UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 5, 2000

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: Dennis K. Rathbun, Director
Office of Congressional Affairs

Linda Portner for

SUBJECT: SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE HEARING ON COMPARATIVE RISK ASSESSMENT

On October 3, 2000, the Senate Environment and Public Works Committee held a hearing on the Environmental Protection Agency's (EPA) use of comparative risk assessment in setting environmental priorities with regard to clean air and chemicals. A copy of the witness list is attached. Also attached are documents may be of interest to the Commission. The statements of the remaining witnesses are available from OCA.

Attachments:
1. Witness list
2. General Accounting Office (GAO) report, "EPA Needs Better Information To Manage Risks and Measure Results"
3. Testimony of Al McGartland, Assistant Administrator, Office of Policy Economics and Innovation, EPA
4. Statement of Dr. Morton Lippman, Professor, NYU School of Medicine

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SENATE ENVIRONMENT AND PUBLIC WORKS

FULL COMMITTEE HEARING
USE OF COMPARATIVE RISK ASSESSMENT IN SETTING PRIORITIES AND ON THE SCIENCE ADVISORY BOARD'S RESIDUAL RISK REPORT

Tuesday, October 3, 2000
9:30 a.m.
Environment and Public Works Hearing Room (SD-406)

PANEL I

Mr. Al McGartland
Director, National Center for Environmental Economics
Office of Policy, Economics, and Innovations
U.S. Environmental Protection Agency

Mr. Peter Guerrero
Director, Environmental Protection Issues
U.S. General Accounting Office

PANEL II

Ms. Katherine Hartnett
Executive Director
New Hampshire Comparative Risk Project

Mr. Michael J. Pompili
Assistant Health Commissioner
Columbus Health Department

J. Clarence (Terry) Davies, PhD
Senior Fellow, Center for Risk Management
Resources for the Future

Dr. Elizabeth L. Anderson
President and CEO
Sciences International Inc.

Dr. Morton Lippmann
Professor, New York University
Chair, Science Advisory Board

PANEL III

Mr. Lee Hughes
Vice President for Corporate Environmental Control
Bayer Corp

Mr. Robert Brenner
Principal Deputy Assistant Administrator for Air and Radiation
U.S. Environmental Protection Agency

Dr. Philip Hopke
Chair, Residual Risk Subcommittee
Science Advisory Board

Ms. Felice Stadler
National Policy Coordinator
Clean the Rain Campaign
National Wildlife Federation

United States General Accounting Office

GAO

Testimony

Before the Committee on Environment and Public Works, U.S. Senate

For Release on Delivery
Expected at 9:30 a.m., EDT
Tuesday
October 3, 2000

ENVIRONMENTAL INFORMATION

EPA Needs Better Information to Manage Risks and Measure Results

Statement of Peter F. Guerrero, Director
Environmental Protection Issues,
Resources, Community, and Economic Development Division

GAO
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GAO-01-97T

Mr. Chairman and Members of the Committee:

We appreciate the opportunity to discuss our observations on the data that the Environmental Protection Agency (EPA) needs to manage its programs more effectively. In reports going back to our comprehensive general management review of EPA in 1988,[1] we have identified numerous long-standing problems in the agency's efforts to collect and use environmental data. Drawing from this work, I will discuss today the limitations in the data that EPA needs to (1) set risk-based priorities for its programs and (2) develop outcome-oriented measures of its programs' results. Our observations are as follows:

- EPA's ability to assess risks and establish risk-based priorities has been hampered by data quality problems, including critical data gaps, databases that do not operate compatibly with one another, and persistent concerns about the accuracy of the data in many of EPA's data systems. While EPA's priorities should reflect an understanding of relative risk to the environment and public health, good data often do not exist to fully characterize risk. In the absence of reliable data, public perceptions of risk can influence how EPA determines its priorities and allocates resources. EPA has taken major steps during the past few years to improve its data and to better inform the scientific community and general public of environmental and public health risks. To finish this job, the agency will need to expand its data improvement initiatives to fill key gaps in its data, take advantage of opportunities to develop and implement data standards to achieve compatibility among environmental databases, and ensure the accuracy of its data.

- Measuring the results (outcomes) of its programs is critical to determining EPA's effectiveness. Nevertheless, the agency historically has relied on activity-based output measures, such as the number of inspections performed, because of inherent technical difficulties in establishing sound linkages among program activities, environmental improvements, and public health. Spurred by the requirements of the

[1] *Environmental Protection Agency: Protecting Human Health and the Environment Through Improved Management* (GAO/RCED-88-101, Aug. 16, 1988).

Government Performance and Results Act of 1993 (Results Act), EPA has made progress in recent years in measuring the outcomes of its programs. To ensure future success in developing outcome measures, however, EPA will need to make a long-term management commitment to overcome major challenges to obtaining the data needed to show the results of environmental programs.

Background

Since EPA's establishment in 1970, the federal government has developed a complex system of laws and regulations to address the nation's environmental problems. Over the years, as environmental threats were identified, the Congress responded by enacting laws to address each problem, incrementally adding to the statutory framework that sets EPA's agenda. However, these laws were not coordinated or integrated to provide EPA with an overall system for prioritizing problems so that the most serious problems can be addressed first.

Impelled by budgetary constraints and a growing list of environmental problems, EPA, in the late 1980s, began to consider whether its resources were being spent on the problems that pose the greatest risks to public health and the environment. The agency concluded that the nation actually was devoting more resources to problems that had captured public attention than to problems that were less well known but potentially more serious. Subsequently, EPA began incorporating the concept of relative health and environmental risk into decisions on environmental priorities and emphasizing the need to identify the most serious risks and to keep the public informed about the relative seriousness of various environmental problems. To assess risks and deal with those likely to do the most harm, EPA has recognized that it needs to have adequate environmental and scientific data to conduct risk assessments, set standards, and develop regulations. It also needs such data to identify and develop measures of environmental quality and to assess the effectiveness of its programs by linking program activities to changes in environmental conditions.

EPA Needs Better Data to Establish Risk-based Program Priorities

Establishing risk-based priorities for EPA's program activities requires good data on the use and disposal of thousands of chemicals. To assess human exposure to a chemical, EPA needs to know how many workers, consumers, and others are exposed; how the exposure occurs; and the amount and duration of the exposure. For environmental exposure, EPA needs to know whether the chemical is being released to the air, water, or land; how much is being released; and how wide an area is being affected. EPA's ability to make such assessments is limited by (1) gaps in environmental and health data, (2) databases that do not operate compatibly with one another, and (3) the lack of an effective system for ensuring the accuracy of the agency's data. Although EPA has implemented several agencywide initiatives to address these problems, each of the initiatives has encountered obstacles that must be overcome to substantially improve the agency's data.

Extensive Gaps Exist in EPA's Information About the Environment and Health Risks

Our work over the past few years has shown that very little is known about the risks of potential exposure to chemicals and environmental conditions for workers, the general public, and plant and animal life. For example, we reported the following:

- EPA's Integrated Risk Information System, which is a database of the agency's consensus on the potential health effects of chronic exposure to various substances found in the environment, lacks basic data on the toxicity of about two-thirds of the known hazardous air pollutants.[2]

- EPA's *National Water Quality Inventory* does not accurately describe water quality conditions nationwide. Only 19 percent of the nation's rivers and streams were assessed for the 1996 *Inventory* (the latest report available at the time of our review),

[2] *Major Management Challenges and Program Risks: Environmental Protection Agency* (GAO/OCG-99-17, Jan. 1999).

as were 6 percent of ocean and other shoreline waters. Pollution of the latter has resulted in an increasing number of beach advisories and closures in recent years.[3]

- Of 1,456 toxic chemicals we recently reviewed, data on human exposure were being collected for only about 6 percent. For example, of the 476 chemicals that EPA identified as most in need of testing under the Toxic Substances Control Act, only 10, or 2 percent, were being measured for human exposure. (See table 1.)

Table 1: Extent to Which Human Exposure Data Are Collected for Potentially Harmful Chemicals Through Surveys of EPA and the Department of Health and Human Services

Priority chemicals		Chemicals measured or being measured	
Description of list	Number In list	Number	Percentage
Chemicals found most often at the national Superfund sites and of most potential threat to human health	275	62	23
EPA's list of toxics of concern in air	168	27	16
Chemicals harmful because of their persistence in the environment, tendency to bioaccumulate in plant or animal tissues, and toxicity	368	52	14
Pesticides of potential concern as listed by EPA's Office of Pesticide Programs and the U.S. Department of Agriculture's Pesticide Data Program	243	32	13
Chemicals that are reported in the Toxic Release Inventory; are considered toxic; and are used, manufactured, treated, transported, or released into the environment	579	50	9
Chemicals most in need of testing under the Toxic Substances Control Act (Master Testing List)	476	10	2

Note: Our analysis was based on human exposure data collected through the Department of Health and Human Services' National Health and Nutrition Examination Survey or EPA's National Human Exposure Assessment Pilot Surveys through 2000.

EPA has recognized that it has numerous and significant gaps in its data and has initiated several efforts to fill at least some of the gaps. For example, under its Environmental Monitoring and Assessment Program, EPA is working with other federal agencies to develop information that the public, scientists, and the Congress can use to evaluate the overall health of the nation's ecological resources. EPA also recently launched its High

[3] *Water Quality: Key EPA and State Decisions Limited by Inconsistent and Incomplete Data* (GAO/RCED-00-54, Mar. 15, 2000).

Production Volume Challenge Program, which asked chemical companies to voluntarily generate data on the effects of the chemicals they manufacture or import. As of December 1999, over 400 participants had agreed to make public, before the end of 2005, basic hazard data on over 2,000 of 2,800 high-production-volume chemicals, which are chemicals manufactured or imported into the United States in amounts equal to or greater than one million pounds per year. Furthermore, EPA's new information office will be responsible for encouraging the agency's program offices to reach out to other federal agencies as well as to universities, research institutes, and other sources of environmental information for data that EPA does not collect but that may exist elsewhere. To date, however, such efforts have been hampered by technological limitations imposed by the myriad of incompatible information systems in use across the government.

Moreover, much of the information needed, such as environmental monitoring data, will be expensive to obtain. Thus, it will be important for EPA to work with the states and industry to reduce the reporting burden and to encourage efforts to use data that may already have been collected by other federal agencies or other entities. Likewise, as we recommended to EPA in our September 1999 report on its information management activities, it will be essential for the agency to develop a strategy that prioritizes its requirements for additional data and identifies milestones and needed resources. EPA can then use this information to support its budget requests.

Incompatible Data Systems Limit the Usefulness of Environmental Data

Over the years, EPA has developed and maintained "stovepipe" data systems that are not capable of sharing the enormous amounts of data gathered. EPA now recognizes that common data definitions and formats, known as data standards, are essential to its efforts to integrate data from various databases, including those of its state partners. EPA also considers data standards as key to reducing the reporting burden on industry and the states because such standards would permit integrated, and thus more efficient, reporting of information to the agency. In recent years, EPA has undertaken several efforts to develop standards for some of the data items in its information systems.

According to the Office of Environmental Information, EPA recently approved six data standards and expects that all of these standards will be implemented in the relevant data systems by fiscal year 2003.

EPA recognizes that its current data improvement efforts are only first steps toward its goal of full data integration. For example, EPA has focused primarily on the compatibility of its data with those of state environmental agencies, rather than of other federal agencies and nongovernmental sources. In a May 2000 report, we stated that improved collaboration among federal agencies in meeting the needs for human exposure data is essential because individual agencies have different capacities and skills and separate attempts have fallen short of supporting the large efforts that are needed.[4] EPA's Science Advisory Board[5] has also recommended that EPA do more to link the agency's databases with external databases. The Board noted that "answering many health-related questions frequently requires linking environmental data with census, cancer or birth registry data, or other data systems (such as water distribution maps) to determine whether there is a relationship between the environmental measures and health."[6] EPA officials acknowledge the importance of linking EPA's databases with those of other agencies at all levels of government. However, they told us that their actions to do so have been limited by resource constraints and by the fact that EPA's statutes do not give the agency the authority to require that other agencies collect or report data using formats compatible with those used by EPA.

Concerns Persist About the Accuracy of EPA's Data

In various reviews, we and others have identified persistent concerns about the accuracy of the data in many of EPA's information systems. EPA acknowledges that data errors exist but believes that, in the aggregate, its data are of sufficient quality to support its programmatic and regulatory decisions. However, EPA has not assessed the accuracy of

[4] *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans* (GAO/HEHS-00-80, May 2, 2000).
[5] The EPA Science Advisory Board was created by the Congress to provide advice to EPA from scientists outside the agency.
[6] Science Advisory Board, *Review of the Agency-Wide Quality Management Program*, EPA-SAB-EEC-LTR-98-003 (Washington, D.C.: EPA, July 24, 1998).

its information systems agencywide, and preventing errors and correcting them once they have been identified has proved daunting for the agency. For example, in January 1998, an EPA advisory council on information management issues described the difficulty of correcting errors in EPA's databases: "Once an error is stored in one or more of the agency's systems, making corrections to all those systems is an exercise in frustration and futility. There is no simple way to ensure corrections are made to all possible systems."

To address such problems, EPA revised its agencywide quality system in 1998 to expand and clarify requirements for how environmental data are collected and managed. Although the Science Advisory Board recently commended the agency for its development of this system, the Board also found that its implementation has been uneven within the agency. Moreover, the Board reported that more than 75 percent of the states authorized to implement EPA's environmental programs lack approved quality management plans for all or some of these programs and thus are likely to be generating data of unknown quality. We recently reported that EPA's *National Water Quality Inventory*, which EPA uses as a basis for measuring progress under the Clean Water Act, does not accurately describe water conditions nationwide. While EPA prepares the *Inventory* on the basis of data submitted by the states, the states do not use a statistical sampling design that provides a comprehensive picture of water quality. The Science Advisory Board has pointed out that EPA programs that rely on data of unknown quality are exposing themselves, the reliability of their decisions, and their credibility to criticisms.

Correcting errors in the agency's data is an important responsibility for the new information office. This office recently developed an Internet-based system to identify, track, and resolve errors found in national environmental databases. The system currently allows individuals to notify EPA of suspected errors in some of the agency's major databases, and EPA intends to implement the data correction system in additional databases during the next two years.

Efforts to Develop Outcome-Oriented Performance Measures Are Constrained by Data Limitations

Well-chosen environmental measures inform policymakers, the public, and EPA managers about the condition of the environment and provide for assessing the potential danger posed by pollution and contamination. They also serve to monitor the extent to which EPA's programs contribute to environmental improvement and can be used in future priority-setting, planning, and budgeting decisions. EPA has been aware of the need for environmental measures since the mid-1970s. Nevertheless, the agency made little progress in developing such measures until the Results Act mandated their use by requiring federal agencies to report annually on their progress in meeting performance goals. Under the Results Act, EPA has begun to set goals and measures that are intended to help the agency, as well as the Congress and the public, assess the environmental results of the agency's activities. While EPA has made progress in adopting more measures that reflect the environmental or health outcomes of programs, the overwhelming number of EPA's measures reflect outputs, such as the number of inspections performed or regulations issued, and additional progress is needed.

EPA considers getting the data needed to measure results its biggest challenge in developing outcome-oriented performance measures. To date, EPA and the states have made limited progress in developing such measures, as these examples indicate:

- Of the 364 measures of performance that EPA has developed for use during fiscal year 2000, only 69 (19 percent) are environmental outcomes; the other measures reflect program activities, such as the number of actions taken to enforce environmental laws. (See table 2.)

- Given inherent uncertainties about the results of research and development activities, the problem of developing outcome-oriented measures is particularly difficult for EPA's science activities. Of 36 measures related to EPA's strategic goal of "sound science," only 2 reflect outcomes.

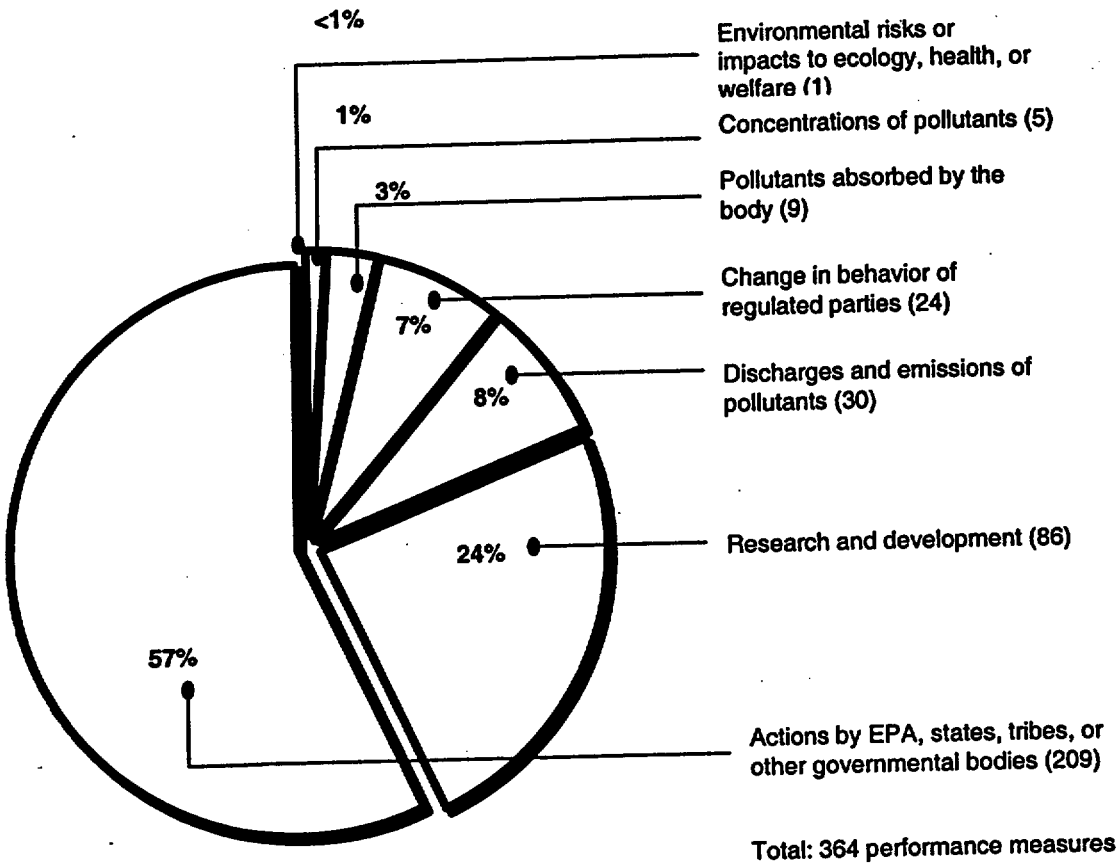
Table 2: EPA's Analysis of the Number and Type of Annual Performance Measures for Its Strategic Goals for Fiscal Year 2000

	Number of annual performance measures		
EPA's strategic goal	**Output**	**Outcome**	**Total**
Goal 1: Clean Air	19	14	33
Goal 2: Clean and safe water	65	17	82
Goal 3: Safe food	16	1	17
Goal 4: Preventing pollution and reducing risk in communities, homes, workplaces, and ecosystems	28	14	42
Goal 5: Better waste management, restoration of contaminated sites, and emergency response	34	8	42
Goal 6: Reduction of global and cross-border environmental risks	27	7	34
Goal 7: Expansion of Americans' right to know about their environment	28	3	31
Goal 8: Sound science, improved understanding of environmental risk and greater innovation to address environmental problems	34	2	36
Goal 9: A credible deterrent to pollution and greater compliance with the law	15	3	18
Goal 10: Effective management	29	0	29
Total	**295**	**69**	**364**

Source: GAO's analysis of EPA data.

In addition to establishing output-and outcome-oriented performance measures, EPA has adopted a framework for categorizing its performance measures according to the type of outputs or outcomes to be achieved. As shown in figure 1, most of the performance measures are outputs involving either research and development efforts or actions by EPA, states, tribes, or other governmental bodies, such as establishing standards for hazardous levels of lead in paint, dust, and soil. The other categories represent outcomes, including measures that focus on risks to ecology, health, or welfare; pollutants absorbed by the body; and concentrations of pollutants in the environment. Over time, EPA plans to increase the number of such measures, as it is able to obtain better data linking its program activities with changes in environmental and health conditions.

Figure 1: Number and Percentage of Performance Measures for Each Type of Activity



Even with better data, it will be a major challenge for EPA to link its environmental programs and activities to outcomes. Environmental conditions may change because of a number of factors, including variables such as the weather or economic activity, many of which are beyond the control of EPA and its state partners. Likewise, it may be difficult to show the relationship between EPA's annual program activities and some outcomes that may not be apparent until many years later. For example, current EPA activities to reduce the amount of polluting nutrients from fertilizers in the ground may not result in improved water quality for a decade or more.

EPA program officials recognize that they need additional measures that show the outcomes of programs, and they have recently taken actions that should strengthen the agency's ability to develop them. For example, EPA is developing processes and long-

term strategies to improve the quality of performance measures and link the activities of program offices with environmental results. However, substantial resources are required to identify and test the potential measures. Once the measures are established, gathering and analyzing the data can be resource-intensive, and it can take years to show environmental improvement.

Observations

Our prior work has identified numerous problems in the quality of EPA's data and the way that the agency manages its data systems. These problems cut across the various programs regulated by EPA and have limited the agency's ability to assess risks and measure environmental results. To its credit, EPA has initiated actions to improve its information management activities. While EPA has made progress, its initiatives do not provide a long-term strategy to ensure the completeness, compatibility, and accuracy of its data. Furthermore, the initiatives have encountered obstacles that highlight the difficulties facing EPA as it attempts to improve its information management activities.

As we recommended in our September 1999 report, to substantially improve the quality of the data used to set risk-based priorities and report on progress toward improving environmental conditions and human health, EPA needs to develop a strategy that reflects a long-term commitment to resolving data problems. Such a strategy should include establishing milestones and identifying the resources necessary to fill major data gaps, identify and develop all needed data standards and implement them in key databases, and coordinate the agency's data standardization efforts with those of the states, federal agencies, and other organizations. This effort would provide both senior agency managers and the Congress with what is now missing–the information they need to make the best decisions possible on the costs, benefits, and trade-offs involved in providing scarce resources to meet critical data requirements. Although EPA concurred with our recommendation, the agency has made little progress toward developing and implementing a comprehensive strategy. For example, EPA recently informed us that it has not yet completed the first stage of a multi-phase effort to develop an information

plan for the agency. EPA plans to complete the first stage by December 2000, which will identify broad options for information management over the next several years.

Mr. Chairman, I would be happy to respond to any questions that you or other Members of the Committee may have.

Contact and Acknowledgments

For further information, please contact Peter F. Guerrero at (202) 512-6111. Individuals making key contributions to this testimony included Ed Kratzer and Cecilia Lee.

(360000)

TESTIMONY OF
Dr. Al McGartland
ASSISTANT ADMINISTRATOR
OFFICE OF POLICY, ECONOMICS, AND INNOVATION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

October 3, 2000

Introduction

Good morning, Mr. Chairman and members of the committee. I appreciate this opportunity to present EPA's views on the value of comparative risk assessment, and the extent to which we use this tool to attain the Agency's, and the nation's, public health and environmental goals.

EPA's interest in comparative risk dates from 1987, when we produced a groundbreaking report, Unfinished Business, that assessed and ranked 31different environmental programs that we had the legal responsibility for managing at the time. That report marked the first time in the Agency's history that we attempted a comprehensive, cross-media, risk-driven comparison and ranking of environmental risk. Then in1990 EPA's Science Advisory Board (SAB) produced Reducing Risk, a report that examined strategies for reducing major environmental risks, and recommended improved methodologies for assessing and comparing risks and risk reduction options in the future.

Since then, comparative risk assessments have become more widely accepted as an input to the priority-setting process. They have been conducted by a number of state and local governments, and I am pleased to see that representatives from cities and states have been invited to present their perspectives to this committee. For its part, EPA has made use of this tool in our Agency-wide strategic planning processes, in our partnerships with state, local, and tribal governments, and in many specific programs, both regulatory and non-regulatory. There is no doubt that comparative risk assessment today is helping EPA, other levels of government, and

the business community prioritize risks, target our respective risk reduction efforts, and thus reap more environmental benefits for every dollar spent.

At the same time, I want to emphasize that the usefulness of comparative risk assessment is limited. It is not being used by EPA today, and most likely never will be used, as a bright-line, mechanistic way of ordering the Agency's priorities for either strategy, budgets, or actions. A number of other factors also have to be considered, and all these relevant factors, including but not limited to comparative risk assessment, have to be considered when the Agency sets its priorities.

For example, many federal environmental laws set timetables and deadlines for EPA to take specified actions or accomplish specified goals. EPA has an obligation to carry out the laws, which reflect the will of an elected Congress and properly reflect considerations beyond comparative risk.

Another difficult problem arises in any attempt to include human health and ecological risks in the same ranking. How do you prioritize the risks associated with pollutant exposures that may cause cancer in humans, as compared to degraded water quality in the Chesapeake Bay that may deplete oyster beds? The Science Advisory Board recognized this problem when they wrote Reducing Risk, and they did not attempt to include human health and ecological risks in the same ranking.

Community concerns also have to be considered when setting environmental priorities. If a community believes that action must be taken to solve what it considers to be a pressing environmental problem, then EPA has an obligation to respond, even if the problem does not rank high on a list of comparative risks.

Another consideration in setting priorities is the different roles that EPA has, depending on the environmental problem being addressed or program being implemented. For example, budget needs may differ depending on whether a regulatory program is implemented at the Federal level or is primarily implemented by the States. As another example, a program aimed at reducing risk through public education may have different budget needs compared to a program that provides technical assistance.

This is not a complete discussion of all the factors that enter into EPA's priority-setting processes. Other hard-to-quantify considerations, like intergenerational equity and

environmental justice, also have to be weighed. For our purposes here today, I simply want to emphasize that comparative risk assessment provides a useful mechanism for helping us think about environmental priorities, but by itself it cannot provide any complete answers.

Comparative Risk Assessment in Strategic Planning and Budgeting

An important area in which comparative risk information comes into play is in the Agency's planning, priority-setting, and budgeting processes. As required by the Government Performance and Results Act (GPRA), EPA developed a five-year Strategic Plan in 1997, Annual Performance Plans for Fiscal Years 1999 through 2001, and an Annual Performance Report for Fiscal Year 1999. I want to emphasize that EPA is one of the few, if not the only, agency to restructure its budget to match the goal and objective structure of its Strategic Plan. This allows Agency decision makers, Congress, and the public to identify the resources associated with each of the Agency's goals and objectives, and to compare the prospective benefits of these long-term outcomes when making judgments about the Agency's proposed priorities and funding.

In setting its strategic goals and objectives and developing specific budget proposals to achieve them, the Agency uses the best available scientific and economic analysis. The performance targets identified in the Strategic Plan, such as the objective of having 95 percent of the population served by community water systems receive water that meets national health standards by 2005, reflect the Agency's decisions on the relative priority the Agency will place on different environmental problems and programs. In communicating our GPRA goals and objectives, annual performance targets, and actual performance, the Agency has attempted to characterize for Congress and the public the nature of the different health and environmental risks that our programs are addressing.

With regard to annual budgets, comparative risk considerations have been explicitly factored into various internal Agency-wide budget investment and reduction exercises. As an example, our Office of Research and Development uses information on the relative risks associated with environmental problems in its annual cross-goal ranking used in determining research priorities. Furthermore, it would be fair to state that risk information, when available

and relevant, is implicitly included in most discretionary decisions made by Agency program managers, both in setting priorities within major programs and allocating resources across programs.

In recent budget formulation exercises, internal budget guidance specifically required that Agency investment proposals characterize human and ecological risk reductions. While risk information plays a role, GPRA priority-setting and resource allocation decisions are generally made on the basis of multiple criteria. Costs and benefits, equity, institutional and legal feasibility, statutory mandates and other Congressional direction, public values, risk tradeoffs, and government-wide priorities represent some of the factors that enter into budget discussions and decisions.

Many challenges face EPA, Congress, and the interested public in better using comparative risk information in environmental priority-setting and budgeting. Availability of cost and risk data is improving, but varies greatly across and within EPA programs. Methodologies for assessing risk and benefits are at varying stages of development. Finally, the diverse endpoints being addressed by environmental programs – such as cancer versus non-cancer health effects, human health versus ecological protection, reduction of chronic exposures versus prevention of low-probability but high-risk chemical spills and accidents – make direct comparisons of risks and benefits difficult. As we work to improve comparative risk data and tools for use in priority-setting and budgeting, EPA also will continue to improve the links between its budget and its GPRA goals and objectives in order to facilitate the ongoing dialogue with Congress and stakeholders about our priorities.

Comparative Risk Assessment in EPA/State/Tribal Partnerships

A strong partnership between EPA and state and tribal governments has always been one of the most important and effective aspects of U.S. environmental policy. As comparative risk assessments have become more sophisticated and useful over time, they have been incorporated into the EPA/state/tribal partnership in several fundamental ways.

For example, from the time that EPA and the SAB first began to assess and prioritize relative risks, the Agency has encouraged and supported similar processes by states,

communities, and Native American tribes. Between 1990 and 1999 EPA provided financial and technical assistance to states, localities, tribes, and watershed organizations to support comparative risk projects of their choosing. EPA provided expert advice on the process, developed resource materials, supported communications among project directors, and paid for project start-up costs. EPA required all parties involved to meet general project criteria, but the participants decided how they would apply the criteria, and they could use comparative risk assessments to meet their unique purposes. During the decade of the 1990s EPA provided about one million dollars a year to support these comparative risk assessment activities.

In most cases, the projects resulted in a much clearer understanding of local environmental challenges, and sometimes they inspired new environmental initiatives. The results of EPA-supported comparative risk assessments also led to the funding of several environmental risk-management initiatives that were already under consideration by state and local governments at the time. At EPA we are very proud of these accomplishments, and I think the state and local representatives you will hear from today will agree.

As these critical partnerships have evolved over the past decade, comparative risk assessments have played an increasingly important role. Because of our shared commitment to improving public health and environmental quality, in 1995 EPA and the states jointly entered into a new National Environmental Performance Partnership System, or NEPPS. This stronger, more collaborative partnership emphasizes that EPA and the states are mutually dependent on each other in our respective efforts to reach our shared environmental goals. Through NEPPS EPA and the states jointly set priorities for action, and we work together to clarify our roles and responsibilities.

The centerpiece of NEPPS is Performance Partnership Agreements (PPAs) between EPA and individual states. The PPA is the mechanism that allows each state, in conjunction with EPA, to set priorities, solve problems, and make the most effective use of our collective resources. Comparative risk assessment is one of the management tools used by states to determine which programs they want to target for improvement or strengthening as part of their PPAs. These agreements thus give states greater freedom to focus their resources on their highest environmental priorities, and comparative risk assessment is one way those priorities can

be established. However, like EPA, states must comply with federal environmental requirements regardless of their considerations of comparative risk.

Under NEPPS the states also have more flexibility in administering EPA grant funds. With our new Performance Partnership Grants (PPGs), states now can consolidate a variety of individual grants into one. That kind of simplification and consolidation can be driven by comparative risk assessment. For example, if a comparative risk analysis showed that a particular source of drinking water poses relatively high risks, a state could combine funding for drinking water and solid waste programs and target it at the program in need of supplemental funding. Here again, greater flexibility and comparative risk assessment come together to strengthen a traditional partnership.

Let me give you an example of how this works in practice. Delaware's Department of Natural Resources and Environmental Control (DNREC) was the first to utilize a so-called "logic model," which uses comparative risk assessment to help set priorities. Different categories of environmental information were organized to reflect environmental conditions, stressors, and pollution sources. The DNREC then developed a self-assessment that addressed the department's activities and capabilities in relation to this information. The subsequent Performance Partnership Agreement contained joint EPA/state priorities and initiatives that reflected the environmental and program needs identified by the self-assessment. In short, comparative risk assessment was one of the primary forces shaping Delaware's PPA.

Comparative Risk Assessment in EPA's Regulatory Programs

To some extent, comparative risk assessment is used in many of EPA's regulatory programs. I would like to describe three in more detail, because that will give you a sense of how comparative risk assessment has been integrated into the Agency's more traditional activities.

For example, EPA is using comparative risk assessments to help set priorities in its program to control toxic air pollutants. Under Section 112(e) of the Clean Air Act, EPA is required to develop a Source Category Schedule (SCS) for promulgating federal emissions standards for 174 categories of sources of toxic air emissions. In determining scheduling

priorities, the law requires EPA to consider three criteria: 1) the adverse effects of the different hazardous air pollutants; 2) the quantity and location of emissions of each pollutant; and 3) the relative efficiency of different groupings of source categories or subcategories. To help develop this schedule, EPA established a system that combines emissions estimates, health effects data, and limited population information in order to generate an approximate idea of the comparative risks of the various source categories. This system was used in conjunction with other considerations, such as work load efficiency and the time needed to develop different standards, to establish the Source Category Schedule.

EPA also has used a form of comparative risk assessment in developing our Integrated Urban Air Toxics Strategy under Section 112(k) of the Clean Air Act. The law requires EPA to identify at least 30 pollutants that pose the greatest threat to public health in the largest number of urban areas. To address this requirement, EPA developed a methodology composed of three separate ranking analyses that each relied on information relevant to risk assessment, such as toxicity, emissions, ambient monitoring, and air quality modeling. We integrated the results of the three analyses to obtain the list of 33 urban hazardous air pollutants that will guide our actions under the strategy to protect public health in urban areas.

As in the air program, many of the priorities in our national water program are guided by the principle of addressing the highest risks first. For example, the Safe Drinking Water Act of 1996 provides clear direction to the Agency to focus on contaminants of greatest risk. Consequently, over the last few years EPA has issued a number of regulatory actions aimed at controlling high risk contaminants such as disinfectants and disinfectant byproducts. We have proposed criteria for determining when disinfection is required for underground drinking water sources, and proposed added protections for smaller drinking water systems. In addition, EPA now is gathering data on the occurrence and health effects of other contaminants. These data will help the Agency make sound decisions in the future about which drinking water contaminants are high-risk and warrant regulation, while also helping set priorities for drinking water research, monitoring, and guidance development, including health advisories.

Comparative Risk Assessment in Voluntary Programs

Over the past decade, EPA has augmented its traditional regulatory programs with a variety of voluntary partnerships that can be targeted at either regulated or unregulated pollutants. These programs have proven to be remarkably successful, because many businesses have begun to realize that there is a strong linkage between economic and environmental performance. In most cases, as businesses become efficient and reduce or eliminate waste streams, they become more profitable. For these and other reasons, many businesses today are demonstrating environmental stewardship and improving environmental performance in ways that go beyond what government regulations require.

The growth of voluntary partnership programs in the 1990s occurred at the same time that the techniques of comparative risk assessment were becoming more sophisticated and more widely applied. As a consequence, many voluntary risk-reduction efforts – whether conducted by EPA, private businesses, or jointly – include a comparative risk component.

For example, EPA today is trying to find more effective, integrated, and comprehensive solutions to the complex environmental problems caused by specific industry sectors. At the same time, we want to reduce the regulatory burden on those same industry sectors. To meet those goals, we have initiated a sectors program that takes a more strategic approach to environmental protection. We tailor a set of actions – some required by regulation and some voluntary – to address the unique environmental issues, needs, and opportunities presented by different industries. The strategic design and subsequent implementation of these sector programs involve comparative risk assessments as part of the priority-setting process.

When EPA works in partnership with a particular industry sector, we jointly design a targeted set of effective actions that achieve cleaner, cheaper, smarter environmental results. This priority-setting process involves a comparative analysis of the industry's most significant environmental impacts and the likely effects of possible actions to address those problems. This analysis may not take the form of an in-depth, scientific study, but it does involve thorough consideration of existing data sources, current environmental priorities, and expert stakeholder perspectives. The end result is a tailored, sector-specific action plan that, by definition, reflects the sector's comparative risk profile.

For example, EPA's metal finishing sector stewardship program started with a comparative assessment of that industry's multiple environmental impacts. The stakeholders involved, including EPA and industry representatives, reached the common conclusion that the greatest environmental stewardship opportunities in this industry sector were water and energy conservation, reduced metals loadings, and reduced sludge generation. EPA then was able to work with the industry and other stakeholders to develop a first-of-its-kind stewardship program that set voluntary performance targets for those key environmental parameters.

Many of the innovative ideas developed and tested at EPA over the past decade have come together in a new program that the EPA Administrator announced on June 26. Called Performance Track, this program encourages businesses to do more than the law requires to protect human health and the environment. For those businesses that show exemplary environmental stewardship, EPA is going to reward them with a package of benefits that will include lower costs, streamlined administrative operations, and public recognition.

One of the most important actions that we're requiring of Performance Track participants is that they put in place a vigorous environmental management system. These management systems will have to include several specific components, including a facility-wide commitment to pollution prevention, environmental training for all employees, and an emergency preparedness program. We'll also expect participating companies to set specific performance targets and then hit those targets successfully.

And that's where comparative risk assessment will prove valuable. In their environmental management systems companies will have to characterize their environmental emissions, assess the health and ecological risks they entail, and then set risk-based priorities for improving their performance over time. In this sense comparative risk assessments lie at the heart of environmental management systems, and thus they will play an integral role in EPA's Performance Track program.

Conclusion

As these examples demonstrate, over the past decade comparative risk assessment has emerged as an important priority-setting tool at EPA. In most cases, more complete data bases

and more sophisticated methodologies would lead to more robust results, and so at EPA we're continually working to improve our capabilities to conduct comparative risk assessments.

At the same time, I want to emphasize that these assessments will never, by themselves, provide an unambiguous, bright-line way of ranking the Agency's management priorities. No matter how much data we collect or how much further the methodologies evolve, the reality of risk reduction will always demand a large measure of judgment related to ethics, equity, and economics. Widespread public concerns, for example, may raise the profile of a particular risk and necessitate early and forceful Agency action, even if the risk is not very high when compared to other Agency programs. We sometimes may act to control relatively less serious risks if available risk management options are cheaper and more effective. And sometimes we have to apply simple human judgment when deciding on the relative importance of controlling risks to humans versus risks to ecosystems, or risks to current generations versus risks to the future.

In short, when setting priorities for budgets and actions, EPA has to consider a range of factors, one of which is comparative risk assessment. I believe we are using such assessments well today, and we will use them even more effectively in the future. But even as we improve their use and effectiveness, we should not lose sight of their inherent limitations

Thank you very much.

Statement of
Dr. Morton Lippmann, Professor
Department of Environmental Medicine
New York University School of Medicine and
Interim Chair
U.S. Environmental Protection Agency Science Advisory Board
Before the Senate Committee on Environment and Public Works
October 3, 2000

Mr. Chairman and members of the Committee, I appreciate the opportunity to testify on the scientific basis for, current limitations of, and opportunities for future improvements in quantitative risk assessment as a tool for environmental risk management. I'd like to share with you some what I've gleaned from my service on EPA's Science Advisory Board and as a member of the National Research Council's Committee on Research and Peer Review in EPA

DEFINING AND CHARACTERIZING ENVIRONMENTAL RISKS AND BENEFITS

In theory, it should be possible to engage in rational comparative risk analyses as a means of selecting cost-effective means for the protection of the public's health and our common natural environment. At present, however, the available knowledge base is generally too limited to adequately guide risk-based actions by legislators and/or by governmental agencies to protect and/or improve the environment. What we need is a strategic plan to extend the range and depth of knowledge for risk assessment, taking advantage of the scientific and technical capabilities that are advancing so remarkably in the current era. We also need an effective means of organizing that knowledge, effectively communicating it to appropriate stakeholders, and we need processes for the identification of socially acceptable means of risk-based intervention to prevent, ameliorate, and/or to reverse environmental degradation by more efficient and effective means.

In other words, we must be careful to distinguish between what capabilities we can hope for and expect to be available in the not-too-distant future, and what current tools can provide for us now. We must also recognize that advancement and refinement of our tools for quantitatively determining risks and benefits will not just improve on their own. New research resources will need to be invested to further develop and hone these tools. With appropriate investments in risk assessment research, we can look forward to ever increasing capabilities for more quantitative risk assessments, more definitive comparative risk assessments, more definitive benefit-cost analyses, and more efficient and effective risk management options.

In recent years, as a result of my Chairmanship of various EPA Science Advisory Board (SAB) Committees (Clean Air Scientific Advisory Committee, Human Exposure Committee, Secondary Data Use Committee, Environmental Tobacco Smoke (ETS) Risk Assessment

Review Committee, Dioxin Risk Assessment Review Committee), and as my membership on the Steering Committees for the SAB Reports on Future Risk, Reducing Risk, and Beyond the Horizon, my continuing participation in the SAB Advisory Council on Clean Air Act Compliance Analysis (Council) reviews of the Benefits and Costs of the Clean Air Act, and my contributions to the recently completed National Research Council's Report on "Strengthening Science and Peer Review at the EPA", I have become quite familiar with the capabilities and limitations of the predictive models and of environmental and epidemiological data bases available at EPA for risk and benefits assessments. In this regard, I have come to recognize that EPA is heavily dependent on its predictive models for exposure and risk estimation. Unfortunately, many of these models have not yet been fully validated. The adequacy of EPA's models for quantitative risk assessment is discussed in greater detail in the testimony of Dr. Philip Hopke in Panel 3.

This hearing is focused on the capabilities and limitations of current knowledge and technical means of comparative risk assessment for guiding new legislative mandates, societal choices, and individual decisions based on risk avoidance. In my remarks, I will focus on health risks associated with exposures to airborne chemicals and mixtures thereof in our communities.

In order to determine the extent of any health risk existing among the members of the population of concern resulting from the inhalation of airborne chemicals we need to know: 1) the distribution of the concentration of the agent in the air and, for airborne particulate matter (PM), the distribution of particle sizes; and 2) the unit risk factor, i.e., the number of cases and/or the extent of the adverse effects associated with a unit of exposure. For more sophisticated analyses, we may also need to know more about the population of concern, such as the distribution of ages, pre-existing diseases, pre-disposing factors for illness, such as cigarette smoking, dietary deficiencies or excesses, etc.

When basic information on ambient levels and unit risks is available, it is relatively straightforward to compute, tabulate, and compare the risks associated with the different chemicals in our community air. However, based on the experience gained in the Council Review of the Benefits and Costs of the Clean Air Act, such direct comparisons can, in practice, only be made with any quantitative reality for a handful of chemicals, i.e., the so-called criteria pollutants, whose ambient air levels are routinely monitored and for which directly measured human exposure-response relationships have been developed. For hundreds of other airborne chemicals, known collectively as hazardous air pollutants (HAPs), a.k.a. air toxics, there are neither extensive ambient air concentration data nor unit risk factors that do not intentionally err on the side of safety. This disparity has resulted from the different control philosophies built into the Clean Air Act (CAA) and maintained by the EPA as a part of its regulatory strategy.

The rationale for the distinction is that criteria pollutants come from numerous and widespread sources, have relatively uniform concentrations across an airshed, require statewide and/or regional air inventories and control strategies for source categories (motor vehicles, space heating, power production, etc.) focused on the attainment of air quality standards (concentration limits) whose attainment provides protection to the public health with an adequate margin of safety. There is also a long history of routine, mostly daily measurements of criteria pollutant concentrations throughout the country.

By contrast, HAPs sources are far fewer in number and are considered to be definable point sources at fixed locations. Downwind concentrations are highly variable, and generally drop rapidly with distance from the source due to dilution into cleaner, background air. The national emission standards for hazardous air pollutants (NESHAPs) are based on technologically-based source controls and are intended to limit facility fenceline air concentrations to those that would not cause an adverse health effect to the (most exposed) individual living at the fenceline. Also, until quite recently, there has been no program for routine measurements of air toxics in our communities.

Most of the unit risk factors for air toxics are based on cancer as the health effect of primary concern. In these studies, and in studies to assess noncancer effects the data are most often derived from controlled exposures in laboratory animals at maximally tolerated levels of exposure. The translation of the results of these studies to unit risk factors relevant to humans exposed at much, much lower levels in the environment is inherently uncertain, and is approached conservatively, following the model pioneered for food and drug safety beginning in the 1930s by the Food and Drug Administration (FDA). The resulting unit risk factors are generally based on an assumption of no threshold and a linear extrapolation to zero risk at zero dose. They are generally described in terms of being 95% upperbound confidence limits, but this descriptor is undoubtedly conservative in itself.

When these conservative unit risk factors are used for the prediction of the consequences of human exposures, they are multiplied by estimates of predicted ambient air concentrations which are, themselves, in the almost universal absence of air concentration measurements, almost certainly upper bound estimates from pollutant dispersion models that apply to the most highly exposed individuals in the community.

The resulting estimates of health risk are therefore highly conservative upper bound levels. Thus, they are inherently incompatible with population impacts estimated for the more widely dispersed criteria pollutants. The margins of safety for criteria pollutants are generally less than a factor of two, rather than the multiple orders of magnitude of safety factors built into

the risk assessments for air toxics.

The same considerations discussed above, i.e. the limitation of available knowledge for determining realistic unit risk levels has also made it virtually impossible for EPA to meet its Congressional mandate to determine residual risks after the imposition of technology-based controls of air toxics, as discussed in greater detail in the testimony provided to this Hearing by Dr. Philip Hopke in Panel # 3.

The highly conservative nature of unit risk factors for air toxics was well illustrated by a calculation made during work done for EPA during the preparation of the Congressionally mandated report on the Benefits and Costs of the Clean Air Act: 1970-1990. It was determined that the imposition of the vinyl chloride NESHAP had prevented 6,000 cases of cancer. Vinyl chloride is a known human carcinogen that produced a very rare tumor (angiosarcoma of the liver) in highly exposed vinyl chloride production workers. The handful of cancers observed among these workers was not large in relation to overall cancer incidence, but this particular tumor was such a rare one that even the first few cases that were observed among a group of vinyl chloride production workers were sufficient to establish a causal relation. Since the calculated cancer incidence reduction was considerably larger than the historic incidence level for this cancer, it was obvious that the benefit claimed for the imposition of the NESHAP was grossly exaggerated.

The lack of any alternative quantitative approach to the quantitative estimation of health effects due to exposure to air toxics has left EPA with no viable option for the realistic estimation of population impacts. With prodding from the SAB Council, the Agency has recognized the need to develop one. That effort is now underway, through EPA and SAB sponsorship of a first Workshop (June 22 and 23, 2000) in a series designed to address the issue directly. Extension of this initiative would lead to the development of a capability to produce more unbiased predictions of the health consequences of HAPs exposures for benefits assessments.

In the meantime, EPA needs to undertake a public education program about the essential nature of its widely distributed and commonly used unit risk factors. This is especially urgent in view of its recent initiative to support a nationwide network of routine air quality monitoring stations for a large number of representative air toxics. Pilot studies have already demonstrated the multiplication of measured levels times the current unit risk factors suggest that urban dwellers are at lifetime risks of excess cancer greater than one in a thousand. Exaggeration of risks pertaining to the general public could produce a considerable problem for EPA in its communication to the public, and could lead to a loss in its credibility.

Comparative risk analysis, as currently practiced, has other inherent limitations as well. Even when we can reasonably and reliably estimate the exposure-related numbers of cases of premature mortality, hospital admissions, other uses of medical, clinical and pharmaceutical drug resources, lost time from work or school, reduced physiological and functional capacities, we face daunting societal equity and valuation challenges in intercomparing numbers of incident cases of quite variable clinical severity and psychological impacts. For carcinogenic agents, it has become customary to expect regulations to be effective in limiting the risks of lifetime exposures to no more than one-in-ten thousand and often to less than one-in-a-million. For less dreaded diseases that also reduce lifespan, such as chronic obstructive pulmonary disease and heart attack, which also are exacerabated by air pollutant exposures, a much higher risk level has been considered acceptable by regulators and the public. By contrast, economists do not make such a drastic distinction. EPA's recent White Paper on the economic valuation of cancer mortality concluded that the economic literature did not provide a basis for a greater benefit for a prevented cancer death than for other causes of premature deaths.

The National Research Council (NRC) committee that issued its report on "Strengthening Science and Peer Review at EPA" was well aware of the current limitations of comparative risk assessment when it concluded that:

> "Scientific knowledge and technical information are essential for determining which environmental problems pose important risks to human health, ecosystems, the quality of life, and the economy. We need scientific information to avoid wastefully targeting inconsequential risks while ignoring greater risks. We need such information to reduce uncertainties in environmental decision making and to help develop cost-effective strategies to reduce risk. We need science to help identify emerging and future environmental problems and to prepare for the inevitable surprises."

The quotation above provides a good part of the background that led to the key recommendations of the NRC Report regarding the management and use of science in regulatory programs, and the need for and Agency management of its own research program to fill key gaps in our current abilities to quantify risks. Focus on this need should be a priority for the recommended position of Deputy Administrator for Science in EPA. This individual should have the background and judgment essential to ensure that current risk-related knowledge is appropriately used to develop, describe, and guide scientific input into regulations, and to ensure communication of the knowledge gained by the regulatory programs in terms of further research needs for risk assessment and risk management. The Deputy Administrator for Science could also provide oversight for EPA's new Office of Information in regard to facilitating more data

entry into and wider access to and usage of EPA's environmental monitoring data sets that are now seldom used for secondary data analysis and/or model validation.

The NRC Report also concluded that research on risk assessment and risk management was not only needed, but needed to be conducted by EPA, since no other federal agency had the mandate, need, or desire to conduct such research.

Finally, it should be recognized that research on risk assessment and risk management needs to be a long-term core component of EPA's research program. Core research needs stability, a feature which has not been a hallmark of EPA's Office of Research and Development (ORD). Tenure for a Presidentially selected and Senate confirmed Assistant Administrator (AA) for ORD has been three years or less, and Acting AAs for ORD have occupied the position for about half of the whole history of EPA. Thus, the NRC Report recommended that the position be changed to a six-year term-appointment, with the AA selected for expertise in both science and research management. This change would help to ensure the primacy of a longer term view of research goals focused on EPA's unique role as a regulatory agency that relies strongly on sound science to guide the formulation of its standards, guidelines, and cost-effective risk management.

The differences in EPA's current abilities to make estimates of health risks for air toxics on the one hand and estimates of benefits resulting from its successes in source controls on the other, while notable and unfortunate, are remediable, and the research needed to overcome the current deficiencies should be given a high priority. The ORD has come a long way in recent years in terms of its development and updates on its strategic plan, its inventory of science activities and capabilities through the Agency, its closer coordination with research programs in NIH, NSF, and CDC, and its shift of resources toward an extramural grant program in which EPA's research needs are met, in part, through individual investigator-initiated proposals that address critical information needs identified in Requests for Applications. It will also soon occupy new state-of-the-art research facilities in Research Triangle Park, NC that will enhance its capabilities.

In summary, our current abilities to determine residual risks of air toxics and to compare risks quantitatively are quite limited by key gaps in knowledge, and by reliance on unvalidated predictive models for exposure and for dose-response. A major part of the problem is the existence of two very different cultures of risk assessment: 1) for carcinogens; and 2) for other toxicants. Carcinogen risk assessments seldom have been based on relevant data on either low-dose exposure on human exposure-response data at concentrations anywhere near ambient levels. They require high-dose to low-dose extrapolations and generally animal-to-human

extrapolations as well, using unvalidated predictive models. In the face of such a high degree of uncertainty in the output of the models, conservative assumptions are used to ensure that potency and exposures are not underestimated. Thus, yields of risk estimates are almost always far higher than the real risks. Such risk estimates cannot be fairly compared to the risks associated with criteria air pollutants, which are determined largely from the product of measured air pollutant concentrations and measured responses among humans exposed to either ambient air or to controlled exposures in chambers. Fair comparisons can only be done within the separate categories of pollutants.

Comparative risk assessment is an idea whose time is coming, and if EPA is provided with appropriate research resources to harness the new technical approaches and sophisticated research tools now emerging to fill in key knowledge gaps, it can make comparative risk assessment more useful and feasible in the not-too-distant future. If the recommendations in the NRC "Strengthening Science at EPA" report are adopted, the prospects for such advances would be greatly improved.

Dr. Hopke, in his testimony in the next panel will address the major knowledge gaps limiting EPA's ability to perform the residual risk assessments mandated for HAPs in the 1990 Clean Air Act Amendments, even for an industrial sector like secondary lead smelters that is relatively data-rich. In my view, we should celebrate the success of the application of the best available technology approach in greatly reducing emissions and ambient concentrations of air toxics and put off any great effort at quantitating their residual risks until we have the ability to perform more realistic and credible risk assessments. The resources now dedicated to performing such risk assessments would be more productively employed if redirected to improving the technology for quantitative risk assessment and for filling key knowledge gaps that have been identified in the analyses already performed.

Finally, I encourage the Congress to implement the legislative changes needed for the creation of the new position of Deputy Administrator for Science in EPA and for transforming the position of Assistant Administrator for Research and Development in EPA to a six-year term appointment. These changes will help ensure institutional stability and a more long-term framework for core research. I also encourage Congress to consider explicitly giving EPA a mission statement that includes the performance of a long-term research program as a means of enhancing its capabilities for effective and efficient stewardship of its environmental responsibilities.

In closing, I want to thank the Committee for inviting me to testify on these important issues related to scientific aspects of environmental risks and on opportunities to improve the

practice and utility of risk assessment and risk management.

September 29, 2000

MEMORANDUM

To: Members and Staff

From: Staff

Subject: Oversight Hearing on the Use of Comparative Risk Assessment in Setting Priorities and Science Advisory Board's (SAB) Residual Risk Report

Overview

On October 3, 2000, at 9:30 a.m. in Room 406 of the Dirksen Senate Office Building, the full Committee on Environment and Public Works will conduct an oversight hearing to receive testimony on the use of comparative risk assessment (CRA) in setting environmental priorities and on the SAB's Residual Risk Report. The purpose of this hearing is to receive testimony on the lessons learned from the application of comparative risk analysis in defining strategic goals for the environment and setting priorities, at the federal, state, and local level. The Committee will also receive testimony on the EPA's residual risk activities.

Background

In 1987, EPA published *A Comparative Assessment of Environmental Problems (Unfinished Business)*, which was its first attempt at evaluating and comparing risks posed by environmental threats. The Science Advisory Board (SAB), EPA's independent panel of experts, peer-reviewed the EPA's method for comparing risk and in 1990 issued its report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*. The SAB identified many problems with the method, but also endorsed CRA as a valuable tool to assist in setting priorities.

CRA is a tool for estimating and ranking the risk of environmental problems in terms of seriousness and is based on risk assessment. Risk assessment includes: 1) identification of environmental hazards such as chemicals or activities that have the potential to cause death or illness, or harm to ecosystems or welfare; 2) a dose-response analysis, which is an estimate of the ill-effects on health or ecosystem as a function of dose; 3) an exposure assessment, which is an estimate of how much people or ecosystems are exposed to a stressor; and 4) a quantitative and qualitative description of risk.

To date, all EPA regions and over 30 States and municipalities have conducted CRA projects. They have used CRAs to address the question: what are their most serious environmental problems. As a result of conducting CRAs, some States and local agencies have been in a better position to target their resources on the environmental problems that pose the greatest risks to human health and to the ecosystem. Some States are also using, in part, the results of these comparative risk assessments to focus on environmental outcomes and to develop performance indicators as part of the National Partnership Performance System (NEPPS).

Many States and municipalities have ranked environmental problems relative to the risk these problems pose to human health and ecosystems as well to their impacts on quality of life. To characterize and rank risk, they often consider the assumptions, judgments, and uncertainties related to risk assessments, as well as issues such as aesthetics, uniqueness, and social values such as fairness and equity. All of these considerations are inherently value-laden. Because CRAs contain subjective judgement, States and municipalities have found that the results of CRA projects are most valuable when a wide range of stakeholders, i.e., experts, government officials, industry and the public, participate in the process.

Beyond ranking environmental risks, decision-makers may need to understand risk reduction options, and the associated costs and benefits, in order make decisions related to the effective allocation of resources. Decision-makers are increasingly recognizing a role for such information in improving the management of risks.

Comparative risk assessment offers a framework for incorporating the concept of relative risk into decision-making. When a wide range of stakeholders are brought into the process, it also provides a means to improve communication between regulators, scientists, and the public. While it has its limitations, comparative risk analysis can provide a degree of discipline and consistency which is help in setting and communicating environmental priorities.

The specific focus of this hearing is on the lessons learned from the application of comparative risk analysis in defining strategic goals for the environment and setting priorities, at the federal, state, and local level.

The hearing will also receive testimony on the SAB's Advisory on EPA's Case Study Analysis of the Residual Risk of Secondary Lead Smelters. Under the Clean Air Act the EPA is required to issue MACT (maximum achievable control technology) standards for 174 source categories. Eight years after each MACT standard is promulgated the EPA must review the residual risks from emissions of the 174 source categories. If additional risks are identified then EPA must promulgate new standards to provide an ample margin of safety to protect public health and the environment from those risks. The Lead Smelter Case Study is the first residual risk analysis preformed by the EPA. In addition to other issues, the availability of quality data, which has a direct impact on the quality of risk estimates, will be addressed.

The witnesses

Panel 1

1. Al McGartland, Director, National Center for Environmental Economics, Office of Policy, Economics, and Innovations, EPA

2. Peter Guerrero, Director, Environmental Protection Issues, GAO

Panel 2

3. Katherine Hartnett, Executive Director, Comparative Risk Project, New Hampshire

4 Mike Pompili, City of Columbus, Ohio Community Risk Panel

5. J. Clarence (Terry) Davies, Resources for the Future

6. Elizabeth L. Anderson, President and CEO, Sciences International Inc.

7. Morton Lippmann, Professor, New York University, Acting Chair, SAB

Panel 3

8. Lee Hughes, Vice President for Corporate Environmental, Bayer Corp

9. Robert Brenner, Deputy Associate Administrator, Office of Air and Radiation, EPA

10. Philip Hopke, Chair, Residual Risk Subcommittee, Science Advisory Board

11. Felice Stadler, National Wildlife Federation

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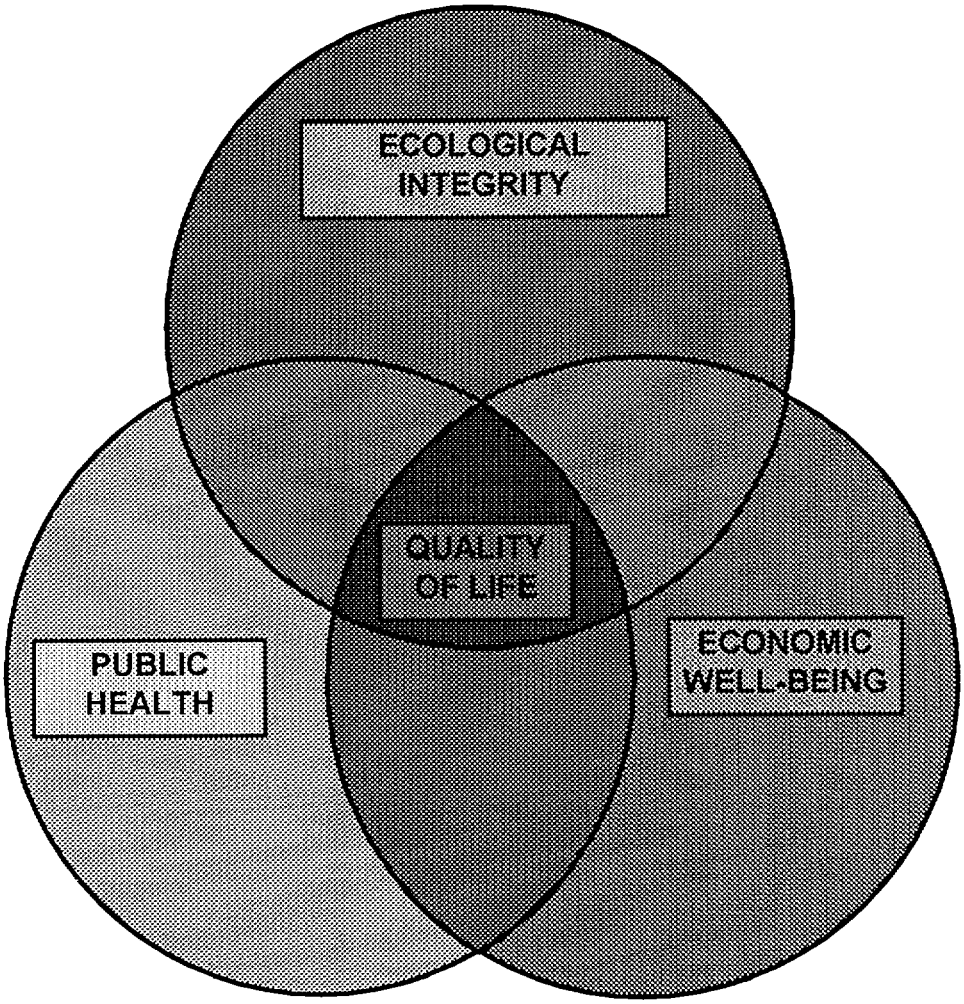

REPORT of RANKED ENVIRONMENTAL RISKS in NEW HAMPSHIRE

Environmental Quality • Public Health • Economic Wellbeing • Quality of Life

NH COMPARATIVE RISK PROJECT

SUMMARY POINTS FOR US SENATE ENV. PUBLIC WORKS HEARING, 27 JULY 00

(1) Thank you—for NEPA, CAA, CWA,SDWA, RCRA, CERCLA, SARA (1970-1986) and reauthorizations. After 30 years, air, water, land are cleaner, economy never stronger.

(2) Try to condense over seven years of work into next five minutes (as locals say, "sugar down").

(3) Fortunately, New Hampshire is small state—44th in area, 42nd in population. The good news is, because of small scale, most effective leaders try to work together (and it's "hard to hide"). So, New Hampshire is a good scale for an inclusive process.

(4) Bottom line—since 1993, worked to separate fear from environmental hazard, and to reduce hazard. Used comparative risk process to identify, study, and rank 55 risks to New Hampshire environmental quality of life ("healthy people, ecology, economy"), documenting influence of accessible science, personal judgment, and individual values in ranking. Traced risks back to 11 sources (i.e. transportation, energy use, land use and development, recreation, water and food, etc.). Identified four key actions to reduce hazard. Current focus on two: (a) sound land use and (b) efficient use of energy, materials, and resources.

(5) Identified transition to next generation of environmental management, with changes from:

- "us vs. them" to "we"
- "problems" to "opportunities"
- "illness" to "wellness"
- "economy vs. environment" to "economy = environment"
- "environmental threats to humans" to "humans threaten environmental quality"

(6) Stepping back, fits into evolution in New Hampshire, and U.S., in 20th into 21st century:

1920-1930's	Conservation
1960-1990	Federal and State Regulation
1990's	Land Protection
21st century	Personal, Corporate, Public Responsibility

(7) **SUMMARY:** Comparative risk process worked at New Hampshire scale. After 30 years of successful federal and state environmental regulation, focused on industrial and other point sources, we are now in a new generation of environmental management. To continue success, we need additional tools, including fresh analysis of environmental conditions and stressors, coupled with public/private and federal/state partnerships, dynamic collaborations, effective incentives, creative funding programs, and targeted education, along with regulation and enforcement, to reduce current hazards and improve overall quality of life.

NOTE: See attached outline and *For Our Future: A Guide to Caring for New Hampshire's Environment* for more detail.

for more info, pls. contact Katherine Hartnett, Exec. Dir. 603.226.1009, katehart@tiac.net

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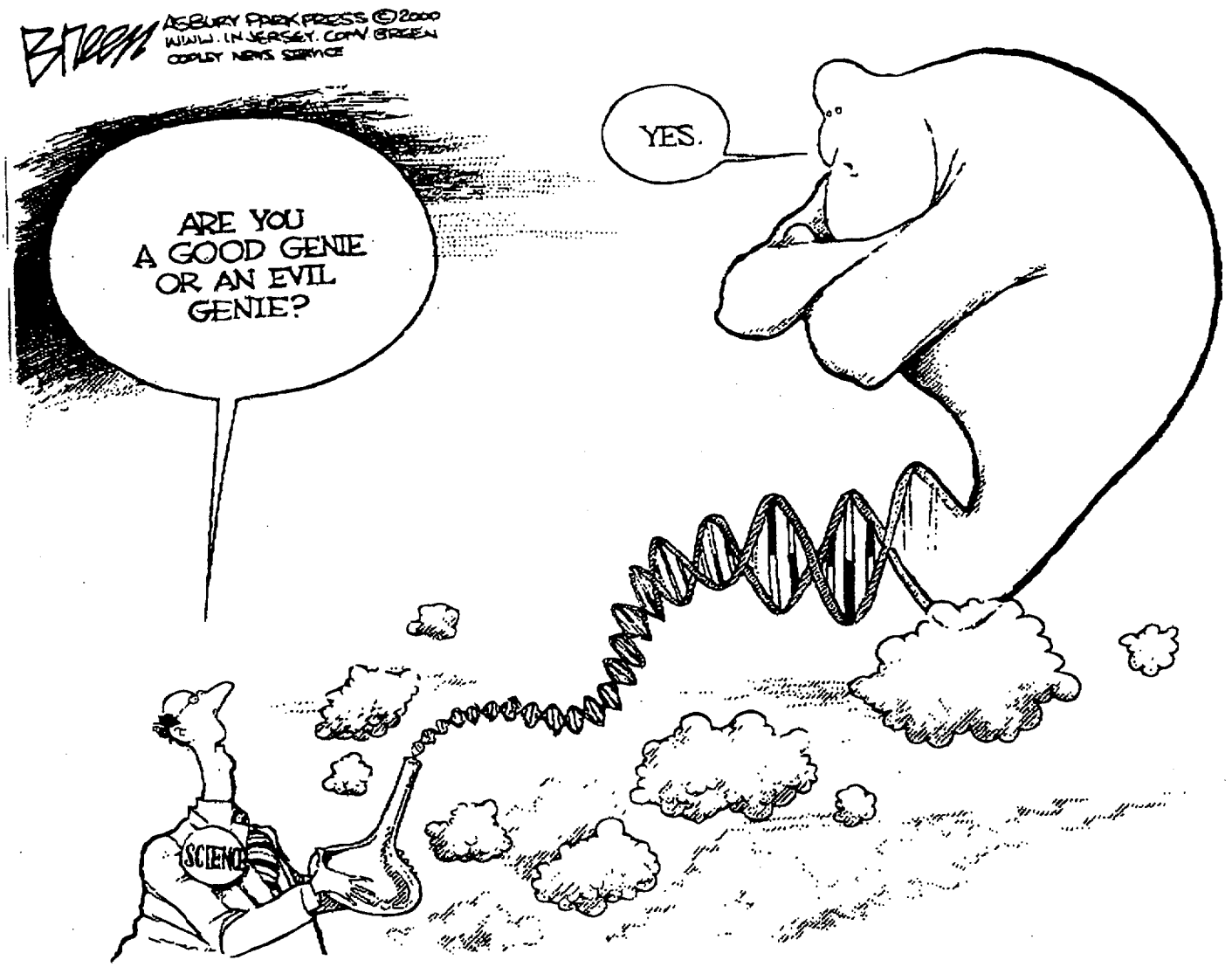

NH COMPARATIVE RISK PROJECT

OUTLINE FOR US SENATE ENV. PUBLIC WORKS HEARING, 27 JULY 00

MESSAGE: Comparative risk process worked at NH scale. After 30 years of successful federal and state environmental regulation, focused on industrial and other point sources, we are now in a new generation of environmental management (from "us vs. them" to "collaboration"). To continue success, we need additional tools, including fresh analysis of environmental conditions and stressors, coupled with public/private and federal/state partnerships, dynamic collaborations, effective incentives, creative funding programs, and targeted education, along with regulation and enforcement, to reduce current hazards and improve overall quality of life.

(1) **Assumed points of agreement:**

- Goal is to maximize environmental protection, with minimal costs.
- By separating fear from hazard, it is possible to more effectively prioritize actions.
- Solutions that benefit multiple problems are preferable.
- Design approaches that productively engage multiple constituencies, and show results.
- Everyone has a role.

(2) **New Hampshire experience:** Designed credible, non-advocacy process. Chose diverse participants that could: (a) leave preconceptions at the door; (b) listen to others, and work collaboratively; and (c) bring a sense of humor to difficult discussions. Put environmental quality of life at the center, comprised of "healthy people, healthy ecology, and healthy economy." Explicitly evaluated hazards using science, judgment, and values. Created continuum of hazards, used common vocabulary of criteria (severity, extent, reversibility, uncertainty). Recognized long-term (7-10+ years) nature of solutions.

- *How different...* **Unique features of New Hampshire's Project:** The New Hampshire project had the advantage of following almost 20 other states through the comparative risk process. Innovations unique to New Hampshire include:

  ★ Initial support and cooperation of state, private, and non-profit participants.

  ★ Project housed at the neutral NH Charitable Foundation (NHCF), rather than environmental regulatory agency, public health agency, or state university.

  ★ Defined "quality of life" considerations to include ecological, public health, and economic components, along with individual values.

  ★ Focused on understanding and reducing hazard, with commitment to developing and implementing focused actions, using an integrated ranked list of risks to human health and ecological integrity as a guide.

  ★ Used separate economic analysis to inform ranking and priorities for action.

  ★ Public Advisory Group was very large (55 members), and took eight day-long meetings over five months to rank the 55 risks into an integrated list that "everyone could live with."

for more info, pls. contact Katherine Hartnett, Exec. Dir. 603.226.1009, katehart@tiac.net

⋆ Benefited from volunteer efforts of over 100 technical experts in ecology, public health, and economics. Technical leaders writing ecology, health, and economic reports received a stipend up to $10,000 each, to ensure timely, accessible synthesis of information, for ease of use by 55 members of Public Advisory Group. Used geographic information system (GIS) for data analysis and presentation.

⋆ Created innovative "quality of life" model that allowed individuals to explicitly identify their values influencing their ranking.

⋆ Participated in concurrent "collaborative assessment" with independent technical experts experienced in supporting 30+ state projects.

⋆ Identified action initiatives involving businesses, state and local governments, environmental and public health groups, educational institutions, and individuals.

⋆ Wrote thinnest final report, containing all technical reports and ranking rationales.

⋆ Work continues on reducing hazard, in context of Comparative Risk results.

- *How successful?:* good process, educated participants, contributed to decision-making such as:

  - NOx— recently announced Northeast Regional Ozone Transport Assessment Group (OTAG) SIP call for ozone
  - NH Clean Air Strategy
  - NH Climate Change Action Plan
  - Lead in natural environment (in sinkers, shot)
  - Mercury (state strategy)
  - Arsenic (program developing)
  - NHDES adding "Resource Protection" to strategic plan
  - Environmental organizations using study as technical reference and in organizational strategy

  Also, *Guide* identifies 4 key actions to reduce hazard—specific projects, such as Minimum Impact Development Partnership, Economy/ Environment Collaborative, and NH transportation strategy, implement those actions.

- *How failed?:* Sludge—could use comp risk process to evaluate management options.
  MTBE—huge focus, while arsenic management only slowly getting underway.

(3) **What was learned?** Change takes time (7-10+ year process to move to next generation of environmental management). Consistent, explicit process built credibility. Useful information, and helpful perspective for action by individual organizations. Knew from beginning that two phases needed: (a) Separate fear from hazard; (b) Reduce hazard. Need support for follow-up actions to reduce hazards.

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(4) So what? NH actions to (a) Separate fear from hazard; and (b) Reduce hazard:

- Studied and ranked 55 risks, using science w/consistent criteria, explicit judgment and values.
- Traced 55 risks back to 11 sources, then 4 key actions.
- New public/private partnership focusing on 2 key actions—(a) sound land use and (b) efficient use of energy, resources, materials—by developing voluntary practices for good development (funded by USEPA Sustainable Dev. Challenge Grant). Also NHCF/McCabe funded Economy/Environment Collaborative, working on economic drivers to maintain NH Advantage of "healthy people, healthy ecology, healthy economy" with "virtuous" cycle.
- Using information, incentives, partnerships, collaboration, good publicity, along with modifying existing regulation, to implement.

(5) Comments to Congress/USEPA: Not certain on advice.

Do have some Q's:

- Is there a thought that there is a need to do things differently, or continue with current process?
- Is the purpose here to understand how to help Federal agencies be more effective?

Some ideas:

- Current set of environmental hazards not amenable to legislation only—there's no single or suite of regulations alone that will work in this generation of environmental management.
- Why not take time to celebrate successes of first generation of environmental hazards reduced? (after 20-30 years of regulation, point sources clearly are much cleaner, and the economy very productive—Congress can show the effectiveness of its laws).
- Challenge today is even more difficult, because there are no clear "villains," or easy solutions—everyone is involved, at work, home, recreation; which is why information and clear understanding of the issues are essential.
- Acknowledge that managing next generation of hazards will need new strategies rather than primarily a regulatory approach. Possible actions:

  (1) Claim success in regulating point sources.
  (2) Now need to take the long view, and dedicate time to understand the problems. Let the public know what you are doing, and why.
  (3) Convene annual hearings for several years; ask for consistent information on regional and local conditions.
  (4) Develop an action plan to support work of locals—encourage community-based solutions informed with accessible data and supported by sufficient funding.

In short, Federal role can be to stimulate—require consistent regional and local information about environmental conditions and trends to assemble a national picture, and then support federal, state, local actions based on environmental data. Convene annual deliberations that encourage results-oriented environmental quality—using environmental. indictors as measures of progress, and linking agency budgets to reducing impacts. Local citizens become involved, get results, and see effects of federal support on the ground, in their communities.

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The Ranked List of Risks

(The rank reflects the blended judgement of the Public Advisory Group and assumes current regulation.)

Higher risk in New Hampshire

Degradation of surface water habitat caused by development
Airborne particulate matter ("soot" and tiny aerosols from gases)
Loss of land habitat caused by development
Physical alteration of water and shoreland habitat
Loss of water habitat by filling or draining wetlands
Acid deposition by rain, snow, and fog on forests, soils, inland waters, and estuaries
Environmental tobacco smoke ("secondhand" smoke)
Ultraviolet radiation (sunlight at "baseline" levels before stratospheric ozone depletion)
Ingested lead (in food, paint, etc.)
Degradation of forest habitat by fragmentation caused by development
Allergens and other non-infectious biologicals (mold, dust mites, pollen, etc.)
Non-native organisms in surface water (milfoil, zebra mussels, etc.)
Ground level ozone ("smog")
Persistent organochlorines (DDT, PCBs, dioxin, etc.)
Food contamination (shellfish poisoning, salmonella, mold, etc.)
Arsenic in groundwater used for water supply
Non-native organisms on land (Dutch elm disease, gypsy moths, etc.)
Stratospheric ozone depletion (reduced shield from ultraviolet radiation; "the ozone hole")
Waterborne diseases (e. coli, giardia, etc.)
Mercury in surface water and on land
Pesticides (insecticides, herbicides, fungicides, etc.)
Carbon monoxide indoors
Diseases affecting humans carried by wild animals (rabies) and insects (Lyme disease)
Petroleum in groundwater used for water supply (spills and other releases)
Nitrogen oxides (a by-product of fuel combustion)
Hazardous wastes (non-petroleum hydrocarbons) in groundwater used for water supply
Infectious diseases in wildlife and fish (from environmental changes or new species)
Climate change (global warming from greenhouse gases, more extreme weather, etc.)
Radon concentrated indoors
Sulfur oxides (a by-product of fuel combustion)
Lead in soil and sediment (ingested by wildlife and fish)
Nuclear reactors and associated high level radioactive wastes
Airborne human disease, spread from person to person (such as "TB" tuberculosis, etc.)
Volatile organic compounds in indoor air (from plastics, glues, solvents, fabrics, etc.)
Nitrates in surface water and groundwater
Petroleum in surface water (from storm water, spills, motorcraft, etc.)
Soil loss (erosion) caused by wind or water
Regulated toxic emissions to outdoor air ("air toxics")
Chlorination by-products in water supply (from treatment to remove bacteria)
Non-reactor sources of low-level radioactive wastes
Other trace metals in surface water, sediment, or on land in localized concentrations
Road salt — impact on adjacent land
Asbestos in indoor air
Road salt — impact on groundwater used for water supply
Carbon monoxide outdoors
Extreme weather
Food additives and preservatives
Sludge and septage (applied on land as fertilizer or to improve soil structure)
Other metals in water supply (iron, manganese, sulfates)
Volatile organic compounds in outdoor air
Polycyclic aromatic hydrocarbons in surface water (from spills, storm water, etc.)
Asbestos in groundwater used for water supply
EMF (electromagnetic) radiation (from electrical equipment, power lines, etc.)
Fluoride (naturally occurring high concentrations in groundwater)
Earthquakes

Lower risk in New Hampshire

Achieving Harmony Among Environment, Economy and Energy

Our economic vitality depends on a healthy mix of development, open spaces

by Katherine Hartnett

How can we sustain increasing prosperity without losing the essence of New Hampshire? Two public/private initiatives are working to answer those key questions, first identified as "A Vision for New Hampshire's Future" in the Business and Industry Association's 1997 *Agenda for Continued Economic Opportunity.*

Environmental quality of life — healthy people, healthy ecosystems and a healthy economy — is a vital component of the "New Hampshire advantage." However, the cumulative effects of individual land development projects are transforming our state's landscape and its communities, threatening the diversity of density and small scale vital to that advantage.

In fact, land use changes and the effects of energy use are major contributors to many of the 55 risks to environmental quality of life studied and ranked by the NH Comparative Risk Project between 1994 and 1997. Eroding quality of life weakens the magnet that attracts so many of the new economy businesses and skilled workers to New Hampshire, which in turn weakens economic vitality.

Imagine, by contrast, a mix of protected open space and sensible development in New Hampshire — homes, workplaces, schools, services and shopping sited to make the most use of sunlight for heat and lighting, supplemented by energy efficient lighting and equipment, constructed of locally available lumber, with excellent indoor air quality.

Outside, rainwater and snow melt flow into grassy swales, then wetlands and then into the ground. Plants and shrubs line the wetlands and the on-site pond. Parking is shared, with separate footpaths and a bikeway connecting to a bus/train center, and additional parking for local services. People, goods and ideas are mobile, with little congestion due to a mix of car, truck, rail, bus, foot and other modes that provides options. Land use and technologies minimize unnecessary travel. Many people choose to telecommute, car- or vanpool, and save highway miles for recreation.

Cumulatively, the mix of open and developed lands preserves a diversity of density, with spaces between places. Residents can live and find work and community in large and small cities such as Nashua, Manchester, Concord or Berlin; suburban towns like Bow or Amherst; small towns and villages like Newport and Harrisville; rural areas such as Columbia and Grantham; and working and wild lands in the North Country.

The Partnership

The Minimum Impact Development Partnership (MIDP) is working on identifying and encouraging implementation of such practices. Started in 1999, with initial funding from a US EPA Sustainable Development Challenge Grant, the Partnership is a collaboration between members of the development industry (developers, engineers, architects, bankers, insurers and builders) and natural and public health scientists. The goal is to demonstrate sound land use and energy efficiency by minimizing:

- air, land and water pollution
- energy use
- habitat loss from development.

Design experts and scientists will describe specific voluntary practices, with performance standards, at the building, site, neighborhood and town scales. The Partnership also will identify measures of progress toward minimum impact development and highlight "leading by example" case studies that do so. A draft practices manual is due out by the end of 2000.

"Eroding quality of life weakens the magnet that attracts so many of the new economy businesses and skilled workers to New Hampshire, which in turn weakens economic vitality."

McCabe Grant

While MIDP is working at the building, site and community scale, another collaboration funded by a grant from the McCabe Environmental Fund of the NH Charitable Foundation is working on the vision described above by exploring the link between the economy and the environment at the regional and state scales.

New Hampshire's economy is a mix of working landscapes of forestry and agriculture, tourism and recreation, and high technology and related industries and businesses. Economists, business interests and environmental representatives are in dialogue to find ways to work together in a mutually reinforcing system that promotes healthy people, healthy ecology and healthy economy. The collaboration will be bringing a draft model to a wide range of groups over the next six months to test the concepts and refine the model.

The overall goal of Minimum Impact Development and the Economy/Environment Collaborative is to preserve New Hampshire's environmental quality of life by integrating principles and knowledge from ecologists, engineers, economists and other experts into specific development practices. Good development can be a major contributor to the vision described in BIA's *Agenda.* ■

Katherine Hartnett is the executive director of the NH Comparative Risk Project. She can be contacted at 603/226-1009 or by e-mail at katehart@tiac.net.

U.S. Senate Committee on Environment and Public Works
October 3, 2000
Testimony of Michael J. Pompili
Assistant Health Commissioner
Columbus Health Department
Columbus, Ohio

Good Morning Chairman Smith and members of the Committee on Environment and Public Works. It is an honor to provide testimony to you this morning particularly on a process which I believe strongly in and which has been central to several programs which have been developed for the Columbus community over the past 10 years. Your willingness to discuss the use of comparative risk assessment in setting community priorities demonstrates your understanding that there are no simple answers to solving environmental issues that impact our communities and that it is critical to involve stakeholders in the process. During my next few minutes of testimony, it is my goal to share with you how we have successfully implemented several comparative risk processes in Columbus, Ohio, identify the central themes which have led to the success of these efforts and to make recommendations to you regarding the role of the federal government in such initiatives.

The Community Environmental Management Plan was established through the Columbus Health Department, beginning in 1992. It is made up of five components:

The Environmental Science Advisory Committee (ESAC) is a body of 18 environmental scientists, educators and other professionals who assist city policy makers on a volunteer basis. ESAC is modeled after the US EPA's Science Advisory Board. Its goal is to help leaders make better decisions by offering advice, opinion and counsel on a wide range of environmental issues.

Priorities '95 is a classic example of a comparative risk assessment. This innovative effort used over 250 community volunteers to develop a comprehensive environmental

blueprint for the City of Columbus. Project participants logged more than 5,000 person-hours in a two-year process that:

1) Identified the City's most pressing environmental problems; 2) Analyzed them to determine potential risk to citizens; 3) Ranked these problems in terms of severity; and, 4) Developed potential solutions to these problems.

Columbus' Environmental Snapshot uses key indicators to provide the public with status and trend information on the state of the Columbus and Franklin County environment. In creating the *Snapshot,* the objective was to compile information already being collected by numerous governmental organizations into a single, easy-to-understand and user-friendly document. The information contained in the *Snapshot* represents both an educational resource and a means of gauging the success of past environmental efforts including a status report on the progress of Priorities '95 initiatives.

Columbus Community Risk Panel is a 35-member committee designed to help Greater Columbus residents make informed decisions about risk. The Panel, through various initiatives, serves as an ongoing resource to help develop a more informed citizenry and provide the community with accurate information on health and quality of life risks. Panel members include public officials and other community leaders from government, professional groups, public and private business, health care and education organizations, and the media. A key goal of the panel is to establish connections with citizens. This is accomplished through a variety of projects including: the establishment of community computer centers in inner-city churches, the Neighbor-to Neighbor program, formation of Community Advisory Panels that bring industrial facilities and neighborhood groups together and establishing a web site for risk related information.

Project CLEAR is a new citizen-driven initiative based on the same principles as our Priorities '95 Risk Project. It is designed to address Central Ohio outdoor air quality, particularly issues related to ground-level ozone pollution. CLEAR's main objective is to involve citizens, businesses, local governments, and other organizations in evaluating and choosing strategies to improve air quality. What is particularly unique about Project Clear is that it moves beyond public opinion toward a public deliberation process

Three basic principles underly all of the components of the Community Environmental Management Plan: promoting the use of science and scientific information whenever possible; developing a more informed citizenry on issues of community health, environment and quality of life; and encouraging public participation in the decision making process.

These principles have not only lead to the success for our efforts but are appropriate at all levels of government: local, state and federal. An excellent example of these principles operationalized at the state level was when Senator Voinovich, then Governor Voinovich embarked on a comparative risk project for the State of Ohio. Similar efforts have been conducted by 25 of the 50 states as well as at least 12 local communities. The process represents a new way of doing things most importantly involving the public in meaningful ways on issues that impact their lives.

So the question remains what role can the federal government play in this effort. The federal government's role is to establish national priorities. The use of a national comprehensive risk process could provide general direction in setting these national priorities, but it is very important to understand the limitations of a federal comparative risk project. A federal comparative risk project is doomed to fail if it means risks encountered in Florida are compared with those found in Oregon. Instead it may be most appropriate for the federal government to serve to support these efforts at the state and

local level and actively promote the principles of sound science, informed citizenry and public participation in all environmental initiatives. Specifically the federal government can serve as a technical assistance center, both generating data and fulfilling the role of information resource. States and local communities will vary widely in their ability to successfully implement a comparative risk process. Federal support and technical guidance may allow for at least some degree of consistency and utility of effort. Because community participation and buy-in are critical in these types of initiatives and essential for any behavioral change to occur on the part of individuals, federal emphasis and support for community participation at the local level may also be appropriate. Shifting from categorical thinking formulas to community thinking formulas will go a long way toward promoting involvement. Further, it may be helpful for states and local communities to look to the federal government for funding of comparative risk projects or at least linking to available funding for such efforts.

Some of what I have described is not necessarily a new role. At one time, the Federal Government funded a US EPA office to directly assist state and local folks interested in doing this type of work. This Regional and Statistical Planning Branch of the Office of Policy, Planning and Evaluation was extremely helpful to us in Columbus providing a $50k grant for our project and direct technical assistance in project formation and implementation. I have heard many other local project directors share these sentiments. Unfortunately, the office was disbanded a year or so ago and its personnel were re-assigned within the agency. To my knowledge, there is now no federal entity that exists concerned with promoting and directly assisting state and local governments with projects dealing with risk-based decision making.

By recognizing the value of local communities in determining their priorities, a further role for the federal government is flexibility. While federal standards and regulations are often warranted, it is important to allow for some tailoring of effort according to a local

communities' need. US EPA's Project XL is a perfect example of this type of philosophy. In its current form, however, Project XL is somewhat cumbersome and a challenge to negotiate. We are quite pleased to have just signed the final agreement for an XL project in Columbus, an effort which took over three years to come to fruition.

In asking for this flexibility, however, local communities need to hold themselves accountable and maintain the high, if not higher standards than those set forth at the federal level. If by your flexibility at the federal level you are demonstrating your trust of state and local government to make sound environmental decisions, we must safeguard this trust and work cooperatively with you towards common goals. Without a certain level of trust at all levels of government, even the most innovative programs are doomed to fail.

In closing, let me once again reiterate the importance of public participation and connecting with our citizenry. More and more our citizenry is expressing dissatisfaction or disinterest in civic responsibility. While they are disengaging from the political process, we must fight to have them actively involved in directing resources and actions that will impact their own neighborhood and their quality of life. We must demonstrate government's trust in the ability of residents to make these programs work. I am a very strong believer that our citizenry will make the "right" choices if they are able to receive information in understandable ways, if they are presented with accurate portrayals of existing trade-offs regarding risk and if the decision making process reinforces the need to consider a full range of options available. If these themes may be woven through the federal, state and local government, we may yet see a public which still seeks out their civic roles.

Thank you for the opportunity to speak before you today.

The Columbus Community Environmental Management Plan

Protecting and Improving the Environment by:

- ✔ Using Science
- ✔ Informing Citizens
- ✔ Emphasizing Community Decision-Making

The Columbus Environmental Management Plan

The Columbus Community Environmental Plan (CEMP) is designed to protect and improve the area environment through three basic principles:

- Promoting the use of science and scientific information whenever possible;
- Developing a more-informed citizenry on issues of community health, environment, and quality of life; and other issues dealing with risk,
- Using members of the community to help make risk decisions where feasible.

The Community Environmental Management Plan is administered through the Columbus Health Department, and has four basic components:

The Environmental Science Advisory Committee (ESAC)

ESAC is a body of 18 environmental scientists, educators and other professionals who assist city policy makers on a volunteer basis. Its goal is to help leaders make better decisions by offering advice, opinion and counsel on a wide range of environmental issues. ESAC considers and evaluates questions submitted by the Mayor, City Council, Board of Health or City Department managers, focusing specifically on the science behind environmental issues. Services can include client meetings; document review, analysis and evaluation; property site inspection and preparation of summary documents.

Priorities '95

This innovative effort used over 250 community volunteers to develop a comprehensive environmental blueprint for the City of Columbus. Project participants logged more than 5,000 man hours in a two-year process that:

1) Identified the City's most pressing environmental problems;
2) Analyzed them to determine potential risk to citizens;
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Columbus' *Environmental Snapshot*

This community document uses key indicators to provide the public with status and trend information on the state of the Columbus and Franklin County environment. In creating the *Snapshot,* the objective was to compile information already being collected by numerous governmental organizations into a single, easy-to-understand and user-friendly document. The information contained in the *Snapshot* represents both an educational resource and a means of gauging the success of past environmental efforts.

Columbus Community Risk Panel

This 35-member committee was formed in January 1998 to help ensure that Greater Columbus residents are making informed decisions about risk. The Panel, through various initiatives, serves as an ongoing resource to help develop a more informed citizenry and provide the community with accurate information on health and quality of life risks. Panel members include public officials and other community leaders from government, professional groups, public and private business, health care and education organizations, and the media.

Environmental Science Advisory Committee (ESAC)

ESAC is a body of 18 environmental scientists, educators and other professionals who assist city policy makers on a volunteer basis. Its goal is to help leaders make better decisions by offering advice, opinion and counsel on a wide range of environmental issues.

ESAC considers and evaluates questions submitted by the Mayor, City Council, Board of Health or City Department managers, focusing specifically on the science behind environmental issues. The committee's resulting work products will differ according to the issue under consideration. Services can include client meetings; document review, analysis and evaluation; property site inspection and preparation of summary documents. Because ESAC is an independent, volunteer organization, it offers decision-makers an objective (different) perspective that can either confirm judgements or suggest new avenues of thought.

Issues considered by ESAC include:

- The possibility of health threats to police officers from lead exposure at the police firing range
- An evaluation of City sewer line construction practices
- Watershed impacts from land application of manure from area egg farm
- Review of Columbus noise ordinance
- Consideration of proposed uses for sewage sludge incinerator ash
- Adequacy of a hazardous waste remediation plan for U.S. Air Force property adjacent to Port Columbus International Airport

Priorities '95

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One of *Priorities '95* greatest strengths was that it incorporated both scientific information and public opinion in determining which environmental problems are most serious and how these problems should be addressed. *Priorities '95* concluded with the development of almost 200 recommendations for environmental improvement.

Since the project's conclusion, the City has worked to address many of the *Priorities '95* recommendations. Notable efforts include:

- Development of a parkland dedication ordinance in conjunction with new residential development

- Development of a rabies public outreach / informational campaign to increase pet vaccinations

- Acquisition of non-productive city properties for redevelopment as community gardens, beautification projects or neighborhood playgrounds

- Establishment of a 6-county coalition to address the issue of atrazine runoff in the Scioto River watershed

- Development of a Recreation and Parks Department containerized tree program that reduces growing time of planting stock by over 50 percent

"The Environmental Snapshot"

This community document uses key indicators to provide the public with status and trend information on the state of the Columbus and Franklin County environment. In creating the *Snapshot,* the objective was to compile information already being collected by numerous governmental organizations into a single, easy-to-understand and user-friendly document.

A comprehensive community process was developed to select the 35 environmental indicators contained in the document. More than 40 governmental personnel, environmental scientists and members of the general public served as advisors to select appropriate environmental indicators. Their participation ensured that the most technically relevant and easily understandable information would be used. Data is presented for five environmental areas, and includes indicators for:

- *Urban Conditions* - *Population; Platted Land; Building Activity; Land in Farms, and more....*

- *Air Quality* - *Ambient Air Trends; County Vehicle Emissions; Registered Passenger Vehicles; and more.....*

- *Drinking Water* - *Finished Water Chemical Levels; County Well Water Chemical Levels*

- *Surface Water* - *Major Sources of Impairment; Fish Tissue Analysis; and more....*

- *Solid Waste* - *Waste Generation, Reduction & Recycling; Destination of Generated Tonnage; and more....*

Over 250 copies of the report are distributed each year to community groups, civic associations, community leaders and individuals. The document is updated annually, an educational resource that can help provide users with greater insight into the direction of environmental trends and a means of gauging the success of past environmental efforts.

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This 35-member committee was formed in January 1998 to help ensure that Greater Columbus residents are making informed decisions about risk. The Panel, through various initiatives, serves as an ongoing resource to help develop a more informed citizenry and provide the community with accurate information on health and quality of life risks. Panel members include public officials; community leaders from government agencies, professional groups, public and private business, health care and education organizations; and the media.

Panel members meet quarterly, however activities of the panel are ongoing. Current Community Risk Panel Projects include:

- Development of **Project CLEAR**, a two-year community initiative designed to produce air pollution reduction strategies for the Central Ohio area. The project will specifically examine issues and strategies related to outdoor air quality, focusing on perecursors to ground level ozone formation.
- Creation of **Community Computer Centers**, providing computing sites with Internet hookup in inner-city areas. The progam's purpose is to provide health and environmental information to populations that may not have computer access. The program is initially focusing on establishing centers in African American churches to build on the strong relationship that traditonally exists between these churches and their congregations.
- **Neighbor to Neighbor**, a community initiative bringing people together to learn about specific things they can do to improve their health, environment and quality of life. Neighborhood residents form teams, which meet regularly with a trained leader in each others' homes. With the help of a trained leader, the teams learn about simple things that all of us can do to improve the health and environment, and choose specific actions to help save energy, minimize waste or improve health.
- Creation of **Community Advisory Panels** (CAPs), an outreach mechanism to bring neighborhood concerns to the attention of local plant facility managers. The CAPs help citizens better understand how facilities are working with hazardous materials on site. Participants meet regularly to discuss plant operatios, facility environmental and safety programs, etc.

TESTIMONY OF J. CLARENCE (TERRY) DAVIES
Senior Fellow, Resources for the Future
Before the
U.S. Senate, Committee on Environment & Public Works

July 27, 2000

I am pleased and honored to be able to share with the committee my views on the important subject of comparative risk assessment. My views are only that and do not represent the institutional position of Resources for the Future (RFF). RFF is a research institution that does not take positions on policy issues.

Comparative risk assessment (CRA) is an important analytical tool that deserves the attention this committee is giving it. The fundamental goal of most of our environmental programs is to reduce or prevent risk. Thus, identifying and comparing risks is a logical starting point for evaluating progress and identifying future directions and priorities.

There are, however, important limitations inherent in the use of CRA. Most importantly, we have no common metric to deal with the many diverse kinds of risk that government addresses. When I was at EPA we referred to this as the "how many whales is your grandmother worth" problem. How do we weigh the risk of pesticide poisoning of trout streams to the risk of causing cancer in humans? How do we compare the risk of cancer to the risk of long-term neurological damage? How do we compare one type of cancer to another?

There are answers that can be given to these questions, but the answers are heavily dependent on values. Even if scientific understanding were perfect and data were complete and accurate, the value elements inherent in CRA would prevent CRA from ever being a purely scientific undertaking. The science and the data in most cases are woefully incomplete, and this adds further elements of uncertainty and value judgment to CRA.

Different Types of CRA

There are different kinds of CRA, and some distinctions are important. In particular, there is a basic difference between comparing individual pollutants or activities and comparing programs. Comparing mercury to lead is very different from comparing air pollution to water pollution. This hearing is focusing primarily on the latter, on programmatic CRA, and it's important to keep this in mind.

More generally, the type of CRA undertaken, and the process used to make the comparisons, should depend on the purpose for which the CRA is being done. Doing a CRA to establish research priorities involves different considerations than CRA to establish enforcement priorities.

Uses of CRA

CRA serves a variety of different purposes. Among the more important:

–CRA serves to focus people on the question of what are the benefits of a program or action, what are we getting for the resources expended. In this sense, CRA and the Government Performance and Results Act (GPRA) serve the same beneficial purpose.

–CRA can be a starting point for setting budgetary and other priorities. In a recent evaluation of pollution control efforts in the United States, I questioned whether EPA priorities were in line with risk considerations, given that most of the risks identified as highest in CRA analyses ranked lowest in EPA budget expenditures. However, such comparisons of risk rankings to budget expenditures are useful only in a broad sense. There are other important factors, aside from risk, that should and do enter into budgetary priorities.

–CRA can serve to identify neglected problems. Indoor radon is a good example of a problem where analyzing the risks highlighted an environmental problem that was receiving little

attention. David Konisky at RFF has recently completed an analysis of all the CRA efforts undertaken to date in the United States, and his analysis shows how some neglected problems have surfaced. With your permission, I would like to submit this paper for the record.

–CRA, like all good analysis, can make the assumptions behind decisions more transparent. These may be assumptions as to why something was not done as well as to why something was. We all know the very high risk of cigarette smoking. Documenting the high risk encourages us to ask why more action is not taken and what alternative courses of action are available.

–CRA helps to identify needed data. Very often, in the process of asking about relative risks, we discover we do not have the data necessary to answer the question. For example, of the 80-100,000 chemicals in commercial use, we have adequate toxicity information about only a few hundred.

–CRA can catalyze and mobilize opinion so that action can be taken. CRA, especially at the state or local level, can be a way of getting people to agree on an agenda for action and then to act. Arguably, most of the recent state CRAs have been as much about political mobilization as about risk analysis.

Limitations of CRA

As I noted at the beginning of my testimony, the assumptions and values that unavoidably enter into both risk assessment and CRA are a major consideration. Risk assessment is an odd mixture of science and non-science, and CRA necessarily suffers from all of the limitation of risk assessment.

CRA suffers from additional methodological problems. For example, how should the risk-reduction effect of current efforts be considered? If there were no public programs to protect

drinking water in this country, drinking water would rank among the highest risks, as it does in many developing countries. However, because there are protection programs, the current risks from drinking water in the U.S. are not great. In the context of budgeting, for example, this poses difficulties for CRA. We cannot do zero-based budgeting if the analysis of risks assumes current levels of spending.

Most importantly, CRA deals only with risk, and risk is only one of several factors that should enter into most government decisions. Cost is an obvious other factor. To the extent that decisions should be based on cost-benefit analysis, risk gives only the benefit side of the equation. Furthermore, you cannot do a cost-benefit analysis of a problem, only of a solution. Whereas CRA deals with problems, cost-benefit deals with solutions. So getting from one type of analysis to the other is not simple because the two types of analysis are analyzing two different sets of things.

Aside from risks and costs, public decision makers need to consider such things as due process, administrative feasibility, legality, and political support. No one has yet developed an analytical method for putting together all these factors.

Two other limitations of CRA should be noted. First, how the CRA is done can have an important effect on its outcome. Konisky's paper shows that how broadly the categories are defined (e.g. particular pollutants vs. outdoor air pollution vs. all air pollution) can make a big difference in the resulting risk ranking. Second, how and when to involve the public in the process poses a variety of questions. The value aspects of CRA mean that the public should play a key role. However, this raises problems of how to incorporate technical and scientific information. Granger Morgan at Carnegie-Mellon University and others are conducting interesting experiments on this question.

The Statutory Context

Congress has given EPA only limited flexibility. With approximately 1,000 pages of legally binding guidance, there are only a few choices left to the Air Office, for example. No amount of analysis will change the basic agenda of EPA, which is set by the environmental statutes.

Many, arguably most, provisions of EPA's laws are not based on risk. For example, most of the standards in the Clean Water Act are technology-based standards, so analysis of risk is, at least in theory, irrelevant to setting these standards. Even where Congress has employed risk-based standard setting, as with the National Ambient Air Quality Standards (NAAQS), the scientific basis is sometimes deficient or outdated. The statutory language on NAAQS assumes a risk threshold (a level below which there is no risk) whereas we have understood for more than a decade that there is no threshold for most of the criteria pollutants. It is difficult to use good science to make decisions if the relevant statutory provisions do not allow good science to be used.

The fragmented, medium-based (air, water, soil) nature of the pollution control laws, programs, and budgets also hinders the use of CRA. Most risks cut across media lines, so the scientific data about risk does not follow the budgetary or program categories. The risks of arsenic are within the purview of the air office, the water office, and the office of solid waste. Nitrogen poses risks in air, water, and soil. Climate change is an air problem, a water problem, and a land problem. The United States is one of the last industrialized countries to cling to a non-integrated pollution control system, and difficulty in using risk information is one of the penalties we pay.

Conclusions

Despite its limitations, CRA is a valuable analytical tool. It may be most useful for the questions it raises and as a way of initiating a process leading to more transparent and defensible decision-making. How well it serves these functions will depend heavily on whether Congress itself asks for relevant risk information and uses the answers in its budgetary, oversight, and legislative actions.

TESTIMONY OF ELIZABETH L. ANDERSON

Before the Senate Environment and Public Works Committee

October 3, 2000

My name is Elizabeth L. Anderson. I am President and CEO of Sciences International, Inc., (Sciences) a consulting firm headquartered in Alexandria, VA, that specializes in providing support to the public and private sectors on health and environmental issues. Previously, I was Director of the first Carcinogen Assessment Group (CAG) and the expanded Office of Health and Environmental Assessment (now the National Center for Environmental Assessment) at the U.S. Environmental Protection Agency (EPA). I established and directed the Agency's central risk assessment program for 10 years, and was Executive Director of the Committee that recommended adopting risk assessment and risk management as EPA's approach for regulating carcinogens and later other toxicants. The Committee also wrote the Agency's first risk assessment guidelines. I represented EPA on numerous interagency committees. I am also a founder and past president of the Society for Risk Analysis and am currently Editor-in-Chief of *Risk Analysis: An International Journal*, which is published bimonthly by the Society and serves as an international focal point for new developments in risk analysis for scientists of all relevant disciplines.

I frequently serve as a peer reviewer for governmental organizations on issues dealing with risk assessment. For example, I recently served as a peer reviewer for the South Carolina Department of Health of the document Assessment and Recommendations for the South Carolina Air Toxics Standard; I am a member of the External Review Committee, Los Alamos National Laboratory; I chaired the External Review Committee, United States Department of Agriculture's Office of Risk Assessment and Cost-Benefit Analysis; and I served on the Board of Scientific Counselors, Committee to Review EPA's National Health and Environmental Effects Research Laboratory. I currently serve on a National Academy of Sciences/National Research Council Committee and am a peer reviewer for the Academy. A copy of my Resume is attached.

32 **Purpose of This Testimony**

33

34 Although Sciences is involved in a wide range of risk assessment issues and
35 investigations, a focus of the research and analysis work conducted by me and my colleagues at
36 Sciences is improvement in the sciences that support human health and environmental exposure
37 and risk assessments, such as those conducted today as part of EPA's comparative risk
38 assessments and the hazardous air pollutant (HAP) residual risk program. A major need in
39 comparative risk assessment is development and use of scientifically supported methods and data
40 to identify and appropriately address areas of most important environmental risk. This need is
41 evident most recently in EPA's mandated HAP residual risk program which involves an
42 unprecedented use of risk assessment and is being required while the science of risk assessment
43 is still very much in flux. In that program, over 175 industry categories subject to maximum
44 achievable control technology (MACT) standards currently being developed must have residual
45 risk assessments completed to serve as the basis for risk management decisions. These risk
46 assessments are required eight years after promulgation of each MACT standard and will in total
47 involve emissions of the 188 HAPs from literally thousands of facilities. The risks must also be
48 estimated for all types of climates and terrains, wide ranges of population distributions, direct
49 and indirect (i.e., multipathway) exposures, human and ecological effects, and consideration of
50 maximum individual as well as total population risk. This would be an extremely difficult and
51 challenging task for any risk assessment program.

52

53 My purpose today is to provide my thoughts on the direction and progress of the use of
54 risk assessment by EPA and what actions might be taken that would make that use more effective
55 and more soundly based in science and, thus, more responsive to our nation's needs. My
56 analysis is based largely on two important recent documents which describe how EPA is
57 currently intending to apply risk assessment. The first is the *Residual Risk Report to Congress*
58 (Report No. EPA-453/R-99-001), which was published in March 1999 and provided the
59 Agency's broad scientific guidelines for managing that program. The second is EPA's first draft
60 residual risk assessment document which was released for Science Advisory Board (SAB)
61 review in January of this year. It provides the first detailed application of the guidance from the

Report to Congress for performing residual risk assessments, and was applied in a case study to the secondary lead smelting industry.

Let me briefly describe the comparative risk and residual risk assessment programs and their goals. Then I will identify a number of issues that make risk assessment complex and implementation of these programs exceedingly difficult. Finally, I will offer several recommendations for improving the risk assessment process.

Comparative Risk Assessment

Comparative risk assessment is broadly the process whereby human health and environmental risks are identified and evaluated and the risks compared to assist in setting priorities and in making informed regulatory decisions. At the core of the process must be sound risk assessment science and stakeholder participation to provide the necessary framework for sound and socially responsible decision-making. Comparative risk assessments typically look at all types of risks in all environmental media and seek to provide sufficient information to make appropriately informed decisions. These decisions must necessarily rely on the identification and use of accurate risk assessment methods and data.

EPA's Residual Risk Regulatory Program

Risk assessment is currently being used in EPA's residual risk regulatory program. The 1970 Clean Air Act Amendments first required the EPA to identify and then regulate HAPs to levels that provide an "ample margin of safety to protect the human health." The term "ample margin of safety" was defined by EPA in 1989, after the U.S. Court of Appeals ruled that the first step in the regulation of a hazardous or toxic air pollutant was to determine a safe or acceptable level of risk based only on health factors without regard for technical feasibility or cost. However, the regulation of HAP exposures without consideration of social and economic costs or technical feasibility was difficult to implement and only seven HAPs were regulated under the 1970 Amendments.

93 Consequently, Congress established in section 112 of the 1990 Clean Air Act
94 Amendments (1990 Amendments) a new regulatory process for HAPs. First, a list of HAPs was
95 specifically mandated by Congress and EPA was required to publish, over an eight-year period,
96 MACT standards for the sources of the listed HAPs. Next, eight years[1] after publication of each
97 MACT standard, the EPA was required to promulgate additional standards if needed to ensure
98 protection of public health and the environment. In other words, the risks remaining after
99 imposition of the MACT standards, the so called residual risks, would be determined and
100 additional controls imposed if those risks are judged not to meet the "ample margin of safety"
101 criterion. The EPA began publishing MACT standards in late 1993 and was supposed to be
102 completed with the entire program this year, although that is unlikely to happen.
103
104 While relatively straightforward in concept, implementation of the residual risk
105 requirements under section 112(f) of the 1990 Amendments has been difficult and is far from
106 complete. One hurdle was cleared with the definition of ample margin of safety in 1989. EPA's
107 published risk decision-making policy set as a goal: "(1) protecting the greatest number of
108 persons possible to an individual lifetime cancer risk level no higher than approximately one in
109 one million (1×10^{-6}), and (2) limiting to no higher than approximately one in ten thousand ($1 \times$
110 10^{-4}) the estimated risk that a person living near a source would have if exposed to the maximum
111 concentrations for 70 years." EPA further stated that a maximum individual risk (MIR) of one in
112 ten thousand should ordinarily be the upper end of the range of acceptability. As risks increase
113 above this benchmark, EPA stated that they become presumptively less acceptable under section
114 112, and would be weighed with the other health risk measures and information in making an
115 overall judgment on acceptability.
116
117 This risk policy has largely been accepted and it was codified in the 1990 Amendments in
118 section 112(f)(2)(B). However, it has limitations in that it only addresses cancer, inhalation
119 risks, and risks to individuals. We now know that many HAPs are not carcinogens, that humans
120 can be exposed through ingestion and skin contact, and that broader population risks must also
121 be considered in addition to individual risks. EPA has not yet provided complete guidance for

[1] The first group of MACT standards was given nine years.

how to treat noncarcinogens and population risks in making decisions under the residual risk program.

Recognizing that substantial work remained to be done in planning and implementing the residual risk requirements of the 1990 Amendments, Congress required in section 112(f)(1) that the EPA submit a report to Congress that describes Agency plans for complying with the requirements of the 1990 Amendments dealing with residual risks. As noted above, EPA submitted in March 1999 the final *Residual Risk Report to Congress* (Report No. EPA-453/R-99-001). The report describes a residual risk assessment strategy design that involves at least two tiers of risk assessment–a screening assessment followed by more refined assessment for those HAPs and sources with a potential for excess human health or environmental risks. A specific concern of mine is that the necessary refined levels of assessment, the methods for estimating the refined risks, and the criteria for determining when and how they are to be used, have not been articulated. Some of the specific scientific and technical issues are described below.

Scientific and Technical Issues

There are several scientific and technical issues that will be important to many future residual risk and comparative risk assessments, issues that have not yet been fully addressed. For example, section 112(f)(2) in the 1990 Amendments requires consideration of the environmental effects (also called ecological effects) of HAPs in addition to human health effects. This requirement was new in the 1990 Amendments and encompasses risks to wildlife, aquatic life, or other natural resources. These risks largely result from HAPs, such as PCBs, dioxins, and mercury, that are persistent and can bioaccummulate. The EPA has published broad guidance for conducting ecological risk assessments (*Guidelines for Ecological Risk Assessment*, EPA/630/R-95/002F, April 1998), but substantial interpretation and judgment are necessary for their application.

As noted above, HAPs in the past were defined and regulated primarily based on adverse effects resulting from inhalation of the pollutant by humans. More recently, the EPA has begun broadening this to consider all potential routes of exposure. For example, HAPs may deposit on,

153 and be adsorbed into soil, plants, and surface waters with which humans can come in contact.
154 Contaminated food crops, animal food products, and fish that are consumed by humans may
155 result. These risks, too, are largely associated with HAPs that can bioaccummulate. Other EPA
156 programs are requiring multipathway risk assessments in some instances but multipathway risk
157 assessment is new to EPA's residual risk program; to date, the principal experience has been with
158 hazardous waste combustion sources and some hazardous waste sites. One problem is that
159 multipathway risk assessments have typically been designed and applied to individual facilities
160 and they require extensive data and analysis. When these applications are focused on facilities,
161 the use of site-specific data in lieu of generic assumptions is found to make an important
162 difference in the risk outcome. Application to broad source categories is a very different matter.
163 These assessments will tend by necessity to rely on conservative (meaning health protective),
164 generic assumptions. However, intensive and focused efforts are needed to identify the generic
165 parameters that are the risk-drivers through a sensitivity analysis to replace the generic
166 assumptions with more accurate scientific data..
167
168 EPA is also considering the estimation of broader population risks in addition to
169 individual risks in the residual risk program. For example, EPA's ample margin of safety
170 language requires the protection of the "greatest number of persons" to a risk no greater than one
171 in one million. However, the manner in EPA will address population risks has not yet been
172 defined. One risk characterization process was described in the 1994 National Research Council
173 report (S*cience and Judgment in Risk Assessment)* as including two population risk metrics: (1)
174 distribution of individual risk across the exposed population (e.g., the number of individuals at
175 risk in various risk intervals such as 10^{-3} to 10^{-4}, 10^{-4} to 10^{-5}, and 10^{-5} to 10^{-6}), and (2) estimated
176 population risk, expressed as average annual incidence.
177
178 **Current Application of Residual Risk Assessment**
179
180 To date, as noted above, EPA has completed just one draft residual risk assessment, a
181 case study of the secondary lead smelting industry, which was reviewed by EPA's Science
182 Advisory Board (SAB) on March 1 and 2, 2000. I reviewed this draft assessment in detail and
183 presented oral comments to the SAB. In my comments, I concluded that the SAB's comments

184 on the earlier *Residual Risk the Report to Congress* had not been fully addressed in formulating
185 the case study. Significant gaps in the science, the methods, and the data remain that can only be
186 resolved through more detailed assessment, often including source and site-specific assessments.
187
188 EPA appropriately described a tiered process where an initial, conservative screening
189 assessment is done to conserve resources. Depending upon the results, the tier one assessment is
190 to be followed by a more refined assessment; where risk outcomes are low, this screening
191 assessment can indicate no further study is needed. However, where risks are of possible
192 concern, a clear commitment is needed to refine the screening level assessment and to articulate
193 criteria for when and how to provide a more accurate assessment. Currently, EPA has not
194 provided clear guidance on the necessary levels of refinement, the methods and data to be used,
195 or even the criteria for deciding when and how to initiate the refined assessment. These are
196 critical to making responsible and scientifically sound regulatory decisions. While I am sensitive
197 to the Agency's resource limitations and the resultant inability to conduct full site-specific risk
198 assessments for every HAP source in every source category, I believe that more refined source
199 data can often be reasonably obtained and utilized to further refine the assessments. The Agency
200 must be equally sensitive to the profound potential economic impacts of further residual risk
201 regulation of sources that have already expended tremendous resources in meeting MACT
202 standards. I strongly support the need to further regulate any source that is found to clearly and
203 unambiguously exceed acceptable risk levels. However, I do not believe it is in the nation's best
204 economic interest to force needless expenditures when residual risks are not excessive. A refined
205 risk assessment is needed in order to make these determinations. The use of upper bound generic
206 approaches usually provides a poor basis for regulatory actions.
207
208 Even implementation of the two-tiered strategy described in the Report to Congress is
209 associated with a number of likely problems. First, given the growing complexity of the science
210 of risk assessment and the wide variability in HAP sources, more than two tiers of risk
211 assessment will usually be needed to ensure relative accuracy as well as cost- and resource-
212 effectiveness. These considerations are necessary because screening risk assessments, with rare
213 exception, estimate risks that are excessive, which can mislead the regulatory process,
214 unnecessarily raise public concern, and possibly miss identification of the most important risks.

215 Recent studies that I and my colleagues at Sciences have conducted concluded that these two
216 tiers of risk assessment can be associated with risk differences of several orders of magnitude.
217
218 The Report to Congress also implied that the EPA would conduct all of the necessary
219 residual risk assessments for the more than 175 source categories. However, our knowledge of
220 the EPA HAP regulatory program and staff, based on past working relationships and recent
221 personal communication, indicate that the Agency almost certainly does not have the resources to
222 accomplish this enormous assignment. The more likely outcome is that the EPA will rely on
223 more simplified models and averaged, rather than site-specific, data. This approach will
224 typically define residual risk estimates that are greater than actual risks. These simplified
225 approaches cannot adequately inform regulatory decisions.
226
227 With inadequate resources and substantial data gaps, I can see no way for EPA to carry
228 out the residual risk program within the prescribed time without outside partnerships to aid in
229 developing appropriate information, working together, where possible, to ensure that the best
230 data and methods are used in the Agency's analyses, and filling the EPA's resource shortfall with
231 analytical and data gathering support. In addition, with risks estimated using "model plants,"[2]
232 and other approaches that rely on averaged data, industrial facilities will often need to ensure that
233 more site-specific data and methods are employed to determine whether the model plant risks are
234 realistic. In our work, we have found that these averaged approaches typically lead to risk
235 overestimates.
236
237 For many industrial source categories, the initial conservative screening assessment could
238 find that residual risks are unlikely to exceed levels of concern at any industrial facility and no
239 further risk-related regulation would be forthcoming. However, for many other source
240 categories, much more accurate and rigorous assessments may be needed in order to determine
241 whether further regulation is required. In other words, if a screening approach indicates risks
242 near or above presumptively acceptable risk levels, or ecological, population, or multipathway

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[2] Model plants are generally composites serving as average examples of groups of typical industry facilities.

risks are potentially indicated, much more detailed and accurate assessments will be indicated. A sensitivity analysis should be performed early in the process to determine those site-specific parameters that are the most important to the risk outcome. These are called the risk drivers. Data collection can then be focused more cost-effectively. In some cases, individual facility, site-specific risk assessments using probabilistic exposure and risk assessment techniques will be required to define the most realistic risks for the facility. The criteria and methods for conducting these more refined assessments must be established, including the following:

1. Detailed characterization of the industry sources (point and area) including location and dimensions of all emission sources, emission quantities, building sizes and shapes, and other relevant factors.
2. Detailed characterization of the surrounding terrain, including U.S. Geological Survey topographical and digital elevation maps.
3. Detailed characterization of the population distribution, often within 50 kilometers around the facilities.
4. Hourly, on-site meteorological data or, if not available, long-term data from the nearest National Weather Service station.
5. Specific emission characteristics, including release height, temperature, and velocity, and duration and upset conditions.
6. Agreement on appropriate dispersion models to be used.
7. Agreement on, and often reanalysis of, appropriate health criteria to be used for the emissions (see the discussion of the IRIS database later in this testimony).
8. Agreement on, and often reanalysis of, other health effects besides cancer risks to be considered.
9. Identification and assessment of possible ecological concerns.
10. Identification and assessment of multipathway effects, including defining realistic pathways and receptor considerations (e.g., it is rare that a farmer eats 100% of his daily diet from farm grown poultry, beef, pork, and produce).

Specific Areas of Concern with EPA's Residual Risk Case Study

274 The process used by EPA in its first residual risk assessment was an appropriately
275 conservative first step that is useful for setting priorities for assessment while conserving Agency
276 resources. However, as presently developed and described by EPA, the process remains a
277 screening tool that can reasonably exclude sources from further assessment, but cannot with
278 accuracy determine whether the residual risks associated with any specific source are above or
279 below accepted levels of risk concern. If used more broadly, the process is almost certain to
280 result in a significant number of false positives–namely, sources for which additional regulation
281 appears needed when, in fact, the actual risks are below acceptable levels of concern. This
282 outcome is likely to occur because screening level risks are calculated without properly
283 accounting for the many limitations and uncertainties in the data, models, and methods used by
284 EPA in conducting the assessment, and because of the intentional bias to protect public health
285 where data are uncertain. Inappropriate regulation can only be prevented by the use of much
286 more refined assessment, often including site-specific or category-specific data, thus allowing the
287 decisions needed to support further regulation of those sources that require further control. One
288 illustrative example of the problem caused by reliance on screening tools was an initial screening
289 level analysis that indicated that most of the nation's coke ovens were above EPA's acceptable
290 cancer risk level as provided in the 1989 benzene decision. Site-specific analysis of several
291 facilities using improved data, a better model which we developed, and health criteria that we re-
292 evaluated, actually found residual risks to be on average three orders of magnitude below the
293 screening level risks and actually well below EPA's acceptable cancer risk level.
294
295 In cases where substantial uncertainties and significant limitations in data exist, risk
296 management decisions should not be made until these limitations are appropriately addressed. In
297 its initial residual risk assessment of the secondary lead smelting industry, EPA concluded that
298 the risk estimates likely fell "between the estimates made with and without fugitive dust
299 emissions." This risk range spanned more than two orders of magnitude and is so large that the
300 results are impossible to interpret. In this case, at a minimum, better quality, site-specific data of
301 such risk-drivers are needed to refine the risk assessment so that the results are useful.
302
303 EPA's use of conservative methods, models, data, and assumptions early in a source
304 category analysis is appropriate to conserve Agency resources and help prioritize actions for later

305 analysis. However, the use of implausible and unrealistic methods, models, data, and
306 assumptions, particularly when better methods and data are easily obtained, is clearly
307 inappropriate and in this case led to a number of potentially erroneous conclusions. For example,
308 EPA's first draft residual risk assessment resulted in risk estimates high enough that (if true)
309 serious adverse human health and ecological effects would likely be easily observable in the
310 nearby areas. However, the lack of apparent evidence of significant human or ecological impacts
311 near the sources of concern gave every indication that EPA's estimates were unrealistic.
312 Inaccurate and incomplete data, coupled with excessively conservative assumptions, lead to
313 excessive risk estimates. Two specific examples are described below:
314
315 1. The assumption in the residual risk assessment that a local farmer obtains
316 drinking water from an untreated local surface water source that exceeds
317 maximum contaminant levels (MCL) for antimony is unrealistic. More
318 realistically, water would be obtained from wells or public water systems. This
319 assumption was not conservative, it was implausible.
320 2. The modeled surface water concentration near one facility resulted in estimates of
321 huge fish tissue concentrations and large potential risks to the recreational
322 fisherman. Moreover, the modeled concentrations were sufficient to cause serious
323 effects for aquatic organisms, such that there would be a question of fish
324 availability for consumption. However, the lack of collaborative evidence (e.g.,
325 fish kills in the vicinity of secondary lead smelters) indicated that the estimates
326 substantially over predicted actual concentrations. High estimated risks need to
327 be flagged and confirmatory information needs to be developed.
328
329 EPA's first residual risk assessment process also was incomplete because it left
330 unaddressed many potentially important issues that could have significant impacts on the
331 ultimate residual risk estimates. For example:
332
333 1. While EPA clearly put a lot of effort into many aspects of the risk assessment
334 process, it did not focus its data collection efforts on the most sensitive risk-
335 driving parameters. EPA further described the assessment as an "iteration,"

336 stating that it would be replaced with a more refined, and possibly site-specific,
337 assessment pending SAB's comments and any additional emissions information,
338 as necessary. Although EPA did not provide further details on the next iterations,
339 I believe that the SAB clearly should review the most refined assessment intended
340 to provide the best basis for their scientific evaluation and comment.

341 2. EPA identified major issues and uncertainties at the end of each section of the
342 assessment but the issues and uncertainties were only dealt with qualitatively and
343 no indication was provided as to how these issues and uncertainties would be
344 addressed in the context of the downstream risk management decisions on this or
345 other industry categories.

346 3. While EPA acknowledged substantial gaps in data, methods, and procedures, it
347 was not clear what the Agency will do about the missing information. EPA could
348 choose to move ahead with residual risk regulation based on this level of
349 assessment for this source category and plan to keep returning to the source
350 category to further revise the regulations every time new guidance or methods are
351 finalized; however, regulation based on inadequate assessment information will
352 undoubtedly lead to inefficiency and waste.

353 4. There was no discussion on how the risk assessment results will be applied in a
354 risk management decision.

355

356 EPA's first draft residual risk assessment also utilized emissions data gathered from
357 limited, short-term stack tests at limited numbers of facilities, which was then assumed to
358 represent long-term averages for all facilities. Fugitive emissions estimation procedures were
359 also admittedly poorly characterized and uncertain. Use of limited emissions data can
360 dramatically affect the risk results. The uncertainties are compounded by the fact that modeling
361 of fugitive emissions is much more difficult than for stack emissions. For example:

362

363 1. In its first residual risk assessment, EPA frequently stated that its estimation of
364 fugitive emissions is uncertain, but continued to use the uncertain data, which can
365 be a risk-driver, to develop risk estimates. The uncertainty in fugitive emission
366 estimates, especially for particulate matter, is common, owing to the technical

difficulty in capturing or measuring the emissions. This fact argues strongly that better data be gathered to minimize the uncertainties in the estimation of fugitive emission rates and composition, before these uncertainties are carried through the risk assessment.

2. EPA also used after-MACT emissions which were estimated to support the proposed MACT published in 1995, rather than actual, measured current after-MACT emissions. Because industries are typically complying with the MACT standards by the time (i.e., eight years after the MACT standard is published) the residual risk assessment is conducted, actual after-MACT emissions data should be used. The use of real world data, when available, even in the initial screening level assessment is appropriate.

Recent multipathway risk assessments typically prepared or overseen by EPA are much more site-specific than the evaluation presented in the first draft residual risk assessment. This assessment utilized numerous assumptions and procedures that were not only implausible, but easily corrected. Furthermore, many of the input parameters were questionable. If realistic comparative risk and residual risk regulatory and economic decisions are to be made using risk assessment, it is essential that the models, methods, data, and assumptions be appropriate, validated, and properly used. A major uncertainty arises from the use of models that are both incomplete and not designed to rigorously address the issues involved with residual risk assessment and regulation. In the residual risk assessment, for example:

1. The oral exposure-dose equations do not include a bioavailability factor, thereby assuming that 100 percent of a chemical is absorbed upon exposure. The assumption that the bioavailability of all chemicals is 100 percent is contrary to the scientific literature and has the potential of leading to considerable overestimates of exposure dose (e.g., absorption of a chemical that is adsorbed to particulates or soil may be significantly hindered).
2. The assessment also assumed that particulate matter concentrations are available in the breathing space of a resident near the source. Air concentrations directly produced from the air dispersion modeling are simply multiplied by an inhalation

398 rate to calculate the inhalation dose, and, hence, assume 100 percent retention and
399 absorption of this air concentration. In fact, a smaller percentage of inhaled
400 particles are retained in the lung, and depending on the size of the particulates,
401 some of the inhaled particulates will be deposited in the respiratory tract, where a
402 considerable fraction will ultimately be swallowed and should, therefore, be added
403 to the ingestion pathway where oral bioavailability would govern the absorption
404 of the chemical.

405 3. In many instances, default parameter assumptions were relied upon without
406 accounting for the characteristics of a site. The reliance on generic default values
407 for key parameters in lieu of site-specific data significantly decreases the
408 likelihood that the modeled exposures will provide a reliable indication of actual
409 exposures. Examples of inappropriate generic assumptions are: the assumption
410 that persons are exposed 24-hours per day to outdoor air at their residence; use of
411 home grown produce and animal products representing 100% of an individual's
412 intake of these products; use of default soil-to-plant uptake factors (these vary
413 considerably depending on soil types and local geochemistry); and, selection of
414 inappropriate exposure pathways.

415 4. Uptake of metals into fruits and vegetables often drives the home gardener's
416 indirect pathway risks and is one of the pathways for which great uncertainties
417 exist. Plant uptake also has important implications for the meat and milk
418 pathways. The generic guidance used in the first residual risk assessment greatly
419 simplified the methodology for assessing concentrations in fruits and vegetables.
420 This process has historically been subject to many different methodologies and
421 data sources and this pathway has been one of the most difficult areas for risk
422 assessors to model. The empirical values used to predict soil-to-plant transfer of
423 metals are approximate over a wide range of soil conditions. Soil geochemistry
424 (e.g., pH) is an important factor in the bioavailability of metals to plant roots and
425 governs metals uptake into the edible portions. It is recognized that sufficient
426 data often may not exist to characterize uptake using geochemical soil parameters
427 and, therefore, default uptake factors are often used. Nevertheless, where
428 pathways that rely on plant uptake drive the risks, a site-specific assessment must

account for the effect that local soil conditions have on plant uptake; the risk outcome most likely will be changed substantively.

5. The draft residual risk assessment concludes that the drinking water pathway accounts for 73% of the total cancer risk and 70% of the total non-cancer risk for a subsistence farmer at the site with the highest ingestion (indirect pathway) risks. Drinking water also accounts for 97% of the farmer's indirect exposure cancer risk and 79% of the indirect exposure non-cancer risk. Notwithstanding the fact that the surface water concentrations are likely to be overestimated due to the assumptions regarding fugitive and stack emissions and shortfalls in the dispersion modeling, the unrealistic assumption was made that nearby surface water is used untreated for drinking water purposes. It would be illegal for any public water supply system to supply drinking water with the estimated levels of contaminants.

6. Several key inputs to the air dispersion model were not included. For example, all of the emission points at a facility were assumed to be co-located at the center of a facility; fugitive emissions were modeled using the same source area at each facility; and building downwash and local terrain features were not accounted for. Inclusion of these inputs is easily accomplished and could have a significant impact on the resulting concentration estimates and risks.

The uncertainty/variability analysis in the first residual risk assessment was limited in its scope and usefulness. The purpose of an uncertainty/variability analysis is to focus on the facilities, pollutants, and exposure pathways with the highest risks identified in the multipathway analysis. The first residual risk assessment does not say how the quantitative uncertainty analysis will be used in the regulatory processes. In addition, the evaluation implied that most of the meaningful uncertainties had been accounted for and that the results supported and validated the point estimates. However, of four possible input parameter categories–emissions, transport and fate, exposure, and dose-response–only two, namely emissions and exposure, were addressed in the uncertainty analysis. Omission of two parameter categories sidesteps the issue of developing a complete framework for treating the risk quantification in a realistic manner. Furthermore, many exposure variables have not been studied to establish their chemical and

460 physical distributions (e.g., variability in consumption of farm grown produce and animal
461 products).
462
463 Even given the limited scope of the uncertainty analysis, the input parameters used in the
464 Monte Carlo analysis addressed only a narrow subset of the factors that influence the
465 deterministic risk outcomes. Emission variables that could not be quantified for probabilistic
466 analysis included: detection limits; test results from one facility used to quantify emissions at
467 another facility; frequency of plant closing; and, fugitive emission estimates. The study
468 ultimately relied on very limited emissions data. These are challenging issues that are resource
469 intensive to address but, nevertheless, can have an enormous impact on the risk outcome.
470
471 In the case study residual risk assessment for the secondary lead smelting industry,
472 screening level ecological risk assessment was conducted to estimate potential risks to aquatic
473 and terrestrial communities from HAPs emitted from the facilities that remained after the initial
474 screening. This screening level ecological analysis was intended to identify which HAPs require
475 more analysis and was designed to be conservative, with assumptions generally overestimating
476 actual exposure concentrations, thus overestimating the actual potential for ecological risks. The
477 ecological screen indicated a high potential for ecological impacts but the results are misleading
478 for the following reasons:
479
480 1. The screening level ecological assessment does not provide sufficient information
481 to draw appropriate conclusions as to whether an adverse environmental effect, as
482 defined in section 112(a) of the 1990 Clean Air Act Amendments, has occurred.
483 Section 112(a) states that "[T]he term 'adverse environmental effect' means any
484 *significant and widespread adverse effect* (emphasis added), which may
485 reasonably be anticipated, to wildlife, aquatic life, or other natural resources,
486 including adverse impacts on populations of endangered or threatened species or
487 significant degradation of environmental quality over broad areas." This appears
488 to provide a much broader definition of ecological effects than was used in the
489 case study, requiring significant and new methodological and data needs.

2. The ecological receptors are representative of sensitive species and communities at a generic site; no regard was given to site-specific information.

The Role of EPA's Integrated Risk Information System Database (IRIS)

The accuracy of comparative risks and residual risks relies heavily on toxicity criteria from EPA's IRIS database. Let me present here a brief history of the development of IRIS and why it is uniquely important to the risk assessment process. I will also discuss the limitations and problems of IRIS in meeting the Agency's current risk assessment goals.

IRIS is an electronic data base containing information on human health effects that may result from exposure to various chemicals in the environment. I played a significant role in establishing the IRIS data base at EPA. The initial purpose of IRIS was to compile health information into one central database, and to ensure internal consistency among the various EPA Regions' and Offices' health assessments. It was originally planned for internal use only, and was never intended for direct regulatory use without the careful scrutiny by the Agency. Indeed, the original disclaimer to the preface of each IRIS file clearly indicated that the IRIS summaries are subjected to constant revisions to incorporate new data and new methodology, are subject to review by EPA scientists, and are designed to be used to support risk assessments. There was no mention of any direct regulatory purpose for the IRIS data base.

In recent years, there has been increasing reliance on IRIS for toxicological information and regulatory guidance, even though the latter is inconsistent with its original purpose. In recognition of the need for a more streamlined approach to preparing IRIS assessments and to establishing consensus, the Agency recently initiated a commendable IRIS pilot program. Briefly, the program entails the development of chemical-specific "Toxicological Review" health assessment documents prior to updating or developing an IRIS summary, input from the public, and external peer review process. On April 1996, EPA announced in the Federal Register that 13 substances will be reviewed under the pilot program. To date, ten of the thirteen substances have been updated. Obviously, the progress made by the pilot program in updating the IRIS files has been slow, which could have serious impacts on a program, such as the residual risk assessment

521 program, which have a required completion schedule. The IRIS database currently contains over
522 500 chemicals, including the 188 HAPs required to be regulated in the residual risk program.
523 Many of the IRIS files are outdated and, while updating is laudable, ten updates in four years is
524 an entirely inadequate response. Reasons for the slow progress include resource limitations. In
525 addition, new advanced methods to perform RfD's/RfC's and cancer assessments are being
526 developed, including new methods for dosimetric adjustments, benchmark dose methodology,
527 categorical regression analyses, biologically-based models with consideration of mechanism of
528 action, and physiologically-based pharmacokinetic (PBPK) models. Thus, updating an IRIS file
529 necessitates not only updating and evaluating the most recent literature but also reassessing the
530 data using these new and complex methods.
531
532 As mentioned earlier, EPA's first residual risk assessment relied on toxicity criteria
533 obtained from IRIS. However, the IRIS files were not reviewed to determine whether they were
534 outdated. If a particular chemical is a risk driver in the residual risk assessment, the validity of
535 the toxicity factors used must be investigated. Acceptance of published IRIS criteria without
536 review can lead to considerable uncertainty in the final residual risk results. For example,
537 reevaluation of EPA's cancer unit risk value for coke oven emissions by my company found,
538 using updated epidemiological data and techniques, that the actual cancer unit risk factor is about
539 one-fourth of the IRIS "official number" for coke oven emissions which was prepared in 1984
540 under my direction. That evaluation was intended only as an initial value pending publication of
541 epidemiology studies that were undertaken at the time. However, our reevaluation was provided
542 to EPA about two years ago, but IRIS still has not yet been updated. Clearly, a 1984 evaluation
543 based on limited and unpublished data is inadequate for use in regulatory decision-making in
544 2000.
545
546 In summary, IRIS was not originally intended to be used for regulatory purposes or for
547 that matter to provide complete toxicological data on a particular chemical. It is most useful as a
548 screen that allows one to quickly access toxicity information that may be of help for risk
549 assessment purposes. It is clear that there is a serious need to update IRIS. The use of outdated
550 IRIS information has serious implications to the use of any risk assessment in decision-making.
551

552 Risk assessment provides a thorough evaluation of scientific literature as a basis for
553 regulatory decision-making and provides the impetus for improving the process in order to
554 facilitate better decision-making. Risk assessments support many different kinds of decisions.
555 In comparative risks assessments, the totality of the risks are viewed to improve priority setting,
556 decision-making, and stakeholder involvement. Residual risk assessments support specific
557 decisions mandated under the risk requirements of the Clean Air Act. These decisions demand
558 well thought out, comprehensive, and scientifically supported risk assessment methodology.
559 This need poses an unprecedented challenge for EPA to develop the processes and then conduct
560 comprehensive risk assessments across a range of chemicals, sources, and regulatory programs.
561 This places heavy resource demands on EPA, and the required resources may not be available.
562 Nevertheless, it would not serve our nation well to make regulatory decisions under any program
563 by defaulting to generic risk assessment approaches or using out of date data files in IRIS
564 because of resource constraints. The best science should form the basis for risk management
565 decisions; otherwise our decisions are not well informed and can be flawed. It is also crucial for
566 all stakeholders to have at least some understanding of how EPA intends to use the information
567 developed in the residual risk assessment to make risk management decisions. Only then can the
568 assessment's adequacy be judged.
569
570 The first residual risk assessment conducted by EPA is not sufficient to meet the needs of
571 decision-makers under the residual risk program. At best, it presents a process that can only be
572 described as a screening assessment, even when including multipathway and ecological analyses.
573 A screening assessment is a necessary part of the initial risk assessment process for this program,
574 but it falls far short of the refined risk assessment (based on more source-category specific data)
575 that is required to make regulatory decisions.
576
577 Earlier this year, the SAB reviewed the EPA draft residual risk assessment method and its
578 first application to the secondary lead smelting industry. Because the method requires
579 substantial improvement, it is essential for the SAB to review the next draft of this approach.
580 More refined risk assessments should not simply be screening assessments with more data;
581 rather, they should rely on new methods and approaches to address important risk factors such as
582 when to refine conservative screening values, how to assess population risks, how to characterize

583 after-MACT standard emissions, how to assess "significant and widespread adverse" ecological
584 risk, when monitoring data are more suitable than modeled data, and what criteria will be used to
585 determine when the risk assessment process will be triggered. These methodological issues need
586 to be reviewed by the SAB because they are not settled matters in the realm of risk assessment
587 and will be of generic importance across most, if not all, of EPA's risk assessment programs.
588
589 Any more refined risk assessment methodology should be characterized by the use of
590 category-specific, and selected site-specific, data for the elements that are the risk-drivers as
591 identified in screening assessments. The generic assumptions used in a screening assessments
592 such as those conducted by EPA are designed to be conservative; consequently, they can
593 generate many false positives. Regulatory decisions cannot be based on such assessments; more
594 specific data are needed to determine whether or not actual residual risks of concern exist. While
595 this task varies in degree of difficulty, EPA can focus its further data collection on those
596 elements identified by the screening assessment as the risk-drivers. Much of those data should
597 be readily obtainable.
598
599 The residual risk assessment methodology should also explicitly incorporate realistic
600 assumptions and data in both the screening and more refined phases of the assessment. As seen
601 in EPA's case study assessment of the secondary lead smelting industry, implausible or
602 unrealistic assumptions, methods, and data can fatally skew the results of an assessment. Such
603 results have the potential to cause needless data gathering by EPA and industry in order to
604 demonstrate that nonexistent risks are not real; unfounded public concerns may also be avoided if
605 the results of a screening assessment are immediately scrutinized to determine if they are
606 realistic.
607
608 Finally, if the IRIS database is to be used for regulatory purposes or for that matter to
609 provide complete toxicological data on any particular chemical, it must be updated across the
610 board and then maintained in an up-to-date manner. The use of outdated IRIS information has
611 serious implications to the use of any risk assessment in decision-making.
612
613 **CONCLUSIONS**

614 Extraordinary complexity of the risk assessment is called for by the comparative risk and
615 residual risk programs. In 1976 when the first risk assessment process began at EPA, risk
616 assessment and risk management focused largely on single chemicals such as air pollutants and
617 pesticides. The complexity of risk assessment has grown over the years with the most complex
618 risk assessments being conducted at Superfund sites and for combustion sources. These risk
619 assessments addressed multipathway risk assessment issues and ecological risks but have been
620 focused on single facility or single sites. The comparative risk program and the residual risk
621 program as prescribed under the Clean Air Act Amendments of 1990, require unprecedented use
622 of risk assessment across the board for over 175 industry source categories and literally
623 thousands of facilities. In addition, the residual risk program, for example, must address the
624 toxicity of all 188 chemicals on the hazardous air pollutant; the comparative risk program needs
625 to address considerably more chemicals. Adding considerably more to the complexity, the
626 residual risk program calls for the use of multipathway risk assessment and regulation of
627 environmental risks with significant and widespread effects to wildlife, aquatic life and other
628 natural resources, including impacts on endangered or threatened species or significant
629 degradation of environmental quality over broad areas.
630
631 The current EPA guidelines for conducting the residual risk program (and there are no
632 such guidelines for the comparative risk program but it probably will follow much the same
633 process), primarily employ available data and generic and upperbound risk assessment
634 approaches. The guidelines mention a tiered approach but do not make a clear commitment to
635 proceeding to a clear approach where risks appear to be high nor are there any guidelines or
636 criteria for when or how to do so.
637
638 **RECOMMENDATIONS**
639
640 1. The unprecedented complexity and cost of conducting the risk assessment
641 program called for by both comparative risk and residual risk must be conducted
642 by a carefully orchestrated tiered approach. The first tier should employ the very
643 best available data and commit to an approach that provides the greatest accuracy
644 possible in the risk assessment at this stage so as to avoid unfounded public health

concerns over issues that may not be of substance. The risks that are so identified should also be subjected to an analysis to see if they appear to be unreasonably high. Several examples of such unreasonably high risk have been given in this testimony. For those sources that appear to have low risk after the Tier 1 assessment, no further work is needed. For other sources, if the risks appear high, a sensitivity analysis should guide further data collection to focus resources on refining those parameters, including toxicity values, to arrive at a more accurate risk assessment. Refined risk assessments that are focused on defining real risk are necessary to guide the risk management decisions. The resources necessary to conduct these risk assessments both within EPA and on the part of involved parties, need to be recognized. In addition, I see no way that these risk assessments can be refined without some kind of partnership to refine data with involved parties.

EPA's current draft guidelines fall far short of addressing a process that will ensure that any of these steps are followed beyond providing the initial upperbound risk assessment. The shortcomings of effort are laid out in considerable detail in this testimony.

2. Policy related issues need to be clarified. Historically, EPA has limited its risk guidance in the hazardous air pollutant regulatory program to carcinogens, inhalation risks, and risks to individuals, and has not addressed how broader population risk must be considered. Further, language in the 1990 Clean Air Act Amendments for residual risk states that environmental risks must also be considered. These policy issues together with how multipathway risk assessment will be considered under the residual risk program should be clearly articulated at this time. There should be an opportunity for public comment to arrive at final criteria to define how these issues are to be addressed and guidance must be developed to more accurately estimate the effects.

3. Emissions data must be improved. Historically, EPA has used readily available emissions data, for example using estimated rather than measured post-MACT

emissions, to estimate current risk. The risk assessment can be no more accurate than are the emissions that are used in the dispersion modeling.

I recommend first that the most accurate available emissions data be used in the Tier 1, screening level risk assessment. Second, for those sources that appear to be associated with risks of concern, I recommend that subsequent refinements in the exposure data be sought before a final risk assessment is completed. Again, I see no way for EPA to arrive at the necessary accuracy in risk assessment without a partnership with the organizations and facilities involved.

4. Use of the IRIS database, as a repository of operational, regulatory toxicity values, must be revised. Historically, the IRIS database was established to provide a repository for all of the information available in the agency with respect to toxicity for particular chemicals. Initially, it was primarily established to ensure consistency across agency programs and to serve as an internal data system to make available work that had been completed to date on individual chemicals. The Risk Assessment Forum, for which I was the first director, set up the IRIS database and commenced the stewardship program to enter new chemicals and to put in information that was existing in the agency at the time the data system was established. In the beginning, it was clear that the database was not necessarily intended for direct use in regulatory decisions without refinement; the preface reflected the fact that the database was not intended for these purposes. Since that time, however, the IRIS database has become not only the most important source of regulatory toxicity values for use across all of EPA's programs, but is widely used across state programs and internationally as well. The files for over 500 chemicals that are contained in this database are in many, many cases vastly out of date both with respect to the current literature and the use of current methods for dose response extrapolation. To illustrate the difficulties, EPA began in 1996 a full-scale review of 13 chemicals in IRIS. At this time, only 10 of those updates have been completed.

The current guidance that has been issued for the residual risk program, and practices for the comparative risk program, use these toxicity values as if they are intended for immediate regulatory use without refinement. This is inappropriate. All risk assessment programs in EPA, in particular in this instance, the comparative risk and residual risk programs, should explicitly recognize that these toxicity values are vastly out of date and must be refined where risk drivers are identified. This recognition should be part of the iterative process for the Tier 2 and subsequent stages of risk assessment refinement for these programs.

I recommend, as everyone else does, that resources be committed to EPA to update all of the over 500 chemicals in IRIS and to keep the database refined and up to date. In making this recommendation, I realize that this is an almost impossible task. Nevertheless, I think all efforts should be made to carry it out to the extent possible. To be totally practical, I further recommend that the preface to the IRIS database be re-stated to recognize reality, that is that the IRIS database can probably never be a current source of all the latest information in the literature with application of the latest risk assessment methodologies necessary to provide the accuracy essential in risk assessment to inform risk management decisions. I further recommend that a partnership be established between EPA and private institutions to refine toxicity values, particular in the Tier 2 part of a risk assessment process where risk drivers have been identified through a sensitivity analysis. By this method, we can focus precious resources on those most important factors that can improve the scientific basis for our decisions.

5. Uncertainty and variability analyses must be applied more explicitly. Historically, EPA has come to recognize the importance of performing variability and uncertainty analysis but to date has been able to do so only for a limited number of factors. the purpose of uncertainty and variability analysis is to focus on the facilities, pollutants, and exposure pathways of greatest concern to the estimated risks identified in the multipathway analysis. Four important parameter categories are emissions, transport and fate, exposure, and dose-response.

Further, historically the uncertainty and variability analysis has been stated in some cases only qualitatively and not quantitatively or, in some limited cases, there have been quantitative statements of uncertainty. All too often, this section of the risk assessment is an afterthought that is never mentioned again in the risk management process.

I recommend that there be clear guidelines developed for the use of uncertainty and variability analysis in making risk management decisions. I recognize that this may be a difficult task to undertake but I think it is an important one. For example, the first guideline could be that where uncertainty is so great, a next tier of risk assessment is necessary before any informed risk management decision can be made. Secondly, where a risk management decision is based on a risk assessment that is highly uncertain, the decision should be considered an interim decision until more refinements in the data and methods can be accomplished. There should be a clear commitment to revisit that decision as soon as the improved risk assessment information is made available. I feel certain that guidelines such as I have suggested here could be developed that would ensure that appropriate use of uncertainty and variability analysis is made during the entire risk assessment and risk management process.

Thank you for the time to address this Committee, I would be happy to entertain any questions you may have.

10/02/00

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Date

STATEMENT OF

LEE P. HUGHES

VICE PRESIDENT
CORPORATE ENVIRONMENTAL CONTROL
BAYER CORPORATION

on behalf of the

AMERICAN CHEMISTRY COUNCIL

before the

SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

on

CLEAN AIR ACT RESIDUAL RISK

October 3, 2000

I. INTRODUCTION

Good morning Chairman Smith, Chairman Inhofe, Senator Baucus, and Members of the Committee. My name is Lee Hughes and I am Vice President of Corporate Environmental Control for Bayer Corporation. I have responsibility for environmental matters for Bayer's United States (U.S.) operations, including compliance with the Clean Air Act (Act).

I am here representing the American Chemistry Council (Council). The Council represents the leading companies engaged in the business of chemistry. Our members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. As we conduct our business, we are committed to:

- improved environmental, health and safety performance through Responsible Care®,
- common sense advocacy on major public policy issues, and
- health and environmental research and product testing.

The business of chemistry is a $435 billion-a-year enterprise and a key element of the nation's economy. The chemistry industry is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. This industry invests more in research and development than any other business sector.

I commend Chairman Smith, Chairman Inhofe, and Senator Baucus for holding this hearing on the important subject of residual risk under the Act. The Council supported the 1990 Clean Air Act Amendments, and for more than a decade has actively and collaboratively worked with the Environmental Protection Agency

(EPA) on its development of many air toxics programs. We are proud of the tremendous progress we have made reducing air toxics. For example, American Chemistry Council members led all other U.S. businesses in cutting emissions of 30 key hazardous air pollutants (HAPs) reported under the Toxics Release Inventory (TRI) since 1990. While all U.S. manufacturing facilities reduced emissions of these HAPs by 52 percent, Council members cut our emissions of these substances by 64 percent.

Our industry supports the Clean Air Act's approach for regulating air toxics, which first requires technology-based controls and then looks at any remaining or "residual" risks. We believe the residual risk effort can build on air toxics reductions to date and evolve into a scientifically credible and effective regulatory program that characterizes, prioritizes, and manages identified risks.

There are some early warning signs, however, that barriers exist to achieving this goal. Your attention to this program, contemplated by the Act, is an important step toward identifying, understanding, and addressing these challenges. I would like to talk today both about the progress we have made on air toxics as well as the issues we need to address to ensure that the residual risk program gets off on the right track.

II. THE CHEMICAL INDUSTRY HAS SIGNIFICANTLY REDUCED AIR TOXICS UNDER THE CLEAN AIR ACT

The Act establishes a phased process for reducing air toxics emissions from various industry sectors. Companies first implement technology-based air toxics regulations, which are designed to establish a common level of superior air

pollution control across each industry. This soon to be complete Maximum Achievable Control Technology (MACT) program is expected to reduce annual HAP emissions from stationary sources by over 1.5 million tons from 1990 levels.

The chemical industry was one of the first industries subject to MACT regulations. The result has been dramatic air toxics reductions from chemical sources according to EPA's own numbers. We are proud of this achievement, as well as the many voluntary efforts our industry has underway, such as Responsible Care®, to continuously improve our environmental and community performance. Responsible Care® represents our commitment to respond to public concerns about the safe management of chemicals and has rapidly become the single most important performance improvement initiative within the chemical industry.

III. KEY ELEMENTS OF A SUCCESSFUL RESIDUAL RISK PROGRAM

Eight or nine years after an industry's technology regulations are promulgated, the Clean Air Act requires EPA to evaluate whether air toxics risks from the regulated processes remain. If risks are identified, EPA must promulgate new standards to provide an "ample margin of safety" to protect public health and the environment from those risks. EPA is now evaluating the chemical and other industries subject to MACT standards to determine if their emissions pose unacceptable remaining risks. If regulations are needed for the chemical industry, they are due in 2003 under the Act's timeframe.

This means that many important decisions are being made now about how the residual risk regulatory program will be designed and carried out. The American Chemistry Council and its members are working collaboratively with EPA on this

effort. We believe that the residual risk program must build on the emission reductions and successes of the MACT program. In addition, our experience to date indicates that the following key principles must be a part of the residual risk program to ensure its success:

- **Prioritize real and scientifically validated risks.** We support the use of prioritization techniques to rank remaining risks posed by pollutants and sources within each evaluated industry category. A prioritization approach to residual risk will screen out negligible risks and focus regulatory efforts where risk reduction will produce the greatest public health benefits. EPA already has taken this approach in some of its work on the lead smelter industry, and we support this effort.

- **Use the flexibility provided in the Act to reduce risks in innovative and effective ways.** We support the risk management process endorsed in the Act, which sets out key issues that must be considered in designing this program. These include the scope of remaining risks, the public health significance of HAP emissions, the cost of further controls, and what risks are acceptable in the world in which we live. The Act endorses a risk management process that considers an acceptable level of risk based on health considerations, and then sets an "ample margin of safety" based on cost, feasibility, and other factors. EPA is not required to set a bright line that all sources must meet regardless of other factors. This means the residual risk program can be flexible, realistic, and encourage innovative approaches to risk reduction.

- **Use high-quality data and peer-reviewed methods to realistically assess risk and make regulatory decisions.** We believe EPA must use realistic exposure

assumptions to accurately characterize residual risks. This approach will place risks in context and avoid overly conservative risk estimates. Also critical are validated risk estimation methods and health benchmarks that fully account for all currently available information. We believe a transparent and open peer-review process also is an essential part of risk assessment. Where there are gaps in our knowledge, we support Congress providing the mechanisms, time, and research to fill these gaps.

IV. KEY LIMITATIONS IN PRESENT INFORMATION, DATA, AND METHODOLOGIES TO ASSESS RESIDUAL RISKS WITHIN THE STATUTORY DEADLINES

To accomplish these important goals and design a successful and realistic residual risk program, we must heed some early warning signs. Our collaboration with EPA to date and other experiences, such as with state air toxics programs, reveal some key limitations and shortcomings in EPA's present information, data, and methodologies to assess residual risks. EPA itself alludes to many of these troublesome areas in its March 1999 *Residual Risk Report to Congress*. The Agency's Science Advisory Board goes into more detail on present limitations in its May 2000 *Advisory on EPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters*. We are concerned that, without attention, these limitations will jeopardize the success of this evolving regulatory program. Our concerns include the following:

- **Outdated health information.** The President's Commission on Risk Assessment and Risk Management, created under the Act, has said that "data to assess the health risks of most hazardous air pollutants for regulatory purposes are lacking" and "the status of exposure data collection is no better." EPA's

IRIS (Integrated Risk Information System) database, broadly perceived as the primary source of health information on hundreds of chemicals, is critically out of date and contains information of varying quality. IRIS' widely acknowledged weaknesses are a true hindrance to the development of accurate risk assessments.

The American Chemistry Council is dedicated to studying and improving our collective knowledge of the health effects of chemicals. Through our Long-Range Research Initiative, our members will spend more than $100 million on health and environmental research related to chemical use and exposure during the next five years. In addition, our High Production Volume Chemical Testing program for screening and testing thousands of chemicals, launched in 1998 as a partnership with EPA and Environmental Defense, will require investments of at least $500 million. These efforts and others, such as the current program at the Chemical Industry Institute of Toxicology to develop a risk assessment for formaldehyde using EPA's new cancer guidelines and the latest science, are aimed at filling the IRIS gaps. Many of our companies also have submitted or are preparing new IRIS assessments. We strongly endorse EPA's recent efforts to open up the IRIS program to such submissions, and encourage the Agency to further expand this initiative.

However, these efforts alone are not enough. Staff and dollars for IRIS must be increased. The process for updating IRIS also must be expedited so new information on chemicals can be integrated or used in regulatory decisions without requiring that the entire IRIS evaluation process be repeated. IRIS is stuck in the last century, and we urge that it be modernized and expanded before its limitations lead to more erroneous risk assessments. Erroneous

assessments may result in unfounded public concern about air quality as well as waste limited resources. Our experience shows that using the best science will significantly reduce the uncertainty in making residual risk decisions and assure that this evolving regulatory program addresses real risks in the most effective manner.

- **Non-peer reviewed data, models and methods.** Good risk assessments depend on high-quality science. We commend EPA for presenting its preliminary secondary lead smelter case study to the Science Advisory Board. This exercise, however, highlighted EPA's data problems and showed that many of EPA's risk evaluation methods are not peer-reviewed. We believe it is absolutely critical that EPA commit that the data, models, and methods used for regulatory decision-making will be consistently and comprehensively subjected to a transparent scientific review process. This process must be balanced and engage academics, industry, states, scientists, and non-governmental organizations in an open process. Adequate time, funding and resources for follow-up to recommendations is also important so scientific input can be fully incorporated and addressed.

- **Incomplete emissions data and site characterization information.** Good risk assessments depend on a highly credible source of post-MACT emissions data for the many sources to be evaluated. Good risk assessments also depend on accurate information about facility locations, distance to neighbors, stack heights, and other important details. EPA's most recent emissions data set is from 1996, which for our industry represents pre-MACT emissions levels. Since this data was not collected for risk assessment purposes it also contains other significant limitations. Our industry is voluntarily providing EPA with

better information about the chemical sources now under review, but the task is immense. More effort is needed by all parties in this area to do a better job collecting, categorizing, and assessing such data.

- **Flawed fugitive emissions estimation methods.** Good risk assessments also depend on accurate estimates of "fugitive emissions"—low-level emissions from, for example, piping connections or valves. More simplistic methods currently in use were not intended for risk assessment purposes and tend to grossly overestimate fugitive emissions. Companies have developed new and more accurate ways to estimate these emissions. To reduce uncertainty in risk assessment, these improved methods need acceptance and use by EPA and other regulatory agencies.

- **Statutory time constraints.** We are concerned that these significant limitations can not be addressed under the present statutory time clock. As noted by the Science Advisory Board, EPA must conduct over 170 residual risk assessments and these "data gaps are likely to be even more of a problem" in future assessments. To add to the challenges, the Act requires compliance with new residual risk standards within 90 days of promulgation—a near impossibility for most sources. Despite our best efforts, it will not be long before a residual risk standard deadline is missed. Unless action is taken now, this program may end up operating under court ordered deadlines and in settlement discussions, hindering our ability to make good decisions founded on science.

IV. CONCLUSION

We are convinced that there is a better way for this program to be carried out, provided we heed these warning signs and keep the key elements for a successful program outlined here in the forefront of our minds. Our industry is committed to working with you, EPA, and other stakeholders to ensure that this regulatory program gets off to a solid start.

In closing, we must strive to prioritize risk reduction efforts and maximize the effectiveness and resources of all stakeholders to achieve cleaner air. To accomplish these goals and design an effective residual risk program, we need to base regulatory action on prioritized environmental challenges, use peer-reviewed and state-of-the-art scientific methods, and generate accurate health and emissions data. I reiterate our commitment to work with you and all stakeholders to achieve these goals.

Chairman Smith and Members of the Committee, thank you for hearing my testimony today. I appreciate the opportunity to provide you with our views on this important topic. I would be happy to answer any questions you may have.

* * * * *

Biography of Lee P. Hughes

Mr. Lee Hughes is Vice President, Corporate Environmental Control of the Bayer Corporation in Pittsburgh, PA, where he manages the environmental function for the firm.

Mr. Hughes joined Bayer (formerly Mobay Corporation, Miles Inc.) in February 1970 in the Polyurethane Division's Process Research Department. After working as a Process Research Engineer and assisting with the initial design and start-up of the firm's Baytown plant, Mr. Hughes transferred to the Environmental Control Group in the Central Engineering Department. During the next twenty years he progressed through a series of engineering and management positions to his present position as Vice President, Corporate Environmental Control.

While in this career path, Mr. Hughes has been involved with such activities as the planning, design and permitting of Bayer's production and environmental facilities, negotiating with the environmental agencies on the development of new regulations, supporting resolutions of customer's environmental problems, and providing environmental expertise to divestitures and acquisitions. Mr. Hughes has been an active member of the American Chemistry Council since 1978 and has worked on a number of Council environmental committees.

Mr. Hughes received his bachelor's and master's degrees in chemical engineering from the Pennsylvania State University.

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TESTIMONY OF
ROBERT BRENNER
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF AIR AND RADIATION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

October 3, 2000

Mr. Chairman and Members of the Committee, I welcome the opportunity today to testify on EPA's plans for implementing the residual risk program, which is one component of a broader strategy mandated in the Clean Air Act Amendments of 1990 to protect public health and the environment against toxic air pollution.

The 1990 Amendments called for a two-phased approach to reducing toxic air emissions from major industrial sources. First, EPA is to issue industry-by-industry standards to ensure that all sources are appropriately controlled. Second, in the residual risk phase, EPA is to assess the remaining risks from those industries and, if necessary, require reductions in toxic air emissions to protect health and the environment.

Congress reached a bipartisan compromise on the residual risk provisions in 1990 after years of dialogue and debate over the best way to achieve effective and reasonable air toxics control. A decade later, EPA continues to believe that it makes sense to evaluate whether Maximum Achievable Control Technology (MACT) standards provide the public with adequate health and environmental protection, and to take action if they do not. Although the job will not be easy, EPA with the aid of the scientific community (including the National Academy of Sciences) has developed risk assessment methodologies and risk management procedures that allow for

making reasoned decisions on whether to require further emissions reductions, based on the available scientific information and consideration of uncertainties.

Today, I will describe the general approach to risk assessment and risk management that EPA will use in deciding whether further reductions in toxic air emissions are needed from industrial facilities that have met technology-based emission limits. To set the stage, it is useful to put the program in context by providing some historical background and outlining EPA's overall air toxics strategy.

Air Toxics and the 1990 Clean Air Act Amendments

At the time Congress amended the Clean Air Act (CAA) provisions on hazardous air pollution in 1990, it was well established that the public is exposed to air toxics such as lead, benzene, dioxin, mercury, chromium, and other compounds. It was also known that toxics found in the air can cause cancer or other serious health effects such as neurological damage, miscarriages, birth defects, or lung damage.

Industry reports required by the Emergency Planning and Community Right-to-Know Act of 1986 revealed that manufacturing industries alone had emitted more than 2.7 billion pounds of toxic chemicals into the air in 1987. Risk assessments indicated that individuals living near some industrial facilities faced potentially high cancer risks. Studies found that millions of people in American cities faced some elevated risks from a complex mixture of toxic chemicals emitted by multiple sources ranging in size from big petrochemical plants to dry cleaners to motor vehicles. And atmospheric deposition of hazardous air pollutants was identified as contributing to toxic pollution in the Great Lakes. Neighboring states and Canada had issued health advisories against eating certain varieties of fish caught in the Great Lakes because they contained elevated levels of PCBs, mercury and other toxics.

All this was highlighted in congressional hearings. During the 1990 revision of the Act, Congress concluded that the pre-1990 hazardous air pollutant provisions had provided fertile ground for 20 years of emotional and often endless debate and litigation. Those provisions called for EPA to list and regulate hazardous pollutants one at a time based on the risks they posed. The result was gridlock. In 20 years, EPA listed only eight pollutants and regulated only seven. The regulations covered only some of the sources emitting those pollutants.

In response, Congress overhauled the Clean Air Act to ensure effective actions to protect public health from nearly 190 toxic air pollutants. The Act mandates a two-phased approach: cut toxic emissions substantially by requiring maximum achievable controls considering costs on major sources, and use targeted approaches to reduce particular types of risks.

In the first phase, EPA is directed to issue technology-based emissions standards on an industry-by-industry basis to bring down the amount of toxics in the air and reduce exposure to air toxics among citizens living nearby. This approach -- requiring dirtier facilities to achieve the level of performance already being achieved by cleaner facilities of the same type -- has proven very successful. MACT standards issued to date will reduce annual emissions of air toxics by 1.5 million tons -- many times the reductions achieved by standards issued during the 1970-90 period. To provide industry with greater flexibility on ways to comply with MACT standards, we develop numerical emissions performance standards whenever feasible, and typically include other features such as alternative compliance options or emissions averaging.

As we work to complete the MACT standards, we are implementing the second phase of the toxics program targeted to particular types of risks. Key components of this second phase include:

- assessing residual risks of toxic air emissions from MACT-regulated sources to determine

whether further controls are needed to protect public health and the environment.

- implementing the Integrated Urban Air Toxics Strategy, which is aimed at reducing risks in urban areas from 33 priority pollutants emitted by small "area" sources, motor vehicles and other sources.
- continuing assessments of atmospheric deposition of air toxics into the Great Lakes, and considering additional actions that may be needed to reduce emissions of those toxics.
- conducting National Air Toxics Assessment activities to provide citizens, localities, states and ourselves with better information on toxic emissions, exposure and risk.

The Residual Risk Program

In crafting the 1990 Amendments, Congress recognized that in the case of some industries, emissions reductions achieved by the MACT program might not be sufficient to protect public health and the environment. So the 1990 Amendments direct EPA to evaluate the remaining risks from each regulated source category. If necessary to protect public health or the environment, EPA is to issue residual risk standards requiring further emissions reductions. Any such standards are to be issued within eight years of the date the MACT standard was issued (nine years for certain early standards).

The details of these provisions represent a hard-won compromise achieved by the 102nd Congress, which spent as much time developing the residual risk provisions as it did on any portion of the 1990 Amendments. The provisions reflect attention to a variety of conflicting concerns -- the concerns of people exposed regularly to air toxics in the air that they breathe, the economic concerns of industrial facilities, and concerns about the uncertainty, imprecision and complexity associated with risk assessments of toxic air pollutants.

Those concerned about elevated risks from air toxics include minority and low-income residents who often are disproportionately represented in neighborhoods near industrial sites. In evaluating residual risks, EPA will look closely at potential exposures in nearby neighborhoods and be cognizant of subpopulations such as children and pregnant women who may be especially vulnerable to some toxic pollutants.

For many source categories, this program will be challenging to implement because of data gaps and uncertainties involved with risk assessments for hazardous air pollutants, and differing views among stakeholders over how risk assessors and risk managers should account for uncertainties. These issues are not new. Under the old pollutant-by-pollutant regulatory system in the 1970 Clean Air Act, these issues severely hindered implementation of the federal air toxics program. While there have been great strides made in the field of risk assessment since the 1990 Amendments, risk assessment by definition will always entail uncertainties.

Knowing this, Congress designed the residual risk provisions of the1990 Amendments to provide for decision making in the face of uncertainties. To lay the groundwork for the residual risk program, Congress required three reports -- two by independent panels of scientists, and one by EPA -- to address issues concerning risk assessments and risk management. Congress also provided a detailed framework to guide EPA's residual risk decisions in a world in which we don't have all the information we would like.

Today, all three statutorily required reports on risk assessment and risk management are complete. A 1994 report by the National Research Council (NRC) of the National Academy of Sciences, mandated by section 112(o) of the CAA , reviewed EPA's risk assessment methods. A 1997 report by the congressionally mandated Commission on Risk Assessment and Risk Management (CRARM), mandated by section 303 of the 1990 Amendments, examined risk

assessment and risk management issues relevant to hazardous substances under various federal laws. After evaluating these reports, EPA in 1999 provided a major Report to Congress describing how the Agency will implement the residual risk program, using the available scientific information and methods.

EPA's implementation approach for the program reflects the suggestions of the scientific committees. For example, the NRC report noted that neither the resources nor the scientific data exist to perform a full-scale risk assessment on all the chemicals listed as hazardous air pollutants (HAPs) and their sources. Therefore, the NRC supported an iterative approach to risk assessment of source categories emitting HAPs. This approach would start with relatively inexpensive screening techniques used to determine whether the evaluated source category is below the statutory level of concern, or whether we need to conduct a more refined analysis before we can make a determination. (We will not regulate based on the results of a screen.) As a particular situation warranted, we would move to a more resource-intensive level of data-gathering, model construction and model application to produce a risk assessment providing greater certainty. The result would be a process that supports the risk management decisions required by the CAA and provides incentives for better data and further research, without the need for costly case-by-case evaluations of individual chemicals of every facility in every source category. The CRARM agreed that the EPA should use an iterative approach when conducting risk assessments and elaborated on the general approach presented by the NRC. The Agency is using an approach that is consistent with that presented by the CRARM to undertake its residual risk assessments.

After a residual risk assessment is conducted, EPA must determine whether a residual risk standard should be established to achieve further emissions reductions. Specifically, EPA is to issue a residual risk standard for a source category if required "to provide an ample margin of

safety to protect the public health, or to prevent, taking into consideration costs, energy, safety and other relevant factors, an adverse environmental effect." Congress provided specific guidance on how this residual risk decision is to be made for hazardous air pollutants that lack a health effects threshold (e.g., many carcinogens) by endorsing the framework EPA developed for the 1989 benzene national emissions standard. This framework -- developed through notice and comment rulemaking in response to a 1987 decision by the Court of Appeals for the District of Columbia Circuit -- calls for a two-step decision-making process considering multiple factors.

In the first step, EPA determines a "safe" or "acceptable" risk level that considers all health information -- including the risk level of highly exposed individuals, the number of people exposed within each lifetime risk range, the overall incidence of health effects, the science policy assumptions associated with the risk measures, and the weight of evidence that a pollutant is harmful to health. EPA ordinarily will presume that a 1 in 10,000 lifetime risk of cancer to the individuals exposed to the maximum level of a pollutant represents the upper end of the range of acceptable risk. However, this is not a rigid line; rather it is a presumption to be weighed with the other factors.

In the second step, EPA determines the level of the enforceable emissions standard needed to provide an "ample margin of safety." In choosing this level, EPA considers again all health information -- including the number of persons at risk levels higher than approximately 1 in 1 million, the nature of the assumptions underlying the risk assessment, and weight of evidence that a pollutant is harmful. In determining the margin of safety, EPA also considers costs and economic impacts of controls, technological feasibility and other relevant factors.

This congressionally endorsed approach is consistent with risk management approaches of other EPA programs intended to broadly protect public health. For example, other EPA programs

use a risk management range of 10^{-6} to 10^{-4} under their reasonable maximum exposure scenario to guide their decision-making for carcinogens.

Also, the methods used to generate risk estimates for the residual risk program are consistent with those of other EPA programs. To address uncertainties, EPA makes scientifically sound judgments and assumptions about hazard and exposure to generate "reasonably conservative" risk estimates. By "conservative" we mean that true risks may be higher, but are likely to be lower. There are parameters that can substantially increase or decrease the estimated risk; EPA does not use conservative assumptions for all of these. For example, where we lack adequate information to support a quantitative assessment for a pollutant, we implicitly assume that the risks from that pollutant are zero. The result, in the end, is that our risk estimates are plausible and do not represent worst case estimates.

This Committee has expressed interest in the findings of an EPA Science Advisory Board (SAB) panel that recently reviewed a case study illustrating the approach EPA plans to use to conduct risk assessments for the residual risk program. The SAB subcommittee said that EPA methodology "is consistent with the methodology described in the Report to Congress," (which the Science Advisory Board reviewed and supported in 1998), and that "the assumptions used are consistent with current methods and practice." The subcommittee also made valuable substantive comments and suggestions for improvements, which EPA is incorporating. While the SAB did not find any "showstoppers" (their word) with the approach used, they did identify several issues that should be addressed such as a more fully evaluated model to predict exposure to toxics through multiple media, and improved data collection efforts. The SAB expressed particular concern about the availability of sufficiently precise scientific information that would support residual risk analysis. EPA is incorporating the Science Advisory Board's suggestions into our residual risk assessments. We are providing the Committee with a copy of our formal response to the SAB. As

we stated to the SAB, EPA will obtain peer review on the full case study risk assessment when it is completed.

As mentioned earlier, we are working to improve our data on air toxics (through our NATA or National Air Toxics Assessment activities) and our risk assessment methods. For example, we are improving the National Toxics Inventory, which is a repository of source specific air toxics emissions data from states; working with states and cities to expand monitoring of ambient air toxics levels (a plan which received a positive review from the SAB); and developing a new, better, multi-pathway methodology in TRIM (Total Risk Integrated Methodology), which has received two very favorable reviews from the SAB. We are also conducting national- and local-scale air quality, multimedia and exposure modeling to help characterize risks associated with air toxics exposures. Furthermore, we have been working with our colleagues in the Office of Research and Development for nearly two years to develop the Agency's Air Toxics Research Strategy. This strategy helps us to prioritize our research efforts on health and environmental effects and exposures to ambient and indoor sources of air toxics. Over time, these activities will help us set program priorities, provide the public with risk information, and track progress toward meeting national air toxics program goals.

In light of current uncertainties, some may suggest that EPA wait for more complete information before attempting to assess and address any risks from air toxics remaining after MACT. The flaw in this approach is that, in some cases, individuals may continue to be exposed to unsafe levels of toxics around these facilities while we fail to act based on information that is available now. For other source categories, available information may reassure concerned citizens that the facilities near them are well controlled. In the field of environmental protection, as in much of life, there are few decisions for which we would not like to have more information. The

reality is that to avoid paralysis, we must make reasoned choices based on the information we have.

Looking ahead, EPA has no preconceived notions of what residual risk analyses will show. Our plan is to use the available information to assess residual risks from each source category. We will use the most up-to-date credible and relevant information on chemical hazards. Taking into account uncertainties and the assumptions in the risk analysis, we will make a reasoned judgment as to whether the weight of the evidence supports requiring further emissions reductions to protect public health and the environment. If there is not sufficient evidence of a threat, EPA will not issue a residual risk standard. If toxic emissions are unsafe based on the framework provided by Congress, EPA will take protective action.

Mr. Chairman, thank you for the opportunity to testify. I would be pleased to answer any questions that you may have.

Statement of
Dr. Philip Hopke, Chair
Residual Risk Subcommittee
U.S. Environmental Protection Agency Science Advisory Board
Before the Senate Committee on Environment and Public Works
October 3, 2000

Mr. Chairman and members of the Committee, my name is Dr. Philip Hopke. I am testifying today as an individual, and I am honored to be here to discuss with you my views of the Residual Risk Subcommittee's (RRS) report on the residual risk methodology as described in EPA's Report to Congress (USEPA, 1999), as applied to the secondary lead smelter source category (USEPA, 2000). I chaired the RRS which is a subcommittee of the U.S. Environmental Protection Agency's Science Advisory Board's (SAB) Executive Committee. SAB is an independent FACA committee established by Congress. My testimony will reflect the consensus views of myself and the other members of the RRS, with added input and endorsement of the report from the SAB's Executive Committee.

On March 1-2, 2000, the Residual Risk Subcommittee conducted a peer review of an Agency draft case study of the residual risk assessment methodology for the secondary lead smelter source category (USEPA, 2000). The SAB understands that the Agency plans another iteration, including additional data collection and analysis before the results are considered for use in a regulatory context. The review of the seven-volume set of material focused on eight specific questions that are addressed in detail in the accompanying SAB report.

In short, the Subcommittee concludes that the Agency developed a useful, self-described "work-in progress." The methodology used in this interim work product, as far as it currently goes, is consistent with the methodology described in the Report to Congress. Further, many of the assumptions used are consistent with current methods and practice. The case study provides an example of how the approach presented in the Report might be implemented. However, it also raises a number of concerns that we have provided in our report on this document (EPA-SAB-EC-ADV-00-005 "An SAB Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters"). The major concerns will be highlighted here.

Because the Subcommittee has not yet seen a full residual risk analysis and, thus, is unable to comment on the complete process, a number of important concerns were identified that should be addressed. Specifically, this interim analysis does not include the following important elements:

1. an ecosystem risk assessment
2. a health risk assessment that includes population risks
3. a full analysis of uncertainty and variability
4. a computer model for assessing multimedia transport and fate that has been adequately evaluated
5. a clear description of the process and how the assessments will be linked to the eventual risk management decisions.

With respect to the specific approaches taken in the interim analysis, a number of questions are discussed in detail in the Subcommittee's report.

Ecosystem Risk Assessment

One of the greatest shortcomings of the case study in its incomplete state is that only the first stage screening analysis has been done for the ecological risk assessment. Even in this screening the top carnivore species were not included. This is the group of organisms at greatest risk from persistent and accumulated toxic chemicals. While the Office of Air Quality Planning and Standards (OAQPS) acknowledges that a full ecological risk assessment is needed, the Subcommittee is disappointed at the pace at which the assessment is being developed and implemented for ecology and natural resources. It would appear that a more concerted and scientifically complete analysis will be needed in order to meet the mandate of the Clean Air Act Amendments (CAAA) with respect to ecological risk.

Health Risk Assessment That Includes Population Risks

Regarding the health risk assessment portion of the case study, the Subcommittee finds that, within the limitations of data and resources, the approaches employed by the Agency were able to qualitatively identify potentially high human health risk situations. However, the Subcommittee also concluded that the currently available science presented in the working

document is insufficient to be comfortable with the quantitative values estimated by the models currently used. In particular, the analysis calls into question the ability of the model to reliably quantify the amount of the deposited contaminant transferred in the food chain. In addition, the current risk assessment will have to be further developed in order to include population risks if it is to meet the needs of the Agency.

Computer Model for Assessing Multimedia Transport and Fate That Has Been Adequately Evaluated

The case of multimedia computer models is one of the other major areas with which the Subcommittee has concerns. It seems that the models were applied without due consideration of the plausibility of the assumptions and the physical meaning of the results. In several cases, results presented in the draft report were implausible in that the predicted concentrations would have produced immediately observable results on the affected human and ecological populations. For example, ambient lead concentrations measured because of the National Ambient Air Quality Standard for Particulate Lead could be used to test the concentrations at site boundaries of these facilities. Thus, it suggests that overly conservative estimates were likely to have been used. Such results could be eliminated if an iterative process were used in which implausible results are flagged so that the Agency can make appropriate revisions in the model and/or its inputs, and the model run again. A number of plausibility checks were described by the Subcommittee, and in public comments, that would provide checkpoints in the analysis and, thereby, indicate the need for alternative assumptions and recalculation. Inclusion of these checkpoints would be helpful to both the Agency and the reader.

In addition the models being used need to undergo rigorous peer review. In this test case, a model, IEM-2M, originally used for mercury movement in the environment was modified for lead. However, this model was never rigorously reviewed even for its utility in the mercury modeling. The Agency has been developing a new multimedia exposure model, Total Risk Integrated Methodology (TRIM), that has undergone an initial review by the SAB that was encouraging. However, it appears now that the completion of this model and its use in risk assessment has been slowed so that it may not be available in the near term. This delay produces

serious doubts in any of the assessments that have to be based on a temporary model that has not been subjected to careful external scrutiny.

Full Analysis of Uncertainty and Variability

The lack of a more rigorous treatment of uncertainty and variability may lend an aura of precision to the risk estimates in the case study that is not warranted and could, thereby, be misleading for Agency decision makers. In particular, the uncertainty analysis omits some important aspects of uncertainty and does not clearly distinguish between uncertainty and variability.

Clear Description of the Process and How the Assessments Will Be Linked to the Eventual Risk Management Decisions

Moving beyond the strictly technical aspects of the document on which the SAB has been asked to provide advice, I would like to share with you my comments on what the subcommittee understood to be the Agency's intention to make decisions based on these results. Specifically, the Agency is mandated under Section 112(f) of the Clean Air Act to conduct the residual risk assessment and to make a decision about whether or not further regulation is necessary in order to protect public health and the environment. In particular, as stated in the Agency's response to the previous SAB review of the Report To Congress (SAB-EC-98-013), "the decision made with the results of the screening analysis is [either] no further action or refine the analysis, while the decision made with the results of the more refined analysis is [either] no further action or consider additional emissions control."

As discussed above, as currently presented, the results of the refined analysis will provide essentially the same answer as the initial screening analysis; that is, an even more refined analysis is needed. Therefore, the case study has not achieved its decision objective, and another level of analysis or iteration is needed. A better-informed decision will be possible if the results of the case study more fully reflect both the best estimate of the risk combined with an adequate uncertainty/variability analysis that will more clearly define the range of risks.

An important policy question arises as to how good do such residual risk assessments need to be. The understanding the RRS came to during its discussion is that when the form of controls specified in Title III was being considered by Congress a decade ago, the expectation for the level of these residual risk analyses was quite low. The scientific basis of risk assessment has grown considerably over the past ten years and thus, the level of expectation from the scientific community such as those who have served on the SAB Subcommittee has risen considerably. Thus, the Subcommittee has expressed its concerns regarding future assessments.

The present source class, secondary lead smelters, is a relatively data-rich category. Because of the existence of the lead National Ambient Air Quality Standard (NAAQS) and the concern for blood lead levels in children, there are more data in the vicinity of these source types than are likely to be available for other HAPs from other source types. The basic Congressional approach of imposing controls and assessing residual risk is a sensible response to the problem of HAPs emissions. However, the number of HAPs and the number of source types, coupled with the limited data on speciated emissions and quantitative dose-response information, makes the residual risk task into a substantial one.

At this time, it appears that there have not been sufficient resources provided to EPA to allow their Office of Air Quality Planning and Standards (OAQPS) to collect and assess all of the pertinent data from EPA, state/local air quality, and public health agencies that could be fruitfully brought to bear on this problem. For example, the Subcommittee was told that it had not been possible to get the lead NAAQS monitoring data from AIRS to provide checks on the fugitive emissions estimates because of resource limitations.

There are certainly not sufficient resources to permit the testing of specific HAPs for their toxicity if those dose-response data are not already available. Such testing would be expensive and may not be the best use of limited resources. In the case of secondary lead smelters, only seven of the 50 identified HAPs were excluded from the residual risk assessment due to the lack of dose-response data. This lack of data will likely pose much greater problems when other source categories are addressed in the future. Such data gaps could lead to the

omission of compounds from the assessment, resulting in a subsequent underprediction of the residual risk. It may be possible to utilize computational chemical methods to provide at least an estimation of the possible risk. However, that would require some limited additional effort.

Accordingly, I wish to use this opportunity to express the RRS's concern regarding the level of analysis that can and should be done to assess the residual risk as part of the control of hazardous air pollutant emissions. The RRS believes it is possible to provide more quantitative and useful human health and ecological risk assessments than is currently envisioned for a reasonable investment of additional resources for data collection and some additional outside expertise as appropriate. The resulting assessments will be much more credible.

As we all know well, science alone does not a decision make. Science can inform but policy decides when making regulatory judgments. I say this, because many non-scientific considerations are taken into account when making decisions (e.g. legal precedent, policies, values, economics, technical feasibility, etc.). Each must be considered carefully and applied wisely if the decisions are to be effective and widely accepted by the public. However, while the decision inputs based on values, politics and other social considerations are often debatable, we expect the science to be based on facts determined by measurable, repeatable observations of nature. More explicit recognition of this problem by members of Congress could help the Agency carry out its duties more effectively and could help provide the public with a clear understanding of how Congress interprets National priorities.

I want to express my gratitude to the Members of the Committee for inviting me and giving me the opportunity to discuss the SAB Residual Risk review message with you. I look forward to your questions.

United States
Environmental
Protection Agency

Science Advisory
Board (1400A)
Washington DC

EPA-SAB-EC-ADV-00-005
May 2000
www.epa.gov/sab

EPA

AN SAB ADVISORY ON THE USEPA's DRAFT CASE STUDY ANALYSIS OF THE RESIDUAL RISK OF SECONDARY LEAD SMELTERS

Prepared by the Residual Risk Subcommittee of the Science Advisory Board

May 19, 2000

EPA-SAB-EC-ADV-00-005

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

RE: Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters

Dear Ms. Browner:

On March 1-2, 2000, the Science Advisory Board's (SAB's) Residual Risk Subcommittee of the SAB Executive Committee conducted a peer review of an Agency case study of the residual risk assessment methodology, described in its Report to Congress (USEPA, 1999), as applied to the secondary lead smelter source category (USEPA, 2000). The review of the seven-volume set of material focused on eight specific questions that are addressed in detail in the accompanying SAB report.

In short, the Subcommittee concludes that the Agency has developed a useful, self-described "work-in progress". The methodology used in this interim workproduct, as far as it currently goes, is consistent with the methodology described in the Report to Congress. Further, the assumptions used are consistent with current methods and practice. The case study provides a valuable example of how the approach presented in the Report is going to be implemented.

However, because the Subcommittee has not yet seen a full residual risk analysis and, thus, is unable to comment on the complete process, a number of important concerns were identified that should be addressed. Specifically, this interim analysis does not include the following important elements: an ecosystem risk assessment; a health risk assessment that includes population risks; a full analysis of uncertainty and variability; a computer model for assessing multimedia transport and fate that has been adequately evaluated; nor a clear description of the process and how the assessments link to the eventual risk management decisions. The attached consensus report contains a discussion of a number of additional issues related to the specific approaches taken in the interim analysis.

Looking to the future and the 173 other source categories to be addressed in the residual risk program, the Subcommittee is concerned about the data gaps that are likely to be even more of a problem than they are in the case of secondary lead smelters. Both the Agency and the

Congress need to recognize this problem in order to ensure that there is an adequate data base to support the residual risk analysis program.

During the review by the Executive Committee, a number of important concerns were raised that will be the subject of a subsequent SAB Commentary. In addition, the Health and Environmental Effects Subcommittee (HEES) of the SAB's Council on Clean Air Act Compliance Analysis (COUNCIL) and the Agency will host a June, 2000 workshop on dealing with hazardous air pollutants (HAPs). The workshop and its outcomes could prove useful insights that are applicable to the implementing of the Residual Risk Program.

We appreciate the opportunity to provide advice on this effort. The Agency staff was open, collegial, cognizant of shortcomings in the document, and accepting of the Subcommittee's suggestions. Given the incomplete state of the document at this time and the precedent-setting nature of this -- the first of 174 -- residual risk analyses, we conclude that a peer review of the final Agency Report on secondary lead smelters is in order. We look forward to your response.

Sincerely,

Morton Lippmann

Dr. Morton Lippmann, Interim Chair
Science Advisory Board

Philip K. Hopke

Dr. Philip Hopke, Chair
Residual Risk Subcommittee
Science Advisory Board

NOTICE

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* Members of this SAB Subcommittee consist of

a. SAB Members: Experts appointed by the Administrator to two-year terms to serve on one of the 10 SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue; in this case, the application of the Agency's Residual Risk Policy to the case of secondary lead smelters.

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APPENDIX C

GLOSSARY C-1

1. EXECUTIVE SUMMARY

On March 1-2, 2000, the Science Advisory Board's (SAB's) Residual Risk Subcommittee of the SAB Executive Committee conducted a peer review of an Agency draft case study of the residual risk assessment methodology, as described in its Report to Congress (USEPA, 1999), as applied to the secondary lead smelter source category (USEPA, 2000). The SAB understands that the Agency plans another iteration, including additional data collection and analysis before the results are considered for use in a regulatory contexts. The review of the seven-volume set of material focused on eight specific questions that are addressed in detail in the accompanying SAB report.

In short, the Subcommittee concludes that the Agency has developed a useful, self-described "work-in progress". The methodology used in this interim workproduct, as far as it currently goes, is consistent with the methodology described in the Report to Congress. Further, the assumptions used are consistent with current methods and practice. The case study provides a valuable example of how the approach presented in the Report is going to be implemented.

However, because the Subcommittee has not yet seen a full residual risk analysis and, thus, is unable to comment on the complete process, a number of important concerns were identified that should be addressed. Specifically, this interim analysis does not include the following important elements: an ecosystem risk assessment; a health risk assessment that includes population risks; a full analysis of uncertainty and variability; a computer model for assessing multimedia transport and fate that has been adequately evaluated; nor a clear description of the process and how the assessments link to the eventual risk management decisions. With respect to the specific approaches taken in the interim analysis, a number of questions are discussed in detail in the attached consensus report.

One of the greatest shortcomings of the case study in its incomplete state is that only the first stage screening analysis has been done for the ecological risk assessment. While the Office of Air Quality Planning and Standards (OAQPS) recognizes that a full risk assessment is needed, the Subcommittee is disappointed at the pace at which the assessment is being developed and implemented for ecology and natural resources. It would appear that a more concerted and scientifically sound analysis is needed in order to meet the mandate of the Clean Air Act Amendments (CAAA).

Regarding the health risk assessment portion of the case study, the Subcommittee finds that, within the limitations of data and resources, the approaches employed by the Agency were able to qualitatively identify potentially high human health risk situations. However, the Subcommittee also concluded that the currently available science is insufficient to be comfortable with the quantitative values estimated by these models. In particular, the analysis calls into question the ability of the model to reliably quantify the amount of the deposited contaminant that is transferred to the food chain. In addition, the current risk assessment will have to be further developed in order to include population risks if it is to meet the needs of the Agency.

The lack of a more rigorous treatment of uncertainty and variability may lend an aura of precision to the risk estimates in the case study that may not be warranted and could, thereby, be misleading for Agency decision makers. In particular, the uncertainty analysis does not consider the propagation of uncertainties of the model parameters throughout the analysis.

In the case of multimedia computer models, the Subcommittee is concerned about the extent to which such models were applied without due consideration of the plausibility of the assumptions and the physical meaning of the results. There should be an iterative process in which implausible results flag problem areas, so that the Agency can make appropriate revisions in the model and/or its inputs, and the model run again. A number of plausibility checks were described by the Subcommittee and in public comments that would provide checkpoints in the analysis and, thereby, indicate the need for alternative assumptions and recalculation. Inclusion of these checkpoints would be helpful to both the Agency and the reader.

Finally, an overarching comment is that the case study should provide more details of what was done, how it was accomplished, and how the results link to the eventual risk management decisions. It is critical that the process be described as clearly as possible, especially articulating why particular choices were made at various decision points in the risk analysis. The current document is lacking in this regard.

Moving beyond the strictly technical aspects of the document on which the SAB has been asked to provide advice, the Subcommittee would like to comment on what it understands is the Agency's intention to make decisions based on these results. Specifically, the Agency is mandated under Section 112(f) of the Clean Air Act to conduct the residual risk assessment and to make a decision about whether or not further regulation is necessary in order to protect public health and the environment. In particular, as stated in the Agency's response to the previous SAB review of the Report To Congress (SAB-EC-98-013), "the decision made with the results of the screening analysis is [either] no further action or refine the analysis, while the decision made with the results of the more refined analysis is [either] no further action or consider additional emissions control." As discussed above, the Subcommittee concludes that, as the currently presented, the results of the refined analysis provide the same answer as the initial screening analysis; that is, they will not suffice as a basis for risk-based rulemaking, and, therefore, an even more refined analysis is needed. Therefore, the case study, at this stage, has not achieved its decision objective, and another level of analysis or iteration is needed. A better-informed decision will be possible if the results of the case study more fully reflect the inability to define the risks more precisely.

Outside the bounds of this particular analysis, the Subcommittee expressed two broader concerns regarding future assessments. First, the present source category, secondary lead smelters, is relatively data-rich. Because of the existence of the lead National Ambient Air Quality Standard (NAAQS) and the concern for blood lead levels in children, there are more data in the vicinity of facilities of this source category than are likely to be available for other HAPs from other types of sources. For many or most other source categories, the number of HAPs and the number of source types, coupled with the limited data on emissions and quantitative information on health and ecological effects, makes the residual risk task substantial.

Second, while the basic Congressional approach of imposing controls and assessing residual risk of remaining HAPs emissions makes sense, in concept, it appears that there have not been sufficient resources provided to collect and assess all of the pertinent data from state/local air quality and public health agencies that could be fruitfully brought to bear on this problem. There are certainly not sufficient resources to permit the testing of specific HAPs for their toxicity if those dose-response data are not already available. In the case of secondary lead smelters, only seven of the 50 identified HAPs were excluded from the residual risk assessment due to the lack of dose-response data. However, lack of data will likely pose much greater problems when other source categories are addressed in the future. Such data gaps could lead to the omission of compounds from the assessment, resulting in a subsequent underestimation of the residual risk. Appropriate recognition of this problem is needed by both Congress and the Agency in order to develop an adequate data base to support the residual risk analysis program.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 25, 2000

EPA-SAB-EC-COM-00-005

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Executive Committee Commentary on Residual Risk Program

Dear Ms. Browner:

The Executive Committee (EC) of the Science Advisory Board (SAB) is writing to alert you to potentially significant issues arising from with the Agency's efforts to implement the residual risk requirements of the Clean Air Act Amendments of 1990.

In 1998, the SAB sent you a report (EPA-SAB-EC-98-013) on its review the Agency's Report to Congress on the methodology to be used in assessing the residual risks associated with the post-Maximum Achievable Control Technology (MACT) emissions of hazardous air pollutants (HAPs) from 174 source categories across the country. The Board endorsed the Agency's plan but identified the need to see the methodology applied to a specific case in order to determine whether the methodology was viable in practice, as well as in principle.

This spring, the SAB reviewed an Agency interim workproduct that indicates how the Office of Air and Radiation (OAR) plans to implement this methodology in practice. The results of that review were sent to you in May in the *"Advisory on the USEPA's Draft Case Study of the Residual Risks of Secondary Lead Smelters"* (EPA-SAB-EC-ADV-00-005). In short, the Board found that the Agency has made a good faith start in using the methodology to assess the residual risks from this source category but went on to cite significant scientific problems that raise serious concerns about the potential for the Residual Risk Program, as currently conceived, to successfully achieve its goals. In particular, we understand that secondary lead smelters were selected as the first HAPs source category for the residual risk exercise, in part, because it contains a limited number (24) of facilities, and because it has a large monitoring data base, compared to most of the other 173 source categories. In light of the relatively favorable knowledge base for this case study and the quite limited success that it has achieved to date, the SAB believes that the large number of data-poor categories will prove to be even more intractable to this type of analysis than the secondary lead smelter category has been shown to be

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to date. In summary, it is not clear that scientific analysis will be able to generate the type of information envisioned in the CAAA. While decisions can be made in the absence of such scientific information, they will not be sufficiently precise for the intended purpose.

While our concerns may turn out to be ill-founded, we recommend that the Agency and Congress seriously re-consider the current Clean Air Act Amendments mandates and their implementation strategy that depends on scientific analyses that will be resource-demanding, at a minimum, and, quite possibly, impossible to carry out in a credible manner.

In summary, while we certainly endorse the concept of science-based decision making at the Agency, we also recognize that no one is well served by asking science to take on an impossible task.

We would look forward to meeting with Agency leaders and Congressional personnel to discuss these concerns and what might be done about them.

Sincerely,

Morton Lippmann

Dr. Morton Lippmann, Interim Chair
Science Advisory Board

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Statement of Felice Stadler
National Policy Coordinator
NWF's Clean the Rain Campaign

Before the
Senate Environment and Public Works Committee

October 3, 2000

With regard to U.S. Environmental Protection Agency's Residual Risk Program

1400 16th Street, NW, Suite 501, Washington, D.C. 20036 Tel: 202-797-6800 Fax: 202-797-6646 Email: action@nwf.org

Thank you, Mr. Chairman, for providing me the opportunity today to submit comments on the U.S. Environmental Protection Agency's residual risk program.

My name is Felice Stadler, and I coordinate the National Wildlife Federation's national Clean the Rain Campaign. The campaign seeks to raise public awareness about how toxic air pollution contaminates our lakes and streams and advocate for national and local policies to phase out the emissions of mercury and other persistent bioaccumulative toxics. In my testimony this morning I will explain why emissions of toxic air pollutants must be reduced by residual risk standards. While we recognize that EPA needs to refine its methodology for performing residual risk assessments, we firmly believe that the program must be preserved and adequate resources be provided to allow the agency to do the critical assessments needed to protect humans and wildlife from actual harm.

This is a timely subject. As you know, mercury is a highly potent neurotoxin. Just two weeks ago, the National Wildlife Federation released a report showing that mercury levels in New England's rain are up to four times as high as EPA's standard for aquatic life in surface waters. One year ago, the National Wildlife Federation released a similar report showing even higher mercury concentrations in rain falling on Great Lakes states. When mercury-laden rain falls into lakes, it contaminates the water, the fish and other aquatic life living in the water, and the people and wildlife who eat the fish. This example illustrates the importance of reducing the emissions of toxic air pollutants that are daily contaminating our rain, our lakes, our fish and our children.

As you are aware, Congress amended the Clean Air Act in 1990 to establish a more effective program to reduce toxic air pollution. Congress required major sources that emit any of 188 listed toxic air pollutants to meet performance standards based on the best industry practices to minimize toxic releases.

Over the past decade, we have witnessed a significant reduction in toxic air pollution emitted by large and small industry throughout the United States. Over 20 technology-based rules have been finalized, affecting over 48 categories of major industrial sources. Each year these rules will remove approximately one million tons of over 100 different air toxics—almost 10 times greater than the reductions achieved between 1970-1990. (U.S. EPA, 1998, Taking Toxics out of the Air: Progress in Setting Maximum Achievable Control Technology Standards Under the Clean Air Act, EPA/451/K-98-001)

Have those reductions solved the air toxics problem in communities and ecosystems throughout the U.S.? Certainly not. People and wildlife continue to be exposed to toxic air pollution which harms their well-being.

I have already alluded to the contamination of our waters by mercury. Mercury emitted into the air is the leading cause of mercury pollution in the Nation's lakes and streams. The National Academy of Sciences recently reported that over 60,000 children a year may be adversely affected by exposure to mercury in the womb. Forty one states and territories have issued formal advisories warning people to restrict or avoid eating the fish they catch because of mercury

contamination. Scientists have documented harmful changes in reproductive patterns in loons exposed to mercury.

Dioxin is another persistent bioaccumulative toxic air pollutant. It is the most potent carcinogen and reproductive toxin EPA has ever evaluated. Dioxin levels measured in food are above those that scientists believe are harmful to people and wildlife.

Clearly, only part of the problem has been addressed, and it is vitally important that EPA move to the next phase of its national air toxics strategy, the residual risk program. If EPA is prevented from implementing the risk-based element of its air toxics strategy, significant air toxics problems will remain. There are three main reasons to move forward with the residual risk program.

First, without a residual risk program, EPA will not be able to address the harm from the most toxic air pollutants, those that, like mercury and dioxins, persist and bioaccumulate in the environment. This special class of pollutants is harmful at extremely low levels, and uniquely harmful to people and wildlife because they become increasingly toxic as they move up the food chain. For example, mercury is one million times more toxic in fish than in surrounding water, so when we eat fish we are consuming concentrated mercury. Those most vulnerable to the effects of these toxic compounds include unborn children, women, low-income communities, and communities of color. EPA is not required to address the full extent of the harm posed by these most toxic compounds through technology standards. Therefore, the residual risk program is critical to ensure these unique risks are appropriately addressed.

Second, EPA's technology standards do not take into account the cumulative risk that occurs when industrial sources are concentrated in an area. There are hundreds of communities throughout the country that face a disproportionate risk from exposure to toxic air pollution because of heavy concentrations of industrial sources. In Memphis, Tennessee, you can see sources of toxic air pollution in every direction—a petroleum fueling station, a six-lane highway, a refinery, a lead smelter, and a factory. Less than a block away from these sources, there is low-income housing and a playground. Unfortunately, this picture is not unique. Risk-based programs enable EPA to evaluate these real life scenarios that are all too common for countless citizens.

Third, Congress and EPA never intended the technology-based program to address entirely all toxic emissions from all listed sources. Technology-based standards provide the best industry can offer at the time they are imposed, but this does not necessarily translate into being the most stringent or comprehensive approach. In fact, when EPA issued the proposed Portland cement kiln rule two years ago, EPA announced it would evaluate the need to make the standard more stringent to address mercury emissions as part of the residual risk phase.

> *It is EPA's tentative conclusion, however, that concerns as to health risks from mercury emissions from these sources may be appropriately addressed pursuant to the timetable set out in the Act, namely through the residual risk determination process set out in section 112(f) of the Act.* 63 Fed. Reg. 14202

The residual risk program allows the agency to revisit a regulatory decision once more information has been collected and the effect of the initial rule has been evaluated. Without the residual risk program, this category of sources, and others like it, would likely never be adequately regulated under the Clean Air Act.

In conclusion, I want to raise the issue of uncertainties relating to the residual risk program. Every risk assessment must contend with uncertainties—who is exposed, how much they are exposed to, the health effects of pollutants. Requiring every uncertainty to be addressed before taking action would effectively mean no action will be taken. EPA is refining its tools to carry out the residual risk program, and should be given the opportunity to go forward and implement the program. But policy paralysis will be the result if EPA is required to address every uncertainty before acting; our children will be the most directly affected by delay.

Finally, I would like to close with two recommendations to improve how we regulate sources of air toxics. First, the risks to people and wildlife from the most toxic pollutants – those like mercury and dioxins that bioaccumulate and persist – are well established: <u>any</u> release of these pollutants causes harm. For that reason, in international agreements the U.S. has committed to "virtual elimination" of these pollutants. To properly address the unique risks posed by these pollutants, EPA need not engage in complicated risk analysis; instead, it simply needs to set a schedule for phasing out the emissions of these chemicals from all sources, and then apply progressively lower emissions standards to meet that goal.

Second, rather than merely relying on pollution controls to solve the nation's air toxics problem, we urge Congress and the agency to look at solutions that encompass pollution prevention. This applies to both the technology-based program and the residual risk program. EPA has the tendency to assume that all pollution is unavoidable and that bolting on technology will solve the problem. Instead, it is time for EPA to begin to assess what pollution could be avoided altogether and develop policies that reflect a commitment to more sustainable and less toxic solutions.

I thank the committee for inviting me to testify and welcome the opportunity to answer any questions.