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EPA JOURNAL

Profiles In Risk Assessment

—New Science

—New Contexts



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United States
Environmental Protection Agency

Carol M. Browner
Administrator

Communications, Education,
and Public Affairs

Loretta M. Ucelli
Associate Administrator

Charles Osolin
Director of Editorial Services

Karen Flagstad
Associate Editor

Teresa Opheim
Assistant Editor

Gregg Sekscienski
Assistant Editor

Ruth Barker
Photo Editor

Nancy Starnes
Assistant Editor

Marilyn Rogers
Circulation Manager

Francheska Greene
Intern

Front cover: Triple exposure photomicrograph of melanoma and carcinoma cell tissues (skin cancer tissues) with indirect fluorescent staining, enlarged 400 times.

Gail MacKenzie, ImmunoGen, Inc.
This photograph won second place in the 1992 Nikon International Small World Competition. For more information or an entry form for this annual competition, contact: Small World Competition, Nikon Inc., Instrument Group, 1300 Walt Whitman Road, Melville, NY 11747-3084

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From the Editors

Let's face it. When the subject is risk assessment, controversy is part of the picture.

What is the risk of Pollutant X? Even with a single pollutant as our scenario, opportunities abound for misunderstanding and disagreement. Scientists may disagree in their interpretation of the available scientific studies. Science policy decisions can be highly controversial, especially when "data gaps" and other uncertainties are involved—as generally they are. There may be uncertainty and disagreement about risk "numbers," the quantitative aspect of risk assessment. The working distinctions between risk assessment (what scientists know about risk) and risk management (what regulators decide to do about it) entail further controversies. This issue of *EPA Journal* explores such current controversies in risk assessment and profiles recent developments in the science that supports it.

Of course, Pollutant X is not the whole story. How does the health risk posed by Pollutant X compare to the ecological risk presented by Pollutant Y? Moreover, how does the risk of X rank in terms of all the other health and environmental risks faced by the nation? by a particular state? by an individual community? These are the kinds of real-world questions that gave birth to comparative risk analysis, a relatively new (and still controversial) practice which was endorsed by EPA's Science Advisory Board in its 1990 report *Reducing Risk*.

How *should* environmental priorities be set in these times of constricted resources? Through comparative risk analysis and risk-based priority-setting? Some participants in the debate reflected in this issue of the *Journal* say yes, definitely so; others suggest alternative paradigms, such as environmental justice and pollution prevention.

It's a high-stakes debate, and it deserves to be conducted in the public eye.

Postscript: As this issue of the magazine went to press, a number of key EPA appointments were announced, including Loretta M. Ucelli as Associate Administrator for the Office of Communications, Education, and Public Affairs. Profiles of the new appointees will appear in the next issue of *EPA Journal*.

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The U.S. Environmental Protection Agency is charged by Congress to protect the nation's land, air, and water systems. Under a mandate of national environmental laws, the Agency strives to formulate and implement actions which lead to a compatible balance between human activities and the ability of natural systems to support and nurture life.

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Chemical Plants to Control Toxic Emissions

EPA has proposed a rule under the Clean Air Act that would reduce toxic emissions from the chemical industry by 80 percent. Such emissions are estimated to contribute to 1,500 to 3,000 cancer fatalities a year. The rule would also reduce emissions of volatile organic compounds (VOCs) from the industry by more than 71 percent; VOCs are a prime ingredient in urban smog. Then-EPA Administrator Reilly commented: "This is the first major air toxics rule ever issued controlling the chemical industry. It will improve public health by reducing air pollution everywhere, providing companies the flexibility to find the most cost-effective way of controlling air toxic emissions."

The Los Angeles Times reported: "... The proposal will now be subject to public comment and possible revision. Consequently, it is expected to be another year before it is put into final form. The rule will take effect three years after that The environmental agency's assistant administrator for air and radiation ... hailed the proposal as the most significant step that will be taken in the next 10 years to

abate toxic air pollutants. The beneficiaries, he said, will be human health, agricultural production, ecosystems harboring endangered species, and streams and forests. Provisions of the complex draft, he said, will reduce releases of 149 of the 189 toxic chemicals explicitly mentioned in the Clean Air Act, including chemicals cited as possible contributors to 1,500 to 3,000 annual cancer deaths. Most significantly affected will be areas of Louisiana, Texas, and New Jersey where the petrochemical industry is heavily concentrated, although the new rules will have bearing on facilities in 38 states. Officials from the most-affected areas joined environmentalists and industry representatives, including the Chemical Manufacturers Assn. and the American Petroleum Institute, in lengthy negotiations over the proposed rule. As the EPA touted the outcome, critics characterized it as weak in several important respects. A joint statement by the State and Territorial Air Pollution Program Administrators and the Assn. of Local Air Pollution Control Officials said

flaws in the proposal not only threaten its control efforts, but also could 'set a dangerous precedent for future air toxic rules.' ... Specifically, critics attacked the proposal because it provides for cost-benefit analyses before control standards can be imposed that are more strict than the 'floor' levels written into the Clean Air Act. It also enables operators of huge industrial complexes to average emissions from control points. If one controlled aspect of their operation is emitting excessive toxics, they could compensate for it by exceeding control requirements at another location"

The Wall Street Journal commented: "... The EPA's proposal to cut cancer-causing pollutants would require 370 chemical manufacturing plants to install devices and techniques to control leaks and other emissions of pollutants, resulting in an estimated 80 percent cut in toxic fumes by 1996. Chemical manufacturers emit the greatest amount of toxic pollution of any industry group in the nation. The proposal will serve as a precedent as the first in a series

of source-by-source controls that will be issued under the 1990 Clean Air Act's program for reducing cancer risks around plant sites The EPA also issued final rules for its program to reward companies that voluntarily make earlier reductions. Thirty-two companies have promised to cut their toxic air pollution at 47 chemical-manufacturing plants 90 percent to 95 percent by Jan. 1, 1994. In exchange, they will get six extra years to comply with new technology standards, which most likely will require them to install additional equipment. Among those promising early reductions are plants operated by Allied-Signal Inc., American Cyanamid Co., Du Pont Co., Hoechst AG's Hoechst Celanese Corp., Monsanto Co., and Union Carbide Corp. The EPA estimated the chemical industry will spend \$347 million in capital costs and \$182 million a year in operating expenses to meet the proposal's new technology requirements for cutting fumes that escape from leaks, processing vents, storage tanks, loading operations, and wastewater facilities."

National Standards Set for Sewage Sludge Contaminants



One of the many uses of sludge is to fertilize home gardens.

USDA photo.

A rule issued by EPA under the Clean Water Act sets pathogen standards and pollutant limits for sewage sludge. It also spells out the practices to be followed in using sludge or in disposing

by-product of treating wastewater from homes and businesses. It is made up mostly of water, but also of solids and dissolved substances. It contains nutrients—nitrogen,

of it. The rule is multimedia in that it seeks to protect surface water, ground water, air, and land. It is also the first rule issued by EPA that considers ecological effects.

Sewage sludge is a

phosphorous—and pathogens—bacteria, viruses, parasites. It may also contain small amounts of organic chemicals, such as chloroform, and inorganics, such as iron. A typical family of four generates up to 400 gallons of wastewater a day. Treatment, including removal of the water, yields about one pound of sludge on a dry weight basis. Sludge must be treated before it is disposed of or used.

Currently, most sewage sludge is disposed of as waste; about 30 percent is put to use. EPA's rule is intended to assure that public health and the environment are protected from any contaminants in sludge, and thereby to promote its use.

Alone, or combined with other materials, it can be used to reclaim land damaged by strip mining or clear cutting, and it can be used to cover landfills. Biosolids derived from sludge can be used on farms, home gardens and lawns, golf courses, and in forests to increase the ability of soil to store water and nourishment for vegetation.

The rule applies to publicly, privately, and federally owned facilities that generate or treat sewage sludge, as well as any person who uses or disposes of sewage sludge or sludge from septic systems. It sets pollutant limits for sludge applied to land, disposed of in a landfill, or fired in an incinerator, and it sets requirements for reducing pathogens that might cause disease.

ENFORCEMENT

Craven Laboratories Suspended from Federal Contracts

EPA has suspended Craven Laboratories and four of its employees from participating in federal contracts, grants, loans, and assistance programs. The suspension derives from a 20 felony count indictment alleging that Craven and the employees concealed and falsified information on pesticide

residue tests. Manufacturers, who had contracted for the tests, were thereby defrauded, and EPA was given false information for setting allowable residues in food and feed. The indictment was brought by a federal grand jury in the U.S. District Court of the Western District of Texas, Austin Division.

Pennzoil and Quaker State Fined for Violating Clean Water Act

EPA and the Department of Justice have announced settlements with two Pennsylvania companies for illegally discharging oilfield brine into public waterways. Pennzoil Exploration and Production Co., of Bradford will pay \$1.15 million in fines; the settlement with Quaker State Corp., of Oil City includes a fine of \$447,694. The Pennsylvania Fish Commission, party to the

Pennzoil case, will receive \$150,000 of that company's fine for environmental restoration projects. Brine is a toxic wastewater that is formed when oil is pumped from a well and processed through a separator. Discharging brine into public waterways without a permit violates the federal Clean Water Act and the Pennsylvania Clean Streams Law.

High-Tech Inspections for Cars and Trucks to be Required

Under a rule issued by EPA under the Clean Air Act, the more than 80 cities with the most serious ozone and carbon monoxide problems will set up high-tech emissions testing programs for cars and trucks. Manufacturers already meet increasingly stringent standards for new vehicles. However, cars and trucks in actual use emit three to four times the pollutants allowed for the new ones. The primary reason is improper maintenance. In announcing the rule, then-EPA Administrator Reilly said: "The high-tech testing program will provide the largest emission reduction of any pollution control strategy EPA has thus far identified. We project that vehicle emissions in the most polluted cities around the country will be reduced by 28 percent for hydrocarbons, 31 percent for carbon monoxide, and 9 percent for oxides of nitrogen. The program also will be more convenient for car owners since testing will only have to be done every other year."

The Wall Street Journal reported: "... Beginning in 1995, vehicles in 83 urban areas with the worst smog and carbon-monoxide problems will face more sophisticated tests of their car exhaust as well as new tests that for the first time will check under the hood for leaks of gasoline vapors. And in a blow to independent service-station

operators, the EPA decided to bar gasoline stations and repair shops from performing the high-tech inspections Audits have shown that when shops conduct inspections and sell other services, such as repairs or gasoline, about half the vehicles that pass the tests should have failed, and thus they continue to pollute. The agency contends that 'test-only centers' will help avoid quality problems, conflicts of interest that could lead to unnecessary repairs or, on the other hand, a tendency to try to please a customer by fudging test results. The result is that test-and-repair shops now operating in areas that must begin the more sophisticated tests will be forced to give up a part of their business. The change will affect portions of California, Colorado, Georgia, Louisiana, Massachusetts, Nevada, New Hampshire, New York, Pennsylvania, Rhode Island, Texas, and Virginia. Test-and-repair shops, though, can continue operating in 98 other urban areas with more moderate pollution. They will conduct simpler exhaust tests of vehicles to reduce air pollution The tests are designed to catch problems in today's highly computerized cars. They will use new \$150,000 computer-assisted treadmills, now found only in



Lyn Alweis photo. The Denver Post.

In cities like Denver with serious ozone and carbon monoxide problems, new high-tech emissions inspections may help clear the air.

test laboratories, that will analyze car exhaust during a four-minute cycle of idling, accelerating, and braking"

The Rocky Mountain News said: "... If a proposal outlined Monday becomes state law, the 900 Denver-area service stations that inspect cars for pollution will be replaced by 20 to 40 high-tech garages. Each would be equipped with at least one \$100,000 dynamometer to conduct emissions tests. Each test would cost \$20, but they wouldn't be required every year. Currently, car owners pay up to \$9 each year for a quick test to determine the amount of carbon monoxide and hydrocarbons the vehicle is emitting. Under the proposal, inspection wouldn't be required of cars 6 years old and less on the theory that their engines usually are so clean that they

contribute little to pollution. Older cars would be inspected every two years. Any car, old or new, would be inspected as a condition of resale The plan, to begin in 1995, calls for a private management contractor to lease 20 to 40 stations, scattered around the metro area, to independent operators. Each year, the stations would test more than 500,000 cars. Several service station owners said they don't like the proposal, saying only companies with a lot of money could afford the overhead. 'It's taking away free enterprise,' said Clay E. Carr of Lakewood. 'You're creating a monopoly.' But Jerry Gallagher, head of the mobile sources unit of the Health Department, said the high-tech, four-minute test on the dynamometer is best because it simulates real driving, braking, and accelerating"

Air Pollution Down Over Last 10 Years

For the period 1982 through 1991, nationwide levels of air pollution have declined, according to the latest trends report published by EPA. Under the Clean Air Act, the Agency has set air quality standards for six major pollutants—ozone (urban smog), carbon monoxide (CO), sulfur dioxide, particulates (dirt, dust, and soot), lead, and nitrogen dioxide. For the 10 year period, all six were down.

In releasing 1991 data for the first time, the report also showed that 41 of 97 areas designated "non-attainment" for smog and 13 of 42 for CO now meet the air quality standards for those pollutants. EPA believes that

these improvements resulted in part from federal limits on gasoline volatility and the replacement of older cars with newer, cleaner ones. The Agency believes that weather also played a role, since heat and sunlight can exacerbate smog, and weather patterns over the past few years have been different from those occurring in the late 1980s.

The report also showed that air pollution is still a serious problem for many communities. More than 69 million people live in counties that exceed the air quality standard for smog, over 19 million in counties that exceed the CO standard, and over 21 million in areas that violate the particulates standard.



Wide World photo.

Nitrogen Oxides from Power Plants to Be Cut

Rules proposed by EPA would cut emissions of nitrogen oxides from existing power plants 1.5 to 2 million tons annually; this is the first time existing plants have been proposed for controls. Electric utility boilers that burn coal, gas, or oil account for nearly 30 percent of nitrogen oxide emissions; by comparison, cars and trucks account for roughly half. Nitrogen oxide contributes to acid rain and urban smog, among other environmental problems.

The Baltimore Sun reported: " ... The Environmental Protection Agency yesterday proposed controls on smog-causing pollutants from factories and electric power plants. But state officials said the rules are too weak and may hinder efforts to improve air quality in urban areas Nitrogen oxide, which is produced by the burning of fossil fuels, is a component of urban smog as well as a cause of acid rain. While the EPA long has controlled the chemical's release from automobiles, it has never before restricted its release from electric power plants and industrial boilers. Under the regulation proposed yesterday, nitrogen oxide emissions from about 200 coal-fired utility boilers will have to be cut by 2 million tons a year by 2000, according to the EPA. A final rule is expected to be issued soon The regulations, however, raised concerns from other state pollution control officials, who called the EPA standards too weak to ensure that cities will be able to comply with federal air quality requirements. 'The EPA's [pollution] limits are disappointing,' said Bill Becker, executive director of two associations representing the country's state and local air pollution control officials. He said the EPA ceiling on allowable nitrogen oxide

releases from industrial boilers is nearly a third greater than levels recommended by the state and local officials as necessary to meet federal air quality improvement goals. The EPA's latest air quality assessment showed that more than 86 million people live in urban areas that do not meet federal health standards for smog."

The Wall Street Journal said: " ... Environmentalists accused the EPA of caving in to utilities and the Energy Department by failing to require boiler technologies that would get even deeper cuts in nitrogen oxides. But utility interests also complained. A spokeswoman for the Edison Electric Institute, a trade group of major utility companies, said two alternative technologies proposed by the EPA still would require more costly and extensive modifications than industry thinks is required by the Clean Air Act of 1990 The rules are in two parts. One, dealing with acid rain, requires coal-fired utilities to reduce nitrogen-oxide emissions; the cost of compliance is estimated at \$300 million a year when the rules are fully in force by the year 2000. The other part of the rules provides guidelines for reductions in nitrogen-oxide emissions in urban areas with unhealthy smog levels; the guidelines would apply to utility and non-utility boilers beginning in June 1995, unless polluters gain extensions, and would cost an estimated \$500 million a year Utilities welcomed an EPA proposal that the new standards apply to average emission levels of companies, instead of requiring that each boiler meet the new requirements. The EPA says the averaging provision will give companies greater flexibility and will cut compliance costs."

130 Cities Exceed "Action Levels" for Lead in Drinking Water

Initial tests of high risk homes in communities served by 660 so-called large public water systems reveal that 130 systems exceed the lead action level of 15 parts per billion (ppb) set by EPA under the Safe Drinking Water Act. Large systems are those that serve more than 50,000 people; high risk homes are those whose service or interior pipes are made out of lead, or those whose interior pipes are made from copper with lead-soldered connections and that were installed after 1982. In announcing the results of the tests, then-EPA Administrator Reilly commented: "Lead is a major public health concern. Although we believe the majority of American homes have safe lead levels in drinking water that are below 15 ppb, we are concerned about the high levels found in some homes. While systems with elevated levels are required to reduce their lead levels through corrosion control measures over the next six years, people served by these systems can act now to reduce their exposure. They should contact their water supplier for information, have their tap water tested for lead, and take some simple steps in the home."

The Wall Street Journal said: "... The drinking water in 130

cities, including New York, Detroit, and Washington, DC, contains excessive levels of lead, the Environmental Protection Agency said. The EPA's initial sampling of 660 large public water systems found that about 32 million Americans drink water from systems that flunked the federal test of 15 parts per billion. In 10 cities, lead was above 70 parts per billion, with Charleston, S.C., posting the worst level of 211 parts per billion Over time, the consumption of excessive lead in water, along with exposure from lead-based paint and contaminated soil and dust, can elevate blood levels of the toxic metal. This, in turn, can delay physical and mental development in babies and young children and impair mental abilities in children. Drinking water contributes 10 to 20 percent of the total lead exposure in young children The EPA cautioned that the findings don't represent average lead levels. The samples were taken only from 'high risk' homes, those that are served by lead service lines or that contain lead interior piping or copper piping with lead solder. The tests also were based on first-draw



Steve Delaney photo.

water, before the system was flushed"

The Washington Post commented: "... The EPA recommends that people served by the water systems cited in its survey can reduce lead exposure by having their water tested, letting tap water run for several minutes before using it and using cold water for drinking or cooking Under rules adopted last year by the EPA, all water systems in the nation serving more than 50,000 people are to begin taking measures to reduce lead by Jan. 1 and complete installation of systems to limit pipe corrosion by 1997 by adding chemicals such as lime

and calcium carbonate to their water. Municipal systems that still do not comply with recommended lead levels after the installation of anti-corrosion systems must replace lead service pipes over a 15-year period, a remedy that could cost \$7 billion. EPA's announcement yesterday was criticized by some environmentalists, who said the agency has incorrectly suggested that lead levels are safe in most large water systems. The EPA's data 'imply that lead levels below the action level of 15 parts per billion are safe, but the truth is, they are not,' said Erik Olson, an attorney with Natural Resources Defense Council."

Negotiated Rule Set for Coke Ovens

An agreement reached by members of an advisory committee is the basis for a rule proposed by EPA to control toxic emissions from coke ovens. The committee, which represented state and local agencies, environmental and citizen groups, labor unions, the steel industry, as well as EPA, agreed to requirements that not only meet but in some cases exceed the coke oven provisions of the 1990 Amendments to the Clean Air Act. At the same time, they provide the steel

industry with the flexibility needed to protect jobs and to encourage new investment.

The agreement, and the rule proposed by EPA, affects 30 coke oven plants in 11 states. Coke ovens convert coal to coke, which, in turn, is used in blast furnaces to convert iron ore to iron. The iron is further refined to make steel. Coke oven emissions are among the most toxic of all air pollutants; they include a mixture of polycyclic organic matter, benzene, and other chemicals

that can produce cancers of the respiratory tract, kidney, and prostate.

The proposed rule would allow industry to choose between two methods of compliance, neither of which would require the purchase of new control technology. The first would cut current emissions by 66 percent through better maintenance and repair of existing equipment. Nationwide, it would require capital costs of \$66 million and annualized costs of \$25 million. The second, tougher method

would cut emissions 90 percent by carrying out the provisions of the first method plus, in many cases, rebuilding existing equipment. Its capital costs would run \$510 million, its annualized costs \$84 million. A coke oven plant that chooses to apply the tougher method of compliance may delay meeting other provisions of the law, which require EPA to evaluate any "residual risks" eight years after the rule is imposed. If the Agency discovers that risks remain, it must issue additional rules. □

Meet the New Administrator

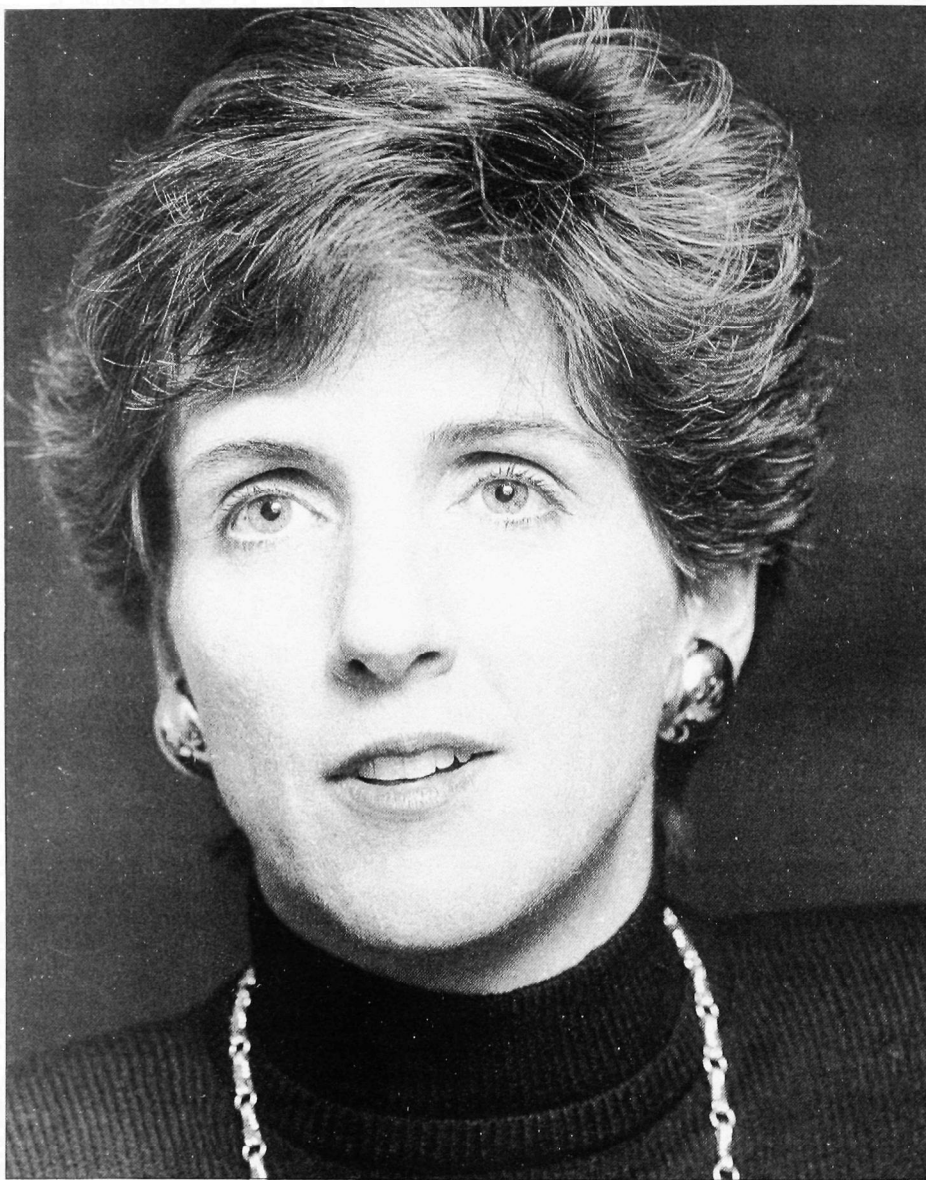
An interview with
Carol M. Browner

Q We would like to begin by asking you to talk a few minutes about your priorities and objectives as EPA Administrator.

A In terms of how we look at the far reaching and very complicated environmental problems facing this country, we need to have a framework in which to work, and that framework needs to be pollution prevention. We must focus our resources upstream, look at new technology, look at source reduction. If we use pollution prevention as a framework, we can decide on the methods that get us to where we need to be in the long term—namely to sustainable development and environmental protection. To that end, I look forward to working closely with EPA's staff, as I will on all issues. There is impressive talent here, and I want all of our work—and particularly our scientific analysis—to be recognized nationally as the very best.

Q What is your prognosis on whether and when EPA might be elevated to Department and Cabinet status?

A The President is very committed to the elevation of EPA to Cabinet status. There is significant support among members on the Hill for it to move quickly. One can



Steve Delaney photo.

never fully anticipate what will happen, but I am encouraged by the support that we have. What is important about the elevation is that it will bring the environment to the table as a full participant. President Clinton has treated the Agency and me thus far as a full member of the Cabinet. But it is important for the future to give environmental issues the high visibility that Cabinet status implies. It is important to keep the environment at the top of the national agenda and at the forefront of public consciousness, and Cabinet status will help us accomplish these goals.

Q You have said that during your tenure, environmental policies will finally move beyond the "either/or" tradeoff between jobs and the environment toward a sustainable economic future. Two questions: How will this goal be reflected in future decision making at EPA? And how does your thinking on this compare with past EPA policies?

A It is important to look at the history of environmental regulation in this country. It has been decades since the enactment of the original Clean Water Act and the other federal legislation that followed thereafter. The initial focus—and rightly so because we didn't have the technology to do otherwise—was on controlling end-of-the-pipe emissions and discharges. Back then, we had a lot of significant, obviously bad practices taking place. We began a series of regulatory schemes that sought to resolve those problems. Oftentimes those schemes did not look beyond the immediate impact; they did not consider possibilities for preventing an activity from happening in the first place or allowing it to happen only within certain parameters. As the regulatory programs developed, they inevitably have had economic impacts.

We are now at a crossroads. Everyone in this country shares the idea of a clean environment for future generations, and they want to achieve that. We are, however, going to have to be mindful of the consequences of environmental protection. We need to use economic incentives to encourage businesses to make the right decisions. We need to look at the true cost of the actions that we take—not just what it costs today—but what it is going to cost over, let's say, the next 10, 20, 40 years and beyond. Factoring in all these considerations is important so that when we make decisions under the regulatory scheme, we make them using all of the information available.



Steve Delaney photo.

Q You are coming to EPA from Florida's Department of Environmental Regulation (DER). Do you see a prominent role for state and local governments in environmental initiatives during your administration? If so, how can EPA best help states and localities deal with increasing environmental responsibility?

A The states have a lot to offer. There is a lot to be done. There is more to be done than any one agency could ever hope to achieve. We at EPA need to facilitate. We need to encourage those states where the state legislature, the governor, or the citizens of the state have decided that they are going to put resources into environmental protection. We have other states which have not made that decision. We need to work with them, to help them understand their environmental commitments.

We must respect the states' prerogatives. There are many issues where states really are best suited to decide how to strike that final balance. As a national agency looking at the entire country, we must come up with rules that fit for Florida, Maine, Hawaii, Alaska, and Iowa, to pick random states. There are similarities between those states, but there are also great dissimilarities. A state can look more closely at the situation that exists within its boundaries. We have to respect that, and we have to encourage that.

Q What do you view as your major accomplishments as head of Florida's DER?

A We brought an integrity to environmental protection and environmental regulation in Florida. We worked very hard, and I'm proud of the efforts we made. We started looking broadly at ecosystem protection, which helped us get beyond some of the kinds of problems that we're seeing all over the country in a lot of the applications of environmental regulation. I'm proud of the clean air act that we passed and the coalitions we were able to forge between business, environmental groups, and state agencies. In almost every instance, our successes were because we worked in a cooperative manner. We brought everyone to the table from the beginning and received input on how we were going to address each issue.

"There is impressive talent here, and I want all of our work—and particularly our scientific analysis—to be recognized nationally as the very best."

Q In the past, you have worked closely with Vice-President Al Gore. What lessons have you learned through your working relationship with him?

A I served as Senator Gore's legislative director for almost two years. It was an opportunity to work in an important way in the U.S. Senate in formulating policy on a variety of issues of significance, including environmental issues. Along with the understanding of policy that comes from having worked for the Senate, I have hands-on regulatory experience. It's not often that you get both of those experiences. If I were to go back to the policy side with the experience I have now, I would probably do things differently. I'm forever thankful to Senator Gore for the experience with him.

Q Relations between EPA and the corporate world have been said to be improving. Does your agenda involve working toward less adversarial roles for business and regulators?

A Absolutely. Most businesses recognize that, for a variety of reasons, a clean environment is important, and they are willing to work cooperatively toward that goal.

Q President Clinton has been quoted as saying that one reason he wanted you to be EPA Administrator is "because she knows ... what it's like to be governed by EPA and how awful [the result] can be when it is done wrong; what it is like to see an agency take two contradictory positions at the same time and put the heat on that state and the private sector; what it is like to see the EPA take one position, then another, and then another." Can you elaborate on what he meant here?

A Well, when a state is subject to federal government regulations—whether the agency is EPA or any other federal regulator—inconsistencies occur. And they are

extremely frustrating. The inconsistencies are at times understandable; at other times they are not. The more we, as a federal agency, respect that states are attempting to do the right thing, give them clear guidance in what we will accept, and then adhere to the guidance that we gave them, the better our relationship with them will be.

We've certainly had the experience in Florida of being in touch with our regional U.S. EPA office and being told, "See if you can make 'X' happen," only to find out later that it was "Y" we needed to accomplish. There may have been legitimate reasons why it was now "Y," and "X" was no longer right, but something got lost in the communication. For some reason, we didn't find out until we were so far down the "X" path that the change involved going back to the state legislature or going back through the rulemaking process. That experience is not unique to state government. It is something that businesses legitimately complain about.

There needs to be consistency in the decision making, and there needs to be timeliness. I believe you can have both of these without foregoing environmental standards and environmental quality. For a long time, people in the environmental community argued that streamlining the permitting process would result in the degradation of the environment. I don't think that is true. I don't think, in the end, that's what the business community is advocating. What they are saying—and rightly so—is that time is money to them. And they want answers. That is what we found the business community saying in Florida: "You can say no; just don't take four years to do it. Tell us no in a timely manner." □

"There needs to be consistency in the decision making, and there needs to be timeliness. I believe you can have both of these without foregoing environmental standards and environmental quality."



Steve Delaney photo.

A New Era ...

A Profile of the New Administrator



Browner testifies at her confirmation hearing.

Steve Delaney photo.

To Carol Browner, the greatest challenge of environmental regulation is clear: to balance environmental protection with the need for economic growth.

"I hope my tenure will mark a new era in communication between the EPA and America's business community, between environmentalists and business people," Browner said during her January 11, 1993, confirmation hearing before the U.S. Senate Committee on Environment and Public Works. EPA's seventh Administrator, Browner brings to her new position experience in a variety of roles that will aid her as she works toward that era.

Before serving as legislative director to then-Senator Al Gore from 1989 to 1991, Browner, 37, was the chief legislative aide for environmental issues to then-Senator Lawton Chiles (D-Florida). During that three-year stint, she helped negotiate a complicated land swap that expanded Florida's Big Cypress National Preserve.

Browner became director of Florida's Department of Environmental Regulation (DER) in 1991. At the Florida DER, she negotiated a deal with the Walt Disney Co., that allowed continued development in the Orlando area, while also transforming an 8,500-acre ranch, Walker Ranch, into a wildlife refuge. She streamlined Florida's permitting process, cutting red tape by decreasing the number of state agencies involved. She won passage of Florida's clean air act, which included provisions allowing the Florida DER to obtain delegation from EPA to implement the federal clean air program. Browner also established a coalition of business leaders who implemented an annual fee structure for major sources of air pollution in advance of the federal deadline.

President Bill Clinton has cited Browner's innovative approach and strong administrative background as among her

qualifications for the EPA post. Sierra Club Chairman J. Michael McCloskey said that special interest groups will not be favored over middle-class Americans under her aegis. *The Wall Street Journal* opined, in an editorial in part on Browner, that "it's good to see some real-worlders coming to Bill Clinton's Washington."

Browner is "a tremendous choice considering the massive undertaking states face in implementing environmental regulations over the next two years," said William Becker, executive director of the State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials. Said former-Administrator William K. Reilly, in lauding Browner's valuable state government experience, "So many of the best ideas for the environment have come from the states."

Browner graduated from the University of Florida at Gainesville in 1977 and earned a degree from the university's law school in 1979. She began her career as general counsel for the Florida House of Representatives Government Operations Committee. From 1983 to 1986, she was associate director of the Washington environmental group Citizen Action, where her husband, Michael Podhorzer, is employed. Browner and Podhorzer have a five-year-old son, Zachary.

"Our families—and particularly our children—have inspired many of us in our work to protect this nation's environment," Browner said at her confirmation hearing. "I grew up in South Florida, in a house from which I could bicycle into the wilderness of the Everglades, and I want my son, Zachary, to be able to grow up and enjoy the natural wonders of the United States the same way I have. I believe that it will now be possible to make the investment in our economy that we so desperately need, yet preserve our air, land, and water." □

The ABCs of Risk Assessment

Some basic principles can help people understand why controversies occur

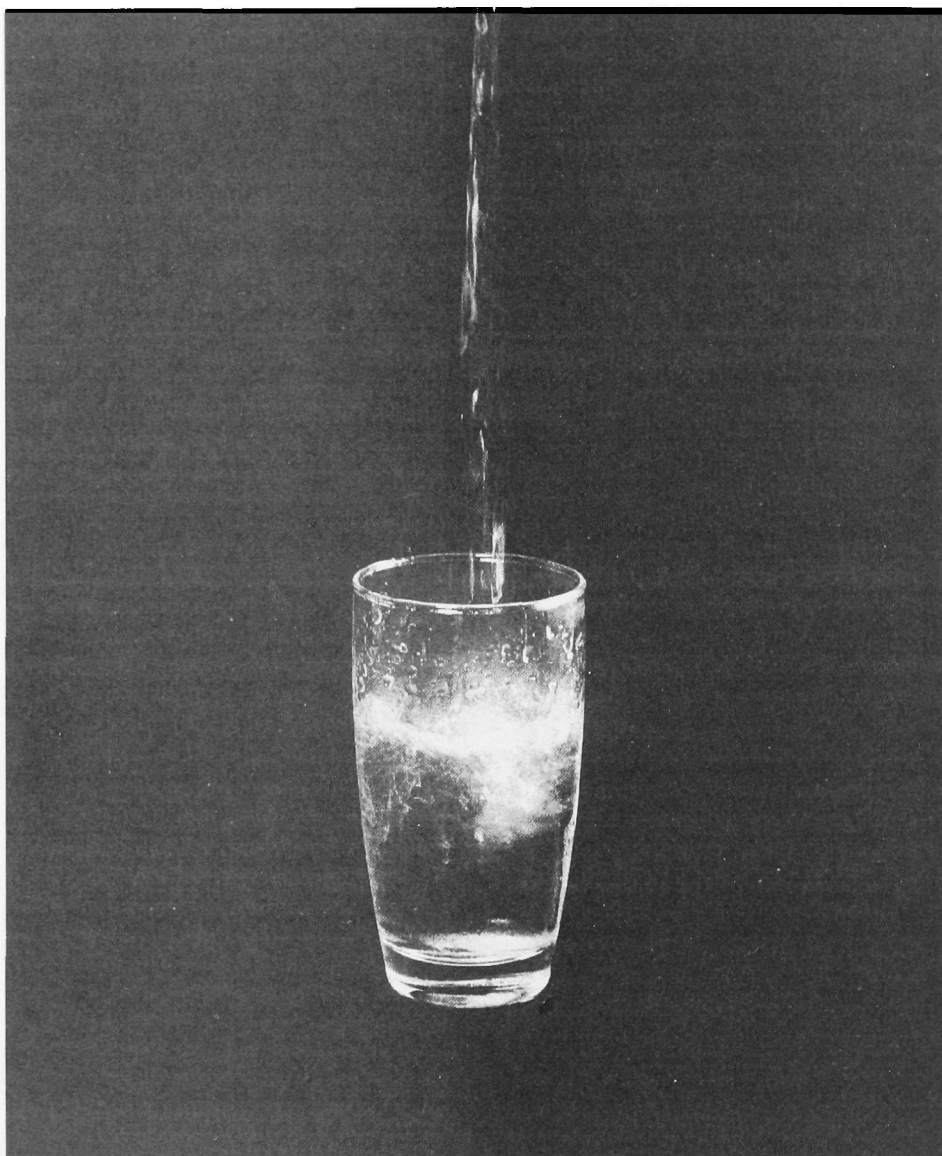
by Dorothy E. Patton

Risk assessment is a cornerstone of environmental decision making. Despite this role as the scientific foundation for most EPA regulatory actions, risk assessment means different things to different people—a point that comes across in subsequent articles in this issue of *EPA Journal*—and is thus a source of misunderstanding and controversy. Some points of controversy involve the interpretation of scientific studies. Others have to do with science policy issues. Still others center on distinctions between risk assessment and risk management.

The scope and nature of risk assessments range widely—from broadly based scientific conclusions about an air pollutant such as lead or arsenic affecting the nation as a whole to site-specific findings concerning these same chemicals in a local water supply. Some assessments are retrospective, focusing on injury after the fact—for example, the kind and extent of risks at a particular Superfund site. Others seek to predict possible future harm to human health or the environment—for example, the risks expected if a newly developed pesticide is approved for use on food crops.

In short, risk assessment takes many different forms, depending on its intended scope and purpose, the available data and resources, and other factors. It involves many different

(Patton is Executive Director of EPA's Risk Assessment Forum.)



Assessing the safety of drinking water is one possible use of risk assessment.

Mike Brisson photo.

disciplines and specialists with different kinds and levels of expertise, representing many different organizations. Moreover, risk assessment approaches differ somewhat in line with differences in environmental laws and related regulatory programs. (See box on

statutory mandates, page 15.)

Even with these differences, some features of the risk assessment process stand out as instructive principles that clarify and demystify the process for expert and novice alike. This article highlights these principles.

Risk Assessment and Risk Management

Risk assessment and risk management are closely related but different processes, with the nature of the risk management decision often influencing the scope and depth of a risk assessment. In simple terms, risk assessment asks, "How risky is this situation?" and risk management then asks, "What shall we do about it?" (For a feature on the interface between risk assessment and risk management, see page 35.)

Also, it is especially important to understand that *risk assessment* and *comparative risk analysis* for ranking environmental problems are not the same. (On distinctions between the two, see box on page 19, and for a more comprehensive discussion of comparative risk analysis, see article

beginning on page 18.)

I use the term "risk assessment," as the National Academy of Sciences (NAS) and EPA risk assessment guidelines have defined it for almost 10 years, to mean the process by which scientific data are analyzed to describe the form, dimension, and characteristics of risk—that is, the likelihood of harm to humans or the environment. Risk management, on the other hand, is the process by which the risk assessment is used with other information to make regulatory decisions.

Contributing Disciplines

What specific kinds of information are used for risk assessment? For risk management?

Environmental risk assessment is a multidisciplinary process. It draws on data, information, and principles from

many scientific disciplines including biology, chemistry, physics, medicine, geology, epidemiology, and statistics, among others. The feature distinguishing risk assessment from the underlying sciences is this: After evaluating individual studies for conformity with standard practices within the discipline, the most relevant information from each of these areas is examined together to describe the risk. This means that individual studies, or even collections of studies from a single discipline, are used to develop risk assessments, but they are not *in themselves* generally regarded as risk assessments, nor can they alone generate risk assessments.

One way to highlight differences between risk assessment and risk management is by looking at differences in the information content of the two

What's In a Number?

Risk values are often stated, shorthand-fashion, as a number. When the risk concern is cancer, the risk number represents a probability of occurrence of additional cancer cases. For example, such an estimate for Pollutant X might be expressed as 1×10^{-6} , or simply 10^{-6} . This number can also be written as 0.000001, or one in a million—meaning one additional case of cancer projected in a population of one million people exposed to a certain level of Pollutant X over their lifetimes. Similarly, 5×10^{-7} , or 0.0000005, or five in 100 million, indicates a potential risk of five additional cancer cases in a population of 100 million people exposed to a certain level of the pollutant. These numbers signify incremental cases above the background cancer incidence in the general population. American Cancer Society statistics indicate that the background cancer incidence in the general population is one in three over a lifetime.

If the effect associated with Pollutant X is not cancer but another health effect, perhaps neurotoxicity (nerve damage) or birth defects, then numbers are not typically

given as probability of occurrence, but rather as levels of exposure estimated to be without harm. This often takes the form of a reference dose (RfD). A

RfD is typically expressed in terms of milligrams (of pollutant) per kilogram of body weight per day, e.g., 0.004 mg/kg-day. Simply described, a RfD is a

rough estimate of daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. The uncertainty in a RfD may be one or several orders of magnitude (i.e., multiples of 10).

What's in a number? The important point to remember is that the numbers by themselves don't tell the whole story. For instance, even though the numbers are identical, a cancer risk value of 10^{-6} for the

"average exposed person" (perhaps someone exposed through the food supply) is not the

same thing as a cancer risk of 10^{-6} for a "most exposed individual" (perhaps someone exposed from living or

working in a highly contaminated area). It's important to know the difference. Omitting the qualifier "average" or "most exposed" incompletely describes the risk and would mean a failure in risk communication.

A numerical estimate is only as good as the data it is based on. Just as important as the *quantitative* aspect of risk characterization (the risk numbers), then, are the *qualitative* aspects. How extensive is the data base supporting the

risk assessment? Does it include human epidemiological data as well as experimental data? Does the

laboratory data base include test data on more than one species? If multiple species were tested, did they all respond similarly to the test substance? What are the "data gaps," the missing pieces of the puzzle? What are the scientific uncertainties? What science policy decisions were made to address these uncertainties? What working assumptions underlie the risk assessment? What is the overall confidence level in the risk assessment? All of these qualitative considerations are essential to deciding what reliance to place on a number and to characterizing a potential risk.

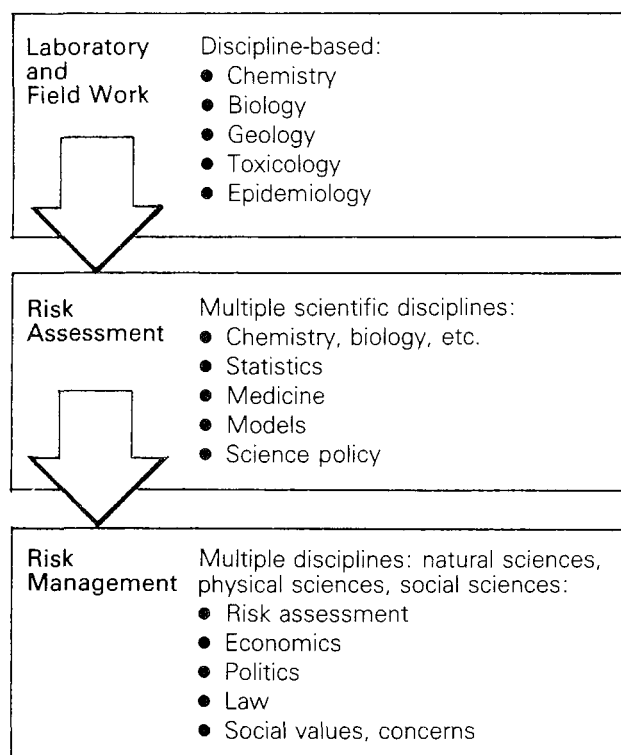
—Eds.

1×10^{-6}

0.000001

10^{-6}

Disciplines Contributing to Environmental Decisions



processes. What kinds of information, then, are used for risk management but *not* for risk assessment? In general EPA practice, data on technological feasibility, on costs, and on the economic and social consequences (e.g., employment impacts) of possible regulatory decisions are critically important for risk management, but not for risk assessment. To the extent called for in various statutes, risk managers consider this information *together with* the outcome of the risk assessment when evaluating risk management options and making environmental decisions. (See chart on how disciplines are used, this page.)

The NAS Paradigm

The risk assessment paradigm put forward by NAS in a 1983 publication called *Risk Assessment in the Federal Government: Managing the Process* (or more colloquially, the "Red Book," alluding to its cover) provides a useful system for organizing risk science information from these many different

sources. Moreover, in the last decade, EPA has used the basic NAS paradigm as a foundation for its published risk assessment guidance and as an organizing system for many individual assessments. The paradigm defines four "fields of analysis" which describe the

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Rarely is there a single
"answer" to an
environmental risk
assessment question.

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use and flow of scientific information in the risk assessment process. (See process chart, page 13.)

One virtue of this system of analysis is clarity: The paradigm makes the risk assessment process accessible so that scientists, regulators, lawyers, journalists,

educators, and committed laypersons can use the paradigm as a relatively simple frame of reference for understanding where and how the data, scientific principles, and science policies have been used in any risk assessment developed in line with the paradigm. (Even where the paradigm is not explicitly used—e.g., certain climate issues—the same kinds of questions are studied to evaluate potential risk.)

The following discussion walks through the four fields of analysis. Note at the outset that each phase employs different parts of the information base. For example, hazard identification relies primarily on data from the biological and medical sciences. The dose-response analysis then uses these data in combination with statistical and mathematical modeling techniques, so that the second phase of the risk analysis builds on the first.

- *Hazard Identification.* The objective of hazard identification is to determine whether the available scientific data describe a causal relationship between an environmental agent and demonstrated injury to human health or the environment. In humans, the observed injury may include such effects as birth defects, neurologic effects (nerve damage), or cancer. Ecological hazards might result in fish kills, habitat destruction, or other effects on the natural environment.

Information on the agent responsible for the effects may come from laboratory studies in which test animals were deliberately exposed to toxic materials, or from other sources such as chemical measurements in the workplace. In addition, studies on a pollutant's effects on genetic material or metabolism, and comparison of such effects in humans and experimental test systems, may be part of the analysis.

The principal question is whether data from populations in which effects and exposure are known to occur together suggest a potential hazard for other populations under expected conditions of exposure to the agent under study. If a potential hazard is identified, three other analyses become important for the overall risk assessment, as discussed below.

- *Dose-Response Relationships.* The dose-response analysis is designed to establish the quantitative relationship between

exposure (or dose) and response in existing studies in which adverse health or environmental effects have been observed. The dose-response analysis is based mainly on two extrapolations. One extrapolation uses the relatively high exposure levels in most laboratory studies (or, for example, human studies at relatively high workplace levels) to estimate the probable magnitude of the effect in the same population at lower environmental levels where little or no data are available.

The other extrapolation entails looking for the expected level of response in humans, or in animals or plants in nature, based on comparisons of data from laboratory and natural test systems. As explained later, each extrapolation involves numerous scientific uncertainties and assumptions, which in turn involve policy choices.

The number produced in the dose-response analysis—perhaps a cancer risk value or a reference dose (see article on noncancer effects on page 30)—is sometimes regarded as a risk assessment because it describes important information from animal and human studies. Under the NAS paradigm and in most EPA practice, however, risk assessment is complete only when human exposure assessment information is joined with dose-response analysis and all relevant information to characterize the risk.

- *Exposure Analysis.* The exposure analysis moves the assessment from the study of known populations (laboratory or epidemiologic) in which dose (exposure) and response occur together, to the task of identifying and characterizing exposure in other potentially exposed populations. These populations may be as general as the nation as a whole for certain widely distributed materials (e.g., contaminated food), or as limited as certain occupation or user groups (e.g., pesticide applicators). Questions raised in the exposure analysis concern the likely sources of the pollutant (e.g., incinerator discharge, factory effluent, pesticide application), its concentration at the source, its pathways (air, water, food) from the source to target populations, and actual levels impacting target organisms.

The exposure analysis relies on many very different kinds of information, some

based on actual measurements and some developed using mathematical models. Measurements of the kind and quantity of a pollutant in various environmental media and, when available, in human, plant, and animal tissues are used to project expected exposure levels in individuals, populations, or both. The

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**Risk assessment asks,
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situation?” and
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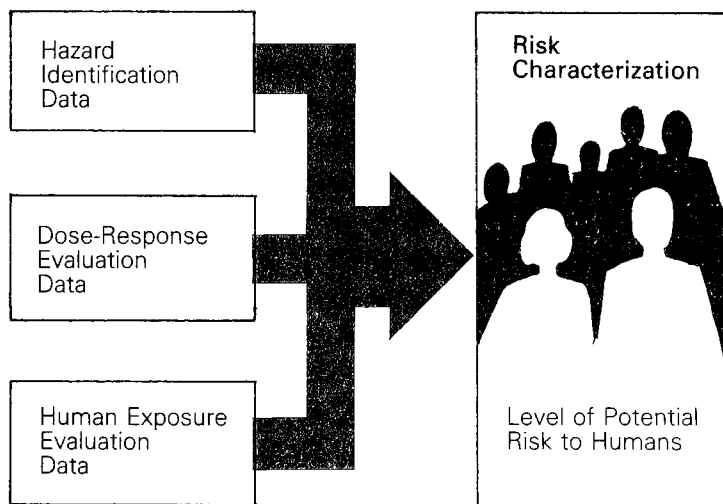
exposure analysis also develops “lifestyle” data to identify and describe populations likely to contact a pollutant. For example, if a chemical that causes birth defects in test animals contaminates tomatoes, the exposure analysis would consider such “lifestyle” information as the number of women of childbearing

age who eat tomatoes, how often they eat this food, and in what quantities. To complete the exposure analysis, the lifestyle information is combined with information on how much chemical, probably measured at very low levels, remains in tomatoes when sold for consumption.

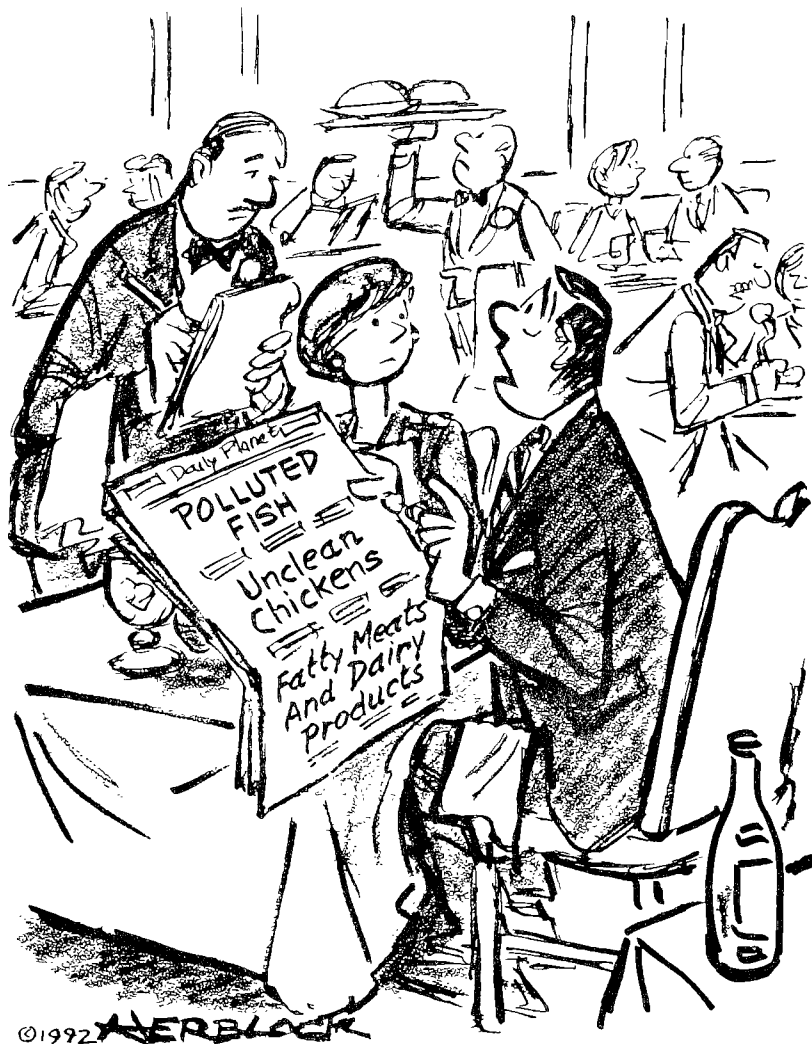
If the estimated exposure for an environmentally exposed population is significantly smaller than the lowest dose producing a response in the study population, the likelihood of injury to exposed humans is smaller; if the estimated exposure is significantly greater than the lowest dose, then the likelihood of injury is greater.

- *Risk Characterization.* Although each of the preceding analyses examines all relevant data and information to describe hazard or dose-response or exposure, under the 1983 paradigm none reaches conclusions about the overall *risk*. That task is reserved for the final analysis, where important information, data, and conclusions from each of the preceding analyses are examined together to *characterize* risk—that is, to fully describe the expected risk by examining the exposure predictions for real-world

Risk Assessment Process



**"HOLD THE MEAT—NO, THE CHICKEN—WAIT
—HOLD THE FISH—WHAT HAVE YOU GOT
IN THE WAY OF UNSPRAYED VEGGIES?"**



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conditions in light of the dose-response information from animals, people, and special test systems.

Risk characterization—the product of the risk assessment—is *much more* than a number. (See box on page 15.) While the risk is often stated as a bare number—for example, “a risk of 10^{-6} ” or “one in a million new cancer cases”—the analysis involves substantially more information, thought, and judgment than the numbers express. These factors take us behind the simple structural framework that the NAS paradigm provides into a complex world of scientific uncertainties, assumptions, and policy choices. As discussed below,

revisiting the NAS paradigm with these conceptual principles in mind sheds new light.

Uncertainties and Policy Choices

Scientific uncertainty is a customary and expected factor in all environmental risk assessment. Measurement uncertainty refers to the usual variance that accompanies scientific measurement such as the range (10 ± 1) around a value. Another kind of uncertainty refers to data or information gaps—that is, information needed but unavailable for any particular assessment. Sometimes the data gap exists because specific measurements or studies that would complete an

assessment are missing; sometimes the data gap is broader, referring to a fundamental lack of understanding about a scientific phenomenon.

The 1983 paradigm and EPA risk assessment guidelines stress the importance of identifying uncertainties and presenting them as part of risk characterization.

In ordinary scientific practice, scientific uncertainties describe new data needs and stimulate further research, with questions remaining open until research provides needed information. Like traditional science, environmental risk assessment invariably identifies new data needs and generates recommendations for additional research.

However, “state-of-the-art” limitations on risk methods, resource limitations, and statutory timetables for regulatory decisions often require EPA as well as other participants in the regulatory process (other governmental agencies, industry, environmental groups) to complete risk assessments in the face of data gaps and other scientific uncertainties. As a result, “science policies”—that is, technically reasonable positions assumed in lieu of scientific data—may be developed to address some of these uncertainties. Some familiar policies relate to use (or nonuse) of animal data to predict human risk, models used to quantify or project cancer risk, and the size of uncertainty factors for health effects other than cancer.

Variability, Misunderstanding, and Controversy

Variability is an often overlooked but important feature of the risk assessment process. Reasons for variability in risk assessment should be obvious from the preceding discussion. The need to use data from many different disciplines, characterized by data gaps and uncertainties, is one source of variability. Assumptions and policy choices spanning a spectrum of scientific theses about the nature of incompletely understood biological processes is another. These diverse elements can lead to diverse results, an outcome that leads to misunderstanding and seeds many risk assessment controversies.

Controversy might be less strident if practitioners and observers recognized that varying interpretations of the scientific information may lead to a range of science-based descriptions of risk for

any particular situation. In addition, depending on data selected, scientific assumptions, policy calls and perspectives, different experts or organizations may describe risk differently. For example, a single data set, applied to different populations with different assumptions, may result in different numerical risk estimates for a single chemical. However, if the risk characterization identifies data and science policy choices, apparently inexplicable inconsistencies may be recognized as responsible, reasonable descriptions of different aspects of the

same problem. The risk characterization process can also aid identification of less responsible, less reasonable descriptions of the problem.

Perhaps this clarifies some of the reasons for misunderstanding and controversy. Rarely is there a single "answer" to an environmental risk assessment question. The risk assessment process has an enormous capacity to expand and contract in line with the available data, science policies, and problems. When risk management information, options, and decisions are examined along with the risk assessment,

opportunities for variability, misunderstanding, and controversy are even greater.

The task is to look behind the process, always keeping in mind the multiple sources of information, the several kinds of scientific analyses, and the related uncertainties and science policy choices that shape each assessment. A related task is to remember that risk assessment and risk management are equally important but different processes, with different objectives, information content, and results. □

Some Statutory Mandates on Risk

EPA is responsible for implementing roughly a dozen major environmental statutes. These laws generally do not prescribe risk assessment methodologies. However, many environmental laws do provide very specific risk management directives, and these directives vary from statute to statute. Moreover, in certain statutes (such as the Clean Air Act) different sections of the law set forth different risk management mandates.

Statutory risk management mandates can be roughly classified into three categories: pure risk; technology-based standards; and reasonableness of risk balanced with benefits.

Pure-Risk Standards

Pure-risk standards (sometimes termed "zero-risk") are mandated or implied by only a few statutory provisions. Two examples in this category:

- The "Delaney clause" of the Federal Food, Drug, and Cosmetic Act prohibits the approval of any food additive that has been found to "induce cancer" in humans or animals. (See articles beginning page 39 on the ongoing controversy concerning the Delaney clause.)
- The provisions of the Clean Air Act pertaining to national ambient air quality standards call for standards for listed pollutants that "protect the public health allowing an adequate margin of

safety"—i.e., that assure protection of public health without regard to technology or cost factors.

Technology-Based Standards

Technology-based environmental standards direct the Agency to focus on the effectiveness and costs of alternative control technologies rather than on how control actions could affect risks. Technology-based controls are considered appropriate to certain kinds of problems, such as industrial water pollution, where the installation of a single control system can reduce risks from a variety of different pollutants.

Consider the several technology-based standards in the Clean Water Act: The Act requires industries to install several levels of technology-based controls for reducing water pollution. These include "best practicable control technology," "best conventional technology," and "best available technology economically achievable" for existing sources. New sources are subject to the "best demonstrated control technology." Total costs, age of equipment and facilities, processes involved, engineering aspects, environmental factors other than water quality, and energy requirements are to be taken into account in assessing technology-based controls.

"No Unreasonable Risk"

A number of statutes require a balancing of risks against benefits in making risk management decisions. Two examples in this category:

- The Federal Insecticide, Fungicide, and Rodenticide Act requires EPA to register (license) pesticides which, in addition to other requirements, it finds will not cause "unreasonable adverse effects on the environment." The phrase refers to "any unreasonable risks to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."
- Under the Toxic Substances Control Act, EPA is mandated to take action if it finds that a chemical substance "presents or will present an unreasonable risk of injury to health or the environment." This includes considering the effects of such substance on health and the environment and the magnitude of the exposure of human beings and the environment to such substance; the benefits of such substance for various uses and the availability of substitutes for such uses; and the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

—Eds.

Uncertainty and the "Flavors" of Risk

Let's give risk assessment a reality check

by Robert J. Scheuplein

If you are an average person (or even above average), you're exposed to a large amount of risk. Like ice cream, risk comes in a variety of flavors, and some people like to add nuts and berries to suit their tastes. So it is with risks. But the basic ones—the vanilla, chocolate, and strawberry of risks, if you will—are the following three: personal activities, natural disasters, and chemical exposures.

Consider first certain dangerous *personal activities* like firefighting, coal mining, skiing, motorcycling, driving automobiles, etc.—things you do for a living or for fun. Here the danger in the activity may be self evident, and the risk is ordinarily self imposed. As a class, these risks are the highest, along with risks from ordinary diseases, which personal behavior can also affect. For example, the annual risk associated with motorcycling is about 2 percent, or about 2,000 deaths per 100,000 persons at risk. Firefighting is much safer, only about 80 annual deaths per 100,000, or 0.08 percent. The annual death rate from motor vehicles is around 24 per 100,000, or 0.024 percent. This is just the death rate; of course, the accident rate and injury rate are much higher.

The risks above might be described as part of the price we pay for living in a civilized world, but the next category of risks, *natural disasters*, are not wholly our fault. The risks from floods, hurricanes, earthquakes, lightning, meteorite hits, etc., are the price we pay for our 70-year or so lease on the planet. Of course, if you want to live on an earthquake fault,

you share some responsibility. These risks in the aggregate are quite small. But try telling that to the folks in South Florida who experienced Hurricane Andrew. Lightning kills 0.05 people per year per 100,000, or about 0.00005 percent. The risks from meteorite hits are about 0.000006 per 100,000, or 0.00000006 percent.

Now the last major category of risks, the "strawberry of risks," derive from *chemical exposures*. Before we discuss them, let me emphasize an important point. The risks above are real, obtained by counting victims. They are actuarial risks. They depend only on how

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Currently the regulatory objective is often fulfilled at the expense of the scientific one.

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accurately the deaths and the populations at risk were attributed and recorded. They are not based on inferences from animal data, nor on prudent extrapolations of adverse effects in animals. This distinction is essential to make because the risks from chemical exposures are for the most part based on such inferences and extrapolations.

Everyone knows about poisons, drugs, and acute occupational exposures to industrial chemicals. For many of these exposures there is human data. But for chronic low-level risk from chemicals in the environment we live in, in the air we breathe, in the water we drink, or in the

food we ingest, we need to depend on animal data. These risks are ordinarily small. For example: The cancer risk from chlorinated drinking water has been estimated as 0.8 per year per 100,000 persons exposed or 0.0008 percent. While this number looks the same as the others and can be expressed in the same units, it is not the same and can be compared with the actuarial risks only if the differences are kept in mind.

What are these differences?

First, as stated above, chemical risk is based on the finding of an adverse effect in an animal study. In the case of chlorinated drinking water, it is based on several carcinogen bioassays conducted in mice using various chlorinated compounds. It is inferred that humans will be similarly susceptible to these same compounds. But this is not necessarily true.

Second, the quantitative result is a worst-case estimate sometimes called an upper-bound estimate. It is based on a mathematical extrapolation of adverse effects in animals, exposed at high dose levels, to the much lower levels anticipated for humans. Why is this done? Why not just expose the animal to the appropriate lower doses? The reason is there would be no effect at low doses, unless the number of animals in the experiment were increased dramatically—say to several thousand. The problem lies in trying to detect in a population of 100 a disease incidence that you might believe to be one in 1,000. So toxicologists need to exaggerate the animal doses and extrapolate downwards—hopefully.

To continue with our particular example, the actual amount of chlorinated hydrocarbon chemicals in

(Scheuplein is Director of the Office of Special Research Skills at the Food and Drug Administration.)

drinking water, the chemical byproducts of the chlorination process, is very small, typically a few parts per billion. The doses to which the animals were exposed are very high, many thousands of times higher than human exposure levels. The high-to-low dose extrapolation is used to estimate the effect of the lower dose using various conservative assumptions. The most important of these assumptions is that there will inevitably be some cancer risk no matter how small the dose.

Third, the risk is an average attributed risk; it applies to no one in particular and to everyone on the average. If you're an average person and you drink the expected amount of water with the expected concentration of chlorinated compounds, your possible risk is no greater than the given risk number.

But in no way is this intended to be a predicted risk for you individually; your particular pattern of exposure, your exposures to other carcinogens, your genes, your diet, and other factors determine your particular susceptibility.

This is the way carcinogenic risks are determined for most regulated chemicals: foods and cosmetics, pesticides, household chemicals, most industrial and workplace chemicals, air and water pollutants, and toxics and waste site contaminants. (Drugs and biologics are usually regulated with human data.)

Of course, not all chemicals present a cancer risk but they can pose other risks. There are chemical substances that affect developmental, reproductive, neurobehavioral, and other body functions. Typically, such substances are regulated by determining "no-effect levels" in animals and applying safety factors. Numerical risk estimates are not made because thresholds are assumed. In other words, unlike for carcinogens, risk is not assumed to be present at all doses.

Cancer risks of less than 10^{-6} —one in a million per lifetime or one in 14,000 per year or 7 per 100,000 per year or 0.007 percent—are usually not considered worth regulating. (Lifetime risks are



Downhill skiers take chances voluntarily, while risk assessment generally is concerned with characterizing involuntary risks.

Crested Butte Mountain Resort photo

approximately 70 times higher than annual risks if the risks are similar from year to year for a lifetime.)

The inherent conservatism in estimates of the cancer risk may be illustrated the following way. Suppose you work for a regulatory agency and you are asked for the agency's official estimate of the average height of a person. You remember that the average height of an American male is, say, 5 feet, 10 inches. But that applies only to American men, and probably doesn't include modern American basketball players, some of whom are over 7 feet.

Getting the data on all the people in the world is impractical, but unless you do, you can't really give a figure without including some certain error. And the size of the error is also impossible to obtain. So in order to be absolutely clear and correct in your response you decide to give a worst-case estimate. You will cast your response in the form: "The average height of a man will in no case exceed"

This is a very strong statement, so to hedge your bet and to be sure you're right, you will have to make conservative assumptions. One you might make is that the average height of a person will in no case exceed the tallest person in the

world. This contains the inherent reliability one likes to have when called upon to defend the regulatory decision against tall activists. Now, the tallest people you know about from your research are all less than 8 feet. But there may be giants somewhere, and there is some anecdotal evidence. (Remember the stories about "Bigfoot.") Let's assume you find a record of a 12-foot giant now deceased. On the possibility that he might have left living relatives, you assume a maximum height of 15 feet because there is plenty of data indicating that better nutrition over the last 50 years has increased the average body size by about 20 percent. So your official response, supported by several pages of data, reads:

"The average height of a person will in no case exceed 15 feet."

This statement has all the required regulatory qualities needed for the *Federal Register*. It is impeccably correct. It will withstand any legal challenge. It is prudent and does not underestimate the height. It also has at least two undesirable qualities: It is not very helpful. And it discriminates against short people. (Translation: The recasting of the regulatory problem away from *probable risk* (average height) to *worst-case risk* results in the under appreciation of risk-lowering factors.)

The linear extrapolation of rodent bioassay data embodies the regulator's credo ("It's better to be safe than sorry") far more than it does the scientist's, ("It's better to be right than wrong"). Currently the regulatory objective is often fulfilled at the expense of the scientific one.

When carcinogens were few, biological understanding of mechanisms more primitive, and analytical sensitivity in the parts per million range, the differences in these two points of view were not large and didn't really matter much. Today, for many substances, the situation has changed in each of these areas, and we face an ever-growing separation between the application of good science and credible, efficient regulation. □

The Role of Comparative Risk Analysis

Without risk-based priorities, we are shooting blind

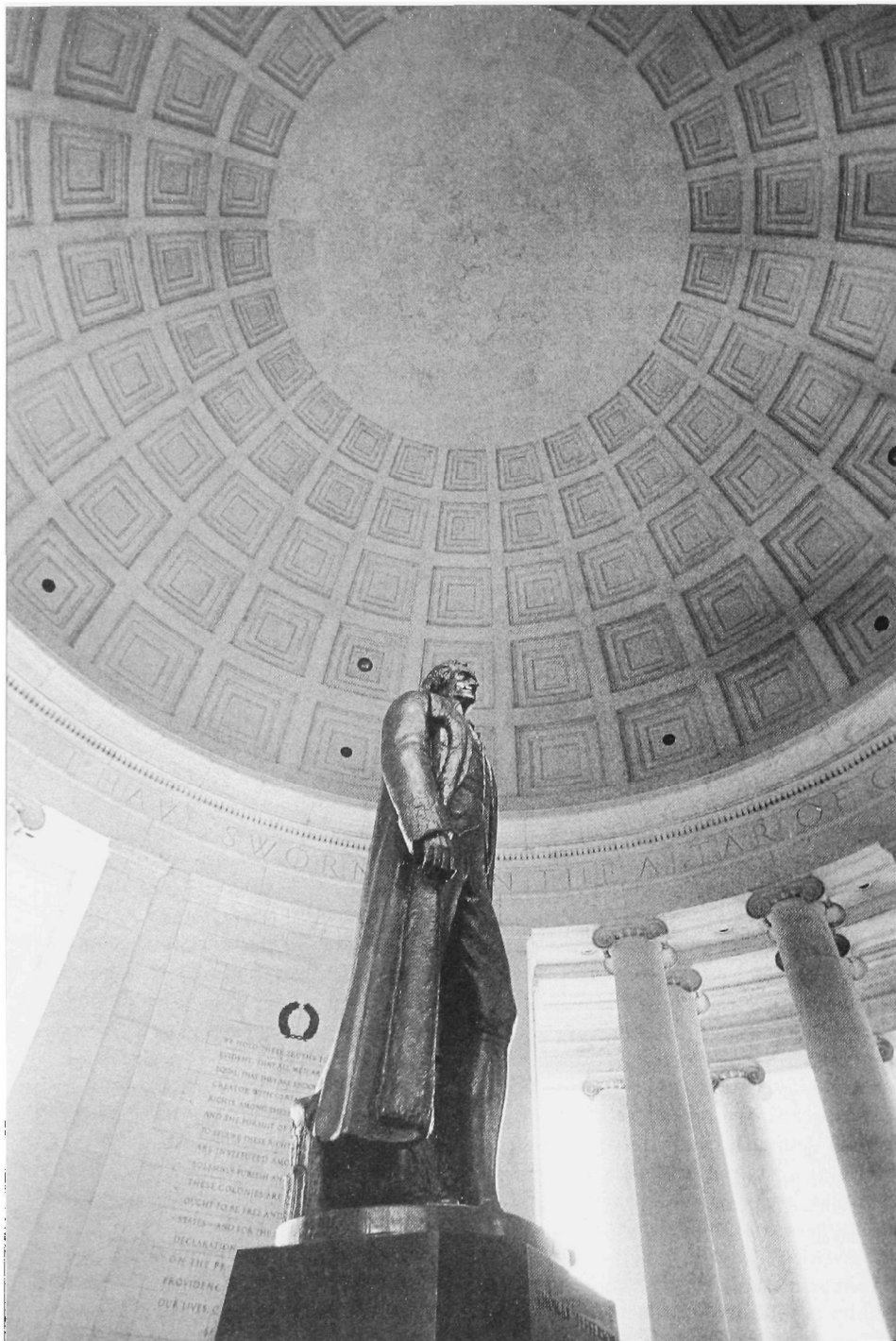
by Wendy Cleland-Hamnett

EPA's support for using comparative risk analysis to help set the Agency's priorities has been no secret. Building on the lessons and insights gained in the 1988 *Unfinished Business* report, the Science Advisory Board's 1990 *Reducing Risk* report, and our experience in implementing strategic initiatives, we have seen how valuable it can be to have a grasp of the relative risk of various problems in narrowing our focus to the most important ones—especially as fiscal reality has dictated that we must.

Of course, other forces play critically important roles in directing policy, including statutory mandates, traditional considerations of costs and benefits, the state of technology, environmental equity, and, above all, public values and concerns. But comparative risk analysis, and its promise of objective, relevant, and even-handed guidance, has definitely "made it to the table" at EPA. The challenge for the Agency and its stakeholders will be in deciding the precise role it will play in delineating our priorities.

The particular ways we have tried to use relative risk and the conditions under which we operate are not universally understood. Some think risk ranking affects our entire budget, and some think it derives from a backroom dialogue with cloistered scientific gurus. Perhaps most

(Cleland-Hamnett is Acting Deputy Assistant Administrator for Policy, Planning, and Evaluation at EPA.)



Enlightened public participation in risk-based decision making is a goal in the tradition of Jeffersonian democracy.

Steve Delaney photo.

often it is viewed as the only factor we intend to include in our decision making. It is important to note that we have never understood priority setting to be one dimensional, where comparative risk analysis is the last word. In *Reducing Risk*, the SAB made it clear that establishing the relative risks of different environmental problems was only "one tool" that could help make integrated and targeted national environmental policy a reality. It also stressed that the "dichotomy" that exists between the perceptions of the public and the "experts" on which risks are important

"presents an enormous challenge to a pluralistic, democratic country."

As good as our intentions have been over the last few years, there is ample room for EPA to do a better job in meeting the challenge of piloting the doctrine of risk through a democratic society. A quotation from Thomas Jefferson provides valuable insight:

I know of no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a

wholesome discretion, the remedy is not to take it from them, but to inform their discretion.

This piece of wisdom implies, among other things, that a democratic government operates at its peril if it becomes so arrogant that it makes important decisions without informing, involving, and taking guidance from average citizens, and it should never underestimate the citizens' ability to understand. Jefferson is warning us not to lose touch. He is not recommending that all technical decisions of a

Two Faces of Risk

The terms *risk assessment* and *comparative risk analysis* are sometimes confused. Actually, they have very different meanings.

Risk assessment, which in rudimentary form, at least, is older than EPA itself, is a complex process by which scientists determine the harm that an individual substance can inflict on human health or the environment. For human health risk assessment, the process takes place in a series of steps that begins by identifying the particular hazard(s) of the substance. Subsequent steps examine "dose-response" patterns and human exposure considerations, and the conclusion is a "risk characterization" that is both quantitative and qualitative. The risk characterization then becomes one of the factors considered in deciding whether and how the substance will be regulated.

Risk assessments are not infallible. For one thing, information on the effects of small amounts of a substance in the environment is often not available, and data from animal experiments must be extrapolated to humans. Such extrapolations cannot be made with absolute certainty. As described by several authors in this issue of *EPA Journal*, considerable research is being focused on improving the risk assessment process.

Unlike risk assessment, which for years has provided regulators the basis for deciding whether or not an individual substance needs to be controlled, **comparative risk analysis** and its derivative relative risk have arrived on the scene only

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Risk assessment and comparative risk analysis are sometimes confused. Actually, they have very different meanings.

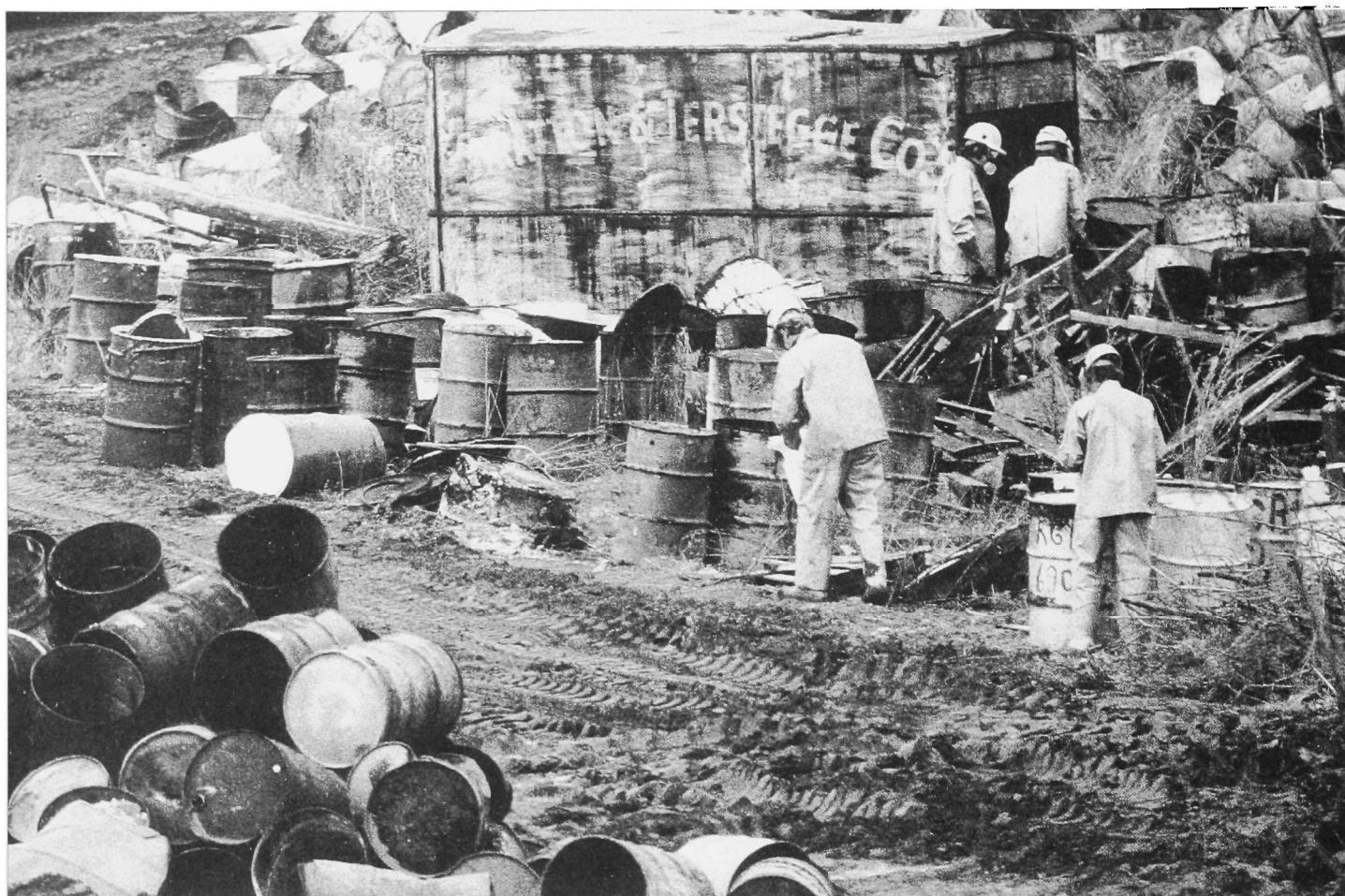
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recently. Very simply described, comparative risk analysis is a procedure for ranking environmental problems by their seriousness (relative risk) for the purpose of assigning them program priorities. Typically, teams of experts put together a list of problems then sort the problems by types of risk—cancer, noncancer health, materials damage, ecological effects, and so on. The experts rank

the problems within each type by measuring them against such standards as the severity of effects, the likelihood of the problem occurring among those exposed, the number of people exposed, and the like. The relative risk of a problem is then used as a factor in determining what priority the problem should receive. Other factors include statutory mandates, public concern over the problem, and the economic and technological feasibility of controlling it.

Not unexpectedly, comparative risk analysis has its critics. As one skeptic asked in the pages of *EPA Journal* two years ago: "How does one compare a case of lung cancer in a retired petrochemical worker to the loss of cognitive function experienced by an urban child with lead poisoning? How do we make choices between habitat and health?" Nonetheless, in its September 1990 report *Reducing Risk*, EPA's Science Advisory Board urged the Agency to order its priorities on the basis of reducing the most serious risks. The board argued, in part: "... There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower priority problems at the expense of higher priority risks, then society will face needlessly high risks. If priorities are established based on the greatest opportunities to reduce risk, total risk will be reduced in a more efficient way, lessening threats to both public health and local and global ecosystems"

—Eds



Scientists and the public tend to see risks differently. For example, toxic waste sites such as Kentucky's "Valley of the Drums" rank as a high-risk problem in public opinion polls. Experts have rated the same problem as medium to low in risk.

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government agency be made only through town meetings. But his statement is a persuasive argument for broader inclusion of the public in the basic decisions that determine the direction of all the policy minutiae that follows.

It is becoming clearer to those involved in this debate that risk-based decision making should be based on a synthesis of inputs broader and deeper than was envisioned in the past. Risk-based priority setting will be a major element of the kind of informed and effective dialogue that raises the quality of environmental action across the board, especially in the state and federal legislatures. To achieve this, though, we need a more participatory model of prioritization—a risk system much broader than the stereotypical one in which "experts" make their pronouncements about risks with clinical dispassion; one which is an organic part

of a broad-based, decision-making process in which equity, social concerns, fiscal feasibility, technological innovation, and legislative mandates are fully considered alongside the science.

Comparative risk analysis has definitely "made it to the table" at EPA.

To ensure a proper place for comparative risk in developing environmental priorities, we must build the strongest possible foundation of individual risk assessments. I see three basic guiding principles in the building of that foundation. The first involves an

early step in the risk assessment process, the characterization of risk. A memorandum on the subject issued in February 1992 provided that EPA needs to offer more useful information when characterizing a given risk—we need to give more accurate predictions than a single point estimate would allow, and we need to evaluate more realistic exposure situations than the unlikely worst-case scenarios sometimes used as the basis for policy. We must characterize individual risks using straightforward, consistent terminology identifying uncertainties and data gaps so that both experts and citizens can more easily compare one risk to another.

This challenge remains enormously important as more attention is focused on the need to take into account both hard science factors and societal elements in the comparison of risks. The question "What is really at stake here?" will need to be answered realistically and usefully,

again and again, in terms that all can understand.

The second guiding principle is the need to bring varied expertise into the risk assessment process from the earliest stage. Our work in relative risk stands much less chance of acceptance if the common perception persists that assessments of specific risks emerge from a black box. Therefore, just as the whole enterprise of priority setting needs to be broadly inclusive, the work of our Agency professionals in working through the important issues of specific risks needs to be exposed to the critical eye of independent experts, peers, and colleagues in their fields. This both enhances the quality of the work and maximizes the number of people who understand what the work attempts to accomplish.

The Agency's existing peer review process should be expanded as far as possible into the earliest segments of the life cycle of our risk-related work, and active peer involvement in the characterization and assessment of individual risks should become standard procedure. We are implementing the recommendations made by the SAB and an independent panel in the March 1992 report *Credible Science, Credible Decisions* by establishing science advisors for the Administrator and Assistant Administrators, and I hope future administrations build on this collegial network.

We have also participated extensively in interagency organizations such as the Risk Assessment Working Group of the Federal Coordinating Council on Science Engineering and Technology (FCCSET), mindful that cross-pollinating expertise and real coordination on cross-cutting issues with other parts of the government can improve the quality of our work. This cooperation must continue and must extend not only to specific risk assessments but also to the important guidelines that are establishing the state of the art in process and methods for cancer, noncancer, and ecological risk end points.

The third guiding principle we must observe in building a foundation of credible risk assessment is the need for basic research and state-of-the-environment data. One of the most fundamental reasons for the controversy surrounding the uses of relative risk is the persistent belief that

our risk assessments are based on default assumptions rather than on hard facts. Simply put, facts and hard conclusions from data are better than estimates based on extrapolations and interpolations. Facts are what our research operations

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Environmental decision making in a democracy is not a math problem.

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must give our risk assessors if their work is to have dependable credibility at the priority-setting table. These facts can then be brought to life through advanced computer visualizations in geographic information systems, which will allow us to target risks and develop more meaningful geographic strategies.

Even if these principles are followed and our risk assessments become more widely accepted, there will remain major

legislative barriers to the widespread use of relative risk, which makes it imperative that Congress be an integral part of the dialogue. As it stands now, EPA policy makers implementing risk-based priority setting can have an impact only at the margins of funding. The two funds set up for construction of wastewater treatment plants and the cleanup of abandoned hazardous waste sites under Superfund dwarf all other EPA spending areas, accounting in fiscal year (FY) 1990 for over 70 percent of the Agency's \$6 billion budget. Only 16 percent of the full budget is allocated toward the higher risk areas identified by the SAB in *Reducing Risk*. In FY 1992, for example, indoor radon, indoor air, stratospheric ozone, and climate change accounted for a little more than 2 percent of our total budget, although they were listed by the SAB as high risk.

Adding to the pressure is spending for congressional projects: In FY 1993, Congress added about 100 specific items while approving an essentially flat budget from FY 1992. These new responsibilities have to be met at the expense of both existing Agency priorities and new initiatives. To be sure,



Monitoring for radon in soil. Radon is another example of a "disconnect" between expert judgment and public opinion. Experts have characterized radon and other indoor air pollution as a high risk problem, whereas the public regards radon as comparatively low in risk.

there is not always a direct correlation between funding levels and results—EPA programs such as “Green Lights” prove that rich results can be achieved through small budgetary investments. These budgetary facts do indicate, however, that comparative risk has a long way to go before it becomes a dominant element of priority setting at EPA.

Nevertheless, there are a number of things going on within EPA to prepare the way for a more inclusive and more credible role for comparative risk in priority setting. The current dioxin reassessment (see article on page 24), sparked by new findings on the mechanisms of dioxin toxicity, has been widely praised as evidence that the

Agency will practice what it preaches concerning dedication to good science and meaningful risk assessment, and has involved both extensive peer review and public participation. Agency professionals used the techniques of inclusion in the development of the forthcoming neurotoxicity and immunotoxicity guidelines, and EPA

EPA's IRIS Data Base: Accessing the Science

by Linda Tuxen

What is the potential human health hazard of exposure to benzene? What are the possible cancer and/or noncancer effects? One source of information on questions such as these is EPA's Integrated Risk Information System (IRIS). IRIS is a data base containing EPA consensus scientific positions on potential adverse human health effects that may result from exposure to environmental pollutants. Currently, IRIS contains information on approximately 500 specific substances. IRIS was created for EPA staff as the official repository of consensus information in 1986; in 1988 it was made available to the public.

Background

In the 1980s, as health risk assessment became more widely used across Agency programs, the need for consensus and consistency in the areas of hazard identification and dose-response assessment became clear. In 1986, EPA work groups were convened to establish consensus Agency positions on a chemical-by-chemical basis for those substances of common interest and to develop a

system for communicating the positions to EPA risk assessors and risk managers. IRIS currently contains summaries of EPA human health hazard information that support two of the four steps—hazard identification and dose-response evaluation—of the risk assessment process.

Since IRIS was developed in 1986, and made available to the public in 1988, its use by EPA and by the environmental health community, in general, has grown substantially. EPA uses the data base to provide consistent risk information across programs and regions. States, national and international organizations, and other public and private organizations involved with assessing potential health hazards of exposure to a variety of environmental contaminants use IRIS as a source for EPA scientific opinion. EPA's goal is that IRIS contain high quality human health information, based on credible science.

Development of IRIS Health Hazard Information

Two EPA work groups—the Carcinogen Risk Assessment Verification Endeavor (CRAVE) and the Oral Reference Dose/Inhalation Reference Concentration Work

Group—develop the consensus health hazard information for IRIS. Each group consists of EPA scientists from a mix of disciplines and EPA program areas. The work groups serve as the Agency's final review for EPA health hazard information.

When the work groups reach consensus for a particular substance, they add a descriptive summary to IRIS. The information may become part of the supporting materials used to develop EPA health hazard assessments. Combined with specific assessment information on situational exposure, the data may be used in evaluating potential public health risks to environmental contaminants. The summary directs users to the underlying animal and human data on which this risk information is based. IRIS risk information is not a risk assessment or a risk management judgment; it should be used carefully and with scientific judgment.

Data Base Contents

IRIS is comprised of three sections: noncancer health effects resulting from oral exposure, noncancer health effects resulting from inhalation exposure, and carcinogen assessment for both oral and inhalation exposure. Generally, the information is for chronic effects, those that may result from lifetime exposure to a given substance or mixture.

IRIS contains full bibliographic citations for each substance file, directing the user to the primary cited studies and pertinent scientific

(Tuxen is EPA's IRIS Coordinator in the Office of Health and Environmental Assessment.)

demonstrated its willingness to reach out to peers outside the Agency by involving a professional association, the Society for Risk Analysis, in issues associated with the cancer risk-assessment guidelines.

Successful development of an inclusive system of risk assessment at EPA in the future will require sustained attention to some very ambitious and large-scale

initiatives. The principles in the February 1992 memorandum on risk characterization must be fully implemented. Development of information for EPA's computerized health risk-assessment database—the Integrated Risk Information System, or IRIS—is currently subject to very little peer review or public involvement, and

literature. In addition, IRIS substance files may contain one or more of three supplementary information sections: a summary of the Office of Water's Drinking Water Health Advisory, a summary of EPA regulatory actions, and a summary of physical/chemical properties.

EPA Review of Some Aspects of IRIS

As part of an Agency-wide effort to improve the quality of science used to evaluate and manage risks, EPA has initiated a review that seeks ways to improve the way IRIS information is developed and the way it is used by risk managers. The intent of the review team is to study the entire IRIS process, from nomination of substances through delivery of information.

As a first step, the team is focusing on public involvement and external peer review. Currently, peer review of the technical bases for IRIS descriptive summaries is undertaken by EPA scientists familiar with the particular substance. Many undergo external peer review as well, from groups ranging from the Agency's Science Advisory Board and the Office of Pesticide Programs' Scientific Advisory Panel to specially convened panels and workshops.

EPA seeks ways to increase and improve public involvement and external peer review. The Agency wishes to identify mechanisms that can involve qualified outside scientists and members of the public in improving the quality of information in IRIS, while not unduly

delaying the process of adding critical new information to the data base.

As part of the information gathering effort supporting the Agency's review of IRIS, a *Federal Register* notice was published on February 25, 1993 (58 FR 11490) that, among other things, solicits public comments on the review. The notice also announces the availability of a background paper describing IRIS, its contents, and the current processes used by the two Agency work groups responsible for developing the IRIS information. Interested persons are encouraged to obtain a copy of the IRIS *Federal Register* notice and companion background paper.

IRIS will continue to be an important EPA resource and a successful public product of the Agency. The consequence of that success is a substantial responsibility to provide the highest possible quality and credible information to IRIS users. That responsibility is taken seriously by the Agency as evidenced by the current self-appraisal activities.

(Editors' Note: For further information on how to access IRIS and for a copy of the Federal Register Notice on IRIS and the IRIS Background Document, contact: IRIS User Support (staffed by Computer Sciences Corporation), EPA Office of Research and Development, Environmental Criteria and Assessment Office (MS-190), Cincinnati, OH 45268, Telephone: (513) 569-7254, Fax: (513) 569-7916.)

this vulnerability must be addressed if we are to bring the credibility of the information up to par with the influence that this very important database has developed since it became public in 1988. (See box, at left, on IRIS and its present reassessment.)

The Environmental Monitoring and Assessment Program, or EMAP, is a centerpiece of the Agency's enhanced focus on risks to the ecological health of regions and ecosystems. Yet the massive amounts of information gained from the environmental indicators it monitors form so broad a cut of cloth that there is a real challenge to link this information to new, concrete understandings about risk, and then to develop indicators that measure the progress of our prevention programs. And, in the wake of the June 1992 United Nations Conference on Environment and Development in Rio de Janeiro, risk assessment will necessarily be an international issue as well, and the Agency will have a direct stake in the attempt to build upon the work of the U.N.'s Organization for Economic Cooperation and Development in coordinating risk assessment activities by scientists and governments around the globe.

Government cannot do everything, and the question of which things matter the most is inevitable. Environmental decision making in a democracy is not a math problem. As a result, comparative risk will never be the only criterion for setting priorities. But if EPA's findings are built upon a foundation of good science and the public is fully informed and involved in the dialogue, then comparative risk will be an increasingly important factor. By building integrated strategies based upon solid facts, and by harnessing the power of communities and markets, I am absolutely confident EPA can stimulate entire new generations of clean production and give new expression to the concept of "sustainable development." □

A Flagship Risk Assessment

EPA reassesses dioxin in an open forum

by Peter W. Preuss and William H. Farland

Every day brings new advances in toxicology, biochemistry, molecular biology, and other sciences that add to our understanding of the interactions between human activity and the environment. Occasionally, these advances give us much insight into complex issues, insight whose implications may greatly alter the way we conduct our work.

Such advances have occurred with respect to scientific data on the effects of dioxin, one of the most prominent environmental health issues of the past decade. EPA began to assess the risks of dioxin in the early 1980s; these efforts resulted in a 1985 risk assessment that classified dioxin as a probable human carcinogen, primarily based on findings from animal studies available at that time.

Two recent scientific advances caused us to consider reexamining our position. The first was an October 1990 meeting at the Banbury Center in Cold Spring Harbor, New York, at which some 30 prominent experts reached consensus as to the probable processes through which

dioxin causes toxic effects in humans and animals. The second was the January 1991 publication of a major National Institute for Occupational Safety and Health (NIOSH) study of cancer mortality in U.S. chemical workers exposed to dioxin.

The implications of these advances were uncertain. Some argued that they

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This open scientific
process has thus far
been well received
by the public.

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meant the risks weren't as high as previously estimated. Some made the opposite argument. A significant amount of new data had to be obtained and analyzed to reach a conclusion.

After much discussion, we in EPA concluded that we should proceed with a reassessment. We also concluded that since the question of dioxin's risk had been marked by considerable controversy for more than a decade, we should pursue a process that would achieve

scientific consensus on this issue.

As a rule, our risk assessments—such as the original assessment of dioxin—had been written by our own scientists. The public and the broad, outside scientific community were not involved until the assessment was sent to the Science Advisory Board (SAB) for peer review—the last step before the risk assessment became a final document. By that time, the process had advanced too far for the Agency to seek a consensus by the mainstream scientific community.

We decided from the outset to make the dioxin reassessment as open and participatory as possible. As a first step, it would be conducted as a cooperative effort, written by both EPA scientists and external scientists and peer-reviewed by scientists outside the Agency who were experts on dioxin. We hoped this would help ensure not only that the most current, most scientifically accepted information was used, but also that all scientific views would be heard and debated. We also deemed it critical to keep the public informed and involved during the process by announcing the reassessment, holding public meetings, and using peer-review workshops to evaluate the reassessment's progress.

Specifically, we asked seven prominent outside scientists to author chapters assessing the potential effects of dioxin

(Preuss is Director of the Office of Science, Planning, and Regulatory Evaluation and Farland is Director of the Office of Health and Environmental Assessment in EPA's Office of Research and Development.)

on human health. These chapters would reflect the latest, peer-reviewed, scientific information; they would address general toxicity, reproductive and developmental effects, carcinogenicity, immunotoxic effects, disposition and pharmacokinetics (what happens to dioxin in the body), epidemiology, and dioxin's mechanisms of toxic action (the biochemical reasons why dioxin is toxic).

At the same time, we enlisted other outside scientific expertise to develop a biologically based dose-response model that would advance our understanding of how dioxin acts at the cellular level at various doses. And, we asked our own EPA scientists to update our understanding of environmental exposures of dioxin to humans.

Work began in May 1991. We held public meetings in November 1991 and April 1992 to report progress. Draft chapters were completed by the outside authors and made available to the public in late summer and fall of 1992. At a public meeting in September 1992, we convened a panel of outside scientists to hear comments by the scientific community in a peer review of the draft exposure document. That same month, we called a similar meeting of other outside experts to review the draft health assessment chapters and to review progress in developing the dose-response model.

Immediately thereafter, members of the health panel and the chairman of the exposure panel—all of whom by this time had the benefit of understanding the latest science in these areas—began to formulate a summary statement regarding the potential health impacts of dioxin. As of this writing, they had not completed the statement; however, the salient aspects of the public deliberation were as follows:

- Risk characterization should encompass the broad range of health effects attributable to dioxin exposure, not focus primarily on cancer as was the case in the previous dioxin assessment.
- Certain noncancer effects—including changes in endocrine function associated with reproductive function in animals and humans, behavioral effects in offspring of exposed animals, and changes in immune function in animals—have been demonstrated. Some data suggest that these effects may be occurring in people at body burden

levels that can result from exposures at or near current background levels.

- Although recent epidemiology studies indicate that dioxin and related compounds may be carcinogenic in humans, a focused review of those studies by a panel of epidemiologists is required. EPA should then reconsider its current classification of dioxin, which is based primarily on the results of laboratory animal studies.

- Based on the key role played by a cellular protein, called the "Ah receptor," in the sequence of biochemical reactions that may lead to toxic effects from dioxin and related compounds in the body, the dioxin risk characterization should consider the full range of compounds that bind to this protein after exposure. Additional work will be needed to better understand the impact of dioxin-like polychlorinated biphenyls (PCBs).

- Additional data are needed for application of biologically based statistical models for predicting carcinogenic effects of dioxin and related compounds. Studies under way at the National Institute of Environmental Health Sciences and EPA may provide the needed data in early to mid-1993.

- Available data on early steps in the responses to dioxins in human cells are largely consistent with the results of mathematical calculations used to predict

the effects of exposure at low doses. However, predictions cannot be made with certainty about cancer effects at low doses.

- Risks from everyday background levels of dioxin in the general population need to be carefully considered.

We want to emphasize that these points are our interpretation of the discussions and should not be viewed as final. These views may be modified as the summary report is completed.

The Agency is considering comments from the reviews of the individual chapters, as well as the above preliminary advice, and the chapters are being modified as appropriate. An additional public peer review of the epidemiology chapter is being organized. Our schedule for forwarding a draft risk characterization to the SAB has been moved back to May 1993 in the interests of making sure that the report represents the best possible estimate of the health effects of dioxin.

Once the draft risk characterization has been reviewed and approved by the SAB, it will become EPA's scientific position on this subject and will form the basis for changes, if any, by the Agency in its regulatory policies. We plan to make the draft available in May 1993.

This open scientific process has thus far been well received by the public. More than 70 people attended the



Soil sampling in Times Beach, Missouri. Times Beach was evacuated in 1983 following the discovery of dioxin contamination after the Meramec River flooded the town. Dioxin-tainted oil had previously been sprayed on roads and parking lots to control dust.

EPA Region 7 photo

exposure assessment peer review, and more than 130 participated in the health assessment peer review. Scientists have applauded our extensive effort to solicit information

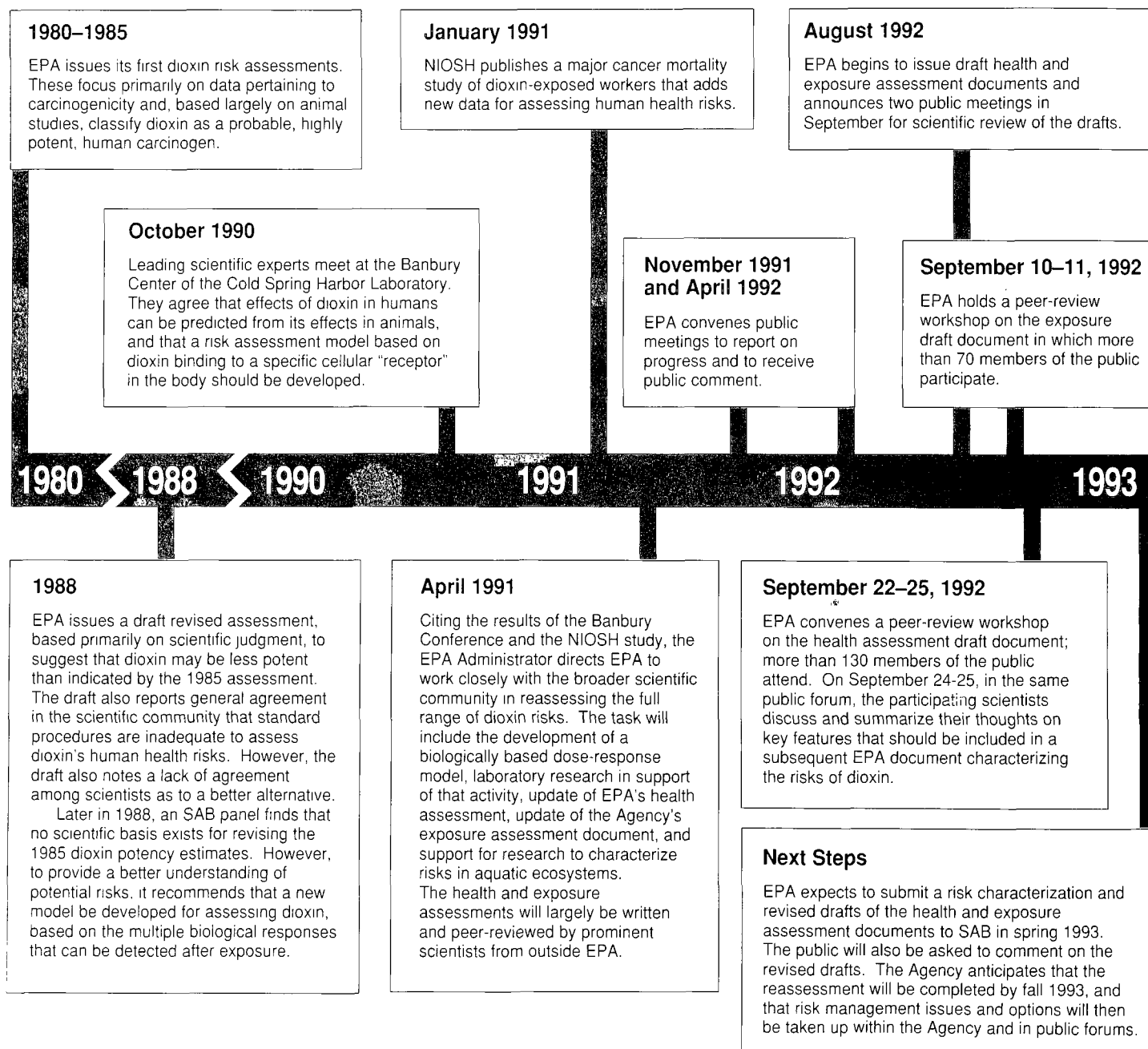
and comment from outside EPA.

Once the reassessment is complete, we will evaluate the success of this new approach. On the basis of the results that we've seen so far, we are enthusiastic that

we have developed a procedure that will be key to ensuring public confidence in the soundness of our science in major future risk assessments. □

The Search for Answers: A Dioxin Timeline

What degree of risk does dioxin pose to human health? What are the intricate molecular and cellular processes that may lead to biologic effects from dioxin in the human body? How prevalent is dioxin in the environment? These questions have been widely debated by scientists, policy makers, and the general public ever since dioxin emerged as a leading health issue with the evacuations of Love Canal in Niagara, New York, in 1980 and Times Beach, Missouri, in 1983. Here, briefly, is a chronology of EPA's efforts to find the answers:



Breakthroughs in Cancer Risk Assessment

With new tools, scientists are learning more about how cancer occurs

by Stephen Nesnow

Scientists are continually trying to improve cancer risk assessment by incorporating new information on the cancer process and on how different carcinogens affect the process. Preferably, cancer risk assessments would be based on epidemiological studies, studies that link actual human cancer cases with human exposure to specific agents. More often than not, however, such information is not available, and risk assessments are made by extrapolating from experimental results on laboratory animals to the human situation.

Many uncertainties are inherent in both approaches. Epidemiology studies depend heavily on accurate assessments of human exposure. Generally, these assessments rely on external exposure measurements. This doesn't account for what happens to a carcinogen once it enters the body, a factor that can greatly influence the quantitative exposure-to-tumor relationship. Extrapolations from laboratory data entail even greater uncertainties. For example, we cannot be entirely sure that the carcinogen-induced process in the animals, the so-called mechanism of action, has relevance to humans.

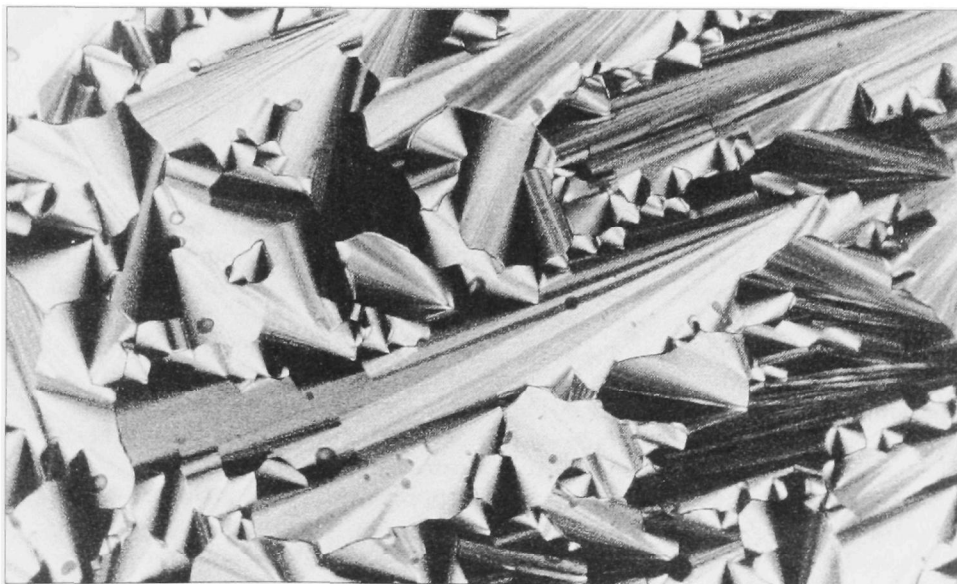
Recent scientific discoveries are helping us to refine our estimates of human exposure to carcinogens and to

better understand the mechanisms of action of carcinogens both in experimental animals and in humans. While there is still much to learn, we know that the induction of cancer by chemicals is a very complex process. Cancer, a set of diseases characterized by uncontrolled cell growth, is thought to be the result of a process involving multiple steps. Carcinogens can initiate the process; they can also influence the development of cancer in several of the steps. Each alteration can trigger a new cascade of events that may eventually

lead to tumor formation.

At one time, it was thought that the process of cancer induction by chemicals was similar for many carcinogens. We know now that this is probably not correct: Carcinogens vary in how they initiate, alter, and otherwise affect the steps of the cancer process.

Moreover, research has now identified many cellular targets and biochemical and biological processes that carcinogens can affect in such a way as to result in the eventual formation of tumors. One target is DNA, which contains the genes that



DNA, which contains the genes that control cell growth, has been identified as a "target" of carcinogens.

Dr. Randolph Rill photo. Polaroid. This photomicrograph of DNA liquid crystals was reproduced from a colored slide that won third prize in the 1987 Polaroid International Instant Photomicrography Competition.

(Dr. Nesnow is Chief of the Carcinogenesis and Metabolism Branch at EPA's Health Effects Research Laboratory in Research Triangle Park, North Carolina.)

control cell growth; another can be the biochemical processes involved in cell growth, cell growth regulation, cell signaling, and cell-to-cell communication. Other targets of chemical carcinogens may be processes involved in cell toxicity and death or processes that alter hormone levels. Still others may be receptors involved in cell growth, enzymes that metabolize carcinogens, the immune system, and the systems that allow cells to repair damage caused by carcinogens.

One major scientific advance lies in clarifying the body dose absorbed by humans following exposure to a carcinogen. Recently, mathematically based computer models have been developed that can help predict the dose of a carcinogen or its metabolites in specific animal and human organs and tissues after exposure. These models are used mainly to clarify tissue dose at the site of tumors resulting from external exposure. Referred to as physiologically based pharmacokinetics (PB-PK) models, they incorporate anatomical, physicochemical, biochemical, metabolic, and physiological parameters specific for the route of administration, frequency and duration of exposure, the carcinogen, and the test animal.

The models are initially developed using animal exposure data; after their validation in animals, they are applied to humans to obtain target organ doses. They may then be used to predict the magnitude and time course of human organ or tissue target doses under different exposure scenarios—for example, acute or chronic exposure conditions. The models are also used to extrapolate from animal data (usually obtained at high doses) to humans (generally exposed at much lower doses) and to extrapolate from data obtained from one route of exposure (e.g., ingestion) to another (e.g., inhalation).

While predicting the tissue or organ dose of carcinogens is essential to assessing risk, we must also measure the binding of carcinogens to the DNA. There is ample evidence to suggest that some carcinogen-bound DNA forms, called carcinogen-DNA adducts, can cause heritable changes (e.g., mutations or chromosomal alterations) in the DNA, and that these changes can eventually result in tumor formation. Since DNA can be a primary target for carcinogens, the ability to identify and measure

Cancer Risk Guidelines Under Review

EPA, working in cooperation with the Agency's Science Advisory Board, is in the process of revising and updating its 1986 *Guidelines for Carcinogen Risk Assessment*. Several activities are part of this process:

- Currently, a discussion or "working paper," on cancer risk assessment issues prepared by Agency scientists is being circulated among outside scientists for comment.

- Last December, EPA, California, and the Society for Risk Analysis held a workshop on carcinogen risk and guideline development. The workshop focused on the following issues: statistical "meta-analysis" of human epidemiological data, risk characterization methodology, and the use of new advances in molecular biology in identifying and quantifying cancer risks.

- This May, the National Academy of Sciences will issue a report to Congress—required under the 1990 Clean Air Act—on EPA's risk assessment methods, emphasizing cancer hazard and air exposure assessment.

EPA is aiming to publish the proposed revisions in the *Federal Register* for public comment by fall 1993.

—Eds.

carcinogen-DNA adducts will assist in better characterizing human exposure.

There is a new tool for this purpose. A new technique, the ^{32}P -postlabeling assay for DNA adducts, developed by scientists at Baylor College of Medicine, can measure carcinogen-DNA adducts obtained from exposed humans at an extremely high sensitivity: Approximately one carcinogen-DNA adduct per single human cell can be detected. This exquisitely sensitive technique significantly advances our understanding of the basic chemical carcinogenesis process as it relates to alterations in DNA. Studies are now in progress in which cigarette smokers or

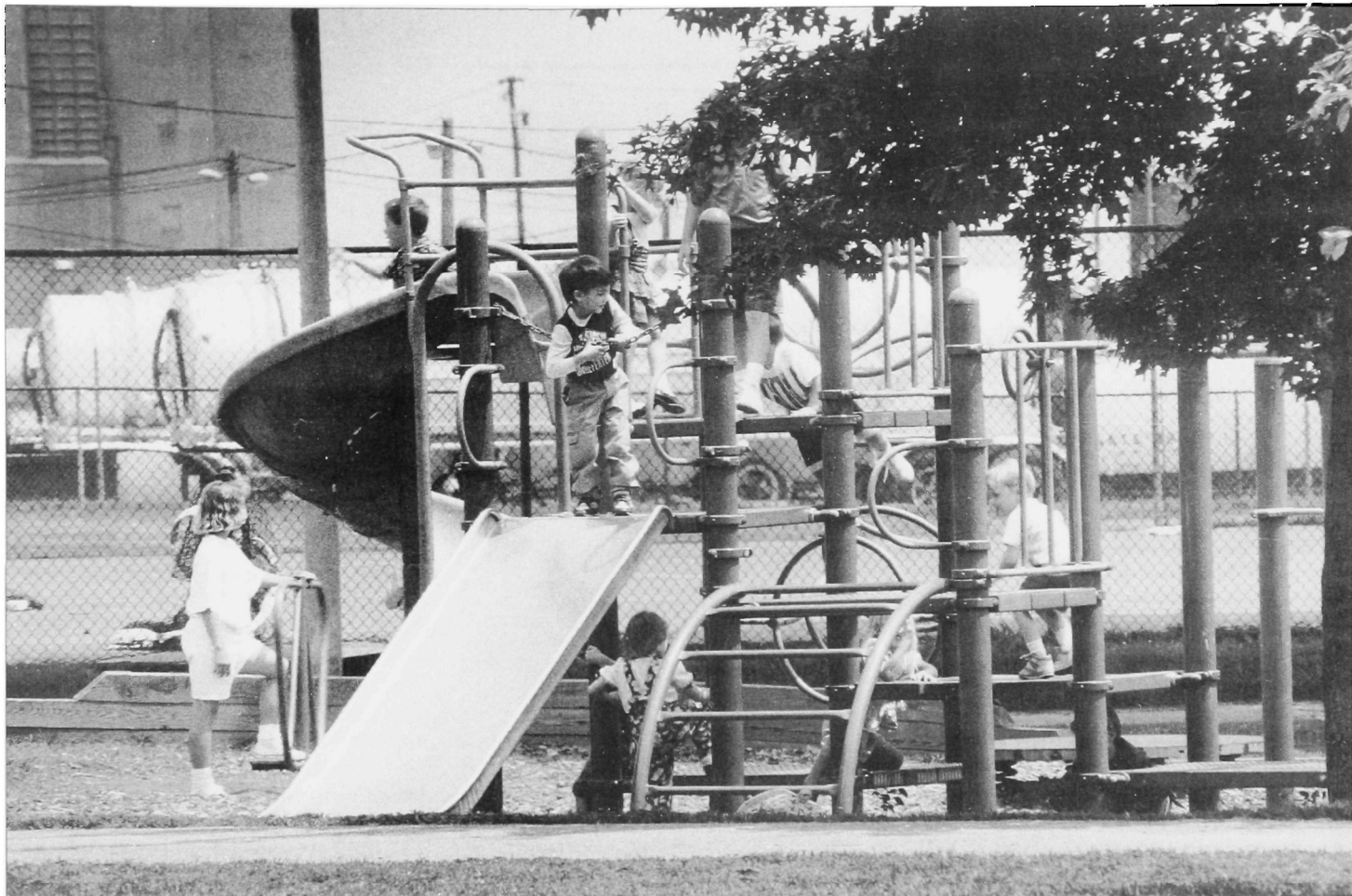
occupationally or clinically exposed individuals are being monitored for the presence of specific DNA adducts. Their purpose is to explore the sensitivity and selectivity of this assay, to further refine it, and to examine the relationships between exposure and DNA adducts.

Not only can the ^{32}P -postlabeling assay be used to further refine the estimate of human exposure to chemical carcinogens, but it can be applied to studies of experimental animals. Similarities in carcinogen-DNA adduct patterns, or "fingerprints," obtained from animals and humans exposed to the same carcinogen can be used to strengthen the links between animal cancer data, its extrapolation to humans, and its use in risk assessment. In a related approach, techniques to detect, identify, and quantitate carcinogens bound to proteins, particularly blood proteins (e.g., hemoglobin), are being developed and evaluated for their ability to more accurately assess exposure in humans.

To relate carcinogen exposure to biological effects in humans, we need to know the biological consequences of the exposure on DNA and chromosomes. Fundamental advances in the understanding of the cancer process have come from studies in molecular biology. Scientists have discovered two classes of cancer genes—protooncogenes and tumor suppressor genes—that are involved in the normal control of cell growth and cell differentiation (conversion of one cell type to another). When mutated or genetically altered by carcinogens, they can cause abnormal cell growth and differentiation, and they are therefore implicated in the pathogenesis of tumors.

Genetically altered protooncogenes and tumor suppressor genes have been found in the DNA from several types of human tumors, as well as in the DNA of tumors induced in experimental animals. Identifying such changes in tumors of workers in high risk populations, smokers, or individuals exposed to high levels of dietary carcinogens may set the stage for their use in cancer risk assessment.

A new molecular technique has made significant impacts on this area of research. The polymerase chain reaction, or PCR, is a semi-automated technique whereby very small amounts of DNA (or DNA fragments) obtained from almost any tissue (e.g., blood, skin, tumors) can



Some population groups, such as children, are more susceptible than others to certain risks. In cancer risk assessment, new molecular tools can help identify high-risk groups.

Steve Delaney photo

be amplified as much as a million-fold. This allows detailed and complex investigations to be performed on the genetic changes that the DNA has undergone, including changes in specific protooncogenes and tumor suppressor genes.

New molecular tools can also be used to help identify high risk groups as part of the risk assessment process. We already know that certain population groups can be more susceptible than others to certain risks. In the risk assessment supporting the National Air Quality Standard for lead, for example, EPA identified children as a high risk group that was especially vulnerable to neurological and hematological impairment. We know that factors such as genetics and nutrition play an important role in determining the susceptibility of population groups to environmental carcinogens and that these factors contribute to variability in the risks posed to different groups.

Knowledge of the mechanisms of action of carcinogens in experimental animals is important not only in identifying carcinogens that may pose a

hazard to humans, but also in deriving the methods by which animal data are extrapolated to predict human tumor rates. Data from experimental animals are usually obtained at high exposures to maximize the probability of an effect;

Recent scientific discoveries are helping us to refine our estimates of human exposure to carcinogens.

human exposure is often many orders of magnitude lower. The extrapolation of high to low dose has been accomplished either through statistical models, which assume that humans vary in their susceptibility to carcinogens, or through stochastic (random event) models, which assume that everyone is equally

susceptible and that cancer occurs after one or more randomly occurring independent events. Neither approach is grounded in the biology of the cancer process as we know it today.

A new class of biologically based dose-response models is being developed that incorporates the ability of carcinogens to alter DNA and the effects of carcinogens on the processes that control cell growth and cell death. Although these models are in the early stages of development, they can already explain the increase in human cancer rates with age, the decrease in tumor rates after cessation of smoking, and the effects of hormones in breast cancer. These phenomena are not readily explained by the non-biologically based statistical or stochastic models.

In short, the complexity of the cancer process continues to pose challenges to the practice of risk assessment. However, recent exciting advances in our basic knowledge of how carcinogens induce cancer and the development of new tools and models that can assist in characterizing exposure and effects will undoubtedly improve cancer risk assessment in the future. □

Update on Noncancer Assessments

New initiatives are improving the science base and the process

by V. L. Dellarco and C. A. Kimmel

Although public attention tends to be drawn to cancer, many other serious health effects with long-term consequences may result from exposure to environmental pollutants. In its health assessments of

(Dellarco is Chief of the Genetic Toxicology Assessment Branch in EPA's Office of Health and Environmental Assessment within the Office of Research and Development. Kimmel is a senior-level developmental toxicologist within the same office.)

pollutants, EPA considers the potential for adverse effects such as reproductive impairment, birth defects, genetic damage, neurological and immunological disorders, and respiratory and liver diseases. For example, in the control of air pollutants—ozone, carbon monoxide, lead, and oxides of sulfur and nitrogen—the Agency has long been concerned with potential adverse respiratory and neurological effects. (See box, below, for other examples of risk management decisions that were

driven by health risk concerns other than cancer.)

Health risk assessment is an integral part of making regulatory or risk management decisions. As explained in the article beginning on page 10, risk assessment combines an evaluation of the health effects data with the human exposure estimates to determine the potential risk to humans of exposure to a chemical substance. The evaluation of health effects is usually based on the results of laboratory tests, but may also

Actions Based on Health Effects Other Than Cancer

- Acrylamide has been observed to cause cancer in animals at high levels of exposure; neurotoxic effects have been observed at lower levels. To protect workers from the neurotoxic risks associated with dermal and inhalation exposure, EPA recently proposed a ban on grouts containing acrylamide and N-methylolacrylamide. The grouts are used, for example, in sealing water mains.
- Lead has been regulated on the basis of its developmental neurotoxic effects. Exposure of fetuses, infants, and young children to very low levels of lead can have a subtle but long lasting effect on the child's IQ. In the late 1970s, as a

consequence of lowering lead levels in gasoline, both ambient air levels and blood levels showed a correlated decrease. Another major source of lead is paint used in older housing. EPA, the Department of Housing and Urban Development, and the Department of Health and Human Services are actively pursuing risk reduction programs for lead, since it is estimated that one out of every six children in this country has a blood lead level that exceeds the Centers for Disease Control's current intervention level of 10 micrograms per deciliter.

- Dinoseb-containing pesticide products, used to control broadleaf weeds and vegetation growth on certain crops, were suspended in 1986 and canceled in 1988 after EPA reviewed data showing that dinoseb was acutely toxic to humans and had the potential to cause birth defects and reduce male fertility.
- The Agency is reassessing the data on dioxin, a potent animal carcinogen and suspected human carcinogen. It is also considering health effects such as immunotoxicity and developmental and reproductive toxicity, which have been observed at very low exposure levels in animals.

include human data, when available.

Many types of health effects must be considered in the assessment of noncancer risks. The term "noncancer risk" encompasses a wide range of responses, including adverse effects on specific organs or organ systems, effects on reproductive capacity, the viability and structure of developing offspring, and survival. To manage the complexities of these systems, EPA has developed guidelines that defined the toxicity "end points" of concern in each area, established the methodology and assumptions made in assessing risk, and promoted a consistent approach to data evaluation and estimation of risk. (See box on guidelines.)

EPA's risk assessment guidelines are meant to be "living documents," that is, flexible enough to be revised to keep pace with advances in science. Currently, health risk assessment at EPA is evolving on a number of fronts. The following discussion touches on some of the major issues in risk assessment for health effects other than cancer and on some of the Agency's research efforts for developing new risk assessment methods.

Scientists seldom have at hand direct evidence that pollutants cause particular adverse effects in humans. It is usually necessary to rely on laboratory animal data to identify potential hazards and to estimate the amount of risk associated with exposure to a given pollutant. This approach has several shortcomings. For example, responses to a toxic agent may vary between laboratory animals and humans because of differences in metabolism and genetically determined sensitivity, or differences in the route, timing, and duration of exposure. Moreover, to ensure that adverse effects can be observed, exposures in animal studies are set high, usually higher than humans normally encounter. In addition, the exposure regimen in animal studies may not replicate the conditions of human exposure.

To address the uncertainties inherent in extrapolating from high to low doses and from animals to humans, EPA has established a program known as Research to Improve Health Risk Assessment (RIHRA). RIHRA, in concert with other initiatives, is providing the foundation for developing improved exposure, pharmacokinetic, and dose-response models by generating such information as mechanisms of toxicity

Health Risk Assessment Guidelines

EPA has published or has under development several specific guidelines for assessing health risks other than cancer. These guidelines are meant to be "living documents," that is, flexible enough so that they can be revised to keep pace with advances in science:

- Mutagenicity (published 1986)
- Developmental toxicity (published 1986, amended in 1991)
- Male/female reproductive toxicity (publication expected in 1993)
- Neurotoxicity (proposal publication expected in 1993)
- Immunotoxicity (under development)
- General Quantitative Methodology (under development).

and relative sensitivity across species. Following are a few examples of current research initiatives.

Adverse effects can be elicited in some cases after only one or a few periods of exposure; in others, longer term exposure is required. An important challenge is to develop an understanding of how variation in exposure scenarios affects the nature of toxicological outcomes and the amount of risk to humans. Research is underway to examine the effects of short duration exposure and of relationships

extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population. The result is a reference dose (RfD)—or reference concentration for inhalation exposure—which is assumed to be without appreciable risk for adverse health effects. There are several limitations to this approach, one of which is that it does not provide a basis for estimating risk at exposures above the RfD. This limitation is particularly problematic when one asks the question, How much residual risk, if any, remains after enforcement of control technologies to reduce emissions of pollutants. This is the approach to controlling air toxics called for under the Clean Air Act Amendments of 1990.

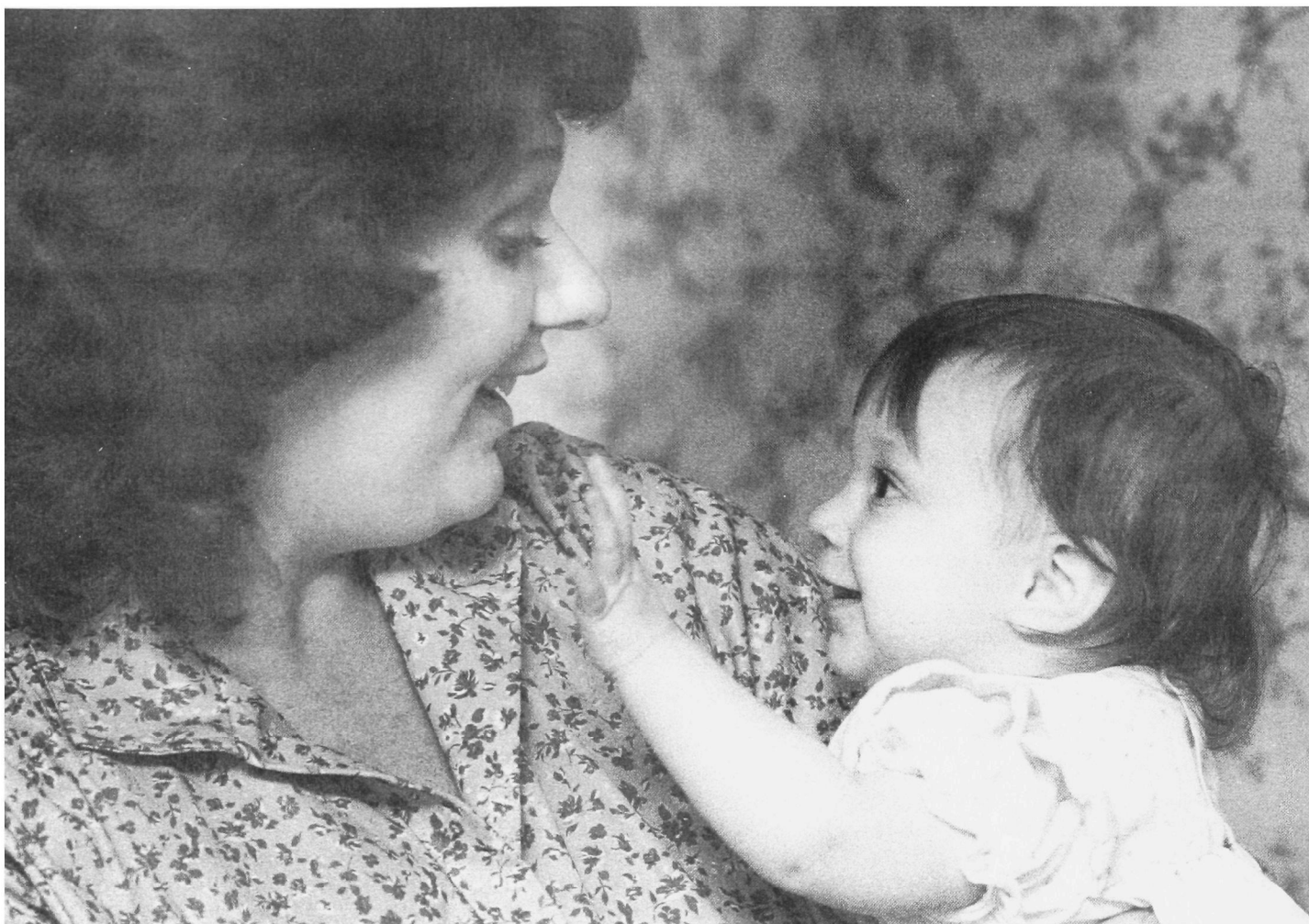
EPA is supporting a number of projects to advance quantitative methods of estimating risk, including both statistical and biologically based dose-response models. For example, as a first step, the Agency is exploring, under the RIHRA program, the use of a "benchmark dose" to replace the NOAEL. Unlike the NOAEL, the benchmark dose is a quantitative estimate that applies a mathematical model to take into account all of the dose-response information provided by a study. The benchmark dose for a specific level of response (risk) is then divided by uncertainty factors to calculate the RfD.

Finally, to improve hazard identification and quantification of health risks, we must develop and incorporate an understanding of the molecular

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**The EPA's risk
assessment guidelines
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"living documents."**
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between exposure level and exposure duration. They include the development of models to predict effects at exposure levels and durations other than those evaluated experimentally.

The current practice of estimating risk for health effects other than cancer is to begin with a "no-observed-adverse-effect-level" (NOAEL), which is usually determined from animal studies. This NOAEL is divided by numerical "uncertainty factors" to reflect uncertainties inherent in the



Steve Delaney photo.

EPA is advancing research on health risks other than cancer, including reproductive effects and effects on the unborn.

mechanisms of toxicity. For example, it is becoming increasingly clear that certain pollutants have the ability to interfere with some developmental and cell regulatory events that are controlled through hormones. Scientists are finding that organochlorines and other chemicals can harm a fetus and cause reproductive impairment or other toxicities by mimicking natural hormones. Even minute exposures to these chemicals may produce toxic responses. Also, major advances are being made in identifying the genes that control embryonic development. Recent work has shown that there are natural agents (e.g., vitamin A and its derivatives) that can alter the way these genes control the development of the embryo; it is conceivable that environmental pollutants may also alter the activity of these genes.

EPA is supporting efforts to find ways to incorporate such mechanistic information into the risk assessment process for both noncancer and cancer end points. (See article on page 27.) Our emerging understanding of the mechanisms of carcinogenesis and other health effects suggests that the underlying basis for certain noncancer and cancer end points may have several commonalities. For example, chemically induced toxicity can cause cell death and tissue degeneration. Surviving cells may then compensate for that injury by increasing cell proliferation (hyperplasia), which may underlie many types of toxic responses. If this proliferative activity continues unchecked, it may result in tumor formation. Thus, the same basic toxic mechanism may be related to both the cancer outcome and to other types of toxic effects. This could ultimately result

in use of similar quantitative approaches for risk estimation for certain cancer and noncancer health effects.

EPA is pursuing a variety of initiatives to improve the science base for assessing risk. This is being accomplished by requiring that appropriate biological data be collected on pollutants, establishing consistency in data evaluation and risk assessment, and developing better estimates of human exposure. To continue to promote the upgrading of current methodologies and improved approaches for risk assessment, an understanding of basic mechanisms and their relationship to toxic responses must be pursued. □

(The authors wish to acknowledge Jeanette Wiltse, David Reese, Elaine Francis, Sue McMaster, Eric Clegg, Annie Jarabek, and John Vandenberg for their reviews, contributions, and helpful discussions.)

The Lessons of Commencement Bay

A pioneering study in Puget Sound helped advance ecological risk assessment

by Patricia Cirone and Matthew Coco

The lobes of the glacier that carved Puget Sound thousands of years ago created numerous bays that became natural locations for port cities. Unfortunately, many of these bays then became natural sumps for the accumulation of toxic chemicals that those cities produced. One example is Commencement Bay on the shoreline of Tacoma, Washington.

More than 280 point sources, including a pulp mill, petroleum refineries, aluminum processors, sewage treatment plants, and an active ocean port, have polluted Commencement Bay. Many nonpoint sources also drain into it. Concerns about the potential ecological and human health effects of hazardous substances in sediments of the nearshore/tidal flats area of the bay led to its addition, in September 1983, to the National Priorities List (NPL) for cleanup under EPA's Superfund program. These concerns grew from earlier studies by the National Oceanic and Atmospheric Administration and others, which had identified chemical contamination in nearshore sediments and abnormalities in fish.

Once Commencement Bay became an NPL site, a Remedial Investigation/Feasibility Study (RI/FS) was initiated, as required under the Superfund law, the Comprehensive Environmental Response, Conservation, and Liability Act (CERCLA). The study was intended to define the risks to public health and the Commencement Bay environment

and to prioritize areas for remedial action. As part of this RI/FS, a pioneering ecological assessment was conducted.

In the absence of a formal framework or guidelines for conducting the risk assessment, scientists working at Commencement Bay grappled with the methodology problems confronting them and inductively developed a working approach. As a practical matter, it was not possible for the assessment to focus on chemical contamination in the water column, because the chemicals dispersed with water movement and became diluted; instead, the study focused on the benthic community, the flora and fauna at the bay's bottom. In general, the task

was made more difficult by a lack of existing protocols for sampling sediments and benthic organisms or for performing bioassays and other procedures. Moreover, because complex mixtures of chemicals were found in the sediments of contaminated areas, it was simply not possible to ascertain cause-effect relationships between exposure and the effects of particular chemicals.

Two methods were developed for characterizing ecological effects for Commencement Bay:

- Comparison of conditions at contaminated sites to benchmark locations, or "reference sites." Two reference sites were selected: Carr Inlet,

A Step Toward Ecological Risk Guidelines

The *Framework for Ecological Risk Assessment*, published in February 1992 by EPA's Risk Assessment Forum, is a first step in the development of risk assessment guidelines for ecological effects. Lessons learned at Commencement Bay and elsewhere contributed to the development of the *Framework*, which provides a three-stage process for analyzing ecological risk:

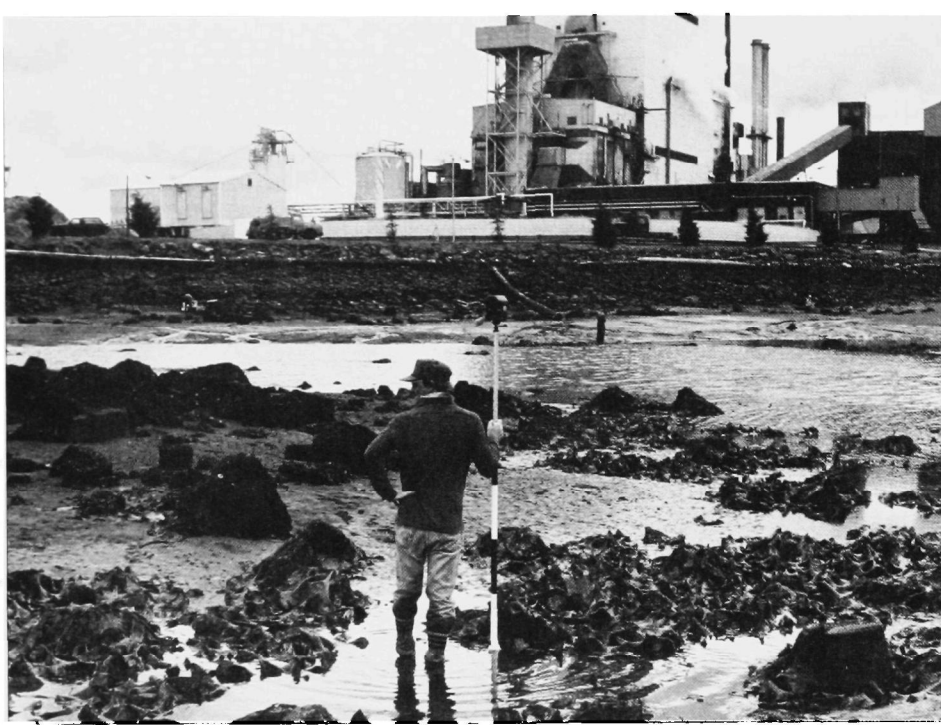
- *Problem formulation.* The goals, breadth, and focus of the risk assessment are established. The end product of this step is a conceptual model that identifies the environmental values to be protected (the assessment

"end points"), the data needed, and the analyses to be used.

- *Analysis.* Exposure is characterized to determine the extent of contamination by a stressor and its relationship with species. Concurrently, ecological effects are characterized to measure the adverse effects associated with the stressor and to identify cause-and-effect relationships.
- *Risk characterization.* The results of the analyses of exposure and ecological effects are evaluated to determine the likelihood of environmental harm associated with a stressor.

—Eds.

(Cirone is Associate Director of Investigation and Evaluation Programs and Coco is a program analyst in EPA's Region 10 office.)



A pioneering ecological assessment was done at Puget Sound's Commencement Bay after it was added to the National Priorities List for Superfund cleanup. The bay was contaminated by point and nonpoint sources of pollution.

which had the lowest detection limits for most substances of concern in Puget Sound embayments, and Blair Waterway, which was the least chemically contaminated of the seven waterways of Commencement Bay.

- Use of an Apparent Effects Threshold (AET) approach. Since data on biological effects were not available for all portions of the study area where chemical data were available, the AET method was developed to estimate "threshold" concentrations of contaminants, *above which* biological harm would be expected.

These threshold values were generated for each of three biological indicators: amphipods, oyster larvae, and benthic macroinvertebrates. For amphipods, the AET value was the level just below that at which specimens began to die. For oyster larvae, it was the concentration just below that at which abnormalities developed. For benthic macroinvertebrates, the threshold effect was diminished abundance.

The assessment as a whole was designed to examine three aspects of the benthic community: biological (through field measurements of the number and type of organisms), physical (through examination of sediment grain size and depth), and chemical (through chemical laboratory analyses of sediments).

To begin the Commencement Bay study, researchers compiled and evaluated existing data and performed extensive field sampling to collect

additional data. The field sampling involved 50 field surveys, 500 sampling stations, and 2,000 samples of water, sediments, and biota. Close to 120,000 individual specimens belonging to 407 species of bottom-dwelling organisms, including marine worms, round worms, clams, crustaceans, sea cucumbers, and brittle stars, were collected and analyzed. These species were considered appropriate indicators of the extent and magnitude of environmental stress, because they interacted extensively with the sediment. If they failed to reflect harm from the chemicals in the sediment, impacts on other species that fed on them were considered unlikely.

The field surveys of population abundance and diversity of benthic species were used to characterize areas where pollutants might have eliminated ecologically significant organisms. Also, species of fish and crab that spend at least part of their life cycles in Commencement Bay and feed on the benthic organisms of the Bay were tested for toxic substances and multiple abnormalities. In addition, sediments were analyzed for a host of chemicals commonly termed "priority pollutants," including arsenic, lead, zinc, and cadmium.

Results of the testing indicated that the abundance of major benthic taxa increased with increasing distance from the four major sources of contamination that scientists had identified. Tests showed bioaccumulation of toxic substances and multiple abnormalities in

fish and crab samples. In particular, PCBs were detected in muscle and liver tissue of English sole throughout the study area at concentrations substantially elevated above those found at the reference sites.

High levels of toxic chemicals were found in the sediments of many areas of the bay. Ten chemicals even had concentrations that were 1,000 times greater than reference area concentrations.

As indicated earlier, scientists conducting the RI/FS found that establishing a cause-and-effect relationship between contamination and measurable harm would be too resource-intensive and time-consuming. They chose instead to follow a preponderance of evidence approach: Any identifiable site in Commencement Bay that failed the AET test for any of the three biological indicators cited above would require remedial action.

Application of the Apparent Effects Threshold/preponderance of evidence approach identified nine "hot spots" in Commencement Bay. Eight of these were eventually chosen for remedial treatment. The Superfund Record of Decision prescribed four clean-up strategies:

- Site use restrictions—local health advisories and educational programs to reduce potential exposure to site contamination during the estimated 15- to 20-year remedial period.
- Source controls—development and implementation of regulations and requirements; monitoring for compliance with water and sediment quality standards; and permit requirements.
- Natural recovery—Sediments would be allowed 10 years to recover by means of chemical degradation, diffusion across the sediment-water interface, burial, or remix of contaminated surface sediments by recently deposited clean sediments.
- Sediment remedial action—Options include capping in place with clean fill, confined aquatic disposal, dredging and dumping contaminated sediments in the nearshore area, and upland disposal above tidal influences.

In implementing the Record of Decision, EPA's Region 10 and the Washington Department of Ecology are continuing the joint effort that began with the Remedial Investigation at Commencement Bay. □

Relating Risk Assessment and Risk Management

Should risk assessment be considered distinctly separate from risk management? A 1983 National Academy of Sciences report concluded that it should and government agencies since then have generally operated on that assumption. Recently, however, some experts have been reevaluating the relationship between the two. Presented here are two views on the controversy.

Complete separation of the two processes is a misconception

by Sheila Jasanoff

Should risk management (what we wish to do about risk) be allowed to influence risk assessment (what we know about risk)? The very idea is anathema to environmental policy makers who came of age in the 1980s. It is like asking whether politics should control science. We are reminded of Galileo bowing to his inquisitors or of Lysenko delivering to Stalin the genetics that served the ideology of the Soviet state. Trained to think of science as value-free, we believe that the inevitable result of subordinating knowledge to politics must be the corruption of both.

Closer to home, EPA watchers may recall the sorry events of the early 1980s that helped give rise to the doctrine of separating risk assessment from risk management. In one especially unfortunate incident, the Agency's Office of Pesticides and Toxic Substances exempted formaldehyde from designation as a priority chemical under Section 4(f) of the Toxic Substances Control Act, even though this widely used compound had been definitively shown to cause cancer in rats. Legally

and scientifically flawed, the underlying analysis seemed to have been unduly influenced by the concerns of the formaldehyde industry. It was a blatant case of risk management objectives overriding the risk assessor's impartial evaluation of scientific data. Later EPA administrators were determined not to see this error repeated.

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**Judgment, moreover,
must remain sensitive to
the policy context.**

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The specter of improper interest group influence was one of the concerns that guided the National Academy of Sciences' (NAS) authoritative study of risk assessment practices in the federal government. In its "Red Book" report of 1983 (so named because of the report's red cover), the NAS espoused the now-classic position that regulatory agencies should clearly separate risk assessment from risk management. Even the perception that risk management considerations were influencing risk

assessment, the "Red Book" authors asserted, would diminish the credibility of the assessments themselves and of management decisions based upon them.

But careful practitioners of risk assessment have recognized from the start that theirs is not a purely scientific activity. Indeed, risk assessment is often described as an "art" rather than a "science." This formulation emphasizes that risk assessment, like any artistic endeavor, requires the exercise of subjective judgment. It cannot be done by mechanically following the rules. Judgment, moreover, must remain sensitive to the policy context.

Risk assessment operates in the ambiguous borderland between systematic observations of the physical world ("science") and politically accountable decisions about public health and welfare ("policy"). Even the NAS report recognized that such a process must be conditioned by factors deriving from both the scientific and political domains. The choices involved in risk assessment, the report states, rest "on a mixture of scientific fact and consensus, on scientific judgment, and on policy determinations."

The need for judgment in risk assessment is often attributed to scientific

(Jasanoff is professor and chair of the Department of Science and Technology Studies at Cornell University.)

Risk management at work. New York City workers install the framework for a plastic encasement over an apartment building splattered with asbestos-laced mud as a result of a steam pipe explosion in August 1989. The building could then be cleaned without contaminating the neighborhood.

David A. Cantor photo Wide World

uncertainty. If uncertainty were the only problem, then risk assessors would not have to look much beyond science for answers to their questions. More knowledge would automatically make for better risk assessments, because additional facts would reduce uncertainty. But the focus on uncertainty misses the mark. The choices that must be made in risk assessment are not due only to gaps in existing knowledge; they have their origin in the very methods by which we assess uncertainty, and they cannot be resolved simply by asking science to fill in more facts as needed.

Risk assessors explore the physical world through necessarily stripped-down models of reality. In order to estimate the probability of bad events, risk assessment has to reduce the immense variability of natural and social systems to dimensions that can be easily mapped, measured, and modeled. Many simplifying assumptions are needed to construct a microcosm whose risks can reliably be investigated. Thus, in models conventionally used for health risk assessment, adult human beings live exactly 70 years, stay indoors all day in radon-contaminated homes, drink precisely seven cups of water per day, smoke heavily or not at all, and exercise while inhaling abnormal quantities of airborne pollutants.

In other risk scenarios, water and smoke plumes flow along mathematically exact pathways, dense population clusters are located immediately downwind from polluting factories, pregnant women and small children eat steady diets of pesticide-laden foods, and acid rain falls relentlessly on forests of red spruce. We know that nature and society actually behave in more complex and unpredictable ways, but we cannot begin to estimate the magnitude of particular risks except by building little model worlds where all variation is artificially restricted.



If risk assessment proceeds by mapping facts onto such approximate versions of "reality," then risk management is the guide that tells us when these approximations are acceptably accurate. Is it appropriate, for example, to set standards for hazardous air pollutants based on the exposure of the so-called "porch potato"—that mythical being who spends 70 years immobile on the porch of a house at the fence line of the emitting factory? Or is this a "worst case" that risk assessors

should ignore in favor of a more behaviorally realistic scenario? The answers have to come from risk management, for only the risk manager can say how conservatively we should draw up our policies for protecting public health and the environment.

Should default assumptions be chosen so as to safeguard the most highly exposed, the most vulnerable, or the most "normal" individual? Do we want to eliminate risks that are unacceptably high for some subpopulations or only to

reduce those that occur at too high a frequency for the entire population? Questions like these require the regulator to cross the borderline between risk assessment and risk management. The answers bear on core elements of the risk assessor's work: how to select among competing models, how to balance conflicting scientific inputs, when to revise prior assumptions, how to register

and represent uncertainty, and when to hold out for more scientific information. Yet, the questions themselves are firmly planted in the policy domain.

Too rigid a separation between risk assessment and risk management seems in the light of this analysis to be both naive and misguided. Risk assessment does indeed offer a principled way of organizing what we know about the

world, particularly about its weak spots and creaky joints. But the principles by which we organize the "facts" of risk have to derive, at least in part, from the concerns of risk management. In the end, we cannot order, arrange, or supplement our knowledge about risk without a clear, framing vision of the social and natural order that our risk-management policies are seeking to create.

If risk management is broke, why fix risk assessment?

by Bernard D. Goldstein

It has been interesting to follow the twists and turns of the fortunes of risk assessment in the less than a decade since the National Academy of Sciences' "Red Book" thrust this nascent paradigm toward the center of environmental regulation. Predictably, the initial burst of enthusiasm was followed by a cautious reappraisal when it became clear that risk assessment could not solve all the problems faced by risk managers, and that there was a limit to its accuracy imposed both by scientific uncertainties and by policy directives.

Some critics of risk assessment now are arguing that risk assessment is really not separate from risk management. Not surprisingly, this argument is primarily being made by risk managers who appear to have forgotten that a major impetus for the adoption of the "Red Book" formulation was the public perception that EPA's science was being manipulated for policy purposes.

Risk assessment is one of the major recent advances in moving forward the environmental regulatory process, rivaled perhaps only by the "bubble concept." (EPA's "bubble policy" allows a plant with several emission points to be treated as if it were in a "bubble." The total emissions are averaged for the entire plant, not each emission point, allowing

the plant's operators flexibility in meeting emission standards.) Risk assessment is enshrined in various laws as the driving force for regulatory actions and has proved to be a valuable tool in making decisions and in assigning priorities for the eradication of existing environmental problems. It improves the credibility of the entire regulatory process, particularly in comparison to regulatory approaches that violate the basic laws of toxicological

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The deconstructionist approach, which argues that there is no absolute truth, may hold for the policy world but not for science.

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science by treating all chemicals as if they are equal. In addition, risk assessment is particularly valuable in developing a research agenda that is responsive to crucial uncertainties underlying the decision-making process.

Organizations seemingly devoted to advancing the field of risk management spend much time and resources on critiques of risk assessment. Why the preoccupation with risk assessment? One possible reason is that risk

assessment has been oversold. The tendency toward overuse of risk assessment by risk managers partly represents an attempt to achieve credibility for preconceived policy goals, but unquestionably it also reflects the failure of risk assessors to adequately explain the basics of risk assessment, including its inherent limitations. Two examples are the misuse of risk assessment as the sole determinant for establishing priorities and in setting so-called "bright lines"—a bright line is a specific point, under any and all circumstances, where a particular level of risk is "acceptable" or not—for regulatory decisions.

Those who argue that risk assessment and risk management should not be independent say that risk assessors—scientists—have values and therefore risk assessment cannot be an apolitical effort. The deconstructionist approach, which argues that there is no absolute truth, may hold for the policy world but not for science. There is a knowable law of nature that describes the risk of dioxin or benzene, but no immutable law as to the best management approach to deal with these risks. At the very least, risk management is contextual, with the best decision being related to time and place, while risk assessment inherently embraces the concept that there is a single right assessment for all time.

As with any area of science, the fact that there is a natural law with one right answer which eventually will become

(Goldstein is Director of the Environmental and Occupational Health Sciences Institute at Rutgers University and the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School.)

known is very inhibiting to the risk assessor whose scientific reputation is continually at stake. The scientist in essence wrestles with formulas attempting to depict the real world in the full knowledge that, if the formula is wrong, the real world will win the match.

In contrast, it often seems to the risk assessor that the policy maker wrestles with the real world in order to contort it into fitting into a preconceived risk-management formula. While the risk manager has every right to attempt to amend the various social, economic, legal, and political pieces that go into making a regulatory decision, it is bad public policy to allow the manager the seeming opportunity to amend the laws of nature.

Perhaps risk assessment should be considered analogous to one of the many economic statistics supplied to us by the government, such as the unemployment figure or the amount of money in circulation. The latter includes what you and I have in our wallets and clearly must be an estimate with a whole variety of uncertainties built into it. Although such economic estimates are frequently given as preliminary figures and revised later, I have never heard of them given in

such a way as to include a statement of the extent of uncertainty.

I wonder why economists and other policy makers involved in environmental regulation ask for the laying out of all the uncertainties in the biological and mathematical aspects of risk assessment. Risk assessment should be viewed as a useful approximation of risk. Similar to economic statistics, a risk number should be particularly valuable for comparisons, should be arrived at in a way that is free of the inference of political interference, and should be subject to reevaluation based on new data, but not on policy preferences.

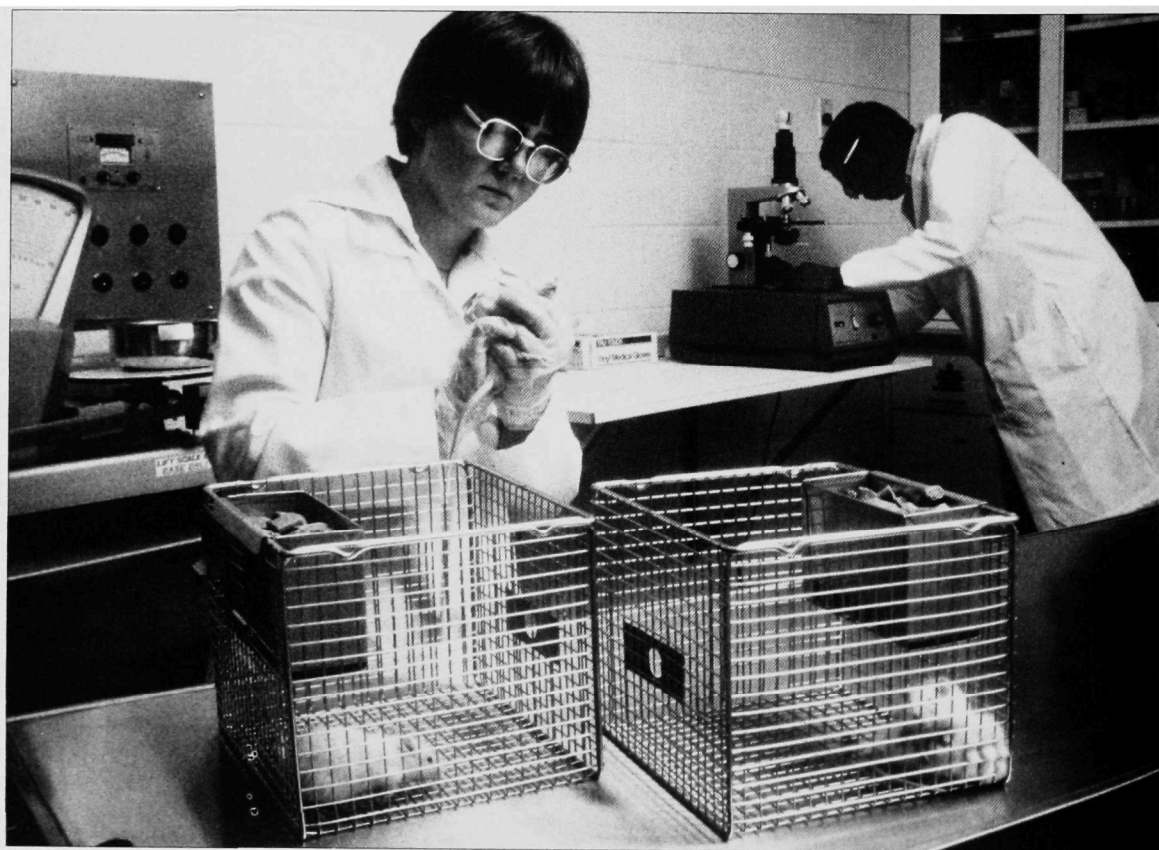
Much of the attention given by risk managers to risk assessment has been on the risk characterization step. To some extent this is reasonable, but the amazed horror at which some view the revelation that how one characterizes risk can affect the public's perception often seems either naive or strained. Surely, this is a basic fact of life in public health, and, although frequently forgotten, most environmental laws are aimed at protecting public health. Consider how the lack of available jobs could be trivialized if we were presented with employment rather than unemployment figures. A fall in the

employment rate from 96.8 percent to 95.2 percent does not sound as bad as the corresponding increase in unemployment from 3.2 percent to 4.8 percent.

I suggest to those who are concerned with the policy aspects that are built into risk assessment, such as the extent of conservatism, that the appropriate step at which the issue should be dealt with is not at the risk characterization step, but rather in the science policy step that precedes risk assessment. We really are dealing with a three-step process. The first step, before risk assessment and management, is the establishment of generic risk assessment guidelines combining both science and policy. These guidelines should cover every step in the calculation and characterization of the risk. They should be as explicit as the procedures for estimating unemployment or the gross national product, but sufficiently flexible to allow alterations in the performance of an individual risk assessment when justified by scientific data as supported by an open peer review process.

It is time for risk assessors to stop being defensive. Because risk management is broke is no reason to fix risk assessment. □

In extrapolating from laboratory animal test results to real-world conditions, practitioners of risk assessment confront controversial questions of science policy.
Monsanto Company photo.



The Delaney Clause Dilemma

EPA is calling for a public dialogue on the issues

by Victor J. Kimm

On July 8, 1992, a federal appeals court made a decision in *Les v. Reilly* that has unfortunate implications for pesticide decision-making and food-safety policy in the United States. Specifically, the court ruled that EPA may not allow any level of pesticide residues in processed food greater than the level permitted in the raw food if the pesticide presents *any* carcinogenic risk, however negligible. This decision was based on a strict interpretation of a provision of the Federal Food, Drug, and Cosmetic Act (FFDCA) that was enacted in 1958 and has come to be called the "Delaney clause" after its Congressional sponsor.

EPA believes the court's recent interpretation of the Delaney clause could adversely affect the nation's food supply by making it difficult for farmers to use the safest pesticides on their crops. In fact, the impact of the court's interpretation of the unusually complex statutory framework in which the Delaney clause is embedded could be, paradoxically, to discourage the use of safer new pesticides in favor of more risky chemicals.

The court acknowledged that EPA's interpretation of the FFDCA's statutory structure—namely its policy of applying a negligible risk standard across the board to all potentially carcinogenic pesticides—might produce a more "enlightened" scheme than does a literal interpretation of the Delaney clause. But it indicated that while Congress might have created a defective—or, at least,

outdated—framework, only Congress could correct or update the law. Since the Supreme Court declined to review this case in February 1993, the law stands; therefore, barring legislative action by Congress, EPA will have to move to implement the court's ruling.

Consequently, the Agency believes that this court decision intensifies the need for all interested parties to work together with federal agencies and Congress to reform pesticide regulation. Our goal must be to bring U.S. pesticide

respectively. Tolerances and food additive regulations are generally expressed in parts per million (ppm).

Under FFDCA section 408, EPA sets—and the U.S. Food and Drug Administration (FDA) enforces—tolerances for pesticides in or on raw agricultural commodities, such as vegetables, fruit, and grains. For example, a tolerance of 5 ppm of Pesticide X on apples allows residues of that pesticide to remain on harvested apples up to the level of 5 ppm. EPA issues tolerance regulations in conjunction with pesticide registration decisions governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); a pesticide registration under FIFRA constitutes a license for use of the pesticide under specified conditions.

Under FFDCA section 409, a pesticide residue is considered a food additive. This provision authorizes EPA to issue (again, with FDA enforcement) food additive regulations for pesticides on the processed food forms of raw commodities—such as, for example, fruit and vegetable juices, flour, and tomato and almond pastes. Section 409 is also the provision under which FDA sets limits on other food additives—such as, for example, the amount of preservatives or artificial sweeteners that can safely be added to foods.

The FFDCA "Flow-Through" Provision

So far, the scheme is relatively straightforward. But complications arise in setting tolerances for processed commodities under FFDCA section 409. Section 408, the raw food provision, is

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The court's
interpretation will
produce some
strange results.

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regulation into conformity with current science and ensure that the nation's pesticide safety laws provide the best available protection to consumers.

A Complicated Statutory Framework

In order to understand the court's ruling and its impact on pesticide use, one needs to have some idea of the complicated interplay between different provisions of the FFDCA. Even the undisputed basics of that scheme are difficult to understand.

The FFDCA authorizes EPA to set legal limits through "tolerances" and "food additive regulations" on the amounts of pesticide residues allowable in raw food commodities and processed foods,

(Kimm is Acting Assistant Administrator for EPA's Office of Pollution Prevention, Pesticides, and Toxic Substances.)

Crops that are sold raw, such as fresh apples, are not subject to the controversial "Delaney clause" of the Federal Food, Drug, and Cosmetic Act.

Steve Delaney photo.

linked to section 409, the processed food provision, by a section of the statute known as the "flow through" provision. Under this provision, pesticide residues in processed foods will not be considered unsafe under two conditions:

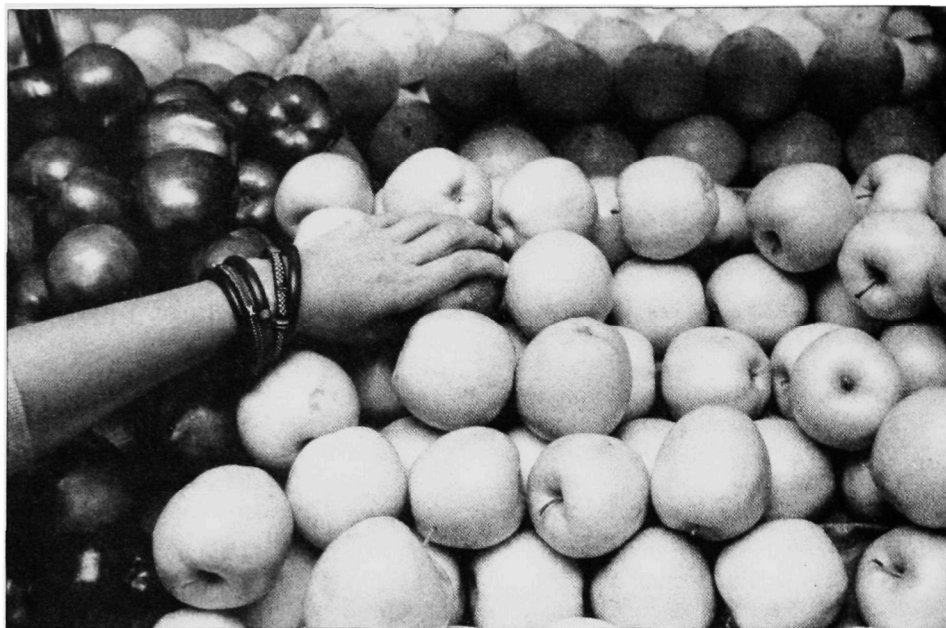
- First, good manufacturing procedures must be used to remove as much pesticide as possible during the processing of the food.
- Second, and more important for our purposes, the processed food will not be considered unsafe if the residues remaining after processing do not exceed the tolerance limit set for residues on the raw commodity under section 408.

Hence, this provision allows section 408 raw food tolerances to "flow through" to cover pesticide residues in processed food. Consequently, EPA's policy concerning when a section 409 food additive regulation is needed turns on whether there is a possibility that the processing of a raw food containing pesticide residues would result in residues in the processed food *at a level greater than the raw food tolerance*.

EPA believes there is a possibility of over-tolerance (illegal) residues in processed food in cases where a processing study shows that significant concentration of residues occurs through the processing of raw commodities. If significant concentration does occur during processing, then, theoretically, if residues in the raw food are at or near the tolerance level when the raw food is processed, the processed food may exceed the level of the raw food tolerance.

EPA's Coordination Policy

Because the raw food and processed food provisions of FFDCA relate to each other as explained above, it has been EPA's policy to consider pesticide registrations and related raw food and processed food tolerances in holistic decision scenarios. In other words, it has been EPA's policy to revoke or refuse to issue section 408 raw food tolerances or FIFRA registrations for pesticide uses on foods that might become processed foods in



cases where a section 409 tolerance cannot be allowed. Largely because it is often difficult at the time a pesticide is applied to predict whether the crop will be eaten raw or processed, EPA refuses otherwise acceptable raw food tolerances if for some reason a food additive regulation cannot be issued for residues of the pesticide in processed food.

The policy just described is known as the Agency's "coordination policy," sometimes called its "concentration policy." It is based on the rationale that EPA should not approve uses of a pesticide under FIFRA and FFDCA section 408 if the use could result in illegal residues in processed food.

EPA's coordination policy has been challenged by the National Food Processors Association (see article on page 44). The NFPA argues that linking action under sections 408 and 409 is illegal, and that data show that EPA's concerns with residues in processed food exceeding the raw food tolerance are unsubstantiated.

Inconsistent Standards in FFDCA Sections 408 and 409

At this point, the statutory scheme appears to be complicated yet logical. Not true: There is a serious problem in the framework because the standards for setting tolerances under section 408 and for establishing food additive regulations under section 409 are fundamentally different. On the one hand, section 408 provides that in setting tolerance levels,

EPA must balance any dietary risks to the public health against the benefits of the pesticide in producing an adequate, wholesome, and economical food supply. On the other hand, the Delaney clause, which appears in section 409 only, provides that no substance found to cause cancer in man or animals may be added to food.

In *Les v. Reilly*, the court agreed with the Natural Resources Defense Council's interpretation of the Delaney clause as prohibiting the addition to food of any substance carrying any carcinogenic risk, regardless of how small that risk might be. This means that even negligible carcinogenic risks are prohibited by the Delaney clause. It follows that this interpretation precludes any risk/benefit analysis where even the tiniest risk of cancer is involved. The court disagreed with EPA's interpretation of the statute as containing an implicit exception for negligible risks, although such *de minimis* exceptions have been recognized for other FFDCA provisions.

Results of the Court's Interpretation

The court's interpretation will produce some strange results. For example, because the Delaney clause does not affect FFDCA section 408, a pesticide carrying a negligible risk of cancer could be used on crops that will be consumed raw, such as apples and tomatoes. And because the Delaney clause, which is in section 409, does not affect the "flow-through" provision, pesticide residues

carrying a negligible risk of cancer could appear in processed food—as long as the residue level does not exceed the tolerance limit for the raw commodity.

Thus, for example, a grocery store could legally sell raw apples containing Pesticide X residues that carry a negligible risk of cancer. And the store could also sell applesauce containing residues of Pesticide X, as long as the residues in the sauce were not higher than the tolerance for residues in the raw apples (calculated in both cases as the parts per million of residue in the food).

But if the residues of Pesticide X in applesauce happen to exceed the residues in the raw apples, the Delaney clause would prohibit sale of the applesauce. The applesauce would be legally “unsafe” even if the carcinogenic risk presented by the residues in the apple juice were less than the risk in the raw apple or applesauce. This is an entirely plausible scenario because risks from pesticide residues in processed food may be less than from the same pesticide in raw foods. The reason is the magnitude of risk depends on both the *level* of residue and the *amount* of food consumed.

Considered in conjunction with EPA’s policy regarding the coordination of its various pesticide regulatory authorities, the court’s interpretation of the FFDCA statutory framework produces even more striking anomalies. As mentioned above, it is EPA’s policy not to issue a section 408 raw crop tolerance or FIFRA registration if a section 409 food additive regulation is needed but cannot be granted for a processed food that could be made from the crop.

Under the *Les v. Reilly* decision and EPA’s coordination policy, to continue the example above, EPA would prohibit pesticide residues in apples, applesauce, and apple juice, and consequently, the pesticide could not be used on apples. All applications to apples would be prohibited, even though only the residues in apple juice, a processed food, could not be approved under the governing statutes.

Under this scenario, whether or not a pesticide concentrates during processing is more important than the level of resulting risk, if any. The fact that residues concentrate in one processed food—rather than the level of carcinogenic risk in any raw or processed food—eliminates the pesticide from U.S.

markets for use on that food. Contrast this outcome with the outcome of the statutory and regulatory scheme on use of Pesticide Y, which is also applied to apple crops and has a carcinogenic risk similar or greater to pesticide X, but which does not concentrate. Because the “non-concentrator” does not need a section 409 food additive regulation, its use is not governed by the Delaney clause.

Consequently, if Pesticide Y can meet the standards in FIFRA and FFDCA section 408, the Delaney clause has the effect of increasing the public’s dietary cancer risk from pesticides by keeping the lower-risk pesticide off the market. Not surprisingly, in its report entitled *Regulating Pesticides in Food: the Delaney Paradox* (1987), the National Academy of Sciences concluded that the FFDCA’s focus on the concentration-during-processing criterion “make[s] no discernible sense in terms of public health protection.”

Conclusion

The current framework is illogical in that it results in opposite outcomes for pesticides having similar risks, benefits, costs, and efficacy. The situation becomes even more troublesome when the anomalies in the law result in the elimination of safer pesticides in favor of

more risky pesticides.

Thus, the appeal court’s ruling that the Delaney clause contains no implicit exception for negligible or *de minimis* carcinogenic risks, and the Supreme Court’s recent decision not to consider the case, highlights the need for all parties to begin a working dialogue to resolve the controversy. The goal should be to come to an agreement on how to proceed to ensure the nation’s pesticide safety laws provide the best available protection to consumers.

In the meantime, EPA will necessarily begin action to rescind the food additive regulations for the four pesticides that were at issue in the appeals court decision. Moreover, on February 2, 1993, the Agency publicly released a list of over 30 pesticide chemical/crop combinations that might also be affected by the court decision and EPA’s current policies. In addition, on February 5, EPA published in the *Federal Register* a notice soliciting public comment on pesticide regulatory reform. The notice invites public comment on issues related to the Delaney clause and the *Les v. Reilly* decision, including the petition of the National Food Processors Association. The *Federal Register* notice requests comments to help the Administrator formulate policy on how to deal with these complex and serious policy issues. □



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The Delaney Clause: Point/Counterpoint

Let's reform a failed food safety regime

by Al Meyerhoff

The essential premise of the Delaney clause of the Food, Drug, and Cosmetic Act is as simple as it is powerful: What we understand best about carcinogens is the limited extent of our knowledge. Accordingly, the famous clause is grounded in a policy of prevention: prohibiting the addition of carcinogens in the food supply to prevent avoidable cancers in humans. This approach was deemed necessary by Congress since the entire nation's population would otherwise be routinely exposed to carcinogens in their daily diet.

More than three decades after the Delaney clause was enacted in 1958, the public policy issue now presented is whether science has evolved to the point where this premise is no longer valid. Are the principles and practice of cancer risk assessment up to the task of providing complete protection from cancer to consumers exposed to carcinogens in their food? Or, to put the question differently, Can those industries responsible for that exposure affirmatively demonstrate that it does not jeopardize public health?

Perhaps unfortunately, but demonstrably, the answer remains no. Inevitably, to quote from a *Federal Register*

notice published by EPA in 1991 (56 FR 7750, 2757), "There are inherent uncertainties in quantitative risk assessment because, among other things, of the necessity of relying on data from animal studies to predict human risk."

As a result, the same starting data in risk assessments can yield predictions that vary over several orders of magnitude, depending on the assumptions that go into the model. As FDA Deputy Director Robert Scheuplein

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Since the Delaney clause
was enacted, pesticide
use has increased
dramatically in the
United States.

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warned in 1987, in a paper called "Risk Assessment and Food Safety: A Scientist's and Regulator's View," agencies like EPA "risk losing the integrity of the science and objectivity they need from it by continuing to suggest risk assessments are better than they are and that cancer risk can be so clearly self-evidently dismissed as *de minimis* solely on a scientific basis. We

have not seen a scientific breakthrough which now permits the precise assessment of low-level cancer risks."

Existing risk assessments also virtually ignore the special risks toxic chemicals may pose to infants, young children, or various subpopulations, yet they may be at greatest risk from dietary exposure to carcinogens. Moreover, taking a chemical-by-chemical, use-by-use approach as the long-term policy objective, rather than an interim step to overall pesticide use reduction, ignores the fundamental deficiency of risk assessment—that it looks at only one chemical at a time.

The reality of life is that we are exposed to a multiplicity of toxic substances. Calculating the combined risks of these exposures is problematic; some 300 pesticidal active ingredients are used on food as well as an imperfectly examined large number of "inert" ingredients. For the most part, existing EPA pesticide tolerances for allowable pesticide residue levels do not even attempt to calculate the aggregate human health risks presented, nor do they address the cumulative and synergistic effects on multiple pathways of exposure. For this reason, ultimately, the overall policy underlying the Delaney clause—that we should avoid unnecessary and involuntary exposure to cancer-causing agents—remains as valid today as when enacted.

(Meyerhoff is a Senior Attorney in the San Francisco office of Natural Resources Defense Council.)

In the subsequent commentary, perhaps seeking a "quick fix," industry representative Clausen Ely focuses on a rather arcane question: whether EPA's policy that pesticides that concentrate during processing must be treated as food additives subject to the Delaney clause is lawful and correct. It is both. But the far more important question is how what most acknowledge to be a failed food-safety regulatory regime can be reformed. The importance of this cannot be overstated. During the Reagan administration, in describing dietary risk, the former Director of EPA's Pesticide Program said, "Pesticides dwarf the other environmental risks the Agency deals with. Toxic waste dumps may affect a few thousand people who live around them. But virtually everyone is exposed to pesticides."

Yet, to date, EPA's consistent approach to carcinogens in food has been to ignore or evade the Delaney clause, the most health-protective statute governing pesticides. This approach is no longer legally permissible. Last July, a U.S. Court of Appeals held in *Les v. Reilly* that pesticides present in processed foods, either due to concentration during processing or post-harvest application, are subject to the strict proviso of the Delaney clause that "no [food] additive

shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." The Agency's *de minimis* policy, allowing carcinogens based on the purported low level of cancer risk, was also rejected by the court: "The language of the Delaney clause, its history, and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved." EPA has now issued an initial list of 32 pesticides subject to the *Les* rule. Since EPA is unable to determine in most cases which raw commodities will or will not be processed, the presence of these carcinogenic pesticides in raw commodities is foreclosed as well.

Since the Delaney clause was enacted, pesticide use has increased dramatically in the United States, now approaching 3 billion pounds per year. There is also an emerging consensus that the existing food safety scheme, with its different and contradictory legal standards, long delays, and inadequate monitoring and enforcement procedures, is in need of serious reform. In this regard, as EPA Administrator Browner recently noted, the Clinton administration and newly elected Congress will be confronted with important policy choices. However, the fundamental principles reflected in the

Delaney clause—of preventing unnecessary exposure to cancer-causing substances while providing incentives to reduce pesticide use—must be the centerpiece of any new legislation.

Given its vagaries and ambiguities, risk assessment should not, by itself, serve as the linchpin for pesticide reform. Instead, it should be used as an interim tool to achieve a deserved result—overall reduction of the use of pesticides in agriculture and the promotion of alternative technologies. Thus, any legislation reopening Delaney clause issues should necessarily include a scheduled phaseout of food-use pesticides that EPA has found are "probable" human carcinogens, together with incentives for reducing overall pesticide use.

Since the Delaney clause became law, much new scientific knowledge has been developed. Yet we still do not know whether humans are more or less sensitive than experimental animals to various carcinogens. We don't know how to assess the contribution of one carcinogen in relation to the impacts of exposures to other carcinogens. We don't know the cumulative impact of dozens of carcinogens now permitted in the food supply. We should, therefore, follow Rachel Carson's advice three decades

ago: "The ultimate answer is to use less toxic chemicals. This system of deliberately poisoning our food and then policing the result—is too reminiscent of Lewis Carroll's 'white knight' who thought of a plan to dye one's whiskers green and always use so large a fan that they could not be seen."

(Point/Counterpoint continued on next page.)



California public health chemists test apple juice and applesauce for pesticide residues. Under a strict interpretation of the Delaney clause, any residue of a carcinogenic pesticide in processed foods is simply "unsafe"—no matter if EPA finds the risk negligible.

George Olson photo Wide World

The Delaney Clause:

Point/Counterpoint (continued)

An obscure EPA policy is to blame

by Clausen Ely

EPA's current dilemma with respect to application of the Delaney clause to pesticide tolerances is a self-generated problem for which there is a readily available solution. The dilemma is not really caused by a conflict or gap in the law. It stems from EPA's adoption of an obscure administrative policy. EPA is free to rescind that policy, and the National Food Processors Association (NFPA) and a coalition of food trade associations have petitioned the Agency to do so. However, if EPA declines to modify its administrative policy, the *Les v. Reilly* Appeals Court decision of last July is likely to have far-reaching adverse consequences.

The administrative policy in question, EPA's "coordination policy," sometimes called its "concentration policy," requires application of the Delaney clause to pesticide residues in many processed foods. The EPA policy also disallows the raw product tolerances for any pesticide that EPA concludes may concentrate in a processed food but because it triggers the apparent zero-risk standard of the Delaney clause does not qualify for a separate processed food tolerance. This policy is at odds with governing law, inconsistent with pesticide residue survey data, and contrary to the public interest.

(Ely is a partner in the law firm of Covington and Burling and serves as Counsel to the National Food Processors Association.)

Every food-use pesticide must be registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); at the same time, a tolerance must be established for that pesticide use under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for each raw commodity for which use is approved. Both FIFRA and section 408 of FFDCA embody a general safety standard that authorizes EPA to ignore

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**This policy is at odds
with governing law,
inconsistent with
pesticide residue survey
data, and contrary to the
public interest.**

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de minimis or negligible risks, require a risk-benefit evaluation of each pesticide use, and contain no special safety requirement for carcinogens.

Under the "flow-through" provision of FFDCA, a pesticide residue in a processed food is lawful as long as the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw

commodity from which the processed food was made. The clear purpose of the flow-through provision was to apply the same safety standard for pesticide residues in raw *and* processed foods and to avoid the necessity of establishing separate tolerances for pesticide residues in processed food. Where a pesticide residue in a processed food exceeds the raw product tolerance, the food is legally adulterated and the Food and Drug Administration (FDA) has ample authority to seize or enjoin shipment of the product.

EPA's so-called coordination policy ignores the language and intent of the flow-through provision by requiring separate tolerances for pesticide residues in processed food. Because processed food tolerances must be issued under the food additive provision of FFDCA (section 409), EPA's concentration policy imposes the restrictive standard of the Delaney clause on pesticide residues in processed food. Moreover, by linking section 408 and 409 tolerances, EPA's policy unlawfully incorporates the Delaney clause into the standard for raw product tolerances.

Under EPA's policy, a separate processed food tolerance is required whenever EPA concludes, on the basis of conservative processing studies, that it is hypothetically *possible* for the processed food residue to exceed the raw product tolerance. However, extensive residue studies conducted by the U.S.

Department of Agriculture, the FDA, and the food industry demonstrate—and EPA has conceded—that, in fact, pesticide residues in processed food rarely, if ever, exceed raw product tolerances. This is because raw commodity tolerances are set at levels to ensure that all legal applications of a pesticide will result in residues below the tolerance level, and residues in raw crops are generally reduced through processing and otherwise greatly dissipated prior to sale as processed products. Thus, not only is EPA's concentration policy inconsistent with the statutory scheme, but it does not reflect marketplace reality.

In view of the importance of EPA's concentration policy, it is surprising that the policy is not explicitly set forth in any regulation. Nor has it been legitimized through notice-and-comment rulemaking. Although the Appeals Court held in *Les v. Reilly* that EPA has no discretion to permit *de minimis* risks under the Delaney clause, the court did not rule on EPA's concentration policy. Nothing in the court's decision indicates an endorsement of EPA's policy; nothing indicates any agreement that there is a

reasonable legal or factual basis for the policy.

Clearly, however, retention of the EPA coordination policy, coupled with the court's restrictive interpretation of the Delaney clause, will lead to the loss of numerous valuable food-use pesticides. Although the *Les v. Reilly* case directly involved only four pesticides, EPA has acknowledged that more than 30, and probably more than 60, food-use pesticides may be required to be banned as a consequence of the decision: This will be the case if EPA continues to require separate tolerances for processed food and to revoke the raw commodity tolerances for pesticides that are ineligible for processed food tolerances. The result will be multiple adverse public health impacts.

- First, the reduced number of effective pesticides will disrupt agricultural production, diminish food quality, increase food costs, and reduce the availability of nutritious fruit, vegetable, and grain products. Farmers will be hurt, consumer choice will be restricted, and the public health will suffer, without any countervailing social benefit.

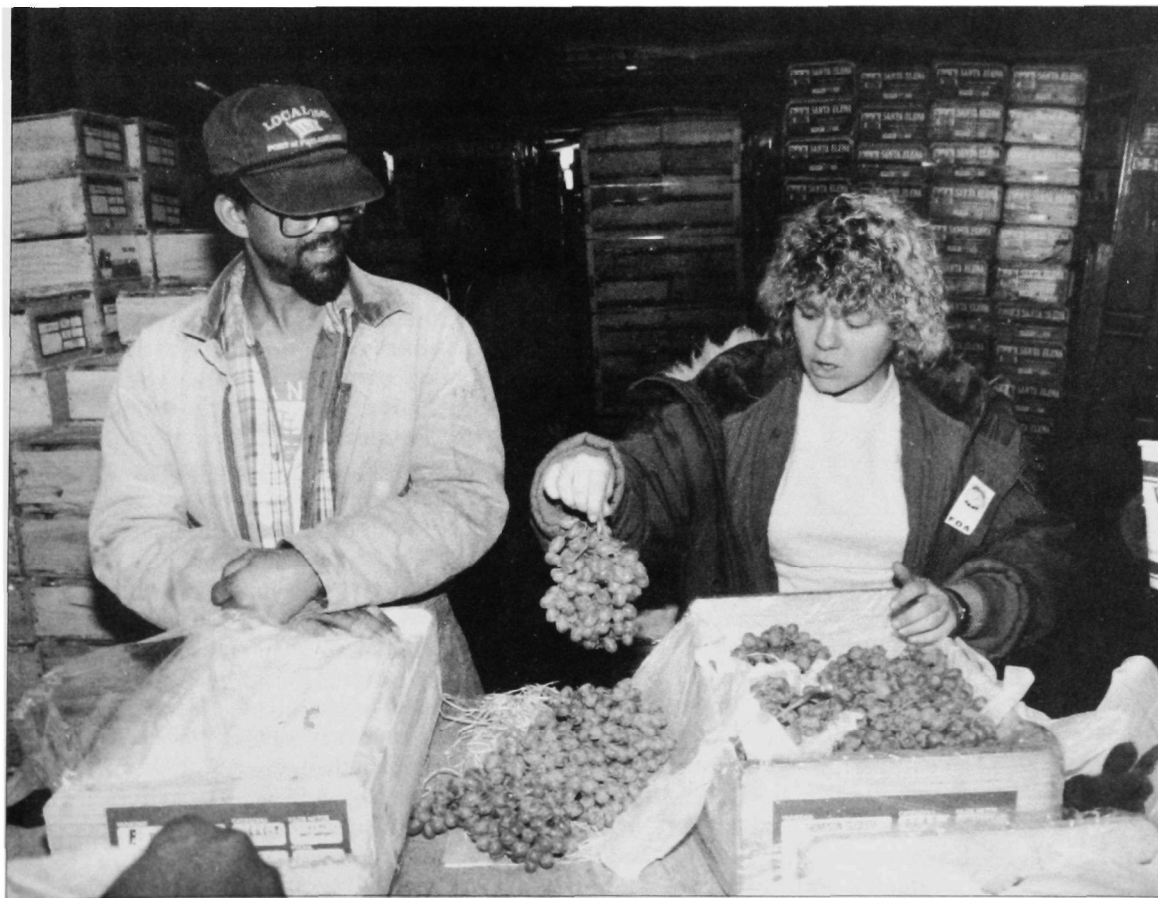
- Second, EPA will be required to undertake lengthy and burdensome administrative proceedings to revoke existing tolerances for pesticides now conceded to pose negligible cancer risks. This will divert already strained EPA resources.

- Third, the risk to the public will be increased by forcing EPA to ban beneficial pesticides that pose *de minimis* cancer risks and requiring the substitution of pesticides posing greater health risks which are not associated with cancer.

- Finally, EPA prohibition of pesticides approved and used in other countries, which export food products to the United States, will have an adverse impact on international trade.

EPA's pesticide program is constrained by many unavoidable burdens and challenges. It is difficult to understand why EPA has elected to saddle itself with the enormous additional burdens associated with an inappropriate administrative policy. It is unnecessary and counterproductive for EPA to superimpose its so-called coordination

policy on statutory tolerance requirements that were designed to work perfectly well without it. Accordingly, as the NFPA et al. have petitioned, EPA should effectuate Congressional intent and avoid the current Delaney clause impasse by rescinding this policy. □



A Food and Drug Administration official inspects imported fruit. FDA is empowered to seize or enjoin shipments of foods that do not comply with pesticide residue limits set by EPA.

Wide World photo

A Legislative Proposal

Why not enact a law that would help us set sensible priorities?

by Senator Daniel Patrick Moynihan

Environmental decisions are difficult in any circumstance, and especially so when the economy is weak and there is competition for resources both in the private sector and in government. People want a clean environment, but they don't want to pay more than is necessary. We can't do everything at once. The question of priorities arises, almost unbidden. We would rather not have to think this way but there you are. The choice is not between having priorities or not having them. Rather it is between setting them consciously or setting them by default. An informed and involved public is critical to setting workable priorities and acting effectively. Easier said than done!

I am convinced that risk ranking and cost-benefit analyses are valuable tools for making environmental decisions. They are not our only tools, but they do offer the means to set priorities and to measure success. It took over half a century for the dedicated public servants in the Bureau of Labor Statistics and the Council of Economic Advisors to learn how to fashion economic indicators. It will no doubt take a long time to develop

(Sen. Moynihan (D-NY) is the former chairman of the Committee on Environment and Public Works and chairs its Subcommittee on Water Resources, Transportation, and Infrastructure.)

a reliable methodology to assess costs and benefits of environmental regulations, and to reliably measure the risks associated with environmental exposures. But this is no reason not to begin. If we don't start now, we will never learn. And it must not be forgotten that there are some things that science cannot tell us. Values, for instance. Do we care more about this species or that

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Let us have the courage
and foresight to make a
conscious decision.
In public.
With people watching.

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one? Or fairness. Some questions are a matter for the legal system, not for scientists.

But we do have problems. During the presidential campaign and transition, much discussion focused on the economy, getting and keeping it going. At a hearing last September on the bill I proposed as the Environmental Risk Reduction Act, Dr. Paul Portney of Resources for the Future testified that compliance with environmental laws

costs about \$130 billion per year—something like 2.2 percent of the U.S. gross national product (GNP). Our next closest competitors in terms of money spent on environmental protection, perhaps not surprisingly, are Germany and Japan, which each spend about 1.6 to 1.8 percent of GNP. While this may not be too much money to spend on environmental protection, it is too much to spend unwisely.

Obviously, we are seeing a new trend. Federal environmental laws are being questioned by state and local governments, which say they can't afford to comply with all environmental laws. Their resources are finite and must make do for competing needs such as maintaining roads and providing social services. For example, a report done for Columbus, Ohio, indicates that new environmental initiatives will cost Columbus more than \$1 billion over the next decade—an extra \$856 per year of local fees or taxes for every household in the city by 2000. (See article on page 48.) Another study showed a similar impact in eight other Ohio cities.

As far as we can tell, this pattern is being repeated in other places. An editorial in the January 8, 1993, issue of *Science* magazine alerts us to the "growing questioning of the factual basis for federal command-and-control actions," all because of concerns over

regulatory costs. The message is clear. State and local governments will hold Congress and EPA more accountable in the future about obligating them to spend their resources on federal requirements. They will want "proof" that there is a problem and confidence that the legislated solution will solve it. California's threat to return enforcement of its drinking water program to EPA last spring speaks volumes. The most environmentally advanced state in the Union close to rebellion—a sobering prospect. The *Science* editorial suggests we are seeing the "beginning of a revolt."

Clearly risk ranking and cost-benefit analyses aren't the sole factors for decision making. Social concerns (who should bear risk for whose benefit?), public preference, and basic fairness must be considered too. Truth be told, I suspect that environmental decisions have been based more on feelings than on facts. This is understandable in a prescientific field, but we are being overtaken by events. The questions that are key to making decisions about the environment are slowly but surely being identified.

There are those who dismiss relative risk ranking because the assumptions

needed to assess risk are myriad. Facts often seem scarce. What are we exposed to? What effects does this produce? What portion of the population is affected? Or might be affected? There are no precise answers to these questions. And so risk assessments are controversial, at times very controversial. But we cannot forget that knowledge need not be precise to be useful.

Relative risk ranking and cost-benefit analyses are tools. Crude tools today, yes, but perhaps they are sufficient in some cases to rank activity "A" as riskier than activity "B." Costs or political realities may dictate that we should control "B" before "A." Let us have the courage and foresight to make a conscious decision. In public. With people watching. History shows that crude tools give way to more refined ones. Experience teaches.

Last session, I sponsored the Environmental Risk Reduction Act to help advance the practice of environmental risk assessment and cost-benefit analysis. The bill would put into law the major findings of the 1990 *Reducing Risk* report by EPA's Science Advisory Board. I introduced the bill because I agree with former EPA

Administrator William Reilly's belief that science can lend much needed coherence, order, and integrity to costly and controversial decisions.

In September 1992, we held a hearing on the Act before the Committee on Environment and Public Works. There wasn't time to modify the bill and bring it to the floor in the last Congress, so I have introduced S.110, the Environmental Risk Reduction Act of 1993, as a first-day bill in the 103rd Congress.

America's environmental laws are a large and diverse lot. We have only two decades of experience on this subject, and we are still learning, feeling our way. The relative risk ranking and cost-benefit analyses called for in my bill provide some common ground for looking at our environmental laws. The bill also provides the public and Congress with access to the findings. To quote from *Reducing Risk*, "relative risk data and risk assessment techniques should inform [the public] judgment as much as possible." Not dictate it, but inform it.

All this will take time, decades perhaps. But let us take heart. Questions that seem difficult now can, with a certain amount of effort, yield to the scientific method. □

B.C.

By Johnny Hart



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What's A City to Do?

Columbus, Ohio, documents its problems with the feds

by Edward F. Hayes

With the recent flurry of federal environmental laws, Columbus, Ohio, like other cities, is facing dramatically higher compliance costs. These costs will compete with spending on other priority needs such as education, health care, and public safety. Columbus wants to be sure that mandated spending for environmental compliance yields the greatest possible benefit. However, the uncertainties in environmental risk assessments and the failure of federal laws to account for local variability lead inevitably to inefficiencies. As communities have begun to look at the costs involved and at the competing financial priorities, critical questions have been raised about the particular means that these laws have mandated to achieve our environmental goals.

Environmental laws already on the books will cost this city of 632,910 people more than \$1 billion (1991 dollars) in the next decade, according to a recent study, *Environmental Legislation: The Increasing Cost of Regulatory Compliance to the City of Columbus*. Columbus, with an annual budget of \$591 million, spent \$62 million on environmental compliance in 1991. In 1995, the figure will be about \$107 million, in 1991 dollars. By 2000, each Columbus household may pay \$856 per year in new costs to meet these requirements. (The figures exclude private sector compliance.) The Ohio

(Hayes is Vice President for Research for Ohio State University and the chair of Columbus's Environmental Science Advisory Committee.)

Metropolitan Report Work Group has found that other Ohio cities face even heavier costs.

Federal regulatory laws increasingly require local and state action without providing federal funds to help. Congress has released a flood of such environmental mandates in the past few years, under the authority of several laws: the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act (SDWA), the Resource Conservation and Recovery Act, underground storage tank regulations, amendments to the Superfund legislation, the Asbestos

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Cities have a unique perspective on priority setting that needs to be heard.

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Hazard Emergency Response Act of 1986, and others. With these regulations have come myriad state and federal agencies to ensure compliance.

In some cases, there is room for doubt that the risks or costs—especially at the local level—are properly estimated in preparing some federal regulations. The risk assessments themselves are subject to great scientific uncertainties. In addition, the laws' requirements may offer too little latitude for local adaptation. Thus, we may be paying too much for small

benefits while larger ones go begging. Today's fiscal conditions make such inefficiency doubly unacceptable.

New amendments to the SDWA illustrate both the rigidity and uncertainty of some federal regulations. Under the amendments, water utilities must analyze drinking water for at least 133 specified pollutants, beginning in 1993. Many of the substances are not present in significant quantities in Ohio. One of them, DBCP, a chemical whose use was discontinued 15 years ago, was used almost entirely on pineapples in Hawaii. EPA's promised guidelines on the conduct of "vulnerability assessments"—which project local impacts of a particular pollutant—to obtain local waivers have not appeared. Regulations that let state and local governments develop their own water quality programs could produce better results at lower cost.

The herbicide atrazine, used widely on Ohio cornfields, is an example of the costs of scientific uncertainty in SDWA regulations. Because of certain effects on the offspring of rats and the hearts of dogs at very heavy doses, atrazine is deemed dangerous for humans. Atrazine levels, therefore, need to be monitored quarterly at each surface water intake, and twice yearly at ground water intakes. If a yearly average of those measurements exceeds 3 parts per billion (ppb) of atrazine, the city will need to take action.

From previous measurements we know that Columbus's water supply exceeds the standard every year or two,



The herbicide atrazine is commonly used on Ohio cornfields. Under a federal EPA regulation, the city of Columbus must monitor its water supplies for the presence of atrazine and take action if yearly average measurements exceed 3 parts per billion—a costly prospect for the municipality.

Gene Alexander photo. Soil Conservation Service. USDA.

in brief “spikes” triggered by rainfall in spring and summer. Thus, although typical levels are far below 3 ppb, the city may be required to install costly EPA-specified technology for atrazine removal.

In the face of such costs, the weakness of the science underlying the standards is troubling. The chain of reasoning is tenuous by which the effects of massive short-term doses to rats are extrapolated to estimate the risks to humans of infinitesimal but long-term doses. The uncertainties are such that regulators add a safety factor of 1,000 to their best estimate of the risk: a factor of 10 to account for the extrapolation from animals to humans, another factor of 10 to protect the most susceptible people, and a third factor of 10 to account for the fact that atrazine causes mammary tumors in rats at very high doses and is therefore rated a “possible carcinogen.”

Uncertainty is inherent in environmental regulation, of course. Society must be conservative in estimating risks, or it may be taken by surprise by unsuspected illness or death. But attempts to reduce uncertainty should accompany (if possible, precede) any major regulatory legislation. A costly regulatory program like the SDWA needs to be guided by research to quantify risks.

Consider the benefits of reducing uncertainty, so that atrazine could be regulated with a safety factor of, say, 100, instead of 1,000. The upshot might be higher or lower atrazine standards, but the better defined risks would give a

clearer sense of priorities. Columbus might find, for example, that money spent on health clinics for poor neighborhoods would save more lives than the federally mandated technology for controlling atrazine.

Consider, too, the benefits of better local knowledge. A national data base of agricultural chemical use by watershed would let EPA tailor regulations locally. Columbus would need to monitor only the chemicals known to be present. Instead of the rigid “best available technology” requirement, Columbus and federal regulators might negotiate alternatives for safeguarding health, such as reducing runoff from fields or finding ways to alter atrazine use in the watershed. There is no such data base.

Sen. Daniel Patrick Moynihan (D-NY) has offered a plan for working toward better environmental priorities in his proposed Environmental Risk Reduction Act. Moynihan’s bill would require EPA to seek independent advice in ranking environmental risks and benefits, to fund scientific research on risks, and to use this information in managing regulatory resources. Among other things, EPA would develop and publish risk assessment guidelines for the range of environmental risks, and promote consistency and technical quality in these assessments—a requirement for setting priorities.

No matter how sound EPA’s risk assessments are, of course, Congress will remain the source and shaper of most environmental regulation. Regulatory priorities can benefit from better scientific

analysis but will continue to be set by politics and public opinion. Still, the act would make EPA a more potent force for rationalizing regulatory programs by giving legislators objective information about risks and the costs and benefits of abating them.

At the local level, we in Columbus have embarked on an important experiment in cooperation with federal regulators. Mayor Greg Lashutka has established the Environmental Science Advisory Committee (ESAC) as a source of independent scientific and engineering advice about environmental risks and remedies. ESAC, as requested by the mayor, will assess the scientific rationales of current and proposed federal and state environmental regulations. Such reviews, we hope, will give the city the information needed to cooperate with federal regulators and legislators in shaping environmental requirements and strategies that meet local needs. If successful, the state of Ohio may want to replicate the program and devise a network of advisory groups that could assist communities that lack the capacity for such a program.

The early landmark environmental statutes, such as the Clean Water Act and Clean Air Act, brought dramatic improvements in relatively short order through a cost-sharing partnership of federal, state, and local governments. The risks that regulators set their sights on today are increasingly subtle, uncertainties correspondingly great, and gains more costly. Costs are more likely to be borne locally.

The nation must be sure the greatest risks are tackled first and in the most cost-effective way. Cities have a unique perspective on priority setting that needs to be heard. They know that diverting funds from schools, police protection, and assistance to the poor to deal with environmental mandates can have a hidden “toxic” effect that can be more lethal than the environmental toxicity that needs to be eradicated. □

Alternative Paradigms

Comparative risk is not the only model

by Adam M. Finkel
and Dominic Golding

We suspect that one of the enduring legacies of EPA in the 1990s will be the way it defined its central problem and the solution it advocated. The problem statement is relatively noncontroversial: EPA's budgetary and regulatory priorities, and consequently the nation's overall environmental agenda, have become so haphazard that large amounts of financial and human resources are being wasted, while at the same time, serious problems are being ignored or glossed over. The solution is not as widely accepted—that EPA should use scientific judgment to identify the best opportunities for reducing risks to health and the environment and should try to shift resources and our national attention accordingly.

Over the past decade, the practice of assessing the risks of individual substances has been applied routinely in the regulatory process; it has gained ardent supporters as well as detractors. Both the strengths and the weaknesses of this "plain vanilla" risk assessment are magnified as it takes on the new task of comparative risk assessment (CRA)—ranking a portfolio of disparate risks. Prompted by EPA's *Unfinished Business* report in 1987 and spurred on by the 1990 Science Advisory Board report *Reducing Risk*, many observers have stressed the advantages, if not the necessity, of using CRA to set priorities. "Our most reliable compass in a

turbulent sea of siren songs" was the metaphor former EPA Administrator William K. Reilly coined in his speech releasing *Reducing Risk*.

Other observers have questioned the methods and feasibility of CRA or have tried to slow the momentum toward an environmental agenda built on estimates of risk. However, most of these criticisms have been somewhat marginal rather than fundamental. For example, an entire issue of *EPA Journal* in 1991 was devoted to endorsements of and caveats about CRA, but nearly all of the critiques (including one written by one of us) assumed that as long as we could

improve CRA by firming up its scientific underpinnings and/or "soften" it by actively involving laypeople in the ranking exercises, it would remain our best chance to achieve more sensible priorities.

The Center for Risk Management at Resources for the Future convened a national conference in November 1992 at which many familiar as well as some novel suggestions for improving CRA were aired. The conference was perhaps the first occasion in which leaders from diverse fields and organizations also debated fundamentally different ways to set environmental priorities.

Environmental Justice Paradigm

Robert Bullard, professor of sociology at the University of California-Riverside, asserted that environmental protection is not a privilege to be doled out according to a process of "environmental triage," but a right for all individuals. Bullard accused CRA of helping to institutionalize a system of unequal environmental protection across racial and class lines, and cited a litany of examples, including: inattention or delayed attention to problems that affect minorities and the poor (e.g., lead in paint); preferential siting of hazardous waste facilities in minority communities; a high correlation between the proportion of minorities in a given county and the levels of criteria and toxic pollutants therein; and EPA's alleged preference for conducting less ambitious cleanups of Superfund sites in minority communities than in

predominantly white communities. Bullard alleged that risk-based priority setting may perpetuate our failure to tackle these true "hot spots" and argued for an environmental justice approach which puts priority on all of the obvious geographic areas where minorities and the poor face multiple risks from many sources.

Albert L. Nichols, of National Economic Research Associates Inc., claimed, instead, that such a rights-based framework might actually harm those it was intended to protect by returning our society to the *status quo ante* when political power determined environmental priorities. Nichols also claimed that the more intensive protection Bullard advocates would carry with it higher costs that would be borne primarily by the lowest income groups.

(Finkel and Golding are Fellows in the Center for Risk Management (CRM) at Resources for the Future.)

The State of the Art

It was evident from the presentations and discussions at the conference that despite widespread enthusiasm for using empirical information to rank environmental problems, CRA has serious drawbacks. Methodological problems thwart all efforts to rank risks reliably; the most prominent seem to be how to address issues of uncertainty, variability, and commensurability, especially given major data deficiencies. No less daunting is designing a ranking process that blends expert judgment with public values, while at the same time avoiding other forms of elitism and undue influence from special interests. Finally, the biggest obstacle to implementation seems to be that of maintaining a logical priority-setting process that still gives states the flexibility to respond to local concerns in a timely fashion.

Criticisms and Alternatives

Many of the criticisms of CRA raised during the first half of the conference were serious and potentially daunting, but none of them really called into question two basic tenets of the current mainstream of thought about environmental priority-setting:

- Risk reduction, broadly construed, is the *raison d'être* of environmental programs, and hence of environmental resource allocation.
- Risk assessment—or at least a “softer” brand of analysis—is the right way to gauge how large, or how socially important, various problems are and is the right guide for reducing risks efficiently.

Clearly, EPA's efforts over the last four years have squarely embraced both this goal and this means—the Agency has essentially defined “risk-based priority setting” as encompassing a reordering of priorities both *for* risk reduction and *by* risk reduction.

The second half of the conference opened up the debate to include fundamentally different premises. Two speakers questioned the advisability of

making risk reduction the fundamental goal of environmental protection, while a third embraced risk reduction as the goal but asserted that the greatest advances can come via a wholly different type of analysis. (See boxes.)

Interestingly, although all three speakers eschewed or downplayed CRA, they did not seem to be viscerally opposed to risk assessment *per se* or ignorant of its details, which is the caricature some observers draw of the clash between “rationalism” and its opponents. Rather, they clearly saw the virtue of CRA as one tool to inform the debate, but had concerns that were unaddressed by (though not necessarily antithetical to) the quantitative outputs of risk assessment exercises. We see their efforts as more enriching than divisive, as we believe our national debate over environmental protection should not begin and end with discussions of the *consequences* of our actions, but must leave room for the discussion of moral duties and proscriptions.



Some poor and minority communities experience a disproportionate pollution burden. Proponents of environmental justice say equity issues may fall by the wayside in risk-based priority setting.

Steve Delaney photo.

Conclusions

Our conference ended just as it seemed to be poised to offer practical answers to the central questions of how our environmental priorities ideally should be set. As two of the organizers, we believe we can identify three emerging themes in this debate where our participants seemed to be moving toward common ground. First, wherever it is being pursued, a “hard” version of CRA needs to be “softened” by incorporating public values concerning the more elusive qualities of risk, such as voluntariness, dreadedness, blame, and so forth; risk is a complex, multi-dimensional concept that cannot be characterized adequately on the basis of one or two attributes. Second, citizens and state and local governments need more

than mere access to the priority-setting debates; they need to be “empowered” as integral players in the process. Third, although quantitative risk estimates should not necessarily have the status of “trump card” over other factors, we should continue to refine them and give them serious consideration.

There was much less agreement, however, over the question of whether the paradigms that had been presented were really in conflict or could be pursued simultaneously. Some participants seemed to resent being asked to choose among “risk, prevention, justice, and innovation,” saying they were for all these ideas equally. Others found it ironic that, at a conference about how society can't address every environmental problem at once, some “rationalists” were arguing that society can embrace every priority-setting framework at once.

The real conflict, then, if there is any, consists in whether one or more of the three non-risk approaches—or still other

Pollution Prevention Paradigm

Barry Commoner, director of the Center for the Biology of Natural Systems at Queens College, distinguished between two fundamental strategies for solving environmental problems: "end-of-pipe" control *versus* pollution prevention. He argued in favor of pollution prevention as the preferred strategy and in favor of public opinion as the only means for setting priorities that logically follows from that choice for two reasons. Commoner first argued that CRA is wedded inextricably to the "failed national enterprise" of pollution control, because it is designed to identify the largest risks and only reduce them down to the level of the rest of the "environmental landscape." Secondly, he observed that pollution prevention on a large scale, such as a shift to electric

cars, would engender massive social and economic changes, which may make the environmental impacts "a subsidiary, though welcome, consequence rather than the prime mover." Logically, only public judgment is broad enough to determine if these changes are desirable, he said; CRA is not.

John Graham, professor of health policy at the Harvard School of Public Health, countered that pollution prevention and CRA are complementary, not mutually exclusive, because pollution prevention is just one strategy for tackling high-priority problems identified by CRA. In some cases, prevention may even be more expensive than control, or may present new risks.

approaches, such as targeting resources to geographic regions, setting priorities via "regulatory negotiation," or having Congress reconcile conflicts among statutory mandates—should be grafted on to a risk-based foundation, or whether they should flourish on their own, with CRA as the subsidiary consideration.

Although we aren't prepared to endorse any particular method (or combination thereof), we strongly believe that at the very least it *does* matter, both symbolically and functionally, which organizing principle for priority setting emerges as the "default" or "the trump card." For one example of how important this distinction might be, consider the same set of problems as addressed by two different ranking schemes. Among the long list of environmental problems that EPA is trying to prioritize are risks that are exacerbated by single, nondurable consumer products, such as the daily newspaper. Production of this good contributes to the nation's water pollution problems, to air pollution, to the shrinking capacity of solid waste landfills, to deforestation, and to other problems outside EPA's purview, such as occupational hazards. If this problem is seen as a collection of risks we should try to control or prevent in some rational sequence, the path towards amelioration is clear: Eventually, the newspaper producers would install pollution control devices on their effluent points and on

their process and fugitive air-emission points, change to less toxic inks, encourage more recycling of newspapers, plant more trees, etc.

Suppose, instead, that our first cut at setting priorities used a "solution-based" approach, such as Ashford's model. (See box.) Government might then consider, among a menu of actions, subsidizing or otherwise promoting the development and proliferation of user-friendly electronic newspapers, wherein ink never touches paper. A similar net amount of risk reduction—that is, risks reduced minus any new risks created by

the control devices or by the new electronic product—might eventually come by either path. But the speed and efficiency of the transformation might be far greater in the latter case, and the net cost to the economy might be far less.

If space permitted, we could sketch out an analogous example contrasting the risk-reduction and social-transformation consequences if risks to particular minority and poor communities were addressed either as special priorities under a CRA framework or as the centerpieces of a "reduce first, assess later" scheme. Such examples merely scratch the surface, however. The point is that, as risk assessment practitioners, we personally have no desire to turn society's back on this useful tool. Indeed, we would encourage experts and representatives of the public to come together to craft a broader, less restrictive, and more reliable version of CRA, whatever its final role might be. We believe that the unsettled end to the conference in November augurs well for the future, as it leaves open the door to a broader national debate on the choice of priority setting tools, strategies, and goals. □

(For a detailed synopsis of the conference "Setting National Environmental Priorities," which was sponsored by CRM with financial support from the Pew Charitable Trusts, EPA, the Chemical Manufacturers Association, and the U.S. Department of Energy, contact the authors via fax at (202) 939-3460.)

Technological Innovation Paradigm

Nicholas Ashford, professor of technology and policy at the Massachusetts Institute of Technology, asserted that strict regulation, properly designed, can trigger technological innovation and yield more risk reduction at lower cost than can risk-based priority setting schemes. He argued that existing approaches have ceded too much control to the polluting industries, triggering only the diffusion of existing technologies. Rather than attacking the "worst risks first," he said, EPA and other agencies should identify which industrial sectors are most "ripe" for innovation, perhaps to the extent of adopting enforcement strategies that

give some leeway to companies experimenting with new prevention or control ideas. If agencies made these areas their high priorities, he argued, products and processes that create many risks could be improved in a directed rather than a happenstance manner.

James Wilson, regulatory issues director for Monsanto Co., endorsed the promotion of innovation but was skeptical about the efficacy of Ashford's proposal. He emphasized that individual companies seldom know which innovations will succeed environmentally or economically and said it is folly to believe that the federal government would know better.

Going Electric

A book review by Karen Flagstad

Thinking of buying a commuter car? Maybe you should think electric. No gas. No oil. No antifreeze. No guilt about heavy duty emissions during all that stop-and-go driving

Too futuristic, you say? Consider these facts from transportation history:

- On the first day of this century, nearly half the cars in the United States were electric. True, there were only a few thousand motorcars in this country then. But by 1910, the number had grown to 458,000, and still nearly half of these were electric.
- Ninety years ago, all the taxis in New York City were electric vehicles.
- The first electric ambulance in the United States went into service in February 1900. It delivered patients to St. Vincent's Hospital in Manhattan.
- In 1903, eastern Massachusetts had a network of 42 battery charging stations, analogous to gasoline filling stations, for servicing electric motorcars.
- Not gasoline powered cars but electric vehicles were the first to feature power steering. As early as 1897, electric taxis with power steering were cruising around Paris.

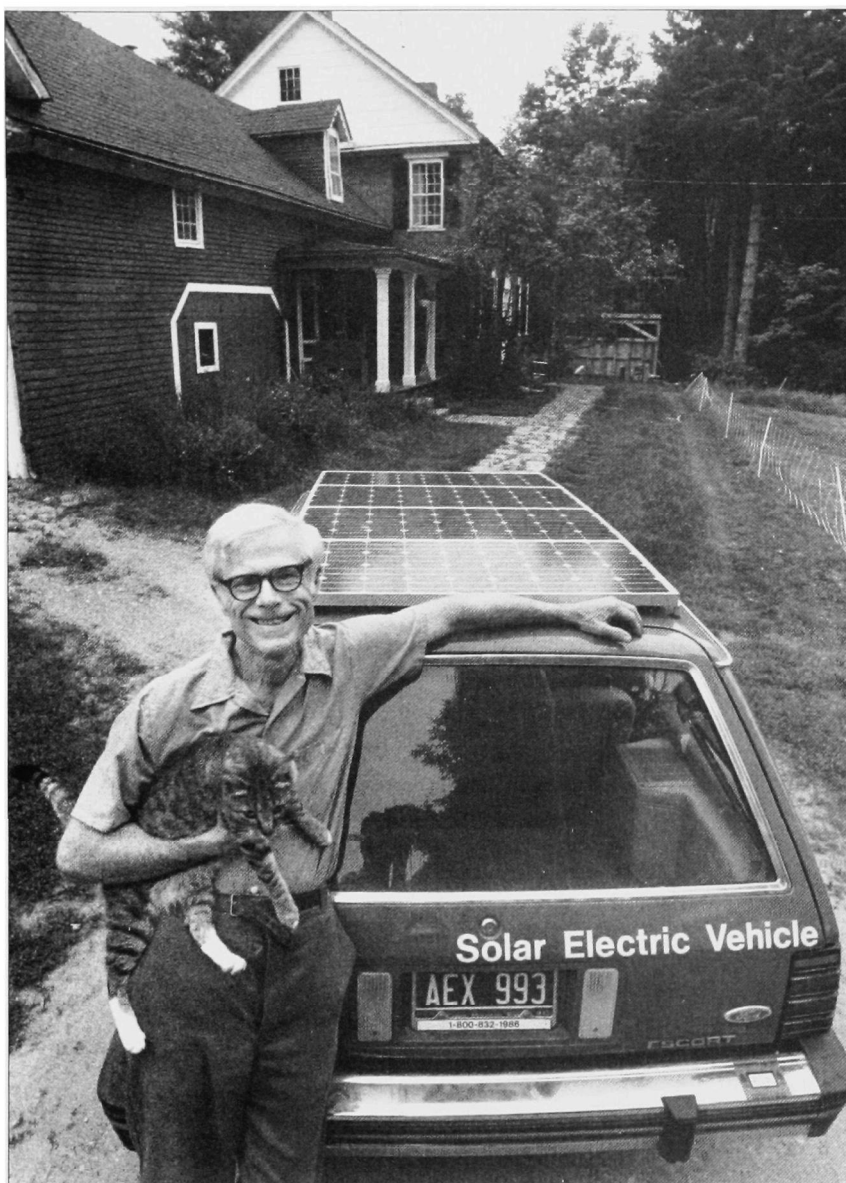
In *Solo: Life with an Electric Car* (W. W. Norton, 1992; 191 pages), Noel Perrin, a professor of Environmental Studies at Dartmouth College, tells two stories—one historical concerning the rise and decline of the electric car in the early decades of this century; one personal, dating from his decision in January 1990 to acquire an

environmentally friendly commuter car of his own. The several events mentioned above are just a few pieces of the historical narrative that weaves in and out of Perrin's tale of how he came to own and operate the shiny red solar electric car that earned the name "Solo." The eponym has a double meaning: It refers to Solo's solitary adventures on U.S. highways vastly dominated by gasoline powered cars and trucks, and it alludes to solar energy. (Solo has six solar electric panels, four on the roof and two on the hood, and Perrin, determined to have a clear conscience when he walks into Environmental Studies class, has equipped his Vermont farmhouse with 28 solar panels that generate energy to recharge Solo's 18 batteries.)

Readers of Perrin's book may be surprised at the early prominence that electric cars had in this country. Yet early electric vehicles had several advantages over their gasoline driven competition: They started up easily with the turn of a key (no cranking required); they operated cleanly and quietly, whereas the early gas cars were notoriously dirty and noisy; many were fully enclosed and featured plate glass windows, thus shielding their occupants from the elements, whereas the early gas cars were characteristically open to the air, presumably to keep gas fumes from asphyxiating occupants; and electric vehicles avoided the worrisome combustion dangers associated with gasoline. Some disadvantages: They lacked the increasing range and speed of gasoline powered cars, and they were necessarily limited to urban driving. (After all, at the turn of the century, 97 percent of the United States lacked electricity.)

If Perrin is correct, electric vehicles are on the verge of a renaissance in the 1990s and beyond.

(Flagstad is Associate Editor of EPA Journal.)



Dartmouth professor Noel Perrin, the solar electric car he has named "Solo," and his pet cat.

Photography
staff photo.
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Valley News
1991.

Ironically enough, the turning point in the competition came when, in 1912, gasoline cars began featuring an item borrowed from electric vehicles: the electric starter. After that, starting a gas car was no longer the dirty, chancy, and undignified business it had been. In the post-World War I era, with petroleum in plentiful supply, electric cars ceased to be really serious competition—even though they were manufactured by various companies well into the 1920s, and by one company until 1940.

Then, in the 1970s, electric vehicles began to seem potentially feasible again, although their speed and range had scarcely changed since the 1920s. The reasons: their ability to do without gas and oil, and their ability to reduce air pollution. For these compelling reasons, if Perrin is correct, electric vehicles are on the verge of a renaissance in the 1990s and beyond.

But in January 1990, when the author resolved to obtain an electric car, it was not easy to do so; in fact, it was difficult enough to warrant writing a book about the whole endeavor. We live in a gasoline car culture. As an indication, notes Perrin, "If you want a gas car, the whole world conspires to help you get one. There are constant ads on TV and in the magazines. There are dealers in every town, special lots where you can buy secondhand machines at low prices, whole companies devoted to auto loans, classified ads in every newspaper"

Not so for electric cars. In early 1990, there were only two small companies making electric cars in the United States, and two companies abroad, neither of which sold cars here. (Several U.S. companies that began manufacturing electric vehicles in the 1970s and 1980s had gone out of business by 1990.) Professor Perrin learned of the existing companies only through arduous research and a syndicated "want ad" in the form of an open piece lamenting his frustrated quest for an electric car. The want ad brought results.

The market is rapidly changing, however. The epilogue of the book lists several current makes of electric vehicles now for sale in this country as well as a couple of used electric car dealers. And, according to the prologue, "Almost every major automobile manufacturer has experimental or prototype electric cars on hand, and several are already committed to mass production. General Motors is, and so is Ford Abroad there are so many it's hard to keep track." Peugeot, Fiat, and BMW are mentioned.

In February 1991, Perrin contracted with Solar Electric Engineering of Santa Rosa, California, for a solar electric car in the form of a converted Ford Escort Station Wagon (cost: \$15,700 for the electric car plus \$1,800 for the six solar panels). The following May, he flew to California, took some informal lessons in the care and operation of an electric car, and drove off in the 56th electric car made by the company. His destination: home in Thetford, Vermont, via an itinerary planned on the basis of bicyclists' maps. Figuring on an average range of 63 or 64 miles a day, perhaps double that on some days, the intrepid Professor Perrin hoped to get home on battery and solar power in roughly a month or six weeks.

Why drive an electric commuter car across the continent against the practical advice of the manufacturer? Two reasons: to avoid shipping charges and to make a little history by being the first to drive an electric car all the way across the country. On the latter point, Perrin subsequently found he was mistaken; the feat had already been accomplished. (Of course, if Professor Perrin hadn't given the trip the old college try, the book might have lost much of its plotline.)

Solo didn't make it, at least not entirely on his own, although he did pretty well until the

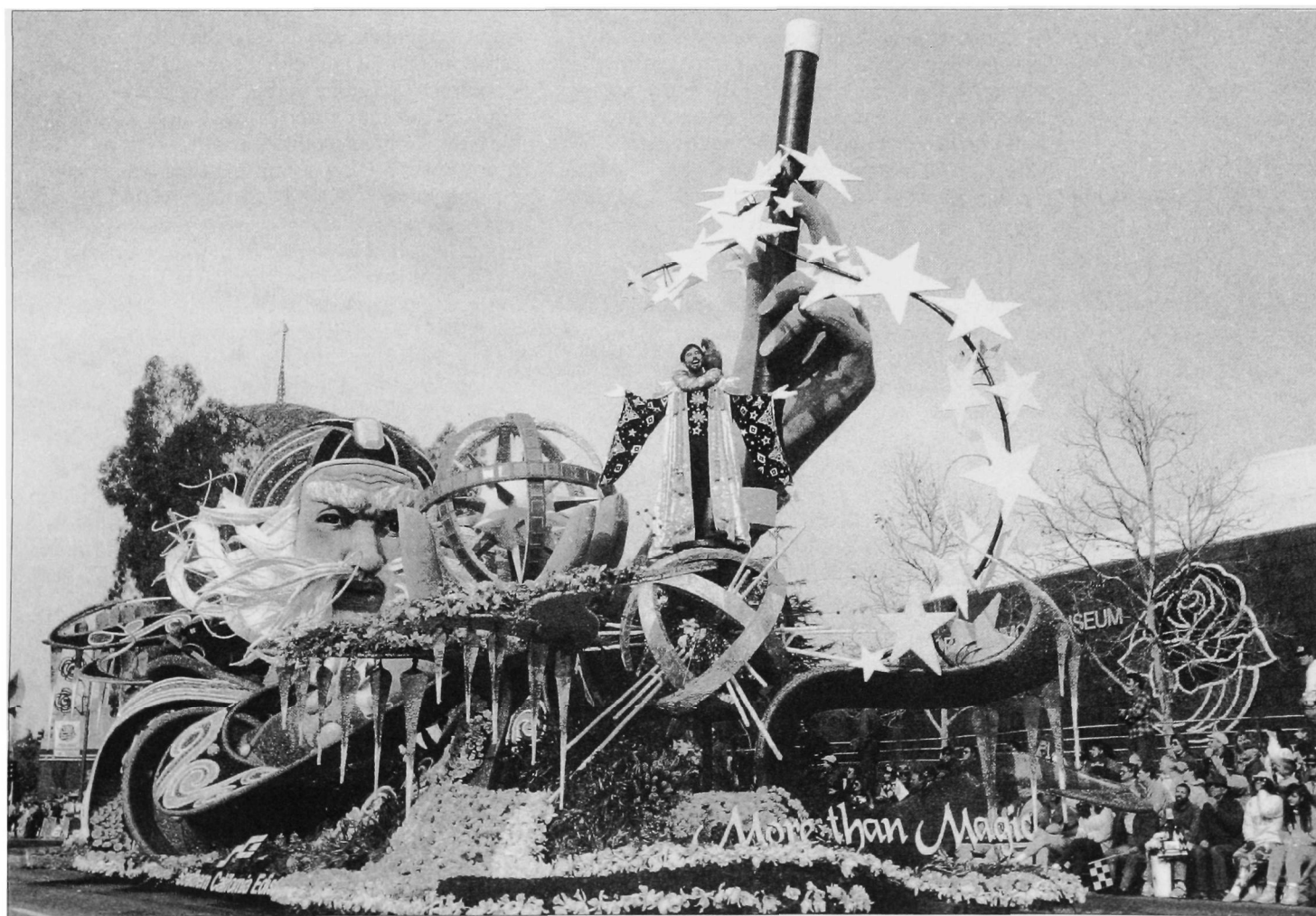
approach to Donner Pass in the California Sierras. But that seems not to be the point so much as what happens along the way. One thinks of *Travels with Charley*—with an electric car in tow playing the roughly the same part as Steinbeck's pooch.

Moreover, once Solo is safely home in Vermont, he performs admirably well in the role for which he was intended: commuting between Perrin's farm and Dartmouth College 13 miles away.

But are electric vehicles really so much more environmentally sound than gas cars? There is some debate on this question, and a chapter of *Solo* is devoted to the controversy. After all, it doesn't make sense simply to compare the emissions of gas versus electric cars. You have to consider where their electricity comes from and how much of what kind of pollution is created in the process of generating that electricity. (Not every potential driver of an electric car can be expected to invest in solar panels, as did Perrin, to supply the car with pollution-free energy.) Perrin argues convincingly in favor of figures from the California Air Resources Board that suggest that

"mile for mile, [electric vehicles] that charge from power plants cause less than one-eighth the damage that gasoline cars do."

So what's the near-term outlook for electric cars in the United States? According to this book, they definitely have a future, but there are questions and contingencies. One contingency concerns the development of better batteries to boost the range and power of electric vehicles. Questions include whether federal and state government agencies will encourage a transition to electric cars. (Right now, two states actively encourage the purchase of electric vehicles: California offers substantial tax incentives to purchasers of electric vehicles, and under the state's new zero-emissions law, by 1998, 2 percent of all new cars sold there must be completely nonpolluting—graduating to 10 percent by 2003; Arizona offers dramatically reduced vehicle registration fees to electric vehicle owners.) And what about the general public? Will substantial numbers of us opt for battery-run electric cars in the interest of the environment? Says Perrin, "Ask me again in two years." □



Said to be the world's largest electric-powered vehicle, Southern California Edison's "clean air float" performed in the Tournament of Roses Parade on New Year's Day 1993 in Pasadena. Solar cells power the wizard's spinning crystal ball.

Clearing the Air

by Rich ten Wolde

In the past, the environmental dangers of wood smoke too often have been ignored, and improvements in stove design have been slow to come.

The off-white haze lingered for days over the Rocky Mountain town of Crested Butte, Colorado. Days accumulated into weeks and drifted into months, offering nothing but sporadic views of the royal blue winter sky. With the approach of spring, the disheartening haze disappeared, but the following year it returned, settling on the town of 1,200 for the entire winter.

At the time, the residents of Crested Butte didn't realize that they, together with Mother Nature, were the source of the problem. The haze was actually pollution. Crested Butte's dilemma was similar to that of other towns in which many citizens rely on wood-burning stoves as a principal heat source. Older stoves with no pollution control equipment were emitting dense smoke, laden with particulate matter, that became trapped in the town during temperature inversions. An inversion occurs when a layer of warm air traps a cold one close to the ground, inhibiting normal circulation. The town's residents were breathing unhealthy levels of smoke that violated EPA's air quality standards.

To rectify the problem, EPA's Region 8 joined forces with the Crested Butte town council, the Colorado Department of Health, and the Wood Heating Alliance, representing private industry. Together, they transformed the town into a living laboratory for testing the emissions reductions that new, high-tech stoves promised. And they established programs to get homeowners to replace their polluting stoves. The results of the Crested Butte experiment will help solve a problem that exists in many towns and communities across the nation. In 70 small American cities, levels of small particles exceed the National Ambient Air Quality Standards, and in

about half of those towns, wood stoves are the source for a portion of the pollution, according to Jack Hidingier of EPA's Region 8.

In the past, the environmental dangers of wood smoke too often have been ignored, and improvements in stove design have been slow to come. Benjamin Franklin invented the first free-standing metal stove in the 18th century. With Franklin's design, wood burned more slowly, and the stove emitted six times as much heat as fireplaces. The slower burning time was made possible by restricting the air supply, and the increased heating was the result of the exposed metal sides that were part of the stove's design.

The same basic stove design was followed until the mid-1960s, when the first air-tight stove was produced by the Fisher Stove Company. The Fisher design permitted longer burning time of fuel and increased heating efficiency. Unlike the Franklin model, the new stoves also allowed the homeowner to control the amount of heat given off by adjusting the air intake.

Unfortunately, however, the Fisher design also produced more pollution than previous models. Subsequent studies of air-tight stove performance concluded that, although the stoves were about 50 percent more fuel-efficient, they produced six times as much particulate matter as fireplaces and three times more than Franklin stoves.

Blaze King of Washington and Jotul of Norway developed the first "new-tech" or "high-tech" stoves, which lowered particulate output about 60 percent compared to air-tight stoves. Pollution was reduced by using an automobile-type catalytic converter on the stoves, which filtered out smoke particles. Companies also designed non-catalytic stoves that burned more cleanly.

EPA had a number of objectives planned for the Crested Butte study, in which the Agency supplied crucial technical, coordination, and

(ten Wolde, who graduated from the University of Maryland in December, was an editorial intern for EPA Journal last fall.)

financial support. According to Jack Hiding, the Agency wanted to characterize the emissions of existing and new technology stoves and assess the results of converting an entire town over to new stoves. EPA also wanted to check the validity and accuracy of a short-term test that measured particulate emissions from stoves.

In order to succeed, the experiment, which was organized by Hiding and Bob McCrillis of EPA's Office of Research and Development, needed cooperation from the wood stove industry, whose future sales would be affected by the study. Hiding and McCrillis negotiated an agreement with the Wood Heating Alliance, which represents stove manufacturers, that defined the roles the participants would play in the study.

The State of Colorado and the Crested Butte town council also joined the efforts. The town council passed an ordinance outlawing the use of older model stoves and provided the residents with information on the hazards of wood smoke. In addition, the local government and industry representatives held a fair that promoted high-tech stoves and offered them at discounted prices. At the fair, information was circulated on clean and efficient wood stove operation.

In-home emissions testing of old and new stoves was another important aspect of the program. Virginia Polytechnic Institute contributed to the project by designing an in-home

emissions testing device that EPA has since approved for emissions measurement.

During the 1988-89 winter, Crested Butte residents had 349 conventional stoves and 85 high-tech ones. The following year, as a result of the changeover program, the town's residents had 276 high-tech stoves and 68 conventional models. Some residents only occasionally used their stoves, so they removed them rather than convert to newer stoves; others decided to switch to an alternate heat source.

The high-tech, EPA-certified stoves were found to reduce particulate emissions by almost 70 percent over the old stoves. In total, airborne particulate matter for Crested Butte decreased by an average of 40 percent over the measuring period. Visibility, which was measured hourly during both years, improved about 60 percent for 1989-1990 over the previous year. Because meteorological data revealed that the two years were comparable, weather didn't significantly affect data.

The Crested Butte program brought the town within compliance of the 1990 Clean Air Act. Because EPA and others carefully crafted a politically and economically feasible plan, other communities will be able to use the plan to improve their air quality. Moreover, the residents at the foot of Mount Crested Butte no longer have a wintertime haze lingering over their town. □

High-tech stoves were sold at discount at the Crested Butte, Colorado, wood stove fair in the summer of 1989. Colorado Dept. of Health photo.



Peregrine Falcon

From *Refuge* by Terry Tempest Williams

Not far from Great Salt Lake is the municipal dump. Acres of trash heaped high. Depending on your frame of mind, it is either an olfactory fright show or a sociological gold mine. Either way, it is best to visit in winter.

For the past few years, when the Christmas Bird Count comes around, I seem to be relegated to the landfill. The local Audubon hierarchy tell me I am sent there because I know gulls. The truth lies deeper. It's an under-the-table favor. I am sent to the dump because secretly they know I like it.

As far as birding goes, there's often no place better. Our urban wastelands are becoming wildlife's last stand. The great frontier. We've moved them out of town like all other "low-income tenants."

The dump where I count birds for Christmas used to have cattails—but I can't remember them. A few have popped up below the hill again, in spite of the bulldozers, providing critical cover for coots, mallards, and a variety of other waterfowl. I've seen herons standing by and once a snowy egret, but for the most part, the habitat now is garbage, perfect for starlings and gulls.

I like to sit on the piles of unbroken Hefties, black bubbles of sanitation. It provides comfort with a view. Thousands of starlings cover refuse with their feet. Everywhere I look—feathered trash.

The starlings gorge themselves, bumping into each other like drunks. They are not discretionary. They'll eat anything, just like us. Three starlings picked a turkey carcass clean. Afterward, they crawled inside and wore it as a helmet. A carcass with six legs walking around—you have to be sharp counting birds at the dump.

(Tempest Williams is Naturalist-in-Residence at the Utah Museum of Natural History in Salt Lake City.)

I admire starlings' remarkable adaptability. Home is everywhere. I've seen them nesting under awnings on New York's Fifth Avenue, as well as inside aspen trunks in the Teton wilderness. Over 50 percent of their diet is insects. They are the most effective predators against the clover weevil in America.

Starlings are also quite beautiful if looked at with beginner's eyes. In autumn and winter, their plumage appears speckled, unkempt. But by spring, the lighter tips of their feathers have been worn away, leaving them with a black, glossy plumage, glistening with iridescences.

Inevitably, students at the museum will describe an elegant, black bird with flashes of green, pink, and purple.

"About this big," they say (holding their hands about seven inches apart vertically). "With a bright yellow bill. What is it?"

"A starling," I answer.

What follows is a dejected look flushed with embarrassment.

"Is that all?"

The name precedes the bird.

I understand it. When I'm out at the dump with starlings, I don't want to like them. They are common. They are aggressive, and they behave poorly, crowding out other birds. When a harrier happens to cross-over from the marsh, they swarm him. He disappears. They want their trash to themselves.

Perhaps we project on to starlings that which we deplore in ourselves: our numbers, our aggression, our greed, and our cruelty. Like starlings, we are taking over the world.

The parallels continue. Starlings forage by day in open country competing with native species such as bluebirds for food. They drive them out. In late afternoon, they return in small groups to nest elsewhere, competing with cavity nesters

Suddenly, the flock pulls together like a winced eye, then opens in an explosion of feathers.



Illustration by
Stacey Stevenson

such as flickers, martins, tree swallows, and chickadees. Once again, they move in on other birds' territories.

Starlings are sophisticated mimics singing songs of bobwhites, killdeer, flickers, and phoebes. Their flocks drape bare branches in spring with choruses of chatters, creeks, and coos. Like any good impostor, they confuse the boundaries. They lie.

What is the impact of such a species on the land? Quite simply, a loss of diversity.

What makes our relationship to starlings even more curious is that we loathe them, calling in exterminators because we fear disease, yet we do everything within our power to encourage them as we systematically erase the specialized habitats of specialized birds. I have yet to see a snowy egret spearing a bagel.

The man who wanted Shakespeare's birds flying in Central Park and altruistically brought starlings to America from England, is not to blame. We are—for creating more and more habitat for a bird we despise. Perhaps the only value in the multitudes of starlings we have garnished is that in some small way they allow us to comprehend what vast flocks of birds must have felt like.

The symmetry of starling flocks takes my breath away, I lose track of time and space. At the dump, all it takes is the sweep of my hand. They rise. Hundreds of starlings. They wheel and turn, twist and glide, with no apparent leader. They are the collective. A flight of frenzy. They are black stars against a blue sky. I watch them above the dump, expanding and contracting along the meridian of a winged universe.

Suddenly, the flock pulls together like a winced eye, then opens in an explosion of feathers. A peregrine falcon is expelled, but not without its prey. With folded wings he strikes a starling and plucks its body from mid-air. The flock blinks again and the starlings disperse, one by one, returning to the landfill.

The starlings at the Salt Lake City municipal dump give us numbers that look good on our Christmas Bird Count, thousands, but they become faceless when compared to one peregrine falcon. A century ago he would have seized a teal.

I will continue to count birds at the dump, hoping for under-the-table favors, but don't mistake my motives. I am not contemplating starlings. It is the falcon I wait for—the duckhawk with a memory for birds that once blotted out the sun. □

*(From REFUGE by Terry Tempest Williams.
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The Felling of the Great Lakes Forests

by Teresa Opheim

"Centuries will hardly exhaust the pineries above us," a Minnesota booster predicted in 1854 of the pines that blanketed the North Woods of Michigan, Wisconsin, and Minnesota. Fifty years later, however, the pines were largely gone. Today, the swiftness and thoroughness of that decimation deserves to be remembered as a prime example of unfettered forest exploitation in the days before the practices of forest ecology, reforestation, and sustained yields.

When white pioneers moved onto the grasslands of the continent's mid-section in the early 1800s, only one element rivaled soil in its importance: lumber, which was scarce on the prairie but essential for homes, barns, fence posts, and ties for the railroad that was beginning to snake across the continent. The settlers looked north for much of their wood, and the lumber barons of the North

Woods offered a gem of a supply in white pine, which was easily worked, straight-grained, strong, and durable. White pine also floated well, an invaluable trait as, before the railroad, logs were floated to market via the region's small rivers and streams, Lake Michigan, and the Mississippi River.

Settlers viewed the steady supply of pine coming from the north as Providence. How could "our munificent Maker," one contemporary asked, "have left two thousand miles of fertile prairies down the river, without

an adequate supply of pine lumber at the sources of the river, to make those plains habitable?"

Lumber production in the North Woods reached a peak in 1892, but then dropped off an average of nearly 300 million board feet per year for the next three decades, according to historian Michael Williams. By 1900, all the merchantable pineries in Minnesota and Wisconsin had been exploited, and those in Michigan had long since gone. An area probably totaling 50 million acres had been laid bare, Williams says. By then, savvy lumbermen already had shifted their operations to the South and to the Pacific Northwest.

When the North Woods logging operations closed down, they left behind great piles of slash—timber, branches, and debris of little economic value—that were the cause of a number of powerful fires, including an 1871 fire at Peshtigo, Wisconsin, that killed 1,500 people and devastated an area of 50 square miles. The fires were often started by settlers burning off the debris in order to farm the land. Because of its poor soils and harsh climate, however, the land never did become, as one visitor had predicted, "a great rolling prairie of grass and grain." Many of the farms were abandoned within three decades, and the northern portions of Minnesota, Michigan, and Wisconsin came to be dotted with sagging farmhouse structures and derelict fences, historian William Cronon reports.

Today, a second growth of aspen, birch, balsam fir, and some pine covers the region, which sustains a paper industry and many resorts and vacation homes. Many now value the North Woods because they are "forested"; a century ago, the utilitarian settlers saw them as simply "timbered." Then, the pioneer of the North Woods prized only "the works of man," French statesman and author Alexis de Tocqueville wrote in 1831. "He will gladly send you off to see a road, a bridge, or a fine village. But that one should appreciate great trees and the beauties of solitude, that possibility completely passes him by." □

(Editors' Note: "Chronicle" is a new EPA Journal department that will briefly retell environmentally significant events from U.S. history.)

Breaking a jam. If teams of horses or dynamite failed, workers ventured out to loosen the piled up mass on the river.
State Historical Society of Wisconsin photo.



(Opheim is an Assistant Editor for EPA Journal.)

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Farewell

Departure has a sadness. For me, it is in the memory of 62 issues and more than eight years as editor of *EPA Journal*. Back copies of the magazine are my “scrapbook”—every issue has its story, the triumphs, the things that could have been done better, the surprises, and yes, the mistakes. Every issue meant something to me and, I believe, to somebody out there. We—the staff and I—did succeed, I believe, in carrying out the magazine’s tradition of objectively and comprehensively addressing the big, current environmental issues with the idea of contributing to the public dialogue about them.

What’s next for the *Journal*? I might imagine that it won’t be able to get along without me. “You and the magazine are inseparable,” a friend said recently. A flattering thought, but not so by a long shot. The talented and energetic staff is already taking charge. They are doing the work of the magazine now, and this departing editor is experiencing the new, challenging feelings of “not being needed.” It is part of the sadness, but also, part of the joy—life rolls on, endlessly finding new ways, making new choices.

But just as the American dream passes on generation to generation, adapted, amended, but still, basically the same, on the rock of a society’s conviction, I believe the *Journal* will pass on, based on the rock of an idea that a government magazine can be credible, forthright, balanced, and brave in reporting the issues with which its agency is involved.

What’s next for this editor? There will be his “fingerprint” in the magazine, in the form of a regular, short essay in the Departments section. In these essays, I will try to give the reader something to think about, a fresh, creative angle that he or she may not have seen before.

And beyond this? I’ll be trying to contribute to the public dialogue in other ways, in an independent ministry of stewardship, utilizing the wonderful experience and insights EPA has given me.

Thanks for these eight years.

John Heritage

Back cover: Aground off the Shetland Islands, northeast of Scotland, the tanker Braer breaks apart, spilling 25 million gallons of oil and putting rich ecological resources at risk.

John Emmons photo Photoreporters, Inc