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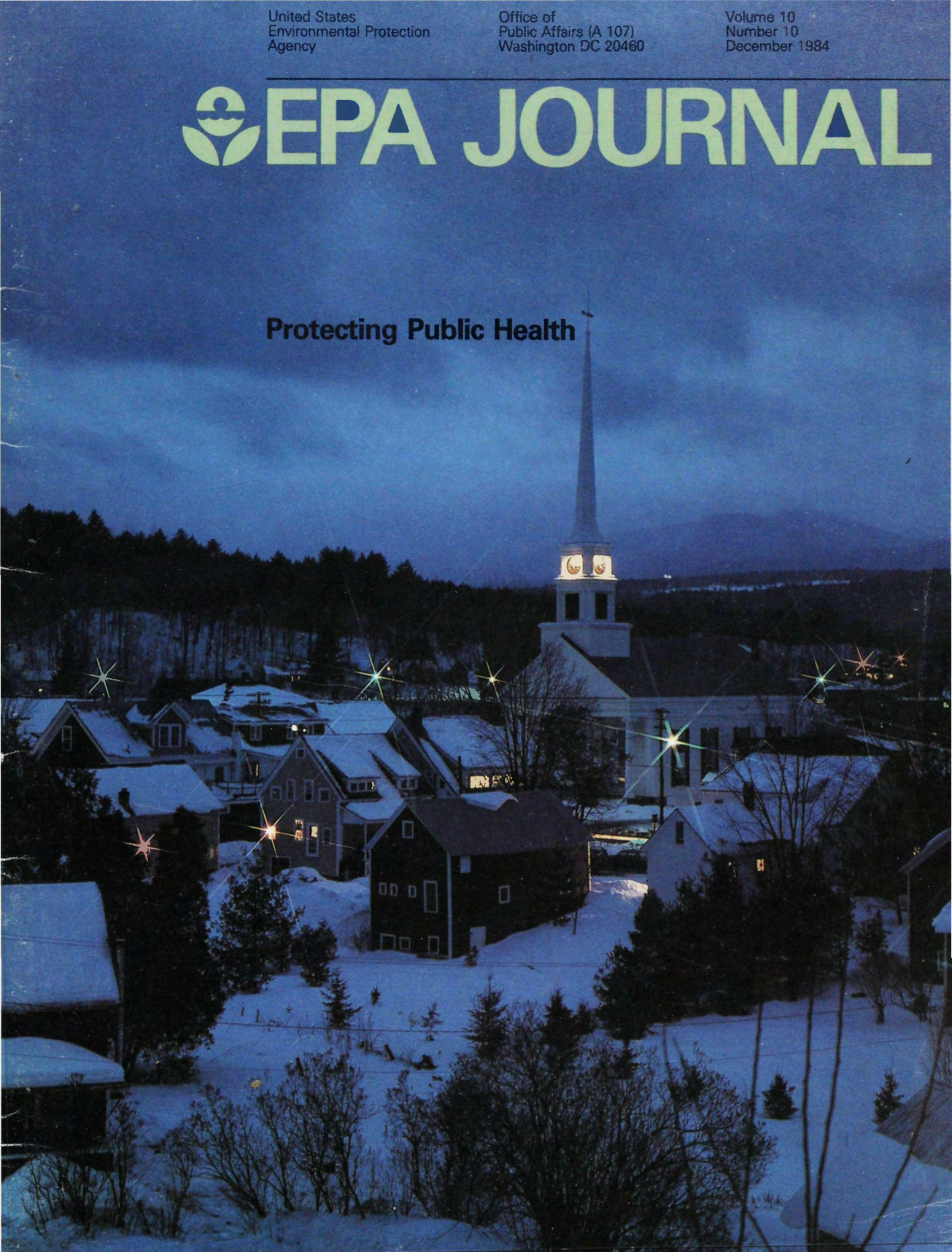
Protecting Public Health



Steve Delaney

Rush hour commuters at a busy downtown intersection in Washington, D.C. EPA assesses and manages environmental risks to protect all segments of the population.

Protecting Public Health

Why are risk assessment and risk management so important in EPA's efforts to guard public health? What do they mean? How are they working?

EPA Journal asked such questions in an interview with the agency's administrator, William D. Ruckelshaus, who has established risk assessment and risk management as basic tools at EPA. The interview is featured in this issue of the magazine.

The *Journal* then asked three top agency officials to explain various aspects of risk assessment and risk management. Bernard Goldstein, Assistant Administrator for Research and Development, reports on developments that will be strengthening the practice of assessing risks to health. John Moore, Assistant Administrator for Pesticides and Toxic Substances, explains the nuts and bolts of some risk management decisions. Josephine S. Cooper, Assistant Administrator for External Affairs, describes the challenge of communicating risk to the public. Strategies to unify EPA's approach in using risk assessment and risk management are spelled out in an article by Bob Burke, who is on the staff of the agency's Office of Public Affairs.

Judith E. Ayres, administrator of EPA's Region 9, describes the use of risk assessment and risk management in environmental decision making. Her piece, the fourth in a series in the *Journal* by the agency's regional offices, views the cleanup effort in California's Santa Clara Valley, better known as Silicon Valley.

The pros and cons of using animal testing to assess chemical risks to human health are discussed from two different viewpoints by Dr. David P. Rall, Director of the National Institute of Environmental Health Sciences and the National Toxicology Program, and Dr. George Roush, Jr., Director of Medicine and Environmental Health at the Monsanto Company.

Several articles in this issue look at other subjects of interest at EPA: the recently passed amendments to the Resource Conservation and Recovery Act (RCRA); the kind of people who work at EPA; and the use of trained dogs to track down hazardous wastes. A drive by the 3M Company in Minnesota to stop industrial pollution before it occurs is described in another article.

Wrapping up this issue of the magazine are two regular features—Update, which sums up recent developments at EPA, and Appointments. □

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Daljit

EPA 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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As the *EPA Journal* went to press, President Reagan named Lee M. Thomas as his choice to succeed William D. Ruckelshaus as Administrator of the EPA. Thomas is currently the agency's Assistant Administrator for Solid Waste and Emergency Response. Ruckelshaus has announced his resignation to become effective January 5.

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EPA's Strategy to Reduce Risks

An Interview with
William D. Ruckelshaus

EPA Journal *discussed with Administrator William D. Ruckelshaus the concepts and the issues involved in risk assessment, risk management, and risk communication as practiced by the agency. The interview follows:*

Q In a speech to the National Academy of Sciences last year, you established risk assessment and risk management as guiding principles for EPA's future. What do these terms mean, and why are they so important?

A Let me answer your second question first. I think it's important for the agency to have a consistent conceptual framework as a basis for understanding our mission and how we're going to achieve that mission. When we first started at EPA in 1970, we didn't have that conceptual framework. To a certain extent, we were groping in the dark. During the decade between the time I left here and came back, an awareness developed that the needed framework might be founded on the distinction between the assessment of risk and the management of risk.

As for our definitions of the terms: risk assessment is simply an effort to understand what the problem is—what is the risk that you're attempting to reduce in order to protect the public health and environment? Strictly speaking, even the assessment of risk isn't a purely scientific exercise. We do have to make some assumptions—which have a scientific base, but, nevertheless, are assumptions.

Now, once we've defined the problem, we can move to the next stage of our regulatory responsibility: deciding what to do about the risk. This is the risk management stage. We try to balance the risk against other social concerns, such as the benefits associated with the use of a particular chemical, and the cost of reducing its use.

Q Looking over the past 18 months, what progress has the agency made in implementing the concepts of risk assessment and risk management?

A We have just proposed guidelines for assessing risk across all of the program areas of the agency. They are primarily for internal guidance, to ensure consistency across the agency in the way we assess risk for carcinogens, mutagens, teratogens, etc.

EPA will be using these proposed guidelines internally while the public comment process is going on. Meanwhile, we are attempting to come up with a consistent set of guidelines within the risk management agencies of government for the assessment of risk. It could be that through that process we'll change our mind about exactly how risk should be assessed. But if we're going to have any chance of getting a consistent assessment of risk across all the risk-management agencies of government, we've got to start inside EPA.

Q Should our environmental statutes be modified to better reflect the concepts of risk assessment and risk management?

A Congress has given us such a wide array of assignments that it, like EPA, is sometimes confused as to exactly what we're supposed to do and whether or not we are making progress. The task of overseeing our administration of the laws would be much easier if the statutes themselves explicitly distinguished between what is primarily a scientific exercise in assessing risk and the political—small "p"—political exercise of deciding what to do about it.

Q Does EPA intend to propose such statutes in the next Congress?

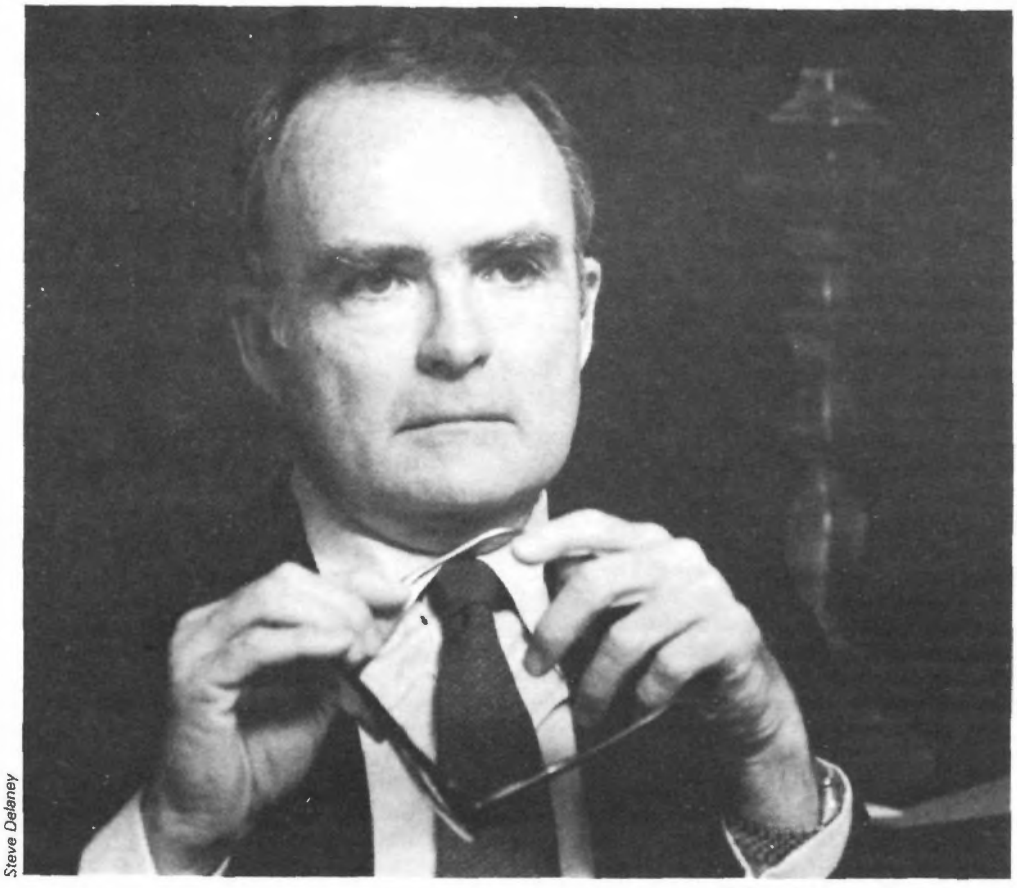
A The short answer to your question is yes. So far, however, I have refrained from recommending such changes because I've felt the Congress was unlikely to be receptive. I haven't wanted to run the risk of discrediting any useful approach by suggesting it in a highly politicized climate. The longer answer to your question, therefore, is that, assuming the climate is modified, I think we have a chance of getting a fair hearing in Congress.

Q Could you cite a particular instance in which risk assessment and risk management have been utilized particularly well?

A Actually, we operate under the same general formulation in virtually every decision that we make. In my own view, the effort that the agency made to control EDB was a success. The risk assessment of EDB exposure contains great scientific uncertainty insofar as the ability to extrapolate to humans the information we had on EDB's effects on animals. Given that uncertainty, we did a fair job of describing the risk to the public. Then we managed the phasing down, and eventually the phasing out, of EDB, taking into account the cost of doing it, the pace of doing it, and the residual health exposure of people. I think we integrated these things into a risk management approach that carried the day in a highly politicized, emotional atmosphere.

Q How are you ensuring good science in risk assessment?

A In the first place, I think we're very open about the assumptions we make in assessing risk. We subject our methodologies to extensive peer review. We subject the scientific studies on



Steve Delaney

Administrator Ruckelshaus

which we base our risk assessment decisions to peer review. Then the risk assessment documents are reviewed by our own Science Advisory Board. So that we go through a widespread, open, peer review process before we come to some judgment about the nature of the problem. That does more to ensure that our science is sound than anything else.

It also is important that we manage our scientific research effort in such a way that we ask the right questions in sufficient time so that the decision making can be based on a solid scientific foundation.

Q What about disagreements? What does EPA do when scientists within the agency offer conflicting risk assessments for the same substance?

A We have recently established a risk assessment forum. When there is a lack of consensus on a chemical's risk, the forum attempts to find out why. Differences may be caused, on the one hand, by scientific uncertainties, or they may result from different methodologies being applied to come up with a risk number. In the latter case, the forum can help straighten things out by seeing that common methodologies are utilized.

Once we agree on the facts, people may still disagree on how we ought to assess the risk. As I pointed out earlier, there are assumptions involved in risk assessment. I've had scientists sit here in my office and be poles apart on the risks associated with a particular substance. Then it's up to me to make a judgment.

Q As the facts are being gathered on the risk assessment side, when does the policy-maker step in and say, "That's enough. We have sufficient information to make a decision"?

A That's going to vary. Sometimes the decision is hastened by public pressure to act on a particular substance. Sometimes a certain time frame is mandated by statute. And sometimes the policy-maker decides that we know enough, even though a lot more information would be helpful and make the policy-maker feel more comfortable.

Getting information can be very expensive and very, very time consuming. There is such a thing as paralysis by analysis, and it can come into the area of risk assessment just as it can in any analytical forum. Sometimes you simply have to act in order to ensure that local, state, and federal governments can move forward.

Q When emotionally charged issues, such as the threat of cancer or declines in real estate values, are involved, do you think that rational public dialogue on risk is possible?

A It's not only possible, it's essential if the public's involvement in the risk management side is going to be intelligent, informed, and worth anything to us. It is extremely hard to communicate these risk assessment judgments to the public, because the public does not react well in the face of scientific uncertainty. They tend to believe that we really know what the problem is and that we just won't tell them.

Q Wasn't this the problem you faced concerning the smelter in Tacoma, Washington?

A Exactly. When the residents of Tacoma first heard about the uncertainties associated with our risk assessment of arsenic, they became angry, suspicious, and, in some cases, outspokenly hostile. But after we spent literally weeks being as open as we know how to be about this risk, and communicating it to them, and they saw the kinds of steps that it was possible to take to reduce the risk, they then moved toward a consensus that we should reduce that risk as much as possible and, at the same time, permit the smelter to continue to operate.

Q How much does public involvement mean in your decision-making?

A The public input will be weighed very heavily in certain cases. In Tacoma, the health impact was almost exclusively local; beyond a certain circumference around that plant, the population's health was essentially unaffected. In many cases, the people within that circumference were also affected economically. Therefore, "How do you

believe this balance should be struck?" is a very logical question to ask these people. Nobody has a bigger stake in that question than they do.

The judgment is mine. But I weighed heavily what the people of Tacoma thought, simply because they have a large and identifiable stake in the outcome of my decision.

Public involvement is much more difficult to get on a national scale. Where I have a decision that affects the whole country, such as setting an ambient air quality standard, I tend to fall back on more general principles. I do weigh the public input, but I don't give it as much weight as I would when the effects are mostly local.

Q What is the agency doing to create trust and understanding between the public and EPA?

A The only initiative that will work is openness. We simply lay out, for everybody to see, the factors we take into account in arriving at a risk assessment and the criteria we use to make a judgment as to how that risk should be balanced against other social concerns. To the extent that the public understands what we're doing, they will give us the benefit of the doubt. To the extent they think that politics or any sort of extraneous factor is involved, they won't trust us.

Q How close is the agency to your goal of winning the public confidence?

A We're a ways away, and I don't know that we're going to get to the ultimate anytime soon. Part of that is because we've been given assignments by Congress, in the form of these abandoned hazardous waste sites, to deal with a lot of local problems where the people see no benefit whatsoever in a balance of a reasonable level of risk against other social concerns. There's essentially no cost to those people to go to zero risk: the cost is borne by the whole society. And the benefit in going to zero is great for the local population. This creates constant pressure on the agency to act in ways that are inconsistent with the broader definition of the public interest that we're assigned to pursue; and it puts us, in many respects, into an irreconcilable conflict. And that ensures that our trustworthiness, wisdom, and objectivity will be constantly attacked by those affected.

Q What future do you see for the implementation of risk assessment and risk management concepts?

A I hope, as we get these hazardous waste sites cleaned up to a reasonable level and some of the public outcry subsides, that we would see our statutory base encompassing the distinction between risk assessment and risk management. Likewise, I'd like to see that same formulation applied to all risk management activities within government. If that were done, then I think there would be a greater likelihood that the public would understand what it is we are trying to do in both assessing and managing risk and, thereby, accept that the government was acting in the broad public interest.

Q Is trying to harmonize risk assessment and risk management practices among federal and state agencies a major agency concern?

A I think it's more a concern of mine than it is of EPA's. As the administrator of this agency, as somebody working within a governmental complex that involves more than one effort to manage and assess risk, I think it's my responsibility to ensure that that consistency across the government takes place. To the extent that I can advance that possibility, I think I will have contributed a considerable amount in my current role.

Q Do you have anything that you would like to add?

A Only that I think that it is very useful to use the concepts of the assessment and management of risk in determining how we go about dealing with the myriad of problems that EPA and other agencies wrestle with in this country. I underscore "in this country," because what we're really about here is seeing whether free institutions can successfully wrestle with the management of risk in the face of uncertain science, high public emotion, and disproportionate impact of the cost of managing that risk. It's an open question how successful a free society can be in dealing with these problems. But I think this country will only prosper to the extent that we improve our ability to do so.

It is likely that other free societies throughout the world will adopt free institutions if they see that they work here. Therefore, I think the work that we're engaged in here is very important, not only for the protection of public health and environment, but for the advancement of freedom in the world. □

Strengthening the Assessment of Risk

by Bernard D. Goldstein

EPA has taken several steps to strengthen its risk assessment process by improving the consistency and technical quality of its risk assessments, and by narrowing the inherent uncertainties as much as possible.

When Administrator Ruckelshaus and Deputy Administrator Alm returned to EPA, they convened a task force to study ways to improve the consistency and technical quality of EPA's scientific decisions. The task force endorsed the National Academy of Sciences' definitions of risk assessment and risk management and the agency's intent to honor that distinction. The task force also recommended the development of cross-agency risk assessment guidelines to ensure consistency and technical quality in EPA's scientific decisions. It further recommended establishment of a Risk Assessment Forum of senior-level scientists to resolve scientific disputes.

The guidelines were developed by cross-agency work groups of scientists skilled in each topic. Then they were submitted to groups of 10-30 experts in government, academia, industry, and environmental groups for comment. The work groups were chaired by personnel from EPA's Office of Health and Environmental Assessment/Office of Research and Development. The guidelines define EPA's procedures for assessing risk in the areas of carcinogenicity, mutagenicity, developmental toxicity, chemical mixtures, and exposure.

The proposed guidelines published in November are the first product resulting from implementation of the task force's recommendations. These five guidelines are open for public comment for 60 days, and will be reviewed by the agency's Science Advisory Board (SAB) before being issued late in 1985. The agency intends that they be living documents, and will continually revise them as risk assessment approaches change and as test methods improve. In addition to these five guidelines, work is continuing on guidelines for systemic toxicants (i.e., toxicity to specific organs and organ systems), and on male and female infertility aspects of reproductive toxicity.

One of the aims of the guidelines is to promote consistency across EPA risk assessments by developing common approaches to risk assessments. Another aim is to promote quality of the science in EPA risk assessments by:

- external scientific review of the guidelines,
- public comment on the guidelines,
- SAB review of the guidelines, and
- establishment of the Risk Assessment Forum.

The guidelines will:

- explicitly set out EPA's approach to risk assessments,
- be general enough to allow appropriate technical judgment, and
- be used by skilled scientists; they are not cookbook, step-by-step procedures for non-scientists.

The guidelines should have an indirect effect on the regulatory process. Through peer review of the guidelines, together with uniform application of them across the agency, EPA's risk assessments will be more consistent. Risk assessors from industry, state and local governments, and environmental groups will be able to estimate EPA's scientific response to problem situations. For example, this could help in:

- planning new products, or new uses for existing products,
- setting priorities for cleanup strategies, and
- developing controls for specific point sources.

The ultimate goal is to have a common, explicit, consistent, technically sound approach to risk assessment. This

(Goldstein is EPA's Assistant Administrator for Research and Development.)

At EPA's Analytical Chemistry Laboratory in Beltsville, Md., chemists Diane Rains and Everett Greer conduct an analysis to determine if the pesticide EDB is present in baked food products. The agency has carried out a major effort to assess and manage EDB's risks.

does not prevent the risk managers—the administrators of the laws EPA carries out—from using the resultant scientific assessment in ways consistent with the particular law for which they are responsible, or from blending legal, political, economic, or social considerations into their decisions. The evaluation of the scientific information, however, will remain the same.

The next step in strengthening risk assessment is the establishment of the Risk Assessment Forum. Although the guidelines build a framework for consistency in risk assessment, they are of necessity general enough to permit use of good technical judgment. Therefore, scientists can and will differ in their evaluations. The Risk Assessment Forum is a panel of senior scientists/managers who meet regularly to resolve scientific disputes. The Forum provides a mechanism for interchange on science issues in risk assessment, advises the Administrator and Deputy Administrator on precedent setting cases and important risk assessment issues, and recommends revisions or updates to the risk assessment guidelines, as appropriate.

The Forum is the managerial responsibility of the Office of Research and Development, and is chaired by the Office of Health and Environmental Assessment (OHEA). It includes scientists from every part of the agency. As of this writing, the Forum has delivered its first report to the Deputy Administrator and has a half dozen issues under consideration.

Finally, the risk assessment process can furnish a research agenda for the agency. It can do so in one of two ways. First, individual risk assessments may be particularly uncertain because of missing scientific information. Agency scientists can organize their experiments around developing this critical information. For instance, it may involve better monitoring of exposure to hexachlorobenzene, recommending an appropriate new cancer bioassay for trichloroethylene or perchloroethylene, or evaluating more completely the metabolic pathways of a particular pollutant like arsenic.

Secondly, the risk assessment process can provide a research agenda aimed at narrowing uncertainty by doing basic research to better define and resolve the factors that give rise to uncertainty. Narrowing these uncertainties is important to risk managers and to society, because cleanup of pollution is costly. When we are uncertain about risk assessments, we tend to err on the protective side in setting allowable levels. If we can make our scientific judgments more accurate and precise, we can learn just how much control is appropriate, and, hopefully, save dollars as well as lives.

I am confident that EPA's new guidelines will improve the quality of EPA's science by making our judgments more consistent and by narrowing uncertainty as much as is now technologically possible. However, their greatest long-term impact may be in focusing on the remaining areas of uncertainty, and suggesting areas for risk assessment research. By using the guidelines as an outline, we can lay out a research program that will, over the next decade, make significant progress in bringing more certainty to risk assessment.

I would like to discuss the challenge of narrowing uncertainty with several examples. The first has to do with health risks where we have a sufficient data base to define some of the specific issues which have led to the uncertainty. Because we can pose the specific questions, much of our needed knowledge can be obtained through carefully planned and focused research over the next decade.

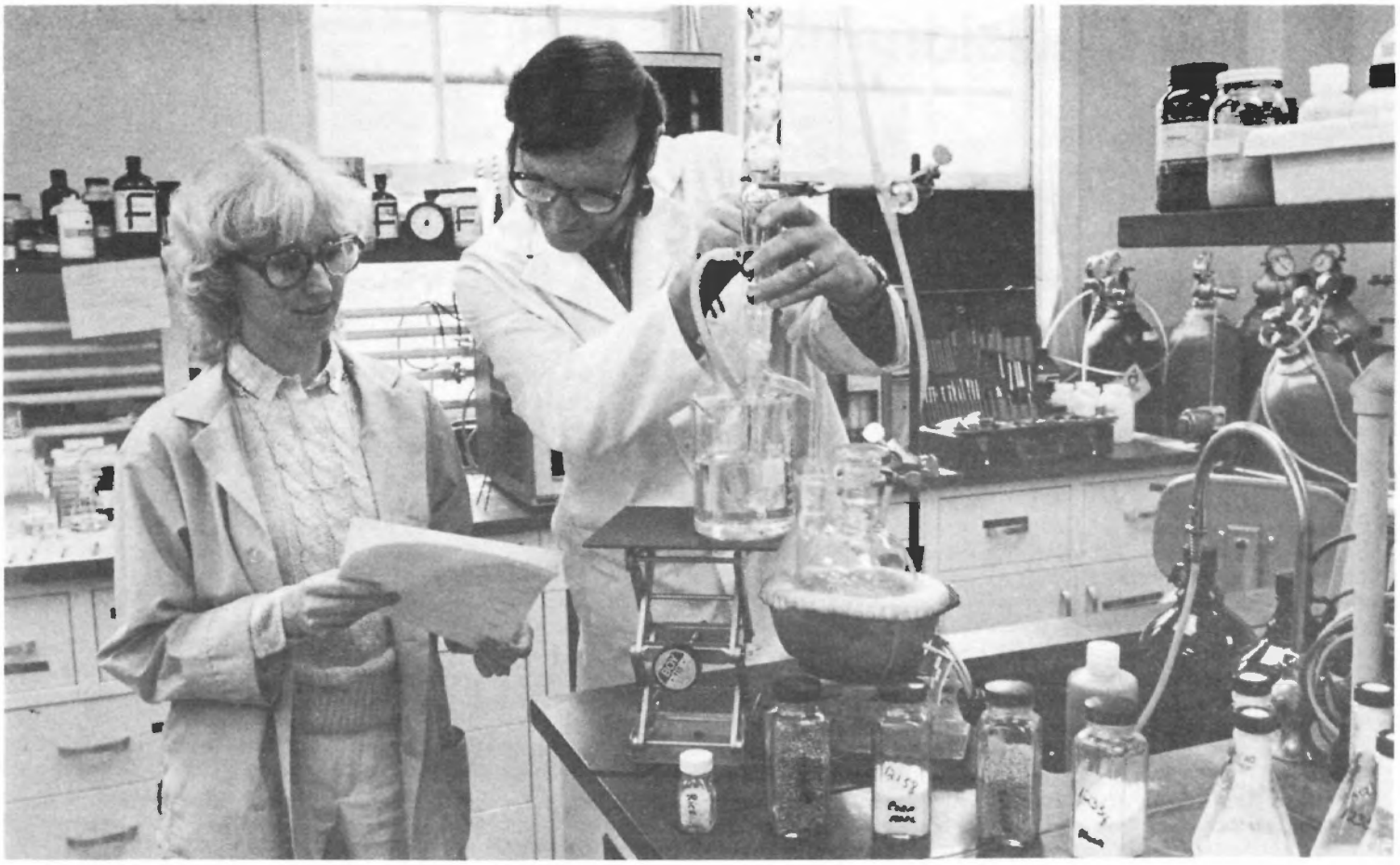
There are several such problems in the field of cancer risk assessment. Scientists throughout the world are seeking to understand the basic mechanisms of cancer, how and why it starts, and how it spreads. We cannot predict just when the research progress that is being made will be translated into an unraveled mystery. However, we can identify some areas of research that will help EPA scientists and others to better understand the significance of various data. Two of these topics include:

- Evaluation of the significance of mouse liver tumors. Some strains of mice used in cancer evaluations exhibit a high spontaneous incidence of liver tumors even when there has been no exposure to chemicals. There is substantial scientific controversy, which needs to be resolved, over the significance for assessment of risk to humans when mice exposed to pollutants develop these liver tumors and no others.

- There is a need to develop appropriate risk assessment models to reflect the different biological mechanisms of cancer. We currently use one risk extrapolation model. However, we believe there are at least two steps—cancer initiation and cancer promotion. We need to understand these processes and their interaction, and then develop appropriate mathematical models for each of the processes.

EPA currently intends to convene a workshop to look at this cancer risk assessment area for purposes of developing a comprehensive research program which will help narrow these uncertainties.

The above relates to the hazard assessment aspects of risk assessment. Let me also discuss another component, exposure assessment. Currently, EPA



Steve Delaney

exposure analysis is based on available, usually limited, ambient monitoring data coupled with use of computer estimates of pollutant dispersion. Improving the quality of our data collection and the sophistication and reliability of these dispersion models will improve our knowledge of whole body exposure, but not of the effect of these doses on the organs at risk. An emerging research area is that of biological dosimetry. We must develop *in vitro* or external test systems which properly evaluate dose response relationships at the affected organ. Then from improved exposure estimates and metabolic information, we can estimate more precisely the amount of pollutant invading the liver or the lung or other affected organs. The product of these two efforts is more precise knowledge of the relationship between ambient exposure and health effects.

Often our research data base is more limited, and we are not as able to ask the right questions and pinpoint our research. Many of these are non-cancer related problems in which the agency's efforts are much newer.

One of these newer areas of interest is assessment of mutagenicity, i.e., the likelihood of a pollutant causing changes which can then be passed on to future generations. Until recently, mutagenicity experiments had been used primarily as screening indicators of potential carcinogenicity. More recently, we have become interested in mutagenicity as a health effect, *per se*. We have knowledge of many test systems which exhibit mutagenic effects, but we are less confident of their relevance for evaluating the potential for creating human defects that can be passed from generation to generation. EPA's proposed guidelines are steps in that direction, but much basic research still needs to be done to establish that link with certainty.

Similarly, much more information is needed to understand and assess chronic systemic toxicity due to pollutants. These include cardiopulmonary disease, immunotoxicity, neurobehavioral toxicity, and liver and kidney toxicity. Little information exists about specific toxic effects, let alone the uncertainty of the risk assessments. Prime examples are the potential effects from low dose, long-term exposure. Because of the historic focus on cancer and on acute short-term effects, this area has had little research.

For instance, we have much data on the acute reversible respiratory effects of the criteria air pollutants (the six major air pollutants EPA regulates); in fact, much of our information here is based on human experimentation, precisely because the effects are acute and reversible, and disappear as soon as the exposure is reduced. We do not know, however, whether long-term low-dose exposure causes long-term effects, e.g. emphysema, or leads to secondary disease, e.g. increased respiratory infection.

These, then, are our steps for strengthening risk assessment: development and use of risk assessment guidelines, establishment of a Risk Assessment Forum to resolve scientific disputes, and use of our risk assessment experience to establish a research agenda for acquiring risk assessment information and developing new risk assessment methods. As this occurs, EPA's established reputation for scientific quality in decision-making and pioneering in risk assessment will further improve. There can be no better legacy for a scientist in a regulatory agency. □

Making Decisions About Risk

by John Moore

"So what are you gonna do about it?" This statement—part question, part challenge, and part cry for help—goes to the heart of the *risk management* decision. In general, once the *risk assessment* procedure has resulted in some estimate of the potential dangers associated with a specific situation, the decision as to the appropriate course of action still remains to be made. Or as someone has said, "Now comes the hard part."

I would like to discuss the risk management process from the point of view of someone who has sworn to use the legislative authorities at his command to protect public health and the environment from "unreasonable risk" (in the language of TSCA, the Toxics Substances Control Act) and from "unreasonable adverse effect" (in the language of FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act). Furthermore, risk management activity is carefully constrained by the specific legislation applicable to any given circumstance. Although the process will be somewhat different for EPA risk managers who administer other laws, such as the Clean Air Act and Superfund, many of the elements and concepts are common to all risk management decisions.

Definition and Operation

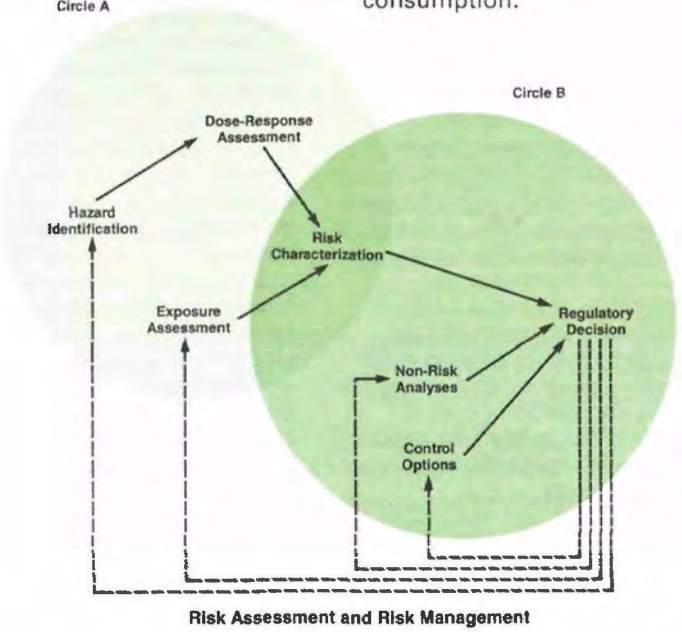
The flow diagram illustrates the conceptual framework in which we consider risk: how to estimate it and decide what to do about it. Risk assessment involves the elements included in circle A: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Risk management involves the elements included in circle B: risk characterization, non-risk aspects, and the final decision on "unreasonable risk."

The need to determine the "unreasonableness" of the risk/adverse effect involved distinguishes FIFRA and TSCA as "risk/benefit statutes." That is, risk of some magnitude is not sufficient to justify action. Non-risk factors—such as the availability and effectiveness of controls, the existence of alternatives, and any benefit that would be lost as a result of control—must be considered in the process of reaching a decision. In some cases, the weighing of the risk and benefits will be such that the benefits outweigh the risks. In such a case, the risk management decision would be to take no regulatory action. In other cases, the risks are such, relative to the benefits, that the reasonable thing to do is to take action to reduce the risk. As the diagram illustrates, this decision feeds back to earlier elements in the framework, usually resulting in a reduction in the exposure to the extent that the risk is put back into balance with the benefits.

Both FIFRA and TSCA present a range of control strategies to the risk manager. For example, a pesticide can be declared a "restricted use" pesticide, which means that in order to use the chemical, a person must first have taken a course designed for pesticide users. The special training focuses on the proper methods for handling these materials so that human and environmental exposure is minimized. Therefore, the most important uses of the pesticide are retained, since someone who thinks using the pesticide is important will take the course. Other possible controls authorized by FIFRA include cancellation of registrations for some or all uses, lowering of tolerance levels on food crops, restrictions on levels of impurities in the product, and formulation or application restrictions. The array of control options available under TSCA includes banning, labeling, formulation controls, geographic controls, process quality controls, and record keeping. The legislation instructs the decision maker to choose the least restrictive control that will reduce the risk to a level which is not unreasonable.

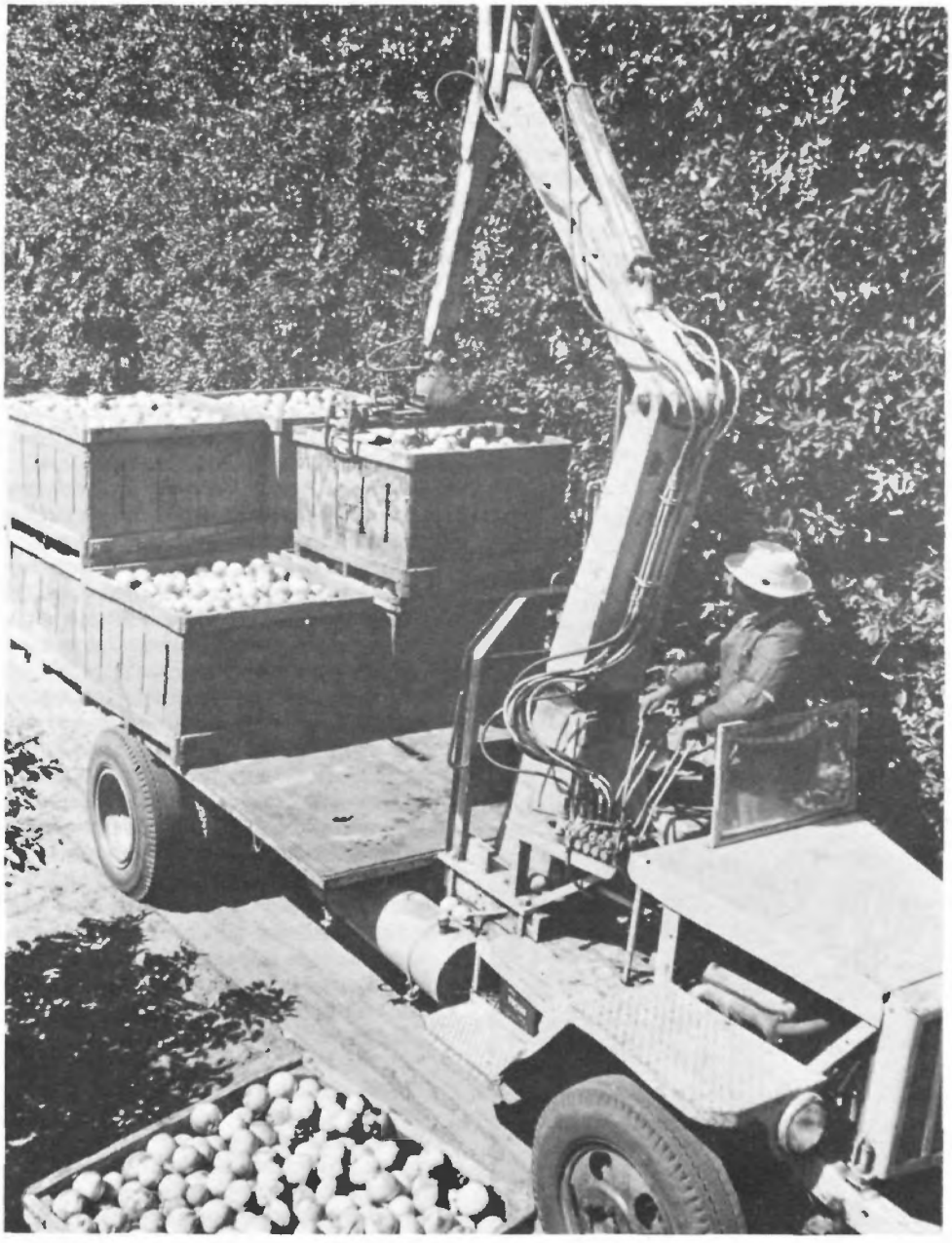
The risk management process usually involves more than one decision. This is because the degree of risk often varies in the different phases of product use. For example, pesticide "X" is capable of being absorbed through the skin and causing damage to the kidneys, that is, it has *hazard* potential. Further, the doses that can cause this effect are quite low. In evaluating its method of production and use there are four areas where exposure may occur—when the chemical is made, when it is mixed and applied, when a vegetable is picked, and when it is eaten. Since the chemical is rapidly destroyed by sunlight, the level of exposure during picking and eating is practically zero, so no risk management issue is involved. Exposure during manufacture of the chemical is kept to acceptable levels because the manufacturer plans to use a method of production that is totally enclosed. Exposure during mixing and application of the liquid pesticide approaches levels that may cause kidney damage. However, it is known that the chemical can be made in a granular as well as the originally planned liquid form. In this form, absorption through the skin is decreased 500-fold. The risk management decision is to deny use as a liquid, and permit use in a granular form.

This risk management decision only could be reached because one was able to reduce the exposure part of the risk assessment equation. There might also be two other risk management decisions associated with this theoretical pesticide: prohibit entry for 1-2 days immediately following treatment of the vegetable field and require harvest intervals between the date of last treatment and harvest. These actions would be to ensure breakdown of the pesticide prior to harvest and consumption.



Risk Assessment and Risk Management

(Moore is Assistant Administrator for Pesticides and Toxic Substances.)



Florida Department of Citrus

Harvesting grapefruit in Florida. EPA makes risk management decisions regarding the use of pesticides on fruits and vegetables.

The regulation of polychlorinated biphenyls (PCBs) further illustrates important aspects of risk management. PCBs are chemicals which have significant benefits when used in certain large pieces of electrical equipment (like transformers), found in most large buildings across the country. Because PCBs also happen to be toxic, very persistent (long-lived once they get into the environment), and tend to bio-accumulate in fish and other food sources, Congress decreed in the original TSCA bill in 1976 that PCBs should be banned.

Consequently, EPA has been implementing processes that remove PCBs from our environment. These chemicals are no longer produced or sold in this country. The agency has issued regulations designed to ensure that PCBs are disposed of without generation of unreasonable risks.

In 1979, we began permitting the use of high temperature incinerators to dispose of PCBs. Careful EPA investigations revealed that the emission of chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) was associated with the incineration of PCBs. Among the CDDs/CDFs formed was the notorious 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD), which has gained fame as a toxic contaminant of the herbicide Agent Orange and is the subject of a 1984-85 study by the agency to determine the extent of contamination at a variety of sites in our country. The chemical is sometimes loosely referred to as "dioxin." The hazard identification and dose-response assessment case for this compound were well established.

The agency conducted a series of emissions tests during PCB incineration to determine the extent of human *exposure* in neighborhoods near the incinerators. The study revealed that something like one tenth of a millionth millionth of a gram would be inhaled daily by a person under the worst case conditions. The *risk characterization* associated with this extremely low level of exposure was so small compared to *non-risk factors* like alternative methods of disposal (e.g., land disposal or "midnight dumping") that the benefits of incineration were judged to outweigh the exposure risk; the risk management decision was to approve incineration as an appropriate method for disposal of PCBs.

The decision not to take regulatory action in this case does not mean, however, that there are no "unreasonable risks" associated with PCBs. In recent years we have learned that when PCB-containing transformers and capacitors are involved in building fires, the production of "dioxin"-like compounds can result in cleanup costs that run into the tens of millions of dollars.

This PCB case differs from the incineration situation primarily in the *exposure assessment*. Smoke from low temperature, low efficiency building fires can lead to much higher acute and chronic exposures to combustion products than can the very low levels emitted from high temperature, high efficiency incinerators. Therefore, I have reached the risk management decision that the risk related to PCBs involved in building fires is unreasonable and should be brought back into balance with the benefits of continuing to use PCBs until the equipment can be replaced.

After considering the costs involved, I am recommending that we introduce a series of control options ranging from isolating this equipment from the building ventilation system to marking the buildings so that firefighters will be aware of the special nature of the fire that may be burning within.

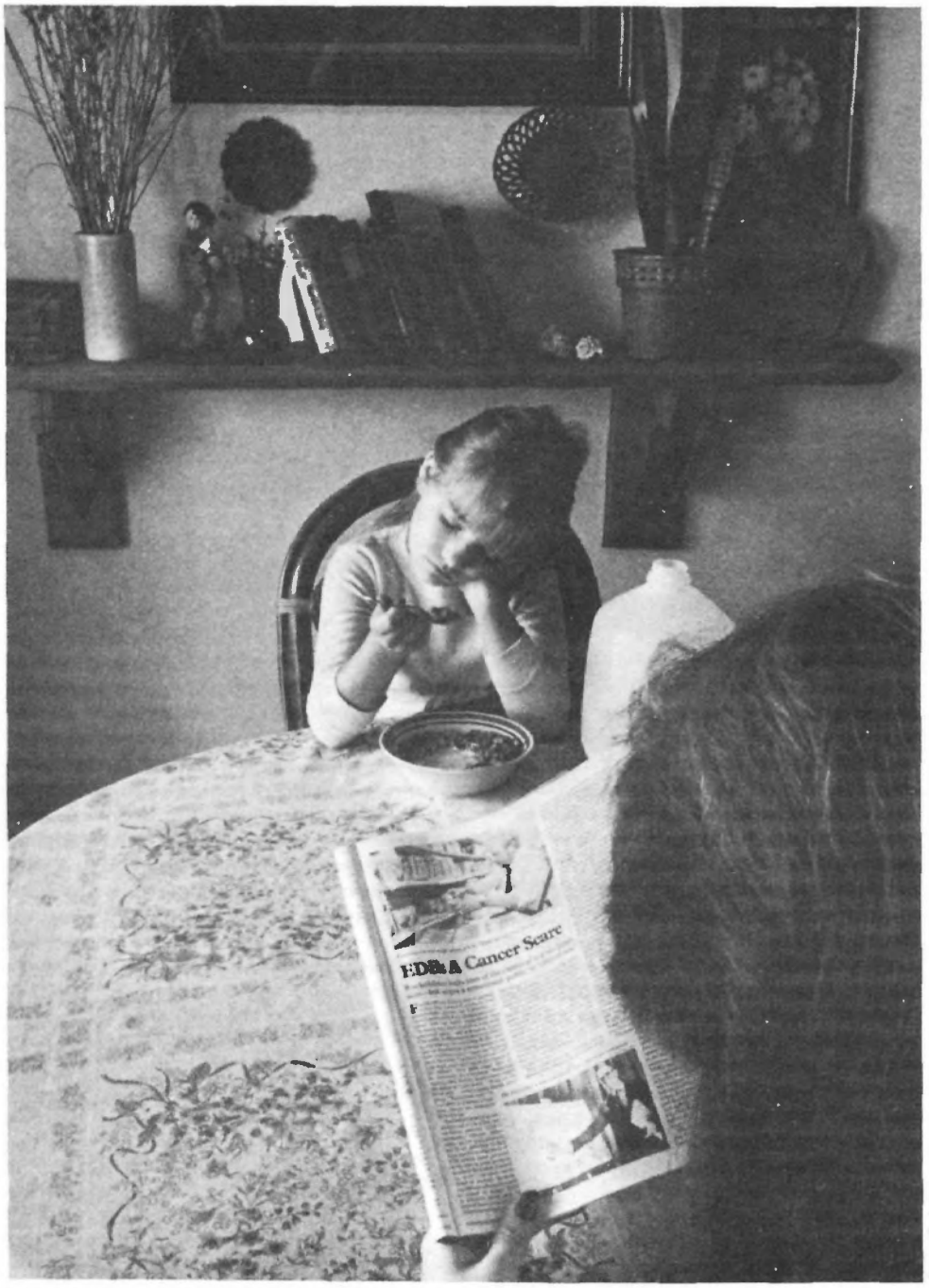
Conclusions

The activities leading to characterization of risk are more fraught with assumptions and subjectivities than one would like. Similarly, the methods available for analyzing the non-risk factors in a quantitative manner are weak. Therefore, risk management decisions are anything but "cut-and-dried." But then, that's the way it is with risk assessment/risk management...not predictable perhaps, but always interesting!

Risk managers need to use their best judgment, carefully weighing all the factors, and make what is often a very difficult decision that will affect millions of citizens. As one of those risk managers, I can only promise you that in this process I do my best to assure that human health and the environment are protected from unreasonable risk. □

Helping the Public Weigh Health Threats

By Josephine S. Cooper



Steve Delaney

One of the challenges to EPA in addressing health risks is to translate technical information to help the average consumer make decisions about the use of food and other products.

(Cooper is EPA's Assistant Administrator for External Affairs.)

The head of an intelligent corps of scientists, engineers, and managers, whose mission is to protect people and their surroundings, stands before a bank of television cameras and asks the nation to "calm down."

"We have a problem, but it is not one of monumental proportions," he reports. "It's a chronic circumstance—one we can deal with in an orderly fashion without going into a panic and disrupting our lives and our economic stability."

This in essence is what EPA Administrator William D. Ruckelshaus said on February 3, 1984, when he opened a press conference to announce actions EPA was taking to protect the people from ethylene dibromide—EDB.

It sounded like a rather simple message. At the beginning it was.

It was followed, however, by information that was highly technical. It included recommendations for maximum allowable residue levels at specific parts per billion in raw grain, in products made with processed grain such as flour and cake mixes and, finally, in ready-to-eat foods such as bread and cereal.

It was so technical that no housewife or store owner or grain elevator operator in the country could have gone to the cupboard, or the shelves, or the grain bin, and figured out what had to be thrown out and what could be kept.

It was technical because, of the thousands of words used to describe the outcome of the risk assessment process, the only ones that carried a commonly understood message were flour, cake mixes, muffins and CANCER. And it's hard for many people to calm down when they see experts discussing a relationship between the foods they eat every day and CANCER.

Still, the broadcast was one of the most successful efforts to date to communicate with the American public about risk. It was successful perhaps because an individual with recognized credibility stood before the people and gave them a personal assurance that they could relax—that they could "calm down."

Clearly communicating risk is one of the ultimate challenges we face. Administrator Ruckelshaus, in speeches, in reports, and in interviews, has pointed out the need to find ways to explain risk "in terms that the average citizen can comprehend."

When dealing with matters affecting the environment and public health, our society through its laws has decided the public must be involved more than ever before in history in the decision making process.

We need, Ruckelshaus points out, public understanding so people can participate effectively in the decision making process; and, conversely, they need a government that

speaks in language they understand so they can join in the dialogue.

In the end we may find it impossible to communicate, to scientists' satisfaction, the nature and degree of risk to a public not sophisticated in the conventions of risk assessment methods and risk management decision making. We can, however, give people the facts they need in a form they can understand so they can follow and participate in the process and act in a rational way.

The question is: how do we address the problems of risk communication without giving an impression that we are trying to manipulate the public instead of bringing it into a full partnership role in this process?

First, it is critical to recognize that risk assessment and risk management are fledgling sciences. With microscopes, spectrographs, and sophisticated calculations, scientists weave a cloth of uncertain threads. The blanket they produce is supposed to offer the public security—security based on uncertain beliefs in uncertain risks with uncertain solutions.

Communicating the result of this complex effort means communicating uncertainty. Yet social psychologists such as Paul Slovic point out with well-documented research that people fear most the things they don't understand, can't see, and can't control. In short, the thing they fear most is uncertainty.

Of course, those in the business of measuring risk and trying to communicate it want a different kind of response. They want the public to see that inherent in the process are complex hazard identification steps: studies of dose-response relationships, exposure assessments, and analyses of risk exposure channels. The results of these steps are then expressed in conservative, probabilistic outcomes, still containing uncertainties.

Furthermore, they want the public to see the importance of balancing various risks in a risk management process that, depending upon the risk involved and the legislative dictates for how such risks are to be handled, analyzes alternative actions in the context of complex analytical tools called risk-benefit, benefit-cost, and cost-effectiveness.

Scientists are coming to know the precise meaning of these terms of art. But the general public—people worried about whether or not they should feed their children cereal in the morning—hasn't the foggiest notion what these terms mean. While people may not be averse to accepting risk, they want to be able to understand and have some choice regarding the risks they accept.

The second step we must take if we are to succeed in meeting the risk communication challenge is to look at what we have been doing and candidly test the results.

In the EDB case, the Roper organization asked some questions in their periodic surveys that would test the public's reaction to EPA's communication effort. They had heard Mr. Ruckelshaus say, "Calm down." How had they reacted?

The returns indicated a total of 33 percent of those polled said EPA acted "very responsibly," while 26 percent said the state governments acted "very responsibly." EPA got a stronger vote of confidence despite the fact that some states had gone beyond the EPA guidelines in setting allowable residue levels. The only group ranked higher in the public's eye was the supermarkets. People in this group, whom the public saw actually removing food from shelves as a protective step, were given a 37 percent confidence rating.

Another analytical effort now being carried out by consultant Harold I. Sharlin looks at the EDB event and asks exactly what EPA was trying to communicate and how well it succeeded.

Sharlin's work indicates that, like two trains safely passing in the night, the agency and the public were traveling on separate, albeit parallel, tracks.

EPA was sending out messages about risks to the public at large while John and Jane Citizen were sitting at home waiting to hear whether or not their cupboard should be cleaned out. In Sharlin's words, EPA was talking about "macro risks" while the people wanted to know about the "micro risk"—the risk to them personally and to their families.

In the national print media, EPA efforts to communicate were received and presented to the public in the sophisticated, analytical "macro risk" form.

In local newspapers and in television reports, however, the message was confused as reporters and commentators searched in vain for solid, salient quotes about the micro risk—the risk the individual faced from eating an EDB-contaminated bran muffin for breakfast in the morning.

The third step in meeting the challenge we face in risk communication then is to find a way to fill the need for micro risk information so people can understand or at least get some idea of what the risk means to them so they can participate in the dialogues and act in a rational manner.

Some new measures, simpler techniques, or perhaps some better words or symbols would help. Many scientists, however, respond that their work is too complex or complicated to communicate simply. Communicators, on the other hand, might suggest that this response is a modern-day "cop out."

Something of the same dilemma existed in another scientific area back in the 1930s. People were designing buildings, roads, and dams, and making risk management decisions by juggling complex sets of information on a range of geological variables.

One scientist, however, came up with a logarithmic scale ranging from one to ten, that has since been used to express the magnitude of total energy released by a sudden geologic shift—information, incidentally, that is used to communicate future risk to people and structures. It is known as the Richter Scale. "One" means a slight tremor, while a "ten" means disaster. Not only did his colleagues understand the measure; so did the man in the street.

The U.S. Forest Service offers another example. When you drive into a national forest you pass a sign on the side of the road with five colors on it—red, orange, yellow, green, and blue. An arrow points to one of the colors. If it points to red you learn immediately—while traveling at 55 miles per hour—that the risk of fire is too great to allow you and your family to have a campfire that evening. The risk is assessed and, once assessed, is communicated almost instantly.

The average citizen is also accustomed to dealing with risk in the context of the weather and, in some cities, air pollution indices. A 50 percent chance of rain may mean Joe takes a raincoat to work with him. The main point is that risks can be communicated and people can make responsible decisions on how to deal with them.

Of course, from a pure communication perspective, it doesn't take a marketing genius to recognize that consistency in use, repeated exposure, and easy understandability could be keys to success.

People respond to fear as scientists do in the risk assessment business when faced with conflicting data and uncertainty. They feel a duty to stack up conservative assumptions—better to err on the side of conservatism when dealing with a macro risk to public health. Likewise, when protecting themselves and their children, people want to err on the side of safety. This means they too are going to go with the most conservative assumption, or statement, on the market. In short, they'll believe the widely broadcast worst-case scenario.

To communicate risk we perhaps need to collectively search for ways to do so conceptually just as Richter did, just as the forester does, just as others have. We need to talk simply to people, and we need to find ways to answer their questions.

It can be done. It will simply take creative concentration. □

Some ABCs in Addressing Risk

by Bob Burke

EPA is forging an integrated strategy for assessing and managing risks because the major health and environmental challenges the agency now faces from heightened public concern about toxics issues are more complex and more subtle than those it confronted at its inception in 1971. This article briefly describes these challenges and the risk assessment approaches EPA is developing to address them.

The Toxic Chemical Challenge

There are four distinct yet interrelated problems associated with health and environmental risks from toxic substances which must be addressed by an integrated risk strategy.

Numerous and diverse toxic wastes: More than 65,000 industrial chemicals have been produced since 1945. Several thousand of these demonstrate various toxic effects or exist in sufficient volume to be of concern.

Elusive hazardous substances: Hazardous substances often do not respond to actions that are meant to isolate or destroy them. The task of keeping tabs on the movement and safe disposal of persistent pollutants is complicated by the fact that they can often produce health risks at exceedingly small concentrations.

Varying mandates on toxic substance risk: The issue is complicated by the fact that EPA is regulating toxic substances under no fewer than eight different legislative acts. Each statute has resulted in the establishment of independent EPA programs with different risk requirements and mandates. Some require or allow EPA to base regulatory decisions on risk reduction, while others are based solely on employing the best available control technology to reduce toxic pollutants in the environment.

Dealing with internal integration: Legislative and program differences have often led to different risk assessments within EPA for the same substance. Risk decisions must be integrated to prevent transfer of pollution from one medium to another (i.e. from air and water to the land), and to prevent the duplication of research on essentially the same chemical or set of chemicals. The strategy for integrating risk assessment isn't intended to abrogate these legislative responsibilities. But it does seek to strengthen the credibility and coherence of what EPA says about the risks of individual toxic substances to reflect the harm they cause to health and the environment, independent of whether they did it through air, surface water, drinking water, or the land. Most people probably don't care as much about the medium a chemical traveled to get to them as they do about the risks it poses to their health, and what can be done to identify and reduce these risks.

EPA is working to achieve this risk assessment process through two sets of steps. The first involves the confirmation of a logic for assessing risks. The second is to strengthen certain risk assessment guidelines pertaining to specific adverse effects of toxic chemicals.

Risk Assessment Logic

The logic that EPA is employing to integrate the assessment of health involves a four-step process that can be framed almost as a set of questions to which answers are sought.

1. How hazardous is the substance? This first step involves weighing available evidence to determine if a particular chemical substance has the inherent capacity to cause harmful effects. This analysis is wholly independent of how much of the substance is involved or whether any living thing has had contact with it. The substance could be located in somebody's backyard or in the safest confines of a laboratory.

2. How much is harmful? If the substance is likely to cause a particular effect, it is then necessary to know how potent it is. This step looks at the risks posed by the substance at various levels of exposure. For example, both saccharin and dioxin cause cancer in animals, but it takes literally millions of times more saccharin than dioxin to produce equivalent effects in laboratory testing.

3. What is the nature of the exposure? The next step is to estimate the nature of exposure in terms of how many people it affects and the time span in which this exposure has occurred. For many substances and incidents, exposure analysis involves an entire population of consumers who have been exposed over several years. For others, a shorter-term focus involves the maximum level of exposure on people living near a specific source.

4. What are the risks in a particular situation? The final step in the risk assessment logic focuses the preceding factors to determine the actual risks of a certain substance in a particular circumstance. This process considers the strengths and weaknesses of all the evidence and recognizes that the assumptions which go into assessing risks invariably have individual and collective margins of error.

There may always be uncertainties about the environmental and health risks of a toxic substance even when legislative deadlines and regulatory mandates require that some decision be made about controlling its use or presence in the environment. It should also be clear that the risk assessment

A risk assessment process may consider health threats to special segments of the population such as children, the elderly, people with respiratory disease, or pregnant women.

(Burke is on the staff of the EPA Office of Public Affairs. This article is based primarily on a soon to be published report entitled Risk Assessment and Risk Management Framework for Decisionmaking. *The report was prepared by EPA's Toxic Integration Task Force.)*

logic described earlier is simply what its name implies. In the case of risk assessment, this logic must be supplemented with methods for evaluating specific adverse health effects and the conditions under which they cause risk. This is why EPA is proposing new guidelines for risk assessment or proposing amendments to the ones it already has. These guidelines are being proposed to standardize the scientific assumptions used, and therefore to aid in improving consistency and credibility in risk assessment.

Risk Assessment Guidelines

EPA's risk assessment guidelines are aimed at improving the consistency and technical quality in assessments of human health risks from the thousands of toxic substances under the agency's purview. The six risks are:

1. Cancer: That certain toxic substances cause cancer and that others may do so is no longer seriously questioned within the scientific and health community. Guidelines developed in 1976 to assess these risks are being updated to reflect more recent knowledge about the causes of cancer and recent developments in methods for assessing cancer risk.

2. Mutagenicity: Mutagenicity refers to the potential of an agent or substance to induce alteration in the genetic material of living organisms. Until recently, mutagenicity information was used exclusively to predict the potential for cancer. In 1980, EPA proposed guidelines for assessing mutagenic risks as health effects, *per se*. These new guidelines are an update of the 1980 proposal.

3. Reproductive effects: The male and female reproductive systems and the developing fetus are potentially sensitive targets for the action of toxic agents. Birth defects research includes an extremely diverse set of impacts, and there have not been any previous risk assessment guidelines published for this class of effects. Guidelines for assessing risks to developing fetuses were proposed in November 1984. Work on guidelines assessing male and female fertility effects is just beginning.

4. Systemic effects: Exposure to toxic substances can also lead to adverse health effects on other organs of the body such as the liver, the kidneys, or the lungs. These effects can range from very minor impacts to severe organ dysfunctions, physical debilitation, and even death. Because of the number of toxic effects and organ systems involved, work on this guideline has been slower. It should be proposed next year.

5. Assessment for chemical mixtures: Most risk assessments address the health impact of individual chemicals, but EPA has a need to know what happens when people have been exposed to a mix of chemicals since this is often what happens in the real world. The new guidelines will include procedures for assessing the risks from exposure to chemical mixtures.

6. Exposure assessment: As noted earlier, decisions on controlling toxic substances must often be made in the absence of complete environmental data. As such, the decision maker must often make a risk assessment based only on estimates. What tools can be used or developed to make these estimates as accurate as possible? The new risk assessment guidelines tell what information is needed for exposure assessment, and articulate a format for reporting this information. The guidelines also propose a method for estimating and reporting uncertainties in exposure assessment.

Gene Young, D.C. Department of Recreation

A Word About Risk Management

An integrated risk assessment process can organize the scientific information needed to make regulatory decisions about controlling substances, but it can't make these decisions. Judgment is needed to integrate risk assessment with economic and financial considerations, considerations of feasibility, and "common sense."

This is where risk management comes into the equation. Risk assessment and risk management are two distinct though complementary parts of the regulatory decision process. Risk assessment is the process used to estimate risks to public health. Because of the uncertainties in currently available scientific information, the agency estimates risk conservatively and reports that estimate as an upper limit of hazard or virtually safe exposure level together with estimates of increased risk, if measurable, from higher exposure levels. Risk management then looks at the economic and social implications of each level of protection.

Therefore, EPA's objective is not to join risk assessment and risk management but to clearly separate the two so that scientific judgments comprising risk assessment can be made independently and then balanced against the economic, social, and community considerations that might be adversely affected by any decision addressing the risks involved. □

Controlling the Dangers from High-Tech Pollution

by Judith E. Ayres

This is the fourth article in a series by EPA's regional offices on major environmental problems they are addressing. The topics of the articles have ranged from efforts to clean up Boston Harbor pollution to the involvement of the public in protecting the Biscayne Aquifer in Florida. Ayres is Regional Administrator of EPA Region 9.

How can risk assessment and risk management best be used to address actual environmental problems? EPA is now engaged in a special project in the Santa Clara Valley of northern California to explore this question. The agency's Integrated Environmental Management Project, conducted in close cooperation with state and local governments, industry, and environmental groups in the area, is designed to help officials at all levels of government manage the complex problems of toxic substances in the air, surface water, ground water, and land of the Santa Clara Valley.

The Santa Clara Valley is better known as Silicon Valley, a remarkable center of high-technology manufacturing which has become the symbol for our national industrial renaissance. In the past twenty years, hundreds of electronics, semiconductor, and computer firms have located here—or have sprung up from the inventiveness of local engineers. Today, Santa Clara County is one of the fastest-growing areas of the country, and San Jose, once a sleepy orchard town and now a center of the high-tech development, is one of the nation's fifteen largest cities.

All of this industrial activity is hard to notice, however. Driving from Stanford University in Palo Alto to the green hills east of San Jose, one sees no smokestacks at all, and hardly anything that even looks like a factory. Semiconductors and electronics components are made in campus-like buildings interspersed with housing. The air above San Jose is clear, except for occasional smog from the ever present autos; the industries that dominate the area have a long-standing reputation for cleanliness. It is largely due to Silicon Valley's reputation that state and local governments all over the country have been encouraging similar developments within their borders.

Recently, however, it has become obvious that the absence of smokestacks does not mean an absence of environmental problems. The industry uses a wide variety of solvents and other organic substances and these have been leaking from underground storage tanks so as to threaten the Valley's drinking water aquifers.This has generated widespread public concern, and resulted in a reassessment of the industry's impacts on the environment. These contamination incidents have also, unfortunately, led some elements of the press and the community to overstate the magnitude of the environmental health problem: "high-tech toxics" make best-selling headlines.

EPA responded in 1984 to the immediate threats to the area's ground water by adding 19 sites in Santa Clara County to Superfund's National Priorities List. The agency was involved in the area even earlier through its Integrated Environmental Management Project (IEMP). This innovative project uses state-of-the-art techniques of risk assessment to define risks to public health from exposure to toxics in the Valley. These assessments will then be used to develop strategies to manage those risks more effectively.

This project is a joint effort of Region 9 and the Office of Policy Analysis at EPA headquarters. It embodies three of the agency's central principles: the separation of science from political concerns in order to guarantee sound, credible risk assessment; the use of risk management to make sure that we are reducing risk the furthest where it threatens us most; and a firm commitment to doing the public's business in a public way.

For risk assessment, this means considering exposures to toxics in a highly site-specific context. The agency has learned in recent years that the nature and magnitude of toxics problems vary widely from place to place, depending on local hydrology, meteorology, industrial patterns, and so on. This is nowhere more obvious than in Silicon Valley, where futuristic manufacturing processes present problems far distant from those of smelters and steel mills. The hydrogeology of the Valley, too, is like that of few other places in the country; ground water here moves at several feet per day. The routine application of national models will not do. Through a detailed case study of a particular area, however, we can take those site-specific factors into account.

The IEMP also aims explicitly at comparing the risks from toxics problems in all environmental media—air, surface water, ground water, and land. Public attention in the Valley has been riveted on ground water, yet half of the Valley's population drinks surface water imported from elsewhere in the state. Are our surface water problems just as serious as those from ground water, in terms of their impacts on human health? How are the relative risks from surface and underground supplies likely to vary in the years ahead? What about toxic air pollution? We don't currently know the answers to these questions. But we are finding out. Without this kind of comparison of risks, we will never know whether we are spending our resources, those of state and local governments, and those of the industries we regulate, in ways that buy the most public health protection for the money we collectively spend.

Ways to achieve those larger payoffs will be the focus of the second stage of the project, which is scheduled to begin in January 1985. For any given problem, we can apply any number of "fixes"; the question is which will do the most good.

In the case of ground-water contamination in the Santa Clara Valley, we can apply tighter controls on new or existing underground tanks. We can require more monitoring around the tanks, so as to catch any spills before they escape to the aquifer. We can contain and clean up certain spills. We can impose tighter controls on other possible sources of ground-water contamination, such as pesticide application, or landfills, or sludge farming. We can monitor the drinking water wells more frequently and more closely. We can even institute treatment of ground water, parallel to the ways that surface water is now treated. Which of

Sam Forencich, The Peninsula Times-Tribune

U.S. Rep. Norman Mineta (D-Calif.), right, answers questions from citizens attending a "toxics town meeting" in Sunnyvale, Calif., in July 1984. Sharing the podium with Mineta were Harry Seraydarian, left, Director of the Toxics and Waste Management Division in EPA Region 9, and U.S. Rep. Ed Zschau (R-Calif.)

these options, or what combination, will reduce risk the most? At what cost? At *whose* cost? These are some of the questions the IEMP will answer in Santa Clara. Again, the answers must be site-specific, because no real problem fits the national average case.

An undertaking like the IEMP could never succeed without the active involvement of state and local agencies. In the Santa Clara Valley, we are working with upwards of a dozen such bodies, sharing data, expertise, and insights on the problems. In an important sense, the project is an experiment in a new partnership of federal, state, and local governments, in which true cooperation and collaboration replace traditional delegation and oversight. The results, so far, are extremely encouraging. "Getting people to sit down at the table" and "sharing data among agencies" are two of the oldest chestnuts in government, but the dividends are enormous when the cooperation is real and continuous.

Our efforts in this regard are supported from the very top of the local government structure. At its outset, the IEMP established an Intergovernmental Coordinating Committee, consisting of county supervisors, mayors, city council members, and members of the elected boards of regional regulatory agencies. The committee meets once a month with EPA staff to discuss the progress of the project, to suggest modifications and new directions for the work, and to ensure that the project remains useful not only to EPA but to the local governments and regional agencies in whose communities we are working. Their support has been indispensable to the project.

If improved ties among various agencies of government are crucial to the IEMP's success, so is the active involvement of the public. We have been fortunate, in the Santa Clara Valley IEMP, to work actively with industry, with the leaders of the environmental community, and with the universities whose presence helped create Silicon Valley in the first place. Once a month, EPA staff meets with the IEMP's Public Advisory Committee, where these and other groups offer criticisms and suggestions. This is no public relations exercise. We firmly believe that only in the light of such scrutiny can we develop sound, defensible strategies for the complex problems confronting the Valley. And only if we are open with the public can we earn the public's confidence.

EPA has not, of course, abandoned its traditional role in the Santa Clara Valley. We maintain a strong enforcement presence, and stand ready to act swiftly in cases where direct federal involvement is called for. Our Superfund listings are a case in point. We will not allow the IEMP to be used as an excuse for procrastination where EPA determines that action is necessary. Analytic projects like the IEMP were never conceived as a substitute for active, aggressive regulatory programs; instead, the two must work hand in hand.

The IEMP can, however, help us to achieve several important goals. It will result in better long-term strategies to manage environmental risk in the Santa Clara Valley, strategies hammered out in conjunction with the state, with local governments, with industry, and with the public. It will also, we hope, help EPA address toxics issues nationally; along with companion studies in Philadelphia and Baltimore, the IEMP sheds new light on variations in those problems from place to place, and on flexible strategies to control risk. Finally, by working toward the rational solution of the problems which now confront the Santa Clara Valley, we are helping to ensure that the new industrial renaissance, symbolized by those smokeless factories, will not occur elsewhere at the expense of human health and the environment. With the help of our state and local partners, the industrial community, and the public, we can ensure environmental health here in Silicon Valley, and in other Silicon Valleys not yet built. □

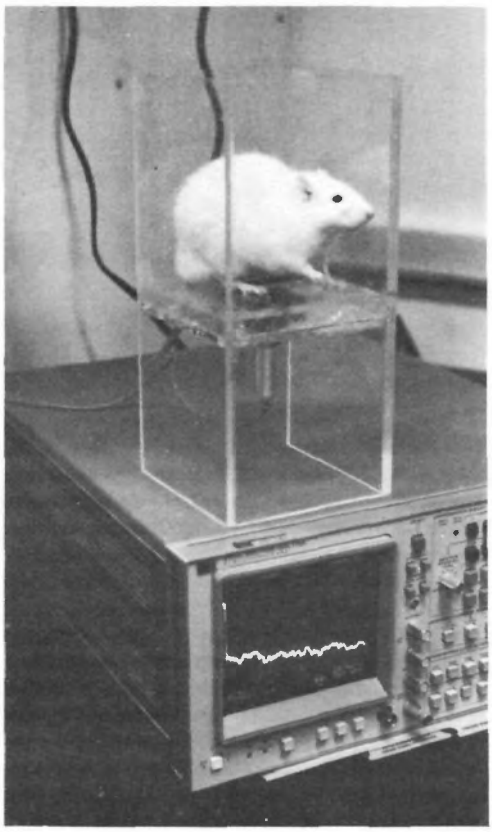
Is Animal Testing Overrated?

Two Views

by Dr. David P. Rall

Testing the health effects of chemicals in laboratory animals is an approach in wide use. How accurately does it indicate dangers to human health? The EPA Journal *asked two scientists concerned with the assessment of chemical hazards to humans to speak to the subject. Their articles follow.*

The first piece is by Dr. David P. Rall, Director of the National Institute of Environmental Health Sciences and the National Toxicology Program. The second is by Dr. George Roush, Jr., Director of Medicine and Environmental Health for Monsanto, a chemical manufacturing company.



National Institute of Environmental Health Sciences

Modern civilization has learned to develop methods and to use the products of these methods to provide for human sustenance and comfort. This technology has created tremendous benefits as well as rapid changes in our environment. The lifespan of the average U.S. citizen has increased dramatically in the last century. While curative medicine and preventive vaccines played an important role, the results of technological innovation have been critical factors—improved nutrition, sanitation, shelter, and water supply. However, this increasingly rapid rate of innovation and our inability to anticipate the consequences of these changes should continue to be cause for concern.

One of the most innovative areas has been in the chemical process industry, leading to inexpensive plastics, agricultural chemicals, etc. These have contributed to a better, longer life for all of us. We have come to learn, however, that some chemicals can act like a double-edged sword: while most offer real benefits to mankind, a few can also pose a threat. Society obviously needs the fruits of the chemical industry, but at the same time it needs protection from those few chemicals that can adversely affect human health.

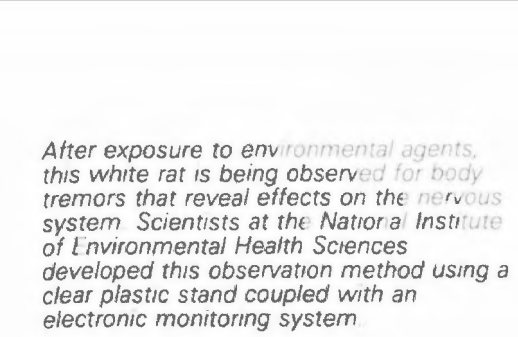
The hazards of some of these chemicals have been well studied. It is known that many human diseases can be traced to chemical exposure: male sterility to Kepone and dibromochloropropane; neurologic disease to Kepone, methyl mercury, lead, and methyl butyl ketone; lung cancer to asbestos, arsenic, bis(chloromethyl)ether and others; liver hemangiosarcoma to vinyl chloride; mesothelioma to asbestos, etc.

Fortunately, most chemicals are relatively non-toxic and require few if any controls to protect human health. It appears that only a small fraction of chemicals are highly toxic. Thus, to protect the public health and to prevent disease, this fraction should be accurately identified so that appropriate methods of control can be considered.

The mainstay of this hazard identification process is the laboratory animal toxicity study. A lifetime toxicity study of experimental animals, usually rats and mice—beginning at weaning, ending at death, using multiple dose levels of the chemical being tested—provides information on the kinds of toxic effects caused by the chemical and the doses or concentrations causing these toxic effects. This standard test determines if a chemical causes cancer and produces damaging effects on certain organ systems in animals—liver, lung, kidney, and endocrine systems. In the absence of relevant epidemiological/clinical data, these data typically constitute the primary basis for human hazard identification.

Historically, laboratory animal investigations have provided the basis for understanding disease processes and for developing new and better medicines. It should not be surprising that the results of toxicological testing in laboratory animals predict reasonably well the effects of chemical exposure in humans.

The molecular, cellular, tissue and organ functions are strikingly similar in all animal species; processes such as Na^+ and K^+ transport, ion regulation, energy metabolism, and DNA replication vary little as one moves along the phylogenetic ladder. The classic work on the transmission of neural impulses in the squid axon is directly relevant to man. Extensive studies of renal function



After exposure to environmental agents, this white rat is being observed for body tremors that reveal effects on the nervous system. Scientists at the National Institute of Environmental Health Sciences developed this observation method using a clear plastic stand coupled with an electronic monitoring system.

in fish, rodents, and dogs provide the basis for current understanding of renal function and the treatment of hypertension in man.

As long ago as 1966, *Cancer Chemotherapy Report* in Volume 50 described the testing of a series of 18 anti-cancer drugs in laboratory animals after the toxicity of these compounds had been determined in clinical trials with cancer patients. The animal tests mimicked the dose schedule and route of administration. The results in mice and rats showed that the toxicity—essentially the maximum tolerated dose in laboratory animals and patients when expressed on a chemical doses per unit body surface area basis—was quite close, generally within a two- to three-fold range. The greatest differences were about ten-fold.

The relevance of laboratory animal toxicity studies as well as carcinogenicity studies has been extensively considered and was reaffirmed in the 1977 National Academy of Science-National Research Council report on *Drinking Water and Health.* Almost all of the known human carcinogens as defined by the International Agency for Research on Cancer (IARC) are carcinogenic in appropriate laboratory animal studies. In fact, animal data showing a carcinogenic response to a chemical have even preceded human case reports or epidemiological findings in a number of instances. Examples of chemicals for which initial indication of carcinogenic potential occurred in animal studies include aflatoxin, 4-aminobiphenyl, bis(chloromethyl)ether, diethylstilbestrol, melphalan, mustard gas, and vinyl chloride.

It is certainly true that not all animal carcinogens have been shown to cause cancer in humans. This may be because we have not yet developed the epidemiologic or clinical tools we need to relate disease to a specific chemical which has been shown to be toxic in animal experiments. However, most scientists recognize the importance of animal data as an indicator of human carcinogenic potential. For instance, the IARC has long taken the position, as stated in its most recent monograph on the evaluation of the carcinogenic risk of chemicals to humans, that:

> In the absence of adequate data on humans, it is reasonable, for practical purposes, to regard chemicals for which there is sufficient evidence of carcinogenicity in animals as if they presented a carcinogenic risk to humans. The use of the expressions 'for practical purposes' and 'as if they presented a carcinogenic risk' indicates that at the present time a correlation between carcinogenicity in animals and possible human risk cannot be made on a purely scientific basis, but only pragmatically. Such a pragmatical correlation may be useful to regulatory agencies in making decisions related to the primary prevention of cancer.

In conclusion, it seems clear that laboratory animal data will continue to play an essential part in identifying the potentially toxic effects of chemical exposures and in protecting the human population from them. In addition, such data will often be used to confirm the identification of hazards and support the findings from epidemiological investigations. Further, as increasing emphasis is placed on the question of biological relevance in assessing possible human health hazards, laboratory animal data may provide essential scientific insight into issues such as mechanisms of action and effective target dose. Data emanating from clinical or epidemiological studies remain the best indicators of toxicity. However, when adverse health effects are observed in humans, it indicates that we have failed to prevent human exposure, which is the goal of public health.

Finally, in the absence of relevant epidemiological data, laboratory animal studies will continue to offer the primary means for determining and perhaps preventing the likelihood of adverse effects on human health. It is this critical first step which provides the basis for effective regulation of hazardous chemicals and can help to prevent unnecessary regulation. □

by Dr. George Roush, Jr.

Few recent scientific endeavors have been subjected to more criticism than the use of mice and rats in determining whether certain chemicals may pose a cancer risk to people. This criticism has ranged from the highly technical to the simply ludicrous—cartoons of bloated rats guzzling hundreds of cans of diet soft drinks.

All of this attention indicates the importance of the issue, namely whether feeding large amounts of a suspect substance to several hundred test animals for two years, then probing their organs for cancer, can tell us anything valuable about the potential effects of the same substance on ourselves. And while animal studies of this sort may be an easy target for the satirist, their importance to human health decisions and to the fate of everyday products merits a more thoughtful discussion.

To begin with, there is almost no aspect of the animal-to-people translation not beset with uncertainty and embroiled in intense scientific debate. Points of contention include the extent to which human versus animal cells are able to combat potentially carcinogenic molecules, how human organ systems may differ from those of animals in the way they handle or metabolize various substances, and how actual human exposure to these substances compares with that of laboratory animals under test conditions.

All of these factors come together in a fundamental dilemma of animal testing for potential cancer agents. This is that many of the 20 or so known carcinogens, such as asbestos and vinyl chloride, also cause cancer in rats or mice, but the vast majority of the more than 1,000 compounds that cause cancer in one or more animal species do not do so in people, to the best of our collective scientific knowledge. Substances in this category include saccharin, lead and phenobarbital.

So, while there are apparently some similarities between people and animals in reacting to some cancer agents, this relationship is hardly simple, direct or consistent. If it were, the past few

decades of our exposure to substances that have caused cancer in rodents should have steadily driven up the occurrence of the disease among ourselves. But they haven't. Too many Americans now die of cancer (about one in four), but the age-adjusted death rate from cancer among the population as a whole has remained nearly constant since the 1930s. Further, the rate of occurrence of most types of cancer has remained stable or declined. One notable exception is lung cancer which has been increasing, due mostly, the experts feel, to the effects of smoking tobacco.

Despite the tentative nature of its usefulness, animal testing remains the best experimental tool now available for detecting substances with a carcinogenic potential.

Obviously, we cannot deliberately expose people to questionable materials in order to judge the outcome. Further, despite the arguments of the proponents of such short-term, test-tube screens as the Ames test, most experts agree that not enough research yet exists to support their use in place of animal studies.

In addition, our collective experience with animal tests has taught us a number of things to bear in mind as we both design these studies and attempt to interpret their results. For example, we know that some substances will cause cancer in some animal species but not in others. Thus, the dye intermediate, beta-naphthylamine, causes tumors in dogs and hamsters but not in mice and rats. In fact, we know that for some species and some substances, sex differences exist in the development of tumors. To control for problems of species differences, all reputable researchers in government, industry and academia now use more than one species in testing a substance.

We also know that considerable caution must be used in drawing conclusions about the potential carcinogenicity of a substance based upon studies in mice. These animals are particularly prone to spontaneous development of tumors, especially liver and lung tumors. As a result, some researchers avoid using mice, and others again compensate for this problem by employing a second animal species. But the knowledge of these and other caveats still does not give us much confidence in drawing conclusions about cancer for people from animals. To improve this process, we must do more basic research in the area of pharmacokinetics. This means we must learn more about the similarities and differences between people and specific experimental animals regarding:

- how test substances behave in the bodies of each;
- how these substances are transformed or metabolized in the bodies of each, and what breakdown products or metabolites are formed;
- how long these materials remain in the bodies of people versus animals;
- which organ systems they affect;
- and whether the metabolites, rather than the parent compound, may be carcinogenic.

The recognition of the importance of these questions is growing among all of those involved in the animal-testing debate. Experts in and out of government are starting to focus on the need for answers. Provided the right research is undertaken, we will be able in the near future to make more meaningful use of animal test results than we are now.

No discussion of animal testing would be complete without touching upon that issue which has sparked so much of the human versus rodent debate: the use of the "maximum tolerated dose" or MTD. This is the highest dose that won't reduce an animal's lifespan due to effects other than tumors.

Critics of the MTD approach point out the absurdity of its size in relation to human exposure. For example, they might cite two studies on trichloroethylene (used to decaffeinate coffee and for many other purposes) which involved the human equivalent of millions of cups of coffee a day.

The scientific critics also make a more technical objection: that tumors produced in animals under high-dose conditions may reflect not the inherent toxicity of the test substance but the effects of bodily stress caused by organ systems attempting to metabolize the high doses in unusual ways.

Advocates of the MTD approach contend that because so few animals (relative to the human population) are used in these studies, they must be exposed to extremely high doses to determine if the chemical has any cancerous effect at all, particularly if it is thought to be a weak carcinogen.

Fortunately, the debate is not at a standstill. For product registration purposes, regulatory agencies such as EPA sometimes recommend the use of three doses in chronic animal feeding studies—the MTD, a low dose aimed at a no-effect level, and a dose somewhere between these two. Similarly, the National Toxicology Program, the federal government's principal animal-testing arm for chronic effects, now has begun to employ three doses in its studies.

These procedural changes are a commendable attempt on the part of federal agencies to obtain a more complete and realistic picture of the carcinogenic potency, if any, of test substances. For example, the variety of data yielded by several dosing levels can help regulatory agencies construct better "dose-response curves" against which human exposure levels can be measured and from which estimates of human risk can be drawn.

Of course, this will only happen if regulatory agencies use the data in this way. But their record in this regard has been spotty at best. Too often, we in industry still see risk assessments consisting mainly of mathematical calculations based upon high-dose levels in single animal species. These are of

Weight check for a rodent, a routine part of tests for the effects of cancer agents on these animals.

Monsanto Co

limited use. They are only one piece in what ought to be a more fully developed picture of potential human hazard. To get this picture, the full complement of information on a substance must be considered, including its biochemistry and pharmacokinetic aspects.

I would offer two other thoughts regarding risk assessment. They concern both how regulatory agencies, such as EPA, use animal tests in this work, and how they don't use other, equally (or perhaps more) valid information.

Single positive animal studies have been sufficient to put the agency's rulemaking wheels in motion. But no number of negative animal tests seems adequate to keep these wheels from spinning. A single negative study ought not neutralize a positive, but several negative findings contrasted with one positive ought to cause regulators to consider whether the appropriate next step should be further research as opposed to precipitate regulatory action.

A more troubling aspect of the agency's risk assessment process is its apparent lack of respect for well conducted human epidemiological studies. Now women and men seem to count less than rodents in the decision-making process. This despite the fact that numerous scientific bodies have stressed the importance of epidemiology in determining human risk. As recently as last August, an interdisciplinary panel convened by Oxford University's Dr. Phillipe Shubik reported that: "Human data provide the only direct evidence that a chemical produces cancer in man....Because of their central role in the identification of human risk, epidemiological studies are indispensable and require substantial expansion."

I'm not arguing for the use of human evidence to the exclusion of animal data. Instead, I'm urging that EPA take into account as much quality information as is available on a particular substance: animal test results, human mortality and morbidity, the route and extent of human exposure, and studies that elucidate species' similarities and differences.

The Roman poet Horace wrote that "the mountains will be in labor, and the birth will be an absurd little mouse." The controversy over animal testing has turned this couplet on its head: the mouse has produced a mountain of scientific debate. But as we scale up and down this mountain, we need to keep in sight the common destination—animal testing systems that will allow us to do what is right and reasonable in protecting both our health and our economic well-being. □

Summing Up the New RCRA Law

by Jack Lewis

In November President Reagan signed into law a bill reauthorizing and amending the Resource Conservation and Recovery Act (RCRA). RCRA is administered by EPA's Office of Solid Waste and Emergency Response (OSWER).

RCRA is intended to prevent hazardous waste disposal practices known to pose a threat to human health and the environment. Its provisions, geared to the present and the future, complement those of another EPA statute, also administered by OSWER. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—better known as "Superfund"—cleans up sites polluted by unwise disposal practices used in the past. Because of its preventive orientation, the long-range importance of RCRA is likely to be even greater than that of CERCLA.

The new RCRA legislation will broaden government restrictions on land disposal of hazardous waste and greatly increase the number of waste generators subject to EPA regulation. Other provisions in the new bill will significantly improve the quality of landfills and surface impoundments and place underground storage tanks under EPA regulation.

Singled out below are the amendments likely to have the greatest impact on the future of hazardous waste disposal in the United States.

Land Disposal Bans and Restrictions

By specified dates, EPA must decide whether it is safe to continue land disposal of a large variety of hazardous wastes. Should EPA fail to meet these deadlines, so-called "hammer clauses" go into effect prohibiting such disposal.

(Lewis is Assistant Editor of the EPA Journal.)

Deadline	Hazardous Waste
November 1986	Solvents and dioxin
July 1987	"California" wastes (Wastes currently banned by the State of California)
August 1988	1/3 of EPA's listed hazardous wastes
November 1988	Underground injection of solvents, dioxin, and California wastes
June 1989	2/3 of EPA's listed hazardous wastes
May 1990	All listed and characteristic wastes

If EPA fails to make a determination during the allotted time for California wastes, dioxins, solvents, characteristic wastes, and the "last third" of listed wastes, land disposal of such waste will be prohibited.

If EPA fails to make a determination by August 1988 and June 1989 for the "first and second thirds" of the listed wastes, disposal in a landfill or surface impoundment may continue only if (1) the generator certifies that there is no alternative capacity available, and (2) disposal takes place in compliance with the minimum technology requirements. However, if EPA still has not made a determination by May 1990, land disposal of all such waste will be prohibited.

In addition to ruling on various types of land disposal, EPA must promulgate regulations specifying methods of treatment capable of substantially reducing the toxicity of the waste or its likelihood of migration from a disposal unit or injection zone. Wastes which are so treated will be exempt from the ban on land disposal.

Petitioners defending any disputed method of land disposal must demonstrate to EPA that there will be no migration from a disposal unit or injection zone for as long as the waste remains hazardous.

Regulation of Underground Storage Tanks

The new RCRA legislation brings underground storage tanks containing hazardous substances under EPA regulation for the first time. Corroded or leaking underground storage tanks have been linked with serious instances of ground-water pollution. EPA must set final standards for three types of underground storage tanks according to the following schedule:

Deadline	Type of Tank
February 1987	Petroleum tanks
August 1987	New tanks containing CERCLA hazardous chemical products
August 1988	Existing tanks containing CERCLA hazardous chemical products

By May 1985, installation of certain types of underground storage tanks must cease.

EPA's final standards must include certain requirements for existing and new tanks. Regulations for existing tanks must cover leak detection and tank testing, record-keeping and reporting, corrective action, financial responsibility, and closure. Regulations for new tanks must include design, construction, installation, release detection, and compatibility standards.

The states have the option to administer their own equally stringent version of EPA's underground storage tank program. They may apply for such permission 30 months after enactment.

By November 1985, EPA must complete a study of petroleum tanks. The agency has until November 1987 to conduct studies of (1) underground tanks containing other "regulated substances," and (2) certain "exempted" tanks.

Work crew installs double liners at new landfill in Cape May County, N.J. Under new amendments by Congress, EPA will issue regulations or guidance on the use of double liners.

Camp Dresser & McKee Inc

Improvements in New and Existing Land Disposal Facilities

The new version of RCRA calls for upgrading standards applicable to new landfills, surface impoundments, and waste piles. It also proposes improvements in existing surface impoundments through a process known as "retrofitting."

EPA has until November 1986 to issue regulations or guidance documents on the use of double liners. In the past, single liners have been sufficient to meet EPA requirements. Liners are continuous layers of synthetic or earthen material placed beneath hazardous waste to prevent its escape into areas surrounding a landfill or surface impoundment. Prior to the November 1986 deadline, EPA's new double liner requirement may be satisfied through the installation of a synthetic or clay liner system that meets certain specifications.

Owners or operators of interim status land disposal units that first receive waste after April 1985 must comply with RCRA requirements for double liners and leachate collection when expanding or replacing landfills, impoundments, and piles. In addition, most interim status surface impoundments must retrofit with double liners and leachate collection within four years of enactment of the RCRA amendments. (Interim status facilities are those that comply with a certain set of EPA requirements and are allowed to operate, while their application is being processed.

Inclusion of Small-Quantity Generators

Prior to enactment of the new RCRA legislation, EPA regulated persons who generated at least 1,000 kilograms/month of hazardous waste. Now EPA must promulgate standards, no later than March 31, 1986, for persons who generate between 100 and 1,000 kg./month of hazardous waste. This provision will expand the population of RCRA-regulated waste generators from 14,000 to approximately 100,000.

By July 1985, waste generated in quantities between 100 and 1,000 kg./month must be accompanied by an EPA manifest if shipped off-site. By September 1, 1985, all manifests must contain a certification by the generator that the quantity and toxicity of the waste shipped off-site has been reduced to the maximum degree economically practicable.

Subtitle D Facilities

Subtitle D of RCRA deals with solid waste management facilities (e.g., municipal landfills). EPA's previous criteria for these facilities were enforceable by the states, but not EPA. The new RCRA also gives EPA enforcement authority. EPA is to step in if the states fail to meet deadlines for developing programs to ensure that their solid waste management facilities comply with RCRA's existing and added criteria.

By March 31, 1985, EPA must revise its criteria for solid waste management facilities that may receive hazardous household or small-quantity generator waste. At a minimum, EPA must require ground-water monitoring, establish location criteria, and provide for corrective action, where appropriate.

Listing of Hazardous Wastes

The new RCRA legislation stipulates that EPA must make listing determinations on 21 specific substances. After analyzing their proportions, the agency has to decide which of these substances should be regulated as hazardous wastes. Deadlines have been set for agency action on each substance.

By November 1986, EPA must also make various additions to its list of hazardous characteristics. First, RCRA requires the agency to determine measurements of organic toxicity. Second, the law requires EPA to identify a medium for toxicity testing that accurately predicts the leaching potential of hazardous wastes.

The new RCRA also changes the way EPA must handle petitions to "delist" specific wastes. Companies submit delisting petitions to EPA if they believe a specific waste differs significantly from its apparent counterpart on the EPA list, so much so that it can be considered not hazardous.

Under the old law, EPA could consider only factors weighed in its original listing decision when processing delisting petitions. The new RCRA states that EPA must consider additional factors when evaluating delisting petitions. The law also specifies that "temporary" delistings granted by the agency are to lapse automatically after 24 months if EPA does not finalize them.

Carlisle SynTec Systems

Underground storage tanks will be regulated by EPA under amendments to RCRA (Resource Conservation and Recovery Act)

Permitting of Hazardous Waste Facilities

The new RCRA requires that permits for hazardous waste facilities be renewed every ten years. Land disposal permits, however, are subject to more frequent review: every five years.

Applications for permit renewal are subject to all the regulations that pertain to the issuance of new permits. RCRA also specifies that these applications must reflect improvements in control and measurement technology that have occurred since the previous permit was issued.

The new RCRA legislation sets the following timetable for Part B permit applications. Part B is a more detailed, narrative application that must be filed pursuant to a briefer Part A form. Facilities run the risk of losing their interim status if they miss these Part B application deadlines:

Facility	Interim Status Terminates	Unless Part B Submitted
Land disposal	November 1985	November 1985
Incinerators	November 1989	November 1986
Other facilities	November 1992	November 1988

Part B permit applications for landfills and surface impoundments must be accompanied by an assessment of the potential for public exposure to any hazardous substances that might be released from these units.

EPA, for its part, has to meet the following deadlines in processing Part B applications:

Deadline	Type of Part B Application
November 1988	Land disposal
November 1989	Incinerators
November 1992	Other facilities

Under the new RCRA legislation, EPA is authorized to issue temporary permits for experimental facilities without first issuing permitting standards. Such permits are limited to one year, but are renewable each year for up to four years. They are designed to foster innovation in the hazardous waste industry.

Corrective Action Requirements

Under the new RCRA, EPA will be required to promulgate regulations requiring handlers of hazardous waste to furnish evidence of financial responsibility for corrective action. The new legislation extends responsibility for corrective action beyond the facility boundary and mandates that EPA should issue regulations to this effect as soon as possible. All permitted facilities and interim status landfills, impoundments, and piles that received waste after July 26, 1982, will be subject to these new regulations. EPA also is authorized to require corrective action for releases of hazardous waste or constituents from any solid waste management unit, regardless of when the waste was placed in the unit, or whether the unit is closed. Owners or operators of such facilities must also ensure that they have adequate funds to cover the cost of cleaning up these releases.

Under the new RCRA, EPA is also authorized to issue an administrative order requiring corrective action for releases of hazardous waste from interim status facilities. In addition, the agency is empowered to commence a civil action for appropriate relief. EPA will exercise these powers as necessary on a case-by-case basis to protect human health and the environment.

Citizen Suits

Under Section 7003 of the new RCRA legislation, private citizens are authorized to bring legal action in cases where past or present hazardous waste management practices pose an imminent danger. They can bring this action against companies, governmental entities, or individual citizens engaged in imminent hazards.

Section 7003 applies to past generators as well as to situations or sites where past acts or failures to act may have contributed to a present endangerment to human health and the environment.

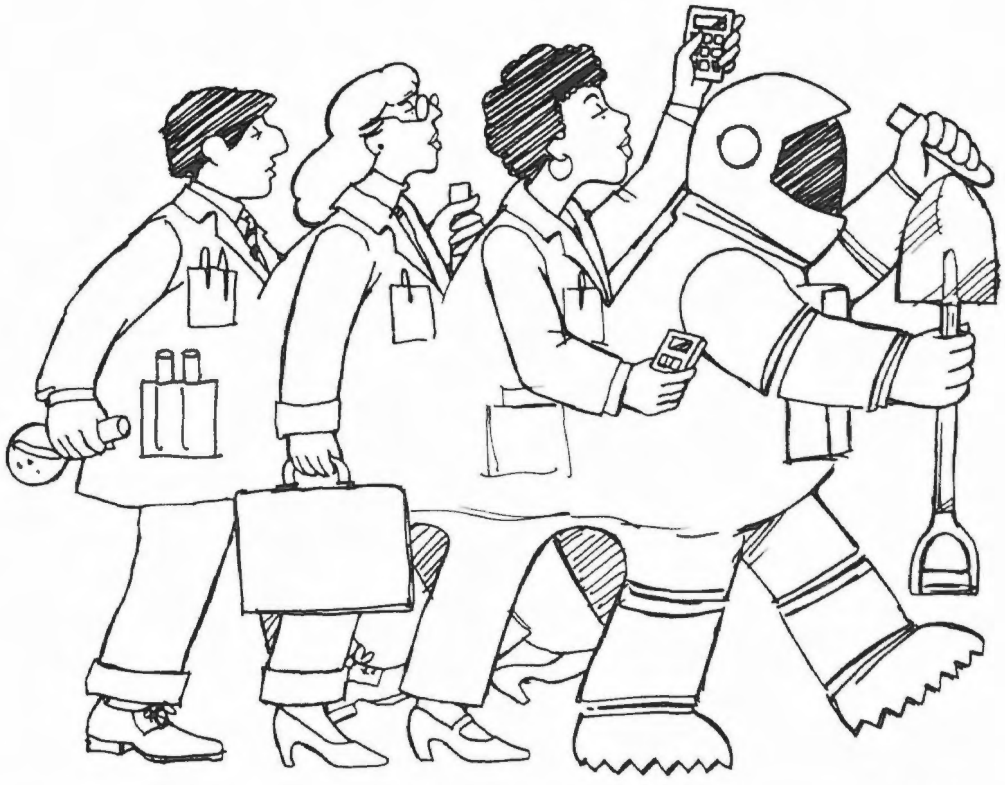
Citizen rights to sue are limited, however, (1) if EPA or the state government is diligently bringing and prosecuting a related action under Section 7003 of RCRA or Section 106 of CERCLA, or (2) if EPA or the state has settled a related action by entering into a consent decree.

Neither citizens nor EPA can take action against common carriers for imminent hazards arising after shipments are delivered to the consignee.

EPA has several responsibilities pertaining to citizen rights under RCRA. The agency has to notify local officials and post a sign at any site thought to pose an imminent and substantial threat to human health and the environment. EPA also has to provide for public notice and comment before it enters into any settlement or covenant not to sue under Section 7003. Finally, RCRA stipulates that EPA must establish an Office of Ombudsman to provide information to the public, and to receive and assist in resolving citizen complaints. □

The People at EPA

by Margherita Pryor



Bureaucrat is not a nice word. It's usually preceded by words like "paper-pushing," "faceless," or "petty." Even the dictionary refers to a bureaucrat as "an official who works by fixed routine without exercising intelligent judgment."

And if movie images are any gauge of popular sentiment, bureaucrats occupy a niche in the public's heart only slightly above that of used car salesmen. Whether foreclosing on family farms, nitpicking businesses into bankruptcy, or harassing innocent citizens, they exist only to inspire instant loathing. When the obnoxious EPA official in *Ghostbusters* was insulted by the stars and then drowned in marshmallow fluff, audiences cheered.

Once government agencies were the good guys. Their employees were represented by the likes of Robert Redford. Now they are portrayed as a collection of nerds, wimps, and pettifoggers. Beyond the lure of a steady paycheck, what could possibly induce people to work for an organization supposedly characterized by red tape, low public esteem, and frustration?

(Pryor is on the staff of EPA's Office of Public Affairs.)

At EPA, the motives are as varied as the 13,000 people who work here.

They're a diverse lot professionally. As might be expected, many pursue occupations such as engineering, chemistry, office management, law, economics, accounting, computer science, and public administration. But others are involved in less expected areas such as urban planning, horticulture, psychology, geography, genetics, agronomy, sociology, and meteorology.

Many employees applied to work for EPA because they wanted to help solve environmental problems; some were "inherited" from other agencies and offices when EPA was created in 1970; still others just needed a job. Once they reached the agency, however, most employees came to share a deep belief in EPA's mission and a desire to contribute to its success.

David Hawkins, a former Assistant Administrator for Air, Noise, and Radiation, came to EPA from the Natural Resources Defense Council. Having worked on both sides of the environmental fence, he concludes that almost everyone at EPA is genuinely motivated to do the best job possible. "If you're interested in the implementation of federal environmental laws", says Hawkins, "EPA is the only place to work. Its mission is strongly supported by the public, so you feel that you're working in the public interest. But even though the public supports what you're doing, that's not the feedback you get. The typical feedback comes from the regulated industry or some member of Congress complaining that you are doing your job. Out of 50 complaints, I'd say that 49 are that you're doing your job too diligently."

Nevertheless, Hawkins recommends working at EPA. "The agency has many different types of people, and I enjoyed that variety. It was a very positive experience, very stimulating. It was a challenge."

"Challenge" and "meaningful" are the two words most frequently used to describe work at the agency. "My expectations were very low when I started here", says one employee. "I didn't think it would be possible to see real changes. But in fact, I've experienced a lot of satisfaction. My background is in health and nutrition, and my M.S. is in public policy. I'm being challenged to use all my experience to help bridge that gap between science and government.

"Sometimes I feel like I'm using a chisel to hack at a mountain, but I really enjoy my work and the people I work with. EPA is just not like any place else in government."

Many employees have also found EPA an exceptional place for reasons aside from its environmental mission. "I

Steve Delaney

EPA employees work in more than 200 different job categories, but share a common belief in the agency's mission. Here, Administrator William D. Ruckelshaus shakes hands and chats with agency employees at an informal picnic last May marking the first year after his official swearing-in.

started here as a secretary," says one woman, now a program analyst. "The agency has challenged me. EPA is one of the few government agencies that encourage and allow people to cross from clerical to professional positions. Its upward mobility program really is a good incentive for people and it's taken seriously."

This perception by EPA employees that they and their agency are a breed apart was confirmed in a recent study conducted by the National Academy of Public Administration (NAPA). It included a questionnaire survey of more than ten percent of EPA employees, and was based on extensive interviews with top EPA leadership, with employees in all regional offices and major laboratories, and with outside experts. NAPA found that:

- Many employees joined government solely or primarily to work for EPA;
- Many employees view their jobs as "noble challenges" rather than just economic necessities. (Ninety-one percent of those polled in the survey said that the chance to accomplish something worthwhile was very important to them); and
- Many employees in offices not directly related to environmental concerns—administration, personnel, finance—nevertheless view their jobs in terms of helping EPA do its work.

EPA has more than 13,000* employees in over 200 job categories, but almost 40 percent of them fall into four groups:

sanitary engineer	1,673
secretary	1,129
physical scientist	1,082
environmental protection specialist	1,000

Here is another way of looking at the EPA work force.

Men	7,599
Women	5,707
Blacks	2,263
Hispanics	367
Asians	346
American Indians	35

* *All figures as of 9/30/84*

As one employee commented, "I studied business and management in college. I came when the agency was formed because I felt that the environmental field was the only place to work, that it was something I could be enthusiastic about on a day-to-day basis. I guess I really was affected by Earth Day. In spite of the last few years, I still have enthusiasm, still enjoy working for the agency. I'll probably end my federal career right here at EPA."

NAPA concluded that the agency's success is in great part due to the commitment and dedication of its employees, almost 2,000 of whom have been with EPA since it began. "They clearly want to be where they are, and doing what they are doing. . . . That the agency works as well as it does is a tribute to its people."

EPA Administrator William Ruckelshaus said the same thing before a Senate committee in May 1983: "EPA's greatest resource today is the same as when we started: its people." And as another employee says, "Yes, this is socially responsible work that contributes to the world's betterment, but what it really comes down to is this: I'm doing this for my children. It's their future I'm taking care of." □

Four-Footed Detectives

by Susan Tejada

At 10:30 a.m. on November 9, 1983, about 40 people gathered at the site of an old World War II Army depot in Edison, N.J., to find out if a newly trained hazardous waste worker could make the grade.

On this pleasant, breezy day, the worker's task was specific: go to a half-acre site normally used as an obstacle course in training emergency response personnel, and find samples of toluene that were hidden either in the obstacles or in the ground.

Before the test began, an examiner with an organic vapor analyzer moved toward one of the toluene targets. His instrument should have been able to detect less than one part per million of toluene. But the examiner couldn't get any reading at all until he placed the probe of the instrument right next to the ground where the sample was buried.

The crowd was skeptical. The scientific instrument hadn't performed so well. How could a new worker do any better?

The test began. Approaching from 50 feet away, the worker almost immediately uncovered the first toluene sample hidden in the jack of a flatbed truck. A few minutes later the worker discovered the same toluene sample that the instrument had failed to detect from a distance and, a few minutes after that, another sample partially submerged in rainwater in a tire.

The worker had passed a difficult test, but didn't seem anxious to celebrate with a beer down at the local hangout. Instead, this worker was more interested in playing with a Frisbee. This worker was a dog.

Common sense

"It's common sense that a dog can be sensitized to identify specific pollutants," says Hugh Masters. "They've been doing it for years with other substances like narcotics."

(Tejada is Associate Editor of the EPA Journal.)

Masters is the project officer for the recently completed EPA experiment officially known as "Toxic Area Delineation by Canine Olfaction." Over an eight month period running from August 1983 to April 1984, the project tried to find out if trained dogs could be safely put to good use in environmental programs. The project was carried out under subcontract to EPA's Oil and Hazardous Materials Spills Branch in Edison, part of the agency's Municipal Environmental Research Laboratory.

Masters' reference to a long-standing reliance on the scent detection capabilities of dogs is accurate. Use of dogs to track people or sniff out bombs and narcotics is well known and well documented. Some dogs have also been trained to detect termites and gypsy moth nests.

Glen Johnson, operator of the Guardian Training Academy for tracking dogs in Windsor, Ontario, has trained dogs to detect leaks of insulating fluids from underground electric power transmission cables. In his book, *Tracking Dog: Theory and Methods*, Johnson describes another environmental use for dogs.

"In 1974," Johnson writes, "I was commissioned to train dogs to search for and locate leaks in a brand new natural gas pipeline...The consulting engineering firm that designed the line...had attempted, unsuccessfully, to locate these leaks with every instrument known to modern technology..."

Johnson trained three dogs to detect the odor of butyl mercaptan, a substance in the leaks. "By the time we had completed [going over the 94-mile] pipeline three times," Johnson reports, "the dogs had successfully detected over 150 leaks, 4 leaky valves (one of them over 12 feet above the ground), through snowstorms, zero degree weather, [and] quicksand...and over rivers, highways, and plowed fields. The smallest leak was microscopic [and] was buried 18 feet deep..."

As a professional dog trainer with 15 years of experience, Herb Skovronek was familiar with the tracking dog work of Glen Johnson and others. As a professional scientist with a Ph.D. in chemistry and several years of experience at EPA's Edison lab, Skovronek was also familiar with the problems encountered at hazardous waste sites.

Seven years ago, Skovronek proposed to EPA the idea of using canine olfaction at such sites. His suggestion evoked no interest at all, probably, he explains, because "we weren't as keyed in to hazardous waste issues then as we are now." Two years ago Skovronek, by then a private consultant, tried again, and this time the Edison lab decided to give it a shot. Masters was named project officer not only because of his scientific qualifications, but also because he, like Skovronek, moonlights as a dog trainer.

For the project staff, says Masters, in addition to Skovronek, "We went to the best experts we could find": Glen Johnson and dog breeder and trainer Don Arner, co-founder of the North American Canine Olfaction Society.

With the human staff complete, the next task was to find the right animals. In order to produce search and retrieval results fast, the staff decided to use dogs and handlers who had already carried out scent-related work successfully. The two dogs selected were Justa, handled by owner Joyce Arner, and Niner, handled by owner Melvin Manor.

Search and retrieval

The goal of the first stage of the project was to train Justa and Niner to recognize toluene and 2,4,5- and 2,4,6-trichlorophenol at levels that could not be detected as quickly or efficiently with conventional field instrumentation. The animals were to seek out and retrieve articles contaminated with these chemicals, or dig at the site of a simulated ground contamination.

The particular chemicals were chosen partly because of their potential presence at actual sites. Toluene is a component of

The smell of success: Justa, a trained German Shepherd, leads handler Joyce Arner to a hazardous waste sample hidden in a tire.

gasoline. Trichlorophenols are often found along with dioxin, and in fact are often the precursor of dioxin.

The chemicals were applied by hypodermic syringe to cotton balls placed inside containers (wooden dowels and plastic film canisters) perforated with holes. While vapors diffused out of the containers, the animals were protected from direct contact with the compounds. At the low levels used, the odors soon became undetectable to the handlers. Blanks—containers without chemicals—were also hidden to further test the dogs.

As training proceeded, concentrations of toluene were reduced, samples were allowed to age up to 24 hours, and distances were increased. Both dogs rapidly reached the point where, according to the project report, they could "smoothly and consistently find 0.1 gram of toluene that was as much as 24 hours old and from distances of as much as 50 feet. To chemists familiar with the volatility of toluene, this must be quite surprising, since it is unlikely that any toluene remains at the source after 24 hours, much less in the ambient air at such distances from a source." Training with the trichlorophenol also progressed quickly.

By November 1983, the dogs were ready for their field test. Justa worked outdoors; Niner, indoors. As described above, Justa found three contaminated samples. Returning later in the day with Niner, she found all the remaining samples except one.

Indoors, Niner worked in a large warehouse where samples had been hidden in tires, wooden pallets, drums, and chunks of concrete. He found four samples and one blank during the test.

Perimeter delineation

In the second stage of the project, the staff wanted to train a dog to respond at the first whiff of toxic and hazardous chemicals without advancing to the source. Since this goes against both the animal's instincts and normal training protocols, the staff decided to use a dog with no previous training. Yeller was acquired from the local pound, and trained and handled by Don Arner.

The goal was to teach Yeller to sit the moment he detected the scent of his target chemical. The intent was to demonstrate that a dog could delineate the *perimeter* of a contaminated area without entering the hot zone. The chemical—1,2,3-trichloropropane—was chosen because it was a key pollutant at the planned test location, Tyson's Dump, an abandoned waste site near King of Prussia, Pa., that is on the Superfund priority list.

There was a bad storm on March 28, 1984, the day of the field test, with heavy winds and torrential rain. Yeller responded as he had been trained to do when he was brought to a nearby seep from the downwind direction, but his other responses were inconclusive.

Viable

Based on training and field test results, the project team determined that "the concept of using dogs to assist environmental workers in locating pollutants and in defining the perimeter of toxic and hazardous chemical presences in the environment is viable...Once a dog has been trained to a search protocol with one or more specific chemicals, it is possible and practical for him to adapt quickly to other chemical stimuli, thus allowing one trained dog to be used for a multitude of specific problems as they arise."

Last April, this experiment to find out just how much a dog's nose knows ended. According to Hugh Masters, the New Jersey Institute of Technology, in collaboration with Herb Skovronek, has submitted a proposal to continue the experiment with more dogs and more sophisticated equipment. If this cooperative research project is awarded, predicts Masters, scientifically defensible data supporting the use of dogs will be the result.

For the present, Masters and Skovronek view two uses for trained dogs as most promising. The first is detecting gasoline leaks from underground tanks. It is estimated that underground tanks at one-fourth of the nation's 2.3 million operating service stations are leaking, and Congress recently authorized EPA to regulate such tanks. The challenge, Skovronek explains, is to train a dog to differentiate between the odor of fresh gasoline, the odor of gasoline coming up from underground, and the odor of gasoline that has aged in ground water. "Can the dog differentiate between these scents?" Skovronek asks. "We think it can. We have to prove it."

The second use they foresee is in double-checking decontamination of heavy equipment after a site cleanup. Normally the equipment is hosed down after use, and decontamination is verified by random swab tests. Dogs could speed up the process by locating contamination in inaccessible parts of equipment that are not easily swabbed.

These particular uses are so promising because they are relatively safe. Gasoline vapors are not highly toxic, and decontamination checking puts a dog in contact only with small amounts of chemicals.

Other potential applications are at a standstill right now because the safety of the animal cannot be guaranteed. For example, it is sometimes necessary to take a large number of samples at a suspect site to define the extent of contamination. At one dioxin site in Missouri, about 8,000 samples out of

more than 10,000 collected turned out to be negative. Using dogs to pretest or screen samples could save considerable lab costs, but, says Skovronek, "I have not yet found a way to design a dioxin experiment that would be safe to the handler and the dog, and that stymies me." He thinks that, were it not for the same safety problem, dogs could also be used to delineate the area of a PCB spill or to detect PCB leaks. But the first questions you have to ask, says Skovronek, are "What's there? Is it dangerous? If it is, I'm not going to bring my dog there."

It is unlikely that dogs will ever be used to scout out an abandoned site where there is no information on the chemicals present. For one thing, explains Royal Nadeau, a member of EPA's Environmental Response Team, "You need prior knowledge of the site to know if the dogs have been trained to detect what's out there." For another, it's too dangerous. "You would never let the dogs go to ground zero," says Nadeau. "You would never go into a situation where the handler has protective gear and the dog doesn't."

Of the three dogs who participated in the project, none exhibited any ill effects due to that participation. In fact, it was the consensus of their handlers that the animals would have been exposed to more hazardous chemicals in a flea dip than through working in this experiment.

The project report concludes "the use of canine olfaction introduces an innovative and potentially cost-effective technique for quickly locating pollutants in the environment." After working with the dogs, handler Joyce Arner agrees. Once a dog has been trained to locate the pollutants, she says, "it can do it a lot faster and more accurately than human beings, and can find more minute doses at greater distances than instruments." As a matter of fact, warns Skovronek, the dog's ability to locate minute doses can actually be a problem. "Do we really need to detect parts per quadrillion?" he asks. And though the dogs may detect chemicals before instruments do, use of instruments is not likely to disappear. "If I used a dog," says Nadeau, "I would still want instrumentation for backup in case we went to court for cost recovery."

Masters and Skovronek have few doubts about the ability of trained dogs to assist at hazardous waste sites. Nevertheless, they caution that the animals' contributions should be kept in perspective. "The dogs won't solve all our problems," says Skovronek. "But they will solve some of them." □

(Copies of the Toxic Area Delineation by Canine Olfaction *project summary sheet are available from Hugh Masters, Environmental Protection Agency, OHMSB/MERL, Edison, NJ 08837; phone 201/321-6740.)*

Making Pollution Prevention Pay

by Dr. Robert P. Bringer

Pollution Prevention Pays. That phrase was put into capital letters in 1975 when the 3M Company made it an integral part of its worldwide manufacturing operations and environmental policy.

And 3P—short for Pollution Prevention Pays—has, indeed, paid off.

Now 10 years old, the 3P program in the United States can point to these totals for pollution prevented annually:

Air pollutants—85,000 tons.

Water pollutants—10,000 tons.

Wastewater—590 million gallons.

Sludge/solid waste—142,000 tons.

Most of 3M's manufacturing is done in the United States, at plants in 37 states. But the company also has manufacturing operations in 30 foreign countries on six continents and there, too, 3P is helping the environment. Overseas, the totals of pollution prevented annually are 8,000 tons of air pollutants, 400 tons of water pollutants, 400 million gallons of wastewater and 3,000 tons of sludge and solid waste.

The environment hasn't been the only beneficiary of 3P.

Worldwide, the program has achieved savings of more than $200 million in the past decade, 80 percent of it in the United States.

The savings are the result of pollution control equipment purchases that were eliminated or delayed, raw materials saved and operating costs reduced, energy saved, and sales retained on products which might otherwise have been taken off the market as environmentally unacceptable.

"Pollution Prevention Pays" became a part of 3M manufacturing operations at a time when many new and complicated environmental laws and regulations were being generated by the states as well as the federal government. The new requirements were generally viewed by industry as a no-alternative mandate. The conventional response was to install costly add-on pollution control equipment in order to filter out contaminants at the end of the manufacturing process.

3M Company

At the 3M Company's Riker Laboratories in St. Paul, Minn., Byron Seelig holds medicine tablets coated with an aqueous solution. Seelig helped develop a substitute for a solvent solution coating, an idea which reduced operating costs and made purchase of air pollution control equipment unnecessary at the lab.

The company looked beyond the negatives of cost and paperwork in this new regulatory climate and found a positive side, an alternative way to show concern for the environment: *Don't create pollution in the first place.* Eliminate or minimize pollutants at the source, in the manufacturing process.

As a result, 3P was born. Today, ten years later, it keeps growing, reducing pollution, conserving resources, saving money and spawning innovative technology.

The pollution-prevention approach is not unique and does not, of course, displace pollution control as an important strategy to ensure continued environmental compliance by the firm's numerous and widespread manufacturing activities. But as an *organized company-wide program*, 3P has been an increasingly profitable and valuable ally in the firm's environmental management strategy. The program seeks pollution prevention answers in four areas:

(1) Can the product be formulated with substitute, non-polluting raw materials?

(2) Can the process be changed?

(3) Can the equipment be redesigned?

(4) Can materials be recycled and reused?

Technical employees in manufacturing, engineering, and product research laboratories have provided the answers. Since 1975 more than 1,200 proposals have won the coveted designation, "Approved 3P Project."

A proposed 3P project has to eliminate or minimize a pollutant, save resources and money, and also show a technical achievement. Projects are judged by a committee of technical peers. It's a tough jury. More than half the proposals submitted fail to win approval.

The savings don't have to be dramatic or the technology complicated to win recognition. Here are some examples:

- Removing a chemical discharge solved a water pollution problem and *simultaneously created a new* revenue-producing product.
- A hazardous waste was minimized, materials were saved and clean-up time reduced simply by using a shallower pan for a coating solution.
- By substituting an aqueous for a solvent-based coating for medicine tablets, the need for costly pollution control equipment was eliminated.
- Energy-rich solvent-filled air was rerouted from the stack and incinerated in a converted boiler and now provides a fifth of the manufacturing plant's normal steam needs; air pollution was prevented and the energy bill reduced.
- A process modification to reclaim and reuse a solvent cost $4,000 to install and saved $12,000 the first year.

"Pollution Prevention Pays" has provided benefits beyond the more obvious ones of protecting the

(Dr. Bringer is executive director of environmental engineering and pollution control at the 3M Company in St. Paul, Minn. The Minnesota Mining and Manufacturing Company—3M—is a diversified manufacturing firm with international operations.)

3M Company

Solvent-rich air from a manufacturing process at a 3M Company plant in St. Paul, Minn., is rerouted through this big pipe to a modified boiler, where it provides supplementary fuel. This solves an emissions problem, eliminates the need for pollution control equipment, and reduces energy costs.

environment, wiser use of resources, money saved and technology advanced. A significant, though not readily apparent plus is the fact that pollutant-free products don't create cleanup or disposal problems for the consumer. When pollution is exported, it means that ultimately more resources, time and money have to be spent to deal with it.

Facilitating compliance with environmental regulations is a second benefit. With the 3P touch, air and water quality standards are not only met but often are exceeded.

The 3P success story has contributed to an increasing awareness in the industrial community of the possibilities and rewards of pollution prevention. The firm has shared its experiences, including how to organize a comprehensive company-wide 3P program, with hundreds of inquiring private and public organizations in the United States and abroad.

A fourth benefit is that the 3P track record has given us improved credibility with legislative and regulatory bodies. This facilitates technical conversations with the agencies, enabling us to share experience and expertise in a manner that contributes to meaningful and reasonable environmental protection measures.

Finally, because 3P applies to both conventional pollutants such as suspended solids in water and nonconventional pollution such as toxic substances, it has helped position the company to deal with environmental issues no less complicated or demanding than those industry and government have faced in the past. Major ones for the foreseeable future include hazardous waste and toxics control.

The challenges are complicated, but I'm encouraged to see a moderation in the combative climate that, in the past, too often accompanied the resolution of environmental problems. There seems to be a change in attitude from confrontation to cooperation between government and industry, and I think positive industry programs such as 3P have helped bring about the change. Government is now more interested in the technical knowledge of industrial professionals concerning the development of environmental regulations. Where such information was once regarded with suspicion and as self-serving, it is now accepted as valuable input.

When cooperation and understanding replace conflict, technical solutions to environmental problems aren't all that difficult.

Answers to pollution questions don't always have to be hammered out in the public arena, of course. Many are to be found in industry's own house, as 3M's Pollution Prevention Pays program has demonstrated.

The 3P approach, while not a solution to all of 3M's cleanup needs, will continue to solve pollution puzzles to help the environment and many firms throughout business and industry. Its ultimate goal is to eliminate industrial pollution entirely. That's utopian, certainly, but still a goal worth striving for. □

UPDATE

A review of recent major EPA activities and developments in the pollution control areas.

AIR

Rules for Pristine Areas

EPA has proposed federal regulations under the Clean Air Act for new pollution source review and monitoring requirements for 34 states which failed to adopt such measures in order to protect visibility in and around pristine areas.

In December 1980, EPA published visibility requirements for states near certain national parks, wilderness areas, and international parks. Under the requirements, those states were to issue regulations for the review of new industrial sources of air pollution and establish monitoring requirements that would protect the clarity of the air in federal areas where the agency determined that visibility is desirable.

States adjoining or surrounding these areas, which are protected under the Prevention of Significant Deterioration (PSD) requirements of the Act, were required to amend their state implementation plans (SIPs) to provide for visibility protection. Of the 36 states required to develop and adopt plans, only Alaska's and Louisiana's plans have been approved.

In 1982, the Environmental Defense Fund filed suit to compel EPA to develop plans for the deficient states. EPA and EDF reached a negotiated settlement on this issue on April 20, 1984, and EPA's current proposal is a result of that settlement.

EPA is proposing disapproval of the visibility new source review and visibility monitoring provisions of the 34 states' Clean Air Act implementation plans. In addition, the agency proposes that federal regulations be carried out by EPA in lieu of the approved state implementation plans for those provisions.

EPA is proposing a national, rather than state-by-state, visibility monitoring program in cooperation with the Department of the Interior and the Department of Agriculture in order to take advantage of existing federal monitors and ongoing work.

Strip Mines Listing

EPA has proposed making many future surface coal mines, or strip mines, subject to construction permitting requirements for major sources of air pollution under the Clean Air Act.

If finalized, the proposal would require that "fugitive" emissions from these sources be taken into account in determining if a source is a major emitting facility required to meet preconstruction permit requirements. Fugitive emissions are those not vented through a stack. In this case, they often involve dust and particulate matter emitted into the air from mining procedures.

EPA is also issuing a final rule retaining and clarifying its 1980 rules specifying that fugitive emissions from 30 listed source categories be included in determining emissions rates.

Proposed Air Standards

EPA has proposed nitrogen oxide standards for light and heavy-duty trucks and particulate standards for heavy-duty diesel trucks. This represents the first time that particulate emissions from heavy-duty diesels would be controlled.

The new standards would prevent significant increases in nitrogen oxide (NOx) and particulates which could cause difficulty for some areas of the country in meeting the National Ambient Air Quality Standards in the future. With stringent controls on passenger cars, heavy trucks now contribute the bulk of NOx and particulate emissions from motor vehicles.

Starting with the 1987 models, all light trucks weighing up to 6,000 pounds gross weight would meet a 1.2 grams per mile (gpm) nitrogen oxide (NOx) standard. Light trucks weighing over that amount (up to 8,500 pounds) would meet a 1.7 gpm NOx standard. The existing NOx standard for both classes of light-duty trucks is 2.3 gpm.

The agency said the 1.7 gpm standard for these trucks is based on the technological problems of also meeting the applicable particulate standard (0.26 gpm) for the 1987 model year. The interaction between NOx and particulates makes it difficult to control both of them at low levels in heavier vehicles.

Proposed Radionuclides Standards Withdrawn

EPA has announced the withdrawal of its 1983 proposed standards for radionuclide emissions under the Clean Air Act. The standards would have applied to phosphorus plants, Department of Energy (DOE) facilities, non-DOE federal facilities, Nuclear Regulatory Commission (NRC) licensed facilities, and underground uranium mines.

Radionuclides are radioactive materials which break molecules into electrically charged fragments called "ions" and thereby produce chemical rearrangements that may lead to permanent cellular damage. They occur naturally in rocks or minerals and are produced in nuclear reactors, nuclear weapons production procedures, and nuclear accelerators.

The withdrawal of the proposed standards for phosphorus plants, DOE facilities, NRC-licensed facilities, and non-DOE federal facilities is based on an EPA determination that current practices provide an ample margin of safety to protect public health from the hazards associated with exposure to airborne radionuclides. For underground uranium mines, the agency has concluded that the risks are significant, but that rules based on the original proposal could not legally have been issued under the Clean Air Act.

The agency is also issuing an Advance Notice of Proposed Rulemaking (ANPRM) to consider developing standards for radionuclides from licensed

uranium mills and another ANPRM for underground uranium mines to obtain additional information on control technologies.

Voluntary GM Recall

The General Motors Corporation is voluntarily recalling approximately 750,000 1981 and 1982 vehicles to repair catalytic converters that may be defective. California vehicles are included in the recall.

The 1981 vehicles have V-8 engines built by both Pontiac and Oldsmobile. Vehicles included in the recall are the Pontiac Bonneville/Catalina, Firebird, Grand Prix, LeMans and LeMans Safari Wagon; Buick Century, Century Wagon and Regal built with Pontiac 4.3 liter (L) engines, as well as Buick Electra, Estate Wagon, Custom Cruiser Wagon, Delta 88, Ninety-eight and Toronado models built with Oldsmobile 4.3L and 5.0L engines.

The 1982 vehicles are equipped with only V-8 engines built by Oldsmobile. Models involved are the Buick Electra, Estate Wagon and Riviera; the Oldsmobile Custom Cruiser Wagon, Cutlass Supreme, Cutlass Cruiser Wagon, Delta 88, Ninety-eight and Toronado equipped with 4.3L and 5.0L engines.

All of the recall vehicles are equipped with dual-bed catalytic converters which have experienced high rates of failure due to the breakup of the ceramic pellets within the converters.

Voluntary Mazda Recall

The Mazda Motor Corporation will voluntarily recall approximately 47,000 vehicles to service an emission control tube that may deteriorate after contact with road salt.

The voluntary recall campaign will include all 1981 and 1982 Mazda 628 models currently registered in the following high salt usage states: Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont, West Virginia, and Wisconsin. Vehicles registered in the District of Columbia will also be included.

The vehicles are equipped with a steel tube that conveys air from an air pump to the catalytic converter which controls auto emissions. This air provides oxygen which facilitates the reactions that occur in the catalytic converter.

In areas of high salt usage during winter months, the tubes may corrode and may develop leaks. If the tube leaks air, the performance of the catalytic converter will be impaired and the vehicles may exceed applicable federal emission requirements for hydrocarbons and carbon monoxide.

HAZARDOUS WASTE

Storage Tanks Advisory

EPA's Office of Toxic Substances has issued a Chemical Advisory to alert owners and operators of underground storage tanks to the potential problems that can be caused when these tanks begin to leak gasoline and other motor fuels.

EPA has estimated that there are approximately two million underground motor fuel storage tanks currently in use in the United States. EPA's Chemical Advisory discusses the potential legal liability of the tank owner or operator in the event of a leak, the availability of insurance, methods of detecting leaks, and tank repair and replacement. Approximately a quarter million copies of this Advisory were sent to interested groups throughout the country.

Gasoline, other petroleum products, hazardous wastes, and other chemicals are stored in above-ground and underground tanks of varying sizes, construction materials, and designs. These tanks may be operated at commercial gasoline stations, farms, transportation fleet headquarters, military installations, and other facilities.

Preliminary data indicate that leaking underground storage tanks can cause ground-water contamination, which may lead to serious contamination of drinking water supplies.

INTERNATIONAL AFFAIRS

World Industry Conference

The United States participated in the first World Industry Conference on Environmental Management (WICEM), which was held on Nov. 14-16 at Versailles, France. EPA Administrator William D. Ruckelshaus and U.S. Steel Chairman David M. Roderick were convenors for the conference.

The French government was host to the conference, which was sponsored by world industry in cooperation with the U.N. Environment Program (UNEP) and the International Chamber of Commerce.

The United States, Canada, the People's Republic of China, Japan, Kenya, Zambia, and most Western European and Latin American governments were represented at the conference by ministerial level delegations. Other participants included organizations concerned with environmental problems. The primary industry sectors represented at the conference were pulp and paper, oil production and electrical generation, the chemical industry, and iron and steel.

PESTICIDES

Emergency Pesticides Exemptions

EPA intends through negotiations with interested parties to develop proposed revisions to its regulations permitting emergency uses of pesticides.

An EPA project known as "Negotiated Rulemaking," which was first announced in the *Federal Register* of February 22, 1983, will test whether, and under what circumstances, affected interest groups can reach a negotiated consensus on which the agency can base Notices of Proposed Rulemaking (NPRMs). EPA is exploring whether this process can produce better regulations while reducing litigation and uncertainty among affected parties.

The agency recently began addressing the emergency pesticide exemption rulemaking through "Negotiated Rulemaking." In the fall of 1982, the Office of Pesticide Programs performed an internal audit of the emergency exemption regulations. A similar audit was conducted by the House Subcommittee on Department Operations, Research and Foreign Agriculture. Both reviews raised concerns about the current regulations and revealed that they could be improved with some revisions.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows the EPA Administrator, at his discretion, to exempt federal or state agencies from certain pesticide restrictions if he determines that emergency conditions exist which merit the broader use of a particular pesticide.

TOXICS

PCB Transformer Fires

EPA has announced proposed rules to reduce human health risks from fires in electrical transformers containing polychlorinated biphenyls (PCBs).

Based upon EPA's evaluation of recent transformer fires in Binghamton, N.Y., San Francisco, and Chicago, the agency believes that the combustion of PCBs in these transformers presents significant risks to humans and the environment.

To reduce these risks, EPA is proposing an amendment to its August 1982 PCB transformer rules that will place additional controls on this type of equipment.

PCB combustion can result in the formation of polychlorinated dibenzofurans (PCDFs). Tests on rats have show PCDFs to cause anemia and other blood problems. When chlorinated benzenes are present with the PCBs, combustion can result in the formation of polychlorinated dibenzodioxins (PCDDs) as well.

PCDDs are a chemical family that includes the dioxin 2,3,7,8-TCDD. This dioxin was found in soot samples taken after a Feb. 5, 1981, fire in Binghamton and in the May 15, 1983, fire at the One Market Plaza Building complex in San Francisco.

PCB transformers are frequently found in or near apartment buildings, office buildings, and shopping malls. They may be located in basements, or on floors of buildings. The fact that the vast majority of PCB transformers are located in or near buildings where pollution created by combustion can enter areas of high human occupancy is of particular concern to EPA. □

Appointments at EPA

Dr. Tudor T. Davies has been appointed Director of EPA's new Office of Marine and Estuarine Protection. This position gives Davies responsibility for administering the Marine Protection, Research and Sanctuaries Act and for such Clean Water Act issues as incineration of hazardous waste at sea, ocean dumping of sludge, and secondary treatment waivers for sewage treatment plants that discharge into marine waters.

Dr. Davies has been at EPA for over 13 years. He joined the agency in November 1971 as a consultant in the Office of Research and Monitoring, the forerunner of today's Office of Research and Development. For five years prior to 1971 he was an Associate Professor of Geology at the University of South Carolina.

After serving a year in the Office of Research and Monitoring, Dr. Davies was appointed Director of EPA's lab in Grosse Ile, Mich. He held that position for three years. In August 1975 Davies became Deputy Director of EPA's Environmental Research Laboratory in Gulf Breeze, Fla., where he worked for the next four years.

In December 1979 Dr. Davies became Director of EPA's Environmental Research Laboratory in Narragansett, R.I. He returned to EPA headquarters in January 1983 to become Director of the Office of Program and Management Operations in the agency's Office of Water.

Dr. Davies studied geology at the University of Wales (Swansea), where he received his B.S. in 1960 and his Ph.D. in 1964.

Dr. Peter W. Preuss has been named Deputy Director of EPA's Office of Health and Environmental Assessment. In his new position, he will assist Dr. Elizabeth Anderson, the Director of that office, in supervising technical assessment groups at headquarters, in Cincinnati, and in Research Triangle Park.

Dr. Preuss comes to EPA from the Consumer Product Safety Commission, where he has been Associate Executive Director for Health Sciences for the past five years. From 1974 to 1979 he was Special Assistant to New Jersey's Commissioner of Environmental Protection and Director of the New Jersey Toxic Substances Program. During that time, Preuss also served as a member, and then as Chairman of the EPA Administrator's Toxic Substances Advisory Committee.

From 1971 to 1974, Dr. Preuss was Senior Scientist and Acting Deputy Director at Israel's Environmental Protection Service. For two years prior to that, he worked as a research scientist in the Department of Organic Chemistry at the Hebrew University in Jerusalem. From 1967 to 1969, Preuss was a National Institute of Health postdoctoral fellow.

Dr. Preuss studied chemistry and mathematics at the Polytechnic Institute of Brooklyn and at Brooklyn College, where he received his B.A. in 1963. He was awarded a Ph.D. in biology by Columbia University in 1967.

Dr. Preuss is the author of numerous scientific papers. In 1980 and 1983 he was honored with the Chairman's Award, the highest award of merit at the Consumer Product Safety Commission. □

T.C. Flanigan, Folio Inc

Snow-covered tree near Buffalo Mills, Pa.

Back cover: Skiing in Bolton Valley, Vt. Risk assessment and risk management are concerned with protection of the natural environment as well as public health (see interview on p. 2). Photo by Michael Philip Manheim, Folio Inc.

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