Reducing Risks from Toxic Substances
Reducing Risks from Toxic Substances

EPA has major responsibilities under the Toxic Substances Control Act to help protect Americans from toxic chemicals. In this issue, the EPA Journal examines how these duties are carried out.

The agency's policies and directions under the Toxic Substances Control Act (TSCA) are presented by Marcia Williams, EPA's Deputy Assistant Administrator for Pesticides and Toxic Substances. In an interview, Don R. Clay, Director of the Office of Toxic Substances, discusses the issues involved in administering TSCA.

EPA's program to reduce risks from new chemicals is explained and six observers of this key TSCA component present their views on its strengths and weaknesses. Another article describes how TSCA fills a major gap in the federal government's armament of environment statutes.

A feature explains the science behind TSCA—a story of detective work in parts per billion. An article describes the launching of a new toxics control program to aid schools in asbestos cleanup.

Concerning other issues, excerpts are provided from a recent speech by EPA Administrator Lee M. Thomas spelling out directions for the agency. Another article in the Journal series EPA Diary reports on three days in the life of an on-scene coordinator on an emergency.

An article describes EPA's strategy to deal with toxic chemicals in the nation's air. A new "preventive medicine" approach to ensuring compliance with EPA rules is reported.

In the ninth article in a Journal series, EPA Region 8 describes its response to pollution fears that swept a Denver suburb.

The issue ends with two regular features—Update and Appointments at EPA.

EPA employee Kitty Miller totes a heavy load: all five volumes of the Chemical Substances Inventory, compiled under authority of the Toxic Substances Control Act. The Inventory includes data on more than 62,000 chemicals.
EPA Journal

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Update

On this cover: A worker takes a chemical sample during the production process at a plant in Westville, N.J. EPA has a major role in regulating industrial chemicals under the Toxic Substances Control Act. Photo by Earl Dotter/American Labor Education Center.

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Regulating Toxic Substances: An Overview
by Marcia Williams

Society has become increasingly dependent upon chemicals over the last 40 years. Most of the products that make our standard of living so high and allow us a long and full life would not exist without the benefit of the myriad of chemicals produced by the chemical industry. Yet even as we enjoy the benefits of chemicals, there can be no doubt that as a society we need to be aware of and concerned about the possible risks associated with exposure to chemicals, whether in the workplace or in everyday life. We need to balance the benefits of a chemical against its potential risk in deciding whether a particular use of the chemical makes sense.

I believe that we in government and industry and environmental groups have all done a relatively poor job of educating the public about the various factors that go into such a balancing. When we as government regulators deal with chemicals in a public way, we need to be especially careful to explain the trade-offs involved, rather than just presenting the dry numbers found in our risk assessments.

In some cases, people accept risks in order to enjoy the benefits of a product. Thus, the public by and large is willing to accept the risk of a therapeutic agent (such as a drug for chemotherapy) when viewed in the context of the benefit it will provide (hopefully, remission of cancer).

But in most contexts people tend to see risks in absolute terms, e.g., if a chemical is a “carcinogen,” it is often thought it should just be banned without regard to the potential benefits which it brings to society, the magnitude of the risk from a particular use (which can be quite small), and the availability of safe (or safer) substitutes. That is, the public seems to think that the chemical should be banned unless doing so would infringe too greatly upon people’s personal lifestyles, as in the case of cigarettes, saccharin, or alcohol, where, by and large, the public seems willing to accept relatively large risks.

It is in the context of balancing the various factors about a chemical that TSCA comes into the picture. TSCA is a risk/benefit statute. Unlike some other EPA offices, the TSCA office is not at liberty to ban a chemical just because it is a carcinogen, or causes any other particular effect. We are charged with the task of carefully balancing the potential health and environmental impacts of chemicals against the benefits they bring to society. We are only permitted to act when our analysis of all the facts indicates that an unreasonable risk is present.

That does not mean that we use a strict mathematical model to balance the various benefits of a chemical against its potential risks in terms of lives lost, chronic or acute diseases caused, fish killed, etc. What it does mean is that we need to be especially sensitive to the conflicting values present in our society.

Thus, when we make decisions about chemicals we think about such factors as likelihood of harm and costs to society (in terms of reduced standard of living or effects on particular companies or industries). At best, science will only give us partial answers to the difficult questions which we must address. Common sense must be used to reach a conclusion on whether and how particular chemicals need to be regulated.

TSCA contains a wide array of statutory authorities to help us protect public health and environment. EPA has the power and authority to follow chemicals from their first introduction into commerce, through their life cycle, to their ultimate disposal. We have far-reaching and powerful information-gathering tools. We are able to require the testing necessary to allow the federal government to make reasoned decisions.

Also, we have the ability to evaluate and take appropriate actions with respect to multi-media chemical problems. Looking at chemicals from a cross-media perspective is quite important because it helps to ensure consistency among governmental actions. Perhaps most importantly, it also reduces the chance that a problem found in one medium will just be transferred to another. Finally, TSCA has important preventive aspects—it helps us to prevent some of tomorrow’s “Superfund” sites, the development of new “PCBs” without any review by government, and so forth.

I see a number of significant challenges which we in the Office of Pesticides and Toxic Substances must meet over the next several years to allow TSCA to achieve its full potential. We have generally proceeded chemical by chemical, but we will need to make more effective and bold use of categorical approaches to really make a dent in the review of the 62,000 chemicals with which we are confronted.

While we have a great deal of information at our disposal, we have not been as effective as we would like in getting others to know about and use our data. We have tended to focus our attention on cancer but we need to broaden our focus to consistently encompass other health and environmental effects. We need to devise more efficient ways to require the submission of testing and other data to support our needs. Finally, we need to devise more direct ways to be of support to the other EPA programs (such as the Office of Ground-Water Protection in the implementation of its ground-water strategy).

I am confident that TSCA’s goal of protecting society and the environment from unreasonable risks from chemical substances is obtainable and that it will be even more fully realized as we continue toward TSCA’s full implementation.
How does TSCA differ from the other environmental statutes administered by EPA?

A Most EPA statutes are organized by media. That is, a statute such as the Clean Air Act focuses attention on issues involving emissions to air, the Water Act is concerned with discharges to water, etc. TSCA, on the other hand, is not specific to any particular medium. It allows us to focus on all possible routes of exposure, and follow chemicals from cradle to grave.

Why would Congress pass a law that cuts across all the particular media with which the agency is familiar?

A Well, I think Congress saw that chemicals often present multi-media problems. One chemical can be a problem in the air, in the water, in the workplace, etc. I think Congress was looking for a place that could analyze the problem in all the media and then try to figure out an appropriate strategy. Which could mean referring the chemical to another agency. Or it could mean that EPA would do its own regulation of the chemical under either TSCA or the other EPA statutes depending on what made the most sense in the particular circumstances.

TSCA was formed about eight years ago, and yet it isn't as well-known as some of EPA's other programs. Why is that?

A A lot of the things we do are not as much in the public eye as many other EPA actions. For instance, if there's a Superfund site near your house, that's something that gets a lot of attention. If TSCA requires that a low-volume chemical be tested, that's helping society because someday that chemical may be a high-volume chemical, but in terms of the public attention or interest in such an action, there's very little.

Could you tell us a little bit about the information you have gathered under TSCA?

A A great deal of significant data has been gathered under TSCA.

First, we have produced the only complete inventory of industrial chemicals in commerce in the United States. This involves over 62,000 substances and excludes only foods, drugs, cosmetics, or pesticides. The inventory also gives underlying information on those chemicals. It'll tell you generally what the production volume is, where it's manufactured, and other very basic information.

Second, we have more detailed data on the production, use, and emissions of over 300 chemicals, many of which are chemicals on the action lists of other EPA programs. Examples include toluene, methylene chloride, various phthalate esters, and more specialized chemicals such as alkyl tins. We have
unpublished health and safety data (including monitoring data) on the same group of chemicals. There currently are over 7,300 studies on the same chemicals.

Finally, we have a very active chemical testing program that allows us to require industry to conduct whatever health, environmental, or exposure testing (or anyone else in the agency) need if certain basic findings are made. To date we have taken action on over 500 chemicals, and received over 400 new health or environmental effects tests.

Q How does your new chemical review program work and what chemicals are covered?

A The law requires that 90 days before any company can manufacture or import a chemical which is not on the inventory, it must notify us. We call this premanufacture notification or "PMN". If we identify problems, we can order the company to test the chemical and we can require controls pending testing.

In the period since this program began in 1979, we have reviewed nearly 5,000 PMN submissions. We are currently receiving about 1,200 chemicals a year for PMN review. Last year we regulated 47 chemicals received in the PMN program. Whenever issues arise during PMN review that might affect other EPA programs, we make it a point to consult with them. We also are issuing follow-up rules for PMN chemicals which, while not presenting an unreasonable risk during their initial introduction into commerce, would be of concern to us if the production volume increased significantly, if the uses changed, or if certain control practices were not followed.

Q You mentioned that you also act to prevent unreasonable risks posed by chemicals. What does the term "unreasonable risk" mean?

A There's no clearcut definition of unreasonable risk, but it involves a balancing process. The Act does not seek absolute safety, realizing that that would be an impossible goal. Instead it takes the concept of risk and puts it into the real world. It does this by taking into account factors such as the health and environmental effects of the chemical, the exposure to the chemical, the economic value of the chemical, and the cost of regulation. EPA is then asked to balance these factors and determine whether the chemicals under evaluation present an unreasonable risk, and if they do, to limit those risks.

Q What kinds of action have you taken to limit such risks?

A First, let me state that there are a variety of ways in which we can act. There is the direct exercise of regulatory authority, ranging from banning a chemical to requiring simple labeling changes. Second, we can decide that the type of problem identified can best be resolved using a different statutory authority and refer the chemical to another agency or program. Finally, we have issued what we call "chemical advisories".

With respect to direct control actions, we have issued a variety of rules concerning the use and disposal of PCBs; regulated aerosol use of chlorinated fluorocarbons; and regulated the disposal of dioxin-containing materials. We have issued a rule requiring local schools across the country to check to see if their buildings contain asbestos in what we call a "friable" form, that is, in a form which crumbles when you touch it. If they have friable asbestos, they have to notify parents and employees. There didn't seem to be any other authorities in the government that could deal with that type of issue, so it was a good use of the TSCA authorities.

We are also in the final stages of evaluating control needs for various other chemical substances, including 4,4-methyleneedianiline, MBOCA, nitrosamines in metalworking fluids, formaldehyde, glycol ethers, 1,3-butadiene, and asbestos. About 60 other chemicals are in various stages of our detailed evaluation process.

Q What are these chemical advisories you mentioned?

A Chemical advisories are non-regulatory documents which advise the public and affected industry about the likely risks posed by particular chemical substances, giving practical ways to minimize the risks. We have issued advisories on used motor oil, nitrosamines in cutting fluids, leaking underground storage tanks, and P-TBBA.

Q What would you say your key priorities for TSCA are right now?

A I would say that the first thing we need to focus on is getting more test data on existing chemicals. We are getting a fair amount of test data now, but I think that we should be able to get data on a considerably larger number of significant chemicals in an easier way, both for us and industry. I also think that one of the things that's very important for us to do is to make a clearcut decision on how we fit with other federal agencies and EPA programs in terms of controlling chemicals that present unreasonable risks. Those are the two things that are really important to us now.

In the new chemical area, I would say that the program we have now is an evolving one, but I don't anticipate any dramatic changes in that area. Our goal is to get more data on new chemicals without unnecessarily impeding innovation.

Q Has the existence of TSCA changed the way manufacturers in America do business?

A Well, I think that especially in the new chemical area it's had an impact. We've been told by several companies that the mere fact that a company has to let the government know 90 days before it intends to manufacture these chemicals means that some companies are not going to be manufacturing some "nasty" chemicals. Just our very existence has had that generally positive effect. In addition to that, the fact that we are reviewing new chemicals means that companies must take that into account. We believe that this has led to more testing being conducted prior to introduction into commerce. Companies tend to look at the issue of whether or not a new chemical presents an unreasonable risk more carefully than they did before because of the existence of TSCA.
**TSCA Compliance Program**

Enforcement of the Toxic Substances Control Act (TSCA) is carried out by personnel in EPA's ten regional offices. Regional offices target, schedule, and conduct compliance monitoring inspections at facilities subject to TSCA requirements for PCBs, asbestos, chemical testing and reporting, importing, and premanufacture notification. In Fiscal Year 1984, EPA, along with four state agencies (Ohio, Massachusetts, Connecticut, and Maryland) cooperating under the terms of enforcement grants-in-aid, conducted 1,440 PCB compliance monitoring inspections. With the American Association of Retired Persons and the State of California operating under cooperative agreements, EPA also conducted 1,945 asbestos-in-schools inspections. Additional compliance inspections were made for chlorofluorocarbons, dioxin, premanufacture notification, chemical testing and reporting, and imports.

Where violations of TSCA are identified, EPA may levy either administrative or criminal penalties, as well as civil actions to compel compliance. In FY 1984, most of the enforcement actions involved violations of the PCB rule, the asbestos-in-schools requirements, and premanufacture notification requirements. The agency filed a total of 283 administrative complaints as a result of PCB inspections; eleven complaints were issued for violations of the premanufacture notification requirements, and 82 complaints were issued for violations of the asbestos-in-schools requirements.

At mid-year in FY 1985, the regions have conducted 2,517 TSCA inspections and have issued 309 complaints. The compliance accomplishments achieved by the cooperative efforts of regional and headquarters personnel and state agencies reflect the high priority given to enforcing the various sections of TSCA.

**Q** Do you think that this has had an adverse effect on innovation?

**A** We have had an impact on innovation, but we generally find it to be minor. There are some specialty chemical companies that need to deliver chemicals on a week's notice. And if these are new chemicals, that creates a problem, because EPA makes them wait at least 90 days. We have done two things about this. We've issued an exemption for chemicals manufactured in small quantities (under 1,000 kilograms per year) and another exemption for certain kinds of low-risk polymers. But other than that, I think most people would agree that it is really important to make sure that new chemicals get a close look, and we do that. In other areas, our evaluations show only the most minimal of effects, except where prohibition of manufacture or use is clearly called for. In these instances there is a significant boost to the development of safer substitutes.

**Q** Is the information that you have proving to be useful to other parts of EPA or other federal agencies, even state agencies?

**A** Yes, and we are looking to increase the flow of information to other agencies and to the states. An example is asbestos, where we required all the asbestos manufacturers and most of the processors to identify themselves and to tell us how much exposure there was to how many people and so forth. That was an important rule, and we got a tremendous amount of information which we made available to the Occupational Safety and Health Administration and to various parts of EPA. We also make risk information available to the states and to other parts of the agency. We have computerized data bases; we do qualitative risk assessments, chemical hazard information profiles, and a wide variety of other information that we make available.

**Q** Is there a danger that in carrying out TSCA, EPA will interfere too much with the marketplace, become too much of a presence in the marketplace?

**A** I don't think so. If we were seeking a zero risk from these 62,000 chemicals, then I think that there would be potential to have undue impacts. But TSCA takes into account the impacts on innovation, the impacts on the economy, and so forth, while nevertheless preventing unreasonable risks. We do see our primary job as dealing with risks that are unreasonable, and dealing with them in the least burdensome way that will accomplish the goal of protecting our health and environment.

**Q** The TSCA program has been underway for several years. Do you feel that TSCA needs amendments to make it work better?

**A** I think TSCA is a very rational statute. The notion of dealing with unreasonable risks and not seeking a risk free society makes a lot of sense. The only area that I think we ought to look at is the procedures under TSCA. I can get done what I feel needs to get done, but it takes me longer than I'd like it to take.

**Q** The last question is: Do you have any further comments that you'd like to make?

**A** Yes, I think that TSCA is a statute that has just begun to realize its potential. It has incredible potential because it has a wide array of unique authorities to gather information, to have chemicals tested, to have companies identify the chemicals which they manufacture, and to control chemicals posing unreasonable risks. I would look for TSCA over the next several years to have a more active and visible role, especially in the information-gathering area.
We all live in a safer world because of TSCA's new chemicals program. The purpose of this program is to identify chemicals that might pose unreasonable risks and require that they be controlled or tested before they are used extensively in the United States. Congress instructed EPA to carry out this task without unduly impeding new chemical innovation.

Under TSCA—which became law on January 1, 1977—manufacturers and importers are required to notify EPA 90 days before they intend to manufacture or import any new chemical for commercial purposes. The notification, called a PMN, must contain certain information and be filed on a special form. New chemicals are those that are produced or imported in the U.S. and are not listed on EPA's 1979 Inventory of Existing Chemical Substances. About 5,000 new chemicals have been reviewed by EPA since the program was put in place in the summer of 1979. In FY 1985, the agency expects to review at least 1,500 new chemicals.

Section 5 of TSCA gives EPA a wide range of responsibility for regulating new chemicals. The statute requires the agency to review new chemicals for both health and environmental effects throughout their total life cycle. Thus, the agency reviews the potential effects in the factory, water, air, and at disposal sites. Consumer exposures are also carefully reviewed.

The review of a new chemical must take place in an atmosphere of considerable uncertainty. A high degree of certainty can only be obtained from a wide range of tests for both health and environmental effects. Because of the high costs associated with such testing (often well over one million dollars), it is not practical to require such testing on most new chemicals. Therefore, data from similar existing chemicals are used to identify potential hazards of new chemicals.

Because new chemicals vary so much, decisions on what testing is appropriate for a given chemical are made on a case-by-case basis. This allows the agency to focus its resources and the resources of industry on chemicals of potential concern.

Teams of highly trained EPA experts conduct the agency's PMN review of new chemicals. The agency's new chemical program has a matrix organization that brings together chemists, chemical engineers, pharmacologists, oncologists, economists, and other specialists. They evaluate and weigh the new chemical's possible risk to public health and environment as well as the economic benefits of the substance.

As of June 1985, more than 200 PMNs were identified as potentially posing unreasonable risks. All have been subject to some kind of agency regulation. In nearly 100 other cases, industry has voluntarily completed toxicity studies to address EPA concerns about possible health risks.

One significant group of EPA-regulated new chemicals are corrosion inhibitors used in metalworking fluids. EPA found that when nitrosating agents are added to these formulations, nitrosamines are formed. These are powerful carcinogens. Acting under Section 5 of TSCA, EPA issued immediately effective bans on the addition of nitrosating agents to four new corrosion inhibitors used in metalworking fluids. The agency is also conducting a regulatory investigation of similar existing chemicals used in metalworking fluids. In addition, EPA issued chemical advisories on similar existing corrosion inhibitors to let users know about the problem.

What about the roughly 4,700 new chemicals EPA has decided not to regulate? It turns out that these...
chemicals do not appear to present any significant risks under the conditions of use. If the intended use of new chemicals could change to a riskier one, then EPA issues a Significant New Use Rule which allows EPA to review the new use and regulate, if necessary.

EPA has issued two broad exemptions for new chemicals. The first covers high molecular weight polymers which constitute roughly 25 percent of the PMN's filed with EPA. These substances, used in the manufacture of plastics and other products, are generally viewed as posing little or no risk to health or the environment. Consequently, EPA has recently exempted them from the standard PMN review process by providing for a shortened notification and review period.

The second exemption covers low volume chemicals produced at less than 1,000 kilograms. These constitute approximately 20 percent of the PMNs filed. As with exempted polymers, EPA has introduced a streamlined 21-day notification and review process. The exemption stipulates that producers of low-volume new chemicals must undergo the full 90-day review should future production volumes rise above 1,000 kilograms.

TSCA's new chemicals program has a proud record of achievement and a promising future. EPA will continue to zero in on problem chemicals. As a result, the American public can look forward to even better protection in the years ahead.
Information:
TSCA’s Cutting Edge
by Frank Kover

When a “chemical of the week” like formaldehyde or methyl isocyanate hits the news, EPA’s Office of Toxic Substances (OTS) is flooded with calls for additional information. More and more, other program offices in EPA, other government agencies, and a variety of non-government organizations rely on the unique information data bases of the Toxic Substances Control Act (TSCA) to help serve their data needs.

Until Congress designed and enacted TSCA, a notable deficiency in the federal government’s armament was the authority to gather the exposure data and toxicological information needed for reliable assessments of the risks presented by chemicals to human health and the environment.

Risk assessments require information on both exposure and hazard. The use of chemicals usually involves both exposure and hazard to varying degrees, and EPA considers the magnitude of both components in order to assess the risk.

For chemicals now in commerce, TSCA concentrates data-gathering authority mainly in two sections: in Section 8, which requires industry to report certain existing information to EPA and keep records; and in Section 4, which enables EPA to require testing by industry. Also, Section 5 requires that information be submitted when industry develops new chemicals and significant new uses of certain existing chemicals.

Notices of Substantial Risks
The first reporting requirement under TSCA was effective with the Act on January 1, 1977. When industry obtains new information indicating that a chemical presents a substantial risk of injury to health or the environment, EPA must be notified immediately. Since the effective date of TSCA, more than 540 initial submissions have been received by EPA and given priority evaluation and follow-up attention. In addition, companies have volunteered more than 390 “For Your Information” submissions.

Substantial risk notices often include preliminary findings from toxicity testing programs, such as cases of excess tumors developing during the course of a study on rats or mice. Other notices may report untoward effects on humans in the workplace, or ecological effects data, while a few have reported ground-water contamination.

EPA’s implementation of this provision has brought about heightened industry awareness of potential chemical risks. For example, many companies reported that in direct response to their submissions, they voluntarily took action to notify workers, customers, and others; changed labeling and handling practices; initiated further toxicity and exposure studies; or ceased production.

Filing Allegations
Another TSCA regulation requires the chemical industry to keep records of alleged “significant adverse reactions” to chemical substances and mixtures. An allegation is a statement of an individual’s belief that a chemical substance or mixture has caused harm to him or her, another person or persons, or to the environment. Proof or evidence is not required, but written allegations must be signed and there must be a link between the substance or process involved and the claimed effects. The allegations can be made to the company by employees, their unions, health authorities, plant neighbors, or other parties. EPA can inspect the files and request copies of the allegations.

Subsequent investigations by companies as a result of receiving allegations have sometimes involved additional test findings or identification of a pattern of effects. Such results have led to submission of notices of substantial risk.

Since almost anyone anywhere has the right to file these allegations, EPA has undertaken an outreach program to extend awareness and understanding of the rule.

TSCA Inventory
A major early task under TSCA was to compile an inventory of all chemicals in commerce in the United States. EPA published the first issue of this TSCA Chemical Substances Inventory in 1979, based on information reported by domestic manufacturers and importers. The Inventory numbers more than 62,000 chemicals that are now or have been in commerce at any time since January 1, 1975.

The inventory provides a listing of substances according to chemical name, synonyms, molecular formula, and a unique accession number or Chemical Abstracts Service Registry number for each, and information on production volume, plant location, and whether the substance is site-limited or shipped from the production site.

Since the inventory has become increasingly outdated, the agency proposed recently to update its most critical elements. Under these new provisions, data will be updated every two years where production has changed significantly.

(Kover is Chief of the Chemical Screening Branch in the Existing Chemical Assessment Division of EPA’s Office of Toxic Substances.)
Health and Safety Studies

EPA can require chemical companies to submit unpublished health and safety studies on chemical substances and mixtures. Respondents to these rules must submit two types of data: copies of studies in the possession of, or available to, the company; and lists of ongoing or completed studies that the company knows about, but does not have.

By using a "model rule," EPA is able to ensure, in a relatively easy fashion, that it has all available unpublished health and safety data on specific chemicals of concern. A model rule is used by simply adding those chemicals for which reporting is desired to an established list of reporting requirements. Reported data are used to assess potential risks and, in some cases, to support decisions about whether to require industry to test those chemicals when data are insufficient.

Data-Gathering

TSCA also allows the collection of production, use, and exposure data from chemical companies, and can be used to require the retention of certain records. Because rulemaking is often a lengthy, difficult, and expensive process, EPA developed a "model rule" to collect the basic, readily obtainable data needed for preliminary risk assessments on specified substances. To date, EPA has used this rule to gather data on approximately 350 chemical substances.

The agency now is planning a second model rule to gather more detailed information. To be called the Comprehensive Assessment Information Rule, its reporting form will include an extensive list of questions for which answers by chemical companies may be required. Each time data are needed EPA will amend the rule by adding the subject chemicals and identifying the specific questions to be answered.

Toxicity Testing

As a result of ongoing OTS evaluations, some existing chemicals will be found to have insufficient data available on them to allow an assessment of risk. In such cases, OTS may require toxicity testing to develop the needed data. In addition, the Interagency Testing Committee (ITC), created by TSCA, periodically recommends to EPA priority lists of chemicals for which toxicological (or other) testing may be necessary. When the ITC designates chemicals to EPA, OTS collects basic production and exposure data and health and safety studies. Where data collected are insufficient to characterize risk, OTS may require development of the needed data through appropriate testing.

Follow-Up Activities

Of growing importance is the Office of Toxic Substances follow-up program. After a preliminary assessment of a chemical's risk, OTS may defer regulation because of a low or unknown degree of exposure concern. In such cases, follow-up monitoring of future uses of the chemical by rule will ensure that the agency is made aware of potential increases in the exposure, which in turn may indicate increased risk. This affords EPA an early opportunity to act if necessary to reduce potential risks.
The Importance of Billionths
by Miles Allen and Roy Popkin

Imagine yourself sipping from a freshly brewed cup of coffee while standing beside a 50-meter Olympic-sized swimming pool. A competitor climbing from the pool jostles your arm slightly and a few drops of coffee splash into the water. As you watch, the spot of java quickly diffuses into the pool. Now imagine returning several hours later, after scores of swimmers have assisted the mechanical pumps in churning the pool so that your small splash of coffee is evenly distributed throughout more than 200,000 gallons of water. Taking a clean cup, you scoop up some water and examine it. You cannot see any coffee color. You cannot taste any coffee flavor. And you certainly cannot detect any hint of that lovely aroma. You may think that no one could ever tell that any coffee had spilled in that enormous pool.

In reality, you'd be wrong. There would be about one part of coffee per one billion parts of pool water in that cup, an amount which scientists could readily find with today's technologies. But why should anybody care? Certainly, such small amounts could be of no significance...Wrong again! Consider this information from a recent EPA publication on dioxin:

"The Centers for Disease Control considers one part per billion of dioxin in soil to be a level of concern in residential areas. The Food and Drug Administration recommends...not eating any fish with greater than 50 parts per trillion of dioxin." (To reach a ratio of 50 parts per trillion, you would have to spread your coffee droplets through 20 swimming pools.)

Like searching for a needle in a haystack? If you had a rather large haystack, the proportions would be about right (one billion needles would fill approximately 10 cubic yards) but the task is even more difficult because the "needle" would be broken up into almost infinitely small pieces scattered randomly throughout the stack.

Not too long ago, determining the presence of chemicals in such small proportions was not possible. As recently as 1972, EPA was forced to cancel hearings on dioxin because the analytical technology was insufficient to determine risks. Yet it took only five years to remedy that situation, and today scientists are measuring some substances at levels of parts per quadrillion. (A quadrillion is a thousand trillion, or a million billion.)

Even when dealing with substances that are not toxic in such small amounts, the need to measure minute levels remains. Some chemicals tend to accumulate in the fatty tissues of humans so that, in time, even the tiniest amounts may build to dangerous levels.

The main tool used by EPA sleuths on the trail of toxic contaminants is gas-liquid chromatography, coupled with either an electron-capture detector or a mass spectrometer to identify the chemicals in the specimens. The electron-capture detector is extremely sensitive for detecting small amounts of material, while the mass spectrometer provides a unique signature for each residue detected. A key element in the improved ability to detect trace quantities of chemicals is the agency's development of procedures to remove unwanted materials from the specimen prior to its analysis with gas chromatography.

EPA's scientists have often employed these high-tech methods to determine levels of a particular chemical. For example, the General Services Administration once requested a study of PCB levels in the blood and tissue of government electricians who worked around transformers containing the toxic substance. Or, the scientists may search for numerous chemicals, as in a recent study of milk samples from mothers residing in industrial urban areas.

In both cases analytical techniques capable of measuring chemical residues at the parts per billion level were required.

The agency's detection skills have been utilized in international projects, such as a recent seven-nation program seeking to determine the levels of lead and cadmium in the blood of people not occupationally exposed to these metals. The study, which used atomic absorption spectrometry, was done in collaboration with the World Health Organization and the United Nations.

Whether used to discover levels of contaminants in exposed populations, or to establish baseline data for comparisons (see box), or to determine the relationship between dose rates and medical problems, the ability to measure residues present at the parts per billion level can be helpful in assessing environmental risk. Most of us cannot even conceive of a quadrillionth of anything. So it's comforting to know that there are scientists capable of scouting the micro-frontier and alerting us to the molecular dangers hiding there.

(Allen and Popkin are on the staff of the EPA Office of Public Affairs.)
Discovering What We’re Made Of

In order to protect the public health through sensible and effective regulations, EPA must often set limits on how much of a given substance may be discharged into our environment. To determine limits, it is helpful to have information on the amount of a substance in the environment and the amount taken into, and retained by, the human body. This requires a clear picture of what chemicals are normally in the body and at what levels they occur throughout the population.

It is difficult to say whether a specific source of contamination—sewer pipe, smokestack, waste dump, or whatever—has actually contributed to increased levels of a toxic substance in the exposed population without having baseline data available for comparison.

To establish these baseline data, EPA operates a continuing human tissues monitoring program. The Exposure Evaluation Division of the Office of Toxic Substances (OTS) runs the program, which obtains specimens from a network of pathologists and coroners around the country. About 45 such sources are used each year, with approximately 1000 adipose (fatty) tissue specimens collected on the basis of demographic requirements and specified as not to come from individuals who worked in the chemical industry or who were involved in a hazardous materials accident.

Tissue samples typically weigh about 5 grams (approximately the size of a large grape). They are packed in chemically clean containers provided by EPA and shipped frozen to designated laboratories operating under EPA contracts. Over two-thirds of the specimens tested each year come from autopsies, the remainder from routine surgical biopsy procedures. All are collected in accordance with Department of Health and Human Services requirements on privacy and informed consent.

The primary goal of the tissue sampling program is to establish the distribution of levels of selected toxic chemicals in a national cross-section of the U.S. population, which allows comparisons based on age, sex, and place of residence. Martin Halper, Director of EPA’s Exposure Evaluation Division, is looking for OTS to expand the program in 1986 and 1987 to include blood and mother’s milk specimens as well as to broaden the range of TSCA-related chemicals being analyzed.
Debating EPA's New Chemicals Program: A Forum

The public has a right to expect that the EPA is making good on the promise of the Toxic Substances Control Act that newly marketed chemicals will not later harm public health or the environment.

Like the preacher's wife, the new chemical review program should be above reproach. Not only should it fulfill its mission, it should be beyond doubt that it is doing so.

How does the program measure up to this goal? Not well, I fear, and the fault lies as much with Congress as it does with the agency. Consider these facts:

- Staff levels have remained steady while the number of chemicals that require assessment has increased dramatically since the program's inception;
- At the present time, the agency must, on the average, perform a new chemical assessment and reach a decision every 90 minutes;
- Half of these assessments are performed without benefit of any toxicity data whatsoever;
- Voluntary new chemical testing guidance issued over four years ago has been ignored;

- Virtually all risk-relevant data that are included in premanufacture notices are screened from public view by the industry's blanket claims of confidentiality.

The message from the industry and the agency is simply this: "Trust us. Trust us to make reliable assessments without benefit of data and with only sketchy ideas of future uses and amount of exposure." And that is the program's major disadvantage. It is a black box. No one outside the process can know how decisions are made. No one can tell whether it is working well or not. I would venture to say that informed critics will continue to question the integrity of decisions made inside that black box until they see more data going into it and glimpse its internal decision machinery.

Perhaps the major advantage of the present program is simply that it exists. Chemical industry officials have told me that the prospect of taking a potential new product to EPA for review has changed substantially the way companies make product research and marketing decisions. Many new chemicals that once would have been marketed now are laid aside because they are unlikely to pass muster with the agency. Even so, dozens of new chemicals have been blocked or restricted by agency action. But how many that should have been restricted have passed undetected because of inadequate test data? There is no way to know.

Considering the burdens placed on the agency and the inability to require needed risk data, I believe the able and dedicated agency staff has made a good showing. The agency should continue to develop the authorities it already has in present law, and Congress should consider improving those authorities, especially as they relate to new chemical test data and confidentiality. Only then can the agency and the regulated industry give credible assurances that the program is working as intended.

What are the strengths and weaknesses of EPA's effort to reduce risks from new chemicals? EPA Journal asked six observers with different vantage points to comment. The answers follow:
As an association, one of SOCMA's key roles parallels that of the agency—making certain our companies, most of which are small to medium-sized, understand the complex regulations and find ways to comply without seriously weakening the innovation which is so critical to many of them.

From that perspective, we believe the agency's recent decision to provide an exemption for small-volume chemicals which clearly do not pose a public health risk is a significant step forward. It will remove an important millstone which has slowed new product development over the last few years as lines of research have been abandoned because complexities or costs of a formal PMN process simply could not be justified.

One area where the agency's approach is continuing to cause problems for SOCMA's members involves the increasing use of Section 5(e) as a regulatory mechanism. This in effect delays PMN approvals for the significant period of time necessary for the PMN submitter to negotiate and EPA to approve a consent order.

It is important for EPA to continue to work closely with industry, public interest groups, and others in better defining the kinds and quantity of data needed to do effective PMN reviews, how to handle new or growing use of particular chemicals, and how best to apply Section 6 to gather necessary information. SOCMA is already talking with such groups about the changes Congress should consider in reauthorizing TSCA; such a "reasoning together" process can be a very effective way of making the system work.

We continue our commitment to working with Congress and the agency in ensuring that our members meet both the letter and spirit of TSCA while at the same time finding ways of doing so which will not threaten the viability of the hundreds of companies which make up the organic chemical industry in this country. Despite occasional disagreements, we believe TSCA is working, we believe the agency is doing a good job under very difficult and complex conditions, and we hope cooperation rather than confrontation will form the basis for addressing legitimate public concerns in the future.

As a five-year legislative campaign was waged by environmental and labor organizations to pass the Toxic Substances Control Act. After nine years of implementation, what have we accomplished?

The labor movement wanted to stimulate basic changes in the direction of chemical innovation, manufacture, and use. It wanted the generation of, and access to, more information. Generic market and pre-market regulation of chemicals was seen as an expected result of complementary social and technical paths: research, enforcement, testing, and information dissemination. Labor wanted these objectives achieved in a program not only integrated with other activities in EPA, but in close collaboration with other agencies that regulate the environment and with the health research institutions of the Public Health Service. By these standards, very little has been accomplished. Why?

With the exception of the regulation of PCBs, the agency was given overly broad discretion to achieve these objectives. The industry to be regulated was given easily-abused responsibilities (which they quickly abused) in testing, reporting, and in the determination of confidential business information.

The naive assumption was made that any President would have sufficient concern about the issue and the power to ensure interagency coordination and to protect the public interest (as distinct from the special interests of industry, labor, consumer, and environmental organizations).

Incredible, retrospectively ludicrous. Confidence was placed by government, the environmental-labor coalition, and industry in a sub-set of our culture called "science" to define the adjective "toxic"—or at least develop a consensus on its meaning—through the production of objectively interpreted laboratory, clinical, epidemiological, and ecological data reflecting a broad range of effects.

New necromantic techniques consistent with the shamanism of current environmental assessment produce increasingly controversial data on an increasingly narrow set of effects agent-by-agent. We know, for example, that about 1,500 chemicals have possible cardiovascular effects. The development of methods to test for these effects is hardly taking place and what little we now know is not being applied.

Scientists respond to market demands, just like the rest of us, but the market for better determination of "toxicity" has not been created.

In assessing the agency's performance in implementing the Act, it is easy to point to instances of lax, co-opted, or shortsighted administration. A company called CBI (Confidential Business Information) seems to manufacture and use most of the chemicals in our society. The formula, effects, and identity of the exposed populations have a common name called BLANK. Expertise to understand the work environment—which the Act treats as a concern equal to the ambient environment—is so sparse and diffuse as to effectively not exist.

Defenders of the agency can point to an equal list of achievements, which would have to include gathering some of the best scientists and most dedicated administrative staff found in either government or the private sector into one agency to at least begin the very hard work of regulation.

Criticism or defense of EPA's effort to reduce risks from new chemicals that excludes an examination of the assumptions of the program is unlikely to reveal the fundamental lesson of the past: chemical innovation is a runaway chain reaction that will be contained only by a new program built on a new set of assumptions.
additional safety tests or controls if needed.
For all of its benefits, EPA's administration of TSCA's new chemical review provisions has not been trouble-free from Monsanto's viewpoint. Perhaps the most burdensome aspect of EPA's work has been the time delays and unnecessary costs associated with the review of new compounds that pose minimal risks. To date, the agency has been overly cautious with materials such as polymers, site-limited intermediates, and other low-exposure materials.
This sometimes has caused manufacturers to delay new chemical introductions by six months or more and has cost them certain customer opportunities. Monsanto, in a few instances, has actually abandoned the development of new chemicals because of costly health-effects testing requirements not warranted by the risk to health or environment of the new products.
Both industry and EPA resources that are expended to resolve EPA concerns in these low-risk areas could be put to better use in other more significant elements of the PMN process, such as follow-up of new chemicals after they enter commerce. The current TSCA orders and Significant New Use Rules (SNUR) used for follow-up, while effective, are burdensome to develop and implement. Commitment of resources to improve this phase of the PMN process seems justified.
Monsanto has been working with EPA to overcome problems of this sort and, in general, we feel the strengths of EPA's PMN program far outweigh its weaknesses. We want to cooperate with others interested in EPA's PMN program to build upon its strengths. Pushing the program to its limits through overzealousness or battling over its administration through the courts does not serve any of us well.

J. Ronald Condray
Director
Regulatory Management, Toxic Substances
Monsanto Company

Jacqueline M. Warren
Senior Staff Attorney
Natural Resources Defense Council

The purpose of premanufacture notification (PMN) is to permit EPA to make a reasoned evaluation of the health and environmental effects of new chemicals, before rather than long after their entry into commerce. In order to carry out this statutory responsibility, EPA must necessarily have a certain amount of toxicity and exposure data about the new chemical.
As presently written, however, the Toxic Substances Control Act does not require PMN submitters to generate and submit any toxicity data on the new chemical or any information on exposure beyond the workplace. Thus, the agency has assumed the burden of assessing the potential hazards of new chemicals without specific data on the effects of the new chemical being evaluated.
To accomplish this feat, the agency has had to rely almost entirely on information concerning structure-activity relationships (SAR), i.e., EPA assesses the potential risks of new chemicals by studying available information on similar chemicals. The problem is compounded by the fact that relatively little toxicity information is available on the vast majority of existing chemicals, as the National Academy of Sciences pointed out in a 1984 report entitled Toxicity Testing.
In NRDC's view, the existing PMN program is not accomplishing the objective of accurately identifying potentially hazardous new chemicals before they enter commerce. Since the program began in 1979, EPA has received more than 4,500 PMN notices. Agency figures show that consistently
Dr. Thomas A. Burke

Director
Office of Science and Research
New Jersey Department of Environmental Protection

From a state perspective, the preventive approach of Section 5 of the Toxic Substances Control Act is perhaps the most important part of this legislation. Properly implemented, this section provides EPA with a broad range of information on new chemicals prior to their manufacture. This should enable the agency to anticipate and prevent environmental and public health problems which may be associated with the manufacture and use of new substances.

The legislative history of TSCA strongly suggests that Congress intended in Section 5 to put an end to the “use first, test later” approach to chemicals manufacture. Nevertheless, eight years later, it is clear that EPA is still allowing most new chemicals to enter commerce with little or no toxicity testing and very little information about potential exposures. To remedy this problem, the agency should use its authority under Section 5(e) more aggressively to require data for suspicious new chemicals. At the same time, Congress should amend TSCA to authorize and require pre-market testing of new chemicals so that chemical producers selling in the United States will have to do at least as much to anticipate the adverse health and environmental effects of their chemicals as they are required to do before entering the European market.

JUNE 1985
Launching a New Toxics Program
by Michael Stahl

On August 10, 1984, Congress approved the final version of the Asbestos School Hazard Abatement Act (ASHAA). The major provision of the Act called for establishment of a loan and grant program to help schools pay for asbestos abatement projects. Less than 10 months after ASHAA was passed, EPA was scheduled to distribute $45 million in grants and loans to schools and meet the deadline of June 6, 1985, imposed by ASHAA.

The tight statutory deadlines, the visibility and emotionally charged nature of the asbestos-in-schools issue, and the problem of translating statutory language and Congressional intent into workable program policies and procedures, all combined to make implementation of the loan and grant program a formidable challenge for EPA.

ASHAA provided procedural guidelines for the loan and grant program. First, EPA develops and distributes an application form to all LEAs (Local Education Agencies), i.e., public school districts, private school systems, and individual private schools. Next, LEAs forward these applications to their state Governors (or the Governor's designee) so the applications can be ranked by the state. Once ranked, the states forward all applications and rankings to EPA. Then, EPA reviews all applications to assess the severity of the asbestos problem within a given school and the financial need of the LEA.

The agency was faced with two very difficult questions in connection with its new responsibilities under ASHAA: How can EPA identify and resolve the literally hundreds of policy and procedural issues associated with the implementation of the loan and grant program? And how can EPA best utilize its scientific, technical, and administrative resources to meet the June 6 deadline for distribution of funds?

EPA's First Steps

Responsibility for administering the ASHAA loan and grant program was assigned to a newly created Asbestos Action Program (AAP) headed by Susan Vogt. The AAP is a staff unit of the Office of Pesticides and Toxic Substances.

The agency's first task was to develop an application which would elicit all the information EPA might conceivably need to evaluate an applicant's asbestos hazard and financial need. Drawing on the experience of EPA's asbestos experts and on the knowledge of education association officials and Department of Education personnel, a work group headed by Cindy Stroup of the Office of Toxic Substances (OTS) developed an application form. In mid-December, EPA mailed applications and asbestos guidance documents to 33,000 LEAs across the nation. This was followed in January by a loan and grant program policy statement which explained how EPA would administer the loan and grant program.

The next task was to develop a uniform method for evaluating and ranking asbestos hazards so that states could rank the hazards in their schools and EPA could produce a national ranking. After considerable discussion and review among EPA's asbestos specialists, David Mayer of AAP and Joe Breen of OTS developed a method which sorted asbestos hazards into six categories according to the degree of damage to the asbestos-containing material, whether the material was exposed, and whether the material was located in an air plenum (a space between a roof deck and a false or suspended ceiling). These characteristics were judged to be the most important in categorizing asbestos hazards and evaluating their severity. The method utilized a limited set of data from the form, and proved relatively simple to use.

Developing a financial need formula was the next task in implementing the program. Discussion with representatives of public and private school associations led to the conclusion that there was no single school financial indicator which EPA could use to assess the resources available to public and private schools. Sharon Hagan of the Economics and Technology Division of OTS developed a formula which measures the cost of an LEA's abatement projects against the amount of per capita income for a public school district or the amount of operating budget per pupil of a private school. The fewer resources a private school or public school district possessed, the more money it would receive.

Assisting the States

Given the difficult time constraints of the program, EPA recognized that assistance to states in fulfilling their ASHAA responsibilities was going to be crucial to the success of the program. EPA recommended that states impose a deadline of February 15, 1985 for LEAs to submit their applications to state ASHAA designees. This would give states one month—until March 15, 1985—to review and rank the applications and submit them to EPA.

To assist the states during this period, EPA provided temporary assistance through a contractor: a data entry clerk, a personal computer, and a hazard ranking software package to any state that needed these resources to complete application processing. Forty states took advantage of this assistance, and all participating states submitted their applications to EPA by the deadline.

Reviewing the Applications

EPA received 1,100 applications from LEAs around the country. These applications contained funding requests for 8,300 abatement projects in 4,800 individual schools.

Bryon Griffith and Steve Young of EPA's Office of Information Resources
Management managed the formidable task of completing data entry for all applications in 10 days, developing the computer programs necessary for analysis of the application data, and setting up systems to maintain and retrieve LEA records in an orderly fashion. This work was indispensable to the successful completion of the program.

It was necessary to mail requests back to many LEAs for clarifications and corrections of certain key data elements. Hundreds of correction requests were mailed out and returned between March 25 and April 3.

The next task was to develop a preliminary award list which ranked all projects in each hazard category according to the number of exposure hours. Each project on the list also had an award amount assigned to it based on the financial need of the LEA as assessed by the program’s financial need formula.

A “working list” of awardees was now in hand, and we requested that on-site Inspections of potential awardees be conducted by regional personnel. EPA’s Regional Asbestos Coordinators, along with regional staff hired under an existing grant with the American Association of Retired Persons, conducted more than 700 pre-award site inspections.

The reports filed by the inspectors were used in the technical review of each individual project. This phase allowed a detailed review of the hazard, financial need, and grants regulations aspects of each abatement project on the preliminary award list. The principal architect of this review was Larry Culleen, an attorney on the staff of the AAP. During technical review, pictures of all project sites were reviewed, and, if necessary, the inspector or the LEA was called for further information. Kathy Chovan and Karen Hoffman led the effort to make these personal contacts with the regions or LEA. The technical review team analyzed over 900 projects during the first half of May. Final approvals or disapprovals for each of these projects resulted from this review.

After final approvals totaled $45 million, the final award list was handed to Tom Hadd of the Grants Administration Division. About 500 award offers were processed over a 10-day period by Division personnel, an extremely quick turn-around for such a high volume of awards. A policy for offering and monitoring loans was also developed, the first procedures EPA has ever put together in this area.

Meeting the Deadline

As the Journal went to press, EPA was scheduled to notify all applicants of award decisions and announce the results of the grant and loan program in accordance with the June 6 deadline. Through the talent and cooperation of state officials, school district personnel and EPA headquarters and regional staff, a very complex task was made manageable. Although everyone associated with the program can think of ways to simplify or improve the process, the ASHAA loan and grant program was a significant achievement.
Spelling Out Directions for EPA

by Lee M. Thomas

EPA Administrator Lee M. Thomas recently addressed the National Press Club in Washington, D.C., spelling out the priorities of the agency. Here are excerpts from his speech:

George Bernard Shaw once observed that there were two kinds of work in the world. The first consisted of moving objects from place to place on the surface of the earth and the second consisted of telling other people to do so. While environmental protection consists largely of the first type—moving stuff from a place where it may do harm to a place where it won't—EPA's role is to define when, where, and how the move should take place.

Doing this sort of work right requires an enormous amount of careful thought. "Careful" because the laws of nature, which rule that work, are unforgiving, and not subject to amendment on Capitol Hill. Doing it right also requires a minimum amount of stability, continuity, and consistency. It can't be done in a firehouse atmosphere. If it is done "carefully" and "right", the benefits for us and our children can be immense.

For that reason, we must dedicate the next four years to obtaining measurable environmental results. We must improve the management of our programs and increase our understanding of what the federal environmental protection enterprise can really accomplish.

Beyond that, we must begin to pursue a neglected facet of EPA's original charter. That is the integration of all environmental programs into a managed system, capable of focusing federal authority on the reduction of environmental impacts wherever they are found, in the most effective and efficient way.

This is a pragmatic approach to a set of issues that have often been dominated by symbolic and political concerns, but I think its time has come. EPA has been given—perhaps not in the most thoughtful way possible—an almost frightening armory of powers. It can affect almost every aspect of American life—what we eat and drink and how much we pay for it, what we drive, what kind of gas we use, the kinds of jobs we can work at. From the laundry room to the board room, EPA is there.

We must make sure that our efforts over the next four years are concentrated on the reduction of important environmental risks, at places and in situations where the federal power is essential. It is not efficiency alone that demands this discipline.

Nothing erodes the public's tolerance of a regulatory agency more than the imposition of burdens that appear to have only petty results in terms of some substantive public benefit. At the same time, nothing erodes the public's faith in a regulatory agency more than the appearance that it is not, for whatever reason, acting aggressively in the public interest.

My perception is that we have at this point achieved a reasonable balance between these two poles. I don't want to see the pendulum start swinging again, because if it does, the agency will once again be distracted from its important goals by controversy and political friction.

What, then, are some of the important problems? Where do we think our efforts must be concentrated over the next four years to achieve the maximum environmental improvement? Such efforts must involve taking fresh looks at the problems of the older programs that form the backbone of EPA. They also include ensuring that some of the newer ones are making progress in real environmental terms.

Sewage treatment is important. We have spent nearly $40 billion on this program. The good news is that a steadily increasing percentage of Americans are being served by adequate treatment; 57 million people have been added to the system since 1972.

However, 13 percent of the 3,600 largest systems do not comply with their permits. Others are overloaded or subject to frequent breakdowns. Many communities have chosen not to, or are not able to, operate and maintain their plants properly.

Our efforts in this area will be focused on stiffening our enforcement against municipal facilities, and providing technical advice to the states on
operation and maintenance problems. Additionally, we must do this while exploring ways for converting the federal construction grants program to something states and localities can manage on their own. It was never intended to be a permanent federal program.

Controlling ozone and the other major air pollutants is another important area. While I appreciate the concern about more exotic toxic air pollutants, we should not forget that controlling the criteria pollutants remains the best way of preventing public health and property damage from the effects of air pollution.

There are still 54 urban areas that clearly do not meet ozone standards and 72 areas that do not meet carbon monoxide standards. We have until 1987 to bring all of them into compliance. Also, we are starting to see that our basic strategy for dealing with these pollutants, a strategy that assumes that the major environmental effects are in the airshed where they are released, may be mistaken in some important cases. We may have to start taking a regional view when establishing pollutant limitations.

It is now also becoming apparent that atmospheric chemistry is far more complicated than we imagined only a few years ago. Many pollutants interact, changing the level of one may decrease or increase the level of another. Part of the difficulty we have faced in deciding on the best way to deal with the acid rain issue is only the most familiar of these problems. There are others.

Non-point source water pollution—another important area. If we don't do something about this kind of water pollution, which comes from drainage off farms and urban areas, then on many water bodies we will never reach the ambitious goals of the Clean Water Act. It won't matter how hard we clamp down on point sources such as industrial outflows, the water will stay dirty.

What we do about non-point pollution will have an enormous impact on the nation’s wetlands—and wetlands are important. They are the most productive areas for a host of environmental values. In the past two centuries we have converted about half of America’s original body of wetlands in the lower 48 states to other uses.

We have the problem whose apparent importance has eclipsed that of all others in recent years—what to do about toxic substances and all that hazardous waste.

I think we recognize that nothing is more critical than continuing and completing our review of all existing chemical and pesticide products. We must ensure that our most stringent health-based standards are complied with. At the same time we cannot neglect the thorough review of new products proposed for the market.

As far as hazardous waste is concerned, I am beginning to sense a change in attitude on the Superfund side of this issue reflected in the kinds of questions we have been getting from Congress. I believe this is the result of our increased understanding of the dimensions and complexity of the problem.

In its recent report, the Office of Technology Assessment (OTA) came to an important realization, one that we in EPA had reached through first-hand experience. It is that our clean up program is operating on the cutting edge of pollution control technology. Each site
presents a complex and unique problem, whose solution strains current analytic tools.

Although we do not want to slow the momentum of the Superfund program, we must realize that we run the risk of serious errors if we try to force technical solutions at sites where they are really not appropriate. OTA recognized that it makes little economic or environmental sense to undertake costly long-term cleanup projects until we are sure that we have the technology to do it right.

Of course, we must continue to locate immediate environmental and public health threats and deal with them effectively, which is what we have been concentrating on. Our proposed extension of Superfund will enable us to continue with these important actions.

I believe we need to pay a lot more attention to community relations in those places most affected by hazardous wastes, in the belief that local people can help us make intelligent risk management decisions when we share the available information with them. For that matter, citizens can contribute to making better decisions in all environmental areas. I intend to stress community involvement in each of our line programs.

I have been talking about concentrating on the important problems, but just as important is the manner in which we exercise this concentration. It is by now well known that pollution can move among the environmental media—from air to water, surface water to ground water, from water to soil, and so on.

But EPA is composed of individual programs, each carrying out a particular statutory mandate. These are typically focused on individual media. It is understandable that someone under the gun for instituting water cleanup may not have paid the closest attention to the effect on the air resulting from that cleanup. But someone should have. From now on, someone will.

I mentioned the importance of improving sewage plant performance. I will add that the settling ponds and lagoons used in many of these plants are, in a number of industrial areas, a significant source of toxic air pollutants. The toxics come from industrial plants that discharge into the sewer system.

We will be able to control much of this problem through pre-treatment—the removal of the toxic material at the source. But if you have followed my argument you can see that this is yet another inter-media transfer—from water into hazardous "solid" waste, which will have to be disposed of in some way.

This circle game has to stop. It is expensive. At best it is misleading—we think we are solving a problem and we aren't. At worst, it is perverse—it may increase rather than reduce pollution risks. It seems to me that the solution to this problem is the consistent application across all agency programs of what we have been calling risk management.

Reducing risk—to human health and environmental values—is after all the reason we remove pollutants from the environment. It is the currency of our business. By closely watching the movement of pollutants that results from regulatory options and calculating the attendant risks for each, we can assure the public that our actions are indeed connected with a measurable, permanent good.

In summary, then, I see a four-point environmental management plan emerging over the next four years. First, we will make sure that our priorities are those that can have important environmental results. We will take steps to ensure that measuring those results becomes a central part of agency management. Over the next few years I want to complement and in some cases replace the largely administrative measures in our internal accountability system with indicators of environmental progress for each program.

Second, we will continue the strong movement envisioned in our environmental statutes to decentralize our programs and delegate additional responsibility to regions and states. Environmental protection is too large a dog to be wagged by a tail clutched in Washington. We intend to do everything we can to increase the flexibility with which states and localities may implement federal standards. We will also strengthen our technical support and oversight role. We must continue to change policies and long-standing practices that impede this movement.

In this regard, we will continue our efforts to collect information on risk in particular areas subject to unusual environmental stress. Such information gives us the ability to work with states and localities to tailor environmental solutions to the varying needs of different geographical areas.

Third, we will increase the emphasis we give to community involvement and public education. At present, we require a detailed community relations plan for all Superfund sites. We have recommended that this be embodied in law. I have also asked that all the line programs develop community relations and public outreach strategies. If what we are doing makes sense, we ought to be able to communicate that to the grass roots better than we have in the past. We must also establish forums that consistently provide input to us from the public as we make decisions which affect people's lives.

Finally, we must plan control solutions with a multimedia perspective. We have to reduce risk and not merely transfer it. Building an integrated management structure at EPA will not be easy. But we have some of the elements in place, and we have the will to do it. We must focus our resources on the most important problems, and fix them so that they stay fixed.
EPA Diary

On-Scene Coordinators Don't Eat Quiche
by Susan Tejada

(Another special report on how some EPA employees spend their working days.)

Some people call them “cowboys” because of their independence and machismo. Others call them “little corporals” because of their Napoleonic flair for commanding the troops in a crisis.

But in the more prosaic terms of the bureaucracy, they are On-Scene Coordinators, or OSCs.

Under the Superfund program, On-Scene Coordinators from EPA take charge of hazardous waste emergencies on land and in non-tidal inland waters. (The U.S. Coast Guard handles oil and hazardous waste spills in coastal and inland tidal waters, and the Army Corps of Engineers handles longer-term cleanups.) About 70 OSCs are stationed in EPA regional offices across the country.

For On-Scene Coordinators, life is an endless string of midnight dumps, highway accidents that release hazardous cargo, pesticide fires, chemical explosions, and polluted lakes, lagoons, and wells. OSCs work accompanied by a persistent chorus of vocal citizens, aggressive reporters, and never-ending paperwork. The “on-scene” in their title is accurate. They have to spend many of their days in mobile command posts, many of their nights in tacky motels.

George Moein, 48, came to the United States from Iran 30 years ago as an exchange student in engineering and earth sciences. After graduate studies and work for the U.S. Navy in oceanography, Moein joined EPA in 1970. He spent three years working at a desk in Washington, D.C., writing regulations for cleaning up oil spills. But he had an itch to work on the “front lines,” as he puts it, so in 1973 he joined the staff of the EPA regional office in Atlanta as an OSC. He became Chief of the region’s Emergency Response and Control Section in 1982. For the past year and a half, his region has led the country in total number of emergency responses undertaken and completed.

This article describes one of George Moein’s emergency responses.

January 30, 1985, 11:00 a.m.

In the office catching up on some paperwork, George Moein receives an urgent call from his boss Al Smith, chief of the region’s Emergency and Remedial Response Branch. Congressman Bill Henton of North Carolina has just informed the regional administrator of an immediate need to remove two chemical drums discovered in his district. According to labels on the drums, they contain BZ/CS, a chemical warfare agent manufactured for the Army during the Vietnam war for the purpose, as Moein later puts it, of “immobilizing enemy soldiers and making them go crazy.”

BZ/CS, which was never actually used during the war, is an extremely potent combination of hallucinatory drug and tear gas. A mere speck of the BZ, an odorless white powder, can induce severe disorientation for up to seven days. A release from the drums could spill disaster for the several hundred workers at the North Carolina chemical plant where the drums were found and for the general public.

In OSC jargon, another “screaming emergency” is under way.

Moein immediately sets out to learn what he can about the two drums. They are sitting above ground in a wooded area at a site where various companies have been manufacturing chemicals for the U.S. Army since World War II. Many chemicals have been stored or buried throughout the 1,000-acre facility; and the two drums in question represent, says Moein, “the tip of the iceberg in terms of what is there.” The site is already on the Superfund National Priority List for remedial action.

Exactly how dangerous is the BZ/CS? Moein talks to a former employee who worked for the company that manufactured the now-discontinued drug. After being accidentally exposed to a minute dose of the substance, the employee had spent five days in a hallucinatory nightmare, wandering aimlessly through the woods until he was found.

Moein calls the company to begin discussions about who will dispose of the drums and who will pay for the operation. The upshot of the conversation is the scheduling of a meeting between Moein and company officials for 9:00 the next morning.

1:30 p.m.

In the midst of a furious ice storm, windshield wipers slapping the sleet off the glass, Moein leaves Atlanta and starts the four-hour drive to the company site in North Carolina. “Emergencies,” he notes wryly, “either happen in awful weather or outside normal working hours.”

2:30 p.m.

In Commerce, Ga., Moein pulls off the road to make some phone calls. No less accurate than the “on-scene” part of an OSC’s title is the “coordinator” part. With a lot of the coordinating done by phone, it’s hardly surprising that, in a school assignment, her young daughter once described her father as a man “with glasses, curly hair, and a phone in his ear.”

Moein dials Andrew Anderson, a civilian expert on BZ for the Army, to discuss procedures for neutralizing the drug. The next call—back to the regional official in charge of EPA’s remedial investigation at the site—confirms Anderson’s technical information.

7:00 p.m.

Delayed for more than an hour by the storm, Moein arrives at the motel where he will be staying near the company site in North Carolina. A stack of messages waits for him and, for the next few hours, Moein returns “a whole bunch of phone calls” from company and regional officials.

[Tejada is Associate Editor of EPA Journal.]

JUNE 1985
January 31, 1985, 8:00 a.m.

Moein notifies the EPA emergency response contractor to put workers on standby for neutralizing the contents of the drums. Then he checks in with his office. "It's an unwritten policy in Region 4," Moein explains. "to call the office twice a day when you're in the field. You let management know what's going on, and get their feedback. You also need to let them know how well you're holding up in some rather bad situations."

9:00 a.m.

Moein sets out for his meeting with company officials. What he finds when he arrives gives him a jolt: an army of reporters representing newspapers and TV stations from as far as 200 miles away. "They were standing outside the company gatehouse in the sleetin rain," Moein recalls. "They weren't allowed inside until later. But they were persistent. They stayed all day."

Though Moein did not expect to find so many reporters hot on the story, he isn't surprised either. "An OSC becomes seasoned to this," he explains. "In fact," he continues, "sometimes you worry if the reporters are not there. Because if you're frank and aboveboard with them, in many cases they can help a lot. If they're accurate, and don't overplay a story, they can inform citizens of the facts they need to know without creating panic."

9:20 a.m.

The scheduled meeting begins. Representing EPA are Moein and Freda Griffis, a contractor with the region's technical assistance team. Representing the company are its president, environmental coordinator, and several technical people.

The company agrees to the fact that the drums do indeed contain BZ/CS—not pure BZ/CS, but debris contaminated with the substance. EPA wants the company to take responsibility for disposal of the drums. However, since the substance was manufactured by another firm, long before the present firm occupied the site, the company feels the Army should take responsibility for disposal.

A conference call is put through to Anderson, the Army's point man for the site, and negotiations begin. The Army refuses to accept the fact that the drums contain BZ/CS unless the contents are confirmed by lab analysis. It refuses to accept liability for moving the drums to its incineration facility in Pine Bluff, Ark. And it says that the neutralization procedures discussed earlier will be 99.99 percent effective.

At this point, a company official produces an official Army document stating that the neutralization procedures are not effective. This, says Moein in a classic example of understatement, "caused a lot of confusion."

10:00 a.m.

Moein calls Al Smith, who tells him that the company lawyer has relayed a message to the regional administrator: get Moein out of there until the regular remedial process is completed. The average length of a remedial cleanup, from planning to construction, is about four years.

Such interference is a common delaying tactic, Moein contends. "It just doesn't work in this region because our regional administrators trust the technical judgment of the OSCs."

10:30 a.m.

Moein finds a lab in North Carolina that will accept samples of the drum contents and run tests on a priority basis. He puts the lab on standby.

10:53 a.m.

With Moein present, company officials call Anderson to continue negotiations. Because information on BZ/CS is classified, a literature search will turn up little useful material. But the Army now provides additional information on exposure levels, and it is not reassuring. A release of minute doses of BZ/CS would be enough to warrant an Army designation of "alarm level."

Neutralization procedures are discussed. The earlier discrepancy between Anderson's advice and the Army study is resolved: the study had been based on neutralization of pure BZ/CS, while the advice was based on neutralization of BZ/CS-contaminated material, the situation that exists on site.

1:12 p.m.

Although disposal plans have not been finalized, Moein begins emergency planning arrangements in case of an accident. He notifies local hospitals and rescue squads about the situation. He gives physicians an Army telephone number to call for information about the drug's effects and antidotes. And he advises on the best treatment for someone exposed to BZ/CS: keep the individual locked in a padded cell to prevent self-destruction until the drug wears off. The local medical community, says Moein, is not exactly thrilled to hear all this.

Such planning is routine. "We always do it in these kinds of cases," says Moein. "If someone gets hurt, the hospitals have to know how to treat him."

Moein is particularly anxious about accidents at this site because of the continuing bad weather. "I don't worry about explosions, fire, all hell breaking loose—that stuff we can control," he says. "It's the simple little freak accidents that concern me. It had been raining and sleeting for days. The ground was slippery. Someone could easily fall and spill the contents of the drums."

2:00 p.m.

Having eaten nothing for the past 30 hours, Moein decides it might not be such a bad idea to grab a bite. As he and Griffis drive to a restaurant, he notices a startling sight in his rear view mirror: eight cars filled with reporters are on his tail.

"As I munched on a sandwich, they bombarded me with questions," Moein recalls. "I told them no decisions had yet been made on who was responsible, but I would give them a decision by the end of the afternoon, because if no one else would take responsibility, EPA would."

3:00 p.m.

Back at the company, Moein finds another stack of messages. The company had made a conference room available to him, and it is from here that Moein returns the calls. When no phone lines are available, he runs outside to the phone in his van, where the reporters, huddled in the rain, follow him in an attempt to eavesdrop.

The phone calls do not bring good news. The lab that had earlier agreed to test drum samples now refuses to do so. The lab's chemists have threatened to stage a walkout rather than handle BZ/CS.

4:35 p.m.

The company president reaches a decision. The next morning, when it is light, he will have the contents of the drums neutralized and removed to a disposal facility.

That was the first good thing I'd heard all day," recalls Moein.

5:00 p.m.

More good news comes from the EPA contractor in Atlanta, who informs Moein that he has located an approved landfill in Pineview, S.C., that will accept the neutralized contents of the drums for disposal.

February 1, 1985, 7:00 a.m.

The contractor's site crew, having arrived at midnight, takes samples of the drum contents, although a lab that will accept the samples has not yet been found.
8:00 a.m.
In a reversal of the president's decision of the previous day, the company attorney informs Moein that the company can accept no responsibility for the remaining drums and can take no action to neutralize or remove their contents at this time.

In that case, Moein states, he will undertake an emergency response under Superfund. The attorney says he is not very happy about that. "Neither," says Moein, "am I."

1:15 p.m.
As sleeting rain continues to fall, members of the EPA contractor's site crew use a sodium hydroxide-based solution and chemical hydrolysis to neutralize the contents of the two drums. They stay in radio contact with Moein, who has established a command post in a nearby shack.

1:50 p.m.
Moein holds a press conference in an open field to inform the shivering reporters that the neutralization process is underway.

2:10 p.m.
Region 4 Director of Public Affairs Frank Redmond informs Moein that the State of South Carolina is having second thoughts about allowing the neutralized drum contents to be disposed of in Pinewood. The civil defense director in Pinewood has threatened to shut down the landfill unless he receives assurances that all traces of BZ/CS in the drums have been neutralized.

3:45 p.m.
The site crew completes the neutralization process without incident and returns to the command post. The drums are then packed into larger recovery drums supplied by the company. The recovery drums are sealed to secure them against tampering and protect them from the weather.

For the next two hours, Moein tackles the paperwork required to document the events of the past two days, and wrestles with the Catch-22 dilemma the response now presents: Pinewood will accept the drums only after their contents have been certified as BZ/CS-free by a lab, but no lab will touch the stuff.

7:30 p.m.
In weather just as crummy as when he started out, Moein begins the drive back home to Atlanta.

Over the next four days, Moein continues the search for a lab that will accept the drum samples for testing. He uses all his persuasive powers to convince the Army to provide the lab with classified material on BZ/CS so it can perform the analysis. Test results show that no trace of BZ/CS remains in the drums. That means that the neutralization has been successful, and the Pinewood landfill will accept the drums for disposal.

On February 5, 1985, the drums, followed by a convoy of reporters, are shipped to Pinewood. George Moein holds a new conference to announce completion of the emergency response.

The life of an On-Scene Coordinator, according to Moein, takes a heavy toll. OSCs work on a rotation system. Being on call day or night, weekday or weekend, their lives lack a normal routine. "You can't take evening courses," says Moein, "or watch your kids' soccer games, or go to church on Sunday. A couple of times, my beeper went off when I was receiving communion. After that I decided to forget the beeper and just stay close to the phone."

OSCs operate under enormous pressure. Part of that pressure is the power they wield: power to authorize expenditures of up to $1 million with the stroke of a pen, power to control a diverse team of scientists, laborers, and company presidents. To handle the pressure without burning out, an OSC, according to Moein, needs three characteristics: the strong desire to accomplish something, the ability to manage incredibly complex and dangerous operations, and the gift of serenity. "An OSC," he says, "has to stay cool while everyone else around him is shouting. As for me," he continues, "I stay calm. Then I go back to the motel and start kicking the walls. There are a lot of gray hairs in this program."

Why do OSCs take it? "EPA's mission," Moein explains, "is to protect public health and the environment. OSCs work at the grass roots, doing exactly that. We are the firefighters of this agency."

Moein doesn't see the need for OSCs diminishing any time in the near future. "In Region 4," he says, "there are about 1,500 to 2,000 incidents involving oil and hazardous substances a year. Seventy-five to 80 percent of the incidents are spills caused by transportation-related accidents. To think that these accidents aren't going to happen is utopian."
Protecting the Public from Toxic Air Pollutants
by David R. Patrick

(At press time, EPA plans regarding an air toxics strategy were under way. Announcements regarding that strategy are possible at any time.)

Toxics, dioxin, methyl isocyanate, formaldehyde, asbestos: these and similar alarming terms are frequently front page news. We ask ourselves: "Will I or my family get cancer from the air we breathe? Should I move away from the industrial operation nearby?"

How much of this alarm is well-founded is a very difficult question to answer. Certainly, Bhopal was real, as real a tragedy as can occur. But, was it a freakish accident that is unlikely to happen again?

More and more is being learned about the complex issues that make up the toxic air pollutant problem, and EPA is building a strategy for better management of this problem in the future.

The Air Toxics Problem

Almost any human activity, from making steel to driving automobiles, releases pollutants into the air. The pollutants disperse. Some break down under action of sunlight while others react to form new substances. Still others remain unchanged and build up in the air or soil. Because the atmosphere is vast, humans normally are exposed to relatively low concentrations of each of these substances, usually concentrations measured in parts per billion.

While these numbers may seem vanishingly small, some of these toxic substances can adversely affect humans at those low levels. Others may eventually build up to levels of concern. Then too, none of us is exposed to just one substance, but to many substances whose effects may be additive or even synergistic. The task for the regulator is to identify which substances may result in significant harm to humans and to determine how to control them.

Initially, EPA followed the lead of the Clean Air Act and viewed the toxics problem predominantly as one of industrial origin. This has resulted in eight substances being formally designated as "hazardous" under Section 112 of the Clean Air Act. Many believed this was an inadequate response to the air toxics problem as they perceived it. For this and other reasons, EPA undertook a comprehensive analysis to examine the nature and magnitude of the toxics problem. The analysis, popularly referred to as the Six Month Study, revealed a problem more complex than expected. Pollutants from many types of industrial, commercial, public and private activities are involved, in amounts which vary substantially across the country, and even within cities.

The Six Month Study concluded that the air toxics problem was significant, but not serious enough to warrant emergency actions. For example, it concluded that perhaps 1,300 to 1,700 of the nation's 450,000 cancer deaths each year might be attributed to the air we breathe. In addition, risks to individuals in larger cities or near some industrial complexes may add measurably to an individual's risk of getting cancer in a lifetime. The study also found that much of today's air toxics risk may result from such small and widespread sources as service stations, wood stoves, and solvents.

On the positive side, the study showed that toxics in the nation's air have decreased substantially over the last decade as a direct result of the combined EPA and state air pollution control programs aimed at smog, soot, and automobile emissions.

A different study that helped increase our understanding of the air toxics problem took place in Philadelphia, which joined EPA in a study of air, water, and solid waste toxics pollution. It was found that significant risks occur over large urban areas, and are increased by many sources (e.g., sewage treatment plants) not traditionally thought of as air pollution sources.

Also, the Bhopal incident caused us to look again at accidental releases of very toxic substances and to reconsider how they relate to the total air toxics problem. That early morning industrial accident, compounded by human errors, led to an unprecedented tragedy. But, while accidents could always happen, it seems much less likely that a similar tragedy can occur in the United States. Companies, as well as community and government officials, have planned for emergencies and have shown a remarkable ability in the past to minimize loss of life and property when accidents have occurred.

Strategy

If all our study and analysis tells us anything, it is that the pollutant-by-pollutant, industry-oriented approach of the past only addresses a portion of the air toxics problem. As a result, an effective strategy for the future must be broader and more flexible to deal with the huge variety of toxic air pollutants, sources, source sizes, and estimated risks.

EPA's current view is that the air toxics problem consists of three major components, each requiring a different solution.

Nationwide problems - A portion of the air toxics problem arises from large or widespread emissions of toxic substances which result in significant nationwide public health impacts. This was the focus of legislation requiring nationwide federal emission standards for pollutants causing serious illness in humans. These emissions can arise from large-scale industrial activity as well as smaller, more pervasive sources such as gasoline marketing, wood stoves, and municipal incinerators. EPA's response to this portion of the problem will encompass the existing Section 112 program as well as other authorities. Examples of the latter include fuel and fuel additive regulations under the moving source part of the Clean Air Act, and hazardous waste treatment, storage, and disposal regulations under the Resource Conservation and Recovery Act.

(Patrick is Chief of the Pollutant Assessment Branch in EPA's Office of Air Quality Planning and Standards and is contributing to the air toxics strategy under development in the agency.)

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Localized problems - Another portion of the air toxics problem arises from sources of pollutants that, while not national, are big enough to possibly affect people in the limited areas where such sources are located. In these instances, local regulations likely can be implemented more quickly and cheaply than federal regulations, and can be better tailored to the specific situation of the source and the surrounding population.

A pilot state control program is currently underway on the chemical acrylonitrile. This chemical, which causes cancer in animals, is made and used at 26 industrial facilities in the United States but, because of various local regulations and other factors, only a fraction of these facilities result in relatively high risks to humans. While state and local governments will handle primary regulation of these situations, EPA will play a large role by providing technical, administrative, and resource assistance.

Multiple source problems - The final portion of the air toxics problem deals with areas of the country impacted by several sources of toxic air pollutants. These geographic situations usually occur in industrialized cities or industrial complexes. At present, EPA is furthest from understanding and dealing with this part of the air toxics problem. Current activities include developing more comprehensive inventories of sources, pollutants, and locations.

The Future

Although many different issues remain to be resolved, it is clear to EPA that a fundamental change in the air toxics program in the future is necessary to better protect the public health. The Section 112 program is moving and being expanded; a state/local pilot program is underway to verify the usefulness of this type of response; and data gathering has begun to better define the potential for, and risks associated with, multiple source problems. EPA also is working with Congress to enact the most useful legislation to deal with air toxics. A more effective air toxics control program is definitely being constructed.

A scenic view of Boathouse Row in Philadelphia. The city is one of three urban areas in the country that participated in an EPA study to identify pathways of air toxics into the environment.
Environmental Audits: A New Enforcement Tool

by Richard H. Mays

A new "preventive medicine" approach to environmental compliance holds great promise for greater protection of the public from environmental mismanagement by large companies.

Called an environmental audit, this new approach to improving a company's overall environmental performance was initiated in a December 1984 consent agreement between EPA and Chemical Waste Management, Inc., which addressed violations of environmental regulations at the company's facility in Emelle, Ala.

For the first time, EPA insisted on provisions in an enforcement agreement which required a company to conduct an "environmental audit" of the company's organization, policies, and procedures to determine whether they were designed to achieve compliance with environmental laws.

When EPA finds violations of environmental regulations, it traditionally responds by requiring corrections of the specific violations and assessing penalties. This approach frequently does not address what may be the root of the problem: the lack of a clear company policy encouraging compliance with environmental laws and regulations, along with procedures which would effectively implement such a policy.

That all manufacturing concerns do not already have clear environmental policies and procedures is not surprising. Corporate acceptance of environmental regulations has frequently been grudging or benign. Since management of waste is almost totally an expense under current technology, the incentive exists to get rid of waste as quickly and cheaply as possible. The "flush and forget" philosophy frequently leads to violations of environmental laws.

Even when corporate environmental policies and procedures are in existence, the company's organizational structure and management system may be such that they are ignored. Frequently the manager of a facility is charged with the dual responsibility of operating the facility to obtain the highest profit, and also complying with environmental regulations. These may be conflicting interests, and environmental compliance often loses the conflict, notwithstanding that the company may have—on paper—a policy encouraging compliance.

For example, Union Carbide, a large multinational, multiple facility corporation, claims to have in place a

Waste-deep in a wheat field, two employees of Pennsylvania Power and Light Company conduct an environmental audit at a PP & L Co. plant near Danville, Pa. They are recording visible emissions readings from the plant.
comprehensive environmental assurance program. Yet, the company's own report on the disaster at its subsidiary in Bhopal admitted that key elements of that program were not followed. When asked about the failure of that program to safeguard against such a disaster, Warren Anderson, Chairman of Union Carbide's Board of Directors, stated: "Safety is the responsibility of people who operate in our plants. It's a local issue." That is a potentially dangerous delegation of responsibility.

A number of recent events vividly demonstrate that business, corporate oversight of environmental safeguards is needed—not only because of possible EPA or state enforcement action, but also because the very future of the company may be severely affected by failure to observe environmental diligence.

Consider the following cases:

Love Canal, the infamous hazardous waste landfill, has generated claims running into hundreds of millions of dollars for cleanup, property damage, and personal injury against its former owner, Hooker Chemical Co., and its successor, Occidental Chemical Co.

The claims of thousands of asbestos workers and their families for disability or death benefits due to exposure to that substance have driven Johns-Manville Corp. and other asbestos companies to seek the protection of bankruptcy courts.

The release of a highly toxic cloud of methyl isocyanate from the Union Carbide plant in Bhopal, India, reportedly claimed some 2,000 lives and caused 200,000 injuries, resulting in damage claims running into the billions of dollars.

There are many other, less spectacular cases in which releases of chemicals into the environment have caused and continue to cause business losses to incur major costs. EPA's Superfund program alone envisions expenditures by the private sector of several billion dollars. As science continues to develop methods of linking chemical exposure to illness and disease, "toxic tort" suits will undoubtedly increase. The potential for corporate exposure to liability for harm to the environment and health grows daily.

In many cases, the financial health of some of the country's largest corporations has been or may be severely affected. The threat of financial ruin through an environmental disaster is just as real as failure due to faulty business transactions. This threat will undoubtedly do more to get the attention of top corporate management than any EPA or state enforcement action. The incident at Bhopal—which is to the chemical manufacturing industry what Love Canal has been to hazardous waste disposal—has already caused some companies to reassess their environmental and safety programs.

The need for such reassessments throughout industry may be too important to rely on the voluntary action of individual corporate management. More environmental calamities should not be required to convince corporate management to examine its environmental policies and procedures. There is a growing school of thought within EPA that the agency should do more to encourage a higher level of corporate consciousness toward compliance with environmental laws.

This encouragement could be supplied in the context of EPA enforcement actions against a company for violations at one or more of its facilities. As part of those actions, the company might be required to assess its environmental policies, procedures, organizational structure, operations, and management—or lack of them—to determine whether they are designed and implemented to ensure maximum compliance. This is called an environmental audit.

This approach would have effects far beyond those produced by the traditional enforcement action. Any improvements in the company's environmental operations resulting from the assessment would apply throughout the entire company, raising the level of environmental compliance at all facilities. This would also be a highly efficient and effective use of EPA's enforcement resources, a fact important to EPA at this time of expanding enforcement workload.

An "environmental audit" could be similar to an audit of a company's financial records and procedures, performed by an outside consultant or—less desirably—by a company's internal environmental audit team. For a number of years, EPA has been interested in the concept of environmental auditing as a method to promote voluntary compliance with environmental laws, and we encourage the regulated community to conduct these audits as a matter of good business practice. However, the idea of using an enforcement action to negotiate for an environmental audit is relatively new.

The inclusion of environmental audits in enforcement actions is particularly appropriate. Inspections at some company facilities may indicate a pattern of violations which reflect a lack of sound corporate environmental policies and management procedures. That pattern of violations is likely to be repeated at all of the company's facilities. Likewise, environmental audits would also be appropriate in cases involving any company which has a history of repeated significant violations.

An environmental audit may be as broad or as narrow as the number, scope, and severity of a company's violations seem to require. In a narrowly focused audit, a company with an otherwise good record of compliance might be called upon to review only a small part of its operations which had been presenting chronic instances of noncompliance. In its broadest form, an audit might require a company to examine its entire environmental management policies, procedures, and organizational structure, and programs affecting all company employees and operations.

This new dimension to enforcement will undoubtedly be met with mixed emotions among the many companies regulated by EPA. Some will view it as an investment toward reducing their exposure; not only to future EPA enforcement action, but also to the potential corporate-wrecking environmental disaster. Others will oppose what they will characterize as government intrusion into corporate management. Environmental audits will probably be opposed as much over principle as over costs.

As with any innovative concept, there are many questions which will be asked of our agency. Will the company get a credit against penalties if it agrees to perform an environmental audit? Will EPA be entitled to access to the audit report or its supporting documents? If the audit report discloses violations of which EPA was unaware, will the agency use the company's own report to initiate an enforcement action?

These are all legitimate questions. To anticipate and answer them, EPA is developing a policy on the role of environmental audits in enforcement actions. We will attempt to preserve enforcement prerogatives and capability, while providing sufficient latitude and flexibility to give companies the incentive to perform an environmental audit.

If EPA is successful in requiring violators to perform environmental audits, it will have gone beyond the traditional enforcement response of addressing only the outward manifestation of the problem—the violation—to look behind that violation for what may be the real cause of noncompliance. If corporate management is required to focus on addressing the root problem—the lack of environmental management policies and procedures—then the company, EPA, and the public will all benefit greatly.
Responding to the public's fears of cancer and other threats from environmental contamination can be costly, complicated, and time-consuming. And one is never sure how it will end... as recent events in Region 8 well demonstrate.

It all began with a phone call to EPA's Denver offices from Rebecca Parr. Late in 1982, Mrs. Parr had begun to think that her Denver suburb of Friendly Hills might be misnamed. She had learned that several children within a few blocks of her home had developed cancer. Two had died of neuroblastoma, a cancer which attacks brain cells. Another had succumbed to leukemia. And one child had died of spinal meningitis. Feeling that the illness rate was unusual for a neighborhood of about 4,000 people, she asked EPA for help.

Her information was sketchy at best, neither comprehensive nor detailed enough to warrant the immediate diversion of limited staff and budget resources from other priority activities. Nevertheless, she was advised to document the problem as fully as possible to clarify the basis for her concern and the need for an official investigation.

So Parr set out to gather more information. Using a questionnaire first developed by environmental activists at Love Canal, volunteers canvassed surrounding homes, asking residents about unusual health problems experienced since moving to the area.

The results were disturbing. Within a one-mile radius of the Parr home, in addition to the children's diseases, 17 people reported kidney problems. There were 28 cases of tumors, including four in children. Neighborhood concern increased. Environmental and health agencies began to pay attention.

Also paying increased attention was Colorado's chapter of the Citizen Action Network (CCAN). Tied in with the National Campaign Against Toxic Hazards, CCAN was actively promoting reauthorization of Superfund and the Resource Conservation and Recovery Act. CCAN linked itself to the emerging Friendly Hills issue, urging Parr and other neighbors to go public. The newly linked organizations fired off a letter to EPA Regional Administrator John Welles. They then held a news conference at which a "cancer map" of the area was displayed, and official agencies were charged with being unresponsive to the situation.
Some public officials were reluctant to spend scarce time and money chasing what they perceived to be a will-o'-the-wisp. After looking at maps, earlier reports, and the results of various limited spot investigations, they were ready to dismiss the citizens’ concerns as unfounded.

But residents needed answers to very real questions. Can we eat vegetables from our garden? Can our children play here? How many other Denver areas are contaminated with whatever it is? Will Superfund buy us out? Are we still being exposed? And, overriding all others, the questions: When will EPA and the State of Colorado do something about this? When will they give us the answers?

Each day, the news media covered escalating developments. As the government’s response took shape, the agencies and elected officials urged citizens to form an advisory group through which all new information would be channeled to cut down the proliferation of anxiety-producing rumors.

The residents seemed to be divided into three groups: those who were convinced there was a menace to their health; those who felt it was a rumor-fueled panic which was destroying their property values; and a third group willing to wait and see. The second group urged residents not to participate in the expanding health canvassing by Parr and CCAN. Everyone agreed, however, that more information was needed.

The residents, of course, wanted quick answers. Scientists who were called in wanted to progress deliberately with a careful sampling plan. Under this plan, EPA would look for environmental contamination and the Colorado Department of Health would check cancer registries and other medical data to determine if significant variations in disease rates were present. The state was forced to patch a team together to do this; the health department’s epidemiology section had lost its funding three months earlier.

Congressman Dan Schaefer (R-Colo.) hosted a community meeting where the plans were presented to residents and other interested groups. By now, the story had become national news and some commentary added to the residents’ anxieties by comparing the situation to Love Canal and the Valley of the Drums. This comparison was strengthened one Friday afternoon when investigators found 62 abandoned drums across the street from a water supply that served the troubled neighborhood. More stories flared up over the weekend, before it was determined that the drums were not leaking and that their contents were not toxic.

The activists saw the methodical approach as agency foot-dragging. They continued their own research and held a news conference to announce an “obvious” health hazard the experts had missed: abandoned uranium mines that dotted the area.

Was radioactivity the problem? People began to report strange odors and found mysterious white crystals on basement walls. A former county health official reminded everyone that fires at a weapons plant several miles away had released plutonium in 1957 and 1969. Other commentators raised the specter of microwave radiation from broadcasting towers on a nearby mountain.

EPA moved to check the mines, invited citizens along on the inspections, and quickly discounted the abandoned mines as a contributor to the problem.

Air samplers were placed in homes where disease was reported and in control homes. Outside radiation concentrations were measured by hand-held detectors and by an EPA van equipped with instruments so sensitive they could register, from the street outside, radiation from a radium-dial clock inside. Samples were taken of soil, surface water, drinking water, and water that had collected in sumps in basements. The samples were analyzed for radium, thorium, uranium, cesium, and radon gas. Microwave radiation had been tested and ruled out years earlier. Conclusion: Radiation was not a problem.

Similar thoroughness marked the other sampling work. The area’s general setting was analyzed in terms of geology, hydrology, history, and weather— aspects that could be important in interpreting test results. Samples were collected of air, drinking water, surface water, basement sump water, sediments, soil, and fertilizers used in the area. Analyses were done on these samples to identify organic and inorganic chemicals, pesticides, and heavy metals. By mid-December, almost all of the 6,500 sample analyses had been completed and, in the careful and precise language of the scientists, “no exceedences of criteria applicable to human health were observed.”

So, no cause was found... but what of the problem?

State health officials, upon completing their cancer registry analysis, concluded that the number of childhood cancers was higher than “normal” but represented a statistical “clustering of cases.” Such clustering is not unusual with cancer. nor is the prevalence of the disease in children—it is the number two killer of children in America. There was no pattern which indicated an environmental threat.

These facts were presented to the residents in a public meeting. Most were satisfied and tremendously relieved. Their children could play outside again. Realtors could close deals again (although the stigma still affected negotiations). Many were anxious to put the matter behind them and resume their lives. Some set about closing the rifts that had opened between neighbors.

Some residents and reporters pressed for absolute answers. “Does this mean the area has a clean bill of health?” The scientific answer, while reassuring, wasn’t absolute. The exhaustive sampling plan was designed to look for environmental contamination that could account for an apparently high level of illness in the area. None was found. But sophisticated monitors had not been placed in, around, and under each and every house. Cancer and other health records had been reviewed, but intensive health testing was not done on each and every resident. According to the scientists, it was possible, though very unlikely, that some key variable was overlooked.

Even if those extra steps had been taken and the same results achieved, would everybody have been satisfied?

It comes down to a question of trust—which was why the investigation was done in the first place. Although some scientists felt there wasn’t sufficient reason for the probe, and some managers worried about diverting staff and money from other priorities, the public concern had been real and had to be dealt with. People had been worried about their family’s health and had turned to EPA and the state for answers and reassurance. They got both, and said so at the final public meeting.

Even though no pollutants or toxics had been found and dramatically removed on the evening news, the “danger” had been removed from their minds. The agencies had served the community well.
Update
A review of recent major EPA activities and developments in the pollution control areas

AIR
Ford Recall
The Ford Motor Company is voluntarily recalling approximately 180,000 1981 model year passenger cars to ensure that the vehicles will meet federal exhaust standards for hydrocarbons and carbon monoxide.

The affected 1981 model year cars are the Ford Mustang, Granada, and Fairmont models and the Mercury Capri, Cougar, and Zephyr models equipped with 2.3-liter, four-cylinder engines. California vehicles were recalled in September 1984 to remedy similar emission problems.

Ford decided to recall the cars after EPA testing revealed that they were exceeding the 1981 hydrocarbon and carbon monoxide exhaust standards.

The repairs will consist of modifications to the air injection system as well as inspection and— if necessary— repairs of the exhaust gas oxygen sensor and exhaust gas recirculation system.

Ford will send notification letters informing owners of the recall and requesting that vehicles be brought to Ford or Lincoln-Mercury dealers where the repairs will be made at no cost to the owner.

HAZARDOUS WASTE
Clean Sites
EPA has authorized Clean Sites, Inc., a private organization created to expedite private-party cleanup at abandoned hazardous waste sites, to begin considering whether and how the group should get involved in the cleanup of 19 sites.

Clean Sites requested authorization to evaluate these 19 sites under an earlier agreement in which EPA said it would indemnify the group against third-party liability. Under the indemnification agreement struck earlier this year, EPA agreed to indemnify Clean Sites and certain representatives against third-party liability at preauthorized sites, up to $5 million per site, and $10 million per fiscal year, to be paid directly from the Superfund trust fund. The trust fund, earmarked for cleanup of hazardous waste sites, was established under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).

All 19 sites are on EPA's National Priorities List (NPL). That means EPA considers them candidates for priority long-term cleanup, either directly with the aid of Superfund or through private-party cleanup.

Dioxin Wastes
EPA will regulate the management of dioxin-containing wastes, the agency has reported. The dioxin wastes will be added to the list of those subject to the hazardous waste management standards of the Resource Conservation and Recovery Act (RCRA).

This regulation is a key part of EPA's dioxin strategy, which is designed to prevent mismanagement of dioxin-contaminated wastes. By listing these wastes under RCRA, EPA is taking broader control over the disposal of dioxines than it has previously exercised under the provisions of the Toxic Substances Control Act (TSCA). The chemical 2,3,7,8-TCDD was the only variation of dioxin regulated under TSCA.

Regulation of Underground Storage Tanks
Service stations and certain other small businesses, industries, and individuals may no longer install many types of commonly used underground storage tanks containing petroleum products and hazardous substances. EPA has announced.

The prohibition is effective under the November 1984 amendments to the Resource Conservation and Recovery Act (RCRA). Under the amended version of RCRA, EPA is now required to develop a comprehensive program to control the quality and operation of underground storage tanks used to store petroleum products and many hazardous substances.

The RCRA amendments will affect as many as 100,000 new tanks installed each year. They prohibit the underground installation of new storage tanks and piping unless the tank will prevent releases caused by corrosion or structural failure. Leakage from these tanks may result in soil and ground-water contamination.

From now on, the only types of underground storage tanks that may be installed are those that are constructed of a noncorrosive material, cathodically protected, steel-clad with a non-corrosive material, or designed to prevent releases of stored substances. In addition, material used to construct or line tanks must be compatible with the stored substance to prevent corrosion. An exception for corrosion protection applies to tanks located in certain types of soil.

PESTICIDES
Emergency Pesticide Uses
EPA has proposed revising its pesticides regulations to clarify when the agency will grant state and federal agencies emergency exemptions to use pesticides for applications for which they were not registered.

These proposed revisions were developed through the regulatory negotiation process. This process allows persons outside EPA with different interests to actively participate in the development of agency rules and regulations. During these negotiations, all interested parties can meet face-to-face to discuss and resolve issues.

The revised regulations would set stricter conditions for agencies to meet before EPA grants them an emergency exemption.

Cyanazine Review
A special review of the pesticide cyanazine has been initiated by EPA after the agency determined that workplace exposure to this product may pose an unreasonable risk to public health.

The agency's action is based on data which show that cyanazine causes birth defects in the offspring of laboratory animals and may pose a significant risk to women of childbearing age who apply this pesticide. EPA is principally concerned with risks from exposure to cyanazine by mixer/loader and applicator personnel. There is no significant exposure from eating food crops treated with this pesticide.

A special review is a formal public process in which the agency assesses all the risks and benefits of a pesticide before reaching a final regulatory decision on its continued use.

Cyanazine, a herbicide, was first registered with EPA in 1971. It is manufactured by Shell Chemical Co. under the trade name Bladex. Ninety-six percent of the cyanazine produced is used on corn to control annual grasses and broadleaf weeds. It is also used on cotton, grain sorghum and winter wheat crops.

Dinocap Use to Continue
EPA will allow continued use of the pesticide dinocap based on the agency's review of new laboratory studies undertaken to determine the product's potential risks.

In early November 1984, Rohm & Haas—the sole manufacturer of dinocap—voluntarily suspended until April 1, 1985, all sale and distribution of dinocap products after tests showed that this pesticide caused birth defects in rabbits which were fed with it. Since then, EPA has conducted another study which produced similar effects in mice who had ingested dinocap. In the meantime, Rohm & Haas completed additional skin penetration and birth defects studies. EPA has evaluated these tests. They show that exposure...
Canada goose and goslings near an island in the Chesapeake Bay. Preserving the nation's wetlands by controlling non-point source water pollution is an important concern of EPA. See story on page 18.

Back cover: An outing on a sunny day. Photo by Edward Clark, Folio, Inc.