mandating a huge waste of resources by chasing a 1 in 1 million goal in other contexts. Clearly, EPA’s implementation of its “acceptable risk” concept cannot qualify as a rational basis for risk-based regulation.

If EPA knew what level of risk was acceptable, the agency could design a system to consistently reduce risk to that level. Because regulatory decisions based on a uniform risk standard would essentially ignore the cost side of the cost-benefit equation, economists might complain that such decisions are inefficient. It may be possible to save more lives at the same cost by meeting more stringent risk standards when control costs are low, and relaxing standards to accept more risk when costs are high. And a level of risk that seems reasonable in some circumstances might be almost impossible to meet in others. But these problems are not necessarily fatal. For example, feasibility and efficiency considerations could be built into the system by creating an escape valve, similar to the Superfund National Contingency Plan’s provision for rejecting cleanup proposals that involve “costs that are grossly excessive compared to the overall effectiveness.”

Alternatively, as Professor Bruce Ackerman and attorney William Hassler suggest in their famous 1981 book, Clean Coal/Dirty Air, if EPA knew how many of society’s dollars Congress wished to have directed toward risk reduction, the agency could use risk-based decisionmaking to get the most risk-reduction bang out of this regulatory budget. Economists might still be unhappy, since such an approach would keep costs under control but at times ignore the benefit side of the cost-benefit equation. Thus, risk-reduction would stop once the regulatory budget was exhausted, even if the benefits of more risk-reduction would outweigh further costs. Nevertheless, such a regulatory budget would give EPA a rational basis for incorporating the concept of limited resources into its decisions about environmental risks.

Finally, if Congress were to assign dollar values to life and health, EPA could conduct credible cost-benefit analyses — which might please economists if few others. So long as these dollar values are unknown, cost-benefit analyses compare apples to oranges — dollars to human lives or health. But if EPA really knew how much life and health were worth, the agency could, at least arguably, compare apples to apples. Other analytical problems would remain to be solved. But having assumed a Congress that is willing to tackle the bottom-line problem of “pricing the priceless” (in the words of Professors Frank Ackerman and Lisa Heinzerling) we may assume further that this Congress will make the political judgments necessary to set reasonable parameters for cost-benefit analyses — rather than pretending that such questions can be resolved by scientific best principles alone.

Each of these three alternatives for providing a context for rational risk-based decisions has merit, as well as drawbacks. But each also relies on the assumption that some force or event will motivate a congressional majority to go out on a public limb to compromise fundamental values in deference to limited resources. Politicians, however, are famous for shying away from complex and controversial issues. It thus seems only natural for them to avoid the position that government should tolerate any number of excess deaths or cancers (other than zero) to save money — a position that is easily characterized as cold-hearted or out of touch with societal values. Indeed, for thirty-some years, Congress has been unwilling to make the policy determinations that would be essential to the credibility of a risk-based antipollution system. There is no reason to expect this situation to change anytime soon.
There is still another barrier to rational risk-based regulation. As acknowledged in 1997 by the Presidentl/Congressional Commission on Risk Assessment and Risk Management, decisionmakers “seldom have enough information to accurately determine hazards, exposures, or exposure-response relationships.” In other words, most risk assessments are not based on reliable data. Indeed, an early step in the education of any professional who is responsible for developing or evaluating risk assessments is becoming comfortable with the fact that we know so little about environmental risks. This is not surprising. When it comes to scientific facts, we are most secure in knowledge rooted in the scientific method. That method—which presumably is still drummed into the heads of most school students—has six basic steps: (1) observe the phenomena you are studying; (2) come up with a hypothesis to explain your observations; (3) use the hypothesis to make predictions; (4) perform experiments to test your predictions; (5) adjust your hypothesis as necessary to explain the results; and (6) repeat the preceding steps until you have a hypothesis you cannot disprove. Related to the scientific method is the expectation that experimental results will be evaluated against results observed in a “control group” subject to the same conditions as the experimental group except for the variable that is the experiment’s subject.

For thirty years, Congress has been unwilling to determine the policies essential to the credibility of a risk-based anti-pollution system. There is no reason to expect this situation to change anytime soon.

The most obvious problem in applying the scientific method to risk assessment is that it is unethical to conduct experiments on people by exposing them to potentially harmful doses of chemicals. Another problem is that the general prevalence of cancer creates a “noise” level that obscures chemical effects that might otherwise be observable. Even at relatively high occupational exposures, a powerful environmental carcinogen may cause cancer in a fairly low percentage of the people exposed to it, and between a third and half of us eventually get cancer anyway. Thus, for epidemiologists to notice and explain “cancer clusters” or other trends in population groups, they must bridge significant data gaps and filter out a host of confusing factors. Environmental professionals respond to the resulting uncertainties by relying on questionable extrapolations: (1) from high doses to low doses; (2) from short-term exposures to long-term exposures; and (3) from animals to people. The many assumptions risk assessments incorporate belie the precision implied by the risk characterization, such as $1 \times 10^{-4}$. Yet, in what Professor Wendy E. Wagner has called “the science charade,” regulators use this unscientific tool to provide pseudoscientific assurances to community members that they have nothing to worry about. By using scientific language to present risk characterizations that assume away unknowns, risk assessments offer decisionmakers the opportunity to pretend such uncertainties do not exist.

As Professor (and medical doctor) Troyen A. Brennan pointed out in the 1993 Vanderbilt Law Review, there are no “brightline distinctions” between most substances EPA regulates as “toxic” and “other forms of pollution.” Instead, “Congress, regulators, and the courts . . . typically rely on lists of toxic substances, treating the distinction as if it were self-evident.” Notwithstanding their lack of hard data, regulators essentially divide the universe of potentially dangerous chemicals into three major categories. The first and largest category comprises chemicals and combinations of chemicals that are not known to harm people or laboratory animals, and are therefore assumed to be risk-free. The next two categories depend on the endpoints of exposure, that is whether regulators think the chemical causes cancer or a non-cancer health effect, such as brain-damage, asphyxiation, or some other effect of toxicity. For non-cancer effects, regulators’ working assumption is that there is a threshold below which exposures are completely safe, and that the government can eliminate risk by reducing exposures below observed “no effect” levels. For carcinogens, the working assumption is that there are no such thresholds.

Often, the practical effect of the “no threshold” assumption is to justify a technology-based approach to setting supposedly risk-based standards. For example, a regulatory analysis under the Safe Drinking Water Act of a chemical associated with a laboratory animal cancer would typically go like this: (1) the chemical is a probable human carcinogen because it gave a laboratory animal cancer; (2) we assume that there is no “no ef-
fect” threshold below which exposure to human carcinogens is completely safe; and (3) therefore regulations should reduce human exposures to this chemical as much as practical, given the capabilities of available, feasible technology. While, as this essay argues, there are good reasons for EPA to adopt a technology-based approach, the embrace of an unverifiable assumption about the mechanisms of carcinogenicity is not a firm foundation for such an approach. Indeed, that foundation is undercut when scientists show that the mechanism responsible for the laboratory animal’s cancer does not occur below a threshold dose.

At about the same time EPA announced its intent to use the “no threshold” dose-response assumption to bridge scientific uncertainty, Nobel-prize winning physicist Richard Feynman published his autobiography. In discussing his experience with scholars of various disciplines, Dr. Feynman provided his take on biology (of which toxicology is a relatively new branch): “Right away I found out something about biology; it was very easy to find a question that was very interesting, and that nobody knew the answer to. In physics you had to go a little deeper before you could find an interesting question that people didn’t know.” Science is not static, however, and since those words were published, biologists have learned a few things. For example, they can now make sheep. Clearly, basing our regulatory system on what scientists do not know creates an inherent risk that the system will be undercut as scientists figure out more things. And, sure enough, as scientists have learned a few things. For example, they can now make sheep. Clearly, basing our regulatory system on what scientists do not know creates an inherent risk that the system will be undercut as scientists figure out more things.

When scientists use lab animals to test chemicals for carcinogenicity, they typically expose them to a dose just below the level that would actually poison the animals. As it turns out, high-dose exposures of some types of chemicals appear to affect lab animals in ways that are not relevant to understanding the effects of chronic low-dose exposures. Essentially, these high experimental doses have toxic effects that, rather than simply killing the animal, kill a lot of cells, which leads to “regenerative cell proliferation.” Byron E. Butterworth and Matthew S. Bogdanoff, in a 1999 article in Regulatory Toxicology and Pharmacology, call regenerative cell proliferation a “driving force in the carcinogenic process.” Granted, the animal gets cancer — but that cancer is explainable in terms of a physical reaction to a toxic dose and would not occur if the dose were below a “no effect” threshold.

The regulated community has been clever or fortunate in the development of this new information about thresholds in animal studies. Early litigation about the information’s significance concerned chloroform — a chemical byproduct of chlorination of public water supplies. Thus, chloroform results from the process of protecting drinking water from pathogens with a capacity for swift and sure mayhem. Moreover, the costs of meeting stringent standards will be borne by municipal water suppliers and their ratepayers (that is, practically all of us) rather than profit-making industrial polluters. The issue of chloroform in drinking water therefore provides a context for the “threshold/no threshold” decision that allows the most public sentiment possible to be marshaled on the side of reducing control costs.

In a 1998 rulemaking to set a regulatory goal for chloroform in drinking water, EPA tried to duck the challenge of dealing with new scientific evidence. EPA stuck to its “no threshold” assumption, arguing that it did not have time to fully assess the new data. In a March 2000 decision, however, the D.C. Circuit declined to defer to the agency’s unwillingness to grapple with new information. In Chlorine Chemistry Council v. EPA, the court remanded the chloroform decision, leaving EPA poised on a potentially slippery slope. If chloroform’s carcinogenicity is a result of a toxic reaction, as appears to be the case for cancers in laboratory animals, eliminating doses in excess of the threshold for toxicity.
With toxicologists busy generating too much new science, unwilling politicians, and reliable risk information still out of reach, how should EPA decide on an appropriate level of regulation? ...

With toxicologists busy generating too much new science for the continued credibility of the “no threshold” assumption, politicians unable or unwilling to make the fundamental policy decisions necessary for a rational risk-based regulatory system, and reliable risk information still out of reach, how should EPA decide on an appropriate level of regulation? The obvious answer is to refocus regulatory standard-setting on the capabilities of state-of-the-art technology. An advantage of technology-based standards is that they can be explained honestly and justified compellingly to the public. In contrast to risk-based standards, which are generally touted misleadingly for their basis in science or controversially in terms of economic efficiency, the requirement of best available technology embodies a policy judgment as attractive as apple pie: Businesses that expose the public to chemical wastes should install state-of-the-art controls to minimize any potential for harm. True, economists will continue to wince at the inefficiencies of uniform standards with no direct tie to risk-reduction benefits. But market-type efficiencies depend on ready access to reliable information. Justifying costs in terms of benefits therefore may not increase efficiency if the benefit side of the equation is based on unreliable data and unjustified assumptions.

Scientific thought about the mechanisms of carcinogenicity and other toxicological issues is fascinating and is based on creative and valuable work. But it takes nothing away from the respect due to scientists working in the field to note that toxicology and epidemiology are still young, fundamentally “soft” sciences. They are not capable of churning out the kind of reliable information about risk that EPA needs to create a coherent risk-based anti-pollution regulatory system. One might argue, of course, that scientific conclusions are always imperfect and that we should regulate according to our best data. Much of the point of this essay, however, has been to show that neither available risk data nor government institutions are up to this task. In contrast, while technology-based standards may sometimes under- or over-regulate, they are grounded in principles that are subject to confirmation or debunking through the scientific method. Engineers, lawyers, and bureaucrats can argue about technology-based standards without...
immediately falling into the risk assessors’ trap of assuming facts to paper over uncertainty.

It would nonetheless be overly pessimistic to argue that scientists will never develop risk data reliable enough to form a basis for anti-pollution standards. Accordingly, health protection standards should generally be subject to adjustment on the basis of reliable risk data. In fact, refusing to allow such adjustments in the face of convincing evidence of safety or continuing danger would risk the system’s credibility. Similarly, if abating one risk would increase another, adjustments to technology-based standards would be appropriate, just as the National Contingency Plan now allows EPA to waive applicable standards for cleanup of hazardous substances when “compliance with the requirement will result in greater risk to human health and the environment than other alternatives.”

Congress has addressed this issue before. In 1990 — to respond to the failure of the Clean Air Act’s prior risk-based approach to control hazardous air pollutants — Congress mandated a system of technology-based standards. But Congress added a risk element as well. The act requires EPA to drop a pollutant from its list of hazardous air pollutants if “there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.” Conversely, the law requires EPA to strengthen standards for hazardous air pollutants if particular standards are insufficient to meet a one-in-a-million risk standard. Thus, standards are set according to technology, but advocates on both sides are free to attempt to convince EPA that reliable risk data are available to modify the regulatory scheme.

Data from risk analyses should only be used to relax technology-based standards if those data provide solid assurance of the existence of thresholds for safety. Most conclusions from current risk-assessment techniques would not meet this burden, since those techniques rely so thoroughly on unverifiable assumptions and extrapolations. Moreover, relaxation of technology-based standards should be permitted only when consistent with societal goals other than safety. For example, Congress intended the Clean Water Act not only to provide safety but also to eliminate discharge of pollutants into U.S. waters. Thus, as the D.C. Circuit recognized in 1978, Congress rejected “the use of any river, lake, stream, or ocean as a waste treatment system . . . regardless of the measurable impact of the waste on the body of water in question.”

For a recent documentary, “Trade Secrets: A Moyers Report,” television commentator Bill Moyers had his blood tested for “residues of the chemical revolution.” The tests looked for 150 chemicals and found 84 in Mr. Moyers’ blood — 83 of which reportedly would not have been there before the chemical revolution. Dr. Michael McCally, of the Mt. Sinai School of Medicine, explained: “We didn’t know this until we looked, but suddenly we find out that the industry has put a bunch of chemicals in our body that, you know, are not good for us, and we didn’t have any say in that. That just happened.” Given the paucity of reliable information about chemical risks, what would be the better defense to the charge that businesses and government agencies are treating people like guinea pigs: That chemical exposures are kept below thresholds derived from unverifiable regulatory assumptions? Or that exposures are reduced to the lowest achievable levels following investment in state-of-the-art technology?

Nobody knows when we will be sufficiently confident in our knowledge of chemical risks or of society’s risk-tolerance to develop a rational risk-based regulatory system. In the meantime, our surest road forward is to base health protections on what we do know. Regulatory decisions should require the best level of control that is economically feasible given available technology, subject to adjustment if and when truly reliable information about environmental risks becomes available.