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COMPARATIVE RISK ASSESSMENT: SCIENCE ADVISORY BOARD'S RESIDUAL RISK REPORT

HEARING AND INFORMATIONAL MEETING

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

OCTOBER 3, 2000

ON

HOW THE U.S. ENVIRONMENTAL PROTECTION AGENCY WILL MAKE USE COMPARATIVE RISK ASSESSMENT STRATEGIES AND METHODS TO PROTECT THE HEALTH AND SAFETY OF AMERICANS

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COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

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COMPARATIVE RISK ASSESSMENT: SCIENCE ADVISORY BOARD'S RESIDUAL RISK REPORT

TUESDAY, OCTOBER 3, 2000

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

The committee met, pursuant to notice, at 9:31 a.m., in room 406, Senate Dirksen Building, Hon. Robert C. Smith (chairman of the committee) presiding.

Present: Senators Smith, Inhofe, Moynihan, Lautenberg, and Baucus.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE [assuming the chair]. The committee will come to order.

I thought we would start while waiting for the chairman to get here.

Before doing any opening statements, let me pay a special tribute to my good friend Patrick Moynihan. Not many people are aware of the fact that he is a Tulsa boy, from Tulsa, OK. In fact, one of his roommates in school—what was John's last name? John Barry, that is right, John Barry was a very liberal Democrat and he is my next-door neighbor.

Some people accuse me of being a very conservative Republican. Finally, he came to me one day. We used to have these conversations about you. That was the only thing we agreed on, nice things about Patrick Moynihan. He finally came to me one day and he said, "You know, this neighborhood isn't big enough for both of us."

And he left. So, that was the end of your friend there.

You know, in Tulsa we have a very well known morning show that is heard far beyond the confines of Oklahoma. It is called "The Early in the Morning Show." He just absolutely worships Daniel Patrick Moynihan. In fact, he was after me since the 8 years I was in the House and the 6 years in the Senate to line up an interview. That did finally happen.

So, even though he was quite young when he left Tulsa, he is one that we claim as our own, Daniel Patrick Moynihan.

Our chairman has just arrived. Chairman Smith, I started without you. Let me finalize this comment because I know that your family was with the Tulsa Tribune at one time. I ran into—and I hadn't seen him for 10 years—Jake Jones on the airplane yesterday. You know, the paper is no longer there any more. I hadn't seen him in probably 12 years and I ran into him on the plane.

So, anyway, we are very proud of Pat Moynihan to be a native Tulsan. He is part of our area.

Senator MOYNIHAN. You are very generous, sir. I am proud to have such an origin.

Senator INHOFE. Well, if you hadn't been so young, you wouldn't have been willing to leave, I am sure.

Senator LAUTENBERG. Mr. Chairman.

Senator SMITH [assuming the chair]. Senator Lautenberg.

OPENING STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. May I ask, we have a Transportation Conference about ready to start, miracle of miracles, and I did want to have just a couple of minutes to talk about my friend to my right, and that is often the position. May I have that time now?

Senator SMITH. Go ahead.

Senator LAUTENBERG. I would ask the involvement of the witnesses. Pat Moynihan and I are probably on our—I want to say "last legs," but on our last committee, the Environment and Public Works Committee. I think it is fair to say that in the year that you joined this committee, Senator Moynihan, it was called the Committee on Public Works. Then the word, "environment" was added. Is my briefing paper correct?

Senator MOYNIHAN. I believe, sir, Senator Muskie had just added "environment."

Senator LAUTENBERG. Well, I am sure your influence helped. I am awfully glad you did because Senator Moynihan and I are from either sister or brother States, however you phrase it. The fact of the matter is that we are inextricably linked because of the necessity to function together in our region.

For me, Senator Moynihan, it has been a distinct honor and pleasure. We have worked together on some fairly important issues that under the jurisdiction of this committee: clean water, clean air, trying to make sure that the harbor keeps functioning so that we have the depth to accommodate the ships that are now plying the harbor waters, but also those in the future.

We dare not stand by and let changing conditions impair our economy, whether it is heavier trucks on the highways, which we had to accommodate, or changes in our aviation system, we stepped up to the plate and did it.

In the case of dredging in the harbor, it is a phenomenon resulting from new technology and larger vessels. So, I remember that it was in 1985 that we stood at the top of the World Trade Center calling for tougher standards to control air toxics. Ultimately, we were able to beat back the Administration's efforts to weaken the requirements on midwestern power plants that spewed air pollution all over our two States.

Senator Moynihan's conscience, intellect, and integrity have made him a fearsome adversary. By the same token, if you need a friend and a soldier in the ranks or a partner in duty, Pat Moynihan was the person you could call on.

Pat Moynihan also has the distinction of recognizing the tremendous toll of air pollution in terms of acid rain and its effect in the

Adirondacks and other mountainous and lake areas in his beautiful State.

So, I say that the Senate will be a poorer place as a result of the retirement of departure of Pay Moynihan from the Senate. One of the things that we hope is that he will continue to stay involved in public policy.

There is such a wealth of experience and information there. As I said earlier, also the intellect to support the use of that knowledge and that experience, whether it has to do with our international relationships or whether it has to do with making sure that we pay attention to the needs of our railroads and our transportation system or making certain that the water that our people drink is safe.

So, I say this, Senator Moynihan, that is not bottled water. I want everybody to know that.

Thank you, Mr. Chairman, for this opportunity to say these few words.

Senator MOYNIHAN. Mr. Chairman, I would like to thank my dear colleagues from Oklahoma and from New Jersey. We have been together a long while and we will continue. Thank you.

OPENING STATEMENT OF HON. BOB SMITH,
U.S. SENATOR FROM THE STATE OF NEW HAMPSHIRE

Senator SMITH. Well, I know we are embarrassing you, Senator Moynihan, but in reflecting, you have the same unfortunate experience that I did in that you assumed the chairmanship upon the death of a colleague in the middle of the session. Senator Burdick passed away and you assumed the chairmanship, as I did when Senator Chafee passed away. So, we have, unfortunately, something in common there.

But I also wanted to remind you of the time that you, not long after having assumed that chair and when I was a fairly young, in terms of tenure here, Member of the Senate.

You came to my office after having assumed that chairmanship and insisted on coming to my office rather than me coming to yours and gave me a great opportunity to have significant input into the transportation bill which you were then working on. I have never forgotten that.

You hear oftentimes the expression of people who are both a gentleman and a scholar, and you are both. I mean that. It is very, I think, well, it is certainly timely but perhaps no accident that you are here. This is your last hearing. Yet, it is on risk assessment and you have had so much to do with it. I have a long litany of things, which I am not going to read, but I will put in the record your conversations in that area.

So, it has been a real pleasure to serve with you.

Senator MOYNIHAN. Thank you, Mr. Chairman.

Senator SMITH. I appreciate your friendship.

Senator MOYNIHAN. It will be a pleasure to hear our witnesses if you want to get on with it.

Senator SMITH. Senator Lautenberg, this is also your last hearing, I believe. It seems like we have had four or five "last hearings" for you.

Senator LAUTENBERG. Keep them going.

Senator SMITH. You really enjoy this. But, I did make some comments the last time on the record for you.

Senator LAUTENBERG. You did. I don't feel deprived, Mr. Chairman. I truly appreciated it. I would appreciate one more courtesy, and that is, if I could submit my statement on this hearing into the record.

Senator SMITH. All members' statements will be submitted for the record.

Senator Baucus has just come in. Why don't we just have the first panel come up while Senator Baucus makes a few remarks?

Senator BAUCUS. Thank you, Mr. Chairman. This is quite a day. It is bittersweet. It is a time when we are happy for the Senator from New York but we will also sorely miss him.

Senator Moynihan has been a friend to all of us on the committee. He has certainly been a mentor to me. He teaches the best way, which is by example, not by telling people what to do, but by example, by coaxing out our better angels.

Senator Moynihan is optimistic. He is positive. He appeals to the more noble side of human nature, and again, by example. He always encourages us to think a little harder, think a little more deeply, think about something that is off the beaten path, and listen a little more carefully. He is always stressing honor and always stressing civility.

He elevates our debates in many ways, with his sharp intellect, and certainly with his very, very deep, broad grasp of public policy, often bringing up historical references that help clarify matters a little, put things in perspective, focus our minds a bit more.

Every once in a while, I try to match him, and I try to impress him coming up with an historical reference of my own. I must say that each time he corrects me.

I will never forget the moment I told him that it was that great statesman, Disraeli, who said that, "In politics a week is a long time."

Right away he corrected me and said, "No. I think that was Baldwin."

And he was right.

A few months ago, though, we passed a law naming Foley Square Courthouse in New York after Senator Moynihan. I worked very hard on this speech. I wanted to use the occasion to describe Senator Moynihan's extraordinary contribution to our Nation's public architecture. It is well known, both in the District of Columbia and New York. I closed by quoting the inscription in St. Paul's Cathedral memorializing Sir Christopher Wren. The quote is, "If you would see his memorial, look around."

Well, I said the same could be said about Pat Moynihan. That is, if you look down Pennsylvania Avenue or up to the new courthouse you could see his memorial by just looking around.

Well, the Senator seemed pretty pleased with my remarks and he thanked me profusely. He also corrected me in his ever-so-courteous, gentlemanly, civil way. He said, "Max, I must note that your translation was correct. But the inscription is actually in Italian."

I was crestfallen. I had tried to come up with something that was accurate that would just be the perfect statement that would capsulize the Senator. Well, I must say I have done a little further re-

search. It is true the inscription marks Sir Christopher Wren's resting place. It is also true it is under the east end of the church. But my very, very good friend, it is hard for me to say this, was slightly off. It is not in Italian, but it is in Latin, "Lector, situation monumentum requiris, circumspice."

Senator MOYNIHAN. Well, I got that right.

Senator BAUCUS. You always have the last word, and always accurately and always teaching. I will say no more, except that he is one of the most wonderful human beings that I have had the pleasure to know and certainly one of the best Senators that we have all had the pleasure to work with. Again, just a wonderful, wonderful person.

Senator MOYNIHAN. I am deeply honored, my dear friend.

Senator SMITH. Thank you, Senator Baucus.

Let me welcome everyone to the hearing this morning on the use of comparative risk assessment in setting our environmental priorities. We will hear testimony on the Science Advisory Board report on EPA's case study analysis of residual risk.

I think the materials that we received today for the hearing show that there is a real interest in using the comparative risk assessment to prioritize our resources.

I am particularly pleased that Ms. Kate Hartnett, the executive director of the New Hampshire Comparative Risk Project is here today to talk about New Hampshire's experience with comparative risk. Her testimony demonstrates the continued passion and the innovative spirit that the States and the local governments are bringing to environmental protection that sometimes we forget.

This is the third in a series of general oversight hearing conducted by the full committee. Our first hearing looked at the EPA's proposed budget for fiscal 2001. Our second focused on State successes and the need for a new partnership between the States and the Federal Government.

Today's hearing takes us to the next level, beginning the process of identifying the tools that we will improve our environmental programs with. A comparative risk assessment is one of those tools. We all recognize that there are not enough resources available to address every environmental threat. I think that is the problem, that we forget sometimes that there are not enough resources to address every single environmental threat that we have. So, we have to prioritize.

The Federal Government, States, local communities, private sector and even the environmental organizations all have to target limited resources on the environmental problems that present the greatest threat to human health and the environment.

Our focus therefore is and should be on getting the most out of our dollars. Comparative risk is the tool that enables us to prioritize the risks to human health and the environment and target those limited resources on the greatest risk.

It provides the structure for decisionmakers to do three things. No. 1, identify the environmental hazards. No. 2, determine whether there are risks posed to human beings or the environment. No. 3, characterize and right those risks. Risk managers can then use that analysis to achieve greater benefits.

Finally, we will hear how EPA is using comparative risks to focus on the right problems and strategies and to what extent this approach has led to the development of a results-oriented strategic plan, an overview.

We will hear how many States and local governments are already using comparative risk assessment, a public and open process that allows cooperation instead of confrontation, encourages dialog instead of mandates, and States are setting priorities. They are developing partnerships. They are achieving real results by using this comparative risk as a management tool.

They are using good science to maximize environmental benefits with limited resources. I believe we should encourage and promote that. Hopefully, we will hear that this morning from the witnesses.

Let me welcome this morning Mr. Al McGartland, Director of the National Center for Environmental Economics, Office of Policy, Economics, and Innovations of the Environmental Protection Agency. Welcome.

I would also like to welcome Mr. Peter Guerrero, Director of the Environmental Protective Services at GAO. We are glad to have you here.

Senator Baucus, did you have an opening comment?

OPENING STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR FROM THE STATE OF MONTANA

Senator BAUCUS. Mr. Chairman, first of all, I really appreciate your holding this hearing. It is a very important subject that we are going to have to delve into more deeply as time proceeds.

The second, longer statement I would like to include in the record.

I would like to begin that it is always important for this committee to look at new tools for improving the way we protect public health and the environment. I believe that is a given.

I believe that risk-based tools such as comparative risk assessment can help us. There is not much doubt about that. But when we proceed thoughtfully examining comparative risk and residual risk, I think we should also clearly understand that these are tools, I mean these are mechanisms. They are ways to help us achieve our goals.

It is important for us to realize what these tools can do, but also what they cannot do. As with any tool, any mechanism, there is always a limitation. In the case of risk assessment, one inherent limit is that the science on which it is based isn't, and it really never can be complete. That is simply the nature of science. Science is an analytic logical pursuit which is just that.

We also have to factor uncertainty into our decisions. We also must recognize in addition to science there are other very important values, values such as fairness, values such as equity which are essential components of any environmental decision.

The bottom line is that tools such as risk assessment can certainly help us form our decisions, but they can't by themselves tell us what that decision is and what decision to make.

Also, Mr. Chairman, I would like to briefly comment on the subject addressed by our last panel this morning, namely the status of the residual risk program. I know that some have questioned

has the ability or the resources to remove residual risk from the environment, suggesting that EPA doesn't have enough data or does not have the right data or the right models.

I must say, some of those criticisms are frankly correct only in part, but those feelings may have more to do with inadequate funding and organization than they do with the lack of good science. The 1990 amendments to the Clean Air Act, in those amendments, the conferees carefully considered the issue of residual risk. It was not just thrown in at the last minute.

We also knew there would be uncertainties associated with estimating the risk. That is why we required a report to Congress first with any necessary regulation to follow. It is also why EPA must consider many factors including costs, energy and safety before deciding to issue new regulations.

So, in conclusion, I want to thank our chairman for holding this hearing. It is an extremely important subject. I look forward to the testimony.

Senator MOYNIHAN. Mr. Chairman, may I make a very brief remark to continue on what Senator Baucus has said?

Senator SMITH. Surely.

OPENING STATEMENT OF HON. DANIEL PATRICK MOYNIHAN, U.S. SENATOR FROM THE STATE OF NEW YORK

Senator MOYNIHAN. We are beginning to see the maturing of the whole subject of environmentalism. When I first came on this committee nearly a quarter of century ago, with great respect, our hearings consisted of earnest young people telling us the sky was falling. Well, how did they know? Well, everybody knew. Well, everybody didn't know.

We have almost a quarter of century of gradually building into our legislation, as Senator Baucus has said, some specifications about learning to measure. Never do anything serious about a subject until you learn to measure it. We are now doing it. This is advanced mathematics in many cases, but it is a mathematics we know. Linking the mathematics with actual data is the work we are involved with. I think it is a very cheering note with which to take leave of you all.

Senator SMITH. Let me just say to the witnesses, your complete statements will be made part of the record. Please try to summarize them in 5 minutes.

We are going to be interrupted around 10 o'clock by a vote. So, hopefully, we can get through your statements and perhaps a question or two before we get to that point. We will probably have to recess for a few minutes during that vote.

Mr. McGartland.

STATEMENT OF AL MCGARTLAND, DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL ECONOMICS, OFFICE OF POLICY, ECONOMICS, AND INNOVATIONS, ENVIRONMENTAL PROTECTION AGENCY

Mr. MCGARTLAND. Mr. Chairman and members of the committee, thank you for inviting EPA to provide our views on the use of comparative risk assessment. I am honored to be here today.

In my role as the Director of the National Center for Environmental Economics, I provide technical expertise and core research to users of comparative risk analysis. As its name implies, comparative risk analysis involves the simultaneous consideration of a wide range of environmental risks so that the seriousness of risk can be characterized relative to one another.

EPA has invested in the development of comparative risk. Our bottom line is that comparative risk assessment is an important tool to help inform our budget and priority setting processes. While it will continue to improve, there are difficulties and limitations that must be well understood. It is not a white line or a mechanistic solution to our difficult priority decisions.

EPA generally applies comparative risk at the national level. State and local governments undertake these studies at a smaller geographic scale and we are pleased to see that representatives from cities and States have been invited to present their perspectives to this committee.

Recently, private companies and industrial sectors are using comparative risk assessment as they incorporate environmental management systems into normal operating procedures. By ranking the environmental problems associated with their operations, businesses can target their protective efforts to the worst risk to workers and surrounding communities and they can achieve the best results at least costs.

EPA has a growing investment in these studies. Our first comparative risk analysis released in 1987 ranked 31 different environmental problems in four different classes: cancer risk, non-cancer human health risks, ecological risks, and welfare effects.

Later, we asked our Science Advisory Board to review these findings and recommend improved methods for assessing and comparing these risks. Even more recently, EPA has published a detailed national study of the benefits and costs of air pollution. The study broke new ground by making extensive use of original exposure modeling and risk assessment.

Finally, our Science Advisory Board recently finished a report on integrated decisionmaking incorporating comparative risk assessments. We continue to work on additional studies to help us in our priority setting and decisionmaking process. In fact, EPA now routinely incorporates comparative risk assessments in our internal decisions and in our partnerships with State, local and tribal governments.

For example, the performance targets identified in EPA's strategic plan reflect the relative priority the Agency will place on different environmental problems and programs. Comparative risk considerations have been explicitly factored into various internal agency-wide budget exercises.

Furthermore, 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.

For example, we are using comparative risk assessments to help develop our schedule for controlling source categories of toxic air pollutants under Section 112(e) of the Clean Air Act.

Our EPA State-tribal partnership activities also use comparative risk analysis. Between 1990 and 1999 EPA provided financial aid, about $1 million per year, to States, localities, tribes and watershed organizations to support comparative risk projects of their choosing.

In most cases these projects resulted in a much clearer understanding of local environmental challenges and sometimes they inspired new environmental initiatives.

In 1995, EPA and the States jointly entered into the new National Environmental Performance Partnership System, or NEPPS. Under NEPPS, EPA and the States jointly set priorities for actions and comparative risk assessment is one of the management tools used by States to determine which programs they want to target for improvement.

NEPPS also gives the States more flexibility in administering EPA grant funds. States can now consolidate a variety of individual grants into one. In short, greater flexibility and comparative risk have come together to strengthen traditional partnerships.

Despite the data and methodological improvements that have been made over the last decade, comparative risk assessment remains an imperfect tool. EPA does not view comparative risk assessment as a white line or a mechanistic way of ordering the Agency's priorities for strategy, budgets or actions.

A number of other factors also have to be considered. For example, many Federal laws set timetables and deadlines for EPA to take specified actions or accomplish specified goals. EPA has an obligation to comply with those legal requirements regardless of the extent to which they reduce risk relative to other actions we might take.

Another difficult problem arises in an attempt to include human health and ecosystem risks in the same ranking. How do you prioritize risks associated with pollutant exposures that may cause cancer in humans as compared to degraded water quality, say, in the Chesapeake Bay that may deplete oyster beds?

The Science Advisory Board recognized this problem when they completed their reducing risk report and they did not attempt to include human health and ecological risk in the same ranking.

This is not a complete list of all the factors that enter into EPA's priority setting process. Other hard-to-quantify considerations like inter-generational equity and environmental justice also have to be weighed.

For our purposes here today, I simply want to emphasize the comparative risk assessments for providing EPA with a useful mechanism for helping us think about environmental priorities, but by themselves, they cannot provide complete answers.

Thank you very much.

Senator SMITH. Thank you, Mr. McGartland.

Mr. Guerrero.

STATEMENT OF PETER GUERRERO, DIRECTOR, ENVIRONMENTAL PROTECTION ISSUES, GENERAL ACCOUNTING OFFICE

Mr. GUERRERO. Mr. Chairman, we appreciate the opportunity to testify on the challenges that EPA faces in using comparative risk

assessment to set priorities. My remarks are based on GAO's long-standing work in this area from our 1988 Comprehensive General Management Review of the Agency to our more recent efforts by EPA to develop the outcome-oriented measures under GPRA.

In summary, I would like to make two points. First, while EPA's priorities should reflect an understanding of the relative risks of environmental and public health concerns, good data often do not exist to fully characterize these risks.

In the absence of reliable data, public perceptions of risk can influence how EPA determines its priorities and allocates resources. EPA's ability to assess risks and establish risk-based priorities has been hampered by data quality problems, including critical data gaps, data bases that are not compatible with one another and persistent concerns about the accuracy of the Agency's data.

EPA has taken major steps during the past few years to improve its data and to better inform the scientific community and public of environmental public health risks, but more needs to be done.

Second, measuring program results or outcomes is critical to determine EPA's effectiveness and the extent to which it is successfully addressing the most serious environmental problems.

Nevertheless, the Agency has historically relied on activity-based output measures, such as the number of inspections performed, because of the inherent difficulties in establishing sound linkages among program activities and environmental improvements in public health.

Spurred by the requirements of the Results Act, EPA has made progress in recent years in measuring the outcomes of its efforts, but more progress is needed here as well.

A short history is helpful for understanding the challenges that EPA faces in setting risk-based priorities and measuring performance. Since EPA's establishment in 1970, the Federal Government has developed a complex system of laws and regulations to address environmental problems.

Over the years as environmental threats were identified, the Congress responded by enacting new laws to address each new problem. However, these laws were not integrated to provide EPA with an overall system for setting priorities to ensure that the most important problems were addressed first.

Compelled by budgetary constraints and a growing list of problems, EPA began in the late 1980's to consider whether its resources were being spent on the problems that posed the greatest risk. The Agency concluded the Nation was devoting more resources to the problems that had captured public attention than to problems that were lesser known, but potentially more serious.

Subsequently, EPA began incorporating the concept of relative risk and environmental risk in its decisionmaking. However, establishing risk-based priorities, as I mentioned, requires good data and EPA's ability to make these assessments is limited by three factors.

The first factor is the extensive gaps exist in EPA's knowledge about environmental and health risks. Let me give three examples. EPA's integrated risk information system, which is a data base of potential health effects from chronic exposure to various sub-

stances, lacks basic toxicity data for about two-thirds of the known hazardous air pollutants.

The second example: EPA's national water quality inventory does not accurately describe water quality conditions nationwide. Only 19 percent of the Nation's rivers and streams are assessed for the 1996 inventory, the latest available at the time of our review, as were only 6 percent of ocean and shoreline waters.

A third example: Of some 1456 toxic chemicals we recently reviewed, actually human exposure data were being collected for only 6 percent. For example, of the 475 chemicals that EPA identified as in need of testing under TSCA, only 2 percent were being measured for human exposure.

EPA has recognized that it has numerous and significant gaps in its data and has initiated several efforts to fill these gaps.

A second challenge facing EPA is incompatible data systems, which makes it difficult for EPA to effectively use information that it does have to manage risks and set priorities.

Over the years, EPA has developed and maintained stovepipe data systems that make the sharing and integration of data difficult. EPA now recognizes that common data definitions and formats, known as data standards, are essential to its efforts to integrate data from various data bases, including those of its State partners.

In recent years, EPA has undertaken several efforts to develop standards for some of the data items in its information systems. According to EPA's Reinventing Environmental Information Action Plan, six standards will be developed, approved by EPA in partnership with the States and in use in 13 data bases by the end of fiscal year 2003.

However, EPA recognizes that current data improvement efforts are only the first step toward its goal of full data integration.

The third challenge confronting EPA is the data that it does have is often not accurate. In various reviews, we and others have shown that persistent concerns exist about the accuracy of data in many of EPA's information systems.

While EPA acknowledges that data errors exist, the Agency believes that in the aggregate its data are of sufficient quality to support its programmatic and regulatory activities. However, EPA has not conducted an agency-wide assessment of the accuracy of its information systems.

To address such problems, EPA revised its agency-wide quality system in 1998 to expand and clarify requirements for how environmental data are to be collected and managed. Although the Science Advisory Board recently commended the Agency for its development of the system, the Board also found the implementation has been uneven.

Moreover, the Board reported that 75 percent of the States authorized to implement EPA environmental programs lacked approved quality management plans.

Finally, Mr. Chairman, I would like to discuss EPA's efforts to develop performance-oriented measures. Closely linked to EPA's ability to manage risks and set priorities is its ability to measure whether what it does is in fact reducing environmental health threats.

EPA has long been aware of the need for environmental measures; nevertheless the Agency has made little progress in developing measures until the results act mandated their use by requiring Federal agencies to report annually on their progress in meeting their performance goals.

Still, of the 364 performance measures that EPA has developed, only 19 percent are outcome measures. The rest are activity measures such as the number of permits issued or inspections undertaken. Developing outcome focus measures will require better data, resources and strategies and, most importantly, sustained management commitment.

In conclusion, GAO's work has identified numerous problems in the quality of EPA's data and the way the Agency manages it. These problems cut across programs and limit the Agency's ability to both assess and compare risks and to measure environmental results.

To its credit, EPA has initiated actions to improvement information management activities, but while EPA has made progress, it does not yet have a long-term strategy to ensure the completeness, compatibility and accuracy of its data.

That concludes my remarks. I would be happy to answer any questions you may have.

Senator SMITH. Thank you, Mr. Guerrero.

I think we are going to have to make an administrative decision here to go vote. We are about halfway through the vote. So we are going to recess for about 10 minutes. We will get back as quickly as possible. We apologize for the inconvenience. Thank you.

[Recess.]

Senator SMITH. The hearing will come back to order. I think the other Senators will be back shortly.

Mr. McGartland, let me just ask you a couple of questions. In your opinion, is EPA trying to develop a roadmap for ranking these environmental problems as a function of risk?

Mr. MCGARTLAND. The answer to that is yes, and let me explain. I mentioned in my remarks the 1987-released study. When that was done, that was the first of its kind, I think there were a lot of people in the Agency that really thought twice about whether this be done or could it be done, even.

But, as any sort of phenomenon has sort of momentum behind it, it has become woven into the fabric of the Agency in many ways. So, I would be hard-pressed to find a program manager who didn't know the results of the Science Advisory Board studies or even the 1987 study and how they have evolved over time. So, I think it has become almost a backdrop to how we do business within the Agency in terms of thinking about what we should be doing next, et cetera.

Then, I think that each program office is doing this, like the Air Office I mentioned earlier and the comprehensive benefit cost study that they did. I think they have even gone beyond looking at comparative risk, but thinking about the risks that are posed and the feasibility and costs associated with reducing those risks, you know, sort of looking backward and also looking prospectively in to the future.

Senator SMITH. When you look at the way the program offices are designed as well as the way the legislation, frankly, is designed, the stovepipe that Mr. Guerrero mentioned, it is really laid out to compete against the concept of comparative risk assessment, isn't it?

Mr. MCGARTLAND. Well, I think comparative risk assessment is certainly easier to do with any given media like air or water, say, because your expertise and the models that one would deploy, the fate and transport models and the scientific models within a specific media share a lot of things in common, but are different across media.

I am an analyst, and from an analyst's perspective I think you can say a lot more with more certainty about the cost and benefits within a specific media rather than making those leaps across media.

I think the other thing that stopped the Agency from just thinking about comparative risk is the other attributes of risks, like is it an exposed subpopulation? It might be a very, very high risk, but the general population might be at low risk.

How do you rank maximum risk compared to total risk or aggregate or average risk? How do you think about, as mentioned, ecological risk versus human health risks? All those issues, including feasibility, I think, curtail or limit the ability of the Agency to think of just comparative risk in terms of putting its steps forward.

Senator SMITH. Well, I think your critics would say that there is not enough of the interaction, that the stovepipe concept does in fact exist. You know, in the Clean Air Act, we do it here. That is the way the legislation is designed, as well.

If you try to say that more focus should be put on one of the stovepipes over another, then you become anti whatever the one is you are criticizing rather than pro-comparative risk analysis. I mean, if you go to any community, pick any community in America and let's just say they have a Superfund problem, they have a Clean Air problem. Maybe they have a CSO problem, why can't they make the determination what is the most immediate threat to them, to their environment, to their health and safety?

That is not happening; is it? I mean it can't be the way we have it now. There might be some risk assessment and prioritization done within the pipe, but not between the pipes.

Mr. MCGARTLAND. I am not as familiar at the State level since mainly my expertise and analysis is generated more toward national studies. But I do think, both from an institutional point of view, but also from an analytic point of view, it is difficult.

I don't know how to compare sort of Superfund risks to a given subpopulation compared to sort of particulate matter.

Senator SMITH. But I think that really is the issue. There is no Federal entity, at least that is what some of the witnesses have said in their written testimony that are going to follow you, or at least one witness said it anyway, there is no Federal entity that promotes and directly assists any State and local government with risk-based decisionmaking.

I mean if it is a priority with you to use this comparative risk assessment, why not work with the States and local communities

to do it? Is there any entity within your department to do that? There is none that I know of, but the question is why not?

Mr. MCGARTLAND. Well, I think I would have to get back to that, Senator. My shop is sort of supporting the program offices. I would certainly welcome the chance to get back to you and the committee on an explanation for that.

Senator SMITH. Yes, I think it would be good to provide at least your view on it for the record as to how we might go about assisting. I might ask some of the other witnesses what their thoughts are on it as well.

Mr. MCGARTLAND. We did, as I mentioned in my remarks—in the 1990's we had a program that worked with State and local governments to think about comparative risks and to actually take them on.

Senator SMITH. Let me ask you, Mr. Guerrero, do you have any specific recommendations that you would like to make to either of us in the Congress or to the Agency in this regard in terms of how we might do better at comparative risk assessment?

Mr. GUERRERO. Mr. Chairman, I think the heart of the Agency's ability to do this type of risk comparison and risk management depends on the quality of the data. I would want to emphasize the key points that we have made that too often data are incomplete. When they are available, the accuracy of the data is sometimes suspect.

The systems that EPA has to manage with are incompatible with one another. So, there is need for data standardization to allow for the integration of information to allow for this type of risk management to occur.

We have made specific recommendations to the Agency to correct these three problems. Fundamentally, we feel the Agency needs a strategic plan that will set forth a clear understanding of where those data gaps are, which ones need to be addressed first, that would establish clear milestones for taking steps to fill in the gaps and that would identify the resources that would be required to deal with that.

I would say that it is in the resource area that the Congress can be of most assistance to the Agency. Data collection and data management have always, when push comes to shove, gotten the short end of things.

It is so critical and so fundamental to the Agency's ability to set priorities and to manage risk that it is important that the Congress work very closely with the Agency in making sure it has the resources it needs to do that job.

Senator SMITH. What would you suggest that EPA do to develop additional result-oriented assessment?

Mr. GUERRERO. Again, I think the key there is data. This year, as we do every year, we looked at their compliance with the Results Act. We observed, and program managers told us, limited availability of data on environmental conditions and on the health effects of pollutants was a major challenge to developing outcome goals and measures.

We also observed that a number of EPA offices were doing a better job than others in helping to develop these outcome measures and fill in those kinds of data gaps.

The Office of Enforcement, for example, had done a fairly good job. But this was an area that required continued attention by the Agency. So, I would say that central to better performance management is again having the right data to assess conditions and to assess results and make corrections in programs to ensure that they achieve their results.

Senator SMITH. Just a final question for you, Mr. McGartland. Under Executive Order 12866, EPA prepared detailed cost-benefit analysis for all economically significant regulations. Under that order EPA was supposed to review periodically existing regs that are economically significant to determine if they can be made more effective or less burdensome.

How effective has EPA been in carrying out those responsibilities?

Mr. MCGARTLAND. I am familiar with only some of those efforts, not every one, since I am in the policy office and not in individual programs. But I know from the standpoint of the Air program, we did a benefit and cost study of the Clean Air Act. We did both a retrospective look from 1970 to 1990, and a prospective look from 1990 into the 2010 timeframe.

In the process of carrying out those studies, we looked at individual provisions of the laws. In that report we highlight where the regulations are that are the biggest net benefit-producing regs and areas of regulatory programs and which are not.

So, in that sense I think we can take away a pretty complete picture in the air quality arena. We are right now working with the Water Office on a similar study, which should highlight programmatic areas with benefits-cost estimates with them.

Senator SMITH. Well, what kind of followup are you doing on what you find?

Mr. MCGARTLAND. Well, two things. One is that we are taking some of the results from the Clean Air Act study, for example, and we are incorporating that in our programmatic priorities. For example, in the air toxic side, EPA proposed a budget shift to move further away from technology-based standards to more risk-based multimedia standards on hazardous pollutants.

So, I think the study is fairly new and the followup is yet to come. The news on the air side was, in general, the net benefits were quite large.

Senator SMITH. I have been on this community for 10 years and I have seen some movement in the right direction in risk assessment. But I will tell you the way I view it and if either of you disagree, then defend yourselves.

In my view, I think the majority of any risk assessment is done within each of these stovepipes. I don't see a lot of risk assessment being conducted between the pipes. That, I think, is the root cause of the problem as far as local communities are concerned.

You are asking local communities to defend themselves against EPA perhaps on a Superfund site that, yes, it looks ugly, yes we would like to clean it up, but no, it is not causing anybody any health problems, it is really not causing any significant environmental problems immediately to the community or members of the community.

But, you know, we have other problems. We are not in attainment with our clean air or perhaps we have a river that is being polluted or whatever and we can't get the resources that we need focused on that because we have to worry about a Superfund site that we probably don't have the technology to clean up and you are telling us we are in non-compliance.

Unless you are willing at the Federal level to begin to look at this and work with the States to move away from this stovepipe, we are never going to get there. I think we have to get out of the box.

That is my view. I think there are some within the Agency who are talking that way, but I think when you look at the way the programs are structured within the EPA, we are not going there. Now, maybe in concept we are in our minds, but we are not doing it with the way the programs are structured.

You just basically admitted yourself, you said, "Well, I am more involved with the Federal end." Well, we need people at the Federal end involved with the State and local end and vice-versa or we are never going to understand these things and we are never going to get there.

I think we have to get out of the box and start getting into the 21st century here. When we started, and Senator Moynihan referred to it, I believe, in his comments, you know, in the 1960's and 1970's environmental regulations were out of desperation. We needed it. We were polluting the air, the land, and the water.

Now, though, we have made significant progress in that regard. I think it behooves us now to take these resources and focus them on the most immediate list and work down the list and prioritize them the same as you do your household budget. You might be planning a vacation, but if your car breaks down, then there goes the vacation money. You have to fix the car. We make priorities. We make decisions. We are not doing that now.

We are out there throwing what we think is our unlimited dollars at these various problems and seldom prioritizing in a way that we could get some of the most immediate health threats and environmental problems out of the way.

I don't think we are ever going to get there if we don't do that. We are assuming that we have so many resources that we could just do it all. That would be nice. Maybe we will get it all at some point. I think before that we need to get to the point where we can start the prioritization process and cleanup the most serious problems first.

As I say, in all due respect, I don't think that is happening really in terms of the way the programs are structured in the EPA.

Senator Baucus, I was just about to leave this panel, but if you have questions, go right ahead.

Senator BAUCUS. Well, I would like to followup on the resource question. What do we need to do an adequate job? To me risk assessment and the threat of risk assessment is a good tool. As I mentioned, it makes sense. I am informed and certainly GAO has concluded that perhaps we could use more resources. But that sort of begs the question in my mind of how much is enough.

Mr. GUERRERO. I think the resources have to follow a coherent strategy and justification for why those resources are needed. The

Agency needs to have a strategy that says, these are the key areas of data that we need to have to be able to set risks and to be able to compare risks and make better informed decisions and here is the schedule on which we need to develop that to support this type of decisionmaking and here are the resources that will be required to fill in those gaps and to make our systems more compatible with one another and to allow us to answer these kinds of questions.

So, when we observed there were these barriers standing in the way of the Agency using risk management to help set priorities, we don't necessarily say, "Well, it is going to take X or Y dollars to do that." I think what is key in here is the Agency having a good, well-founded plan and strategy for what it needs to do to move this process along. That is what is missing.

Senator BAUCUS. Mr. McGartland, do you agree?

Mr. MCGARTLAND. I think we do need more data clearly. Data is very expensive to obtain. I think I mentioned the toxicological data we need from animal studies. The majority of the chemicals are not yet complete in their risk assessments.

Without completion of those things, it is hard to do risk assessment if we don't have the underlying data base to support the toxicology and the epidemiology.

The Agency recently created Office of Environmental Information. It is the first time in the Agency's history we have had a centralized environmental information office. I know that they have taken on a number of interesting, innovative steps, in addition to having a unique facility identifier for every facility in the country so that we can link cross-media data bases, et cetera.

Senator BAUCUS. Having heard Mr. Guerrero suggest we need a schedule, do you agree with that?

Mr. MCGARTLAND. I think a schedule would help. I think if we have clear needs that have been outlined and conversations with GAO and others. We could identify the low-hanging fruit in areas where we can't do our business currently.

Senator BAUCUS. What would some of those areas be?

Mr. MCGARTLAND. The underlying toxicological data to support the risk assessments of the Agency. I think there is monitoring data for painting a picture of the current baseline of the environment both in the water area and the air area and the other media. I think I would probably start with that. As an analyst, that is the kind of value that you need to think about, benefits and costs and what we are going to buy for future regulations.

Senator BAUCUS. Mr. Guerrero, could you suggest some elements of a schedule or what areas? Can we break this down a bit?

Mr. GURRERO. We didn't make very specific recommendations as to specifically which areas. We did observe that there are a number of gaps. The EPA's integrated risk information system lacks basic toxicity data for two-thirds of the known hazardous air pollutants. So this is a key area.

The limited monitoring of the Nation's waterways to assess the quality of lakes, rivers, streams and shorelines is another area. We recently issued a report where we observed that for some 1450-odd toxic chemicals we reviewed, actual human exposure data were being collected for only about 6 percent of those.

So, there certainly is enough information out there from the work we have done and from the work the SAB has done to help the Agency and guide it in terms of setting these kinds of priorities.

Senator BAUCUS. Do States collect much data that is helpful?

Mr. GUERRERO. Yes, they do. In fact, not only do the States collect information but also sometimes information that might be valuable could be collected at the local level from public health agencies and sometimes it can be collected from other Federal agencies.

Senator BAUCUS. How reliable is it?

Mr. GUERRERO. Well, that is the key. What is needed here, as EPA develops this strategy for producing a more complete understanding of environmental conditions and risks, is a strategy to identify how it will bring in these other sources of information and how we will ensure the reliability of that data.

We do know from the work that we have done that there are concerns that some of the State-developed information is not that reliable and needs to be improved. The Agency needs to work with the States in that regard.

Senator BAUCUS. Is there any protocol problem here? You know, one State might collect data a certain way——

Mr. GUERRERO. Yes, and the Agency recognizing that, is developing data quality standards and will be working with the States.

Senator BAUCUS. How much variation is there today?

Mr. GUERRERO. There is some variation. The variation depends on the results of different frequencies in which different States may sample for different water quality standards. They may be sampling using different protocols. All of these issues need to be addressed in terms of improving data quality.

Senator BAUCUS. To me it seems like a gargantuan task. For example, let us take a very parochial example in my State of Montana. I assume the health agencies obtain data with respect to infectious diseases. It turns out that is not the problem for this one community living in Montana, rather it is contamination from an asbestos mine. It is just not an infectious disease.

How do you know what to look for? It is everything. I mean, you need a super, super, super computer, it seems to me, of some kind. I guess I don't know this very well and I am showing my ignorance. But, in theory it is great. I guess as I was saying earlier, you just have to know its limitations.

Mr. GUERRERO. Well, we certainly wouldn't recommend that the Agency kind of throw a blanket over this issue and try to collect everything you could possibly collect. This has to be a targeted, focused effort. That is why, again, I come back again to what we recommended to the Agency. Who is coming up with a strategy? Because it does need to set priorities. It needs to identify key areas where information is critical for making the major decisions it will have to make over the next few years.

Senator BAUCUS. Is anybody working on setting up the strategy?

Mr. GUERRERO. Yes. Unfortunately, it is going much slower than we would like to see. The Agency tells us now it will be a three-phase effort and the first phase will be completed at the end of this year.

So, the good news is yes, the Agency is working on developing this kind of strategy which, in our opinion, it desperately needs.

The bad news is it seems like it is going to take a long while to get there.

Senator BAUCUS. So, we don't know what the strategy is?

Mr. GUERRERO. We haven't seen it. We don't know it.

Senator BAUCUS. So, we have to be as careful as we can to comment whether it makes sense or doesn't make sense because there isn't one.

Mr. GUERRERO. That is right. What I would urge the Congress to do is to continue to oversee the Agency's efforts in this area.

Senator BAUCUS. Absolutely. Thank you.

Thank you, Mr. Chairman.

Senator SMITH. I would just say as a final point, does the EPA make decisions with data or without data? I mean, that is the issue, isn't it? Are you using the data to make your decisions or are you not using the data and making decisions anyway?

Mr. MCGARTLAND. Well, it is a continuum, of course. There is always something in the limit or in the most simplistic cases where we lack the capability to estimate benefits or risks.

We can usually get a very good handle or a reasonable handle on costs and exposure in some sense from experts and what literature exists on the chemical, about the reasonable toxicity, relative toxicity of that chemical vis-à-vis other chemicals. That would be the limited case in terms of a regulatory proposal.

When we had the benefit of a rich epidemiological database or if we actually have human data, et cetera, we are obviously on much surer footing when we move forward in quantifying our benefits. Probably even on the cost side a dearth of data exists.

The Census Bureau used to do a survey called the Pollution Abatement, Control and Expenditure Survey every year, which gave it a handle on how much industry was spending on pollution abatement. They canceled that survey due to budget cuts or repriorities.

So, we are equally challenged on the cost side and are taking steps, I think, to get a handle on that as well.

Senator BAUCUS. This, to me, is just so important, the resources for the data. My State of Montana, 20 years ago, we got a multiyear baseline data EPA appropriation. It is the best thing we ever did because we are then in a position to know what different actions would have on, say, Flathead Lake, MT, in that area, whether it was Forest Service actions or Glacier park nearby or Canada with the potential coal power plants or coal mines.

We had the baseline data, so we could measure what the effects of some actions on the rivers and lakes would be. I just believe firmly, Mr. Chairman, it is foolhardy when this Congress prevents agencies from having the funds and the resources they need to get this data.

Some of it is priorities of the Agency, but I must say I think some of it is kind of Luddite-like of the way that Congress just doesn't want to know. One way you don't want to know is just don't give money to let them find out. I strongly urge all of us together to help in that regard.

Senator SMITH. Well, we thank the panel. There could be questions submitted to you by other members. We will be keeping the record open until the close of business Friday for that.

Thank you, Mr. McGartland and Mr. Guerrero.

We will call up the next panel please.

Senator BAUCUS. Mr. Chairman, I ask consent to have Senator Moynihan's full statement included in the record.

Senator SMITH. Without objection.

Senator SMITH. Panel II consists of Ms. Katherine Hartnett, executive director of the New Hampshire Comparative Risk Project; Mr. Michael J. Pompili, assistant health commissioner, Columbus Health Department; J. Clarence Davies, Ph.D., senior fellow, Center for Risk Management, Resources for the Future, Dr. Elizabeth L. Anderson, president and CEO of Sciences International, Inc.; and Dr. Morton Lippman, professor, New York University, chair of the Science Advisory Board.

Welcome to all of you. Your statements will be made part of the record and I will just go down the table from left to right. We will start with Ms. Hartnett. Since your statements will be part of the record, please try to summarize in 4 or 5 minutes, if you can, please.

STATEMENT OF KATHERINE HARTNETT, EXECUTIVE DIRECTOR, NEW HAMPSHIRE COMPARATIVE RISK PROJECT

Ms. HARTNETT. Good morning. Thank you very much. I apologize for my voice. I think it will last 5 minutes.

Senator SMITH. Excuse me for interrupting you, Ms. Hartnett. But we are going to have to slightly modify our usual process for hearings because the Minority has invoked what has been called the 2-hour rule. Senate Rule 26.5(a) prohibits a Senate committee from conducting business for more than 2 hours past the time that the Senate begins its daily session, which means we can only go until 11:30.

But Senator Baucus and I have agreed that the rule doesn't prohibit the committee from conducting informational meetings so we will try to do what we can on the record until 11:30, but if the Minority does invoke the rule at 11:30, we will adjourn and reconvene briefly for an informational meeting rather than an official hearing.

Should that happen, it would have no impact on the witnesses. They would still be allowed to present that testimony as well as any additional materials.

At a later date when the committee is conducting business, we will see a unanimous consent order to take the transcript of that meeting and put it in as part of the official record.

I am sorry, Ms. Hartnett, go ahead.

Ms. HARTNETT. Thank you very much. I apologize for my voice. I have been talking too much and on too many airplanes recently.

My name is Katherine Hartnett. I am executive director of the New Hampshire Comparative Risk Project. It is a public-private partnership in New Hampshire; very different than some of the models we have heard about.

My job today is to condense 7 years worth of work into 5 minutes. Fortunately, most is conveyed in this book, which I believe everybody has copies. The Comparative Risk Project in New Hampshire focused on environmental quality of life and hazards to that environmental quality of life as the focus of our comparative risk process.

We identified "environmental quality of life" as an intersection of healthy people, healthy ecology, and healthy economy. After a year of talking about our results, we condensed the information down to 26 pages. So, most of the actual process that I am going to talk about is contained in this book called, "For our Future: Our Guide to Caring for New Hampshire's Environment."

The other thing I will observe is that we couldn't agree more with Senator Moynihan. What really has happened is that there has been a maturing of the environmental movement. In fact in New Hampshire we are recognizing the economic root of most of the environmental issues that we face. In the next few minutes I will describe how we got there.

We agreed at the beginning of the Comparative Risk Project our goal was to maximize environmental protection at minimal cost—this was back in 1993. We wanted to separate fear from hazard to try to more effectively prioritize actions.

We looked for solutions that would benefit multiple problems. We wanted to design approaches that productively engage multiple constituencies and showed results. We recognize that everyone has a role in this process.

The Comparative Risk Project worked. We identified 55 stakeholders from businesses, environmental organizations, public health groups, citizen groups, political leaders, State and local government officials. We all gathered in a neutral, non-advocacy setting. We worked to identify, to study, and to rank identified risks to environmental quality of life.

We had technical staff that summarized ecological, public health and economic information in a consistent format with consistent criteria. The group worked by consensus over 8 daylong sessions. The work was important, so it took a while to do. We did rank into an integrated list 55 risks to New Hampshire's environmental quality of life as I defined, "Healthy people, healthy ecology and healthy economy."

We documented the influence of accessible science condensed in this Comparative Risk Project report along with explicit judgment and individual values in the ranking.

We basically designed what has been recognized as quite a credible process. The diverse participants had three requirements: Leave preconceptions at the door, be able to listen to others and work collaboratively, and finally to bring a sense of humor to difficult discussions.

It was important for people to set aside what they knew and listen to the information from a different perspective. By putting environmental quality of life at the center, it allowed us to focus on the intersection of having all three things together: healthy people, healthy ecology, and healthy economy.

We have created a continuum of hazard from relatively higher to lower. The common vocabulary of the severity, the extent, the reversibility, and the uncertainty of individual risks helped this group of diverse people come to some consensus about how those risks were allocated along the continuum of hazard.

We also recognized the long term, meaning 7- to 10-year nature, of the solutions we were talking about.

Now, basically, what we did when we came up with the list of ranked risks, as we began to separate fear from hazard, was to recognize that while 4 of the top 10 risks in the integrated list were risks to public health, 4 of the top 5 were related to threats of air and water quality.

We then traced those 55 risks back to 11 sources, things like energy use, land use, transportation, recreation, food and water.

We identified four key actions to reduce hazard in New Hampshire. Those four were: (1) to continue work on improving public health in New Hampshire—we found that people were living longer healthier lives for a variety of reasons. (2) to continue to reduce releases of pollutants. That is thanks to everything from NEPA, the Clean Air Act, Clean Water Act, Safe Drinking Water Act, RCRA, CERCLA, and SARA. Between 1970 and 1986, the range of Federal and the equivalent State regulations have been successful. After 30 years of regulation, the air, water and land are quite clean and the economy never stronger.

So, in New Hampshire we are focusing now on something called "Minimum Impact Development." We are looking at (3) how we use land; and (4) how we use energy materials and resources.

In terms of comments to Congress based on our experience, we suggest that there may be an opportunity here for Congress to take credit for the work it has done to date, that the regulations that came during the first generation of environmentalists have been successful. Why not take the time to celebrate those successes, and to recognize also that the current set of environmental hazards we face will probably not be solved by any one regulation or group of regulations.

The challenge today is more difficult. There are not clear villains or easy solutions. Everyone is involved, at work, at home, and how we recreate. Information and clear understandings are essential. Why not take the time to convene annual hearings? Ask for consistent information.

We heard about the important role of data on regional and local conditions. Try to incentivize good data. Then work on developing an action plan to support the work of State and local communities, encouraging community-based solutions informed with accessible data and supported by sufficient funding.

Certainly examples that EPA has been involved in a little bit out of the "stovepipe" or "box" might be things such as is currently funding my work under the Sustainable Development Challenge Grant, or the CARA legislation is another example that relates directly to our experience in New Hampshire.

Also, I must mention the essential role of transportation and the question of how we maintain mobility as we grow to greater density in the State. It plays a key role in our economic activity, and can also then be traced back to a wide range of environmental hazards or environmental benefits, depending on how we answer those questions.

So, in short, a key Federal environmental role can be to stimulate, requiring consistent regional and local information about environmental conditions and trends to assemble a national picture and then support a wide variety of actions based on those data.

We would love to see annual deliberations that encourage results-oriented environmental quality, use environmental indicators as measures of progress, and link agency budgets to reducing environmental impacts.

The key role of getting citizens involved, getting results and seeing the effects of Federal support on the ground would be a true legacy for the second generation of environmental management.

Thank you.

Senator SMITH. Thank you, Ms. Hartnett.

Mr. Michael J. Pompili.

STATEMENT OF MICHAEL J. POMPILI, ASSISTANT HEALTH COMMISSIONER, COLUMBUS HEALTH DEPARTMENT, COLUMBUS, OH

Mr. POMPILI. Good morning, Chairman Smith and members of the committee. It is an honor to provide testimony to you this morning, particularly on a process which I strongly believe 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 the impact on our communities and that it is critical to involve the stakeholders in the process.

During the next few minutes of testimony, it is my goal to share with you how we have successfully implemented several comparative risk processes in Columbus, to identify the central themes which have led to the success of these efforts and to make some recommendations.

This all started with a Community Environmental Management Plan, which was established through the Columbus Health Department in 1992. It is made up of five components. The first component was actually based on the Science Advisory Board from U.S. EPA. We have established an Environmental Science Advisory Committee; we call it ESAC, which is a body of 18 environmental scientists, educators and other professionals that report back to us on scientific issues.

The second component was Priorities 1995. It was our comparative risk project. It took over 2 years and it is a classic example of comparative risk assessment. For this we used over 250 community volunteers and they logged over 5,000 hours to come up with a list of actually 192 recommendations for our community.

They identified the city's most pressing environmental problems, analyzed and determined potential risks to citizens, ranked these problems in terms of severity and then developed potential solutions to these problems.

The third component is called our Columbus Environmental Snapshot. They use key indicators to provide the public with status and trend information on the State of Columbus and Franklin County environmental issues.

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 edu-

cational resource and a means of gauging the success of past environmental efforts including status reports on Priorities 1995.

The fourth component, which we started actually in February 1998, was the Columbus Community Risk Panel. It is a 35-member community designed to help Greater Columbus residents make informed decisions about risk.

The panel, through various initiatives, serves as an ongoing research to help develop a more informed citizenry and provide the community with accurate information on health and quality of life risks. Panel members again include public officials, community leaders from government, professional groups, public and private business, health care and educational 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 establishment of community computer centers in African-American 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 information.

The last component is called Project CLEAR, which is a new citizen-driven initiative based on the same principles as our Priorities 1995 Risk Project. It is designed to address Central Ohio's 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 overall air quality. What is particularly unique about Project CLEAR is that it moves beyond the public opinion forum into a more public deliberation process.

Three basic principles underlie all the components of the Community Environmental Management Plan. First, promoting the use of science and scientific information wherever possible, second, developed a more informed citizenry on issues of community health, environment and quality of life, and finally, encouraging public participation in the decisionmaking process.

These principles have not only led to the success of 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.

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 comparative risk process could provide general direction in setting these national priorities, but it is important to understand the limitations of a Federal comparative risk project.

A Federal comparative risk project is doomed to fail because risks encountered in Florida aren't compared to the risks found in Oregon. Instead, it would be most appropriate for the Federal Gov-

ernment to support these efforts on a State and local level and actively promote the principles of sound science and informed citizenry and public participation.

Specifically, the Federal Government can serve as a technical assistance center, both generating data and fulfilling the role of information resource. State and local communities will vary widely in their ability to successfully implement a comparative risk project.

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 central for any behavioral change to occur on the part of the 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 would be helpful for States and local communities to look to the Federal Government for funding of comparative risk projects or at least linking to the 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 U.S. EPA office to directly assist State and local folks interested in doing this type of work.

The Regional Statistical Planning Branch of the Office of Policy Planning and Evaluation was extremely helpful to us in Columbus, providing a $50,000 grant for our project and direct technical assistance and 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 the personnel were reassigned within the Agency. To my knowledge, there is no Federal entity that exists concerned with promoting and directly assisting State and local governments with projects dealing with risk-based decisionmaking.

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 the effort according to local community's needs.

U.S. 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, actually a week ago today an effort which took over 3 years to finalize.

In asking for flexibility, however, local communities need to hold themselves accountable and maintain, if not higher, standards that those set forth at the Federal level.

If by your flexibility at the Federal level you are demonstrating your trust of the State and local government to make sound environmental decisions, we must safeguard this trust and work cooperatively with you toward 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 of

our citizenry are expressing dissatisfaction or disinterest in civic responsibility.

While they are disengaging from the political process, you 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 the residents to make these programs work. I am a very strong believer that our citizenry will make the right decisions.

If they are able to receive information in an understandable way, if they are presented with accurate portrayals of the existing tradeoffs regarding risks, and if the decisionmaking process reinforces the need to consider a whole range of options available.

If these themes maybe woven through the Federal, State and local government we may yet see a public which still seeks out their civic roles.

Thank you.

Senator SMITH. Thank you very much, Mr. Pompili.

Dr. Davies, welcome.

STATEMENT OF J. CLARENCE DAVIES, SENIOR FELLOW, CENTER FOR RISK MANAGEMENT, RESOURCES FOR THE FUTURE.

Mr. DAVIES. Thank you, Mr. Chairman. 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 my views and do not represent RF's views. Resources for the Future is a research institution that doesn't take positions on public policy issues.

Comparative risk assessment is an important analytical tool that deserves the attention this committee is giving to 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 comparative risk assessment. Most importantly, we have no common metric to deal with the diverse kinds of risks that government addresses. When I was at EPA, we referred to this as the "How many whales is your grandmother worth" problem. The problem was how do you get some comparability among very diverse end points.

I might say that just dividing health risks from ecological risks doesn't solve that problem. Different kinds of health risks, different kinds of ecological risks present the same problem of how do you get some kind of common measurement to compare these things.

There are answers that can be given to these questions, but the answers are heavily dependent on values. Even if scientific understanding was perfect and data were complete and accurate, the value elements inherent in CRA would prevent comparative risk assessment from ever being a purely scientific undertaking.

The science and the data in most cases are woefully incomplete. Other witnesses have commented on that. This adds further elements of uncertainty and value judgment to comparative risk.

There are different kinds of comparative risk assessment and it is important to make some distinctions among them. 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. You use different methods and different approaches to do those two different things. That doesn't make life any simpler, but it is true.

This hearing is focused primarily on programmatic comparative risk assessment and it is important to keep that in mind.

More generally, the type of comparative risk assessment undertaken and the process used to make the comparisons should depend on the purpose for which the comparative risk assessment is being done. Doing a comparative risk assessment to establish research priorities involves quite different considerations than doing one to establish enforcement priorities, for example. So, the kind of priorities that you are working with is a crucial factor.

In my written statement I talk about various uses of comparative risk. I am going to skip over that, but there are a number of uses to which comparative risk assessment can be employed and they are important and it is an essential tool.

I do want to talk a bit about the limitations of comparative risk assessment. As I noted, the assumptions and values that unavoidably enter into both risk assessment and comparative risk assessment are major considerations. Risk assessment is an odd mixture of science, non-science, and comparative risk assessment necessarily suffers from all the limitations 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 program to protect drinking water in this country, drinking water would rank among the highest risks, as it does in many developing countries. However, because we do have protection programs in place, the current risks from drinking water in the United States are not great.

In the context of budgeting, for example, how to deal with existing efforts poses difficulties for comparative risk. We cannot do zero-based budgeting, in a sense, because on a zero-based budget you would have nothing protecting drinking water and that would be a very high risk, but it is a very low risk if you just look at the risks at the present time. So, taking into account current efforts is a major methodological problem.

Most importantly, comparative risk assessment deals only with risk and risk is only one of several factors that enter into most government decisions. Again, other witnesses have commented on this, but cost is an obvious factor.

To the extent that decisions should be based on cost-benefit analysis, risk is only the benefit side of the equation. You somehow have to get cost in there as well.

Furthermore, you cannot do a cost-benefit analysis of a problem, only of a solution. Whereas comparative risk assessment deals with problems—air pollution, water pollution, cost-benefit deals with solutions—inspecting automobiles, installing technology in plants and so on.

So you are dealing with two different universes of things when you deal on the one hand with cost-benefit analysis and on the other hand with comparative risk assessment. Getting from one type of analysis, comparative risk, to the other, cost-benefit, is not simple because you are analyzing two distinct sets of things.

Let me note a few other limitations. First, how the comparative risk assessment is done can have an important effect on the outcome. A paper by my colleague, David Konisky, which I would like to submit for the record, demonstrates that problem. How broadly you define the categories makes a big difference in how you rank the risk.

Second, how to involve the public. Mr. Pompili is absolutely right about the critical importance of involving the public. But that means you have to resolve how you combine technical scientific information with the information that the public brings to bear.

Then, finally, the data problem, which has been commented on extensively. Let me simply say that in terms of the committee's tasks, I think the time is long overdue to create a Bureau of Environmental Statistics, comparable to the Bureau of Labor Statistics or the Center for Health Statistics. We need that. There is no such institution in the environmental area. It would be a major step forward, both in terms of improving the amount and the quality of data. We have no central place to look to for environmental statistics and we need one.

The statutory context makes a big difference. In my written testimony I make several comments about it. Let me just second the comments you made, Mr. Chairman, with regard to the problems of stove piping.

However, let me say that in my view as long as the statutes are drafted in a stovepipe fashion, the Agency cannot organize in any other way than by stovepipe. The stovepipe, medium-by-medium organization is a major impediment to doing comparative risk assessment. It is also a major impediment to data collection.

In the long run we need an integrated single environmental statute. That is the only way we can overcome the stovepipe problem.

In fact, the United States, in a decade or so is going to be one of the few industrialized countries left that doesn't have an integrated environmental statute. The Europeans, the Scandinavians, a number of countries have already gone in that direction of integrated environmental statutes. The United States is going to have to face up to that sooner or later.

Let me conclude by saying that despite its limitations, comparative risk assessment 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 decisionmaking. 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.

Thank you, Mr. Chairman.

Senator SMITH. Thank you very much, Dr. Davies.

Dr. Anderson, welcome.

STATEMENT OF ELIZABETH L. ANDERSON, PRESIDENT AND CEO, SCIENCES INTERNATIONAL, INC.

Ms. ANDERSON. Good morning. I am pleased to be invited by this committee to testify on the important issues of risk assessment, particularly as they are involved in two programs of focus today: The Comparative Risk Program and the Residual Risk Program.

My name is Elizabeth Anderson. I am president of Sciences International, an organization that specializes in the health and environmental sciences.

Previously, I was privileged to be involved in founding and directing the first EPA's carcinogen assessment group. Subsequently, I also directed the expanded office, the Office of Health and Environmental Assessment, where I had the opportunity to essentially direct the Agency's central risk assessment programs for 10 years.

I was also the executive director of the committee that first adopted risk assessment and risk management as a process for regulating environmental toxicants.

Subsequently, this committee wrote the first agency's risk assessment guidelines. I have been involved for many years with the Society for Risk Analysis as a founder, past president and currently editor-in-chief of the society's flagship journal, "Risk Analysis: An International Journal," that serves as an international focal point for developments in risk analysis.

Obviously, a principal focus and interest of mine is improvement in the sciences supporting risk assessment. Two important applications of risk assessment that we are discussing today, the comparative risk assessment program and EPA's Residual Risk Program are of great importance and must rely on the tools of risk assessment.

In the case of comparative risk, we are comparing human health and environmental risk across many programs and many media to set priorities to assist informed decisionmaking. In the Residual Risk Program the regulatory requirement is to assess residual risk in a relatively short period of time following the application—that is 8 years after the application—of maximum achievable control technologies across all of the major industry categories.

Today, I want to discuss essentially the important progress and the importance risk assessment has to these activities. The details of my testimony are presented in my written statement, which thoroughly explores these topics.

I will summarize that testimony by focusing on the five areas that I have selected as the principal focus for my recommendations.

First, the complexity and cost of conducting risk assessments called for by Comparative Risk and the Residual Risk Programs is really unprecedented. For example, when we think of the Residual Risk Program, we are speaking of 188 hazardous air pollutants that must be evaluated for 175 source categories involving literally thousands of facilities. This must be done in a relatively short period of time.

Even more toxic pollutants and sources must be considered in the Comparative Risk Program. The previous experience with programs such as this has been limited. Let me just mention this because I think it is very important. We are considering individual

and population risk and ecological risk in multi-pathway risk assessments across many industries, facilities, and pathways.

The prior experience with these kinds of comprehensive risk assessments has been with individual Superfund sites and individual facilities that are combustion sources, not these comprehensive source categories. So, this is an enormous challenge.

My recommendation is that we must have a thoroughly disciplined tiered approach that everyone subscribes to. The first tier would certainly employ the best available data, but would be recognized as a screening level assessment.

For those sources that have low risk, obviously, no further work needs to be done. For the sources that appear to be posing a risk of any concern, the next tier would involve a sensitivity analysis to focus on gathering data for the most important parameters to express risks more accurately.

Resources necessary to conduct these risk assessments both within EPA and on the part of involved parties needs to be recognized. In addition, I see no way that these risk assessments can really be refined without a partnership with the involved source categories.

EPA's current draft guidelines for this tiered approach really fall far short of specifying this kind of disciplined approach and following the steps that I have laid out in my testimony. That is, to have the initial upper-bound risks serve a screening purpose, but then to very clearly articulate what kind of risk assessment steps would follow and under what guidelines and when they would be triggered.

Second, I wanted to identify several policy issues that these two programs essentially require for clarification. Historically, EPA has limited its risk assessment guidance for hazardous air pollutants to carcinogens, inhalation risks, and risks to individuals, but has not addressed how judgments will be made about multi-pathway risks and how broader population risks will be considered.

Further, language in the 1990 Clean Air Act Amendments for residual risks states that environmental risks must also be considered, there is some very specific language.

How these policy issues will be considered under the Residual Risk Program must be clearly articulated. There should be an opportunity, clearly, for public involvement and comment before arriving at final criteria for identifying risks of concern.

Third, emissions data must be substantially improved. Historically, EPA has used the readily available emissions data that it has. Often these are estimated values rather than more precise measured, post-regulatory emission values.

The risk assessment can be no more accurate than the emissions that are used in the dispersion model. I recommend that in the second iteration these emissions data be improved. Again, I see no way of improving these data without a partnership with the organization and facilities that have the best emissions information.

Fourth, the integrated risk system, the IRIS data base, as a repository of regulatory toxicity values must be revised. The risk assessment forum for which I was the first director, set up the IRIS data base and commenced the stewardship program of employing information readily available in the Agency to establish this data

base principally to ensure consistency across the regulatory programs and to share information.

It was really not intended as a direct use for regulatory decisions. Since that time the IRIS data base has become not only the most important source of regulatory toxicity values for all of EPA's programs, but it is widely used by State and international programs as well.

The IRIS files include over 500 chemicals. Many of these are woefully out of date. I have discussed a number of these issues in my written testimony. My recommendation is that for the identified 188 air toxic chemicals, refinements in the toxicity issues need to be revisited as a part of the Tier 2 risk assessment process. The same concept need to be entered into refinement for the Comparative Risk Programs.

I recommend, as everyone else does, that the resources need to be committed to EPA to update all of the over 500 chemicals in the IRIS file and to maintain this data base in a refined and up-to-date status.

In making this recommendation, however, I recognize that it is an almost impossible task. Nevertheless, I think all efforts should be made to carry it out. To be totally practical, I further recommend that the preface to the IRIS date base be restated to recognize reality.

That is that the data base 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 assure accuracy in risk assessment for risk management decisions.

Finally, uncertainty and variability analysis must be applied more explicitly. Historically, EPA has come to recognize the importance of performing variability and uncertainty analysis, but to date the Agency has been able to do so for a very limited number of parameters used in the risk assessment.

This process needs to be extended to address all parameter categories. However limited or precise the uncertainty analysis and the variability analysis may be though, it is not clear what, if any, role these analysis play in the risk management process.

I recommend that there be clear guidelines developed for the use of uncertainty and variability analysis in making management decisions. I have suggested some ways of doing this in my written testimony.

Finally, I think risk assessment is an exceedingly valuable tool. The underlying sciences have been greatly improved since they were first employed in 1976. I believe progress will continue and these processes can provide the essential bases for risk-based management decisions.

Thank you.

Senator SMITH. Thank you very much, Dr. Anderson.

Before turning to you, Dr. Lippman, I am going to have to implement the rule. It will not mean that your testimony will not be officially received at some point, but it will be informational for the purpose of today.

Because of the Senate Rule 26.5 (a) being called for by the Minority, this does prohibit any committee from meeting beyond the 2-hours after the Senate goes into session. As I indicated earlier,

Senator Baucus and I have agreed to adjourn and go back to an informational meeting, which I will do in just a second.

At some point in the future we will ask unanimous consent of the committee to make this part of the record. So, I would just say to the Clerk, just be prepared to make that indication when we have the unanimous consent agreement.

So, at this point I am going to adjourn the hearing.

[Whereupon, at 11:33 a.m., the committee adjourned, to reconvene at the call of the chair.]

COMPARATIVE RISK ASSESSMENT: SCIENCE ADVISORY BOARD'S RESIDUAL RISK REPORT—INFORMATIONAL MEETING

TUESDAY, OCTOBER 3, 2000

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

The committee reconvened outside of the regular order at 11:33 a.m. in room 406, Senate Dirksen Building.

Present: Senators Smith, Inhofe, and Baucus.

Senator SMITH. I will now call this informational meeting to order.

Our next witness is Dr. Morton Lippmann, chairman of the Science Advisory Board.

STATEMENT OF MORTON LIPPMANN, PROFESSOR, NEW YORK UNIVERSITY, CHAIR, SCIENCE ADVISORY BOARD

Mr. LIPPMAN. Mr. Chairman, I appreciate the opportunity to offer information on the scientific basis for the current limitations of and opportunities for future improvements in quantitative risk assessment as a tool for environmental risk management.

This hearing is focused on the capabilities and limitations of current knowledge and technical means of comparative risk assessment in the roles of guiding new legislative mandates, societal choices and individual decisions based on risk avoidance.

In my remarks I will focus on health risks associated with exposure to air-borne chemicals and mixtures thereof in our communities.

In order to determine the extent of any health risk existing among members of the population resulting from the inhalation of air-borne chemicals, we need to know: (1) the concentrations of the agents in the air and for particles, their particle size distribution; (2) the unit risk factor, that is the number of cases and/or the extent of any adverse effects associated with the risk exposure. We may also need to know more about the population of concern, such as the distributions of ages, preexisting diseases, predisposing factors for illness such as smoking, dietary deficiencies or excesses and so forth.

Such direct comparisons can, however, only be made in practice with any quantitative reality for a handful of chemicals; the so-called criteria air pollutants. Their ambient air levels are routinely monitored. Human exposure response relationships are reasonably well known.

For the other hundreds of air-borne chemicals known collectively as hazardous air pollutants or air toxics, there are neither extensive ambient air concentration data nor unit risk factors that do not heavily err on the side of safety, which is appropriate for many of their intended uses, but not for comparative risk.

This disparity has resulted from the different control philosophies built into the Clean Air Act and maintained by the EPA as part of its regulatory strategy.

Criteria pollutants come from numerous and widespread sources, have relatively uniform concentrations across an air shed, require State-wide and/or regional air inventories and control strategies for source categories such as motor vehicles, space heating, power production, et cetera.

There is also a long history of routine, mostly daily measurements throughout the country. By contrast, HAP's sources are considered to be definable point sources at fixed locations. Downwind concentrations are highly variable, and generally drop rapidly with distance from the source.

The emissions standards for hazardous air pollutants rely on technologically-based source controls and are intended to limit facility fence line air concentrations to those that would not cause an adverse health defect to the most exposed individual at the fence line.

Also, until quite recently, there has been no program for routine measurements of air toxics in our communities. That has just started up and there are essentially no data yet available to analyze.

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 non-cancer effects, the data are derived from controlled exposures in laboratory animals at maximally tolerated levels of exposure; it won't kill them immediately.

The translation of the results from these studies, the unit risk factors relevant to humans exposed at much, much lower levels in the environment is inherently uncertain and has been approached conservatively.

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 them being 95 percent upper bound confidence limits, but this descriptor is undoubtedly highly conservative in itself.

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

Dr. Hopke in Panel III will go into some more of the limitations of this approach in the residual risk analysis.

The resulting estimates of health risk are therefore highly conservative, upper bound levels. 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 multiple orders of magnitude built into the risk assessments for air toxins.

The highly conservative nature of unit risk factors for air toxics is well illustrated by a calculation made during work done for EPA during preparation of the section 812 (cost-benefit) Study. It concluded that the imposition of the vinyl chloride National Emission Standard for Hazardous Air Pollutants (NESHAP) had prevented 6,000 cases of cancer.

Since the calculated cancer incidence reduction was considerably larger than the historic incidence level of this cancer overall, it was obvious that the benefit claim for the imposition of the NESHAP was grossly exaggerated.

The National Research Council Committee report on strengthening science and peer review at EPA not only recommended the position of Deputy Administrator for Science, it 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.

Comparative risk assessment is an idea whose time is coming. If EPA is provided with appropriate research resources to harness the new technical approaches and sophisticated research tools now emerging to fill 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 will be greatly improved. I encourage Congress to consider explicitly giving EPA a mission statement that includes the performance of a long-term research program focused on health and environmental risks 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 the invitation to testify on these important issues. I stand ready to answer your questions.

Senator SMITH. Thank you, Dr. Lippman.

Senator Inhofe will be here in a moment. He is going to chair the last panel because I have to leave.

I am only going to ask each of you one question, if you could respond as briefly as possible, and then I will have some other questions for the record and I think other members may as well.

I think many times we have witnesses here and you get the impression that you testify and nobody listens. Congress doesn't listen. It is all just a bunch of testimony and it goes in the file somewhere. The truth is we do. We get a lot out of the hearings when people come here from various disciplines and testify before the Congress. It is very helpful to all of us in drafting and sometimes in eliminating legislation.

Let me just start with you, Dr. Lippmann. In listening to what you had to say, let me just ask you, here is your chance to respond directly and give us some input. The way I read what you are saying, you basically are saying between the lines that EPA exaggerates risk. Is that true? Is that your position?

Mr. LIPPMANN. I would distinguish between criteria pollutants and hazardous pollutants in the air environment. For criteria pollutants, I don't think so. I think from my experience with CASAC committees, EPA has been quite realistic in setting NAAQS for PM

and ozone that protect the public with a very small margin of safety.

With respect to the very different tradition and ways of approaching air toxics, the IRIS values or risk assessment numbers have been highly conservative for historically correct reasons. Thus, these risks in most cases are grossly exaggerated.

In the absence of sufficient information, it will not be conservative in every case because there are uncertainties in the risk assessment which the safety factors protect against adverse effects. But in most cases, clearly the cancer risks and other risks for hazardous air pollutants will end up being very much exaggerated. It is not intentional, but because that is the nature of the information available and the way in which long-standing procedures for risk assessment have been done.

I think Congress needs to give EPA a more realistic basis, mission statement, and organizational framework. The stovepipe issues that you raised earlier really hinder its ability to do comparative risks or even to want to do them.

Senator SMITH. In moving from that to you, Mr. Davies, you said that you felt that you didn't see how we could get there with the stovepipe approach.

Briefly, how would you reorganize those laws? I mean right now you do have a series of specific environmental laws, i.e., stovepipes. How would you suggest that we reorganize in the way of blending these together, if necessary, or what are you suggesting we do, just briefly?

Mr. DAVIES. I am suggesting that one goes to a single integrated environmental statute. I had occasion 12 years ago to draft such a statute. I would be happy to make it available to the committee.

Senator SMITH. The challenge is accepted. We would like to see it.

In that individual statute you are saying the various components of the disciplines, clean air, clean water, Superfund, and so forth, would be all within that statute and the prioritization would be whose responsibility?

Mr. DAVIES. Well, ultimately, the Administrator's, but the task would be considerably simplified because you would not have individual programs, focused on individual media or individual pollutants, defending their turf in the same way that you do now.

So, it would be easier to set priorities across the entire range of environmental problems.

Senator SMITH. Thank you. We would like to see that.

Ms. Hartnett, as you know, I am very familiar with the leadership in New Hampshire on many of these proposals, especially in risk assessment.

In your view, does Federal law help you or hinder you to do a better job at the State and local level in comparative risk assessment?

Ms. HARTNETT. I will answer actually by referencing a cartoon that is in the record. It is a very good question. The cartoon shows a figure called "science" rubbing a bottle. The genie comes up and the question is "Are you a good genie or an evil genie?" The answer is "yes." I would say the same thing about the role of the Federal Government. Yes. Seriously, there has been a lot of work done, par-

ticularly through work in air resources to relate the nature of the specific chemicals that are regulated to the underlying causes.

In waste, probably less progress.

In water, a mixed record, I would say, in New Hampshire.

Senator SMITH. You reminded me of one of Yogi Berra's infamous remarks when he said, "When you come to a fork in the road, take it."

That is kind of similar to that.

Let me ask you, Dr. Anderson, essentially the same question. As currently organized—as the EPA is currently organized, is it capable of meeting the challenges that you have identified in conducting appropriate risk assessment?

Ms. ANDERSON. I think it is. But there are many other elements to be considered. I think it is not necessarily the organizational structure that is the difficulty.

I have mentioned the complexity of the challenge, and it is an enormous challenge. Resources are always an element, and I have mentioned that as well.

I think the biggest difficulty is to grasp the significance of the advances in the sciences that we are dealing with and find a way to realistically employ them. If there is a commitment to do so, I believe it can be done. But I think there needs to be a very clear prescription for accomplishing this.

I don't necessarily think that the organization of EPA is the impediment to this. I think there are clearly many other barriers because we are not getting there fast enough.

I think the concepts that I presented in my written testimony for trying to correct what Dr. Lippman said earlier, that we have intentionally biased risk assessment to protect public health, this was necessary in the early years because risk assessment approaches would not have been accepted at all had there not been a provision for replacing uncertainty with public health protective assumptions. We were moving from the zero risk tolerance policy to an acceptance policy. So, we had to be sure we didn't underestimate the magnitude of public health.

Having said that, we cannot continue to employ those same approaches for serious regulatory decisionmaking. We said this in 1976. This isn't something new. Therefore, the emphasis needs to be on an iterative process to refine risk assessments, and a commitment to following this process.

Now, whether structure makes this happen or resources make this happen or legislation makes this happen, it is probably some element of all of these. But I think the focus needs to be on the goal and then the way to get there, the implementation process, can be more carefully inspected.

Senator SMITH. That is a good answer.

Finally, Mr. Pompili, you were talking about support and technical assistance from the Federal Government and how it would be helpful to the States. What other role, other than funding, would be appropriate for the Federal Government to assist in your risk-based decisionmaking?

Mr. POMPILI. Right now we are in a situation where we are starting to work with Region 5. We are taking a look at ozone attain-

ment in central Ohio. Now we are using Region 5 a little bit for some technical advice as we are going through this process.

The other thing that comes through, and it is kind of scary but I have been involved with this from time to time, the data that is out there comes across as factual on a local level. Basically, with all this information out there, and it is up on the Web sites and everywhere else, everybody thinks because it is from the EPA, they think this information is always correct.

If we can get that information to be correct and be accurate to what really is going on, it would be very beneficial. So, I talk about having technical information from the regions to help out and second, also having accurate information over the Web that is available on a local level would be a lot more beneficial to our decision-making process.

We know from local experiences that in a great many of decision-making situations the abundance of information causes us more trouble on the local level than it helps. Information is put out there, as the information is out there, there should be an accurate way to distribute data that is useful.

Senator SMITH. Thank you so much for the answers. You have been a very good panel, very interesting. I appreciate all of you coming here. I know many of you came a long distance. Thank you very much for coming and putting up with the little interruption we had to have here because of the 2-hour rule.

I will dismiss this panel and call up Panel III. Panel III is Mr. Lee Hughes, the vice president for Corporate Environmental Control of the Bayer Corporation; Mr. Robert Brenner, Principal Deputy Assistant Administrator for Air and Radiation, Environmental Protection Agency; Dr. Philip Hopke, chair of the Residual Risk Subcommittee, Science Advisory Board; and Ms. Felice Stadler, national policy coordinator of the Clean the Rain Campaign, the National Wildlife Federation.

Welcome to all of you. Since you have one lady, I will start on the right side and move down the panel to the left. Your complete statements will be made a part of the record. Please feel free to summarize in 4 or 5 minutes if you can.

We will start with you, Ms. Stadler.

STATEMENT OF FELICE STADLER, NATIONAL POLICY COORDINATOR, CLEAN THE RAIN CAMPAIGN, NATIONAL WILDLIFE FEDERATION

Ms. STADLER. My name is Felice Stadler. 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 phaseout the emissions of mercury and other persistent biocumulate toxics, PBTs.

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.

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 make performance standards based on the best industry practices to minimize toxic releases.

Have reductions achieved to date solved the air toxics problem in communities and ecosystems throughout the United States? Certainly not. People and wildlife continue to be exposed to toxic air pollution, which harms their well being.

For this reason it is vitally important that EPA move to the next phase of its national air toxic strategy, the Residual Risk Program.

Now, I will mention three reasons for why we need to do this. First, without residual risk, EPA will not be able to address the harm posed by the most toxic air pollutants, PBTs like mercury and dioxins. PBTs are 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 PBTs 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 the most toxic compounds through technology standards. Therefore, the residual risk program is critical to ensure 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 one area. For example, in Memphis, TN, 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 of its sources. Technology-based standards provide the best industry can offer at the time they are imposed. But this does not translate into being the most stringent or comprehensive approach.

In fact, when EPA issued the proposed Portland Cement Kiln rule 2 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.

Without this 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 related 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. It should be given the opportunity to go forward and implement that program. But policy

paralysis will be the result if EPA is required to address every uncertainty before acting.

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 several PBTs are well established. Any release of these pollutants causes harm. For that reason and international agreements, the United States has committed to virtual elimination of these pollutants.

To properly address the unique risks posed by PBTs, EPA may 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.

Thank you for the opportunity.

Senator SMITH. Thank you.

Before I introduce Dr. Hopke, I want to apologize to the witnesses. I have to leave. I do have another appointment. Senator Inhofe is going to finish chairing the hearing.

Dr. Hopke, welcome.

STATEMENT OF PHILIP HOPKE, CHAIR, RESIDUAL RISK SUBCOMMITTEE, SCIENCE ADVISORY BOARD

Mr. HOPKE. Thank you. Mr. Chairman and members of the committee, my name is Dr. Philip Hopke. I am here to discuss with you the views of the Residual Risk Subcommittee on the residual risk methodology as described in EPA's report to Congress, particularly as applied to the secondary lead smelter source category.

I chaired this subcommittee of the EPA's Science Advisory Board's Executive Committee. My testimony will try to reflect the consensus view of the subcommittee with some added input from the Science Advisory Board's Executive Committee, although I am speaking for myself.

In early March the subcommittee conducted a peer-review of an Agency draft case study of the residual risk assessment methodology applied to secondary lead smelter source category.

We understand that the Agency plans another iteration including additional data collection and analysis before these results are considered for use in a regulatory context.

Review of the seven-volume set of materials focused on eight specific questions that are addressed in detail in the SAB report that has been submitted to you.

In short, the subcommittee concludes 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 we provided in the report on this document. The major concerns will be highlighted here.

Because the subcommittee has not seen the full residual risk assessment and thus we are 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: A full ecosystem risk assessment, a health risk assessment that includes population risks, a full analysis of uncertainty and variability, a computer model for assessing multi-media transport and fate that has been adequately evaluated, a clear description of the process and how the assessments will be linked to the eventual risk management decisions.

I would like to highlight a couple of these problems to illustrate a larger concern that we would like to bring to your attention.

The current analysis for secondary lead smelter was done using the multimedia transport and fate model that was originally developed as part of the analysis reported in the mercury report to Congress. However, it was never fully peer-reviewed for its use in mercury, and it was then modified for use with lead without review of assumptions and coefficients.

EPA has been developing a new multimedia exposure model, the total risk integrated methodology that had undergone an initial review by the SAB. It was quite encouraging.

However, it now appears that 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.

Another of the most serious problems was the inability to utilize the available data to test the modeling results. In the secondary lead smelter case, fugitive emissions were found to produce most of the risk.

In several of the cases, results presented in the draft report were implausible in that the predicted concentrations would have produced immediately observable results on the effected human and ecological populations.

In the vicinity of most of these sources, sampling was conducted to test compliance with the national ambient air quality standard for lead and total suspended particulate. Such measurements could be used to test the concentrations at the boundaries of these facilities.

However, the risk analysis could not utilize these ambient monitoring data that are available in the air's data base because of lack of resources to recover and then organize them. An important policy question arises as to how good such residual risk assessments need to be.

It is our understanding that when the form of control specified in title III was being considered by Congress a decade ago, the ex-

pectations for the level of these residual risk analysis were quite low.

The scientific basis of risk assessment has grown considerably over the past years and thus the level of expectation from the scientific community such as those of us who have served on this SAB subcommittee has risen considerably.

Thus, the subcommittee has expressed its concerns regarding future assessments. Accordingly, I wish to use this opportunity to express our concerns regarding the level of analysis that can and should be done to assess residual risk as part of the control of hazardous air pollutant emissions.

The subcommittee 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 needed.

The resulting assessments will be much more credible to both the regulated community and those potentially effected.

I would like to express my gratitude to the members of the committee for inviting me and giving me the opportunity to deliver the SAB Residual Risk Committee's review message.

I look forward to your questions.

Senator INHOFE [assuming the chair.] Thank you, Dr. Hopke.

Mr. Brenner.

STATEMENT OF ROBERT BRENNER, PRINCIPAL DEPUTY ASSISTANT ADMINISTRATOR FOR AIR AND RADIATION, ENVIRONMENTAL PROTECTION AGENCY

Mr. BRENNER. Good afternoon, Senator Inhofe. I welcome the opportunity today to discuss the Residual Risk Program, which is one component of the Clean Air Act strategy for protecting the public from toxic air pollution.

In the landmark Clean Air Amendments of 1990, Congress called for a two-phased approach to reducing toxic air emissions from major industrial sources.

First, EPA is to issue technology-based standards on an industry-by-industry basis to ensure that all plants are well controlled.

In the second phase, EPA must assess the remaining risks from those industries and, if necessary to protect health and the environment, set residual risk standards requiring further reductions in toxic emissions.

A decade later EPA continues to believe that it makes sense to evaluate whether MACT standards provide the public with adequate health and environmental protection and to take action if they do not.

EPA regularly hears from citizens concerned about whether toxics are endangering them. These citizens include minority and low-income residents who are often disproportionately represented in neighborhoods near industrial sites.

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 can help to support reasoned decisions on whether

to require further emission reductions based on the available scientific information and consideration of uncertainties.

When Congress overhauled the Clean Air Act in 1990, it was well established that the public is exposed to toxic air pollutants such as lead, benzene, dioxin, mercury and chromium. It was known that air toxics can cause serious health effects such as cancer, neurological damage, miscarriages, birth defects or lung damage.

In response, Congress rewrote the ineffective air toxic provisions of the 1970 act and mandated a comprehensive strategy to toxic air pollution, including the two-phased approach for major industrial sources that I mentioned earlier.

I am happy to report that the first phase of the program which requires dirtier facilities to achieve a level of performance already being achieved by cleaner facilities of the same type is proving very successful.

Maximum Achievable Control Technology 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 to 1990 period.

As we work to complete those MACT standards, we are in parallel beginning to implement the second phase, the residual risk program.

As Congress directed, we will start with the science. We will conduct risk assessments based on available information, and credible and relevant scientific studies conducted around the world by universities, governments, industry and others.

Considering all the available health information, the law then calls for EPA to make an informed decision whether a source category needs to make further reductions to bring toxic emissions to a safe level.

In the time remaining I would like to talk about some of the issues that are being raised today. A Science Advisory Board panel has reviewed an incomplete EPA case study that illustrates methodologies we will use for screening analysis in the residual risk program.

We asked SAB to review this incomplete case study precisely because we wanted external reviewers to help us improve our methodologies before we finished the study. We are doing just that, based on the very good technical comments that we received.

I would like to submit for the record EPA's response to the SAB. The SAB expressed general concern about data gaps. In response, we are working, for example, to improve the national toxic inventory, a repository of air toxics emissions data from States.

We are working with States and cities to expand monitoring of ambient air toxics levels. We are developing a new, better multipathway methodology called TRIM, the Total Risk Integrated Methodology, which has received two very favorable reviews from the SAB.

We are also conducting modeling on a national and local scale to improve information on the level of air toxics that people are exposed to. We disagree with statements by some individuals that data gaps make it impossible for EPA to carry out the statute.

The law does not require residual risk decisions to be free of uncertainty. For many source categories uncertainties may preclude

a precise risk estimate. Even so, the body of health information often may support a reasoned judgment whether or not public health is protected with an ample margin of safety.

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 an unsafe level of toxics near industrial facilities while we fail to act based on information that is available now.

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.

If there is not sufficient evidence of a threat, however, 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.

Thank you, Senator Inhofe, for the opportunity to testify here today.

Senator INHOFE. Thank you, Mr. Brenner.

Mr. Hughes.

STATEMENT OF LEE HUGHES, VICE PRESIDENT OF CORPORATE ENVIRONMENTAL CONTROL, BAYER CORPORATION

Mr. HUGHES. Good afternoon, Senator Inhofe. My name is Lee Hughes and I am vice president of Corporate Environmental Control for Bayer Corporation. I am responsible for the environmental matters of Bayer's U.S. operations. This includes compliance with the Clean Air Act.

I am here today representing the American Chemistry Council.

Senator INHOFE. Let me ask, for a moment here, on my time, would you elaborate a little more on what the Bayer Corporation does for the record.

Mr. HUGHES. The Bayer Corporation is an operation in the United States, which is owned by our parent out of West Germany. We are a $10 billion operation with 35 facilities throughout the United States employing roughly 24,000 employees making agricultural chemicals, base chemicals, pharmaceuticals, diagnostics equipment, and a pretty multi-service operation.

Senator INHOFE. Thank you. Welcome.

Mr. HUGHES. I am here today representing the American Chemistry Council. The Council represents the leading companies engaged in the business of chemistry. The chemical industry supported the 1990 Clean Air Act Amendments. For over a decade we have worked with EPA in the development of programs that continuously make people's lives better, healthier and safer.

Our industry supports the Clean Air Act's approach for regulating air toxics which first requires the application of technology-based MACT controls and then it looks at any unacceptable residual risks.

EPA has estimated that our industry has achieved a 90-percent emission reduction due to our MACT performance. The residual risk effort can build on these reductions. If residual risk regula-

tions are needed for our industry, they will be due in 2003. This means that important decisions about this program are being made now.

We believe the following key principles will ensure a successful residual risk program. We must first prioritize real and scientifically-validated risks. Second, we must use the flexibility provided in the Act to reduce risks in innovative and effective ways. Third, we must use high quality and peer-reviewed models and data.

These principles are detailed in our written statement. However, we are aware of several barriers that could hinder our efforts to further reduce risks.

EPA's Science Advisory Board has highlighted many of them. These barriers need your attention. The first barrier is outdated health information. The health benchmarks used for residual risk must reflect the best scientific information available. The IRIS data base, the EPA's primary source of health data on hundreds of chemicals is out of date and of varying quality. The Commission on Risk Assessment and the Science Advisory Board agree IRIS's limitations are certain to hinder our ability to identify and then reduce risks.

What can be done? EPA is trying to increase the pace of IRIS reviews and open the process to stakeholders. This process both needs to be supported and expedited so that new information can be used for residual risk assessments.

Staff and resources for IRIS must be increased. Our association members will spend more than $600 million on health and environmental research related to chemical use. The residual risk regulations, however, will be due before we and EPA can complete our work. That is why Congress must ensure that EPA is open to and uses new scientific information in the residual risk regulations.

The next barrier is non-peer review tools. EPA must subject the key tools used in this area to a balanced scientific review. To ensure they are really reducing risks, we must base risk assessments on high quality peer-reviewed science.

Another barrier is outdated emissions and site information. The most recent EPA data on our industry does not reflect significant reductions we have already achieved. To correctly identify risks we need more current information about emissions and facility characteristics. We are voluntarily providing EPA with better information, but the task before both EPA and us is immense.

Finally, the statutory clock is running. There will be a significant challenge to address these limitations within the Act's current deadlines. Adding to this challenge, the Act requires compliance with the risk standards within 90 days of promulgation. This will be a near impossibility if sources must design, procure, and install new technology or change chemical processes to incorporate pollution prevention instead of end-of-pipe controls.

It won't be long before a deadline is missed. Congress should not let this program be carried out by the courts in closed-door settlement discussions.

Again, to achieve success in reducing residual risks we must update health benchmarks and use the most current scientific information. We must peer-review all key tools, obtain better emissions

and site information, and continue this important oversight of EPA's ability to meet the requirements of the Act.

I reiterate our industry's commitment to work with you, EPA and all stakeholders to achieve success.

Thank you for hearing my testimony today. I would be happy to answer any questions.

Senator INHOFE. Thank you, Mr. Hughes.

Mr. Hughes, the thing you brought up last is the thing that concerns me more than anything else. The EPA began the Residual Risk Program by first looking at the lead smelter industry.

It is my understanding that one of the reasons for that was that it is less complicated and there is more data. In other words, you would be able to expedite that a little quicker than some of the rest of the industrial sectors. Is that accurate?

Mr. BRENNER. Well, it happened to be an industry where we had some data that we could begin to look at.

Senator INHOFE. A running start.

Mr. BRENNER. I am not sure it is the one that had the most data available to us.

Senator INHOFE. All right. On the other industrial sectors, have you started those and if so, what is the timeline there?

Mr. BRENNER. We have begun looking at some of the other industrial sectors, yes. You have heard we have begun working with the chemical industry to begin looking at their sources. We have begun looking at coke ovens. The way the act works, the first of these analyses is due to be done at the end of next year.

So, we are trying to conduct a series of screening assessments to see whether additional controls might——

Senator INHOFE. That is the 2002 deadline, the first one?

Mr. BRENNER. I think the first one is actually following 2001 and then there is more following 2002.

Senator INHOFE. Well, you know, I think it is important to talk about this problem today. What I didn't want to happen is to wake up 2 years from now and find out, as Mr. Hughes was suggesting that we are not getting it done in compliance with the laws that we have to live by right now and then end up having the courts getting involved in it.

Even though this has to be very short because of what happened on the floor today, and I will make this real quick, but I am concerned about what choices we have right now.

In the second panel, Dr. Lippman said that we should continue the MACT Program but put off the Residual Risk Program until we can conduct better risk assessments. So, first of all, let me see what reaction to Dr. Lippman's statement you might have at the table.

Mr. HOPKE. I think we are in a position to conduct reasonable residual risk assessments for the purpose of seeing whether any of these post-MACT facilities produce an unreasonable and unacceptable risk.

Again, the precision with which we can do that may not be the best in terms of setting standards or similar kinds of things, but in terms of trying to identify whether there might be any real problems to real people living in the vicinity, I think we have the basic

tools or could have the basic tools in place and time with a bit more focus by the Agency.

I mean, they have been working on TRIM for a while. It was our understanding that it had been slowed down to some extent. We would like to see that really get rolled out and be ready to run.

When you don't even have enough resources dedicated that you cannot poll your own data bases to do reality checks on your models, it seems like something is wrong. So, we think that it is a process with some reasonable fixes that could provide the kinds of information that are going to be needed to make the decisions that are necessary.

Senator INHOFE. Well, Mr. Brenner said that it was incomplete when it was given to the Science Advisory Board.

Mr. HOPKE. We understood that. It was a draft.

Senator INHOFE. Why did you decide to do that instead of trying to get it as complete as possible before giving it? What constraints were you under?

Mr. BRENNER. The reason we did that was we wanted the Board to have an opportunity to look at the methodology before we completed the analysis. That way, if we needed to change the methodology, make adjustments to it, we could do that before we made a final decision on these lead smelters.

Meanwhile, in parallel, we have been collecting additional data to make sure that we have more robust data before we make that final decision.

So, it was an effort to consult with the Science Advisory Board as early as possible in the process. It has proved to be very valuable.

Senator INHOFE. So, now you have had that evaluation so you have a better indication of where you can go from here. What is your timing now?

Mr. BRENNER. Our timing now is to try to continue to develop some of the methodologies that will be used, as you heard. This TRIM model, for example, the Total Risk Integrated Methodology, will be helpful to us in making a final decision on lead smelters.

We are also trying to work to collect additional data, talking to the States, talking to the industry, and talking to some of the health departments in areas where these smelters are located. We want to pull all of that information together and sometime next year be able to make a decision as to whether we should proceed further in the risk assessment process.

We always have the opportunity partway through to decide well, we have looked at the source category, and based on what we found with our initial assessment, there is not enough concern about risks to proceed.

We could decide that we don't need to take additional action in that area and we can turn to other source categories or we may find there is still cause for concern and then we will have to use more sophisticated methodology and data to finally make a decision.

We are hoping to use this screening approach so that in many instances we won't have to spend a lot of time with the industry. Our initial screen will tell us that there is not a significant risk

there and we can return to the areas where our priority should be greater because there is greater cause for concern.

Senator INHOFE. When Mr. Hughes expressed a concern that this end up in the courts, do you all share that concern or what thoughts do you have on that?

Ms. STADLER. I would like to jump back in and respond to the first question and then I can address that as well. We are definitely not done with the MACT program, with the technology-based part of the Clean Air Act.

We would encourage the Agency to continue to invest resources to finish that program and to finish it effectively. There are still a number of key sources that have not been effectively regulated.

At the same time we want to make sure that the residual risk part of the program does proceed and that we don't wait to make sure that all these issues are resolved.

In particular, we would like to see EPA prioritize and start looking at some of the rules that they knew initially were probably not stringent enough. I gave the example of the Portland Cement Kiln Rule.

In the Federal Register notice, EPA did acknowledge that it likely is not an effective rule because it was not regulating some key pollutants. We would like to see EPA go back to that.

In terms of getting things caught up in the courts, we definitely agree, we would like to see this process proceed swiftly, but also not jeopardize quality. But at the same time we don't want to see it get hung up in the courts because then things just basically cease to move forward. That would not be in the best interests.

Senator INHOFE. Are there any other thoughts?

Mr. HOPKE. I don't see that getting it into the courts will be a productive way of protecting public health.

Senator INHOFE. The whole idea is to avoid that.

Mr. HOPKE. Yes.

Mr. HUGHES. I guess one comment which maybe goes to the source of our concern, is seen by just looking at the comparison between that which was done on the lead smelter issue dealing with some 20 facilities and probably less hazardous air pollutants than we are having to deal with in the particular segment of our industry we are currently approaching, which will include over 250 facilities, deal with 100-some chemicals in a lot of different locations.

You know, it is a concern that we haven't, let us say, underestimated the task involved and the complexity involved. When moving from somewhat of a smaller look at the risk assessment approach and now, how are those same principles applied to the larger one?

We will just need to keep watching that, along with the timeframes, to make sure we don't get ourselves in a situation.

Senator INHOFE. When I first walked in I heard Senator Smith—I wasn't sure what context it was in or what question was asked. He was talking about appropriating more money.

Other than pouring more money on this, what role does each one of you see Congress playing in this to try to get this done? Let me start with you, Ms. Stadler.

Ms. STADLER. Well, I think playing an oversight role is always important if it is a constructive role. I think that obviously we need to make sure that the resources are available.

But at the same time I think Congress should support what the Agency is doing to implement this program as opposed to using the oversight process to stall progress.

Congress can make sure that things are going on the right track, that you get feedback from the Agency in terms of whether their resources are adequate, but again, not to use it to basically tie the Agency's hands or to become too prescriptive in terms of how to move the Agency forward.

Mr. HOPKE. I think one of the things would be to clarify just what level of precision and uncertainty in the risk assessment is going to be acceptable.

Again, I think there has been a change in the view of what these residual risk assessments would have entailed when the law was put in place in 1990 relative to then what Congress had asked for from the NAS panel that produced "Science and Judgment" and now a higher level of expectation in terms of the quality of the output product.

I think some clarification as to how good is good enough to make decisions is one of the things that I think we might be grappling with here.

Mr. BRENNER. Senator Inhofe, I believe there are two areas where we could work closely with the Congress on this set of residual risk issues. The first is resources, not to throw money at it, but just the fact that we heard from the earlier panels that to collect data on these chemicals and to collect data on the emissions from the sources of these chemicals is a resource intensive task. Unfortunately, given budget constraints, we have not been able to provide the resources that had been requested in previous years.

Hopefully, there will be some opportunities to work together to address that in the future. Then the second area is on this very difficult decision. If we do find source categories that pose significant risk, then there is a decision as to what level of control might be appropriate, what constitutes what is called in the statute "an ample margin of safety?"

That involves considering risk, the potential for effects on sensitive individuals. It also calls for considering costs and technology availability. That is the sort of thing, where I think as we come to the first few of these categories where such a decision may be necessary, we would probably want to work with you and your staff to talk through these issues and make sure we both understand the set of concerns we would be grappling with.

Mr. HUGHES. I think I will just reiterate on the issue of resources. Without resources the program can't achieve especially the pace that it is expected to achieve. So, supplying resources to make sure that can happen, there you are talking about financial resources to go to the Agency to make sure the programs are funded to where they need to collect data and address those issues from that perspective.

I also think that as we move through the process, I don't have one specific identified at the moment, but there may be cases where we identify, maybe, some problems or some things that need to get fixed.

If there is a way that we can approach something from a more holistic standpoint but we end up getting blocked by a piece of leg-

islation. If there is a way that all the stakeholders could come to agreement that it is a better approach at doing that, support from Congress would be necessary to be able to correct some of those inherent things.

As I said, I don't know or have one specifically at the moment, but as we move through this we typically run into some things like that.

Senator INHOFE. What about deadlines? Primarily, Mr. Hopke and Mr. Brenner, do we need more time?

Mr. HOPKE. Well, at the level of resources currently being allocated, I cannot imagine how they are going to meet the deadlines.

Mr. BRENNER. I think it is too soon to say that we are going to need more time. We are conducting these screening analyses. We are working on collecting the additional data.

I still believe that by working with the industry groups, working with the States, using data that other governments have collected the California EPA, that we can move through the initial screening assessments rather rapidly and then see how many industry categories we need to focus on.

I think until we have gone through those early stages to see how this screening process works, we don't know yet that we will need more time.

Senator INHOFE. Here is what I would like to do and one reason we wanted to have this: To avoid a train wreck, now is the time to be addressing this thing.

What I would like to ask you to do, Mr. Brenner—well any of you while you are working your way through this—if it appears that deadlines have to be changed, that, you know, changes have to be made, that we find out about it early enough that we can do that before we run out of time.

That is one of the major concerns that we have on our side of the table. So, if you can keep us informed as time goes by as to the progress you are making and how much more time you might need, if you do need it, we need to know.

Mr. BRENNER. We will certainly do that and then we can assess, sometimes as we get closer to the deadlines whether more time is needed.

Senator INHOFE. All right. We are right now at the time that we have to quit. I think you know what happened on the floor today. There will be questions that we will send you to be answered for the record.

But right now, if there is any last statement you want to make, the four of you, if you make it brief, this is your chance.

Thank you very much for coming. We look forward to continuing to work with you as we near these deadlines we are talking about.

Thank you.

[Whereupon, at 12:30 p.m., the committee was adjourned, to reconvene at the call of the chair.]

[Additional statements submitted for the record follow:]

STATEMENT OF HON. BOB SMITH, U.S. SENATOR FROM THE STATE OF NEW HAMPSHIRE

Good morning. I want to welcome everyone to today's hearing on the use of Comparative Risk Assessment in setting environmental priorities. We will also hear tes-

timony on the Science Advisory Board's report on EPA's case study analysis of residual risk.

I think the excellent materials that we received for today's hearing show that there's a real interest in using the comparative risk assessment process to prioritize resources. I am particularly pleased that Ms. Kate Hartnett, the executive director of the New Hampshire Risk Project, is here today to talk about New Hampshire's experience with comparative risk. Her testimony demonstrates the continued passion and innovative spirit that states and local governments are bringing to environmental protection.

This is the third in a series of general oversight hearings conducted by the full committee. Our first oversight hearing looked at the EPA's proposed budget for fiscal year 2001. Our second oversight hearing focused on State successes and the need for a new partnership between the States and the Federal Government. We learned about programs that work, and those that don't.

Today's hearing takes us to the next level—beginning the process of identifying the tools that will improve our environmental programs. Comparative risk assessment is one of those tools. We all recognize that there aren't enough resources available to address every environmental threat. The Federal Government, States, local communities, the private sector, and even environmental organizations all have to target their limited resources on the environmental problems that present the greatest threat to human health and the environment. Our focus, therefore, is, and should be, on getting the biggest bang for the limited bucks.

Comparative risk is the tool that enables us to prioritize the risks to human health and the environment and target our limited resources on the greatest risks. It provides the structure for decisionmakers to: (1) identify environmental hazards; (2) determine whether there are risks posed to humans or the environment; and (3) characterize and rank those risks. Risk managers can then use that analysis to achieve greater environmental benefits.

Today, we will hear how EPA is using comparative risk to focus on the right problems and strategies; and to what extent this approach has led to the development of a results-oriented Strategic Plan.

We will also hear how many states and local governments are already using comparative risk assessments a public and open process that allows cooperation, instead of confrontation, and encourages dialog, instead of mandates. States are setting priorities, developing partnerships, and achieving real results by using comparative risk as a management tool. They are using good science to maximize environmental benefits with limited resources. I believe we should encourage and promote these successful programs.

I look forward to hearing from the witnesses this morning.

STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR FROM THE STATE OF MONTANA

I would like to begin by thanking our committee Chairman, Senator Smith, for holding this hearing. The issues of comparative risk assessment and residual risk analysis are not only important, but timely.

COMPARATIVE RISK ASSESSMENT

I believe that it is important for this committee to continue to examine tools for improving the ways in which we protect public health and the environment.

We need to always look for new approaches to addressing lingering or emerging environmental problems. We must determine which of these tools will give us the results, and the efficiencies, that we need.

And at the same time, we must set environmental priorities more effectively than we have in the past so that our efforts, and the money that is available, will address the most pressing problems.

I believe that risk-based tools—such as comparative risk assessment—have much to offer in this regard. Because of this, I have long been a strong supporter of the use of risk assessment as an environmental policy tool.

For example, I worked hard with Senator John Chafee and other members of this committee to find an appropriate role for risk assessment when we amended the Safe Drinking Water Act in 1996. I am proud of what we came up with. I think we significantly improved that law.

At the same time, however, I have also long believed that we need to proceed carefully and thoughtfully as we consider using risk-based tools. We need to clearly understand what each tool can do. And what each can't. Otherwise, we may end up expecting too much or too little of them.

For example, while I'm a supporter of risk assessment, I often think that its most ardent proponents oversell it. They simply gloss over inherent limitations to risk assessment, such as the gaps in data or scientific understanding, the absence of important analytical methods, and the sensitivity of this tool to underlying assumptions.

We need to be honest about risk assessment. We take its strengths—and weaknesses—fully into account in each and every application of risk assessment.

Further, it is important to remember that any tool we may decide to use to assist in decisionmaking is just that, a tool. There are no "silver bullets" for decisionmaking.

One of the reasons for this is that, despite when we may hear sometimes, the "science" we must depend on is, and can never be, complete. That's simply the nature of science.

I recall a speech made by Senator Smith, one he made when he first became this committee's chairman, in which he said that we can't deny a problem just because the science is uncertain. I couldn't agree more. If we waited for scientific certainty, we'd end up deferring action on every single environmental problem we face.

Furthermore, it is critical to recognize that values such as fairness, equity and other subjective judgments are essential components of any environmental decision.

A risk assessment may legitimately find that, for most Americans, hazardous waste sites pose little risk. But it is equally legitimate, from the perspective of fairness or equity, to ask whether this means we should decide not to protect the health of the minority of Americans who happen to live near these sites.

The bottom line is that, when used carefully and thoughtfully, tools such as risk assessment can be extremely helpful in informing environmental policy decisions. But they cannot by themselves make these decisions.

RESIDUAL RISK

Before I end, I would like to say a few words about the second part of today's hearing, residual risk. I look forward to hearing from our last panel about the status of the residual risk program.

As everyone here knows, we're gradually beginning stage two of the ambitious control program for toxic air pollutants that we started in 1990. The MACT standards are almost all done now and EPA has begun to look at reducing the risks to public or environmental health that remain after MACT has been applied.

Some people have questioned whether EPA has the ability or the resources to regulate to get rid of "residual risk." They suggest that EPA doesn't have enough data or the right data or the right models. Some of those criticisms may be partly on the mark, but that has a lot more to do with funding than "science." Residual risk was a carefully considered provision of the 1990 Amendments and it was not adopted lightly. We understood that there would be significant uncertainties associated with estimating risk.

That's why we required a report to Congress first, with any necessary regulation to follow. And, that's why EPA has to consider costs, energy, safety and other relevant factors, before issuing regulations to reduce residual risk.

I look forward to making this program work and further reducing toxic air pollution.

Again I would like to thank Senator Smith for holding this hearing. I hope it provides this committee with an opportunity to learn much more about EPA's residual risk analysis, as well as comparative risk assessment and what it has to contribute to improving environmental decisionmaking.

STATEMENT OF HON. DANIEL PATRICK MOYNIHAN, U.S. SENATOR FROM THE STATE OF NEW YORK

Mr. Chairman, fellow members of the committee, I am delighted to be here for a hearing on risk assessment, a topic on which I held my very first hearing as chairman of this committee in 1992. I am also deeply grateful to my friends for their kind words today.

I remember fondly the many significant accomplishments that we have made together on this committee. In 1980, 1982 and 1990 we wrote significant legislation to curb acid rain and other air pollution that has choked our skies, fowled our waters, and endangered our health. We have come a long way to fix these problems, but we still have more to do and I hope the committee will continue to focus on air pollution and pass legislation next year to address these ongoing threats. In 1986, we passed the landmark Water Resources Development Act (WRDA) which broke a deadlock that had stalled millions of dollars of civil works projects critical to State

and local communities. One of my proudest achievements is our work on the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 which has changed the way we view transportation policy.

I have greatly enjoyed my time serving on this committee since I was first appointed on February 11, 1977. I began my service on the committee under the leadership of Senator Jennings Randolf of West Virginia and served as chairman myself in 1992. More recently the committee has had a wonderful period of productivity under the sage guidance of my beloved friend, the late John H. Chafee. Today, Senator Smith serves as a facilitator who conducts the committee's work in a fair and open process. I will surely miss this committee, its work, and the friends with whom I have had the privilege to serve.

The matter before us today is one that we cannot take lightly. The calculation of risks posed by environmental contaminants and the subsequent determination of appropriate regulatory controls is a complex exercise that involves not only the lives of our citizens and the health of our environment, but the State of our welfare and economy. It is quite clear that environmental regulations have prevented millions of deaths EPA has estimated that the Clean Air Act alone prevents 205,000 cases of premature mortality annually. At the same time, Resources for the Future estimates that $160 billion is spent annually in the United States for environmental compliance. This may not be too much to spend on environmental protection, but it is too much to spend unwisely.

Comparative risk assessment is an example where science must take the leading role. Only science can give us the parameters to estimate the relative risks posed by varying concentrations of toxic substances. However, good science can only be accomplished with adequate resources and data. The Science Advisory Board has reported to us that EPA lacks the resources and data to adequately address some aspects of risk assessment. We must support EPA's request for more research dollars if we are to expect EPA to adequately address this issue.

In conclusion, I have always believed that good science makes good policy, and good policy makes good politics. While factors such as cost, welfare, and even politics indeed play a role, we must ensure that environmental decisions can always be justified by scientific research. I thank the committee for the opportunity to discuss this issue and, again, I am grateful to my colleagues for their kind words today and for their valued friendships throughout the years.

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Thank you, Mr. Chairman, for holding a hearing on this important topic.

Congress tends to address environmental problems one at a time. The Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act are each massive, complex laws, and we rarely take the time to examine where these laws intersect. Last week, this committee held a hearing on the Streamlined Environmental Reporting and Pollution Prevention Act, which I have introduced with Senator Crapo and which, Mr. Chairman, I hope we can mark up soon. That bill reduces the administrative burdens associated with the piecemeal nature of environmental reporting.

This hearing essentially addresses a similar issue. In this hearing, we will discuss whether our current environmental laws are focused on the whole forest, or just a few well known trees.

That may sound like an abstract notion, so let me bring it to life. In Toms River, New Jersey, there has been observed a higher than normal incidence of certain childhood cancers. It's a terrible situation, and one that is likely happening undetected across the country. So what's causing it? How do we prevent it? Was it caused by any of the dozens of chemicals found in tiny amounts in the water? What about the radioactive materials released to the air from the nearby nuclear plant? What about the pollution from the cars on the parkway which bisects Toms River? What are the greatest environmental risks to this community?

And these are just the questions science can answer. When we as policymakers decide how best to prevent environmental risks in this community and across the country, we face other questions that have no scientific answer: How do we compare the risk of an elderly person's premature death to that of a child's asthma attack? How do we compare risks to our health risk to those of our grandchildren and their children? How do we compare a human health risk to the extinction of an animal species? At what point do we decide we know enough about an emerging risk to take a precautionary approach? There are no scientific answers to these questions—yet

we can't decide how best to allocate our risk reduction resources without resolving them.

That all being said, I look forward to the thoughts of our expert witnesses on these challenging issues.

Thank you, Mr. Chairman.

STATEMENT OF HON. JOSEPH I. LIEBERMAN, U.S. SENATOR FROM THE STATE OF CONNECTICUT

As the 106th Congress draws to a close, I would like to take this opportunity to bid farewell to a good friend and a man I deeply respect, Senator Frank Lautenberg, who is retiring at the end of this Congress.

During his 18 years in the Senate, he has admirably served his constituents in New Jersey but he has also served Americans nationwide. With his acute understanding of the issues, his principled nature, and his strong, effective leadership, he has stood firm for families. He has worked tirelessly to build a strong economy, to better the education and mentoring of our children, to rebuild the infrastructure, and ensure equal rights and equal opportunity for all Americans. He leaves a legacy of legislative success from which the Nation will benefit long into the future. Today, however, I would like to pay special tribute to his work to preserve our environment.

In our time together on the Environmental and Public Works Committee, Senator Lautenberg has achieved great things. One that stands out is the role he played in renewing and improving the Superfund program. His insistence that people living near hazardous waste sites be protected from health risks motivated him to address the broader threat posed by poisons seeping into the earth.

Senator Lautenberg must also be credited for another noteworthy achievement: public access to information about toxic chemicals manufactured, used or transported in our communities or released into the environment. His leadership was instrumental in the establishment of the Toxics Release Inventory, which, as part of the Emergency Planning and Community Right-To-Know Act and the Pollution Prevention Act, requires a publicly accessible toxic chemical data base to be developed and maintained by the Environmental Protection Agency (EPA). In great part, because of Senator Lautenberg's vigilance, Americans now have access to this valuable source of information that both encourages companies to better manage their toxic substances and provides citizens with the data necessary with which to challenge violators.

My colleague's love for the environment did not stop with his work to clean up the land. It extended to the air we breathe and the waterways that sustain us. As a longtime advocate for clean air, he led the fight to include a section in the 1990 Clean Air Act Amendments that set specific limits on the allowable levels of specific hazardous air pollutants. This was a significant achievement in Congress' efforts to improve air quality, since before 1990, EPA had not regulated the majority of these chemicals. The language Senator Lautenberg drafted left no uncertainty, and we began to remove these toxins from our skies.

For Senator Lautenberg, the quality of indoor air was equally as important. He championed the ban on smoking on domestic airline flights, an accomplishment that literally allows traveling Americans to breathe easier every day.

He has likewise been a strong advocate of clean coastal areas for the safety and enjoyment of our citizens. My friend wrote legislation to ban ocean dumping of sewage and to clear beach areas of rubbish. He responded to constituent complaints of syringes littering the beaches and actively promoted legislation to control medical wastes. And he worked to stop offshore oil drilling and to prevent oil spills from polluting the water fronts and endangering wildlife.

Finally, Senator Lautenberg's abiding interest in transportation has improved the safety and quality of life for Americans coast to coast. He successfully encouraged states to raise the national drinking age to 21 and has since sponsored legislation to lower the national standard over which a driver is presumed drunk to a blood alcohol level of 0.08. He demonstrated particular leadership in the battle to authorize and fund a national Intelligent Transportation Systems program to reduce traffic congestion and speed motorists to their destinations and successfully sought to block the expanded use of the larger, triple trailer trucks. This was a special victory, for he felt passionately that longer, combination vehicles endangered the lives of others on the road. We must also be grateful for the Senator's longtime commitment to a passenger rail system and mass transit investment. He championed the Boston to D.C. high-speed rail which will open as early as Thanksgiving and sponsored legis-

lation for a major Federal investment in the development of high-speed rail corridors across the Nation.

Through these and many other efforts, the Senator from New Jersey has helped to ensure that Americans live in a cleaner, safer and healthier environment. I commend him for his significant and lasting accomplishments and thank him for his dedication and leadership. It has been an honor to work by his side, and I wish him great happiness in his future endeavors.

STATEMENT OF DR. AL MCGARTLAND, ASSISTANT ADMINISTRATOR, OFFICE OF POLICY, ECONOMICS, AND INNOVATION, U.S. ENVIRONMENTAL PROTECTION AGENCY

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 31 different 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 in 1990 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 use-

ful 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 5-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 decisionmakers, 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 governmentwide 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 dialog 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 startup 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 1990's 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 1990's 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.

RESPONSES OF AL MCGARTLAND TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. In its report entitled "Strengthening Science and Peer Review at EPA", the NRC 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 problems while ignoring greater risks. We need such information to reduce uncertainties in environmental decisionmaking 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.

Do you agree? Please explain what EPA actions are being taken in that regard.

Response. We agree that scientific knowledge and technical information are essential components in the evaluation of environmental problems. As stated in our Strategic Plan, EPA strives to ensure that its efforts to reduce environmental risk are based on the best available scientific information. In its implementation of the Government Performance and Results Act (GPRA), EPA established a strategic planning framework comprising 10 strategic goals with associated long-term objectives. Goal 8 of that framework, Sound Science, emphasizes EPA's commitment to (1) identify the most important sources of risk to public health and the environment and thereby guide Agency decisions, and (2) anticipate environmental and other

changes that might portend future environmental risk and integrate futures thinking into Agency planning.

There are many examples of actions EPA has taken to enhance the use of sound, credible, and relevant science in Agency decisionmaking. One example is the Office of Research and Development (ORD) Strategic Plan, which complements the Agency's Strategic Plan and identifies risk-based criteria for establishing research priorities. Using these criteria, ORD has identified eight high-priority areas where significant levels of input will be required for EPA decisionmaking now and in the future. These research areas will include issues such as: understanding the health risks of exposure to fine particles in air pollution, preserving safe drinking water, and research to improve ecological risk assessment.

Because science activities take place throughout EPA, the cross-agency Science Policy Council is building on the ORD development of both an Agency-wide inventory of scientific activities and a "Strategic Framework for EPA Science" in planning EPA scientific and research activities that focus on the most important environmental risks. Importantly, the technical products that result from these efforts are peer reviewed, thereby ensuring the best and most relevant science is used in Agency actions and decisions. In the area of anticipating future environmental problems, ORD is building upon the National Academy of Public Administration report, "Remembering the Future: Applying Foresight Techniques to Research Planning at EPA" to apply the concept of futures in its research planning.

Additionally, in October 1999, the Administrator created a new Office of Environmental Information (OEI) that has central responsibility over information management, policy and technology because of the growing demand for high-quality environmental information. Creating the office was a collaborative process with input from a wide range of staff and stakeholders, both internal and external to EPA. OEI activities such as strengthening information partnerships, enhancing information quality, and communicating the utility of environmental information will help the Agency to foster information-based decisionmaking. We also hope these activities will generate new trend and outcome-information to promote adaptive and forward-looking environmental management by decisionmakers at all levels.

These examples illustrate some of the steps that EPA has taken to incorporate scientific, technological, and environmental information into the environmental decisionmaking process.

Question 2. Michael J. Pompili, Assistant Health Commissioner, Columbus Health Department Columbus, Ohio testified that:

> At one time, the Federal Government funded a U.S. 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 reassigned 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 decisionmaking.

Please explain why that office was disbanded and what is EPA doing to reinstate support for State and local governments with projects dealing with risk-informed decisionmaking.

Response. The Agency operated a comparative risk program for approximately 7 to 8 years. During that time, we made large contributions to State and local governments for conducting risk assessments. State and local governments have continued to use the tools and methods that we shared during that time to set their priorities. Two years ago, we shifted our comparative risk staff and resources to focus on the Agency's implementation of the President's Clean Water Action Plan.

We continue to encourage our State and local counterparts to incorporate risk and other factors into their priority-setting process. As part of the National Environmental Performance Partnership System, EPA Regional Offices work with our State counterparts in joint planning and priority setting. These efforts are based upon an analysis of environmental information and State and local conditions to determine the environmental problems that deserve the highest attention. Environmental information is coupled with risk assessment to identify the most significant State and local environmental problems. The State Agency and EPA Regional Office then develop work plans to address these problems.

The State/EPA work plans are contained within Performance Partnership Agreements or other similar documents outlining the priorities, what actions will be taken

by which agency, and how State assistance grants will be used to accomplish this work. Under current guidelines and a proposed new regulation governing State assistance grants (the Part 35 rule), EPA and States work together to determine comparative risks and set priorities. With a Performance Partnership Grant (PPG), a State can combine two or more of 16 different categorical grants into a PPG to have funding flexibility to address the highest priority risks. States are encouraged to involve the public in this process of determining priorities.

Some of our program offices also offer assistance to communities for evaluation of local environmental problems. For example, we have a program called the Technical Outreach Services for Communities (TOSC), which is a service of the Hazardous Substance Research Centers program and the Superfund program. Through the TOSC program, communities have access to independent technical advisors through universities. TOSC has helped 118 communities understand the issues and solve problems dealing with hazardous substance contamination.

Question 3. Under executive order 12866, EPA prepares detailed cost-benefit analyses for all economically significant regulations. Under that order, EPA also is to review, periodically, existing regulations that are economically significant to determine if they can be made more effective or less burdensome. How effective has EPA been in carrying out those responsibilities? What would EPA do if a proposed regulation did not pass the benefit-cost test?

Response. (a) How effective has EPA been in carrying out those responsibilities? EPA has a strong record of success under the "lookback" provision of Executive Order 12866. In 1995, in response to the President's request, EPA conducted a page-by-page review of all its regulations and removed over 1200 pages of regulations from the Federal Register. Subsequent to that effort, EPA has reached out to the regulated community to identify cheaper, cleaner, and smarter ways to achieve needed environmental improvements than those codified in existing regulations, including those that are deemed economically significant. Two of our major initiatives in this direction have taken place under the auspices of the Common Sense Initiative and Project XL. A sample of recent improvements stemming from our ongoing review of existing rules includes:

Proposal for a Consolidated Air Rule for Chemical Manufacturers.—A newly issued rule that consolidates 16 Federal air regulations into a single guideline could save the average U.S. chemical plant about 1,700 hours or $80,000 a year. The regulation, which represents the first consolidated rule ever under the Clean Air Act, would afford plant managers a choice. The facility managers could opt to comply with the consolidated rule or continue operating under the existing 16 rules.

Streamlined Certification Process for Auto Makers.—A streamlined process for certifying that new passenger cars and trucks meet Federal standards for air pollution emissions is expected to save automobile manufacturers an estimated $55 million a year. Under the proposed process, testing would be performed on vehicles actually in use on the Nation's highways rather than on brand new vehicles. In addition to cutting burden, the new process creates an incentive for manufacturers to produce more durable emissions-control equipment and gives EPA better date for managing air quality programs.

Simplified Hazardous Waste Management Requirements.—the Agency addressed several barriers that have prevented common-sense practices in managing hazardous wastes. Reforms to the 20-year-old program for managing polychlorinated biphenyls (PCBs) are expected to produce cost savings estimated between $178 million and $736 million each year. Another regulatory revision simplifies the cleanup and closure of hazardous-waste disposal facilities.

Compliance Alternatives for Small Drinking Water Systems.—Under new flexibility offered under the 1996 amendments to the Safe Drinking Water Act, EPA issued regulations to give small-community water systems less expensive treatment alternatives to comply with Federal drinking water standards in the future. Smaller systems can also request more time to achieve compliance and variances from Federal requirements, as long as such actions do not threaten public health.

Lowering the Cost of Lead-Based Paint Disposal.—Based on studies showing that lead-based paint debris could be safely placed in ordinary landfills (under the Toxic Substances Control Act), EPA proposed that this disposal option be provided as an alternative to the traditional, but more expensive disposal currently required under hazardous waste regulations.

(b) What would EPA do if a proposed regulation did not pass the benefit-cost test? The Agency uses the benefit-cost analyses it conducts under Executive Order 12866 as a tool in the decisionmaking process. The key goal of the economic analyses is to provide policymakers with information on the potential consequences of environmental policies. Executive Order 12866 says that Agencies should adopt approaches

that "maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach." However, it is often difficult to determine which regulatory options will maximize net benefits because quantitative environmental and health effects data (e.g., air or water quality, risk factors) are often not available or are sparse. This constraint means that many benefits and cost categories cannot be expressed in monetary terms, which then constrains the use of benefit-cost analyses in the public policy decisionmaking process. Thus, a strict comparison of monetized benefits and costs should not be used in making policy decisions.

Additionally, economic efficiency should not be the sole criterion for developing good public policies because a large number of social goals and constraints motivate and shape environmental policy. For example, the Agency considers environmental justice issues, statutory and judicial mandates, institutional constraints, technical feasibility, and enforceability in the regulatory policy process. Even the most comprehensive economic analyses are but part of a larger policy development process, one in which no individual analytical feature or empirical finding dominates. The results of our benefit-cost analyses serve as important inputs for this broader policymaking process along with other analyses and considerations.

Question 4. Looking back at the last thirty years, what lessons has the Agency learned about improving environmental decisionmaking using: (a) an integrated approach, (b) a risk-informed approach, and (c) benefit-cost analysis.

Response. Looking back in time, the Agency has learned much about using various approaches to managing environmental problems. Following are our experiences with some of these approaches:

(a) *An integrated approach.*—There are many complex, high-profile issues (e.g., children's health, contaminated sediments) that do not easily fit into a single EPA office or a media-specific approach, but nevertheless must be addressed because of the significant environmental problems they represent. EPA has learned that finding solutions to these issues means looking beyond traditional environmental media and programmatic boundaries.

The changing nature of environmental protection with greater attention to multiple stressors, cumulative risk, non-regulatory policy approaches, globalization, and enhanced public access means that science must be integrated across media and programs. EPA has established new offices (such as the Office of Children's Health Protection) and initiatives (such as the Persistent, Bioaccumulative, Toxic chemicals (PBT) Initiative) that recognize the necessity for employing an integrated approach. The Office of Research and Development's (ORD) Strategic Plan for 2000 identifies "Integrate Environmental Science and Technology to Solve Environmental Problems" as one of ORD's five goals for the coming decade. In addition, the Agency is developing an enhanced "EPA-Wide Inventory of Science Activities" that will facilitate cross-agency science integration.

Collaboration among technical experts from across the Agency, as well as the cross-program/media integration of information, provides opportunities for synergism in the scientific process. For example, the Agency's highly successful experience over the past several years with promoting scientist to scientist meetings on important environmental topics bears this out. Efforts to enhance scientific collaboration and integration will increase over the coming years. In this way, the Agency can carry out its mission with a growing understanding of environmental problems in a multimedia context that focuses attention on the greatest risks.

(b) *A risk-informed approach.*—Agency decisionmakers recognize that risk assessment and other scientific information can guide decisionmaking at EPA. Scientific inquiry, investigation, and information lead to the identification of potential risks to human health and the environment, and also point the way toward addressing those risks. Risk assessment weighs heavily in Agency decisions and, as appropriate, these assessments are joined with other scientific information, such as economic data and engineering studies, to provide scientific input to Agency decisions.

Because of the critical role risk assessment plays in environmental decisionmaking, EPA has developed a framework for ecological assessment, cancer assessment guidelines, and other risk assessment tools. These tools promote consistency across the Agency in how risk assessments are performed and used in Agency decisions. Research to improve human health risk assessment and ecological risk assessment represent two of the highest priority research areas of the Agency's Office of Research and Development.

(c) *Benefit-cost analysis.*—Agency decisionmakers recognize that benefit-cost analysis can be a meaningful tool for environmental decisionmaking, along with other analyses and considerations. A thorough benefit-cost analysis of proposed regulatory

alternatives can assist the Agency in developing control requirements that achieve the highest environmental quality and human health standards at the lowest costs. The Agency has learned the importance of developing better ways to measure benefits and costs in order to more meaningfully inform decisionmakers, the importance of communicating information about benefits and cost categories that cannot be monetized, and the importance of working to achieve consistency in our economic analyses across the Agency.

Despite the greater use and prominence of benefit-cost analysis in the environmental policymaking process, it is still only possible to quantify a limited subset of all the important benefits and costs associated with regulatory options. In most instances, significant benefit categories remain unquantified and unvalued. For example, in EPA's Clean Air Act (CAA) Section 812 study, a benefit-cost analysis of the entire CAA, some of the numerous unquantified benefits include: ecological effects, materials damage, behavioral effects, developmental effects, agricultural effects, eutrophication, acid deposition and many human health effects. This limitation also affects the Agency's ability to assess broad programs or strategic long run plans aimed at informing budgeting and planning decisions within public and private agencies. Our inability to quantify and value important benefit categories limits the contribution that benefit cost analysis can add to the policymaking process is necessarily constrained.

The Agency is taking a number of steps to address these problems. An important function of the Agency's newly formed National Center for Environmental Economics (NCEE) is to develop data and methods for benefit and cost assessments through research aimed at filling priority needs common to many programs in the Agency. NCEE is actively performing innovative research on new and improved methods and incorporating cutting-edge advances in the field. In addition, NCEE promotes efforts by academics and EPA staff to improve the means to value costs and benefits. NCEE also works to communicate EPA's research priorities to economics professionals across the Nation, thereby helping to focus their expertise and own resources to better meet EPA's needs.

EPA will soon release its *Guidelines for Preparing Economic Analyses*, which establish a sound scientific framework for performing economic analyses of environmental regulations and policies. They incorporate recent advances in theoretical and applied work in the field of environmental economics, and specifically address the issues of valuation of benefits, presentation of uncertainties in analysis, and consideration of regulatory alternatives. The Guidelines will help ensure that important subjects such as uncertainty, sensitivity analysis, timing, and valuation of costs and benefits, are treated consistently in all economic analyses prepared to inform at EPA's decisionmakers.

Question 5. Why is the Agency's Strategic Plan still an inherently output-oriented plan as opposed to a result-oriented one? Please specify EPA actions in that regard.

Response. The Strategic Plan represents a balance between outcomes and outputs. The Agency's Plan covers all the major functions and activities of EPA and therefore strikes an appropriate balance between the management functions and the environmental results we are trying to achieve. Since the issuance of the 1997 Strategic Plan, the Office of Chief Financial Officer (OCFO) has also worked closely with EPA's program offices through the Annual Plan process and more recently via the revision of the Strategic Plan in improving the measurability and outcome orientation of the Agency's strategic architecture of goals and objectives and performance goals and measures.

Response. In pursuit of strong outcome orientation of the goals and measures, the Agency formed the Performance Measurement Improvement Team. The primary objective of this Team is to work with EPA's programs in their efforts to increase the general quality and outcome orientation of the Agency's performance goals and measures. The Team is involved in efforts such as workshops and training sessions, on-going analyses of annual goals and measures, and Goal-specific performance measurement improvement projects. In addition, our process for revising the Plan incorporated numerous opportunities for providing feedback to the program offices on their proposed revisions to the strategic architecture. Through these processes, we noted substantial improvement in the objective statements incorporated in the 2000 Strategic Plan; half of the objectives in the Plan are environmental outcome-oriented.

EPA continues to work both internally and with our partners to strengthen the outcome orientation and measurability of the Agency's strategic architecture of goals and objectives. For example, two significant obstacles that impede EPA's efforts in developing outcome-oriented metrics are the lack of data on environmental conditions (e.g., the current State of public health and the environment) and the difficul-

ties associated with establishing a direct relationship between these parameters, which are also impacted by many other factors. EPA is conducting and funding research to help provide some of the information and methodologies necessary to overcome these obstacles. First, we are helping to develop and collect baseline data on environmental conditions. In collaboration with the states and other Federal agencies, we are monitoring and measuring indicators of ecological health, such as fish populations and stream concentrations of dissolved oxygen. These indicators will allow us to estimate conditions of the Nation's ecological resources with known degree of confidence. Similarly, the Centers for Disease Control provide estimates of public health, and we are working with them to collect data on exposure to environmental contaminants to further our understanding of the relationships between exposure reductions and improved health.

These activities will serve as the foundation for outcome-oriented performance measures, helping us improve our Strategic Plan to reflect the results of our work.

Question 6. How is the Agency addressing GAO's recommendations regarding data gaps, poor quality of available data, and inconsistencies in data-bases?

Response. EPA has recently initiated the first stage of a multi-phase effort to develop an Agency "Information Plan." The first phase will identify broad options for information management by the Agency over the next several years and the associated implications. Implementation of the plan will transform how the Agency manages its information assets (the people, policies, data, and technology) so that EPA can better provide integrated, timely, and cost-effective access to accurate information to decisionmakers and the public. Phase I of the plan will identify strategic choices facing EPA such as the need to address current and future information needs. We expect to complete the first phase of the Information Plan in December 2000.

With respect to data quality and inconsistency, EPA is pursuing several activities to address these issues. First, the Agency is developing a Data Quality Plan to evaluate the life-cycle of data collection, management and use in EPA in order to identify those places where quality vulnerabilities exist. This information will lead to follow-up actions by the program offices responsible for the data and information. Second, the Agency has created an "integrated error correction process" which allows users of the national data systems to report known or suspected data errors. In this process, EPA and State data stewards research the reported error, make corrections in the data bases if appropriate, and report back to the individual on the action taken. This process was established in June 2000 and is now active for the information systems in EPA's Envirofacts data warehouse; the process will be added to additional systems in fiscal year 2001. Third, EPA's data standards program is improving the consistency of the information collected and used by the Agency. EPA has developed and approved the six major data standards in the Reinventing Environmental Information program. More recently, we joined with the Environmental Council of the States and with representatives of Indian Tribes to create the Environmental Data Standards Council, a cooperative effort to develop and implement additional data standards. The Council is now pursuing the development of four additional data standards. Taken together, these actions will lead to the data quality improvements sought by all concerned.

Question 7. Asked by Chairman Smith during hearing on October 3, 2000. (paraphrased) There is no Federal entity that promotes and directly assists any State and local government with risk-based decisionmaking. Is there any entity within your Agency to do that?

Response. As we explained in our answer to Question No. 2, we continue to encourage our State and local counterparts to incorporate risk and other factors into their priority-setting process. As part of the National Environmental Performance Partnership System, EPA Regional Offices work with our State counterparts in joint planning and priority setting. These efforts are based upon an analysis of environmental information and State and local conditions to determine the State and local environmental problems that deserve the highest attention. Environmental information is coupled with risk assessment to identify the most significant environmental problems. The State Agency and EPA Regional Office then develop work plans to address these problems.

The State/EPA work plans are contained within Performance Partnership Agreements or other similar documents outlining the priorities, what actions will be taken by which agency, and how State assistance grants will be used to accomplish this work. Under current guidelines and a proposed new regulation governing State assistance grants (the Part 35 rule), EPA and States work together to determine comparative risks and set priorities. With a Performance Partnership Grant (PFG), a State can combine 2 or more of 16 different categorical grants into a PPG to have

funding flexibility to address the highest priority risks. States are encourage to involve the public in this process of determining priorities.

In addition, EPA has developed and updated numerous risk assessment guidelines and related documents over the last 15 years. These guidelines, addressing such diverse risk assessment issues as carcinogenicity, reproductive health, exposure, pollutant mixtures, and ecological effects, are published by the Agency following peer review. The published guidelines are often used by state, local, and tribal governments (as well as the international community) as they consider how to develop and use risk assessments for their programs.

RESPONSES OF AL MCGARTLAND TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. The testimony by GAO cites numerous concerns, including data gaps, data base incompatibilities, and data inaccuracy, as well as failures in integrating measured outcomes with EPA programs. You indicated that the Agency is developing a strategic plan that responds to these concerns. Please describe that plan in as much detail as possible. When will it be completed and available for review by the committee?

Response. As we responded to Chairman Smith's Question No. 6, EPA has recently initiated the first stage of a multi-phase effort to develop an Agency "Information Plan." The first phase will identify broad options for information management by the Agency over the next several years and the associated implications. Implementation of the plan will transform how the Agency manages its information assets (the people, policies, data, and technology) so that EPA can better provide integrated, timely, and cost-effective access to accurate information to decisionmakers and the public. Phase I of the plan will identify strategic choices facing EPA such as the need to address current and future information needs. We expect to complete the first phase of the Information Plan in December 2000.

With respect to data quality and inconsistency, EPA is pursuing several activities to address these issues. First, the Agency is developing a Data Quality Plan to evaluate the life-cycle of data collection, management and use in EPA in order to identify those places where quality vulnerabilities exist. This information will lead to follow-up actions by the programs responsible for the data and information. Second, the Agency has created an "integrated error correction process' which allows users of the national data systems to report known or suspected data errors. In this process, EPA and State data stewards research the reported error, make corrections in the data bases if appropriate, and report back to the individual on the action taken. 'this process was established in June 2000 and is now active for the information systems in EPA's Envirofacts data warehouse; the process will be added to additional systems in fiscal year 2001. Third, EPA's data standards program is improving the consistency of the information collected and used by the Agency. EPA has developed and approved the six major data standards in the Reinventing Environmental Information program. More recently, we joined with the Environmental Council of the States and with representatives of Indian Tribes to create the Environmental Data Standards Council, a cooperative effort to develop and implement additional data standards. The Council is now pursuing the development of four additional data standards. Taken together, these actions will lead to the data quality improvements sought by all concerned.

Question 2. What is the recent history of EPA's requests for environmental data collection funding and Congress's appropriation of these requested funds?

Response. Environmental data collection is an activity that is vital to the mission of the Agency and supports the goals and objectives of our program offices. It is spread throughout EPA's overall budget. EPA is working closely with our many partners and stakeholders in trying to improve our information collection programs.

The Agency's data collection is an element of two annual reports submitted to OMB: "Report on Information Technology;" and "Capital Assets Plan and Justification." These reports contain information on the amounts budgeted for all aspects of information technology including resources directly involved in data collection activities managed by various Agency offices.

Question 3. We heard testimony about the New Hampshire and Columbus, Ohio comparative risk projects. Has EPA supported, financially, technically, or otherwise, these projects or other similar projects on a local, state, or regional level? Hay the Agency used any of the results from these projects to help inform national environmental priorities?

Response. The Agency provided financial and technical assistance to interested state, local, and tribal governments interested in conducting comparative risk proc-

esses. The results of the projects were used to improve environmental protection at the state, local and tribal level. Although the results were not formally used in national priority setting, EPA's program offices work directly with our Regional offices (who had worked with the States to identify regional priorities) to develop the Agency's strategic and annual plans. Additionally, EPA goal teams engage in an extensive stakeholder outreach effort when developing strategic objectives, and the Agency consults with State organizations, such as EGOS, when developing its strategic plan.

Question 4. What is your reaction to having a national comparative risk project performed and then using its results to determine EPA's budget and regulatory priorities?

Response. Comparative risk analyses have become more widely accepted as an input to the priority-setting process, and they have been conducted by a number of State and local governments. For its part, EPA has incorporated this useful tool unto our Agency-wide strategic planning processes, into our partnerships with state, local, and tribal governments, and into many specific programs, both regulatory and non-regulatory. However, EPA is not using comparative risk analysis as a brightline, mechanistic way of ordering the Agency's priorities for either strategy, budgets, or actions.

One important limitation of comparative risk analysis is that there is no common metric to evaluate the many kinds of risks that could be addressed. This lack of a common metric raises many questions that cannot be answered by scientific analysis alone. For example, EPA does not typically engage in risk comparisons from widely variant activities such as the risk from radon exposure compared to actuarially determined traffic deaths. How do we incorporate the involuntary versus voluntary nature of the exposure? Making comparative risk comparisons is difficult even if the risks being compared are environmental in nature. How does one compare the asthma problems associated with elevated ozone to reproductive effects in ecosystems exposed to endocrine disrupting chemicals? How should we compare skin cancer to throat cancer?

In addition to these comparative risk questions, a number of other factors also have to be considered when the Agency sets its priorities: Some of these factors, such as meeting statutory mandates and responding to public concerns, are identified in our response to Question No. 5. Moreover, decisions on some of these factors, such as equity and environmental justice, require a degree of judgment that cannot be answered through scientific analysis alone.

Question 5. What are the drawbacks or obstacles to having a national comparative risk project performed and then using its results to determine how EPA's budget should be allocated?

Response. Comparative risk assessment is a useful mechanism for helping us think about environmental priorities, but comparative risk assessment alone cannot provide complete answers. The Agency must consider a number of factors, including but not limited to risk, when setting its priorities. Some of these factors include statutory mandates, community concerns, and the organizational structure of various environmental programs. Additionally, a significant problem inherent in the use of comparative risk assessment is the lack of a common metric.

Many Federal environmental laws mandate specific actions. The environmental statutes also often 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.

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 seem to rank high on a list of comparative risks.

Another consideration in setting priorities is the different roles that EPA has, depending 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.

As discussed in Answer #4 above, there is no common metric for comparing the different kinds of risks that could be addressed. For example, how can human health and ecological risks be incorporated into the same risk ranking? How would we prioritize the risks associated with pollutant exposures that may cause cancer in humans 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.

This is not a complete discussion of the issues associated with using comparative risk assessment alone to make national budget decisions. Other hard-to-quantify considerations, such as distributive impacts and environmental justice, also have to be considered. Therefore, comparative risk assessment cannot be used as a bright line mechanistic way of ordering the Agency's priorities for either strategy, budgets, or actions because there is no one analytical method that can address all of these issues.

Question 6. Please describe each of the data collection efforts which EPA supports, conducts or uses, to get an accurate picture of the Nation's public and environmental health.

Response. Under the Paperwork Reduction Act, the Agency is required to obtain Office of Management and budget approval before it can ask the public to submit information or retain records. In general, any monitoring, reporting or record-keeping requirements imposed on non-Federal respondents will require an Information Collection Request (ICR). EPA has about 350 active ICRs. EPA is developing a web-based, searchable tool, called the Information Collection Request Inventory (ICRI), based on these Information Collection Requests (ICRs). Once completed, the inventory will enable EPA and the public to better understand the types of information EPA collects, from whom, and the cumulative impact of EPA's collection activities. We expect to complete the ICR Inventory in the second quarter of fiscal year 2001.

STATEMENT OF PETER F. GUERRERO, DIRECTOR, ENVIRONMENTAL PROTECTION ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE

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, data bases 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 data bases, 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 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.

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

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 1980's, 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) data bases 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 data base 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), 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.)

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

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

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	No. in list	No.	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 toxic 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 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 data bases, 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 capac-

ities 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 data bases with external data bases. 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 data bases 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 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 data bases: "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 data bases. The system currently allows individuals to notify EPA of suspected errors in some of the agency's major data bases, and EPA intends to implement the data correction system in additional data bases during the next 2 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-1970's. 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 environ-

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[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).

mental 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.

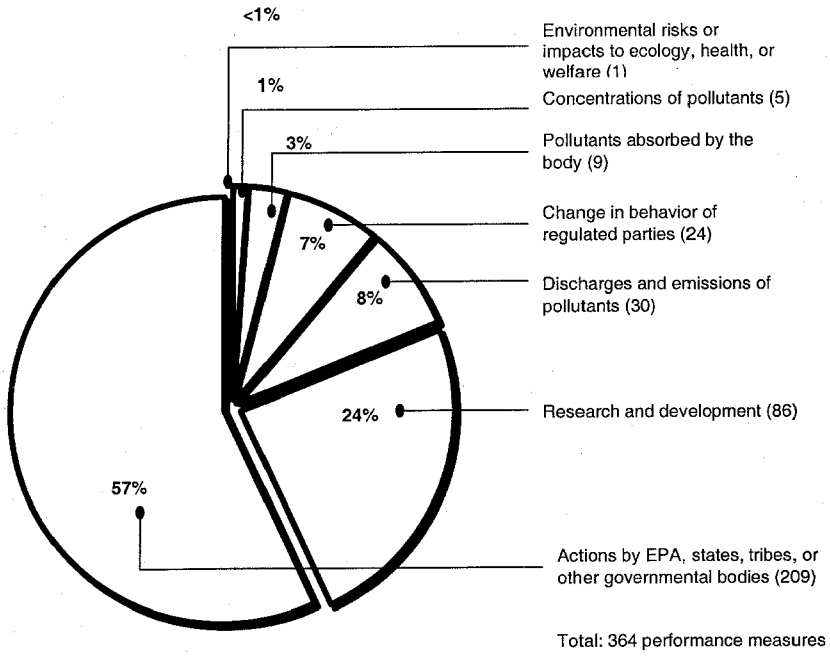
Table 2.—EPA's Analysis of the Number and Type of Annual Performance Measures for Its Strategic Goals for Fiscal Year 2000

EPA's strategic goal	No. of annual performance measures		
	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 data bases, 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 tradeoffs 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.

RESPONSES BY PETER GUERRERO TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. Please elaborate on how improved data and data management can help EPA in developing cost-effective strategies to reduce health and environmental risks?

Response. Scientific knowledge and technical information are essential for determining which environmental problems pose important risks to human health and the environment. This information is needed to avoid wastefully targeting inconsequential problems while ignoring greater risks. EPA also needs to be able to identify emerging and future environmental problems and to have adequate data to develop cost-effective solutions to those problems.

Question 2. What are some of the major obstacles confronting EPA that preclude it from moving faster toward a results-oriented agency?

Response. EPA considers getting the data needed to measure results its biggest challenge in developing results-oriented performance measures. To date, EPA has made limited progress in developing such measures. For example, of the 364 measures of performance that EPA 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.

As we stated in our testimony, EPA is limited by gaps in environmental and health data, data bases that do not operate compatibly with one another, and the lack of an effective system for ensuring the accuracy of the agency's data. Different data collection and analysis methods among states (which EPA relies upon extensively for information) make it difficult to aggregate data and use the information to determine environmental outcomes. For example, states do not use identical survey methods and criteria to assess water equality. EPA officials told us that such inconsistencies from State to State make developing national performance goals and measures for water quality difficult.

Even with better data, it will be a major challenge for EPA to link its environmental programs and activities to outcomes and move toward a results-oriented agency. Environmental conditions may change because of a number of factors including variables such ass 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.

Developing better information to characterize results will require additional resources—to fill gaps, conduct monitoring on environmental conditions, improve data management and quality, and so forth. Improved cooperation among the many parties currently also involved in collecting environmental data—states, tribes, local governments, industry, other Federal agencies and the public—will also be necessary.

Question 3. In its recently issued report on "*Strengthening Science at the U.S. Environmental Protection Agency: Research Management and Peer Review Practices (2000)",* the National Academy of Sciences stated:

> 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 problems while ignoring greater

risks. We need such information to reduce uncertainties in environmental decisionmaking 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.

Does GAO agree with the above statement? Please provide GAO's views on what role should risk assessment and economic analysis have in EPA's decisionmaking. What current attributes in EPA would need to be changed to address the above issues?

Response. Recognizing the fundamental importance of good information, both scientific and technical, GAO agrees with the above statement and supports EPA's efforts to improve environmental information. While both risk assessment and economic analysis are important tools for EPA decisionmakers and should be used, they do not provide precise answers to policy questions. This is because estimates of health risks and economic costs are developed in the face of both scientific uncertainties and data limitations, and inevitably include assumptions and judgments.

Recognizing the limitations of both risk assessment and economic analysis, we believe that EPA can nonetheless make improvements in how it uses both tools in order to assist decisionmakers. The quality of risk assessment is dependent upon the data available to perform the assessment, which in the past have not been as complete as possible. EPA's recent actions to reorganize information activities, develop a comprehensive information plan, and implement various other information initiatives are steps toward providing higher quality data needed to improve the assessments. As we stated in our testimony, however, successfully completing these data improvement actions will not be easy and will require a long-term commitment and sufficient resources. Likewise, EPA needs to take actions to make its economic analyses more useful to both agency decisionmakers and the Congress. Chief among these actions is improving the presentation and clarity of information contained in the economic analyses, such as clearly identifying the values of key assumptions as well as the sensitivity of benefit and cost estimates to key data uncertainties.

Question 4. Your statement focused on data quality, availability, and management problems. Are there specific recommendations you would like to make for either the agency or the Congress in this regard?

Response. As we recommended last September, EPA's information office should develop an action plan detailing the steps the agency must take to ensure that its environmental and regulatory data are sufficiently complete, compatible, and accurate to meet the agency's needs.[1] This plan should specify the resources that will be required to accomplish these tasks. It should also lay out a strategy and milestones for ensuring that EPA obtains the data it needs to effectively set priorities, assess progress in achieving its goals and objectives, and report on its accomplishments in a credible way. Such an action plan would also serve the Congress in its funding decisions and oversight of agency activities.

In addition, Federal efforts to collect human exposure data are very limited—largely because coordinated, long-term planning at the Federal level has been lacking due to sporadic agency commitments to human exposure measurement and monitoring. To help meet the gaps in exposure data, we recommended that EPA work together with HHS and other Federal agencies with environmental health responsibilities to forge a strategic approach that would:

- provide a long-term structure to human exposure monitoring as an interagency effort,
- establish a mechanism for setting priorities in line with agency goals and performance measures,
- clarify agency roles and minimize duplication, and
- help agencies to share expertise.[2]

The Results Act, which requires agencies to coordinate their research activities, also provides an existing mechanism for congressional oversight over Federal efforts to more effectively coordinate research. Continued congressional oversight of the Results Act, with particular attention to this area, would be helpful.

Question 5. What is the status of EPA's use of benefit-cost analyses in managing environmental risks?

Response. We have found that EPA and other agencies could make improvements that would strengthen the clarity and credibility of their economic analyses. For example, some of the economic analyses that GAO reviewed did not incorporate the

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[1] *Environmental Information: EPA is Taking Steps to Improve Information Management, but Challenges Remain* (GAO/RCED–99–261, September 1999).

[2] *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans* (GAO/HEHS–00–80, May 2000).

best practices set forth in OMB's guidance (e.g., 5 of the 20 analyses reviewed did not discuss alternatives to the proposed regulatory action).[3]

Moreover, in our 1997 review of 23 economic analyses developed by EPA in support of air quality regulations under the Clean Air Act, we found that these analyses could be made; more useful by increasing their clarity and thoroughness.[4] For example, many of these benefit-cost analyses did not include executive summaries, which can provide easily accessible information for both agency decisionmakers and the Congress. Some of the economic analyses did not identify one or more key economic assumptions (such as the; discount rate or the dollar value assigned to a human life) that can have a significant impact on the results of the analysis. Furthermore, in the analyses that identified key economic assumptions, the rationale for the values used was not always explained. We recommended that the EPA Administrator ensure that benefit-cost analyses identify the (1) value, or range of values, assigned to key assumptions, along with the rationale for the values selected, (2) sensitivity of benefit and cost estimates when there are major sources of uncertainty, and (3) regulatory and non-regulatory alternatives considered, including those not subjected to benefit-cost analyses.

RESPONSES BY PETER GUERRERO TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. I appreciate your comments on the lack of environmental data. This is a real problem. What is the recent history of EPA requests for funding for environmental data collection and Congress' appropriation of those requested funds?

Response. EPA does not have this information readily available. However, the agency has assured us that it is currently gathering the data needed to answer the question, and we will forward the agency's response to you when we receive it.

Question 2. In testimony from later panels, we heard questions being raised about whether risk assessments accurately predict harm to public health, such as the incidence of certain types of disease which may be caused by exposure to environmental contaminants. Is EPA or any other Federal agency collecting national public health data of this type so that more accurate national risk assessment work can be performed?

Response. In our recent investigations into toxic chemicals and indoor air pollution, we have found that the amount of data collected was extremely limited. As we reported in May 2000, Federal and State efforts to collect data on human exposure to toxic chemicals are limited, despite some recent expansions due to improved technology.[5] Surveys from EPA and the Department of Health and Human Services (HHS) together measure in the general population only about 6 percent of the more than 1,400 toxic chemicals that were included in our review. Even for those chemicals that are measured, information is often insufficient to identify smaller population groups at high risk, such as children in inner cities and people living in polluted locations who may have particularly high exposures. We found that three main barriers limit Federal and State agencies' abilities to make more progress: (1) Federal and State laboratories often lack the capacity to conduct measurements needed to collect human exposure data, (2) there is often a lack of information to help set test results in context, and (3) coordinated, long-term planning among Federal agencies has been lacking, partly because of sporadic agency commitments to do human exposure measurement and monitoring. HHS and EPA officials indicated that they have been discussing the merits of establishing a coordinated interagency human exposure program, but they have not yet formalized or agreed upon a long-term strategy.

In a separate review, we found that EPA is making progress in its efforts to provide communities with more information on releases of toxic chemicals, as required by section 312 of the Emergency Planning and Community Right-to-Know Act (EPCRA).[6] Thus far, public use of the information has been limited. Much of the information has not been computerized to provide easy access and when it has, it is not available in regional or national data bases that permit comparisons among industries or geographical areas. Further, EPA has not developed policies, proce-

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[3] *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses* (GAO/RCED–98–142, May 1998).

[4] *Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can be Made Clearer* (GAO/RCED–97–38, April 1997).

[5] *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans* (GAO/HEHS–00–80, May 2000).

[6] *Environmental Information: Agencywide Policies and Procedures Are Needed for EPA's Information Dissemination* (GAO/RCED–98–245, September 1998).

dures, and standards to govern key aspects of its projects to disseminate information or to assess the data's accuracy.

In our 1999 review of the status of Federal research activities on indoor air pollution, we found that many gaps in knowledge and understanding of the problem remain.[7] These include gaps and uncertainties with respect to (1) the identity and the sources of pollutants, (2) the mechanisms by which people are exposed to them, (3) the health effects resulting from prolonged and intermittent exposure to low-level concentrations of chemical and biological pollutants as well as complex pollutant mixtures, and (4) the most cost-effective strategies for reducing pollutant sources, exposures, and consequent health effects.

Question 3a. Clearly, EPA has an important role and a responsibility in collecting environmental data. However, states too have a role and responsibility in collecting these data. After all, they have a considerable stake in protecting public health and the environment. How much environmental data collection are the States funding themselves?

Response. We have not independently compiled statistics on the amount of data collection being funded by the states. However, a 1999 joint study by EPA and the Environmental Council of States (EGOS) concludes that states are responsible for 83 to 99 percent of the environmental pollutant data contained in six key EPA data systems.[8] For example, more than 99 percent of EPA's air data comes from states; about 91 percent of EPA's water data comes from states; and more than 92 percent of EPA's hazardous waste data comes from states. ECOS also said that it is not necessarily the EPA demand for information that is driving these State efforts. In many cases, states are attempting to meet the demands of their own citizens and policymakers.

EGOS reported that states were spending about $12.5 billion in fiscal year 1996 (the latest date for which data is available) on environmental protection and natural resources, with EPA providing about $2.5 billion (20 percent) of this amount. EGOS does not have specific information on how much of this is for data collection.

Question 3b. On their own, are states funding sufficient collection of data for them to set risk-based priorities and develop results-oriented measures of their environmental programs?

Response. We have not looked at this issue for all types of environmental media. However, as noted in our testimony, we recently performed a review of water quality data during which we surveyed all 50 states and the District of Columbia.[9] All the states and the District of Columbia responded to our survey. The results of our survey highlighted the need for more comprehensive State monitoring and called into question the extent to which unknown and potentially serious problems are going undetected. Only six states reported having the majority of the data needed to fully assess all their waters. Less than half the states have a majority of the data needed to determine if waters that have been assessed should be placed on their lists of waters that do not meet standards.

We also recently completed a review to determine the extent to which State and Federal agencies—in particular the Department of Health and Human Services (HHS) and EPA—collect human exposure data on potentially harmful chemicals, including data to identify at-risk populations.[10] As mentioned earlier, the review showed that Federal efforts to collect human exposure data are limited, measuring in the general population only about 6 percent of the chemicals under review. At the State level efforts were similarly limited: Almost all State officials who we surveyed said they highly valued human exposure data for populations within their borders. However, despite this perceived value, most officials reported that they were unable to collect human exposure data in most of the cases in which they thought it was important to do so.

Furthermore, ECOS told us that, while states are generally collecting the data they need to set risk-based priorities and develop results-oriented measures, they may not have enough information to do risk assessment. However, according to ECOS, it is clear that states have had some success in collecting data needed for risk assessment, based on the comparative risk projects undertaken in the 1990's and used as input into Performance Partnership Agreements with EPA. A number

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[7] *Indoor Pollution: Status of Federal Research Activities* (GAO/RCED–99–254, August 1999).

[8] U.S. Environmental Protection Agency and Environmental Council of States, *Environmental Pollutant Reporting Data In EPA's National Systems: Data Collection by State Agencies,* Sept. 30, 1999.

[9] *Water Quality: Key EPA and State Decisions Limited by Inconsistent and Incomplete Data* (GAO/RCED–00–54, March 2000).

[10] *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans* (GAO/HEHS–00–80, May 2000).

of states have also produced "State of the Environment" reports, which address environmental performance.

Question 3c. What is the correct mix between environmental data collection funded by the Federal Government and that funded by the States?

Response. We agree with the National Academy of Public Administration's 1995 assessment that EPA should focus its activities on problems of national, interstate, or intergenerational interest, while supporting problem-solving at all levels through technical assistance, increased flexibility, and information dissemination.[11] The primary Federal responsibility should be to collect data to identify overall trends and emerging issues, to determine risks associated with exposure to harmful chemicals, and to fill the gaps in existing data needed to set priorities and assess risks. The states, on the other hand, must meet the demands of their own citizens and policymakers while, at the same time, developing the information needed to provide assurance that environmental laws are being properly implemented and enforced.

Question 3d. What, if any, State efforts are underway to standardize environmental data collection to improve comparability and public health protection?

Response. In a recent review on EPA's environmental information management, we found that EPA and the states have taken initial steps to increase data compatibility.[12] As a part of the 1c398 action plan for Reinventing Environmental Information (REI) initiative, EPA and the states are developing six data standards to be used in 13 of EPA's major data bases. The standards being developed will apply common definitions and formats. According to the REI action plan, these six standards will be developed, approved by EPA in partnership with the states, and in use in the 13 designated data bases by the end of fiscal year 2003.

The current initiative is limited in terms of the number of standards being developed (six), the number of EPA data bases in which the standards will initially be used (13), and the amount of data in those data bases (only the new data being entered) that will incorporate the standards. EPA recognizes that its current effort is only a first step toward its goal of full data integration.

In response to the above question, ECOS emphasized that efforts are currently underway to standardize data for the purposes of smoothing the flow of data from states to EPA and sharing comparable data between and among states. The Data Standards Council (a joint effort of states and EPA) is leading the effort. ECOS cautioned, however, that the work will improve the comparability of data, but will not eliminate it as a problem.

EPA responded to the question by also describing the work of the Data Standards Council and starting that the agency has also initiated a new project in partnership with the states, the Information Integration Initiative (I–3), this past fall. According to EPA, the effort is an enterprise-wide approach to integrating, managing, and providing access to environmental information. The agency will work closely with the states and other data partners in developing this comprehensive data exchange network. In its review of the fiscal year 2001 budget request, we found that while the concept of information integration envisioned by EPA has merit, it is critical that the I–3 effort be well thought out, and that all prerequisite requirements be met before embarking on this major investment. Many of the prerequisites, in fact, had not been completed. The Subcommittee on VA, HUD, and Independent Agencies, Senate Committee on Appropriations, also questioned the requested funding for I–3 in fiscal year 2001 beyond the amount needed to perform the prerequisite steps for ensuring that the investment is prudent and the project will be effectively managed.

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[11] National Academy of Public Administration Report to Congress, *Setting Priorities, Getting Results: A New Direction for EPA,* April 1995.

[12] *Environmental Information: EPA Is Taking Steps to Improve Information Management, but Challenges Remain* (GAO/RCED–99–261, September 1999).

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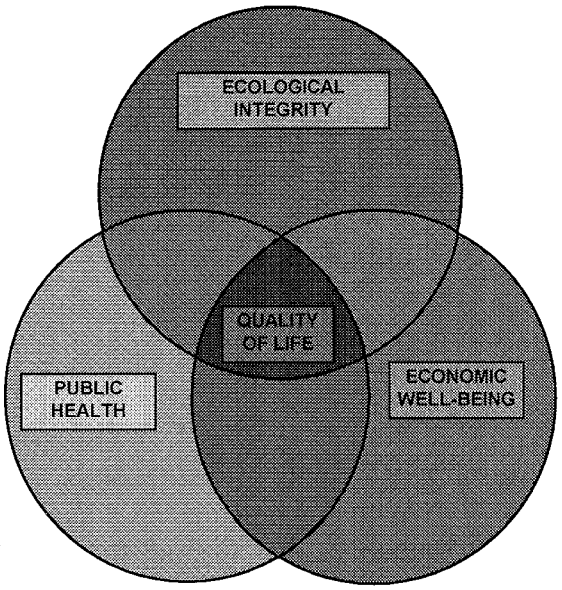

REPORT of RANKED ENVIRONMENTAL RISKS in NEW HAMPSHIRE

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

NEW HAMPSHIRE COMPARATIVE RISK PROJECT
Ranking, Prioritizing, and Managing Environmental Risk
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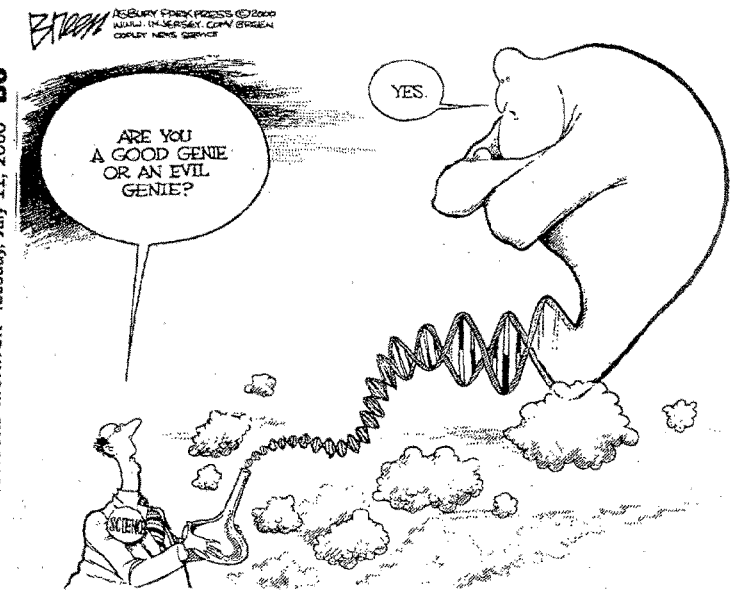
CONCORD MONITOR Tuesday, July 11, 2000 B6



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."

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NH COMPARATIVE RISK PROJECT
OUTLINE FOR US SENATE ENV. PUBLIC WORKS HEARING, 27 JULY 00

★ 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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NH COMPARATIVE RISK PROJECT
OUTLINE FOR US SENATE ENV. PUBLIC WORKS HEARING, 27 JULY 00

(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.)

Lower 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

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.

NEW HAMPSHIRE COMPARATIVE RISK PROJECT,
Concord, NH, October 25, 2000.

BOB SMITH, *Chair and* MAX BAUCUS, *Ranking Member,*
Committee on Environment and Public Works,
U.S. Senate,
Washington, DC.

Attn: Angie Giancarlo

Re: NH Comparative Risk questions

DEAR SENATORS SMITH AND BAUCUS: Thank you for your letter of October 11 with follow-up questions to my October 3 testimony before your Senate committee. In general, we agree wholeheartedly with Senator Moynihan's observation at the October 3 hearing that environmental management has "matured" over the past 30 years. We offer our testimony, and the following comments, with that recognition, confident progress can and will continue in this next generation of environmental challenges.

Definitions: Before you read the enclosed answers, please review the inside cover of the New Hampshire project guide, *For Our Future*, where we define our goal as protecting "*environmental quality of life," created by healthy people, healthy ecology, and healthy economy.*

Also, on page four of the guide, we define "New Hampshire Environment," "comparative risk," "risk assessment," and "cost-benefit analysis." In the answers below, "*comparative risk" means the collaborative, public, non-governmental process* as used in New Hampshire. Our process created a voluntary, public-private partnership—*participants identified hazards to our environmental quality of life along a continuum, explicitly incorporating scientific information, individual judgment, and personal values, using consistent criteria, and a shared vocabulary regarding "risk.*" Other states, and USEPA in Unfinished Business, used a different, internally-based comparative risk process, set within a State or Federal agency. Traditional "risk assessment" is a very different undertaking, where a specific individual risk is studied and the harm of exposure quantified, often using models. We did not address the specific issue of "residual risk" in the context discussed by others at the hearing.

STATEMENT OF KATHERINE HARTNETT, NEW HAMPSHIRE COMPARATIVE RISK PROJECT

SUMMARY

(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 7 years of work into next 5 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) The process worked—55 stakeholders, from businesses, environmental organizations, public health, citizen groups, political leaders, and State and local government officials, gathered in an neutral, non-advocacy setting to identify, study, and rank risks. Technical staff summarized ecological, public health, and economic information in consistent format, with consistent criteria. Group worked by consensus, over 8 day-long sessions, to rank 55 risks to New Hampshire environmental quality of life ("healthy people, ecology, economy"). Documented influence of accessible science, personal judgment, and individual values in ranking.

(5) Bottom line we began to separate fear from environmental hazard, and now, to reduce hazard. While four of top ten risks were to public health, four of top five were related to threats to air and water quality. 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.

(6) 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"[1]

(7) 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 215 century

• Personal, Corporate, Public Responsibility

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.

(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:

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• Work continues on reducing hazard, in context of Comparative Risk results.
• How successful?: good process, educated participants, contributed to decision-making such as:
NO_X—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 followup actions to reduce hazards.

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

RESPONSES BY KATHERINE HARTNETT TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. New Hampshire has been a leader in the use of Comparative Risk assessment. How have you used that method to become more results-oriented?

Response. In essence, we were able to begin to separate fear from hazard, and to focus on reducing hazard to our environmental quality of life, defined as "healthy people, healthy ecology, healthy economy." In New Hampshire, most hazards were traced back to how we use land and energy/materials/resources.

The first generation of environmental management used "command and control" to achieve results the main tools were "end of the pipe" regulation and enforcement to reduce releases of pollution to air, water, and land (the individual "environmental media"), through Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), "Superfund" legislation (CERCLA and SARA), etc., and to mitigate environmental damage National Environmental Policy Act (NEPA). Examples of the effectiveness in New Hampshire are summarized in the right-hand column on page seven of *For Our Future,* and in left-hand column on page six.

The comparative risk process led us to recognize a transition into the next generation of environmental management, where the sources are many, the tools are varied, and everyone has a part. Our new model is outlined below:

Today: People, Ecology, Economy—From ''Illness'' to ''Wellness''

Illness Model	Wellness Model
1970–1980's,	1990–2000+
''Us'' vs. ''Them''	''We''
Public health/economy vs. environment	Integrated public, ecological, economic health
Adversarial/Confrontation	Collaboration
''Point'' sources (smokestacks, wastepipes)	Many sources
''End of pipe''	''Upstream''
Remediation/mitigation	Prevention
Corporate Polluters	Efficient Producers and Consumers
Regulation	Marketplace and Education, along with Regulation
Air pollution control devices	Energy efficiency/Demand reduction
Diseases from environmental exposure	Health through lifestyle (diet, exercise, balance)
''What is the environment doing to us?''	''What are we doing to the environment?''

In New Hampshire, we used an inclusive, non-advocacy, science-based process that involved all players to build credibility and visibility needed to maintain an effort for the long-term (7–10+ years). Expanding on my October testimony, specific results to date include:

- 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 added "Resource Protection" to strategic plan and programming
- Environmental organizations continuing to use study as technical reference and in organizational strategy
- receiving requests for copies the 1997 Report of Ranked Environmental Risks in NH
- hearing frequent reference to the study in a wide range of meetings
- In 1997–98, collaboration with NH Public Health Association in their successful $1.1 million, 7 year "Turning Point" grant from WK Kellogg and RW Johnson Foundation (New Hampshire was one of only 14 states nationally to receive funding).
- In 1999, selection as one of 41 (of 650 applicants) to receive a major national competitive USEPA Sustainable Development Challenge Grant to work on reducing hazard through the Minimum Impact Development Partnership ($117,438 over 3 years).
- In the Spring 2000 session, key participation in the NH Legislature study commission (HB 1390) directed to build on the work of the NH Comparative Risk Project by improving public health and medical practice to reduce environmental exposure.

In summary, the process allowed us to: (1) step back, systematically evaluate current hazards using a process that explicitly combined science, judgment, and values, and separated fear from hazard; (2) establish that we had moved to the next generation of environmental management, where we created a new model to describe our progress and current situation; and (3) create wide range of initiatives to reduce hazard (see page 26 of For Our Future).

Question 2. Has the NH Comparative Risk Assessment project had a lasting impact on the public and on the other stakeholders?

Response. We focused on two audiences: (1) key decisionmakers and (2) members of the public belonging to relevant constituency groups, such as Business and Industry Association of NH, NH Public Health Association, Audubon Society of NH, Society for the Protection of NH Forests, and the NH legislature. Please see answer to question S–1 above for indication of effectiveness—we believe we have had lasting impact on the perspectives of many key decisionmakers, and are making progress on constituency groups. Because of the complexity of this generation of environmental management, we had expected lasting impact to take hold within 7–10 years (from 1994). As illustration, interest in and support for Minimum Impact Development (MID) practices have accelerated within the last year (see S–3 for more information on MID).

Question 3. How are you currently using the results of your project?

Response. Following the rationale illustrated on pages 10–11 in *For Our Future*, we are focused on encouraging sound land use practices, and efficient use of energy, materials, and resources. Since 1997, all but two of the projects listed in the right-hand column on page 26 of *For Our Future* to reduce environmental hazard have been completed or at least partially funded. Currently, as mentioned in my testimony (Section 4 "So What?", at the top of page 3 of 3), our main initiative is the Minimum Impact Development Partnership, a public/private partnership to identify, define, and build "good development," that is energy efficient, protects habitat, and minimizes pollution. Implementing minimum impact development should reduce most of the 55 risk identified, especially those higher ranked risks. Our strategy assumes maintenance of the current regulatory system to continue to encourage reduction in pollution releases.

Question 4. Do you have any legislative suggestions to improve the use of Comparative Risk Assessment in setting environmental priorities?

Response. As mentioned in the introductory paragraph, New Hampshire used a collaborative, non-governmental partnership comparative risk process model for our project, which we believe works best at a State (NH), regional (Elizabeth River, VA), or local (Columbus OH) scale. We defined our purpose as protecting environmental quality of life, comprised of the combination of healthy people, healthy ecology, and healthy economy. Another comparative risk approach is the inter- or intra-agency model, used to directly address agency priorities (such as described in USEPA's *Unfinished Business* or Science Advisory Board's *Reducing Risk*, mentioned in the introductory paragraph and Senator Baucus' Question #2 BACKGROUND).

Both approaches found widespread public recognition of the problems perceived in the first generation of environmental risk. After thirty years of progress and many successes, we found that we have moved into a new set of challenges. For specifics on a process to identify and set this next generation of environmental priorities, please see my testimony, section (5) Comments to Congress/ USEPA on page 3 of 3.

Also, as I mentioned in my verbal testimony, three other Federal initiatives are examples of next generation initiatives that help State and local communities reduce environmental hazard associated with how we use land and energy, materials, and resources: (1) Transportation Equity Act (TEA–21) process and funding to diversify transportation options into an integrated, connected, multi-modal convenient network to reduce congestion; (2) USEPA's Sustainable Development Challenge Grant program and (3) Conservation and Reinvestment Act (CARA).

Responses by Katherine Hartnett to Additional Questions from Senator Baucus

Question 1a. The committee has heard a lot about "good science" and scientific "uncertainty," but I see that the Project ranked particulate matter, ground level ozone, and arsenic in drinking water as among the highest risks in New Hampshire. There are some in Congress who do not believe that the identification of these problems or the estimation of their risks is based on "sound science." Can you tell me how your project dealt with scientific uncertainty in your project?

Response. At the project level, we recognized and accepted that uncertainty is an inherent component of the scientific process, which is why explicit judgment and values are so important in policy and decisionmaking. Two examples illustrate the concept:

Smoking.—The epidemiology of lung cancer associated with smoking has been known since the 1960's. The exact mechanism of the toxicology was established only

very recently. So "scientific uncertainty" created a generation-long debate over the effects of smoking on smokers.

Particulate Matter.—Based on clear trends that showed increased deaths and hospital admissions during periods with higher levels of $PM_{2.5}$, in the mid-1990's, USEPA moved to extend its regulation to smaller particles, even though the causal mechanism was unclear. A non-partisan expert panel recently independently replicated EPA's results, with an analysis that confirmed the association between elevated $PM_{2.5}$ and excess mortality (see attached article from SCIENCE, 4 Aug 2000, p. 711).

At the risk specific level, "uncertainty" was one of the four key criteria evaluated and explicitly ranked, on a defined scale of 1–5, by the ecological and public health technical work groups. The three other criteria were "severity," "extent," and "reversibility."

Question 1b. Did you use conservative estimates, or apply principles of precaution, in the face of uncertainty?

Response. We did both. Technical experts identified the ranges of estimates; and stakeholders often injected principles of precaution on their own. We also wrestled with the inherent conflict between low severity high occurrence risks (such as chlorination by-products in water supply or food additives and preservatives) and high severity low occurrence risks (such as earthquakes or exposure to high level radioactivity).

Question 1c. How were you able to reach the consensus with stakeholders on ranking issues such as particulate matter, ground level ozone, and arsenic in drinking water where there were scientific uncertainties?

Response. Stakeholders were committed to "getting something done" and producing a ranked list of risks that would lead to risk reduction by separating fear from hazard. We created a non-advocacy, accessible science-based, iterative evaluation process, where everyone had their say and all listened to other points of view. We all worked hard to maintain a fair, unbiased, and credible process, to facilitate reaching consensus, by first building trust among stakeholders. Each participant increased their understanding of the nature of science, where uncertainty is expected, and learned more about many controversial issues. Everyone was dissatisfied, to at least some extent, with the final ranked list a hallmark of a consensus-based work product. And each always had the option of deciding "I can't live with this" result—which paradoxically, no one exercised. Additionally, discussions incorporated evaluation of the uncertainty, severity, extent, and reversibility associated with 55 risks to environmental quality of life. Finally, and perhaps most importantly from the perspective of participants, rationales for each risk ranking were recorded in Chapter 6 of the 1997 report.

Question 2. I see that you used over 100 technical experts in a number of sciences to review the environmental issues facing your state. But in the end, you had a public advisory group—not the technical experts—decide how to rank the risks of these issues. In fact, based on your written testimony, which states that a risk ranking was based on what "everyone could live with," it seems these rankings were negotiated. Can you explain why you used this approach rather than basing the ranking solely on the work of the technical experts?

Response. Public perception shapes public policy. And as Congress knows well, public policy is a subjective process, at best balancing scientific evidence with individual belief, experience, values, and the collective political process. The findings of technical experts alone would have become just one more element competing for attention in the larger process.

Our process started with a mix of public perception and expert opinion on environmental hazard, incorporated scientific information with consistent criteria, and then provided a forum for diverse stakeholders to find the common ground "that they could live with." Everyone participating changed some ideas based on new perspectives. The ranking was rooted in science, and began an extended process of public education to update that perception with new information about the changing nature of environmental hazard.

PROCESS NOTE: The objectivity of the ranking process was demonstrated in that participants stuck with a long and intricate process—8-day-long meetings over 5 months. Participants arrived with their initial rankings of a subset of risks, posted those rankings in small groups, discussed their rationales, and reranked. The results of the four small group rankings were aggregated, and mathematically averaged, then discussed again as a large group. *It was very significant that rarely was even a slight adjustment to the aggregate ranking considered, because the aggregate spanned the perspectives of the group. Also, capturing the rationales for the ranking provided context and illuminated the thought process.*

BACKGROUND: The ranking was a product of late 1990's scientific knowledge, judgment about that science, and individual values about what matters most. In 1993 when the New Hampshire project began, public perception of environmental risk had been formed by the images from the 1960' and 1970's—rivers on fire, polluting industrial smokestacks, toxic wastes leaking out of illegally buried 55 gallon drums, etc. In 1987, in *Unfinished Business,* USEPA experts had ranked the most pressing environmental risks of the late 1980's. In the follow-up 1990 report, *Reducing Risk,* USEPA's Science Advisory Board noted that the risk list identified by agency experts was almost inverse to that perceived by the public.

Question 3a. I'm impressed by the inclusiveness of your projects. I'm sure that one of the big benefits was that the participants in these projects developed a much better understanding of the risks posed by various environmental issues. What about the benefits to the understanding of the public at large?

Response. Thanks for your comment about inclusiveness; it was important to us. Pls. see answer to Senator Smith's Question 2.

Question 3b. Have you actually studied whether the project has changed public attitudes or, more generally, whether and what the public-at-large learned from it?

Response. We have not had the time nor resources to study public attitudes. Because of limited resources, we did not set out to influence the public-at-large, but rather focus on two specific audiences, as described in the answer to Senator Smith's Question 2.

Question 4. Could you give me examples of how the results of your comparative risk project has influenced the budget, policies, and/or activities of your State government?

Response. The New Hampshire project intentionally was designed to involve all players who shape environmental policy—business, environmental organizations, public health experts, citizen groups, along with State and local government—because initiatives to improve environmental quality of life will come from all sectors. Please see answer to Senator Smith's Question 1.

Question 5. Has your comparative risk project changed the State's priorities when it comes to how it interacts with, and what it requires of, local governments in New Hampshire?

Response. Not yet. Changing how State government interacts with local government is part of the work of the Minimum Impact Development Partnership. The nature of what the State government can require of local government is very limited in New Hampshire. Most importantly, we intentionally designed our process to empower all citizens to act (see pages 12–25 of *For Our Future*).

Question 6. What were the most important results of your comparative risk project?

Response. Process: Please see answer to Senator Baucus' Question 1c and Question 2 PROCESS. Outcome: Please see answer to Senator Smith's Question 1.

Question 7. What were the keys to the success of your project?

Response. The process, which created a non-advocacy, neutral forum, provided accessible science, with explicit technical criteria, evaluated by judgment informed by belief and experience, and individual values (more at Senator Baucus' Question 1c and Question 2 PROCESS).

Question 8. In implementing the comparative risk assessment, what problems did you encounter that you could not, or could only partially, overcome?

Response. Within the process, a number of participants felt frustrated by the consensus-based nature of the final list, and so, gave it less than full support. Also, one public health advocate continued to believe that ecological risks shouldn't have been ranked above those related to public health.

Additionally, some advocacy groups outside the process didn't "buy-in" on the results—for example, a small group opposed to land application of biosolids ("sludge") have succeeded in polarizing and sensationalizing that issue, despite the relatively low risk ranking. So those interested in "single issue" politics did not agree with a process that built common ground, and placed risk in context.

Question 9. Do you think a comparative risk project similar to the one done in New Hampshire could be performed on a national scale? Why or why not?

Response. As described in the introductory paragraph and elsewhere, there are at least two basic approaches to ranking risks along a continuum of hazard (i.e., "comparative risk"). In my written testimony (section (2), page 1 of 3), I noted the key characteristics of New Hampshire's public, non-governmental process—participants (1) left preconceptions and vested interests at the door; (2) brought an ability to lis-

ten to others and work collaboratively, and (3) had a sense of humor to ease difficult discussions. If Congress or others can create such a setting at the national scale, perhaps it might be possible—depending on the purpose of the effort. USEPA met with some success with the inter-agency process in 1987, and SAB in 1990 (as noted in Senator Baucus' Question 2 BACKGROUND).

Question 10. In the panel on residual risk, many concerns were expressed about EPA's case study residual risk assessment for secondary lead smelters. This seems, in some ways, to be the nature of risk assessments. In fact, it often seems that every time a risk assessment is done these days—whether it is to regulate an environmental problem, update a standard, or better understand a problem such as climate change—it is greeted with an extremely high level of controversy.

Given this, how realistically do you think it is for us to consider doing a comparative risk assessment that would set EPA's budget priorities—something that would require a separate risk assessment for each of the Nation's environmental problems—but still avoid controversies over each and every risk assessment the priorities are based on?

Response. As defined in the first paragraph on page 1, comparative risk process is quite different from that of risk assessment.

Rather than using separate risk assessment, as outlined in testimony on comments to Congress/EPA (page 3 of 3), we believe it is time to move into the next generation of environmental management, using new tools. National Science Foundation under Rita Colwell is doing so, with their focus on "biocomplexity" as the key to effective management in the 21st century.

However, if Congress were to choose to further explore the role of national comparative risk process, much work has been done by the National Academy of Public Administration. Congressional staff are likely familiar with *Setting Priorities, Getting Results* (1995), a clear articulation of the role of risk-based decisionmaking at USEPA. A subsequent report, *Resolving the Paradox of Environmental Protection* (1997), comes with an appendix tracking implementation of the 1995 recommendations at EPA. Their third report, *Environment.Gov—Transforming Environmental Protection for the 21st Century,* is due out next month, in November, 2000, with recommendations building on the previous two. Resources for the Future also studied use of comparative risk, in *Worst Things First*? (1994), and *Comparing Environmental Risks—Tools for Setting Government Priorities* (1996).

Question 11. What should the states and the Federal Government be doing to collect public health data that would help in performing better risk assessments?

Response. Certainly, more data can help illuminate better solutions. Data are most useful when: (a) collected based on a strategic assessment of what we need to know to understand the relationship between inputs and outcomes; (b) analyzed objectively before decisions are made; and (c) reported consistently and regularly. Use of data is an iterative process with making policy. An example: USEPA initially regulated volatile organic compounds (VOC's) as a key component in formation of ground level ozone ("smog"). Over many years, additional data and analysis revealed that in New Hampshire, nitrogen oxides (NO_x) were the limiting factor. Only recently have regulations been changed to incorporate the improved scientific understanding of air pollution chemistry. Another example is current focus on $PM_{2.5}$ as a component in acid rain, ground level ozone, and regional haze associated with the public health outcome of excess urban mortality, ecological outcome of decreased soil and forest productivity, and economic outcome of reduced visibility.

More generally, as outlined in our "illness/wellness" model, public health and ecological health are interrelated; good data on the both are needed, within a context that promotes health, rather than catalogues extent of illness. As discussed in the previous paragraph, "good data" means relevant information, properly collected, effectively analyzed, and consistently reported, in an iterative process that modifies practices as understanding increases.

[From Science Magazine, Volume 289]

AIR POLLUTION

PANEL BACKS EPA AND 'SIX CITIES' STUDY

(By Jocelyn Kaiser)

The Environmental Protection Agency (EPA) has won a major victory in the fierce battle over its tough new standard for particulate air pollution. Dealing a sharp

blow to critics from industry, a nonpartisan research group has reevaluated key data that EPA relied upon to set that standard and has come out firmly behind the agency. Although all scientific debate isn't over, the reanalysis "puts to bed many of the concerns that were raised" 3 years ago, asserts John Vandenberg, an EPA environmental scientist.

At issue was EPA's 1997 decision to extend its regulation from particles 10 micrometers or less in size to those a mere 2.5 micrometers or less across ($PM_{2.5}$). EPA based its decision largely on two controversial studies that linked these tiny particles, released mainly by motor vehicles and power plants, to higher death rates.

In the Six Cities study, Harvard researchers examined the relation between levels of PM and sulfates (a component of fine particles) and death rates among more than 8,000 people in six U.S. cities, following them for 14 to 16 years. The American Cancer Society (ACS) study followed over 500,000 people in 154 cities for 8 years. Both found a slight rise in death rates from health and lung disease in cities with higher levels of $PM_{2.5}$, although the mechanism remained unclear. Based largely on the ACS death court, EPA calculated that the benefits of cutting $PM_{2.5}$ to 65 $\mu g/m^3$ over 24 hours would far outweigh the multibillion-dollar costs.

After EPA proposed the standard in 1996, the American Petroleum Institute (API) and other industry groups blasted the two studies. Some scientists also argued in congressional hearings that the apparent link might result from other air pollutants, a less healthy lifestyle in dirtier cities, or other confounding factors. Industry groups sued to block the new regulations. A federal court decided that the science was sound but threw out the rules based on legal arguments, which will be heard by the Supreme Court this fall. At the same time, skeptical industry groups and some lawmakers demanded that the Harvard researchers turn over their raw data. The researchers refused, saying that subjects' confidentiality would be breached.

To resolve the scientific and data-sharing issues, Harvard turned to the nonprofit Health Effects Institute (HEI) in Cambridge, Massachusetts. HEI assembled an expert panel to reanalyze both studies. In a report released last week, that panel concluded that the association between $PM_{2.5}$ and excess mortality is real. The team, led by statistician Daniel Krewski of the University of Ottawa, replicated the studies from original data sets and got essentially the same results: slightly higher death rates in the dirtier cities (see table). The team probed the data for more than 30 possible confounders, from altitude to health services, and tested the link "in nearly every possible manner" with various analytical techniques. The results still held.

ACS Six Cities

Increase in $PM_{2.5}$ across cities	Increased Death Rate	
	Original Investigators	Reanalysis
18.6 $\mu g/m^3$	1.26	1.28
24.5 $\mu g/m^3$	1.17	1.18

Confirmation. Reanalysis yielded results almost identical to the original studies: a rise in death rate of 28 percent (in the Six Cities study) and 18 percent (in the ACS study) from cleanest to most polluted city.

Bill Frick, an attorney with the API, agrees that the reanalysis has "eliminated some of the uncertainty." Another major epidemiology study released by HEI that looked at daily PM levels and deaths in 90 cities has also cleared up earlier doubts (*Science,* 7 July, p. 22). But Frick argues that researchers still need to figure out which component of $PM_{2.5}$ causes harm and hence what problem needs to be fixed—power plants or diesel trucks, for instance. A slew of new federally-funded research is addressing those questions and will feed into EPA's assessment of $PM_{2.5}$ science this fall. Until EPA decides whether to adjust the standard next year, it won't ask states to comply with the regulations.

Meanwhile, the legal scuffle over access to research data continues. In the wake of the controversy, Congress in 1998 passed a law, sponsored by Senator Richard Shelby (R–AL), mandating the federally-funded researchers release their raw data if requested under the Freedom of Information Act. To the relief of scientific groups, the White House interpreted the law narrowly, limiting it to grants awarded after fall 1999 and only to data used to support regulations. The U.S. Chamber of Commerce threatened to sue to broaden that interpretation and began the process by filing requests last December for the Harvard data. So far, EPA has refused to turn over the data because the study predates the law. Keith Holman, an attorney with the Chamber of Commerce, says the group hasn't yet decided whether to litigate the case.

STATEMENT OF MICHAEL J. POMPILI, ASSISTANT HEALTH COMMISSIONER, COLUMBUS HEALTH DEPARTMENT

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 policymakers 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 1995 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 2-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 1995 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 1995 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 decisionmaking 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 U.S. 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 decisionmaking.

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 3 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 toward 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 tradeoffs regarding risk and if the decisionmaking 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.

REPORT—THE COLUMBUS COMMUNITY ENVIRONMENTAL MANAGEMENT PLAN: PROTECTING AND IMPROVING THE ENVIRONMENT BY: USING SCIENCE, INFORMING CITIZENS, AND EMPHASIZING COMMUNITY DECISIONMAKING

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 policymakers 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 2-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

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 policymakers 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 committees 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 decisionmakers an objective (different) perspective that can either confirm judgments 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

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 2-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.

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 projects 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.

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; 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 2-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 precursors to ground level ozone formation.

• Creation of *Community Computer Centers,* providing computing sites with Internet hookup in inner-city areas. The programs 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 traditionally 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 onsite. Participants meet regularly to discuss plant operations, facility environmental and safety programs, etc.

RESPONSES BY MICHAEL J. POMPILI TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. You recommend that the Federal role be one of technical and funding support to State and local agencies. You also recommend that the Federal Government promote sound science and be more flexible. In return, local and State agencies will be more accountable for results. What specific recommendations do you have for the Congress?

Response. It is important that Congress spend more time on process building instead of dealing with specific media issues. For example, I have been actively involved with the U.S. EPA dioxin reassessment. While having problems with specific parts of the assessment, the use of the U.S. EPA's Science Advisory Board needs to be a very important part of any review. Emphasis should be provided on supporting these organizational mechanisms instead of specific reviews.

Shifting from the current categorical thinking model of addressing a problem to a community involvement model would be a substantial step forward. Because community participation and buy-in are critical, components in solving the complex environment problems we face today, it is important we change how we interact with our local citizenry. The current Federal models are extremely deficient in this area, and need to be examined in just about all phases of environmental legislation such as the Resource Conservation Recovery Act, Superfund, Clean Air Act Amendment, etc. We talk public hearings not public participation. Emphasis is on exact levels of chemical contamination, not public deliberation. Emphasis is on specific levels of testing not how the different levels of government interact with their citizenry.

Question 2. Please describe the feedback you received from your stakeholders during and following the Comparative Risk Assessment Project?

Response. The main benefit that was achieved through the implementation was the; building of trust and the strengthening of relationships between the various stakeholders that exist within our community.

Project stakeholders, regardless of their backgrounds or qualifications, can generally be broken down into three general categories:

(1) community volunteers who had no professional scientific or environmental background,

(2) community volunteers who work in the research or environmental arena, and

(3) city of Columbus department or division representatives.

All of the participants found the project challenging. The necessity of group decisionmaking, the need to make decisions not only on the basis of available technical information but also with information on people's values, and the time required to carry out the project were mentioned by most all participants as significant issues. In addition, some participants were uncomfortable wrestling with technical information.

However, by the end of the project, most of the participants directly charged with analyzing, ranking and making risk-reduction recommendations were grateful to

have gone through the process. All stated they had a much deeper understanding of the environmental issues we studied, and more appreciation for the difficulties in setting appropriate public policies. Our project chair, a former national officeholder for the Sierra Club, stated he learned more about environmental protection in the 2-years with our project than he had in his adult lifetime as an environmental activist.

Some city of Columbus department or division representatives who participated may have been most affected. Some of their comments following the project spoke to their new ability to take many of the concerns or ideas raised through the comparative risk process and work with them on a daily basis. This type of continuity resulted in implementation of a number project recommendations, and a general growth in environmental awareness by some of the very people that are in the best positions to improve the City's environmental protection efforts.

One measure of satisfaction may be seen in that many participants agreed, following the project, to form a new volunteer environmental organization dedicated to helping city officials implement project recommendations. The group has continued to function since its 1996 formation and presents annual awards to civic leaders for their environmental efforts.

We have continued to buildupon this trust by following through on the recommendations and also by reporting back to the community and our participants on the status of their recommendations.

Finally, we have continued to work with our participating local governmental bodies in working with them to implement the various Priorities 1995 recommendations.

Question 3. What were some of the important lessons you and your stakeholder's learned from the process and what would you do differently if you had to do it all over again?

Response. First, the process, if done properly, does result in a valuable environmental planning document and a group of participants that are much more educated about environmental issues. It provides a thorough and systematic way to simultaneously deal with a wide range of environmental issues. It offers a significant way for the public to help governmental decisionmakers craft environmental policy. It is critical that in processes of this type, those that have the ability to implement solutions play a significant role in the comparative risk process.

At the same time, there are drawbacks to the comparative risk process. It's lengthy and can be time-consuming. This can create a problem for some people who may want to serve on a voluntary or short-term basis. Also, getting the public actively engaged in an assessment and planning process can be difficult. Meaningful public participation is critical to the success of the process, but it's often difficult to obtain in the absence of any environmental crisis or hot-button issue. In addition, the lack of data or technical information on local environmental problems can be a significant hurdle. Projects need to gather as many technical resources as possible, both in terms of suitable personnel and information. It is also important to understand that the issue of using *exact* science was not really an issue. Our participants, who actually gathered the information, had the information reviewed by our Environmental Science Advisory Board. After this reexamination, they reviewed the data, incorporated their values and beliefs to achieve their final ranking.

Finally, there's a tendency for projects to spend the majority of time assessing and ranking environmental problems. Project directors must spend an equal amount of time and effort determining strategies for implementing recommendations, creating new programs, etc.

Our process could be improved by: (1) streamlining the process so that projects could be completed or repeated in less than the currently required 2-year timeframe; (2) devoting more time and resources to conducting a more-efficient public outreach campaign; (3) enlisting the support of more environmental scientists/"technical experts" to gather the technical information and complete the technical analysis portion of the project; and (4) spending considerably more time planning; for the risk management portion of the project. We devoted only about 30 percent of the total time to this portion of the project our process.

Question 4. What are the key obstacles you face in setting priorities and managing risk effectively at the local level?

Response. Substantial challenges are occurring at the local level that are having significant impact on setting risk priorities and managing risk effectively at the local level. They are as follows:

- Information overload,
- Complex issues,
- Quick results desired, and

• Limited budgets

Information Overload.—Every day our local citizenry is bombarded with. "important risk information" that is being provided to assist them in making informed choices. Currently this information is provided in a condensed format and is often slanted toward a particular view. Usually this information is provided in a manner that has dueling experts who have totally opposite views and use terms that are foreign to everyone but the experts.

Additionally people now have access to the Internet which opens a whole new myriad of issues.

With the Internet an abundance of information is now available with the vast majority being non peer reviewed and slanted to a particular agenda. This is an issue that will exist for the foreseeable future and I do not think this problem has an easy solution.

Complex Issues.—The easy fixes have been achieved. The issues before us now are complex because they incorporate beliefs and values that require substantial tradeoffs and usually have volumes of conflicting information available to support all sides of an issue. This is why I consistently go back to working on a deliberative process of public involvement and deliberation before an issue is addressed.

Quick Results.—Our public and therefore our elected officials want quick actions and are less patient to wait for the long term sustainability that is desired with most of. our current issues.

Limited Budgets.—As with our local governmental actions, the limited amount of financial resources forces the priorization of resources. This is an area where the Federal Government can be very helpful. In a large amount of situations it would be very beneficial if the Federal Government could provide seed money to demonstrate the value of citizen involvement and participation in local priority settings.

If these initiatives were successful then there is a far better chance that these initiatives will be carried on because of the low relative costs compared to the potential large benefits.

RESPONSES BY MICHAEL J. POMPILI TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1a. I note that one of the outgrowths of your project is a focus on ground level ozone—an environmental problem that some here in Congress believe does not require more stringent regulation because that would not be based on "sound science." Can you tell me how your project dealt with scientific uncertainty in your project?

Response. The goal of Project CLEAR is to recommend strategies to reduce emissions that contribute to formation of ground-level ozone in Central Ohio. The project will develop these recommendations through a combination of public involvement through civic forums and objective analyses by several technical working groups. Project CLEAR is a partnership of the Columbus Health Department, The Ohio State University, and the Mid-Ohio Regional Planning Commission. Stakeholders from business, government, non-profit organizations, and universities are represented and involved.

Two factors led to the initiation of this project. The first is the possibility that Central Ohio will violate existing Federal EPA ozone standards or certainty that our region will violate the proposed Federal standard for ozone. The second is concern among some stakeholders about the health threats posed by ozone.

CHD and other Project CLEAR partners are aware that "scientific uncertainty" exists around the nature and extent of health effects from exposure to ground level ozone.

Having or facilitating a scientific and/or political debate about the ozone standard is beyond the scope of Project CLEAR. Nor is trying to rank the "problem" of ground level ozone among other health and environmental concerns facing our region. In local government, we must comply with Federal and State mandates and enforcement actions. It is important to understand that, fundamentally, the purpose of Project CLEAR is to take a proactive approach toward the standards and the possibility that central Ohio may find itself in violation of it. This fundamental purpose requires us to educate and involve our community and undertake analyses of emission reduction potential of various strategies. While the larger debate is interesting and important, it is not germane to the fundamental purpose of this project.

The project partners selected Dr. Paul Berkman, an Earth Scientist at the Byrd Polar Research Center at The Ohio State University (OSU), as Chairman of Project CLEAR. In 1997, Dr. Berkman convened a national symposium. on ground-level ozone at OSU. The symposium brought together experts from industry, government

and various perspectives within the scientific and health community for a balanced program on this issue. Dr. Berkman has worked diligently to ensure scientific objectivity in Project CLEAR.

Project CLEAR has established a scientific working group that is to provide general scientific oversight to the project.

(2) The Project CLEAR Steering Committee includes representatives from industry, government, non-profit groups, and many others.

(3) Project CLEAR provides information from a wide variety of sources to stakeholder participants and interested members of the public. These sources are linked on the project web site and in other written materials.

(4) Project CLEAR has developed an "issue guide" concerning ground-level ozone in Central Ohio. Several representatives from industry, government, environmental organizations and others worked together to develop the guide. (We have enclosed a copy.)

Question 1b. Did you use conservative estimates, or apply principles of precaution, in the face of uncertainty?

Response. This question is not applicable to the main objectives of Project CLEAR.

Question 1c. How were you able to reach the consensus with stakeholders on ranking issues such as ground level ozone where there were scientific uncertainties?

Response. (1) Project CLEAR is not designed to undertake a process to rank environmental issues. Please see the overview for a more complete explanation; (2) The Project CLEAR Steering Committee will recommend strategies to reduce ozone-forming emissions by the end of 2001. These recommendations will be made by consensus and will be based on cost, ability to implement, emission reduction impact, according to analyses of technical working groups. They also will be based on public involvement featuring up to 20 deliberative issue forums from fall of 2000 through early summer of 2001.

Question 2. I see from your written testimony that two of your prime emphases were science and community-based decisionmaking. Some would see these two as inconsistent, since the general public brings their experiences, judgments, and values "to the table" whereas science is ostensibly objective. (a) Can you explain how science and community-based decisionmaking were melded in your comparative risk project? (b) Please explain why you chose to have the public make ranking and priority decisions rather than simply relying on the work of the technical experts.

Response. My first point would be that it is a misconception to think that science is "objective." In many areas, there are honest disagreements among scientists as to the extent and severity of an environmental problem, the "correct" meaning or interpretation of data, etc. In making their conclusions, scientists themselves use their own values and opinions as a filter through which they look at data and information.

This is no different than what the non-scientific public does in making decisions. The information all of us consider is filtered through our own individual values and opinions. The advantage that the scientist may have is simply that he or she may have access to and knowledge of more information. The strength of the comparative risk process is that it strives to gather all of the relevant scientific information possible and then get it into the hands of project participants for consideration. Linking the concepts of science and community decisionmaking together is not inconsistent, it simply means that the public should have the benefit of knowing and considering all of the relevant information—that the public should have the opportunity to make the most informed choice possible.

We attempted to meld these ideas in our project in a number of ways. First, our technical committee (i.e., our "scientists") wrote environmental analyses based on the scientific information available, their own knowledge and "experiences, etc. These analyses were forwarded to the project's management team for their review. In addition, the analyses were summarized, distributed to members of the general public for comment end discussed at a community open-house.

All comments from if he general public concerning the technical reports were documented and submitted to the project management team. The project management team considered both information contained in the technical analyses and the public feedback from those analyses to rank our 30 environmental issues in terms of severity.

The public, in fact, did not do the project risk ranking . . . it considered the information produced by the project's technical committees, commented on their findings, and their comments were passed to the project management committee for its ranking. We specifically chose not to give ranking responsibilities solely to the technical experts because we felt that the project's success hinged on buy-in from the public.

Leaving the ranking solely in the hands of "technical experts" would hurt our credibility and leave I,us open for public criticism, ultimately damaging; our ability to develop project recommendations that the public would support.

Lawmakers make laws in much the same way . . . they rely on technical experts to provide scientific information, but they realize that the public will not accept policies crafted solely by these experts. They use community feedback, as well as their own values and opinions, to develop appropriate laws, policies and procedures.

It must be stressed that even though our project ranking (i.e., "priority decisions") was done by a project management committee and not the general public, the public's values and opinions played a significant role in the ranking outcome. The project management committee built an explicit mechanism into the ranking procedure to reflect public input on the scientific findings of the technical committees. Individual ranking decisions could be adjusted based on (1) the level of feeling that the public may have registered about a particular environmental issue, and/or (2) whether a particular group is disproportionately impacted by a specific environmental issue. In numerous instances, project management committee rankings were subsequently adjusted to reflect; information gathered from the public.

Question 3a. I'm impressed by the inclusiveness of your project. I'm sure that one of the big benefits was that the participants in these projects developed a much better understanding of the risks posed by various environmental issues. What about, the benefits to the understanding of the public at large?

Response. The Priorities '95 Comparative Risk Project was our attempt to involve the public in setting our communities environmental priorities. Community participation and buy-in are critical components in solving the complex environmental problems we face today. To that end we utilized many various outreach mechanisms to reach our public. These outreach mechanisms included:

- Public Opinion Surveys;
- Community Meetings;
- Distribution of educational materials;
- Community-wide Open House; and
- Media events

As we continue down this path with our CLEAR program, we are further expanding our community outreach efforts to include public deliberation sessions in many parts of the central Ohio community.

Benefits to understanding of public at large:

- As previously explained, even with our substantial community outreach, vast pockets of the public still are uninformed about the process. The areas where the most substantial impacts were achieved were with our State and local (city and county) elected officials and the environmental community.

I do not want to imply that all environmental groups were pleased with the process, since specific environmental groups elected not to participate, but overall the response was positive and this success has now led to our CLEAR program.

Question 3b. Have you actually studied whether the projects have changed public attitudes or, more generally, whether and what the public-at-large learned from it?

Response. Studied whether changes in public attitude have occurred:

- Concerning the studying of public attitudes, we have not formally conducted a public attitudes survey. The main reason, as always, was the lack of funding to perform the surveys. We are trying to perform a more thorough review within the CLEAR program as we are working with the Ohio State University, but again that will be dependent on resources. Additional, we want to critically review the advantage of using a public deliberative process instead of the current public hearing process.

Question 4. Could you give me some examples of how the results of your comparative risk project have influenced the budget, policies, and/or activities of your local and State government?

Response. A number of City department or division representatives actively participated on our comparative risk project committees; working to analyze environmental issues, gauge the public's response to various technical reports, and evaluate implementation alternatives. Since the project's conclusion, these representatives have returned to their City positions and have been able to work with many of the project issues and concerns in the normal course of their employment. This has resulted in a number of initiatives being implemented in direct or indirect response to comparative risk recommendations. The City can point to a number of specific achievements since the project's conclusion. Among them:

- The creation of a Natural Resource Manager position within the Columbus Recreation and Parks Department to oversee and coordinate issues concerning department parkland and park habitat.

• Current City efforts in modifying the Mid-Ohio Regional Planning Commission's Watercourse Protection Ordinance, for eventual submission to Columbus City Council for approval. The ordinance addresses a number of recommendations concerning green space and habitat protection.

• Development of a Stormwater Master Planning Review to review stormwater design criteria and policies so that the natural conditions of ravines, creeks, rivers, meadows, woodlands and wetlands can be preserved or restored if possible.

• Creation of new city code requirements detailing additional requirements for provision of sidewalks when subdividing land, and increasing the Public Service Director's ability to require sidewalks in new developments or enlargements. The work is in addresssing a Priorities '95 recommendation to construct walkways to improve access or reduce walking distances for pedestrians.

• The launch of the Stay Tobacco-free Athlete Mentoring Program (S.T.A.M.P.) pilot. The program matches high school athlete mentors with sixth-grade; students in an effort to discuss issues relating to tobacco use and encourage participants to remain tobacco-free. The effort addresses a recommendation to encourage school and community-based programs on the effect of smoking.

• Adoption of a Parkland Dedication Ordinance, which providers for the dedication of parkland as part of the re-zoning process for residential and non-residential projects of more than one acre. This ordinance, jointly developed by the departments of Trade and Department and Recreation and Parks, addressed a recommendation calling for green-space set-asides in connection with new development.

• The Department of Recreation and Parks receiving a community award for adopting a containerized tree growing process that reduces growing time of planting stock from 7 to 3 years. This has allowed the department to grow more of its own trees, and select particular species, rather than rely on what is available from commercial growers. The city is now growing 5,000 trees annually in efforts to fill 45,000–50,000 vacant right-of-way locations. Plantings will improve aesthetics, neighborhood cooling and reduce storm water runoff. This effort addresses a Priorities '95 recommendation to plant native shrubs and plants whenever feasible.

• The Department of Recreation and Parks assisting the Mid-Ohio Regional Planning Commission in forming a number of citizen river stewardship groups. One of the project recommendations advocates the City encourage creation of Citizen Watch Groups to monitor activities that may adversely impact area waterway corridors.

• Efforts by the Division of Refuse Collection to initiate recycling programs at Columbus apartment complexes. Priorities '95 had recommended that the City encourage development of a pickup system for department recyclables.

• Development of the Neighborhood Quality Interaction Team program, a community-based initiative that consolidates and better coordinates city inspection services among the departments of Health, Refuse, Trade and Development and Police. The pilot office is located in the Franklinton area. Plans are to duplicate the initiative in other City neighborhoods. The effort is in response to an Priorities '95 recommendation to develop neighborhood programs to improve zoning and health code enforcement.

• Establishment of an Urban Pet and Wildlife Management coalition to address a variety of pet and wildlife issues. The coalition; developed by the Columbus Health Department, published a comprehensive report outlining a number of recommended actions to address urban animal problems. The report, and anticipated ongoing efforts by the coalition, address a Priorities '95 recommendation to develop a community outreach program and a public information campaign on rabies.

• Establishment of a 6-county coalition to address the issue of atrazine in the Scioto watershed. The Division of Water helped form this coalition, consisting of representatives from the city of Columbus, Ohio Department of Natural Resources, Ohio EPA, private industry, area farmers, OSU Extension Service, Ohio Wesleyan University and Otterbein College. The partnership is identifying potential pollution sources, conduct field sampling, monitor the watershed and develop an action plan for reducing atrazine use and resulting pollution. The coalition's work addresses a Priorities 1995 recommendation to convene the agricultural, scientific and regulated communities to develop a chemical management plan for Central Ohio watersheds.

Question 5. What were the most important results of your comparative risk project?

Response. The main benefit that was achieved through the implementation was the building of trust and the strengthening of relationships between the various stakeholders that exist within our community.

Project stakeholders, regardless of their backgrounds or qualifications, can generally be broken down into three general categories:

• community volunteers who had no professional scientific or environmental background,
• community volunteers who work in the research or environmental arena, and
• city of Columbus department or division representatives.

All of the participants found the project challenging. The necessity of group decisionmaking, the need to make decisions not only on the basis of available technical information but also with information on people's values, and the time required to carry out the project were mentioned by most all participants as significant issues. In addition, some participants were uncomfortable wrestling with technical information.

However, by the end of the project, most of the participants directly charged with analyzing, ranking and making risk-reduction recommendations were grateful to have gone through the process. All stated they had a much deeper understanding of the environmental issues we studied, and more appreciation for the difficulties in setting appropriate public policies. Our project chair, a former national officeholder for the Sierra Club, stated he learned more about environmental protection in the 2-years with our project than he had in his adult lifetime as an environmental activist.

Some city of Columbus department or division representatives who participated may have been most affected. Some of their comments following the project spoke to their new ability to take many of the concerns or ideas raised through the comparative risk process and work with them on a daily basis. This type of continuity resulted in implementation of a number project recommendations, and a general growth in environmental awareness by some of the very people that are in the best positions to improve the City's environmental protection efforts.

One measure of satisfaction may be seen in that many participants agreed, following the project, to form a new volunteer environmental organization dedicated to helping city officials implement project recommendations. The group has continued to function since its 199Ei formation and presents annual awards to civic leaders for their environmental efforts.

We have continued to buildupon this trust by following through on the recommendations and also by reporting back to the community and our participants on the status of their recommendations.

Question 6. What were the keys to the success of your project?

Response. Two factors were critical in the success of our project. The first was the appointment of our project chair. Because of the complexity and length of the comparative risk process, it is essential that these projects be manned by an individual who:

• has credibility with other project members concerning their environmental knowledge and experience.
• is perceived among project participants as "fair," or neutral, concerning the airing/balancing of different environmental philosophies and goals that are part of these projects.
• is committed to public input and public participation regarding the process.
• will devote the significant amount of time required over the 2 years to assist with project management, task delegation and followup, etc.
• is personally committed to the success of the project.

Unless the project chair can meet each of these criteria, a comparative risk projects faces considerable handicaps in successfully achieving its goals.

The second critical factor was the inclusion of key city of Columbus personnel in the project . . . particularly in the implementation phase. Project organizers recognized that any City implementation efforts would only be realized if city of Columbus personnel were intimately aware of the project and supported its eventual recommendations. To ensure that this happened, they made a conscious effort to build this into to project by recruiting some City staff, mid- and upper-level management personnel to participate. As a result, these participants had knowledge and input concerning the potential project recommendations, their implementation feasibility and creation of initiatives or programming that would meet the recommendations' intent.

Question 7. In implementing the comparative risk assessment, what problems did you encounter that you could not, or could only partially, overcome?

Response. Generating significant public knowledge, awareness and excitement about the project was a challenge. Our public involvement committee was forced to be rather creative at times concerning our public outreach efforts. In a city the size of Columbus, with all of the various initiatives competing for the public's (and the media's) attention, this may have been the most difficult aspect of the project. We would have liked a greater level of public involvement from the community.

Question 8. I appreciate your recommendation that Federal supports are provided so more communities like yours can do their own comparative risk projects and set their own priorities. But putting this aside, do you think a comparative risk project similar to the one done in Columbus could be performed on a national scale and be used to establish budget priorities for the Agency?

Response. The main role of the Federal Government in environmental protection is to provide leadership and direction in meeting our national environmental priorities. Therefore, it is very important that a general direction be provided for insuring the overall protection of our Nations' air, water and lands. What is at issue is not that this is a noble goal, but how as a Nation we desire to reach these goals.

One of the hardest things for us to learn with our Priorities '95 project was to give up control; to trust our citizenry within their specific neighborhoods that they would make the "correct" decisions for the betterment of the greater Columbus community. Well they did! Yes, we had pet projects, specific contentious issues, etc.; but overall they looked at the bigger picture. This is the fundamental issue that has to be addressed by the Federal Government.

Does the Federal Government trust states and local governments with providing meaningful input into setting our national goals? My answer is that this can be achieved through a process of inclusion and openess that needs to be directed within the various regions of the country. Will it be difficult—yes, will it be beneficial—definitely—if it is done correctly. Could it be a disaster—yes, if it is controlled too much by Washington, DC.

I strongly encourage the examination of performing a national environmental priority comparative risk project, but only with significant involvement with governmental stake;holders on the national, State and local levels.

Question 9. In the panel on residual risk, many concerns were expressed about EPA's case study of residual risk assessment for secondary lead smelters. This seems, in some ways, to be the nature of risk assessments. In fact, it often seems that every time a risk assessment is done these days—whether it is to regulate an environmental problem, update a standard, or better understand a problem such as climate change—it is greeted with an extremely high level of controversy.

Given this, how realistic do you think it is for us to consider doing a comparative risk assessment that would set EPA's budget priorities—something that would require a separate risk assessment for each of the Nation's environmental problems—but still avoid controversies over each and every risk assessment that the priorities are based on?

Response. Any risk assessment work will produce some level of controversy. One reason is the nature of the task—the impossibility, because of uncertainties, of absolutely defining the level and likelihood of hazard to people, or groups of people, from an environmental threat. Risk scenarios are all based to some degree on assumptions—assumptions that are open to honest debate or disagreement among individuals, whether they are scientists, members of the regulated community, or the general public. Risk assessment work, particularly in the area of comparative risk, implies to many that winners and losers will be created as the result of the process. Those associated with a "high-risk" issue will probably support the process and results. Others concerned with "low-risk" issues may question or dispute the process out of fear it would de-legitimize their concerns.

But the fact that comparative risk cannot eliminate controversy should not be used as an argument against using the process. By comparing the severity of one problem against another, the process does forces participants to do something that each do daily in our everyday lives—make choices and evaluate various alternatives based on the information we have available. Decisions cannot be made in a vacuum. Actions and choices have impacts that must be considered before decisions are made. The comparative risk process recognizes this in its attempt to consider environmental problems in the context of other problems, and in its attempt to make these decisions using all available information.

In a sense, every organization that puts together a budget uses a type of comparative risk process. The budget process is nothing more than a systematic assessment determining the level of funding that will be attached to each of an organization's various functions, programs or activities. In part, this assessment is made by considering the importance of activities, and the impact of carrying them out relative to other possible budget choices. Agency budgeting using the principles of comparative risk would be nothing more than a formal recognition of this fact. Such a process would simply be a systematic assessment of environmental problems using defined criteria to determine the levels of risk resulting these problems. Potential criteria could include the number of people affected, severity of effect, reversibility of effect, level of uncertainty, disproportionate populations affected, etc. There would cer-

tainly not be unanimous agreement about the budgeted funding levels resulting from this type of assessment. However, a systematic analysis using this type of criteria to determine the EPA priorities would certainly be a step in the right direction.

Question 10. You indicated that the Federal Government could be doing a better job of providing funds and more accurate data to the states so they can do more comprehensive comparative risk assessments. What, if any, efforts are the states undertaking to improve the comparability and standardization of the data that they collect? What public health data do Ohio or other states provide as part of the Federal-State partnership?

Response. Unfortunately, I have very little knowledge within this area. This question would be far more appropriate for Katherine Hartnell of the New Hampshire Comparative Risk Project.

STATEMENT OF J. CLARENCE (TERRY) DAVIES, SENIOR FELLOW, RESOURCES FOR THE FUTURE

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 United States 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 decisionmakers 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 decisionmaking. 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.

RESPONSES BY J. CLARENCE (TERRY) DAVIES TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. You provided some of the benefits of conducting "comparative risk assessments". You also stated how the science and the data in most cases are woefully incomplete. Please explain how Risk Managers at EPA or at the States or Municipalities could improve their performance of risk management if they had a better understanding of type and magnitude of risk they are dealing with.

Response. A better understanding of the type and magnitude of risk would enable managers to focus on the most important problems in the most efficient way. Conversely, it would enable them to avoid wasting resources on minor or non-existent risks, including the critical resource of public attention and concern.

Question 2. You stated that comparative risk assessment is a tool that helps us take the first step in managing risk effectively by defining the problem. You also testified that we need to go beyond defining and ranking the problem. You stated that we need to focus also on solutions. Please describe the tools available to risk managers for identifying alternative risk reduction strategies and the criteria for selecting the right programs.

Response. Identifying alternative risk reduction strategies is not straightforward, and I am not aware of any good analytical tools to assist in the process. In reality, such strategies are usually based on legislative mandates, and the mandates are usually based on strategies that have been tried in other contexts. The most basic criterion for selection is, in my view, cost-benefit analysis broadly defined. By broadly defined, I mean that non-quantitative factors must be included in the selection process.

Question 3. Please provide your recommendation on how to proceed from here to achieve more effective environmental programs.

Response. As I indicated in my testimony, I think two of the most important steps would be legislative creation of a Bureau of Environmental Statistics and enactment of an integrated pollution control statute. My version of the latter includes the former.

RESPONSES BY J. CLARENCE (TERRY) DAVIES TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. You stated in your testimony that comparative risk assessment can be a "starting point" for setting budgetary and other priorities. You go on to say that comparisons of risk rankings to budget priorities are useful only in a "broad sense." Please explain further what you mean by these comments.

Response. CRA is only a starting point because a number of other important factors must be considered in priority-setting. These other factors include cost, equity, legislative and judicial requirement, administrative and political feasibility.

Question 2. Since it is basic to risk assessment, what is the appropriate way for the committee to decide when the science used in them is "good science" or not?

Response. There is no foolproof way to evaluate the science used. Whether the science has been peer-reviewed and whether it has been published in a reputable journal are the usual criteria, and I do not know of better ones.

Question 3. Clearly, science is needed to inform decisionmaking. But what, in your opinion, is the proper role of nonscientific considerations, such as societal values, in informing decisions on the risk rankings and priorities that are developed from comparative risk assessment?

Response. Non-scientific considerations are important and unavoidable. See my response to Question No. 1. Also, consider that science, by definition, can never tell us what *should* be, only what *is*.

Question 4. In the panel on residual risk, many concerns were expressed about EPA's case study residual risk assessment for secondary lead smelters. This seems, in some ways, to be the nature of risk assessments. In fact, it often seems that every time a risk assessment is done these days—whether it is to regulate an environmental problem, update a standard, or better understand a problem such as climate change—it is greeted with an extremely high level of controversy.

Given this, how realistic do you think it is for us to consider doing a comparative risk assessment that would set EPA's budget priorities—something that would require a separate risk assessment for each of the Nation's environmental problems—but still avoid controversies over each and every risk assessment the priorities are based on?

Response. I do not think that it would be realistic to do a CRA that would, by itself, set EPA's budget priorities, but for the reasons stated above and in my testimony, not because of controversy. There is always some controversy about science, and much of the conflict over EPA science is really a conflict over interests and values rather than over science.

Question 5. I would be interested in your thoughts on what problems would likely be encountered, and how successful we would likely be, if we attempted to perform a national comparative risk assessment in order to set EPA's budget priorities.

Response. In Chapter 2 of *Comparing Environmental Risks*, a 1996 book which I edited, I try to describe some problems and choices that are faced by all CRA efforts. How to define the categories to be ranked and how to involve the public are probably the two most difficult problems that would be encountered. Overall, I would not be very optimistic about the success of such an effort.

Question 6. You mentioned that the Nation should have a Bureau of Environmental Statistics. As you may recall, such a proposed independent Bureau was part of legislation in the 101st Congress (S. 2006) but faced significant opposition. Now, the Pew Commission on Environmental Health has proposed a national system for collecting data on public health through the Department of Health and Human Services and States. The committee could benefit from any views you may have on this latest proposal, if you have the opportunity to review it.

Response. I have not had a chance to review the Pew proposal. However, the proposal relates to data on human health, not to data on the natural environment.

STATEMENT OF ELIZABETH L. ANDERSON, PRESIDENT AND CEO, SCIENCES INTERNATIONAL, INC.

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 As-

sessment 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.

PURPOSE OF THIS TESTIMONY

Although Sciences is involved in a wide range of risk assessment issues and investigations, a focus of the research and analysis work conducted by me and my colleagues at Sciences is improvement in the sciences that support human health and environmental exposure and risk assessments, such as those conducted today as part of EPA's comparative risk assessments and the hazardous air pollutant (HAP) residual risk program. A major need in comparative risk assessment is development and use of scientifically supported methods and data to identify and appropriately address areas of most important environmental risk. This need is evident most recently in EPA's mandated HAP residual risk program which involves an unprecedented use of risk assessment and is being required while the science of risk assessment is still very much in flux. In that program, over 175 industry categories subject to maximum achievable control technology (MACT) standards currently being developed must have residual risk assessments completed to serve as the basis for risk management decisions. These risk assessments are required 8 years after promulgation of each MACT standard and will in total involve emissions of the 188 HAPs from literally thousands of facilities. The risks must also be estimated for all types of climates and terrains, wide ranges of population distributions, direct and indirect (i.e., multipathway) exposures, human and ecological effects, and consideration of maximum individual as well as total population risk. This would be an extremely difficult and challenging task for any risk assessment program.

My purpose today is to provide my thoughts on the direction and progress of the use of risk assessment by EPA and what actions might be taken that would make that use more effective and more soundly based in science and, thus, more responsive to our Nation's needs. My analysis is based largely on two important recent documents which describe how EPA is currently intending to apply risk assessment. The first is the *Residual Risk Report to Congress* (Report No. EPA–453/R–99–001), which was published in March 1999 and provided the Agency's broad scientific guidelines for managing that program. The second is EPA's first draft residual risk assessment document which was released for Science Advisory Board (SAB) 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 decisionmaking. 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.

Consequently, Congress established in section 112 of the 1990 Clean Air Act Amendments (1990 Amendments) a new regulatory process for HAPs. First, a list of HAPs was specifically mandated by Congress and EPA was required to publish, over an 8-year period, MACT standards for the sources of the listed HAPs. Next, 8 years[1] after publication of each MACT standard, the EPA was required to promulgate additional standards if needed to ensure protection of public health and the environment. In other words, the risks remaining after imposition of the MACT standards, the so called residual risks, would be determined and additional controls imposed if those risks are judged not to meet the "ample margin of safety" criterion. The EPA began publishing MACT standards in late 1993 and was supposed to be completed with the entire program this year, although that is unlikely to happen.

While relatively straightforward in concept, implementation of the residual risk requirements under section 112(f) of the 1990 Amendments has been difficult and is far from complete. One hurdle was cleared with the definition of ample margin of safety in 1989. EPA's published risk decisionmaking policy set as a goal: "(1) protecting the greatest number of persons possible to an individual lifetime cancer risk level no higher than approximately one in one million (1×10^{-6}), and (2) limiting to no higher than approximately one in ten thousand (1×10^{-4}) the estimated risk that a person living near a source would have if exposed to the maximum concentrations for 70 years." EPA further stated that a maximum individual risk (MIR) of one in ten thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, EPA stated that they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability.

This risk policy has largely been accepted and it was codified in the 1990 Amendments in section 112(f)(2)(B). However, it has limitations in that it only addresses cancer, inhalation risks, and risks to individuals. We now know that many HAPs are not carcinogens, that humans can be exposed through ingestion and skin contact, and that broader population risks must also be considered in addition to individual risks. EPA has not yet provided complete guidance for 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, and be adsorbed into soil, plants, and surface waters with which humans can come in contact. Contaminated food crops, animal food products, and fish that are consumed by humans may result. These risks, too, are

[1] The first group of MACT standards was given 9 years.

largely associated with HAPs that can bioaccummulate. Other EPA programs are requiring multipathway risk assessments in some instances but multipathway risk assessment is new to EPA's residual risk program; to date, the principal experience has been with hazardous waste combustion sources and some hazardous waste sites. One problem is that multipathway risk assessments have typically been designed and applied to individual facilities and they require extensive data and analysis. When these applications are focused on facilities, the use of site-specific data in lieu of generic assumptions is found to make an important difference in the risk outcome. Application to broad source categories is a very different matter. These assessments will tend by necessity to rely on conservative (meaning health protective), generic assumptions. However, intensive and focused efforts are needed to identify the generic parameters that are the risk-drivers through a sensitivity analysis to replace the generic assumptions with more accurate scientific data.

EPA is also considering the estimation of broader population risks in addition to individual risks in the residual risk program. For example, EPA's ample margin of safety language requires the protection of the "greatest number of persons" to a risk no greater than one in one million. However, the manner in EPA will address population risks has not yet been defined. One risk characterization process was described in the 1994 National Research Council report (*Science and Judgment in Risk Assessment*) as including two population risk metrics: (1) distribution of individual risk across the exposed population (e.g., the number of individuals at 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 population risk, expressed as average annual incidence.

CURRENT APPLICATION OF RESIDUAL RISK ASSESSMENT

To date, as noted above, EPA has completed just one draft residual risk assessment, a case study of the secondary lead smelting industry, which was reviewed by EPA's Science Advisory Board (SAB) on March 1 and 2, 2000. I reviewed this draft assessment in detail and presented oral comments to the SAB. In my comments, I concluded that the SAB's comments on the earlier *Residual Risk the Report to Congress* had not been fully addressed in formulating the case study. Significant gaps in the science, the methods, and the data remain that can only be resolved through more detailed assessment, often including source and site-specific assessments.

EPA appropriately described a tiered process where an initial, conservative screening assessment is done to conserve resources. Depending upon the results, the tier one assessment is to be followed by a more refined assessment; where risk outcomes are low, this screening assessment can indicate no further study is needed. However, where risks are of possible concern, a clear commitment is needed to refine the screening level assessment and to articulate criteria for when and how to provide a more accurate assessment. Currently, EPA has not provided clear guidance on the necessary levels of refinement, the methods and data to be used, or even the criteria for deciding when and how to initiate the refined assessment. These are critical to making responsible and scientifically sound regulatory decisions. While I am sensitive to the Agency's resource limitations and the resultant inability to conduct full site-specific risk assessments for every HAP source in every source category, I believe that more refined source data can often be reasonably obtained and utilized to further refine the assessments. The Agency must be equally sensitive to the profound potential economic impacts of further residual risk regulation of sources that have already expended tremendous resources in meeting MACT standards. I strongly support the need to further regulate any source that is found to clearly and unambiguously exceed acceptable risk levels. However, I do not believe it is in the Nation's best economic interest to force needless expenditures when residual risks are not excessive. A refined risk assessment is needed in order to make these determinations. The use of upper bound generic approaches usually provides a poor basis for regulatory actions.

Even implementation of the two-tiered strategy described in the Report to Congress is associated with a number of likely problems. First, given the growing complexity of the science of risk assessment and the wide variability in HAP sources, more than two tiers of risk assessment will usually be needed to ensure relative accuracy as well as cost- and resource-effectiveness. These considerations are necessary because screening risk assessments, with rare exception, estimate risks that are excessive, which can mislead the regulatory process, unnecessarily raise public concern, and possibly miss identification of the most important risks. Recent studies that I and my colleagues at Sciences have conducted concluded that these two tiers of risk assessment can be associated with risk differences of several orders of magnitude.

The Report to Congress also implied that the EPA would conduct all of the necessary residual risk assessments for the more than 175 source categories. However, our knowledge of the EPA HAP regulatory program and staff, based on past working relationships and recent personal communication, indicate that the Agency almost certainly does not have the resources to accomplish this enormous assignment. The more likely outcome is that the EPA will rely on more simplified models and averaged, rather than site-specific, data. This approach will typically define residual risk estimates that are greater than actual risks. These simplified approaches cannot adequately inform regulatory decisions.

With inadequate resources and substantial data gaps, I can see no way for EPA to carry out the residual risk program within the prescribed time without outside partnerships to aid in developing appropriate information, working together, where possible, to ensure that the best data and methods are used in the Agency's analyses, and filling the EPA's resource shortfall with analytical and data gathering support. In addition, with risks estimated using "model plants,"[2] and other approaches that rely on averaged data, industrial facilities will often need to ensure that more site-specific data and methods are employed to determine whether the model plant risks are realistic. In our work, we have found that these averaged approaches typically lead to risk overestimates.

For many industrial source categories, the initial conservative screening assessment could find that residual risks are unlikely to exceed levels of concern at any industrial facility and no further risk-related regulation would be forthcoming. However, for many other source categories, much more accurate and rigorous assessments may be needed in order to determine whether further regulation is required. In other words, if a screening approach indicates risks near or above presumptively acceptable risk levels, or ecological, population, or multipathway 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, onsite 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 data base 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 percent of his daily diet from farm grown poultry, beef, pork, and produce).

SPECIFIC AREAS OF CONCERN WITH EPA'S RESIDUAL RISK CASE STUDY

The process used by EPA in its first residual risk assessment was an appropriately conservative first step that is useful for setting priorities for assessment while conserving Agency resources. However, as presently developed and described by EPA, the process remains a screening tool that can reasonably exclude sources from further assessment, but cannot with accuracy determine whether the residual risks associated with any specific source are above or below accepted levels of risk concern. If used more broadly, the process is almost certain to result in a significant number of false positives namely, sources for which additional regulation appears

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

needed when, in fact, the actual risks are below acceptable levels of concern. This outcome is likely to occur because screening level risks are calculated without properly accounting for the many limitations and uncertainties in the data, models, and methods used by EPA in conducting the assessment, and because of the intentional bias to protect public health where data are uncertain. Inappropriate regulation can only be prevented by the use of much more refined assessment, often including site-specific or category-specific data, thus allowing the decisions needed to support further regulation of those sources that require further control. One illustrative example of the problem caused by reliance on screening tools was an initial screening level analysis that indicated that most of the Nation's coke ovens were above EPA's acceptable cancer risk level as provided in the 1989 benzene decision. Site-specific analysis of several facilities using improved data, a better model which we developed, and health criteria that we re-evaluated, actually found residual risks to be on average three orders of magnitude below the screening level risks and actually well below EPA's acceptable cancer risk level.

In cases where substantial uncertainties and significant limitations in data exist, risk management decisions should not be made until these limitations are appropriately addressed. In its initial residual risk assessment of the secondary lead smelting industry, EPA concluded that the risk estimates likely fell "between the estimates made with and without fugitive dust emissions." This risk range spanned more than two orders of magnitude and is so large that the results are impossible to interpret. In this case, at a minimum, better quality, site-specific data of such risk-drivers are needed to refine the risk assessment so that the results are useful.

EPA's use of conservative methods, models, data, and assumptions early in a source category analysis is appropriate to conserve Agency resources and help prioritize actions for later analysis. However, the use of implausible and unrealistic methods, models, data, and assumptions, particularly when better methods and data are easily obtained, is clearly inappropriate and in this case led to a number of potentially erroneous conclusions. For example, EPA's first draft residual risk assessment resulted in risk estimates high enough that (if true) serious adverse human health and ecological effects would likely be easily observable in the nearby areas. However, the lack of apparent evidence of significant human or ecological impacts near the sources of concern gave every indication that EPA's estimates were unrealistic. Inaccurate and incomplete data, coupled with excessively conservative assumptions, lead to excessive risk estimates. Two specific examples are described below:

1. The assumption in the residual risk assessment that a local farmer obtains drinking water from an untreated local surface water source that exceeds maximum contaminant levels (MCL) for antimony is unrealistic. More realistically, water would be obtained from wells or public water systems. This assumption was not conservative, it was implausible.

2. The modeled surface water concentration near one facility resulted in estimates of huge fish tissue concentrations and large potential risks to the recreational fisherman. Moreover, the modeled concentrations were sufficient to cause serious effects for aquatic organisms, such that there would be a question of fish availability for consumption. However, the lack of collaborative evidence (e.g., fish kills in the vicinity of secondary lead smelters) indicated that the estimates substantially over predicted actual concentrations. High estimated risks need to be flagged and confirmatory information needs to be developed.

EPA's first residual risk assessment process also was incomplete because it left unaddressed many potentially important issues that could have significant impacts on the ultimate residual risk estimates. For example:

1. While EPA clearly put a lot of effort into many aspects of the risk assessment process, it did not focus its data collection efforts on the most sensitive risk-driving parameters. EPA further described the assessment as an "iteration," stating that it would be replaced with a more refined, and possibly site-specific, assessment pending SAB's comments and any additional emissions information, as necessary. Although EPA did not provide further details on the next iterations, I believe that the SAB clearly should review the most refined assessment intended to provide the best basis for their scientific evaluation and comment.

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

3. While EPA acknowledged substantial gaps in data, methods, and procedures, it was not clear what the Agency will do about the missing information. EPA could choose to move ahead with residual risk regulation based on this level of assessment for this source category and plan to keep returning to the source category to further

revise the regulations every time new guidance or methods are finalized; however, regulation based on inadequate assessment information will undoubtedly lead to inefficiency and waste.

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

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

1. In its first residual risk assessment, EPA frequently stated that its estimation of fugitive emissions is uncertain, but continued to use the uncertain data, which can be a risk-driver, to develop risk estimates. The uncertainty in fugitive emission 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., 8 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 rate to calculate the inhalation dose, and, hence, assume 100 percent retention and absorption of this air concentration. In fact, a smaller percentage of inhaled particles are retained in the lung, and depending on the size of the particulates, some of the inhaled particulates will be deposited in the respiratory tract, where a considerable fraction will ultimately be swallowed and should, therefore, be added to the ingestion pathway where oral bioavailability would govern the absorption of the chemical.

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

4. Uptake of metals into fruits and vegetables often drives the home gardener's indirect pathway risks and is one of the pathways for which great uncertainties exist. Plant uptake also has important implications for the meat and milk pathways. The generic guidance used in the first residual risk assessment greatly simplified the methodology for assessing concentrations in fruits and vegetables. This process

has historically been subject to many different methodologies and data sources and this pathway has been one of the most difficult areas for risk assessors to model. The empirical values used to predict soil-to-plant transfer of metals are approximate over a wide range of soil conditions. Soil geochemistry (e.g., pH) is an important factor in the bioavailability of metals to plant roots and governs metals uptake into the edible portions. It is recognized that sufficient data often may not exist to characterize uptake using geochemical soil parameters and, therefore, default uptake factors are often used. Nevertheless, where 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 percent of the total cancer risk and 70 percent 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 percent of the farmer's indirect exposure cancer risk and 79 percent 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 physical distributions (e.g., variability in consumption of farm grown produce and animal products).

Even given the limited scope of the uncertainty analysis, the input parameters used in the Monte Carlo analysis addressed only a narrow subset of the factors that influence the deterministic risk outcomes. Emission variables that could not be quantified for probabilistic analysis included: detection limits; test results from one facility used to quantify emissions at another facility; frequency of plant closing; and, fugitive emission estimates. The study ultimately relied on very limited emissions data. These are challenging issues that are resource intensive to address but, nevertheless, can have an enormous impact on the risk outcome.

In the case study residual risk assessment for the secondary lead smelting industry, screening level ecological risk assessment was conducted to estimate potential risks to aquatic and terrestrial communities from HAPs emitted from the facilities that remained after the initial screening. This screening level ecological analysis was intended to identify which HAPs require more analysis and was designed to be conservative, with assumptions generally overestimating actual exposure concentrations, thus overestimating the actual potential for ecological risks. The ecological screen indicated a high potential for ecological impacts but the results are misleading for the following reasons:

1. The screening level ecological assessment does not provide sufficient information to draw appropriate conclusions as to whether an adverse environmental effect, as defined in section 112(a) of the 1990 Clean Air Act Amendments, has occurred. Section 112(a) states that "[T]he term 'adverse environmental effect' means any *significant and widespread adverse effect* (emphasis added), which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas." This appears to provide a much

broader definition of ecological effects than was used in the 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 DATA BASE (IRIS)

The accuracy of comparative risks and residual risks relies heavily on toxicity criteria from EPA's IRIS data base. 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 data base, 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, 10 of the 13 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 program, which have a required completion schedule. The IRIS data base currently contains over 500 chemicals, including the 188 HAPs required to be regulated in the residual risk program. Many of the IRIS files are outdated and, while updating is laudable, 10 updates in 4 years is an entirely inadequate response. Reasons for the slow progress include resource limitations. In addition, new advanced methods to perform RfD's/RfC's and cancer assessments are being developed, including new methods for dosimetric adjustments, benchmark dose methodology, categorical regression analyses, biologically based models with consideration of mechanism of action, and physiologically based pharmacokinetic (PBPK) models. Thus, updating an IRIS file necessitates not only updating and evaluating the most recent literature but also reassessing the data using these new and complex methods.

As mentioned earlier, EPA's first residual risk assessment relied on toxicity criteria obtained from IRIS. However, the IRIS files were not reviewed to determine whether they were outdated. If a particular chemical is a risk driver in the residual risk assessment, the validity of the toxicity factors used must be investigated. Acceptance of published IRIS criteria without review can lead to considerable uncertainty in the final residual risk results. For example, reevaluation of EPA's cancer unit risk value for coke oven emissions by my company found, using updated epidemiological data and techniques, that the actual cancer unit risk factor is about one-fourth of the IRIS "official number" for coke oven emissions which was prepared in 1984 under my direction. That evaluation was intended only as an initial value pending publication of epidemiology studies that were undertaken at the time. However, our reevaluation was provided to EPA about 2 years ago, but IRIS still has not yet been updated. Clearly, a 1984 evaluation based on limited and unpublished data is inadequate for use in regulatory decisionmaking in 2000.

In summary, IRIS was not originally intended to be used for regulatory purposes or for that matter to provide complete toxicological data on a particular chemical. It is most useful as a screen that allows one to quickly access toxicity information that may be of help for risk assessment purposes. It is clear that there is a serious need to update IRIS. The use of outdated IRIS information has serious implications to the use of any risk assessment in decisionmaking.

Risk assessment provides a thorough evaluation of scientific literature as a basis for regulatory decisionmaking and provides the impetus for improving the process in order to facilitate better decisionmaking. Risk assessments support many different kinds of decisions. In comparative risks assessments, the totality of the risks are viewed to improve priority setting, decisionmaking, and stakeholder involvement. Residual risk assessments support specific decisions mandated under the risk requirements of the Clean Air Act. These decisions demand well thought out, comprehensive, and scientifically supported risk assessment methodology. This need poses an unprecedented challenge for EPA to develop the processes and then conduct comprehensive risk assessments across a range of chemicals, sources, and regulatory programs. This places heavy resource demands on EPA, and the required resources may not be available. Nevertheless, it would not serve our Nation well to make regulatory decisions under any program by defaulting to generic risk assessment approaches or using out of date data files in IRIS because of resource constraints. The best science should form the basis for risk management decisions; otherwise our decisions are not well informed and can be flawed. It is also crucial for all stakeholders to have at least some understanding of how EPA intends to use the information developed in the residual risk assessment to make risk management decisions. Only then can the assessment's adequacy be judged.

The first residual risk assessment conducted by EPA is not sufficient to meet the needs of decisionmakers under the residual risk program. At best, it presents a process that can only be described as a screening assessment, even when including multipathway and ecological analyses. A screening assessment is a necessary part of the initial risk assessment process for this program, but it falls far short of the refined risk assessment (based on more source-category specific data) that is required to make regulatory decisions.

Earlier this year, the SAB reviewed the EPA draft residual risk assessment method and its first application to the secondary lead smelting industry. Because the method requires substantial improvement, it is essential for the SAB to review the next draft of this approach. More refined risk assessments should not simply be screening assessments with more data; rather, they should rely on new methods and approaches to address important risk factors such as when to refine conservative screening values, how to assess population risks, how to characterize after-MACT standard emissions, how to assess "significant and widespread adverse" ecological risk, when monitoring data are more suitable than modeled data, and what criteria will be used to determine when the risk assessment process will be triggered. These methodological issues need to be reviewed by the SAB because they are not settled matters in the realm of risk assessment and will be of generic importance across most, if not all, of EPA's risk assessment programs.

Any more refined risk assessment methodology should be characterized by the use of category-specific, and selected site-specific, data for the elements that are the risk-drivers as identified in screening assessments. The generic assumptions used in a screening assessments such as those conducted by EPA are designed to be conservative; consequently, they can generate many false positives. Regulatory decisions cannot be based on such assessments; more specific data are needed to determine whether or not actual residual risks of concern exist. While this task varies in degree of difficulty, EPA can focus its further data collection on those elements identified by the screening assessment as the risk-drivers. Much of those data should be readily obtainable.

The residual risk assessment methodology should also explicitly incorporate realistic assumptions and data in both the screening and more refined phases of the assessment. As seen in EPA's case study assessment of the secondary lead smelting industry, implausible or unrealistic assumptions, methods, and data can fatally skew the results of an assessment. Such results have the potential to cause needless data gathering by EPA and industry in order to demonstrate that nonexistent risks are not real; unfounded public concerns may also be avoided if the results of a screening assessment are immediately scrutinized to determine if they are realistic.

Finally, if the IRIS data base is to be used for regulatory purposes or for that matter to provide complete toxicological data on any particular chemical, it must be updated across the board and then maintained in an up-to-date manner. The use of outdated IRIS information has serious implications to the use of any risk assessment in decisionmaking.

CONCLUSIONS

Extraordinary complexity of the risk assessment is called for by the comparative risk and residual risk programs. In 1976 when the first risk assessment process began at EPA, risk assessment and risk management focused largely on single

chemicals such as air pollutants and pesticides. The complexity of risk assessment has grown over the years with the most complex risk assessments being conducted at Superfund sites and for combustion sources. These risk assessments addressed multipathway risk assessment issues and ecological risks but have been focused on single facility or single sites. The comparative risk program and the residual risk program as prescribed under the Clean Air Act Amendments of 1990, require unprecedented use of risk assessment across the board for over 175 industry source categories and literally thousands of facilities. In addition, the residual risk program, for example, must address the toxicity of all 188 chemicals on the hazardous air pollutant; the comparative risk program needs to address considerably more chemicals. Adding considerably more to the complexity, the residual risk program calls for the use of multipathway risk assessment and regulation of environmental risks with significant and widespread effects to wildlife, aquatic life and other natural resources, including impacts on endangered or threatened species or significant degradation of environmental quality over broad areas.

The current EPA guidelines for conducting the residual risk program (and there are no such guidelines for the comparative risk program but it probably will follow much the same process), primarily employ available data and generic and upperbound risk assessment approaches. The guidelines mention a tiered approach but do not make a clear commitment to proceeding to a clear approach where risks appear to be high nor are there any guidelines or criteria for when or how to do so.

RECOMMENDATIONS

1. The unprecedented complexity and cost of conducting the risk assessment program called for by both comparative risk and residual risk must be conducted by a carefully orchestrated tiered approach. The first tier should employ the very best available data and commit to an approach that provides the greatest accuracy 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 data base, as a repository of operational, regulatory toxicity values, must be revised. Historically, the IRIS data base 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 data base 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 data base was not necessarily intended for direct use in regulatory decisions without refinement; the preface reflected the fact that the data base was not intended for these purposes. Since that time, however, the IRIS data base 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 data base 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 data base 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 data base be re-stated to recognize reality, that is that the IRIS data base 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. Second, 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.

RESPONSES BY ELIZABETH L. ANDERSON TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. You stated that the science of risk assessment has grown in complexity. How and what changes do you believe need to occur for the EPA to be able to meet those challenges you identified in conducting risk assessments?

Response. The science of risk assessment has grown considerably in complexity since we first Megan to apply it to environmental decisionmaking over 20 years ago, and it will continue to evolve. However, it has reached a State where it can provide highly useful information to risk managers, as long as appropriate assumptions, methodologies, and data are used and proper decisionmaking criteria are applied. In my testimony, I identified a number of issues associated with EPA's initial residual risk assessment. I offered a number of recommended improvements, summarized below, that could be undertaken by EPA in methodology, application, and resource distribution that could help the Agency meet its challenges.

First, multiple tiers of assessment must be utilized in order to cost-effectively evaluate wind regulate residual risks. EPA has adopted the multi-tiered approach but the Agency's initial residual risk assessment only used two tiers. Studies by me and my colleagues have shown that several tiers of assessment are often needed to effectively refine the process to distinguish the significant residual risks from those of low importance. I recognize that this process often requires utilization of more resources, but it minimizes the very real possibility, arising from the use of limited tiers of assessment, of regulating sources that do not in fact result in risks of real concern in the exposed populations.

Second, important issues have not yet been dealt with in guidance or practice by EPA. For example, section 112(f)(2) in the 1990 Clean Air Act Amendments requires the regulation of environmental risks in addition to human health risks; however, EPA has not yet published guidance on how this should be done under the Clean Air Act. Such guidance is critically needed to the risk decisionmaking process. As another example, EPA discussed in the 1999 *Residual Risk Report to Congress* the need to consider broader population risks in addition to the risks to the maximally exposed individual upon which risk assessment has focused in the past. Again, guidance for considering and dealing with broader population risks has not yet been published, and is critically needed.

Third, EPA has historically used available emissions data in conducting risk assessments, even when the data were limited and out-of-date. Risk assessments can be no more accurate than the emissions data used. I recommended in my testimony that EPA strive to improve its emissions data base and that essential to that outcome are partnerships with the organizations and facilities that have the best and most current data. The National Research Council, in its recent report Strengthening Science at EPA: Research Management and Peer Review Practices, also urged EPA to acquire and apply the results of research conducted or sponsored by other Federal and State agencies, universities and industry.

Fourth, EPA's integrated risk information system (IRIS) data base must be revised and updated. As I discuss in the response to the next question, much of IRIS is out of date and if it is to be used in regulatory priority setting and decisionmaking, necessary resources and management direction must be applied to improve it and its application. I expand on specific recommendations in my written testimony.

Finally, the use of uncertainty and variability analysis must be applied more explicitly. While EPA has historically recognized its importance, this process has been used only in a limited way. Guidance for its more explicit use must be developed and then applied systematically in the risk assessment and risk management process.

Question 2a. How many values are there currently in the IRIS data base, and how many of them, to your knowledge, have been updated? What is involved in reviewing and updating an IRIS value and how important is this review to the residual risk program and other risk-driven regulatory programs at EPA? How much could an IRIS value change as a result of this review and what would it mean for the final risk assessment?

What is the Size and Status of IRIS?

Response. According to the EPA *Summary Report: Characterization of Data variability and Uncertainty: Health Effects Assessments in the Integrated Risk Information System,* (August 2000 review draft) stated that there were 537 chemical specific assessments in IRIS as of January 31, 2000. One has been added since that time, for a current total of 538.

According to the September 26, 2000, SAB letter to the Administrator entitled *Review of the Draft Report to the Congress "Characterization of Data Uncertainty and*

Variability in IRIS Assessments, Pre-Pilot vs Pilot/Post-Pilot", the average IRIS file was last changed 10 years ago. In many cases, the last activity was when the file was first added to the data base. In 1995, EPA established the IRIS Pilot Program. Since that time, four substances were added to IRIS and 16 files were revised. Clearly, this pace needs to be greatly accelerated both because so many files are currently out of date and because the State of the science is changing rapidly in response to such initiatives as the HPV program, the Children's Health Initiative, and the endocrine disruptor screening and testing program. Alternatively, the IRIS file should be appropriately labeled as a reference file, not as a source of toxicity values for direct use in risk assessment. I see no way to make informed public health decisions that have significant social and economic costs without making provisions to review and revise the toxicity information in IRIS as a particular agent becomes the risk driver in these decisions.

Question 2b. What is involved in the Review and Update of IRIS?

Response. Much is involved in the review and update of an IRIS file. These files contain scientifically reviewed information on the carcinogenic and noncarcinogenic effects associated with exposure to a substance. The review requires knowledge of inhalation and oral toxicology; methods by which dose-response relationships, risk, and uncertainty are characterized; statistical procedures used to evaluate data; and scientific data bases relative to the health or ecological effects of the substance under study. The sequence of events involved in revising an IRIS file includes the following steps.

Analysis, Interpretation and Synthesis of Information and Data.—The review initially involves obtaining the published information on the toxicity/carcinogenicity and supporting data on the health effects of the pollutant. Analyses of these data for validity, accuracy, generation and characterization of exposure concentrations, and statistical analysis of exposure and response measures determine the usefulness of the information in establishing non-cancer and cancer concentration dose-response relationships. Appropriate data analyses include relatively new qualitative and quantitative dose-response modeling techniques such as: (1) physiologically-based pharmacokinetic (PBPK) modeling, (2) benchmark concentration (dose) analysis, (3) categorical regression, and (4) linear dose-response or mechanistic models. Use of these advanced methods ensures that correct conclusions, correlations, extrapolations, and contradictory results are identified in the process of dose-response assessment. In instances where confidential business information (CBI) information must be used, standard U.S. EPA CBI procedures must be followed.

Data Array Analysis, RfC/RfD/ARE and Cancer Unit Risk Derivation, and Calculation.—Data secured for developing risk reference concentrations (RfCs), risk reference doses (RfDs), acute reference exposures (AREs), and cancer unit risk values must be arrayed in a manner that can be quantitatively evaluated. The analyses involve the identification of the critical effect, principal study, supporting studies, and appropriate mathematical models for fitting the data according to EPA procedures. For inhalation studies, appropriate duration adjustments of the exposure concentration must be made depending on whether the pollutant exists in vapor or aerosol form and the data array modified accordingly. Derivation of the RfC, RfD, and ARE and preparation of confidence statements involve application of appropriate uncertainty factors, evaluation of study quality, and identification of data base deficiencies and discussion of any scientific controversies surrounding the chemical or effects noted. Derivation of cancer unit risk values involves application of appropriate models and explanation for their selection as well as qualitative narratives categorizing the chemical's carcinogenicity. For example, decisions must be made to employ the default approach, the linear non-threshold dose-response model or the more refined approach using the mode of action data, to define more accurately the dose-response characteristics, where data are available. The difference in outcome at low doses can be as much as several orders of magnitude. These quantitative procedures are incorporated into a summary narrative for peer review by the EPA and into a report describing the rationale for developing or not developing an RfC, RfD, ARE, or cancer unit risk values for a given substance. A support document (toxicological review) is also prepared to go with the summary narrative. This support document discusses in greater detail aspects of the studies described in each of the summary narratives (e.g., the RfC, RfD, and cancer assessment). It also provides additional toxicological information, generally of a secondary nature, that relates to a given chemical's effects in both humans and laboratory animals, including any pertinent in vitro findings, such as genotoxicity results, and metabolic or mechanistic studies.

Question 2c. How important is the IRIS review to the residual risk program and other risk-driven regulatory programs at EPA?

Response. Accurate and current IRIS files are absolutely essential to the legal and scientifically supported implementation of EPA's risk-based regulations, or an alternative approach is needed. Regulations that are based on inadequate, out-of-date, or unvalidated toxicological data will almost certainly be challenged and would likely be overturned. More importantly, the Agency has committed to producing regulations based upon sound science and peer review, and many of the current IRIS files do no meet these goals.

Question 2d. How Can a IRIS Value Change Risk Results?

Response. The IRIS value has a significant impact because it is directly proportional to the risk estimate. In one example of the impact of change, reevaluation by my company of EPA's published cancer unit risk value for coke oven emissions found, using updated epidemiological data and techniques, that the actual cancer unit risk factor is about one-fourth of EPA's published IRIS number for coke oven emissions. The published value was derived originally in 1984 under my direction, but was intended only as an initial value pending publication of epidemiology studies that were on-going at the time. However, the file was never updated by EPA, even though the anticipated epidemiology studies were completed. Our more recent reevaluation was also provided to EPA over 2 years ago, but the IRIS values still has not been revised. Clearly, a 1984 evaluation based on limited and unpublished data is inadequate for use in regulatory decisionmaking in 2000. Use of the updated cancer unit risk value for coke oven emissions would lower risk estimates by a factor of four. When combined with reduced exposure resulting from an updated exposure model also developed by my group for the coke oven industry, the estimated maximum individual risks associated with exposure to the coke oven emissions at the Nation's two largest coke facilities were reduced from EPA's estimated values, which were well above the Agency's level of concern, to values well below the Agency's level of concern. Use of EPA's published value could lead to a conclusion that additional regulation to reduce residual risks is likely to be required for this industry. Our revised assessment would suggest that no additional regulation is likely to be required for this industry. If additional regulation were required, it could entail millions of dollars in new control expenditures and the possible loss of hundreds of jobs from plants that may not be able to afford the added costs and, as a result, would close. The most important contribution risk assessment can make to the regulatory process is to present refined information that can distinguish the more important, real risk from the unimportant, insignificant risk. This outcome can only evolve when screening level risk assessments are further refined.

Question 3. What do you recommend that the EPA do to improve the quality of its regulatory decisions in terms of risk assessment and benefit-cost analysis?

Response. As I noted in my testimony and discussed above, I made several recommendations in my written testimony for improvement in risk assessments, recommendations that could significantly improve the quality of the regulatory decisions that are needed. At the heart of these recommendations are three principal needs. First, better guidance and decision criteria must be developed by EPA and agreed upon that detail the necessary processes for reaching appropriate risk decisions. EPA has published only partial and incomplete guidance and criteria to date. Second, partnerships must be formed between EPA and the regulated industries to improve the quality of the data upon which risks are estimated. Such partnerships have been ineffective for the most part and have not been aggressively sought by EPA or the regulated industries. finally, important EPA data bases, such as IRIS, must be reviewed and updated to provide more confidence in the risks that are estimated, or alternative courses of action adopted. I made alternative recommendations in my written testimony. These improvements will take time and resources, but could be expedited through the same kinds of partnerships I recommend for improving the quality of industrial facility emissions data.

Question 4. What can the Congress do to accelerate the adoption of a more effective decisionmaking process?

Response. Section 112 of the 1990 Clean Air Act Amendments establishes the list of hazardous air pollutants (HAPs) and defines a general process for identifying source categories of the HAPs, publishing emission standards based on maximum achievable control technology (MACT), and evaluating and further regulating residual risks at a later date, where necessary. However, section 1121eaves to EPA the exact process for meeting this mandate. In the 10-years since passage of the 1990 Amendments, EPA has published some but not all of the necessary guidance and criteria for this program. The Agency has also allocated resources to the extent possible, given its many other important responsibilities, but there has clearly been a shortfall in resources needed to accomplish what is required in section 112.

I believe that Congress can best influence effective decisionmaking by several means: (1) recognizing the complexity of the tasks that have been assigned to EPA, (2) ensuring that the rush to meet deadlines does not jeopardize the scientific basis for making informed decisions, (3) supporting development by EPA of the necessary criteria and guidance for an iterative risk assessment process that can ensure that sound decisions are made, (4) encouraging reallocation of EPA's resources in ways that facilitate improvement in the risk assessment process, and (5) encouraging partnerships between EPA and outside organizations that have resources and information that can assist EPA in providing refined and carefully conducted risk assessments to inform the regulatory process.

RESPONSES BY ELIZABETH L. ANDERSON TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. Ms. Anderson, you raised many specific concerns about EPA's residual risk assessment case study. It often seems that every time a risk assessment is done these days—whether it is to regulate an environmental problem, update a standard, or better understand a problem such as climate change—it is controversial. Given this, how realistic do you think it is for us to consider doing a comparative risk assessment that would set EPA's budget or regulatory priorities—something that would require a separate risk assessment for each of the Nation's environmental problems—but still avoid controversies over each and every risk assessment the priorities are based on.

Response. I agree that historical risk assessments have often been controversial. However, it is important to recognize that risk assessments can be designed to achieve different purposes and for that reason can vary substantially in their level of sophistication and complexity. The risk assessment aimed at setting regulatory priorities typically would be a national assessment that evaluates broad categories using screening tools and aggregated data. The models, the data, and the methodologies are focused at providing general comparisons of environmental problems to assist in setting regulatory priorities. On the other hand, the risk assessment aimed at establishing source category regulations and necessarily affecting specific facility operations, control costs, and jobs, must not only be much more sophisticated and but also often facility-specific. This assessment process requires more precise models, facility-specific data, and methodologies that are detailed enough to ensure that real risks are being identified and subsequently regulated. I believe that the science of risk assessment is currently at a level that can effectively help us set regulatory priorities, but that to be successfully applied to regulatory decisionmaking there must be additional guidance, direction, resources, and a commitment made to an iterative process to provide accurate, refined assessments for significant regulatory decisions where the social and economic consequences are substantial. Otherwise, it may lead to regulating insignificant risks at great cost while real risks go unidentified and unregulated.

Question 2a. Your testimony suggests that you oppose regulation or making risk management decisions where there are "substantial uncertainties and significant limitations in data."

Are there some good ways that Congress, EPA, or others can identify "substantial uncertainties and significant limitations in data"?

Response. First, when I discussed "substantial uncertainties and significant limitations in data" in my written testimony, I said that risk management decisions should not be made until these limitations are addressed. I also did not mean to imply that these uncertainties and limitations are unanswerable. For example, as I presented in my written testimony, a sensitivity analysis can be used to identify the most important risk drivers. These parameters can then be inspected to determine if better data or methods are available to refine the particular value (e.g., refining a toxicity value from IRIS that may be 10 years out of date or replacing estimated, old emissions data with more current and accurate data). In my written testimony, I noted a number of areas where EPA is moving in the right direction but needs to develop more complete guidelines and criteria for assessment and decisionmaking. For example, to reduce the uncertainties and limitations EPA could make a greater effort to develop and utilize partnerships with the regulated industries to gain access to much more accurate and complete emissions and other facility-specific data. The science of risk assessment is at a stage where it can be accurately used as long as appropriate assumptions, models, and data are incorporated. EPA has been slow to gather and incorporate these techniques but with encouragement from Congress and additional resources I believe that risk management decisions could be made that are realistic and supportable by the science. I have stressed that EPA

has been assigned a most complex task. I am not criticizing EPA for tackling this enormous task; rather, I am offering what I hope are constructive approaches to ensure that decisions are made on the basis of sound science, not highly uncertain and perhaps incorrect portrayals of risk.

Question 2b. Given that data collection is very time and resource consuming, how much data is enough?

Response. I do not necessarily agree that data collection has to be time and resource consuming. Historically, it has not been data collection that has been time and resource consuming; rather, the time and resource consumption has been spent in figuring out the correct process for using the collected data in conducting risk assessments. For example, it took EPA 8½ years to complete and publish the *Residual Risk Report to Congress*, required in section 112(f)(1) of the 1990 Amendments, and almost another year after that to release the first draft residual risk assessment. I do not believe that the delay was data collection; rather, it was in developing a rational and scientifically supportable process. I believe that EPA has now developed an appropriate framework for the job that needs to be done. However, they must go further and develop more complete guidance and criteria to facilitate the ultimate decisionmaking. Finally, I believe that the science of risk assessment is now mature enough that we know when we have enough data and we have uncertainty and variability techniques available to allow us to evaluate the quality of the data we have and its influence on the ultimate risk estimates and on the subsequent cost-benefit analyses.

Question 3a. You indicated that EPA's first draft residual risk assessment resulted in risk estimates high enough that serious adverse human health and ecological effects would likely be easily observable. You go on to State that "the lack of apparent evidence of significant human or ecological impacts" showed that EPA's risk estimates were unrealistic. The GAO stated at the same hearing that there are serious gaps and limitations related to environmental data. My own experience with the town of Libby, MT, has suggested that routine monitoring of the incidence of public disease is inadequate.

Given this, are we really in a position to see the "apparent evidence of significant human or ecological impacts" to which you refer?

Response. I agree that in many instances it is difficult to measure the incidence of public disease. This is most difficult when the incidence of disease resulting from a specific environmental exposure is not significantly different from normal. The tools of epidemiology often are not accurate enough to detect significant impacts because of limitations such as small population size and the presence of many confounding exposures. However, because of the assumptions and methods used, EPA's case study assessment predicted risks in some cases that were so high that serious impacts would almost have to have been observed; for example, the predicted levels of some toxicants were so high that fish would not have survived. Such toxicity impacts in surface waters should be observable. I recommended several actions to prevent a reoccurrence of this. First, EPA should perform a sensitivity analysis and identify the risk drivers. Then it should reassess its assumptions and methods related to these factors and select ones that are more scientifically supported. Second, EPA should evaluate the results of its calculations and determine whether the results are realistic and make sense. Finally, EPA should conduct more complete uncertainty and variability analyses to better understand in the estimated quantities the lack of precision due to imperfect science and the natural variability of the parameters in nature. In summary, I am not suggesting a process of verifying risk based on observations, but rather on applying good scientific principles in an iterative process. First, resources can be conserved by performing upper-bound screening level assessments. Second, for those circumstances where the risks appear to be significant, identify the most significant parameters and attempt to improve the scientific basis for these parameters and, consequently, the outcome of the risk assessment. One check to inspect whether or not risk assessment outcomes are realistic is to compare the predicted levels of exposures with toxicity thresholds. Where levels are predicted to be exceedingly high, relative to these thresholds (e.g., approaching or above fish toxicity values), one can question whether fish kills have been observed.

Question 3b. Is there "evidence" or data that disprove EPA's estimates?

Response. EPA typically does not identify specific facilities in their risk assessments, and industry is reluctant to have specific risks ascribed to specific facilities. Rather, EPA relies generally on model plants (i.e., composites serving as average examples of groups of typical industry facilities). Thus, it is generally not possible to seek specific evidence or data near specific facilities to disprove the estimates because those facilities have not been identified. Our conclusions on EPA's case study

were based on the collective many years of risk assessment experience of myself and my colleagues, and the fact that some of EPA's estimates were so high as to be well beyond the normal distribution and, thus, likely to be observable. In cases where the hazard index is exceeded at the upper bound by 60 fold, if the risks are real, effects should be observable. Such predicted high exceedances are rare but in this case, EPA also noted that the risks are highly uncertain because of uncertainties about fugitive emissions. It is in these circumstances that the scientific basis for the risk assessment must be refined before informed decisions can be made.

Question 4. I would be interested in your thoughts on what problems would likely be encountered, and how successfully we would likely be, if we attempted to perform a national comparative risk assessment in order to set EPA's budget or regulatory priorities.

Response. I absolutely support establishing regulatory priorities on a more scientifically supported risk basis and I believe strongly that this can be realistically accomplished using today's risk assessment science. EPA began its first comparative risk assessment in the mid–1980's, but to the best of my knowledge that assessment was largely exploratory in nature and necessarily utilized available methods and data. Thus, it was almost certainly doomed to failure because the methods and data available at that time were inadequate to consider and compare the many complex issues, issues such as multiple pathway exposures, ecological risks, population risks, non-carcinogenic risks, and others. I also seem to recall that the study was conducted with no substantial added resources to attempt to gather better data or to develop better methods.

However, the conduct of a comparative risk assessment is possible today, given appropriate direction and resources. A significant amount of data would need to be gathered and methods need to be refined to properly focus on the task but, as I noted earlier, I believe that the science of risk assessment is currently at a level that can effectively help us set regulatory priorities.

Question 5a. I understand that you have been critical of the EPA and the data it chooses to use for its analyses.

Do you agree with the SAB's suggestion that, in the interest of "sound science," when industry has data or analyses to inform these risk assessments, industry should provide that information to the Agency?

Response. I want to make it very clear that my comments on EPA's case study were not intended as a criticism of the Agency and its regulatory process. Given the available resources and time pressures, I believe the Agency did the best that it could and I have been very careful to point out that EPA has been assigned a most complex task that has not been tackled before. My comments were more directed at the broader issue of "how can we better evaluate risk and use that information to make the best decisions to protect the public health and the environment, taking into account social and economic costs?" In other words, it is not possible to regulate everything indiscriminately and it may be unnecessary. It is important to identify real risks and assure that public health and environmental protection is appropriate and adequate. Sound risk assessments are necessary to properly inform the process. I provided the SAB with a number of recommendations, many of which I repeated in my testimony. Importantly, I fully support the SAB's suggestion that industry needs to be more involved to help facilitate the collection and use of the best data and to share facility-specific information that is helpful to this challenging task.

Question 5b. Is this what you meant by "outside partnerships" in your testimony?

Response. Yes. Industry has historically been involved in reviewing and commenting upon EPA's regulatory packages. EPA also regularly seeks emissions and source characterization information through information collection requests (ICRs). However, EPA is limited in the number of facilities to which it can send ICRs and industry has a natural reluctance to "open its books" for regulation development to an Agency that also has enforcement oversight. However, I believe that EPA and industry must both decide to work together in partnership if realistic and scientifically supported regulatory decisions are to be made. Without these partnerships, I believe there will be gaps in knowledge (e.g., in data exchange, facility operations, or other factors where information and data exists but may not find their way into the risk assessment process). Where EPA has not used the best information available as a basis for its decisions, it is highly likely that legal remedies will be sought. It is clearly more effective to have a cooperative and well-informed process rather than a distrustful one where the best available information is shared and dissected during legal proceedings.

Question 6a. In your written testimony, you indicated that it is not in the Nation's best economic interest to force needless expenditures when residual risks are not excessive.

What do you consider to be excessive?

Response. Because I do not believe there is any "bright line" which defines an excessive risk, there is no one answer to this question. Risk must be looked at in its totality and include consideration of the type of adverse effect (e.g., cancer or noncancer, chronic or acute), the affected human populations (ranging from a few individuals to a large population), the existence of ecological effects, and other important factors. Each situation must be considered individually and appropriate risk management decisions made using all available information. Only in that context can a decision be made as to whether a risk is excessive or not.

Question 6b. Are you referring to the cancer risks to the maximally exposed individual or some other test?

Response. I noted in my testimony how EPA focused initially only on cancer risks to the maximally exposed individual. However, there are many other adverse health and ecological effects, and much more of the population is exposed than just that person maximally exposed. All of my testimony assumes that proper risk assessments must look at all potentially adverse effects and the total exposed population.

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

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 1930's 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 percent upper bound 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 No. 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 inter-comparing 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 Adminis-

trator 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 3 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 6-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. In the meantime, the resources now dedicated to performing comparative 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.

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 limit the use of quantitative risk analyses of residual risks to the screening out of deminimus risks.

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 6-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.

Dr. MORTON LIPPMANN, *Acting Chair*,
Science Advisory Board (1400A),
U.S. Environmental Protection Agency,
Washington, DC.

DEAR DR. LIPPMANN: Thank you for your letter of May 19, 2000, transmitting the Science Advisory Board (SAB) Advisory on the Draft Agency Case Study Analysis of the Residual Risk of Secondary Lead Smelters (EPA-SAB-EC-ADV–00–005). During the review of the Residual Risk Report to Congress in August 1998, the Science Advisory Board requested that the Environmental Protection Agency (EPA) provide an example residual risk assessment for its evaluation. We submitted our draft assessment of the secondary lead smelter source category and would now like to respond to your letter transmitting the SAB advisory for this case study.

The purpose of seeking an SAB advisory was to get feedback on the methodologies EPA will use to assess residual risks and the application of those methods to a specific source category. We asked the SAB to comment on: (1) the appropriateness of the methods used, given the currently available methods; and (2) the appropriateness of the application of those methods. We sought SAB feedback early in our residual risk assessment process in order to be able to apply the advice received to other risk assessments under the residual risk program which, due to statutory requirements, needed to be started soon.

This draft case study does not include all risk assessment components needed to make a regulatory decision under the Residual Risk program (e.g., an assessment of population risks). Because of this, we agree with the SAB that peer review of the final complete assessment is needed. We intend to seek such a review in 2001.

We are pleased that the reviewers recognize that methods used in this case study assessment are consistent with the methods described in the Residual Risk Report to Congress, that the assumptions used are consistent with current methods and practice, and that the models used for the air pathway are the most appropriate for the task. Our response to additional comments and recommendations highlighted in your review are enclosed.

This SAB advisory will help us design the final iteration of the secondary lead smelter risk assessment. We are also applying your advice to the other risk assessments we are required to conduct under the residual risk program. Thank you for your assistance.

Sincerely,

CAROL M. BROWNER.

ATTACHMENT

RESPONSES BY ENVIRONMENTAL PROTECTION AGENCY TO ADDITIONAL COMMENTS FROM THE SCIENCE ADVISORY BOARD

Comment. Population risk estimates are lacking from the case study.

Response. EPA will include an assessment of population risks in the final iteration of the assessment, following the method we outlined in the draft case study.

Comment. Ecological screen is adequate but refined ecological risk assessment is lacking, as are the methodologies.

Response. EPA did not present a more refined ecological risk assessment in the draft case study, as we have not yet completed development of a refined ecological risk assessment methodology for the residual risk program. We are working to de-

velop a refined methodology and will use our most current methodology in the final iteration of the secondary lead smelter risk assessment.

Comment. Uncertainty and variability analysis should be fully integrated into all phases of the assessment, not just an auxiliary analysis after the deterministic assessment.

Response. EPA agrees with the Science Advisory Board that integrating uncertainty and variability analysis into the overall assessment rather than conducting it as an add-on analysis of the deterministic results is important. EPA is incorporating that advice into our assessments. We are conducting uncertainty and variability analyses at each phase of the assessment to determine how assumptions are supported by the data, and what the implications are for each assumption. While there is no consensus among experts on a methodology to conduct uncertainty and variability analysis, we will continue to seek out experts and use methods which are appropriate to the task.

Comment. The model used for multimedia fate, transport and multi-pathway exposure assessment, the Indirect Exposure Methodology (IEM) has several limitations, and has not been sufficiently evaluated. Results should be viewed with informed caution and results ground-truthed against available data. TRIM is seen as major improvement.

Response. EPA recognizes the importance of evaluating models and ground-truthing the results of the models we use in support of regulation. EPA intends to evaluate model inputs and ground-truth results to the extent data are available. (Data were not readily available on the four facilities we evaluated but may be available for others; for other source categories, such information maybe more (or less) available.). EPA will ensure that the limitations and uncertainties of IEM outlined by the SAB are clearly articulated to the risk managers. We agree that TRIM will generally be an improvement relative to IEM. We look forward to further comments on our approach to multimedia modeling in the peer review of the completed assessment.

Comment. There is insufficient explanation about the interface between risk assessment and risk management; without this context it is difficult to adequately review the assessment.

Response. EPA will explain more about the Residual Risk program mandate and its approach to risk management in the final iteration of the assessment. We will specifically describe how the risk assessment feeds into the risk management process.

Comment. There is incomplete toxicity data on some HAPs and the data in Integrated Risk Information System (IRIS) may be seriously out of date for others.

Response. EPA is not limited to using data within IRIS. EPA has identified a number of additional peer reviewed data sources, from which relevant information can be obtained. These data sources include peer reviewed data bases developed by the Agency for Toxic Substances and Disease Registry and California EPA. The SAB concurred with our use of the data from these sources, which allow EPA to both assess HAPs for which assessments are not currently available on IRIS and to consider information from other sources that may be more current and relevant than that available on IRIS. HAPs with no assessments on IRIS or elsewhere receive priority in our yearly list of IRIS assessment starts. Additionally, we are carefully considering the SAB's recommendation to develop interim methods for assessing HAPs without available assessments.

RESPONSES BY MORTON LIPPMAN TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. In your testimony, you stated that "comparative risk assessment" is an idea whose time is coming. For this to happen, according to your testimony, EPA has to harness the new technical approaches and research tools to fill in key knowledge gaps. Why is it, in your opinion, that EPA has not taken a more aggressive approach to fill those gaps?

Response. The EPA's research program has developed and refined a research. strategy in recent years that includes an increased emphasis on long range generic needs such as quantitative risk assessment. Also, it is about to open its new state-of-the-art research facility in Research Triangle Park, NC, which will give it the capacity for applying new research tools. The basic problems that have limited EPA's progress in addressing the knowledge gaps in this area have been reviewed recently by the National Research Council in their report entitled "Strengthening Science at the U.S. Environmental Protection Agency". These problems include:

• *Lack of a core focus on the art and science of risk assessment*. The NRC report stated that "The Assessment Center should focus on being a research organization dedicated to advancing the State of practice in risk assessment, not a performer of individual risk assessments that could be done by EPA's regulatory offices" (NRC Report: p. 85).

• *The NRC Report noted the absence of published strategic and management plans for the ORD Laboratories and Centers*. Strategic planning has, so far, been a "top-down" effort that is only partially effective. The NRC panel expressed concern that ORD has not yet provided adequate delegation of opportunities for leadership and accountability throughout the organization (NRC Report: p. 68).

• Staff Resources. The NRC reported noted the aging of the ORD staff and the Agency's difficulties, in the face of periodic job freezes and personnel ceilings, in recruiting new talent with appropriate background and training for new challenges.

• *Funding*. ORD capacity to meet new scientific challenges is constrained by living within an overall budget that is essentially flat, at best, in terms of purchasing power, and strained, in terms of flexibility, by an increasing level of earmarks for projects that have not been appropriately peer-reviewed.

The NRC Panel's recommendations, if implemented, could greatly help EPA to better address these problems. For example, a principal responsibility of the new Deputy Administrator for Science and Technology would be to "Ensure that the most important scientific issues facing EPA are identified and defined, including those embedded in major policy or regulatory proposals" (NRC Report: p. 130).

The NRC Panel's recommendation that ORD make a concerted effort to give its research managers a high degree of flexibility and accountability (NRC Report: p. 133) could empower the director of the Assessment Center in ORD to mount a concerted and sustained effort to create and manage a core research program on the art and science of risk assessment as part of the Center's own strategic plan.

Question 2. You testified that EPA overestimates health risk for air toxics. Exaggerating risk when managing environmental programs is counterproductive and a disservice to the public. Conservative assessments have a place, but consistent excessive conservatism is misleading. Resources that could be used to address neglected environmental problems would instead be used to address problems whose risks are exaggerated. When there are critical data gaps, and obsolete analytical tools, the effectiveness of programs and progress cannot be measured objectively. Please explain what the SAB is doing to ensure that EPA understands the significance of the problems you identified.

Response. EPA has established Risk Assessment Guidelines that have been reviewed and endorsed by SAB. These Guidelines have been recognized as having a conservative bias by both EPA and SAB, i.e., in the face of uncertainties involved in having to rely on the limited data bases in the literature, they have incorporated reliance on substantial margins of safety. The objective has been to be protective of public health. Furthermore, the more limited the data base, the greater the overall margin of safety tends to be. In fact, the Food Quality Protection Act has mandated that when adequate data establishing that children are not more sensitive than adults, then an additional tenfold safety factor be used in assessing risks related to the food supply.

The problem of excessive conservatism that you address in the above listed question arises when the EPA risk assessors believe that they have no other option than to use reference doses or reference concentrations and their established technique for modelling exposures (that are also inherently conservative) to: (1) develop quantitative estimates of risks; or (2) to compare the various risks to public health caused by exposures to environmental chemicals. They do not, and in reality cannot, know how conservative their calculated risks really are in each case. The problem is compounded when comparing risks using risk coefficients of varying ages prepared under various historic versions of the Risk Assessment Guidelines.

SAB has recently taken several initiatives to call this problem to the attention of EPA. Our Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters (EPA-SAB-EC-ADV–00–005) was dated May 2000, and our followup letter to the Administrator (Executive Committee Commentary on Residual Risk Program—EPA-SAB-ECCOM–00–005, dated July 25, 2000), put the concerns we had about this issue in a broader context. (A copy of this brief letter Commentary is attached.) Another example is the initiative taken by the SAB's Advisory Council on Clean Air Act Compliance Analysis (Council), in cooperation with EPA, to conduct multidisciplinary Workshops focused on the development of techniques for establishing best estimates of human exposures and risk coefficients that can be used to obtain more realistic health benefits for benefit-cost analyses (EPA-SAB-COUNCIL-ADV–00001, dated Oct. 29, 1999). In its advisory role on the per-

formance of both the 1970–1990 retrospective analysis and the 1990–2010 prospective analysis of the benefits and costs of the Clean Air Act performed by EPA, the Council agreed that substantial health benefits accrue to controls on criteria pollutants, most notably for controls on particulate matter and lead, where credible risk factors and population exposures are well established. On the other hand, such benefits could not be established for the controls imposed on the emissions of air toxics. The first Workshop, focused on Benefits of Reductions in Exposure to Hazardous Air Pollutants: Developing Best Estimates of Dose-Response Functions, was held on June 22 and 23, 2000 The second Workshop, focused on the Distribution of Human Exposures, is planned for early next year. Through these Workshops, the groundwork is being laid for what could become a new and more realistic paradigm for quantitative risk assessment. This is what I had in mind when I stated that "comparative risk assessment is an idea whose time is coming.

Question 3. You testified that a major part of the problem with the current EPA risk assessment stems from having 2 very different cultures of risk assessment: (1) for carcinogens and (2) for other toxicants. Please describe what SAB is doing to remedy this problem.

Response. My response to this question can be found in my response to Question 2, in terms of the SAB advisories and commentaries cited therein.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, DC, July 25, 2000.

EPA-SAB-EC-COM–00–005

Hon. CAROL M. BROWNER, *Administrator,*
U.S. Environmental Protection Agency,
Washington, DC.

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 work product 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-ECADV–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 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,

DR. MORTON LIPPMANN,
Interim Chair,
Science Advisory Board.

U.S. ENVIRONMENTAL PROTECTION AGENCY, SCIENCE ADVISORY BOARD, EXECUTIVE COMMITTEE FY–2000

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NOTICE

RESPONSES BY MORTON LIPPMANN TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. In your testimony, you say that, at present, "the availability knowledge base is generally too limited to adequately guide risk-based actions by legislators and/or by government agencies." In the context of a national comparative risk assessment to define EPA's budget and regulatory priorities, do you mean that it is currently not possible to conduct a comparative risk assessment for such a purpose?

Response. If your question refers to a comprehensive comparison, then the answer is yes. However, it is important to recognize that reasonably realistic assessments are possible. For example, it is generally possible to distinguish the truly large risks from those that are considerably smaller. Also, assessments have been made for the category of criteria air pollutants. For these pollutants, appropriate investments in exposure, risk, and benefits analyses have been made by EPA, and the results are evident in the reports on the Benefits and Costs of the Clean Air Act. However, such investments have not been made for the category of air toxics and, without the data bases that flow from such investments, credible comparative risk assessments are not possible.

At the same time substantial impediments will remain that cannot be "solved" by science. For example, social values—not science—must guide how one weighs health vs. ecologic risk and risks to children vs. risks to adults.

Question 2. Since it is basic to risk assessment, what is the appropriate way for the committee to decide what is "good science" and what is not?

Response. Science is a method of inquiry that generates data that are available in the intellectual market place for all interested parties to buy or not to buy. Its reliability and appropriate usage in scientific analyses is policed by the process of peer-review which, while not infallible, is generally regraded as a stamp of credibility. The usage of scientific information in the formulation of environmental risk assessments, standards, and benefits analyses is the issue here. The basic question is: Has the analysis of scientific data base in the peer-reviewed literature been comprehensive and objective, and has that data base been used in a credible and appropriate manner? Here also, appropriate peer review is the key to the usage of scientific information for "good" or "bad" ends. The Science Advisory Board (SAB) has long been a reliable arbiter of such usage, but it cannot review all such usage in an Agency as large and complex as EPA. Therefore, it is fortunate that EPA has, in recent years, made considerable progress in organizing and using other appropriate mechanisms for scientific peer review of its products. This encouraging progress was noted by the National Research Council (NRC) in its recent report

"Strengthening Science at the U.S. Environmental Protection Agency". Adoption of the recommendation in the NRC report for the creation of the position of Deputy Administrator for Science and Technology at EPA would further advance the Agency's ability to defend its "good" usage of science.

Question 3. Clearly, science is needed to inform decisionmaking. But, in your opinion, is there also a role for non-scientific considerations, such as societal values, in informing decisions on the risk rankings and priorities that are developed from a comparative risk assessment?

Response. Clearly, the simple answer to your question is yes. All risks are not of equal consequences, and risk management options may involve other risks than the one being controlled. Consideration can and should be given to balancing benefits and costs. The SAB has recognized that policy decisions, which must recognize societal factors in addition to the physical and biological sciences, need to be made by properly constituted authorities. The SAB has been expanding its range of expertise by involving social scientists, in order to incorporate the data and technique of their fields to inform the decisionmaking process. At the same time, the SAB has been careful not to cross the science-policy interface in its recommendations to the Agency.

Question 4. In your oral testimony, you talked about the conservative nature of EPA's risk assessments for HAPs. I would like to clarify my understanding of your comments on this point. You appeared to indicate that the reason that EPA uses conservative assumptions, such as safety factors, is because as we learn more about HAPs in the future it could be found that some of the chemicals are as toxic as predicted by the risk assessments made using the current models. Therefore, the convention is that, in order not to underestimate the potential risk associated with these HAPs, conservative assumptions are applied to risk estimates of all HAPs. Is this a correct interpretation of your testimony on this point?

Response. Yes.

Question 5. In the panel on residual risk, many concerns were expressed about EPA's draft case study on residual risk assessment for secondary lead smelters. This seems to be the fate of many, if not most, risk assessments. In fact, it often seems that every time a risk assessment is done these days—whether it is to regulate a environmental problem, update a standard, or better understand a problem such as climate change—it is greeted with an extremely high level of controversy. Given this, how realistic do you think it is for us to consider doing a comparative risk assessment that would set EPA's budget priorities—something that would require a separate risk assessment for each of the Nation's environmental problems—but still avoid controversies over each and every risk assessment the priorities are based on?

Response. As long as the different stakeholders in our society focus on their individual concerns about the impact of regulatory decisions and processes they will engender controversy put pressure on the Agency and Congress to support their view and, at times, bring their concerns into the Courts. Quantitative risk assessments can only inform, not resolve such controversies. When such risk assessments are scientifically credible, as they mostly are for criteria air pollutants, they are especially valuable. When they are highly speculative, and heavily biased in a conservative direction, such as those for air toxics, they are probably only useful in establishing very low (de minimus) risk levels. Such usage is, however, often useful for the many cases where conservatively estimated risks are, indeed, very low. That is, if the admittedly over-estimated risks are low, there is nothing to worry about.

Question 6. I would be interested in your thoughts on what problems would likely be encountered, and how successful we would likely be, if we attempted to perform a national comparative risk assessment in order to set EPA's new budget and regulatory priorities.

Response. As noted above, I believe that comparative risk analyses, when based on appropriately generated data, can help significantly in the priority setting process. However, even with appropriate risk estimates, there will still be difficult, value-based decisions to be made.

For the balance of my response, I would like to broaden the issue of EPA's budget.

First and foremost, I believe that EPA's budget for research and development is far too low for the roles that ORD is expected to play in providing the reliable and relevant data that are needed for the protection of the environment and the public's health. Inadequate funding hamstrings the ability of science to inform regulatory decisions of enormous complexity and importance. The environmental quality issues that impact public health and the environmental future are more complex than they have ever been, but EPA and its ORD are still focused largely on generating scientific and technical information for the short-term regulatory agenda. As noted in

the recent NRC Report, the ORD budget has remained a small percentage of EPA's overall budget and, furthermore, the options for its optimal usage have been greatly reduced by the increasing proportion for "earmarks". In considering the structural changes for EPA recommended by the NRC Report, i.e., the creation of a Deputy Administrator for Science and Technology, and in making the Assistant Administrator for ORD a 6-year term appointment, Congress should also consider giving the EPA a more comprehensive and unified mission that includes a directive to conduct both basic and applied environmental research, as well as a program of environmental monitoring that can generate baseline and trends data of the highest quality. Such data will be essential for the more reliable health, ecological, and environmental quality risk assessments that can truly and effectively inform legislative and regulatory enforcement agendas.

Question 7. In your testimony related to residual risk, were you stating that the residual risk program is addressing risks that are not a problem, or when you look at the array of air pollution problems, such as fine particulates, that these other problems should be a higher priority for the Agency?

Response. Given current scientific capabilities for determining residual risks in a meaningful way for 174 source categories and/or for 189 hazardous air pollutants, the current process will, in my opinion, be overly expensive in terms of cost and a wasteful use of personnel resources. Air toxics releases and exposures have been greatly reduced in recent decades. Some of this progress was directly attributable to the 1990 CAA mandate to apply best available control technology. Of equal or greater importance has been the control of primary particulate emissions and emissions of ozone and fine particle precursors for the purpose of meeting the NAAQS for PM and ozone. Further emission reductions can be anticipated as a result of the need to meet the 1997 NAAQS revisions for PM and ozone in many parts of the country in order to comply with the new NAAQS, and to reduce the impact on the public's health. Real risks associated with PM and ozone exposures that are occurring at and even below the levels of the 1997 NAAQS are now well established. Congress should revise its mandated timetable for residual risk determinations if it desires the Agency to generate credible state-of-the-art best estimates of low-level risks. If, on the other hand, Congress is satisfied with rough screening risk assessments that would identify the most plausible post—MACT risks, then the current approach may suffice. However, more case studies would need to be reviewed to evaluate the utility of such screening.

Question 8. I'm a little confused about where some opponents of regulation might take your comments. You have talked about unvalidated predictive models at EPA. I think you said that we have "no viable option for realistic estimation of population impacts" due to air toxics exposure. Could someone infer from what you are saying that you don't believe that we should reduce air toxics emissions as expeditiously as practicable?

Response. Someone could, and probably will, make such an inference, which would be an unfortunate and unintended consequence of having such comments on the public record. As noted in my response to your previous question, there are serious health effects that can result from air toxics emissions, at least via the role of air toxics emissions on exposures to PM and ozone. These warrant continued and perhaps even tighter control over air toxics emissions. It is also prudent to acknowledge that some specific air toxics are likely to have their own specific adverse effects on public health, even if we can't quantify them reliably at this time with our current risk assessment methods.

Question 9. I believe you stated in your written testimony that we should "put off any great effort at quantitating [their] residual risks until we have the ability to perform more realistic and credible risk assessments." Senator Inhofe seemed to construe that to mean you were advocating that we discontinue any regulatory efforts to reduce residual risk for the foreseeable future, because the science of risk assessment will always have significant quantitative uncertainties. Is that interpretation of your position correct?

Response. No. The reasons for my negative response to this question are provided in my response to your previous question.

Questions 10a and b. You indicated that "yields of risk estimates are almost always far higher than real risks." What is a "real risk" data point in that case? Are there any reliable studies confirming that "yields of risk estimates are almost always far higher than real risks?"

Response. I had two reasons for my perhaps too dogmatic statement cited above. First, I participated in the Council review of the air toxics analyses performed for EPA during the preparation of EPA's retrospective analyses of the Costs and Bene-

fits of the Clean Air Act. Fourteen air toxics were reviewed and for two of them, i.e., vinyl chloride and asbestos, the enforcement of their NESHAPS was credited with having prevented 6000 and 7000 cancer deaths respectively. Vinyl chloride produces a rare tumor in humans, angiosarcoma of the liver: Asbestos, at low exposure levels, causes about equal numbers of mesothelioma and excess lung cancer deaths. Angiosarcoma and mesothelioma, a cancer of the pleural and/or peritoneal linings, are very rarely seen tumors, and the number of cancers that the risk assessments had estimated were prevented were far greater than the historic background incidence of these tumors. Therefore these estimates are not credible as being realistic risk estimates.

My second reason for believing that most risks are overstated was my knowledge about the multiple margins of safety incorporated in the risk assessment methodologies and the conservative nature of the exposure assessment methods. These methods *are not* generally designed to, and therefore cannot, generate accurate estimates of actual risks. Rather, they *are* designed to generate possible regulatory levels that are intended to have *no* significant risk.

[From the Risk Policy Report, September 22, 2000]

IN THE NEWS—AIR

SCIENTISTS QUESTION SAB'S CRITICISM OF EPA'S RESIDUAL RISK PROGRAM

Several members of an ad hoc Science Advisory Board (SAB) panel are criticizing a commentary issued by the SAB's own executive committee that questioned whether EPA was equipped to implement a major residual risk analysis program that reburies EPA to assess 174 industrial source categories.

The residual risk analysis program, mandated by section 112(f) of the Clean Air Act, requires the agency to conduct assessments of 174 industrial source categories after their air toxics emissions sources have been controlled by maximum achievable control technologies (MACT) to determine if further controls are necessary. Under the CAA amendments of 1990, residual risk assessments must be completed 8 years after the MACT standards for each hazardous air pollutant (HAP) are set.

Prompted by the ad hoc SAB panel's critical review of the agency's approach to the residual risks posed by secondary lead smelters, the executive committee July 25 urged EPA Administrator Carol Browner and Congress to "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." While the committee endorsed the concept of science-based decision making at the agency, it also recognized "that no one is well served by asking science to take on an impossible task."

But several members of the ad hoc SAB lead smelters panel now say the commentary goes too far. According to one panelist, "we were highly critical but took a constructive approach by emphasizing that the agency needs to have a probabilistic approach to the data early on." This source says it is "quite possible for the agency to carry out such analyses in a credible manner." Several members reportedly have approached the ad hoc panel's chair, Phillip Hopke, with their concerns about the executive committee's commentary. Another smelter panel source emphasizes that the investment of more time and resources in the program would be worthwhile in the residual risk program "given that you're dealing with a sophisticated industry with some past history of litigation." The issue captured the attention of Senate lawmakers who scheduled a hearing on the residual risk issue in late July, but cancelled it because of scheduling conflicts.

EPA officials, meanwhile, have maintained that the agency has the resources and technical skill to conduct the analysis and will work with industry stakeholders to collect the data required to conduct residual risk analyses and move forward with decisions (*Risk Policy Report,* May 15, p.7; April 18, p33). One of the central reasons the executive committee opted to write a commentary was that EPA has substantial information on lead emissions unlike many of the other HAPs that must still be reviewed. Residual risk analyses call for the characterization of multiple HAPs, ecological risk analysis, population risk estimates and careful assessment of uncertainty and variability (*Risk Policy Report, June 19, p. 15).*

Accordingly to one EPA official "in my view the commentary went beyond what the SAB is charged to do which is to peer review science. Should the board tell the agency when there is an adequate basis for a decision that is the essence of making

a policy call, and without seeing the details of the original analysis, in my view they went over the line."

STATEMENT OF LEE P. HUGHES, VICE PRESIDENT, CORPORATE ENVIRONMENTAL CONTROL, BAYER CORPORATION

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(r), to continuously improve our environmental and community performance. Responsible Care(r) 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) data base, 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 5 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 decisionmaking 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 followup 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 re-

iterate 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.

RESPONSES BY LEE P. HUGHES TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1.—In the likely event that the IRIS values are not updated in time for residual risk standards, do you believe there should be a process for EPA to consider new toxicity information during the residual risk rulemaking process? Isn't this critical to ensuring that the standards are based on the best science possible?

Response. We agree it is unlikely that IRIS values will be updated in time to be used in the residual risk assessments,[1] and for that reason, it is critical that EPA develop an efficient, expeditious process to incorporate the latest and best science into residual risk assessments and the risk management decisions that follow. Due to the significant Maximum Achievable Control Technology (MACT) reductions, it will be important to correctly identify and characterize remaining risks. Application of an out-of-date IRIS value could create the appearance of risks when none exist or underestimate risks that need attention. We are committed to working with you and the Agency to develop an appropriate process that enables EPA to consider new toxicity information during the residual risk assessment and rulemaking process.

Question 2. In your testimony you stressed the importance of updating the IRIS data base at EPA that contains the health benchmarks or values EPA will use in the risk estimation process. Specifically, you stated that the process for updating IRIS must be "opened up." What do you mean by this statement and do you have any specific recommendations?

Response. EPA recently acknowledged that IRIS is a public resource and that its maintenance and upgrading are not merely matters of EPA internal management prerogative.[2] When we referred to "opening up" the IRIS updating process, we were referring to recent positive steps EPA has taken to involve non-EPA parties in the management and operation of IRIS, including:

- More active solicitation of available information about chemicals that EPA is reviewing;
- Allowing outside groups on a limited basis to produce drafts of the toxicological review that will speed the process and can constitute the underlying data for the Agency's conclusions regarding benchmarks; and
- External peer review of the IRIS decisions, with the opportunity for the public to provide comments to EPA.

We also recommend that EPA take the following additional steps to further "open up" the IRIS process:

- *Conduct the IRIS needs assessment requested by the Senate Appropriations Committee's fiscal year 2001 report.*—Congress needs to know the real scope of the IRIS backlog and what priority chemicals are not currently part of IRIS. The assessment should include recommendations from State environmental officials, industry, public interest groups, and the general public. The assessment should address the budget needed to bring the IRIS program up to a high level of quality in an acceptable number of years.
- *Encourage outside scientists familiar with current literature on specific chemicals to provide draft toxicological reviews for EPA consideration.*—This maintains EPA's independence and capitalizes on the private sector's and other government agencies' abilities to perform some of the basic literature reviews that contractors now do for EPA. This approach is being successfully employed in the European Union, where industry groups provide many of the draft science documents and risk assessments that are the starting point for government consideration. European reg-

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[1] Since 1995 EPA has added only four chemicals to the IRIS data base and revised the files for only 16 others. For more details on IRIS' limitations, *see* Science Advisory Board Environmental Health Committee, Review of the Draft Report to Congress Characterization of Data Uncertainty and Variability in IRIS Assessments, *Pre-Pilot* vs. *Post-Pilot* (Sept. 26, 2000) 7; EPA Screening Evaluation Report: Presentation and Discussion of Uncertainty and Variability in IRIS Assessments (July 2000), Table 3; ICF Consulting, Screening-Level Assessment of the Need to Update EPA's IRIS Data base (March 17, 2000), Exhibit 2.

[2] *See* EPA FY2000 Annual Performance Plan and Congressional Justification, at VII–37 ("[IRIS] is widely used for risk assessments and other health evaluations at all levels of government, as well as in the private and public sectors. . . . Risk assessors everywhere look to EPA to provide it.")

ulatory and science review groups use these evaluations to develop potency factors and make health-based regulatory decisions.

• *Allow other stakeholders to nominate chemicals for priority updating.*—This will ensure that the most urgently needed updates are identified and carried out in time to affect future regulatory decisions.

• *Develop interim procedures to account for IRIS limitations.*—For example, EPA could conduct less resource-intensive "partial" IRIS updates where there are important new studies on a chemical, rather than a comprehensive entire file review. Or, new studies could be listed in IRIS with a disclaimer informing users that the health information does not include a consideration of these latest studies.

Question 3.—Comparative risk assessment is a tool used to characterize and rank environmental problems. Do you believe that EPA uses enough benefit-cost analyses (BCA) in characterizing the effectiveness of environmental solutions? Is EPA's use of BCA appropriate?

Response. We believe that EPA should use BCA more often when characterizing and ranking environmental problems, particularly today when many of the easy solutions to reducing pollution have been found and accomplished. Under the decision-making process for residual risk required by the Clean Air Act, however, EPA is required to consider cost, feasibility, and other factors when setting the required "ample margin of safety". See § 112(f)(2)(B) (reference to benzene rulemaking, 54 Fed. Reg. 38,044). Thus, for residual risk the use of BCA is not only appropriate, it is required.

RESPONSES BY LEE P. HUGHES TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1a. You've noted some gaps that you believe need to be filled to adequately characterize residual risk. I assume you mean that must happen before regulations can be issued. Is that correct?

Response. We do not believe that all residual risk regulations should be delayed until all data gaps are filled. Our testimony touched on two key gaps—a lack of post-Maximum Achievable Control Technology (MACT) emissions information and outdated health effects information on hazardous air pollutants (HAPs). In many cases, there is adequate emissions information for the sources at issue, and health effects information on the relevant HAPs for EPA to make sound regulatory decisions.

However, for some HAPs and some source categories, we will need more current and better information to produce sound, scientifically based decisions. We are committed to working with EPA to identify which HAPs need priority attention and to determine what steps need to be taken to allow EPA to make solid decisions. We also will continue our work to voluntarily provide EPA with current, post-MACT emissions information (see response to Question 2, below). EPA still may find that additional data gathering in this area is needed to complete regulatory decisions. These are the gaps that we believe may affect EPA's ability to issue some residual risk rules within the statutory deadlines.

Question 1b. How long would it take to fill those gaps if more resources aren't given to EPA to do the work?

Response. There is no doubt that the "gap filling" workload is heavy and that EPA needs adequate resources to fill key data gaps in emissions information and health effects information. While we cannot predict how long this effort might take, we do have the following suggestions for managing the workload:

• Determine whether EPA has adequate resources to fill these gaps and whether the Agency is properly allocating these resources. We are concerned that there has not been a meaningful increase in the funding EPA has allocated to "air toxics research" or "air toxics standards" in the fiscal year 2000 or fiscal year 2001 budgets;

• Identify and prioritize which HAPs are most critical to the residual risk rulemaking effort and need timely and complete evaluation;

• Determine where better post-MACT emissions information is needed and how we can collectively do a better job gathering this information in the future; and

• Assess how gaps may be filled through the non-EPA and private sector efforts underway to improve our collective knowledge of the health effects and emissions of pollutants.

Question 1c. Do you think the regulated industries would be willing to pitch in and provide additional resources beyond those you mentioned in your testimony?

Response. While we cannot speak for other industries, the chemical industry is already making a serious contribution to chemical research and testing. We are proud of our efforts and believe they will contribute to our overall knowledge. As

our work progresses, we will assess how we can make additional contributions. Some of our present research activities are described below:

- Through the American Chemistry Council's 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 5 years.
- 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.
- Many of our companies have submitted or are preparing new IRIS assessments, which will help fill additional gaps.
- We are working with EPA on a major program to address children's health issues.
- See response to Question 2, below, regarding specific input on post-MACT emissions information for the residual risk program.

Question 1d. Would a per pound tax on HAPs emissions be an efficient way to obtain such resources?

Response. An emissions tax would be a highly inefficient means of promoting accurate risk assessments and risk management decisions for residual risk. Segregation of funds from a dedicated revenue source would create additional resource management problems for EPA. Additionally, in the past two budget proposals EPA sought to allocate significant funds to non-statutory areas (e.g., Clean Air Partnership Fund), rather than to congressionally-mandated programs like residual risk. In fact, there has been no meaningful budget increase for "air toxics standards" or "air toxics research" in 2 years. Congress should evaluate whether present resources are appropriately applied.

A tax also is inconsistent with the Act's structure for managing HAPs from major stationary sources. Industries assessed for residual risk already have installed MACT at a significant cost to many companies. A tax on HAPs would punish these sources for good faith compliance with the law.

Question 2. Has EPA enabled your industry to provide input on the residual risk program and on the specific risk assessment for your industry?

Response. We have had a good working relationship with EPA concerning the overall conceptual framework for the residual risk program over the past several years. We have taken advantage of formal opportunities to provide input to the Agency, such as our commenting on the Report to Congress on Residual Risk and the Secondary Lead Smelter Case Study. In addition, EPA has been willing to meet with us and to share ideas at appropriate times.

This year EPA moved into the risk assessment phase for the sector of our industry subject to one of the first residual risk evaluations (facilities subject to the 1994 Hazardous Organic NESHAP (HON)). We have provided EPA with information about HON facilities, their locations, and emissions. Just last week we contacted over 60 companies requesting their voluntary assistance to provide site-specific emissions information to EPA to improve the residual risk assessment.

Question 3. What improvements could be made to the relationship to ensure an open and collaborative sharing of data?

Response. We will need to work collaboratively with EPA and other stakeholders in the coming months on issues relating to regulatory structure, risk communication, and risk management. One improvement to the relationship could involve open recognition by all parties of the tight: statutory deadlines. Our experience shows that in the face of fast approaching deadlines EPA often reduces stakeholder dialog and input, as stakeholder meetings are viewed as an impediment to achieving deadlines rather than a means to improve the regulatory process. We expect that part of the necessary open and collaborative process will be an honest assessment of what can be accomplished under the Act's deadlines.

STATEMENT OF ROBERT BRENNER, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF AIR AND RADIATION, U.S. ENVIRONMENTAL PROTECTION AGENCY

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 dialog 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 8 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 102d 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 decisionmaking 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 decisionmaking 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 decisionmaking 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 2 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

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 decisionmakers. 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 10 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 re-

sources 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 decisionmake. 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.

RESPONSES BY PHILIP HOPKE TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. Are you suggesting that we stop the residual risk program until the quality of risk assessments can be improved or are you saying that, with some additional effort, this program will work? If you agree with the former point, when will we know whether the appropriate level of quality has been reached to justify regulating?

Response. I believe that adequate quality residual risk assessment can be performed, but that some additional effort will be needed to perform them at a reasonable level of sophistication. The purpose of the residual risk assessment is to be ascertain with a reasonable level of certainty that no undue risk remains after MACT is put in place. The keys are to be able to use what data and other information that are currently available to make it clear that a sensible approach is being taken to estimate the risks. The scientific community wants to make sure that all of the details are dealt with as best we know how so when we observe that there are insufficient resources to poll EPA's own data base to compare modeling results with measurements, we feel that there is something wrong with the process.

There will never be perfect models, but we want to use the best model possible. When the choice is between an unreviewed model developed for another purpose and a general use model like the Total Risk Integrated Methodology (TRIM) that received favorable initial reviews because it tries to provide a more complete picture of reality, it makes sense to vigorously complete TRIM rather than continuing to use the more limited model. It bothered our committee that there was not a clear commitment to get TRIM into service as quickly as practical.

It also did not appear there was a clear plan about how to deal with toxic species for which quantitative dose/response data are available. We are not advocating expensive toxicological testing, but we do believe that some focused structure/activity relationship calculations could set some credible upper bounds on the risks for these untested species.

Thus, the major problems we saw with the process did not require major new efforts but rather the ability to utilize data EPA already had on hand, the Agency's ability to complete the model development and testing they already had underway, and their ability to provide a logical framework to deal with the toxic species for which quantitative data are not and will not be available. We envisioned that a reasonable increase in effort could ameliorate these problems.

Question 2. Do you have any idea of the resources that might be necessary for it to work well?

Response. I do not have a specific dollar figure as I am not sure of typical contractor (researcher?, model developer?) costs. However, there is also added value for these costs. For example, the EPA has a variety of uses awaiting the completion of TRIM and thus, the value in completing and testing this model provides a much greater benefit than for the residual risk program alone. I would anticipate that a modest calculational chemistry effort with an appropriate academic group could provide the unit risk estimates for the unmeasured dose/response values. Given the risk reduction that can be reasonably anticipated as coming from MACT, it is sensible to limit the costs associated with the residual risk estimation. However, given the costs to implement MACT, the regulated industries as well as the potentially exposed individuals should be able to have reasonable confidence in the results of the analysis.

Question 3. During the hearing, I believe you indicated that "Congress should clarify how good is good enough," in terms of the quality of the risk assessments for further regulation. Does that mean that you advocate amendments to the Clean Air Act to provide such clarification?

Response. Yes. It is hard for those involved in the risk assessment to determine the level of assessment needed as the basis of regulatory decisionmaking. Our natural inclination is always to do the most detailed and quantitative analysis possible. However, that is likely to be more detailed, more precise and far more costly than is needed for the purpose of determining if further controls are needed to protect the health of those living in the vicinity of such facilities. Clearly, EPA has a view of how much effort is needed based on their perception of the development of the 1990 Amendments. However, since there is no clear record of what was intended at that time, it is hard for people coming into the process to decide how much effort and rigor are required. Thus, a clearer view of the political context of the risk assessment process would be helpful to everyone involved in the accomplishment and review of this task.

RESPONSES BY PHILIP HOPKE TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. Are the SAB's recommendations for residual risk assessment, such as inclusion of ecosystem risk assessment, population risks, etc., . . . , also valid for conducting "comparative risk assessment"?

Response. Yes, we certainly want to understand the risks to the broader population as well as to the most highly exposed individuals. It is also important to judge the ecosystem risks. Clearly, the public values all of these factors. The relative ranking of these different risks, however, is a management decision that needs to take other factors into consideration in coming to decisions. There is no simple scale of comparability between risks to individuals, to populations, and to ecosystems that would permit an approach to ranking overall risks. They must all be included in the evaluation of the options in order to make the most well informed decision possible.

Question 2. Dr. Lippmann testified that a major part of the problem with the current EPA risk assessment stems from having 2 very different cultures of risk assessment: (1) for carcinogens and (2) for other toxicants. Are your findings consistent with this being the source of the problem?

Response. I think the problems are more complex than simply culture differences within the Agency and come back to some of the discussion we had at the hearing regarding the stovepipe approach that governs much of the Agency's organization and practice. For example, lead in airborne particles is a criteria pollutant for which a National Ambient Air Quality Standard is defined under Title I while according to the Clean Air Act, lead compounds are hazardous air pollutants under Title III. We need to take a more holistic view of the specific problem of air quality and the broader issues of environmental quality management. To a significant extent such a major change in conceptualization must come from Congress since the natural tendency of the Agency will always be to organize around major facets of the governing legislation.

Some of the problems associated with the risk assessment process stem from differences in the level of information available to the risk assessor. There is a much richer data base for possible health impacts of ambient pollutants like the criteria pollutants. The data regarding cancer risks is much more limited. As we obtain a better understanding of the molecular basis for cancer, some of this data disparity will be eliminated, but that will take some time. The question then arises as to how conservative we feel we need to be in estimating the risks and how well these assumptions that are made in conservative risk assessments are explained and justified to the regulated industries and the public.

With respect to our findings concerning the residual risk process, I do not think this dichotomy of information availability is the problem. The problem is more related to the lack of clarity in defining how confident in the quantitative results the Agency need to be in order to make regulatory decisions and what needs to be done in order to attain such quality of results. In the absence of this definition, reviewers typically will demand more detail and the highest level of analysis in order to minimize the uncertainties.

STATEMENT OF FELICE STADLER, NATIONAL POLICY COORDINATOR, NATIONAL WILDLIFE FEDERATION'S CLEAN THE RAIN CAMPAIGN

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 phaseout 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 2 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 United States? 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 2 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: *any* release of these pollutants causes harm. For that reason, in international agreements the United States 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.

RESPONSES BY FELICE STADLER TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. Do you agree with the SAB's recommendations to improve the EPA's risk assessment?

Response. Yes. We agree that EPA could improve upon its risk assessment, especially its analysis of ecological impacts. However, we would reiterate the overarching comment made by the Chair of the SAB: with adequate resources, EPA could overcome several of the limitations noted, including data collection and refinement of analyses.

Question 2. Does the public, in your opinion, benefit from participating in a CRA project?

Response. Yes. It is essential for the public to have the opportunity to participate in comparative risk assessment projects, especially those conducted on the State or

local level. Because the process itself is strongly value laden, all stakeholders should have an opportunity to provide input on how to prioritize issues of concern. Local communities are at the front lines of the pollution problem, and often do not have the resources to become engaged in policy discussions at the State or Federal level. Any dialog that takes place that determines which risks become a priority must involve communities most directly affected by those decisions.

In general, NWF does not endorse using CRA's to drive policy decisions. While intellectually this technique has some appeal, it raises a lot of questions and concerns. For example, how easy is it to compare two different types of activities (air emissions vs. water discharges), one chemical to another (benzene vs. mercury), one health endpoint to another (neurodevelopmental effects vs. cancer). In addition, CRA's would result in key questions never getting raised, questions of responsibility: Who is responsible for the pollution? Can the pollution be prevented? What tools are available to reduce the pollution? These questions are critically important and must be central to any pollution policy decisions.

Question 3. Some have criticized EPA's risk assessments, saying that they are too conservative. Do you believe that to be the case?

Response. No. The SAB did not consider conservative modeling to be inherently improper, either. Rather, it was concerned that EPA failed to validate conservative modeling by checking predicted outcomes against known outcomes.

We support the use of conservative modeling. Policy decisions should be made with the information at hand, rather than delaying action in the face of uncertainty. We will never have the luxury of knowing the answer to every scientific question before needing to act.

In fact, EPA does not always use conservative assumptions. EPA has been criticized repeatedly for designing risk assessment models based on what is safe for healthy, adult, white men. For this reason, EPA needs to be conservative in order to avoid underestimating risks to the most vulnerable populations children, the unborn, women, elderly, and people in overburdened communities.

Moreover, EPA does not appear to be using conservative assumptions with respect to non-carcinogenic HAPs, which may make the risks posed by carcinogenic HAPs seem greater. EPA should address the disparity in the treatment of carcinogenic and non-carcinogenic HAPs in two ways. First, EPA should assess the risks of the most harmful non-carcinogenic HAPs persistent, bioaccumulative toxic substances, such as mercury—using assumptions that are no less conservative than those used in assessing the risks of carcinogenic HAPs. Second, as the SAB recommended, EPA should develop and make greater use of uncertainty and variability ("U&V") analyses. U&V analyses can be used to compare and adjust the results of conservative and non-conservative risk assessments.

In sum, using conservative assumptions and modeling is not inherently inappropriate because we are dealing with HAPs, which are causing real harm not merely creating a risk of harm to human health and environmental integrity.

Question 4. Some of the witnesses have indicated that Congress needs to step in to provide EPA additional time prior to requiring regulations to reduce residual risk. Their main reasons for proposing a delay are the quality of risk assessments, the lack of sufficient resources to conduct these assessments, and the need for Congress to clarify what it considers to be a good risk assessment. What are your views on these reasons?

Response. EPA is making a concerted effort to refine its risk assessments in order to meet the deadlines imposed by the Clean Air Act. Any delay of those deadlines will result in prolonged exposure to HAPs. Rather than extend the deadlines, then, Congress should focus on fully funding EPA's air toxics program. Congress is currently not doing this, which impairs and inhibits the quality and speed with which the agency can complete its initial screening assessments and its detailed risk assessments.

Congress should not attempt to delve into the scientific complexities of residual risk by trying to clarify what constitutes "good risk assessment." The field of risk assessment is continually evolving in scientific circles, and EPA is working to track these developments and update its methodology to reflect the new approaches that are emerging. Congress does not have the expertise to determine whether EPA's risk assessment is sound. If Congress is interested in the evolving science of risk assessment, we respectfully suggest it should request annual briefings from EPA on this subject.

Question 5. Would NWF support requiring HAP emitters to provide financial support for conducting residual risk assessments?

Response. NWF would support such a requirement only if HAP emitters do not receive in exchange any influence over the design or performance of the assessments. Furthermore, should EPA choose to contract with an independent firm to conduct an assessment, EPA must first screen the firm to ensure the absence of any conflict of interest, and must closely oversee the guidelines and protocols the firm uses.

Allowing a single source or a category of HAP emitters to conduct residual risk assessments for their own facilities would be problematic. As you heard at the Senate hearing, issues like uncertainty are often driven by values and priorities rather than scientific justification. Given this fact, a risk assessment conducted by a HAP emitter would be suspect.

In addition, a risk assessment conducted by a single source likely would not take into account the impact of pollution from neighboring sources. It would look only at emissions at its own fence line. Cumulative exposures are critically important and must be addressed through the residual risk program.

Question 6. You mentioned some of the flaws associated with the existing process by which EPA assesses risk—the lack of consideration of cumulative risk, transgenerational risk, etc. How could EPA improve its process?

Response. EPA could begin to improve its process by setting clear priorities based on the type of pollutants being emitted. Toxic compounds that bioaccumulate and persist in the environment, that contaminate our food supply, that are easily passed from mother to child, and that damage critical organ systems, should be phased out. EPA could simplify its risk assessment approach and make policy decisions based on the inherent toxicity of this special class of HAPs, concluding that they should be handled differently.

In terms of addressing cumulative risk, for compounds that are both air and water contaminants, and possibly food contaminants, EPA must consider all these different routes of exposure when calculating risk. Evaluating the risk of inhalation alone is inadequate. If EPA's air division does not address multi-pathway exposures in its risk assessment, and if there is evidence that other routes of exposure are likely, the inhalation risk level should serve as the floor rather than the ceiling. In this case, we would argue that the most conservative minimum risk level one in one million should be used for cancer and non-cancer effects to protect the most vulnerable populations.

STATEMENT OF GEORGE E. PARRIS, PH.D., DIRECTOR, ENVIRONMENTAL AND REGULATORY AFFAIRS, AMERICAN WOOD PRESERVERS INSTITUTE

PREFACE

We are honored to address the Senate Committee on Environment and Public Works. We are also honored to speak for the American Wood Preservers Institute, which represents an industry of many small businesses that has been instrumental in the economic growth of this country by making railroads, marine shipping, rural electric utilities, telecommunications and house construction economically feasible while conserving our forest resources.

The American Wood Preservers Institute strongly supports the use of quantitative risk assessment and risk-cost-benefit analyses in regulatory decisionmaking. Without these inputs from the real world, regulatory decisions would be based on intuition and political considerations. However, the risk assessment methodology is evolving and must reflect our current understanding of science; and the cost and benefits analyses must consider both direct and indirect impacts (inside and outside the regulated community). When applied objectively, risk assessment and risk-cost-benefit analyses are the foundation of rational policy, regulations, and standards. Unfortunately, when obsolete risk assessment techniques are applied and cost and benefits are selectively chosen for consideration, politically motivated policy, regulations and standards can masquerade as being unbiased and rational.

PART I. THE ROLE AND VALUE OF RISK-COST-BENEFIT ANALYSIS IN DECISIONMAKING

The regulations and standards for protection of human health and the environment that are promulgated to implement environmental statutes (1) must use scientifically valid methodologies, (2) must be applied consistently so that decisionmakers apply finite resources in the most efficient way, and (3) must be reasonable in terms of balancing risks, costs and benefits (i.e., they must meet a reasonable threshold of utility).

The Congress (not bureaucrats or political appointees of the Executive branch) must set broad policy guidelines for (1) acceptable risk, (2) equitable allocation of

finite resources to reduce risks, and (3) minimum requirements for risk reduction per unit of money spent by government or the private sector to justify action.

The wood preserving industry provides examples of the types of problems that we believe are currently common in environmental laws, regulations, standards, and enforcement policies. I will address some of these here:

PART II. THE METHODOLOGY OF RISK ASSESSMENT MUST BE SCIENTIFICALLY VALID

The risk of contracting fatal cancer underpins of most of our environmental standards and the public perception of risk of many activities and products. Since most of the communicable diseases that killed millions of children and adults in previous generations have been tamed by better hygiene and antibiotics, cancer has become the leading unpredictable and uncontrolled risk in most peoples' lives. In turn, quantitative risk assessment methodology has been introduced to attempt to make the risk of cancer predictable and to provide a rational basis for control of that risk.

However, the risk assessment methodology that is still used today was invented primarily between 1930 and 1970 at a time when our understanding of the nature and cause of cancer was very rudimentary. I want to briefly recount the history of our quantitative risk assessment methodology and show how it needs to be changed to reflect current scientific knowledge in biochemistry and genetics (see appendix).

It should be noted that the regulatory agencies have clung tenaciously to the original concepts in spite of growing evidence that they are inapplicable in most cases. The exercise of prudence is certainly a desirable trait in a regulatory agency, but the credibility of the regulatory agencies (particularly the U.S. Environmental Protection Agency) is being eroded among knowledgeable observers because they are currently so far behind the state-of-the-art.

My industry is currently affected by EPA risk assessments for dioxins and arsenic. We believe that the methodology used in these risk assessments is fundamentally flawed (as discussed below) resulting in risk projections that are so large that the EPA is being led to actions which will unnecessarily limit the use of our products and which will cause unnecessary alarm in the general public.

Clearly Many Carcinogens Should Not be Assessed by the Target Theory

(1) The Fundamental Requirement of the Target Theory is Not Met

The fundamental requirement of the target theory (linear no-threshold [LNT] model) of mutagenicity/carcinogenicity is direct damage to the DNA independent of any biochemical system. Few chemicals have been shown to directly damage (e.g., form adducts with) DNA. Some chemicals have been shown to form adducts with DNA after being metabolized to active electrophiles or free radicals. Unless, such reactions are demonstrated in vitro, there is no scientific justification for applying the target theory (linear no-threshold model) of risk assessment.

(2) The Target Theory Ignores Chemical and Physical Modulation of Dose Efficiency

Most chemical and physical barriers that stand between a chemical as dosed and the DNA target of mutation are progressively less effective as the dose of the chemical increases. In many cases, there may be a threshold below which a chemical agent never reaches the DNA. Thus, we would expect most dose response curves to be non-linear, i.e., sub-linear.

(3) The Target Theory Ignores DNA Repair

The existence of DNA repair mechanisms means that even for direct acting genotoxic agents (e.g., x-rays), the dose-response curve should be sub-linear at low doses. Since DNA repair occurs after a damaging event, DNA repair would not require, an absolute threshold, but the quantitative difference between a true threshold (i.e., zero risk) and a sub-linear dose-response curve may be un-measurable.

(4) The Target Theory Incorrectly Assumes that Mutant Cells Progress to Cancer

Many cell clones in the body contain mutations, they normally do not progress to cancer because (i) they are not immortal and hence become extinct before clinically significant tumors develop or (ii) they are triggered to undergo apoptosis by proteins that scan the DNA.

Most Carcinogens are Threshold Carcinogens

There are many mechanisms through which a chemical can indirectly cause genotoxicity that leads to cancer. Even in those cases where direct genotoxicity has been observed, indirect mechanisms may be the principal contributor to genotoxicity at high doses. The importance of recognizing that fact and developing our risk as-

sessment policy around this concept is that for those cases, there is a threshold of exposure below which the risk is effectively zero. By managing exposures (through appropriate regulation) such that the total exposure is below the appropriate threshold, a very high level of health protection can be provided with great flexibility in compliance that lead to health, environmental and economic benefits.

In practice the thresholds can be established two ways: (1) epidemiologically (bioassay and environmental) and (2) biochemically. The biochemical approach involves determining in vitro threshold of genotoxicity (it is not necessary to determine the mechanism of action) using appropriate tissue cultures and determining what the attenuation factor is between environmental medium and blood plasma (e.g., what concentration in drinking water is required to give the concentration in blood plasma equal to the genotoxic threshold determined *in vitro*).

PART III. THE COST AND BENEFIT ANALYSES MUST CONSIDER DIRECT AND INDIRECT IMPACTS

(1) Comparative Risk Assessment

The Environmental Protection Agency has excused itself from explicit compliance with the National Environmental Policy Act (NEPA) on the grounds that rulemakings by the USEPA are equivalent to the analysis required in an Environmental Impact Statement (EIS) under NEPA. Unfortunately, that policy has resulted in the programs implemented by the USEPA including the regulation of waste (RCRA), water (SDWA), air (CAA) and remediation of environmental contamination (CELERA) taking unexpected and undesirable directions. Basically, the USEPA has developed implementation approaches that focus on only one element of what is actually a multi-component situation. I will discuss the environmental remediation program under CERCLA (Superfund) as an example.

Basically, the decisions concerning (1) whether or not to remediate and (2) what the target final concentration of contaminant should be are driven either by compliance with applicable or relevant and appropriate requirements (ARARs) or a toxicological risk assessment that addresses the potential risk to persons who may (or may not) actually live on the contaminated land and may (or may not) actually drink the groundwater, etc. Notice that *all* the focus is on hazards and risk caused by the chemical (usually toxicological) in the contaminated media. Once the chemical risk (usually carcinogenic risk) to the people who are exposed (or who may possible be exposed in the future) is deemed to be above a target set by policy (e.g., 40 CFR 300.430) the process is committed to a course of action that requires remediation.

There is a major flaw in this approach. Fundamentally, the decisionmaking guided by the regulation disregards all other risks and impacts of the proposed action. If you look at environmental remediation projects, what you discover is that they are basically construction projects. They involve drilling wells, pumping water, excavating soil, hauling soil and debris from place to place (often on public roads), construction and operation of treatment systems, etc. Disregarding the chemical or radiological hazards to workers and the general public associated with these projects (including the potential hazards presented to people living near landfills where waste may be disposed offsite), the construction work and transportation alone represent risky operations (especially when protective clothing for protecting workers from chemical risks are factored in because they usually increase heat load, restrict vision and make the worker more awkward). Construction projects, of course, also involve environmental impacts (e.g., damage to habitat or taking of wildlife).

It would be desirable to have a more balances weighting of risk in the CERCLA program so that the presumption that remediation is always preferred can be analyzed.

Another example where narrow focus on one element of risk can produce undesirable conclusions is associated with the use of wood preservatives. For example, unnecessarily limiting the use of a wood preservative because of erroneous risk assessments might result in the harvesting of more trees (depletion of natural resources) and more accidents and deaths in the logging and sawmill industry.

(2) Balancing Risks, Costs and Benefits

There should be some reasonable analysis of costs, risks and benefits associated with regulations and standards. The wood preserving industry has provided clear examples of poor risk-cost-benefit decisionmaking by the USEPA. In the 1992 budget process, it was pointed out that the hazardous waste regulations for wood preservatives cost 5.7 Trillion dollars per avoided premature death! This set a record for inefficient use of our financial resources. Viewed differently, spending $2 million on highway safety saves at least one life in a few years, but spending the same

amount on controlling waste from wood preserving does not save a life over a million years. Obviously, the benefits of such regulations are insignificant, while the costs are very real.

In the cases of the current debate over the regulation of arsenic in drinking water, it should be embarrassing for USEPA regulators to go to international conferences where scientists from West Bengal and Bangladesh describe real, widespread, overt clinical signs of chronic arsenic intoxication from drinking water at levels of arsenic approaching 1,000 ppb and then argue that the United States should spend billions of dollars to reduce the concentrations of arsenic in drinking water from 50 ppb to 5 ppb, when benefit of such a move are at best hypothetical. The only cases that the USEPA claims show any damage at the current regulatory standard in the U.S. are actually among people that are not covered by the current standard and would not be covered by the standard because they are on private wells.

Interestingly, USEPA cost estimates for implementation of the current proposed maximum contaminant limit (MCL) for arsenic only addresses some of the most obvious cost (e.g., treatment equipment) to the "regulated community" i.e., public water utilities. The cost of acquiring land to build a treatment plant on and the cost of waste disposal are severely underestimated or ignored by the USEPA. Moreover, entire classes of economic impacts are not even mentioned by the USEPA's proposal. For example, the MCLs are routinely adopted as applicable or relevant and appropriate requirements for CERCLA remediation and in this way, the new MCL for arsenic will affect the wood-treating industry.

Even private real estate values may be affected by the new arsenic MCL. Suppose that you are a private land owner with a well with 40 ppb of arsenic from natural sources. Currently if you sell your house, there is no issue about the purity of the water. But, if the MCL for arsenic were reduced to 5 ppb, you would need to disclose that your well was "contaminated" to prospective buyers. Moreover, the cost to cure this "defect" by installing a point-of-use treatment device will cost (by the USEPA's estimates) several hundred dollars each month (forever). Considering that typical mortgages (principal and interest) are $1,000 to $2,000 per month, an additional burden of e.g., $300 per month will necessarily reduce the value of the real estate by 15–30 percent. It implication for property values in large parts of the western United States, Michigan, Wisconsin, Minnesota and other states is staggering.

Ignore the proposed MCL for arsenic for a moment and focus on the underlying risk assessment. Heretofore, the USEPA has used similar risk assessments to estimating the risk associated with soil contamination and pesticides residues (which have exposure scenarios that have nothing to do with water). But, because the USEPA retained a drinking water standard that was consistent with a much lower level of concern about arsenic, the risk assessment per se was not burdensome. Now that the USEPA is accepting the risk assessment as the driver for regulation of drinking water, the implications for other modes of exposure are enormous. The risk assessment will be used in the waste programs, the pesticide programs, in the air programs as well as the water programs.

Finally, in the context of risk-cost-benefit analysis, I would like to report arsenic contamination of the Madison River in Wyoming. At the source, the concentration of arsenic is 360 micrograms per liter and the pollution can be traced at least 470 km downstream until the Madison River joins the Missouri River where the concentration of arsenic is still 19 micrograms per liter. I am sure that if this were caused by a wood preserving plant, our industry would be expected to pay whatever cost was necessary to stop this flow of arsenic. But, the source of the arsenic (and other toxic metals) is the Yellow Stone National Park.

APPENDIX

HISTORY OF THE EVOLUTION OF QUANTITATIVE RISK ASSESSMENT FOR CANCER

1850: Remember that the microscope was not invented until the early 1800's and that led to the discovery of cells and the identification of chromosomes (i.e., condensed forms of DNA visible under a microscope during the cycle of cell division).

1870: The concept of inheritable traits was introduced in the period 1850–1870 by Gregor Mendel (1822–1884)

1890: The role of microbes in causing some diseases was not understood until 1877–1887 through the work of Louis Pasture (1822–1895)

1890: Cancer was recognized as a disease in the 1800's, but it was not until the late 1800's that exposure to specific chemical substances was associated with the increased incidence of some cancers.

1910: In the period 1890–1910 the work of Paul Ehrlich established the concept of dose-response relationships for pharmacology and toxicology. Much of this research also involved arsenic (III) which was one of the few effective drugs used to treat protozoal diseases (sleeping sickness and syphilis). Invariably, for a specified biological end point (*e.g.,* acute toxicity) there were thresholds below which no effects were observed and the responses of individual members of the exposed population tended to fall into a bell-shaped curve (normal distribution). Integration of this bell-shaped curve produces an S-shaped curve known as the dose-response relationship (i.e., probability of effects at a specific dose).

1920: It was not until the period 1908–1918 that chromosomes were linked to inheritable traits and mutations by Thomas Hunt Morgan (1866–1945).

1935: During the early 1900's, radioactivity was intensely studies including the effects of x-rays on tissue. It was observed that (within the range of exposure considered) the frequency of mutations caused by x-rays was linearly related to the total dose (intensity x duration) not the intensity or the duration of exposure alone. This observation gave rise to the erroneous idea that (for x-rays) intensity did not matter and only the total dose needed to be considered.

1940: "Target theory" became the acceptable way to predict damage to chromosomes (and hence mutations) through bombardment with agents (such as x-rays). This was consistent with the notion held at the time that (1) chromosomes normally were never damaged; (2) if chromosomes became damaged, they was never repaired; and (3) any damage to chromosomes would result in either immediate death of the cell of a mutant cell line.

1953: It was not until 1953 that the structure of DNA making up chromosomes was explained by Watson and Crick.

1961: Normal cell clones were shown to be mortal (normally die after a set number of replications, i.e., generations) and cancer cell clones were shown to be immortal by Leonard Hayflick.

1962: Silent Spring published by Rachael Carson provoking systematic public fear of manmade chemicals.

1970: The process of DNA repair was discovered and articulated by J.E. Cleaver and others while working on the cause of the inheritable disease xeroderma pigmentosum.

1970: The U.S. Environmental Protection Agency was founded and began establishing policies concerning management of risk caused by manmade (industrial) chemicals. The target theory of mutations was accepted and extrapolated in two ways (i) it was applied across the board to chemicals (not just high energy radiation) and (ii) the theory was assumed to relate to cancer as well as mutations. Note that high-energy radiation can go directly to chromosomes without passing through chemical or physical defenses present in the body. Chemical agents must pass through both chemical and physical barriers before reaching the nucleus and the DNA.

1971: Recombinant DNA discovered.

1972: Apoptosis (programmed death and recycling) of stressed and damaged cells was articulated by Kerr, Wyllie and Currie.

1992: Chromosome telomere shorting during DNA synthesis related to cell clone mortality.

2000: Formulation of a new model for cancer risk assessment in progress.

U.S. SCIENCE ADVISORY BOARD,
May 19, 2000.

EPA-SAB-EC-ADV–00–005

Hon. CAROL M. BROWNER, *Administrator,*
U.S. Environmental Protection Agency,
Washington, DC.

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,

DR. MORTON LIPPMANN,
Interim Chair, Science Advisory Board.

DR. PHILIP HOPKE, *Chair,*
Residual Risk Subcommittee,
Science Advisory Board.

NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the U.S. Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the U.S. Environmental Protection Agency, nor of other agencies in the executive branch of the Federal Government, nor does mention of trade names or commercial products constitute a recommendation for use.

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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

RESIDUAL RISK SUBCOMMITTEE MEMBERS: SECONDARY LEAD SMELTERS

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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

*Members of this SAB Subcommittee consist of: (a) SAB Members: Experts appointed by the Administrator to 2-year terms to serve on one of the 10 SAB Standing Committee; and (b) SAB Consultants: Experts appointed by the SAB Staff Director to a 1-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.

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 decisionmakers. 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.

2. INTRODUCTION

2.1 Background

Section 112(f)(1) of the Clean Air Act (CAA), as amended, directs ERA to prepare a Residual Risk Report to Congress (RTC) that describes the methods to be used in assessing the risk remaining, (i.e., the residual risk) after maximum achievable control technology (MACT) standards, applicable to emissions sources of hazardous air pollutants (HAPs), have been promulgated under Section 112(d). The RTC was intended to present EPA's proposed strategy for dealing with the issue of residual risk and reflected consideration of technical recommendations in reports by the National Research Council ["Science and Judgment"] (NRC, 1994) and the Commission on Risk Assessment and Risk Management (CRARM, 1997). As a strategy document, the Agency's RTC described general directions, rather than prescribed procedures. The announced intent was to provide a clear indication of the Agency's plans, while retaining sufficient flexibility that the program can incorporate changes in risk assessment methodologies that will evolve during the 10-year lifetime of the residual risk program.

In 1998, the SAB conducted a formal review (SAB, 1998b) of the draft RTC (USEPA, 1998) and its proposed methodology. In their review, the SAB noted that it was difficult to assess the Agency's methodology without first seeing it applied to a specific case.

In the summer of 1999, the Agency asked the SAB to provide advice on the application of the residual risk methodology to the specific case of lead smelters. This source category was selected since it was relatively small (fewer than 30 facilities nationwide) and data rich.

2.2 Charge

In the months leading up to the SAB meeting, the Agency and the Board negotiated a Charge consisting of the eight questions below.

(a) *Overall.*—Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? (EPA–453/R–99–001)? Are the assumptions used in this risk assessment consistent with current methods and practices?

(b) *Model Inputs.*—Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

(c) *Models.*—Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the State of the science, does the risk assessment use an appropriate multi-pathway model? The assessment uses the IEM–2M model, with some modifications. Is the IEM–2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach that is available at this time that EPA should consider?

(d) *Choice of Receptors.*—The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?

(e) *Ecological Risk Assessment.*—Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

(f) *Health Risk Assessment.*—Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose-response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially

footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose-response assessment appropriate? Are the dose-response assessments appropriately incorporated into the assessment?

(g) *Uncertainty and Variability Assessment.*—Did the assessment use appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

(h) *Presentation of Results.*—Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

The Charge guides an SAB review, but it does not constrain the range of comments that the Subcommittee members can legitimately offer.

2.3 SAB Review Process

The SAB Subcommittee was recruited following nominations received from SAB Members and Consultants, the Agency, and outside organizations. The group met in public session on March 1–2, 2000 at the main auditorium of the USEPA Environmental Research Center in Research Triangle Park, NC. Written comments prepared before and after the meeting by Subcommittee members, and made available at the meeting, form the basis for this report. Individual comments are included in Appendix A for the edification of the Agency as an illustration of the issues identified by the Subcommittee members and of the range of views expressed. Those comments are not a part of the consensus report. A more detailed description of the SAB process for this review can be found in Appendix B.

3. RESPONSES TO SPECIFIC CHARGE QUESTIONS

3.1 Charge Question 1: Overall

Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress (EPA–453/R–99–001)? Are the assumptions used in this risk assessment consistent with current methods and practices?

The methodology presented in this report is consistent with the Report to Congress, as far as it currently goes, and many of the assumptions are consistent with current methods and practice. However, the Subcommittee has not yet seen a full residual risk analysis and is unable to comment on the complete analysis process. More specifically, this was an interim analysis that did not include such important elements as an ecosystem risk assessment, a health risk assessment that includes population risks, a full uncertainty and variability (U&V) analysis, 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. At this interim stage, it looks only at four of the 23 sources from the secondary lead smelters category. Nonetheless, the report does provide a valuable indication of how the approach presented in the Report to Congress is going to be implemented in practice. With respect to the specific approaches used in the case study, there are a number of questions that are discussed in detail in response to the specific charge questions below.

A general comment is that the case study should provide more details of what was done and how it was accomplished. It is critical that the process be as clear and fully articulated as possible. More details are needed on how each model has been modified from prior use. For example, it is not clear how the IEM–2M model was modified from its prior use in the mercury assessment in order to be used for the secondary lead smelter emissions. The interested and knowledgeable reader should be able to follow what changes were made and understand why such modifications were made.

There is clearly a significant problem with how fugitive emissions are being treated. In this analysis, much of the residual risk results from fugitive dust emissions. However, there is little direct information in the Agency's document on how these emission rates were modeled. In the Agency presentations at the meeting, four approaches to modifying the fugitive emissions were provided.

It should be possible to utilize existing data to help refine the emissions estimates. At many or most of these facilities, there are ambient monitors generating data to determine compliance with the lead (Pb) National Ambient Air Quality Standard (NAAQS). These data should provide an opportunity to estimate the routine emissions around the plant and potentially observe the differences in concentrations before and after whatever steps were implemented to comply with the fugitive

part of the MACT standard. Information on the frequency and extent of upset conditions at these plants could be used to supplement monitoring data from routine operations. Anytime data are available to provide ground truth, the Agency should compare those data to the model results. This feedback approach would mitigate against the generation of results that appear unreasonable.

A number of concerns were raised about the manner in which the models appear to have been applied without adequate consideration of the plausibility of the assumptions or the physical meaning of the results. An iterative process is needed in which, even in the absence of external comparison data, when implausible results are obtained, the model inputs can be appropriately revised and the model run again. For example, when excessively high blood lead levels are estimated (e.g., 200 μg/dL), the analyst should reexamine the model inputs and make appropriate modifications. Similarly, where excessively low breast milk contaminant levels were estimated, the analyst should also reexamine the models. A number of such plausibility checks were described by the Subcommittee or in public comments that can provide checkpoints in the analysis to indicate the need for alternative assumptions and recalculation. The resulting discussion of these implausible results and the changes made to the calculation would be a useful modification to the current approach.

Only the first stage screening for potential hazard was available for consideration of the ecological risk. It is recognized by OAQPS that a full assessment of ecological risk is needed, but the rate of progress in this direction has been slow. The methods and supporting assumptions made are general, at best, and would need to be more definitively treated in a refined ecological risk assessment (See Charge Question 5 for more details). The Agency should devote sufficient effort and resources to insure a credible ecological risk assessment for this prototypic case study.

One of the critical problems for future residual risk analyses will be the availability of data. Secondary lead smelters emit lead and other HAPs. Emissions and related ambient monitoring data for lead are generally available. Data on the other HAPs are less available, making future assessments of residual risk associated with these other HAPs more of a challenge. Even when data are available, the data will need to be evaluated to determine their appropriateness for ground-truthing risk estimates. In addition, there is a significant question about how available are the critical input data needed to credibly characterize the residual risks from the other 173 source categories. In the present analysis, missing information, such as the toxicity of a number of HAPs, led to those compounds being excluded from the analysis. There may be molecular modeling approaches (e.g., Quantitative Structure-Activity Relationships (QSAR)) that would permit estimation of relative toxicity of the organic HAP compounds for which data are not available and a screening analysis of their likely effect on the overall risks could possibly be developed.

The Subcommittee felt that, within the limitations of data and resources, the approaches adopted were able to identify potential high human health risk situations. However, they also felt that the science is insufficient to be fully confident in the quantitative values estimated by these models. There are significant concerns regarding the nature of the full ecological risk assessment because a complete analysis has not yet been presented. There is concern that the apparent precision of the resulting risk estimates may be overstated and that more effort is needed to present results that better reflect the uncertainties and variability in the analysis. The review material did not give a clear picture of how the results of the analysis would be used in the risk management process. Such information would have helped the Subcommittee to comment more precisely on the adequacy of the analytic results to support the decisionmaking process.

In any event, it is recognized that at some point management decisions will have to be made based on results stemming from analyses of this type. The Agency is mandated under Section 112(f) to conduct the residual risk assessment and to make a decision to implement further regulation or to make a decision that no further regulation is needed. In response to the previous SAB review (SAB, 1998b) of the Report to Congress, the Agency responded that, "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 results of the more refined analysis provides the same answer as the initial inhalation screen; that is, an even more refined analysis is needed. Therefore, the case study, in its current state, has not achieved the decision objective, and another level of analysis or iteration would be needed. The case study needs better quality input data/estimates on fugitive emissions, a more in-depth and refined analysis, a clearer presentation of the steps taken in the analysis and the results produced, and a more serious effort to fully integrate uncertainty and variability into the analysis. In sum-

mary, a better-informed decision will be possible if the results of the case study more fully reflect the inability to define the risks precisely.

3.2 Charge Question 2: Model Inputs

Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

3.2.1 Inhalation Screening

The fundamental equations used by the Agency to estimate the specific inorganic and organic hazardous air pollutant (HAP) emission rates for process and process fugitive emissions are described by Equations 1 and 2, respectively. These equations provide a technically sound methodology for estimating specific HAP emission rates based on the metal HAP and hydrocarbon emissions data provided in the Background Information Document (BID) (USEPA, 1994). Although the Subcommittee can support the Agency's initial decision to employ the AP–42 based fugitive HAP emissions estimates in the inhalation screening study, the combined effect of using these conservative data with a conservative air pollution concentration model has clearly resulted in an overestimation of ambient HAP air concentrations. On the other hand, "upset" conditions were not assessed with any data in this assessment, and considerable lead may be emitted from these facilities under such circumstances. This could lead to an underestimation of ambient HAP air concentrations. To ensure that the use of SCREEN3 will result in realistic predictions of ambient air pollutant concentrations, the Agency should evaluate the underlying assumptions adopted in the area source emissions algorithm, as well as the quality of emissions data, to determine if they warrant further refinement.

Although the Agency should be commended for its creative and resourceful use of existing data to estimate specific HAP emission rates, the Subcommittee identified several opportunities for the Agency to improve its general description and use of the reported data sets. First, the Agency should provide a better and more complete description of the data elements contained in Tables B.1.1 and B.1.2. A reviewer of these tables would find it difficult to discern what statistical measurement is actually being reported; i.e., mean, median, or upper confidence limit (UCL). Second, the Agency should explore using means as inputs to the HAPs emission rate estimate methodology, since the means of these likely skewed distributions would provide a quick screening tool that is more conservative than the median and less conservative than the 95th percentile upper confidence limit (UCL). The concern is that simply using of the 95th percentile UCL would screen out very few, if any, sources. Countering this concern, of course, is the unknown impact of upset conditions, as noted above, whose analysis also needs attention. Finally, to provide a reviewer of the methodology an opportunity to reproduce any or all of the emission rate estimates, the Subcommittee recommends that the Agency provide an example within the document that illustrates the proper use of Equations 1 and 2.

As noted in the response to Charge Question 7 below, the Subcommittee found that the analysis of uncertainty and variability was incomplete in several respects, thereby depriving the risk manager of important information when making these important decisions.

3.2.2 Multipathway Risk Assessment

To estimate the specific HAP emission rates from both the process and process fugitive emission sources, the Agency employed site-specific HAP emissions information from facility compliance reports, as well as information from the BID data base, where necessary, in the multipathway risk assessment. Although the Subcommittee commends the Agency for demonstrating resourcefulness in employing the best available site-specific data to generate HAP emission rates, there is concern over the general approach used by the Agency in employing secondary data to estimate site-specific HAP emission rates in the multipathway risk assessment.

To improve the scientific defensibility of both the stack and fugitive HAP emission estimates for the multipathway risk assessment, the Subcommittee developed several recommendations for consideration by the Agency. First, prior to using secondary data for site-specific emission estimates, the Agency needs to evaluate the quality of the individual data sets using a clear, easy-to-follow, and well-documented methodology. Development and implementation of a technically sound data quality evaluation methodology will provide the Agency with a framework for establishing the minimum data quality criteria for use in residual risk estimates. Second, to leverage limited time and resources, the Agency should collaborate with its industrial partners to identify and collect additional site-specific monitoring data for use in estimating process and process fugitive HAP emission rates. Third, because of its relative importance in characterizing human health and ecological risk, existing air monitoring data, where available, should be employed by the Agency for the

groundtruthing of site-specific fugitive HAP emission estimates. Information on the frequency and extent of non-routine, or upset, conditions must be considered. Finally, to assist a reviewer in reproducing any or all of the final risk assessment numbers, the Agency should present a detailed example illustrating the basic process by which a data element contained in a NESHAP secondary lead smelter compliance report is used to generate final human health and ecological risk estimates.

3.3 Charge Question 3: Models

Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the State of the science, does the risk assessment use an appropriate multi-pathway model? The assessment uses the IEM–2M model, with some modifications. Is the IEM–2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach that is available at this time that EPA should consider?

3.3.1 Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis?

Both the SCREEN3 and Industrial Source Complex Short Term 3 (ISCST3) models have become widely accepted tools-of-the-trade and probably are the most suited for this point source category. However, there are minor shortcomings in the models that need to be clearly articulated. The conservative screening nature of SCREEN3 is designed to "capture" all facilities that may need further investigation. As a result, the output should result in many false positives which may reduce the credibility of the model.

In the current assessment, the Agency uses the IEM–2M model for its multipathway analysis. Although it is the only multipathway modeling tool that the Agency has readily available for use, there are a number of concerns regarding the model that are discussed elsewhere in this Advisory. In the meantime, it should be noted that OAQPS is in the process of developing the Total Risk Integrated Model (TRIM) as a flexible, state-of-the-art model for evaluating multimedia chemical fate, transport, and risk of HAPs. A recent review of this effort by SAB's Environmental Models Subcommittee found TRIM to be promising and innovative, while providing a number of recommendations for further improvement (SAB, 2000). When TRIM becomes available, it should provide an improvement over the modeling framework used in the current report.

While understanding the need for the Agency to move ahead with the Residual Risk Program, the Subcommittee is concerned that the IEM–2M model, as currently employed, is not able to provide the level of technical information that is needed for making scientifically sound regulatory decisions. Conceptually, the TRIM model is a significant improvement over IEM–2M. However, TRIM faces development challenges of its own that will require resources to address. Therefore, the Agency faces the difficult near-term choice of trying to improve an inferior model or committing to complete a superior model. The Agency needs to develop a plan for how and when they will use these models and how they will effect a transition from one to the other.

3.3.2 Are the models applied correctly?

A number of assumptions in model execution can affect the outputs. For example, it was assumed that all emissions come from the center of the facility, when, in fact, the exact location of emission source—currently unknown—should have a strong influence on predicted downwind exposure levels. Locations of stacks in relation to buildings and building sizes can also result in an incorrect estimation of exposure rate. Also, using meteorological data from the nearest reporting meteorological station is an approximation commonly employed. However, risk assessors and risk managers need to be aware of the suitability of this approximation in some locales, such as those with complex terrain and/or long distances between the facilities and the station.

A major issue which must be addressed is how to consider historical lead and other persistent chemical contamination at the site which was deposited prior to the promulgation of the MACT standard but which may nonetheless substantially contribute to on-going exposures post-MACT. A residual risk analysis that does not add exposures to baseline contamination to the estimates of on-going contamination may vastly underestimate the hazard quotient at the site and incorrectly conclude that the on-going releases pose risks at less than threshold levels.

The Agency chose four cases with relatively high projected risks as illustrative examples, including both urban and rural settings. The Subcommittee understands that the terrain in each of these four cases was unremarkable, and, consequently, it was reasonable to model them in that way. In the final residual risk assessment for this source category, all of the facilities in the category will be modeled individually, and complex terrain, downwash, and other model adjustments will need to be incorporated into that analysis, as appropriate.

Other issues raise questions that should be addressed in subsequent reports. For instance, classification of metals as persistent, bioaccumulative toxicants (PBTs) is problematic, since their environmental fate and transport cannot be adequately described using models for organic contaminants. Also, hazard indices for the ingestion pathway were developed separately from those for inhalation, and the impact of this strategy on the non-cancer results is unknown.

3.3.3 Given the state of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM–2M model with some modifications. Is the IEM–2M appropriate for use in this regulatory context?

The IEM–2M modeling was performed as a set of linked Excel spreadsheets. Although pertinent equations were given in Appendices, the implementation of the modeling effort needs to be carefully examined. The spreadsheets were not provided to the Subcommittee in time for substantive review by the members, and implementation of complex spreadsheet models can often lead to unsuspected errors. Therefore, the Subcommittee was unable to verify the figures and can only encourage the Agency to carefully examine the quality control applied in the construction of the spreadsheets. Further, the spreadsheets should be available to the public.

The Subcommittee understands that use of the IEM–2M model for the case of mercury (Hg) has benefited from some limited peer review. However, adaptation of the model to address HAPs other than Hg does not appear to have been rigorously evaluated (Rimer, 2000). In view of the unique environmental chemistry of mercury, extrapolation of the model to other metals must be made with extreme caution.

Through application of the model to a number of source categories and a number of pollutants with different behaviors, the Agency will have the opportunity to evaluate the model, at least in part. While human exposure data are rare, data on environmental concentrations of pollutants in various media are more widely available. In many cases, simply knowing that the model estimates are within an order of magnitude of measured environmental concentrations would provide much greater confidence in the model as an analytic tool. In particular, it would be important for the Agency to show that the multipathway model produces approximately correct estimates results for the concentrations in food of dioxins/furans and mercury, two important and difficult to model pollutants. If the evaluation exercises indicate that the model is at variance with reality, the model will have to be revised and previous results may need to be recalculated.

At the same time, the Subcommittee recognizes that the Agency is moving toward final development and implementation of the TRIM computer model, which would replace the IEM–2M model. Therefore, the Agency will have to balance the competing needs of making significant improvements to the old model vs. completing development and evaluation of the next generation model.

In its present form, the model can be used to show that there may be a relationship between atmospherically deposited HAP and the total burden of the particular contaminant in a target ecosystem. It cannot reliably quantify the amount of deposited HAP expected to be transferred to the human food chain. While some of the problem could arguably be related to an overestimate of fugitive emissions, it is clear that missing process considerations in the model severely limit its ability to simulate the movement of materials in the environment. For example, the transfer coefficients have been estimated without considering the effects of biogeochemical processes on contaminant reaction rates, speciation, and bioavailability. By ignoring the physical and chemical drivers, the IEM–2M model may have yielded grossly unrealistic concentrations of some contaminants in environmental contaminants. Table 6.8 (p. 160, Vol. I) provides an excellent example of the model inadequacy. The calculated concentrations of lead in surface water near a secondary lead smelter is reported as 103 to 106 μg/L, which is a high enough concentration of lead to sterilize the water. These unrealistic estimates should be identified as such, and appropriate adjustments made. In real life, most of the deposited lead would be adsorbed onto particulates and removed to the sediment. This scavenging removal could readily reduce the dissolved lead concentration to the measured value of 0.002–2.0 μg/L. Exaggerated concentrations, as well as unrealistic risks that have been reported for other contaminants, might likewise be traced to model deficiencies. This is an exam-

ple of how the results of the model can be compared with what can be reasonably assumed about the functioning of a water system. The consequence of this comparison should be a reevaluation of the results so that the estimated concentrations are brought into line with what would be reasonably observed in real ecosystems. A simple re-scaling of the fugitive emissions estimates, alone, is not likely to solve some of these obvious problems.

The IEM–2M has a number of limitations of which the decisionmakers need to be aware. The model does not differentiate between natural and anthropogenic fractions of a contaminant in a given environmental medium. It estimates the incremental levels/effects without considering the levels/effects of the contaminant that have already been built up in the environmental medium. The Subcommittee suggests that the Agency discuss how inclusion of baseline concentrations (that is, contributions from natural plus anthropogenic sources other than the post-MACT facility) would affect estimated total and attributable risks. The model does not insure mass balance, nor does it account for feedback mechanisms between environmental media. While the IEM–2M can be used to estimate individual excess risk, it is not at all clear from the documentation that it can provide the spatial and temporal distributions of exposure that will be needed to provide the link to distributed populations. Therefore, additional refinement made be needed so that the model can be used to estimate the population risk.

Uncertainty analysis, a critical adjunct to risk analysis, is not included in the IEM–2M model. In view of the uncertainties and assumptions in the model, groundtruthing should be an essential aspect of the model analysis.

3.3.4 With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly?

The IEM–2M model should be regarded, at best, as a work-in-progress. The Subcommittee understands that the IEM–2M will be replaced by the TRIM model, referenced above, once the latter has been sufficiently well-developed. In the meantime, in light of the limitations noted about the IEM–2M, its results must be regarded with informed caution.

3.4 Charge Question 4: Choice of Receptors

The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?

The home gardener and the farmer are acceptable receptors for this task, but their assumed exposure scenarios need to be modified in order to provide a more realistic estimate of the risks to typical members of the local community. Specifically, the input assumptions for both scenarios may be unrealistically high compared to the real exposures of the local residential and farm communities, particularly regarding inhalation and food preparation activities. The inhalation exposures assume that the receptor is exposed to outdoor concentrations 24 hours per day. The food ingestion pathway assumes that home-grown produce is not washed. The risk model results are very sensitive to these assumptions. Moreover, these exposure assumptions make it especially difficult to check the model results through comparison with data. Existing and potential data on human exposure levels are likely to be from people in nearby communities who do not have these high-end exposure behaviors. For these reasons, the Subcommittee recommends that the Agency also model the exposure of home gardeners who are not outside all the time and who do wash their home-grown produce.

Further, the case study assumes continuous exposure over a lifetime for inhaled HAPs but exposure over shorter periods for ingestion of soil, water, and produce containing HAPs; i.e., 12 years for a home gardener and 17 years for a farmer. The reason for this apparent inconsistency should be made clear.

The overall characterization of the risks to the local community needs to be clarified when the population exposure assessment is completed.

3.5 Charge Question 5: Ecological Risk Assessment

Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

3.5.1 General Statement

In the previous SAB review of the residual risk issue (SAB, 1998b), the Subcommittee strongly encouraged the Agency to elevate the prominence of ecological risk and to establish a commitment to ecological concern that was more nearly coequal to that of human health. The recommendation was driven by the neglect of

ecological and natural resources considerations in the draft Report to Congress (USEPA, 1999).

At the March 1 briefing, the Agency stated that the risk to ecological and natural resources will not be addressed at this time in other than a screening level analysis; i.e., a hazard assessment, rather than a risk assessment. This position is unfortunate, even for a document that is admittedly a work-in-progress, since this shortcoming was strongly identified in the Board's earlier report (SAB, 1998). Such a position would be unacceptable in the final document in that it would ignore the legal mandate to avoid "an adverse environmental impact" that is "significant" and "widespread" and likely to result in the "degradation of environmental quality over broad areas" (CAAA Section 112(a)(7)). By pursuing a hazard assessment for secondary lead smelters rather than a risk assessment, the Agency will likely generate a large number of "false positives" that will make the task of the risk manager more difficult. It could also have the unwarranted effect of setting a precedent for using hazard assessment for ecological and natural resources analysis in lieu of a risk assessment for future residual risk analyses.

3.5.2 Given currently available methods, are they for the ecological assessment appropriate?

As a matter of first importance, the document should indicate whether the ecological risk assessment presented here is being developed in accordance with the Agency's Ecological Risk Assessment Guidelines (EPA, 1998). These guidelines have been developed over several years, have involved many experts from the ecological science community, and have been endorsed by the SAB (SAB, 1997).

The ecological risk screen is underpinned by five concatenated models, with the term "model" used loosely to include both formally constructed code, as well as more simple spreadsheets. The source, dispersion, deposition, and multipathway models are the same as those used to conduct the human health characterization. The fifth and last model—and the one unique to ecology and natural resources—is the spreadsheet to screen for ecological effects using the Hazard Quotient (HQ) and Hazard Index (HI) methodologies. The only two models that are specifically relevant to ecology and natural resources are the multipathway and ecological effects models.

(a) *Multipathway Models.*—The multipathway model is appropriate for the task of characterization of exposure and supporting a risk assessment. The model has the necessary features to handle the transport, transformation, and fate of organic and inorganic compounds in multiple media; i.e., soil, water, air and biota. In light of the results from both human health and ecology analyses, the "screened risks" appear to result from a few critical parts of the code, most notably soil-to-plant uptake, atmosphere-to-plant deposition and accumulation, bioaccumulation in the food chain, and transport in aquatic environments. Because these processes are so instrumental in the overall risk analysis and because the model's validity was repeatedly questioned, it is recommended that these critical subcodes be peer-reviewed to assure that the mathematical formulation is reasonable, current, and scientifically defensible. However, as noted above in Section 3.3.3, the Agency needs to balance efforts to improve the IEM–2M model against the need to develop and implement the next generation models, such as TRIM.

Although multipathway methods are more than adequate for the task of screening and are certainly the appropriate method for a risk assessment, it is not necessary to use multipathway models in the initial screening assessment. Traditionally, multipathway models are reserved for those compounds that are persistent and bioaccumulative toxicants (PBTs). Unless the entire list of HAPs is made up of PBT chemicals, it would be more efficient to screen using simple fate and direct exposure models. If a PBT compound were to pass the toxicity screen (HQ<1.0), the hazard of direct contact would likely be insignificant, and the Agency could decide if the compound warrants a review of higher trophic considerations based on size and spatial distribution of the industry source category, plus the dispersion potential of the HAP. If the sources were many, large, and widely distributed, it might pass the test of being "widespread" and likely to result in "degradation in environmental quality over broad areas". Otherwise, only compounds with HQ>1.0 would be the subject of the multipathway analysis.

(b) *Ecological Risk Screening (i.e., Hazard Model.*—The Agency provides a rudimentary hazard ranking or screening process for culling through the HAPs associated with secondary lead smelters source category. The method is based on the generation of Hazard Quotients (HQs) which are simple ratios of environmental concentrations to effects-based environmental benchmarks. The benchmark is a concentration level in a medium at which little or no potential exists for an hazard. As a screening tool, this approach is valid, although it necessarily results in a high number of "false positives". Screening ecological hazards with this approach is well-

established for use in ranking and prioritizing hazards associated with chemicals; e.g., new product design and approval, risk-based corrective actions at contaminated sites, and prioritization of resources in regulatory programs.

As is well-stated in the case study, this conservative methodology is only used either to remove chemicals from further risk management consideration (i.e., the risk is acceptable) or to indicate that there is a need for further analysis. The HQ approach with such conservative effects benchmarks is really aimed at protecting all individuals in the ecosystem and, by inference, to protecting the structure and function of the ecosystem in which that individual lives.

3.5.3 Are they (the models) applied correctly

Given that this analysis is a screening exercise (i.e., hazard assessment) and not a risk assessment, the models are applied correctly, with the exception of the summation of HQs, as discussed below. There are several key aspects of the application for a screening exercise that warrant the Agency's attention:

(a) *Top Carnivores.*—This functional group is omitted from the model in terrestrial ecosystems; yet it is likely to be the most responsive functional group for PBTs. The rationale for not including this functional group (i.e., "Data are not available") is contrary to what can be done in a screening exercise.

(b) *Background Concentration.*—For ecological systems, the inclusion of geochemical background concentrations is more important than for human health, particularly for those chemicals that have a natural source; e.g., manganese, mercury, and nickel. The natural background issue should be re-evaluated in order to address the risk to ecological and natural resources.

(c) *Summation of HQs.*—Generating an HI by summation of HQs for chemicals in different classes (e.g., metals and organics) or for obviously different organics (e.g. phthalates and PAHs) goes beyond current good practice in screening ecological risks. The resulting HI is possibly misleading. Summation of HQs should be limited to chemicals that operate via the same mode of action on the same target organ or system.

3.5.4. Are the ecological benchmarks appropriate?

It is not possible to completely answer this question from the information given. The selected benchmarks represent the current State of the practice for screening assessments, many of which have been developed for use at contaminated sites as a means of focusing management action on only the chemicals of greatest concern. For some of these situations, especially those involving water and sediment, there may be different benchmarks for freshwater and marine systems, and it is not clear which was used in this case.

What is clear is that these numbers should not be used in a sophisticated risk assessment. The data behind these criteria may support a risk assessment, but the final "criteria value" can only be used to eliminate chemicals of concern. As HQs are refined, the exposure estimate should be refined to reflect site-specific conditions, and the characterization of effects should also advance from a general benchmark to an estimate of a toxic threshold, based on dose-response data for a representative or surrogate species.

3.6 Charge Question 6: Health Risk Assessment

Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose-response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose-response assessment appropriate? Are the dose-response assessments appropriately incorporated into the assessment?

The Agency has used a reasonable approach to summarize the toxic effects and the dose-response values for the HAPs included in the multipathway analysis. The document succinctly summarizes a tremendous body of information and accurately describes the endpoints upon which reference doses are derived. The important information related to each is adequately summarized.

The toxic effects and dose-response analysis information are derived from multiple sources according to the following hierarchical structure: Integrated Risk Information System (IRIS), Agency for Toxic Substances and Disease Registry (ATSDR) toxicology profiles, Health Effects Assessment Summary Tables (HEAST) and State of California Environmental Protection Agency (CalEPA) values. However, the document does not provide the rationale for the specific ranking. The clarification provided at the March 1 meeting should be a part of the document, including the intent to make chemical-by-chemical decisions about which data base to use and the often

higher quality of information in the CalEPA data base (CalEPA, 19 . . .) than is found in the older HEAST compendium (USEPA, 1994).

The residual risk exercise emphasizes, once again, the importance of having accurate, current information in the Agency's IRIS data base. As it has been stated in the past (NRC, 1994; USEPA, 1999), the SAB continues to encourage the Agency to create and maintain a credible set of data in IRIS. Another SAB panel will review a Congressional-directed study of IRIS later this year.

While the case study has employed methods that are routinely used at the Agency, the Subcommittee has some concerns. The approach appears to utilize the default assumption that all health effects described are of comparable severity and concern. For example, risk estimates derived for some of the HAPs compounds are based on rather vague endpoints, such as body weight loss, which are not explicitly associated with any disease process; whereas, in other cases, the assessment may center on effects, such as pulmonary or neurotoxicological effects, that are of a more grave character. This approach is another example of the conservative stance taken through much of the analysis. However, the risk assessor and the risk manager need to recognize and appreciate these differences in potential severity of health effects when comparing and combining the results of the analysis.

Another supposition which may ultimately prove problematic is the assumption that effects of mixed exposures are additive. In reality, mixtures may produce effects that are additive, synergistic (potentiated), or even attenuated. The current default assumption is necessitated by the absence of any information with which to more precisely model such effects and, therefore, represents a conservative approach.

A related point is the difference in confidence with respect to cancer potencies calculated from human vs. experimental animal data. Unit risk estimates based on human data are generally maximum likelihood estimates calculated from studies that, if anything, have biases toward underestimating human incidence of carcinogenicity because they are usually based on worker populations, not children, who are arguably more susceptible. Exposure estimates in this case usually have substantial uncertainties that tend to bias comparisons of more vs. less exposed workers toward the null and, therefore, toward lower estimates. On the other hand, animal-based unit risk estimates include a number of procedural assumptions that are thought to usually lead to overestimates of risk, such as the use of 95 percent confidence limits, choice of the most sensitive species for projection to humans, etc.

The Subcommittee is concerned about the potential problems associated with a residual risk assessment that must omit HAPs in assessments of the risk of noncancer endpoints due to the fact that there are no dose-response data on these compounds currently available and that Agency policy dictates against using probabilistic values. For example, in the case of secondary lead smelters dioxins/furans are omitted from consideration as a non-cancer risk due to the lack of data. While the Agency indicated at the March 1 meeting that dioxins/furans would be included in the next iteration of the process, other compounds are, and presumably would continue to be, omitted due to the lack of data. The document needs to address this limitation directly and indicate how the decisionmaking process will take these vulnerabilities into account. As one possible way to address the problem, the Subcommittee recommends that the Agency explore the use of quantitative structure-activity relationships (QSAR) to assess whether any of the organic HAPs with insufficient dose-response information might, in fact, be a significant concern that is currently being overlooked. While QSAR would not play a definitive role in the analysis, it could identify potential problem compounds that are otherwise ignored entirely in the current case study.

The Subcommittee understands that the Residual Risk Program is following current Agency guidance by calculating hazard quotients (HQs) for non-carcinogens, with the implicit assumption of a threshold in the dose-response curve. However, the HQ approach is not a true risk assessment (i.e., a probabilistic estimate of the likelihood of harm), is not based on a biologically compelling foundation, and does not explicitly address the possibility of low-dose effects above or below the reference dose (RfD), even for highly non-linear dose-response relationships. As a part of its overall effort, the Agency should continue work on developing and implementing a more scientifically based risk assessment procedure for non-carcinogens that would lead to improved risk assessments. For example, some reports now suggest that the slope defining Pb effects is actually steeper at blood lead levels below 10 μg/dL than above it.

As noted above, the Subcommittee is concerned about how some of the results of this analysis will be treated. In particular, while the generation of hazard index (HI) values can be useful, despite its implicit limiting assumptions (e.g., additivity of all effects), there is no indication in the document of how these values will be used in the final decisionmaking process. Without some indication of how they will be used

and for what purpose, the Subcommittee is unable to comment effectively on the appropriateness of HIs in this case.

Also, as discussed above, it is clear that the residual risk analysis results in an estimate of incremental exposure and, in the case of cancer, incremental risk of disease. However, it is not clear how the Agency plans to use the incremental exposure estimates in the case of non-cancer effects, when these additional exposures (that is, in addition to already existing exposures from other sources) might subject some elements of the population to a "level-of-concern"; e.g., HI>1.

Two examples are included in the document that relate the derived HQs to anticipated consequences of human exposures: the cases of lead and dioxins/furans. The lead case allows some type of human health risk assessment, since blood lead levels associated with specific human health effects have been well documented. However, in both cases, the outcome suggests problems with the models. Specifically, the derived blood lead values are so high that they would be associated with gross toxicity; e.g., acute encephalopathy and even mortality. If such effects are real, it is quite likely that the problem would have already been discovered by the local medical community. Therefore, these derived blood lead values are a clear indication that the multipathway model has problems and needs to be revised.

As noted above, the Agency indicates that some of these problems may not be problems of the model per se, but rather problems associated with overestimates of fugitive emissions. While the Subcommittee agrees that overestimates of fugitive emissions may play a role here, there is no indication of the extent of that role. On the other hand, it is quite clear that the model fails to consider biophysical chemical processes that definitely play an important role and that the model has not benefited from a rigorous peer review. (The model was not a major focus of the SAB review of mercury (SAB, 1998a).) In fact, some consideration should be given to using the TRIM model in its incomplete version rather than continuing to use IEM–2M. A more integrated and complete uncertainty and variability analysis would help to clarify these matters.

Additionally, Table 6.9 compares modeled concentrations of dioxins/furans in human milk with measured concentrations in human breast milk. It shows that modeled concentrations are notably lower than those measured in human milk. These findings are interpreted as indicating that emissions of dioxins/furans from secondary lead smelters are a minor contributor to overall dioxins/furans nationwide. An alternative interpretation (namely, that dioxin is not adequately modeled in the residual risk assessment paradigm) is not even considered, which clearly seems to be an oversight.

Finally, at this stage in the development of the assessment, the Agency has not generated any population risk estimates. The Subcommittee would like to emphasize the fundamental importance of generating such estimates in the final document. Currently, there is little discussion of how this critical step will be taken.

3.7 Charge Question 7: Uncertainty and Variability Assessment

Did the assessment use appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

In short, the uncertainty and variability (U&V) assessment is one of the weakest parts in the draft case study and appears to be a rather peripheral afterthought to a main analysis, rather than an example in which U&V considerations are fully integrated into a project. As noted above, this concern was mentioned prominently in connection with the multipathway exposure model results.

The fact is that U&V analysis has advanced significantly over the past 10 years. The combining of traditional point-estimates of parameters, together with and their separate ranges of uncertainty, hardly qualifies as even a "quick-and-dirty" analysis these days. Instead, readily available computing power and increased experience with distributions for various quantities (e.g., EPA Exposure Factors Handbook (USEPA, 1997) have combined to made distributional analysis of U&V, even simple Monte-Carlo analysis, much more the standard expectation for the field. These techniques have by no means reached the level of being "cookbook manipulations". Rather, they do require skilled, knowledgeable judgments on a case-specific bases. However, they are being applied with much greater frequency, providing the basis for much more informed decisions, particularly in significant decisionmaking contexts, such as the residual risk program under discussion here (Cullen and Frey, 1999; Thompson, 1999; Hattis and Froines, 1992; Hattis and Burmaster, 1994; Hattis et al, 1999).

In the first instance, the terms "uncertainty" and "variability" need to be clearly defined and consistently used. Variability refers to real differences in things or peo-

ple that would be seen even with perfect measurement or estimation techniques; e.g., the differences in the body weights of the individuals in an exposed population around a lead smelter. Uncertainty, by contrast, refers to the imperfection in our knowledge of the values of a specific parameter; e.g., characteristics of the throughput of material at a particular lead smelter. Generally, uncertainty can be reduced by gathering better information, but real variability will be unchanged, although it can be better characterized by better information.

The failure to distinguish variability from uncertainty in the present analysis almost guarantees confusion. Variability and uncertainty are different things and require different techniques for estimation. For example, soil type may vary from facility to facility, but it may be relatively uniform at any one facility. If the soil type is not known at a particular facility, the distribution that describes variability among facilities where soil type is known can be used to construct an uncertainty distribution for the particular facility.

Without understanding the distinction between uncertainty and variability, a risk manager cannot make a fully informed decision based on the results of the U&V analysis. A properly prepared analysis of uncertainty and variability analysis should help a risk manager to answer the question, "What actions must I take in order to assure that no more than Y percent of the population exposed incurs a risk greater than X, with confidence Z?" In other words, the risk manager should be able to understand not only how risk might vary from person to person, as described by X and Y, but also how sure we are about our estimates, as described by Z (cf., Hattis and Anderson (1999), and Hattis and Minkowitz (1996)). That kind of goal for the U&V analysis is not made explicit in the Agency's case study.

Although it is challenging to carry out an analysis that fully separates considerations of uncertainty and variability, and although it is sometimes a matter of perspective whether a given distribution describes uncertainty or variability, the Subcommittee did not find the Agency's justification for combining the two in its analysis convincing. For example, consumption rates of water and food really do vary from person to person, and the corresponding calculated risks due to any specific smelter's emissions would also vary accordingly. On the other hand, the distribution used for the annual average emissions of the smelter is dominated by uncertainty, since so few data are available from post-MACT facilities. However, there is little expectation that annual average emissions (in g/sec) would vary substantially from year to year.

The Agency chose to use distributions for emissions and for some elements of the exposure analysis, but not for the parameters of the fate and transport models or of the toxicity analysis. While the Subcommittee understands that it is currently Agency policy not to undertake distributional analyses of toxicity information, the Agency should reconsider this policy. Some members of the Subcommittee believe that omitting the uncertainties in the toxicity data from the assessment vitiate much of the benefit of performing the U&V analysis, and that the literature does contain early illustrative efforts to estimate uncertainty and variability for risks of both cancer and non-cancer endpoints (Hattis et al. (1999); Hattis and Barlow (1996); Crouch (1996)). Moreover, omitting any distributional treatment of the transport and fate module makes any conclusions from the U&V analysis suspect. Although the Subcommittee agrees that iterative calculations using the full ISCST–3 and IEM–2M models would be computationally intractable, it does not seem unreasonable to introduce some overall uncertainty distribution to represent the uncertainties in risk introduced by all of the assumptions and parameter choices embedded in those models. The governing notion is that the while distributions based on data are certainly preferred, the use of subjective distributions—fairly (unbiased) developed, technically rationalized, and clearly presented—can provide useful and valuable insights that can credibly inform the decisionmaking process.

In this case, the Subcommittee also found that the description of how some of the distributions were derived to be incomplete, even for the parameters that were included in the analysis. Although in many cases the Agency simply took distributions that had already been described for other Agency purposes (e.g., the Exposure Factors Handbook (USEPA, 1997)), in others it seemed to arrive at a distribution with very little evident rationale. For example, the document states, "we assumed that annual lead emissions follow a log-normal distribution, with the emission rate falling within two orders of magnitude of the value given in the compliance report 95 percent of the time" (later corrected to 99 percent of the time). Although the document is far from clear on this point, in oral presentations EPA representatives indicated that this assumption was based on some analysis of emissions observations by a knowledgeable contractor, Dr. Christopher Frey—which was useful, reassuring information. In the next iteration of the document, this analysis should be presented in detail and, to the degree possible, the analysts should consider the need for ad-

justments in observed emissions data across plants to account for differences in throughput characteristics, among other relevant factors. To the degree that day-to-day and/or plant-to-plant variations in emissions can be explained on the basis of factors such as throughput, the estimate of uncertainty in annual average emissions may be reduced.

Another major problem is that the current analysis does not follow existing EPA guidance on the documentation and presentation of distributional analysis (USEPA, 1997). Specifically, that guidance emphasizes that the model itself and derivations of distributions used in the analysis must be transparently presented in sufficient detail that a reviewer can reproduce them. Therefore, the case study itself should have included, as an appendix, both the extensive display of results for each stack, as well as the spreadsheet model equations and the mathematical form of the distributional assumptions that were used. The Subcommittee believes that any report of the results of a U&V model must include documentation of the model spreadsheet itself, the dependencies among parameters that are or (in the case of independence assumptions) are not built into the model, and the precise mathematical form of the distributional assumptions. For example, from the current presentation it is not clear if correlations have been built into the emissions of lead and other HAPs from different stacks that might reflect different processing rates on different days, or whether these are considered as independent.

Finally, the Agency's treatment of "upset conditions" is not clear. While there is a description of the assumptions made to account for such occurrences, the explanation/justification of the assumptions is lacking. Since emissions associated with upset conditions can, in some cases, outweigh the impact of emissions during normal operation, it is especially important that this situation be directly addressed and clearly explained.

In summary, the Subcommittee was unconvinced by the rationale for the selection of variables and pathways to address in the U&V assessment and found the methods for quantifying the U&V suspect in at least some respects. The Subcommittee recommends that the Agency redo the analysis starting with a clearly stated management objective, incorporating a better degree of separation of variability from uncertainty, and generating a more comprehensive treatment of the most important sources of uncertainty and variability.

3.8 Charge Question 8: Presentation of Results

Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

This Charge Question addresses the important issues of (a) risk characterization, which goes beyond numerical presentations of results to qualifications and discussions of uncertainty and data limitations (USEPA, 1999, p. 70), and (b) risk communication, which conveys those results in easily accessible terms to interested and affected parties. The focus of the discussion here is on the presentation of the results. The majority of Subcommittee views on the various aspects of the results themselves are found in response to the earlier Charge Questions.

3.8.1 Initial Screening Analysis

According to EPA, the screening analysis is designed to obtain preliminary inhalation risk estimates for the 23 facilities and 50 HAPs. In the course of the analysis, many other simplifications and conservative assumptions are made, such as generic assumptions about releases of HAPs from smelter facilities. The default release characteristics used in the SCREEN3 modeling are clearly presented in Table 2.2. The Agency has indicated that all of the assumptions used in the initial screening analysis are not conservative and that best estimates (simplifying defaults) are used. A sensitivity analysis or other qualitative discussion of the effect of these selections on the results should be included in order to give the reader a better appreciation of the robustness and the conservativeness of the initial screening analysis.

In some cases, the report identifies areas in which information was not available, e.g., housekeeping procedures for fugitive emissions. During the Agency presentation at the meeting, four possible approaches to estimating fugitive emissions were presented: back calculating from lead monitoring data, theoretical modeling, extrapolating from another source that has conducted fugitive emission testing, and direct measurement. These approaches should be identified in the report, along with general methods for dealing with missing data, to help the reader understand what would be required to gather this information.

The discussion of the screening (Section 2.2.4) portrays easily readable risk results for each HAP for cancer/non-cancer risk. It presents maximum and minimum risk values for each individual organic and metal HAP. The table should include an

explanation of the maximum and minimum values; i.e., they are simply the range of estimates determined for all of the facilities.The text discussion clearly indicates the bottom line (risks above one-in-a-million) and the fact that some of the HAPs are associated with higher values. Procedures for arriving at the risk estimates and identifying where overestimates occurred are clearly presented.

Uncertainty estimates are not presented in the tables, nor are they discussed in this section. This should be explained in the results section. The text should expand on the potential impact of the discussion in footnote 8 concerning the lack of dose-response values for the ten HAPs that have not been considered in the case study due to a lack of available dose-response information.

The form in which numbers are presented in Tables 2.3 and 2.4 (i.e., as exponents) is not easily communicated to the public, and perhaps an alternative means should be considered. The Agency should keep this form for the Tables, but should consider using consistent cancer risk expressions in the narrative of the case study, avoiding the use of different expressions for cancer risk. For example, the use of the expression 8-in-10,000 should be changed to 800-in-a-million. This will allow the lay reader to place the results into the common context of the less than one-in-a-million expression which appears in the CAAA and throughout the case study.

Section 2.2.4.2 identifies a large set of defaults and assumptions, without providing an explanation or rationale. More discussion of these defaults and assumptions is warranted, including statements about how they affect the final result. If the effects of the assumptions are unknown (as identified in this section), some discussion of why this is the case should be included.

The conclusion section for the initial inhalation screening analysis (parts of Section 2.2.4.3), are troublesome because of their lack of specificity with respect to the chemicals being discussed and the sources. For example, in the statement "Metal HAP risk results exceed these levels", the identity of the metal HAP is unclear. Furthermore, any conclusions for this section are questionable since, as is pointed out in the report, the largest source is fugitive dust emissions which are very uncertain due to uncertainties in emission rates and the failure of the estimates to agree with NAAQS measurements made in the vicinity of these facilities.

Section 2.4 (Overall Summary of the Initial Screening Analysis) is very brief and would benefit from a description of the organization of the initial screening analysis and how it leads to the multipathway screening analysis. The selection of facilities for the refined analysis needs to be placed into some type of risk management framework. These facilities were obviously selected since they represented the highest risk (e.g. cancer risk > 9000-in-a-million and HQ>70). However, a defined process is needed for selecting which facilities will be included in the refined analysis. For example, if the 100-in-a-million cancer risk value were used only two of the 23 facilities would pass the screening criteria. The use of this cancer risk range would be consistent with the benzene decision and the Commission of Risk Assessment and Risk Management (CRARM) recommendations by having the total cancer risk from the facility being in the range of less than one to one hundred in a million for the screening assessment. In addition, if a hazard quotient of 10 is used as an action level for the screening assessment, as recommended by CRARM, then a decision to eliminate facilities 6, 9, 12, 20, 25 and 29 for further analysis of noncancer health effects can be made. A section entitled 2.X Initial Screening Analysis: Selection of Facilities for Refined Multipathway Analysis should be added in the Chapter 2 results section in order to present this rationale more clearly.

Section 2 needs to provide a better description of the 23 facilities that have undergone the initial screening analysis. This information would include a general physical description of the facility size, location (urban, suburban, rural or industrial) and terrain, the annual amount of material throughput, the degree of facility enclosures (total or partial enclosure of fugitive sources), and, perhaps most importantly, the current HAP emission inventories for these facilities. The inventory information could be obtained from the 1996 or more current National Air Toxics Assessment (NATA) project that the Agency is working on or HAP emission statements filed with State environmental agencies. Some of this information is readily available from the "Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds" (USEPA, 1998). This information would be very useful for the risk manager when evaluating the initial screen inputs and results and would serve as a check on those facilities which would be selected for further refined analysis. The brief discussion contained in the case study is inadequate.

3.8.2 Multipathway Analysis

Section 3.3 (Results and Key Issues of the Multipathway Analysis), is much too long for a results and issues section. The heart of this material is on pp. 94–96, so a reorganization of this portion of the report would be in order.

The Subcommittee found a need for a discussion about a few key issues, in addition to those already listed in Section 3.3.2. Specifically, these are the lack of consideration of background concentrations in the risk analysis and the effects of the adjustment of the nickel inhalation unit risk estimate which reduces the conservatism of the cancer risk estimates.

The Report to Congress (USEPA, 1999) discusses the need to include background risk and the difficulty associated with this specific issue. The case study does not address background risk issues around any of the 23 facilities in the human health and ecological risk assessment. This is serious omission from the case-study, and the Agency should address this issue at a minimum from a qualitative/quantitative point of view, well beyond the comparisons made in Chapter 6. The absence of an assessment of background risk seriously impacts statements about the conservative nature of the refined screening assessment.

The use of only 25 percent of the inhalation unit risk estimate for nickel subsulfide needs to be explained in greater detail, since it will have a large impact on the total cancer risk estimates in the case study.

Some Subcommittee members thought the tables and figures were clear and comprehendible; others felt they could be clarified. For example, the plots and bar charts presented as a part of the Agency's briefing on March 1 were very helpful and could be added to the document.

HAPs that were not included in non-cancer endpoints should be clearly identified, together with an explanation of why they were omitted.

3.8.3 Uncertainty and Variability Analysis

As indicated in Section 3.7 above, the Subcommittee had serious concerns about the handling of the U&V assessment. The comments below pertain primarily to the format and presentation, rather than the adequacy or completeness, of the underlying analysis. In short, the Subcommittee finds that the presentations (e.g., graphical and tabular displays) are conceptually sound and effective. However, many of the procedures used in the assessment are not as well-laid out as they need to be.

The tables and figures used throughout Section 4 provide a concise and well-thought out approach for the presentation of variability for each scenario evaluated. They allow the reader to evaluate the broad spectrum of risk and the impacts of the various exposure parameters used in the refined multipathway risk assessment. These tables and figures significantly enhance the comprehensibility of the variability assessment results. For example, the use of a 13.3 m3 inhalation rate in the multipathway analysis (Table 4.3), when cross-referenced with Table 4.4, indicates that the inhalation value used is between the 25th and 50th percentile and is really not that much of an extreme conservative assumption. When the inhalation rate is coupled with the 70-year duration of exposure and the fraction of the day at home, the final risk estimate falls into the 95 percentile for inhalation risk. This is consistent with the recommendations contained in the NRC (NRC, 1994) and the CRARM (CRARM, 1997) reports and the language in the 1990 CAAA to estimate risk for ". . . the individual most exposed to emissions from a source . . . " This presentation format allowed the reader to understand in a rather simplistic manner the amount of conservatism that was used in the refined multipathway risk analysis for each exposure parameter. So, if the risk manager wanted to observe the impact of setting each parameter (maximum inhalation rate, maximum exposure duration, maximum ingestion rate , maximum time spent outdoors, etc.) and the impact it has on the risk estimates, it can be done rather quickly.

The inclusion of the point estimates in Tables 4.5 and 4.6 is an excellent way to concisely present information to the risk manager. The use of a large circle to identify the final cancer risk estimates on the probability figures (Figures 4.2a—4.7b) that would be used by the Agency to characterize the risk for the final risk management decision would significantly enhance the presentation of the results and make them easier to interpret. The tables and figures provide the risk manager with the ability to view the broad spectrum of risk predictions, which includes risks to the average exposed individual (AEI), the maximum individual risk (MIR) and the maximum exposed individual (MEI).

The use of distributional analysis is unclear. The technique was used for some steps in the risk assessment, but not all. For example, the distributional analysis was clearly used for exposure estimates, because data from the Agency's Exposure Factors Handbook (USEPA, 1997) were used. However, it is not clear whether the same data source was used for the emission estimates.

As noted in 4.8.7 above, the selection of variables and methods of quantifying variability and the distinction between uncertainty and variability is not clear. Such a discussion should be firmly grounded in the Agency's risk management goals and a clear understanding of how these results will be used to help achieve those goals.

3.8.4 Risk Characterization

In Section 5.7 the focus is whether the HQ values are above or below 1. The Agency should consider the robustness of such "bright line" decisions in light of the uncertainties involved. Section 5.8 was clear and acceptable to the group.

3.8.5 Summary and Discussion

Keeping in mind the limitations and problems identified with the methodology above, this section presents a good summary of results. Tables 6.1 and 6.2 provide a good overview summary of the final results for the refined multipathway risk assessments. The presentation of results could be greatly enhanced with the addition of more site-specific information to the case study. The collection of additional data should not be an overwhelming task. The Agency should consider the importance of such a refinement before the case study becomes a public document.

The discussion in Section 6.2.1.1 should be expanded. The pre-NESHAP monitoring data from New York indicates that the NAAQS for lead can be exceeded and that the stringent control of fugitives can result in a dramatic lowering of ambient concentrations of lead and probably other metal HAPs in the vicinity of secondary lead smelters.

Section 6.2.1.5 needs to be expanded since it provides information on an excellent biomarker for potential exposure; i.e., blood lead levels. The inclusion of this type of information would greatly enhance the case study. The Center for Disease Control and Prevention (CDC) and State Health Departments should be consulted to find out if there is any other information on blood lead levels in children who reside in communities that are in close proximity to secondary lead smelters.

Table 6.7 should be modified by including the distance to the monitors, as well as a brief discussion of siting issues (e.g., predominant downwind or upwind monitoring locations) before any comparisons are made. The same point can be made for the comparisons of the surface water concentrations. However, the Agency does appropriately acknowledge that the comparisons in Table 6.8 are not meaningful.

In summary, the information in the report is generally well-presented in some instances and could be significantly improved in others, as noted above. However, it is important to gather and evaluate more site-specific information, using the risk assessment tools presented in the case study, before any final risk management decisions are made for this source category.

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APPENDIX A

WRITTEN COMMENTS OF SUBCOMMITTEE MEMBERS

Each member of the SAB's Residual Risk Subcommittee prepared written comments, centered on the Charge Questions. These materials were available at the meeting March 1–2, 2000. As a result of the public meeting, some of the Members altered their original drafts and asked that the revised versions be included in an

Appendix to the Subcommittee's consensus Advisory. Other Members chose not to submit their comments for inclusion in the document.

Therefore, this Appendix contains the final written comments from those Subcommittee Members who chose to submit them for this purpose. These materials are included in this SAB document so that the Agency and the public can (a) benefit from the specific comments and (b) appreciate the range of views represented on the Subcommittee.

While all of these statements are commended to the Agency for careful consideration, unless a comment is addressed explicitly in the body of this SAB Advisory, it should be viewed as a statement from an informed individual, not as the collective view of the Subcommittee.

STATEMENT OF DR. GREGORY BIDDINGER, EXXON-MOBIL COMPANY, FAIRFAX, VA

GENERAL COMMENTS

1. A Risk Assessment strategy should be designed in alignment with a risk management process.

Although this may seem like an obvious and generic point, I feel it is very relevant to make at the onset of these comments. It became clear during the review of this case study that the linkage between the ecological risk assessment (ERA) and risk management process is weak and this weakness is likely due to a lack of clear definition on how the risk management process will proceed. I believe this lack of clarity as to how the ERA will be used to support any risk management decisionmakes it difficult to either design an ERA process that goes beyond a screening step or to define what are the Next Steps for ERA in this specific case study.

Recommendation: The footnote on Page 34 of Volume 1 indicates that OAQPS is working on developing a risk management decision framework for the residual risk program. That framework should be presented to the SAB review group to evaluate alignment between the risk assessments and the risk management process. If the strategy is not final, revisions to the case study should be deferred until the framework is available.

2. With regards to Ecological Risk assessment, the Agency needs to define what is meant by the management goal of ensuring that HAP emissions do not result in "an adverse environmental effect".

In order to evaluate the Questions associated with Charge 5, which is fundamentally, were the appropriate models used correctly, it is essential to understand what environmental attributes are being protected and at what spatial scale. In section 5.2.1 the agency sites Section 112(a)(7) of the Clean Air Act Amendments (CAAA) to say it is "any significant and widespread adverse effect, which may reasonable be anticipated to . . . or significant degradation of environmental quality over broad areas ". The key and operative terms in these statements, which require clarification, include (1) significant, (2) widespread (3) adverse (4) environmental quality and (5) broad areas. Without a clear definition of what the agency believes is the intent of these words in the CAAA, it is not possible to assess the correctness of the agencies actions. Based on an assessment strategy that uses hazard Quotients (HQ's) and conservative ecotoxicological screening benchmarks, I would have to assume the Agency's goal is to protect individuals in all populations and in all places.

Recommendation: The Agency needs to provide the appropriate clarifying discussion in Section 5 of Volume 1 or through the development of a technical policy statement which can be cited in this section.

This exercise should not be viewed as a philosophical exercise. In developing this clarifying analysis the Agency should identify some practical rules or decision logic which can reasonably be used to eliminate source categories from ecological risk. Some (but not the only) possible rules for not doing an ERA include:

(a) Source categories with a few small facilities in different regions.

(b) Source categories with a few large facilities but no persistent or bioaccumulative HAP's.

(c) Facilities in source categories where the primary releases (e.g. downwash, etc.) are contained to the site.

3. The Ecological Risk Assessment provided is a screening risk assessment and clearly is not intended to be used for risk management decisions other than "No Action" or "Further Analysis". But the recommendation(s) of the assessors for any followup options are missing.

The Agency is to be commended for so clearly stating in a number of places in the case study that the environmental hazard assessment undertaking is not ade-

quate for making a final risk management decision that would require controls or other actions to mitigate ecological risks. This reviewer is left with the question "What will the Risk manager be able to do with this analysis?" If the assessors felt that more sophisticated or detailed analysis was necessary than they should have at least said so, even if they believed performing that analysis was not in the scope at this point in the analysis. The case study is incomplete with the ERA as provided because the next steps are not clear. It would not at all be a breach of the risk assessor and risk manager roles for the assessors to provide some further definition of what they could do to explore the significance of some of the High HQ's for various aspects of exposure to key metals (e.g. Antimony) from the Fugitive emissions at facilities 3, 4 and 13.

Recommendations: The case study needs to include a section on Next step options with recommendations for the risk manager to consider.

4. The sources of uncertainty in the ERA are understated.

In section 5.7.3 the report reviews the sources of uncertainty associated with the screening level risk assessment. This review on uncertainty doesn't completely account for the uncertainty associated with the exposure estimates. Although it does identify inclusion of assumption of bioavailability and the exclusion of some pathway it does not account or refer back to any analysis of the uncertainty associated with the dispersion and fate. The uncertainty reviewed in section 4 associated with emission rates, dispersion, environmental fate and pathway analysis could easily overwhelm the uncertainty described in section 5.7.3.

Recommendation: Section 5.7.3 should recognize the uncertainty passed through from the dispersion, fate and pathway models.

Charge Question 5: Ecological Risk Assessment

1. Given currently available methods, are the models used for the ecological assessment appropriate?

In addressing this question it is important to consider my general comments listed above. The method of using Hazard Quotients (HQ's) and their summation, Hazard Indices (HI's) to screen ecological hazards is well established for use in ranking and prioritizing hazards associated with chemicals. The method has had significant use in new product design and approval, Risk-Based Corrective Actions at contaminated sites and prioritization of resources in regulatory programs. As is well stated in the document such a conservative technique is only used to remove chemicals from further risk management consideration (i.e., the risk is acceptable) or to indicate that there is a need for further analysis. What this case study does not do is take or even identify the next steps to refine the analysis of those chemicals that fall above an HQ or HI of 1.0. One would have expected that some refinement of the exposure and effects characterization for metals with the highest HQ's would have been explored. If only to see if less conservative or site-specific modifications to the exposure characterization or full use of dose-response data for relevant surrogate species might have brought the HI exceedances into acceptable ranges. As it stands now we are left with some significantly high HQ's implying to an unsophisticated audience that a serious problem exists but without any framing of an approach to validate or refute such an implication. As a risk assessor, I recognize that this is only the first step and that these HQ's can drop orders of magnitude when they are refined, but any lay audience reading this review and seeing HQ's of 400 with no action recommended is likely to be alarmed.

Recommendation: The Agency needs to have a process that goes beyond the initial step of ecological risk assessment that is taken in this draft case study and either (a) refines the hazard screening process by improving the estimates of exposure and selecting more appropriate Toxicity Reference Values (TRVs) or (b) moves into a risk assessment process that is based on more complete and relevant profiles of exposure and effects.

2. Are the (available methods) applied correctly?

For the most part yes but one particular aspects of the application of the HQ approach goes beyond current good practice, that is the summing of HQ across all chemicals. Suinination of hazards for chemicals which are operating with the same mode of action on the same target organ or system may be acceptable. But summarizing across an array of benchmarks which are based on a variety of endpoints, some of which are NOAELs and some are LOAEL's is not conservative it is misleading. I can't see any way that metals and organics could be considered additive to either the individual or at the population.

The only classes of chemicals in this case study which might allow such a summing technique would be the summation of HQ's for Dioxin/furan congeners and the summation of PAH's. But for PAH's it would still be necessary to break the summations into high and low molecular weight categories. If this were being done for as-

sessment of acute hazards I would be more accepting but with chronic toxicity criteria the endpoints could vary across growth, development, reproduction and survivorship.

3. Are the ecological benchmarks appropriate?

It is not really possible to completely answer this question from the information given. The benchmarks that were selected represent the current State of the practice for screening benchmarks. Many of these benchmarks were developed for use at contaminated sites to focus management action on only the serious chemicals of concern. For some of these lists especially the water and sediment benchmark series there may be different benchmarks for freshwater and marine systems. Which were used? The lower of the two? Which ever was available? For screening purposes this is not likely going to be a problem or certainly any error of application could be caught in the next round of refinements.

What is clear is that these numbers should not be used for any sophisticated risk assessment. The data behind these criteria may well support a risk assessment but the final "criteria value" can only be used for what has been done here which is to eliminate chemicals of concern. As HQ's are refined not only should the exposure estimate be refined to reflect site specific conditions, but also the characterization of effects should advance from a general benchmark to an estimate of a toxic threshold based on dose-response data for a representative or surrogate species.

Recommendation: If the Agency is going to do 174 source categories, it is worth the effort to develop a matrix of Toxicity Reference Values (TRV's) for various receptors and endpoints for each of the HAPs that could be used as screening values. If the complete dose-response relationships are available, then the same data could be used for (a) screening (NOAELs), and (b) first risk approximations (EC10 or EC20) and (c) complete risk distributions (Slope of the dose-response curve). Although this is not a small task, such a front-loaded effort could stream-line much of the subsequent source category analyses. If the Agency were to embark on such a task, I recommend leveraging this effort with interested industry coalitions.

SECTION SPECIFIC COMMENTS

Section 5.1

The language in paragraph 1 of page 130 is confusing. Suggest discussing hazard potential rather than potential risks.

Are all of the cited EPA documents available to the public? Is EPA 1999d available? If not should it be cited?

Section 5.2.1

As previously stated in general recommendation No. 2, this section should be expanded to give the agencies interpretation of the management goal from the CAAA. This would require defining such terms as: (1) Significant, (2) Widespread, (3) Adverse, (4) Environmental Quality and (5) Broad Areas.

Section 5.3

This section is weak because of the lack of interpretation of the management goal in section 5.2.1. It should be more clearly stated that the assessment endpoint is No or limited adverse effects to individual members of sensitive populations. There is no real consideration of impacts to structure or function. It is only a simple extrapolation to suggest that if no individual is adversely affected than neither will the service of its population or the structure and function of communities and ecosystem it lives in be affected. This assessment is being done in a fashion to protect individuals; there is nothing wrong with this if that is the agency's interpretation of adverse environmental effects. I would suggest it is a bit stringent but for a screening assessment not atypical. But ultimately the assessment of residual risk should be at a level of population or higher.

Table 5.1

Citations for Suter et.al. and Will, M.E. et.al. are in conflict with the reference list.

Section 5.7.2

The discussion incorrectly states that all facilities had HQ's >1 for metals. Facility 2 was not reported in section 5.7.1.1 or in appendix E to have HQ's >1 with or without fugitives emissions. This inconsistency needs to be corrected.

Section 5.8

As stated previously, this section should address recommendations to the manager about the need for followup actions.

Sec. 2.3 The use of lists to identify Persistent and Bioaccumulative compounds is inappropriate.

Recommendation: The Agency needs to specifically design or adapt a process to support a Residual Risk process.

STATEMENT OF DR. STEPHEN L. BROWN, RISKS OF RADIATION CHEMICAL COMPOUNDS (R2C2), OAKLAND, CA

These comments are submitted to alert the Subcommittee members to some issues I will want to discuss in our meeting on points OTHER than on my main assignment—the uncertainty and variability analysis. Along with my co-discussant, Dale Hattis, I will be submitting a formal, although preliminary, writeup on that subject.

OVERALL EFFORT

Overall, I have mixed feelings about the case study. On the one hand, its overall structure and components are similar to those in many of the risk assessments conducted in the past few years by or for USEPA and other environmental agencies such as the California EPA. It features some standard and generally well accepted models such as ISCST–3 as well as a detailed multipathway model, IEM–2M. It uses values for many of the needed parameters that can be found in standard sources such as the IRIS data base of toxicity information and the Exposure Factors Handbook. It features a screening level analysis prior to the main analysis that is designed to help the latter focus on the most important HAPs and facilities. It includes a variability/uncertainty analysis and a risk characterization section that are both recommended in recent EPA guidance on the conduct and presentation of risk assessments. Many of its assumptions are similar to those in other EPA risk assessments and therefore consistent with them.

On the other hand, it shares most of the deficiencies of those same comparison risk assessments and seems to introduce a few of its own. The conservative assumptions inherent in most Agency risk assessments are repeated here, and are not adequately balanced by the supposedly less biased uncertainty analysis. Many of the case-specific assumptions are inadequately described, let alone well justified, in the text supplied to the Subcommittee. Some of the predictions of the assessment are truly astounding (e.g., the blood lead levels calculated when fugitive dust emissions are included in the assessment), yet there seems to have been little attempt to identify and correct the problems that might have led to such conclusions. Even though the case study is not supposed to be a final assessment for the secondary lead smelter category, it should have included more thorough quality control to demonstrate how such an activity would be included in a final assessment.

In reviewing the assessment, I was struck by how similar the structure was to assessments conducted under AB2588, the California statute titled the Air Toxics Hot Spots Act. That act is specifically designed to evaluate the risks from emissions to air by stationary sources in California. In that case, the risk assessments are conducted by the facility itself using guidance provided by the State, and the assessments are reviewed by the local air district for conformity with that guidance and accuracy of inputs and outputs. The facility may submit an alternative assessment with more site-specific information and less conservative assumptions, including a distributional analysis in some cases, but the local authority is not obligated to review those assessments. The standard assessment is usually conducted with the aid of a computer model such as ACE2588 or HRA96 that was designed to follow the guidance precisely. Users are allowed to use some site-specific information, such as stack characteristics and the location of actual water bodies used as drinking water sources. The models include not only direct inhalation exposures via concentrations calculated by ISCST–3 but also via multimedia pathways similar to those in IEM–2M (although IEM–2M features a more detailed water partitioning model because it was designed specifically for mercury). Another similar multimedia risk assessment model designed for emissions to air is TRUE, developed by the Electric Power Research Institute for assessing fossil fuel power plants. TRUE includes a mercury model similar in design to IEM–2M. TRUE is generally less conservative than the AB2588 models, but is still described as conservative by its authors.

I will now provide comments by Section of the Case Study, more or less in page order.

INTRODUCTION

I was disappointed not to see a clearly articulated description of the decision that this type of risk assessment is to serve. Although the obvious application is to the

residual risk requirements of the CAAA, it is not clear that EPA knows how it will interpret those requirements in evaluating the outputs of the risk assessments. For example, how will risks to highly exposed individuals be weighted in comparison to the population risks for the whole exposed population? How will a highly exposed individual be defined? Some fixed percentile of a distribution? A qualitative representation of such a percentile, such as the RME? A hypothetical maximally exposed individual or MEI? What are the quantitative criteria that will trigger further risk reduction actions? Will those actions be applied to only those facilities whose calculated risks are above the criteria, or will the whole category be affected? What level of assurance will be demanded that the criterion is met in order to State that the residual risk requirement is met? Without knowing rather well what questions will be asked, the Agency may not provide useful answers.

In the Introduction, the concepts of the unit risk estimate (URE) and the reference concentration (RfC) are introduced for inhalation risks. Although it is clear that both of these numbers are applicable to continuous lifetime exposure to a constant concentration in air, it is not clear that calculated concentrations may need to be adjusted for exposure duration before being used to determine risk using the URE or RfC. This lack of clarity is not entirely dispelled in the later section on Dose Response. One stakeholder commenter believes that the duration adjustment was appropriately made for ingestion exposures but not for inhalation exposures. More generally, the document could use considerable improvement in the exposition of what was actually done in the risk assessment.

INITIAL SCREENING LEVEL RESIDUAL RISK ANALYSIS

The idea of screening level analyses to focus further risk analysis on the facilities and HAPs most likely to violate the residual risk limits is sensible. In fact, multilevel screens may be appropriate, not just one initial screen. However, the screening analysis as designed could be improved. First, screening on only inhalation exposures may give a false sense of security about some facilities or chemicals if other pathways are in fact substantial contributors to risk. For some HAPs emitted to air, pathways other than inhalation may be orders of magnitude more important to risk, particularly if the fate parameters are such that concentrations in soil will buildup over a long time before plateauing as removal processes become effective. It may be necessary to build in some HAP-specific screening-level multipliers for multimedia effects into the inhalation risk calculations. On the other hand, it appears that the screen for secondary lead smelters may have been too conservative in that all facilities and many of the individual HAPs exceeded the screening criteria when fugitive dust emissions are included. If a screen does not screen out anything, it is not very effective.

I am also not particularly impressed with the rationale for selecting the HAPs to take forward into the multipathway analysis. The occurrence on a list of "PBT" (persistent, bioaccumulative, toxic) substances is, in my view, a weak substitute for a more quantitative classification. The actual risk posed by a substance depends on all three attributes, and others, in a complex way dependent on the actual conditions of fate, transport, and exposure. It is possible to examine complex multimedia models and create simplified models that reproduce their results in a crude fashion, preserving how the effects of half-life, BAFBCF, and toxicity interact. I again recommend an effort to create HAP-specific multipliers for screening purposes to help identify the HAPs that should enter the multimedia assessment.

MULTIPATHWAY RESIDUAL RISK ANALYSIS

As stated in my overall impressions, in many ways the multipathway analysis is equivalent to or better than other regulatory-responsive risk assessment models, featuring a widely accepted air dispersion model along with a highly detailed multimedia transport and fate model. My reservations have more to do with implementation than with overall concept.

Perhaps my foremost reservation is about the emissions estimates. As I understand it, no facility has more than one set of tests (e.g., a 1- to 3-day measurement protocol) subsequent to achieving MACT. Furthermore, there is no evident attempt to correlate the emissions testing results with any explanatory input such lead throughput during that period, type of operation, or type of emission control equipment. (The latter two factors do seem to be used as a guide to extrapolations from one set of measured results to a different facility, however.) The document does not discuss any inherent temporal variability, such as variation in throughput, that might make a snapshot of emissions inappropriate for calculating an annual average. Perhaps these points are all discussed in the underlying data sources, but they do not appear in the current document. As stated in my preliminary comments on

uncertainty, the variability seen in the lead emissions estimates may be more representative of day-to-day variations than to annual average variability. There is no evident test of correlations between lead emission rates and HAP-to-lead emission ratios, that might occur, for example, if lead emissions followed lead throughput but some other source (e.g., refractory brick) were the source of a different metal. The Agency clearly has little confidence in the fugitive dust emissions estimates—all derived from pre-MACT data, as I understand it—but still presents risk results as some sort of upper bound on risk. I contend that such an upper bound is probably not reasonable, given the failure of monitoring data to confirm the concentrations of lead or other HAPs offsite.[1] Unless the Agency is prepared to undertake empirical studies of fugitive dust emissions from secondary lead smelters, it might be better advised not to do any quantitative analysis, simply stating that risks might be higher had fugitive dust been included. I suspect the same may be true for other source categories.

Another major concern is the seeming inconsistency between the very detailed multimedia modeling, which includes such abstruse topics as sediment-water partitioning with BCF and BAF adjustments to fish concentrations side-by-side with an inability to locate stacks in relation to facility boundaries or the assumption of home garden consumption at a nearby residence. It would seem to entail little work to telephone the facility for information or make a site visit in comparison to developing all the inputs for the IEM–2M model, yet such inexpensive efforts could improve confidence in the risk estimates greatly.

I generally agree with the hierarchy of choice for selecting toxicity values to be used in the model. Some commenters have questioned the use of CaIEPA values as one of the possibilities, but as a member of the Risk Assessment Advisory Committee, I have examined that Agency's methods and believe them, on balance, to be as good or superior to USEPA's. I therefore cannot fault OAR for using the IRIS values when available and ATSDR, CaIEPA, and HEAST values when IRIS is silent. Nevertheless, some of the toxicity numbers appear to affect the results markedly and should be viewed with caution. I am especially concerned about the values for antimony and for manganese. The antimony RfC is based on irritation, for which application of standard uncertainty factors may not be appropriate. The antimony RfD is based on toxicity endpoints that include blood glucose and cholesterol, not clinical illness. The manganese RfC is based on "impairment of neurobehavioral function," an endpoint that is probably to some extent subjective and less severe than endpoints used to define other toxicity values. I recommend that EPA's Risk Assessment Forum explore ways to make the IRIS data base more consistent (perhaps by explicitly considering severity of endpoint) and to verify any values that seem to drive risk assessments.

I note the importance of particle size distributions in defining deposition velocities and other parameters for dry and wet deposition, which can greatly influence the overall deposition rates and risks for the same estimated air concentration. I understand that the distribution for stack and controlled fugitive emissions was assumed to be similar to those observed in emissions from baghouses, and generally ranges downward from 10 microns. However, I did not find this assumption to be stated in the document, nor did I find information on the assumed distribution for fugitive dust emissions or how the particle size distributions were translated to deposition velocities. Generally speaking, reductions in particle size tend to spread deposition over a greater area but reduce peak deposition at the RME location. However, if the particle size distribution is dominated by particles so large that they deposit onsite, reducing the particle size may actually increase the RME deposition.

Although the actual model inputs include a provision for chemical degradation after deposition, this mechanism of HAP removal from soil and water is not mentioned in the text. It should be. I also understand that the locations of actual water bodies were used for the drinking water and fish concentration calculations, not some hypothetical water body co-located with the RME, but again this procedure was not described in the text. I also am not sure whether these water bodies are actual, or only potential, sources of drinking water for the local community. The text

[1] I am not as sanguine about the virtues of "model validation" for the multimedia model as some of the other reviewers of the Case Study. The model is designed to estimate media concentrations averaged over some vaguely specified future time period after continuous operations at MACT conditions with no prior operation. Measurements of media concentrations that can be conducted in the present, however, will not capture the effect of future emissions, so there might be underestimates, and will capture the effect of higher pre-MACT emissions, so might be overestimates, of the desired validation quantity. Moreover, the proper temporal and spatial averaging techniques to make model predictions and measured concentrations strictly comparable are not easy to specify. Perhaps the best we can hope for is the identification of gross inconsistencies.

is also unclear about the fraction of all produce consumed that is assumed to be contaminated by the smelter. In some cases, it appears that a 100 percent assumption was used, whereas elsewhere, it appears that some standard EPA assumptions less than 100 percent were used. I am particularly concerned that any significant part of "grain" consumption is assumed to be locally produced, at least for home gardeners.

Non-cancer risks are represented by the hazard quotient/ hazard index structure that, with all its limitations, is the standard Agency method for the so-called "threshold" toxicants.[2] The averaging period for exposures to be used in non-cancer risk assessments is generally taken to be 1 year in Agency assessments, and that practice seems to have been followed here. On the other hand, the averaging period for exposure to carcinogens is taken to be a lifetime, at least for all carcinogens treated as having linear dose-response relationships with no threshold. That assumption implies that cancer risk varies linearly with duration of exposure if daily exposure is held constant. Although it is reasonably clear that the Agency has taken duration into account in exposure averaging for the ingestion routes of exposure, one of the stakeholder commenters has alleged that the Agency did not do so for the inhalation route, thereby overestimating risk by the ratio of a lifetime to the assumed duration of exposure. If true, this error should be corrected. If not, explanatory text should be added.

I would have expected that lead would be the most important risk from a secondary lead smelter. Cursory inspection of Tables 3.13–3.16 might suggest to the unwary that it is not, because no hazard quotients are presented for the ingestion routes, and the hazard quotients for inhalation are not as high as for some other HAPs. However, this impression is due to two facts that are not as emphasized as they might be. First, the inhalation hazard quotient is calculated from the primary NAAQS for lead, which is not purely a health-based number. Second, the ingestion hazard quotient is not calculated at all, because the Agency refuses to promulgate an RfD because of the asserted non-threshold nature of lead. Therefore, the significant analysis for lead is accomplished through the IEUBK modeling procedure described in Section 3.3.1.4. From Table 3.23, it can be seen that predicted blood lead levels can be quite high, especially for the fugitive dust scenario. Although some discussion of the lack of conformance of these predictions with observed blood lead values is presented, I think that the magnitude of these values casts grave doubts about the validity of the modeling. See, however, Footnote 1 on the difficulties of making comparisons of model predictions with measurements.

INITIAL ECOLOGICAL SCREENING ANALYSIS

Although my expertise is not on the ecological side, this section struck me as more straightforward, polished and easier to understand than most of the health risk assessment sections. I note that it is screening-level in terms of the evaluation of the significance of media concentrations, but is more-than-screening-level in terms of the calculation of media concentrations, as it uses the same ISCST–3/IEM–2M outputs as does the multimedia health assessment. The text suggests that some organics and acid gases might be included in a more detailed assessment, but was not clear what reasons would induce the Agency to include them.

The text states that single point estimates are used to evaluate media concentrations, but does not State at what geographic location. I infer that they are probably the RME locations used for the health assessment, but the location should be made explicit. Averages over some reasonable range for the organisms assessed might be more reasonable.

SUMMARY AND DISCUSSION OF RESULTS

In general, the summary is a reasonable representation of the procedures and findings from the preceding sections. It also attempts to discuss a number of issues that might be troubling to a reader, including the comparison of modeled concentrations with measured ones. However, my overall impression is that the risk characterization is more optimistic about the quality of the analysis than is justified. For example, in Section 6.4, the Agency states: "For any particular pollutant, pathway and exposure scenario the resulting distributions can be used to identify the confidence or probability that risks will be below or above specific risk levels (e.g., ac-

[2] The Agency views lead as a non-cancer risk that nevertheless has no identifiable threshold, and treats it with the IEUBK model. In reality, toxicity data rarely if ever identify a true threshold and the RfD or RfC is set as the practical equivalent of no risk. Probably more at issue is the assumption that risk of cancer is more likely to vary linearly with exposure at low exposure than is the risk of non-cancer effects.

ceptable risk).” Given the deficiencies in the uncertainty analysis, let alone those in the deterministic assessment, I think that is a gross overstatement. Nor do I think that the uncertainty analysis in any way validated the determuustic assessment, although that is also suggested here.

I also found the section on children’s health gratuitous, unconnected to the main analysis, and full of overstatement. For example, the description of newborns having a “weaker immune system” omits the temporary carryover immunity from the mother. Although children eat more food per unit body weight than adults for some foods, they eat less for others (e.g., fish). And those differences are already captured in the exposure analysis by age. The fact that cancer risks, even if due to early life exposures, are expressed later in life is not mentioned, and the reader is left with the impression of a potential epidemic of children’s cancer due to lead smelters.

Finally, I want to share one procedure that I always followed when preparing AB2588 assessments. Because I was usually contracted to a facility owner, I wanted to be sure that the results were not overstated through error, even if overstated through mandated assumptions. I therefore always traced back the dominant risk drivers by pollutant, exposure pathway, and source. I often found simple errors to be responsible, such as entering a number that was expressed in different units than needed, or even copying errors. Sometimes the problem was more subtle, such as including a route of exposure that was actually not possible for the specific facility. I am not convinced from reading the Case Study that the Agency took similar efforts to assure quality, and I recommend it do so. My experience can be extended for those who are worried about risks being understated by looking at pollutants that were expected to show higher risks but did not.

STATEMENT OF DR. DEBORAH CORY-SLECHTA, DEPARTMENT OF ENVIRONMENTAL MEDICINE, UNIVERSITY OF ROCHESTER, ROCHESTER, NY

There are two major but related aspects of the residual risk analysis which are disconcerting. The first is the extensive degree of uncertainly in the models that have been developed and the total or cumulative uncertainty of the overall risk analysis. To the credit of its authors, the models are well thought out progressions that go from an initial identification of what may be the major contaminants from the smelters to a multiple pathway analysis that includes multiple sources of exposures as well as multiple types of receptors. Models for each component of these pathways feed into the overall derivation of the resulting HI values. The logic and inclusiveness of this progression is a major strength of the approach. In addition, the multiple pathway analysis approach includes consideration of different age groups, at least early age groups. However, the actual derivation of the HQ and HI values is almost totally dependent upon substituted values rather than upon actual data and these are propagated through the process. Thus, there is really no validation of the model that has been attempted to date. Certainly no systematic attempt to validate the model was undertaken; but even the assessment against some known entities is not considered. The outcome is really presented in the abstract. While there is repeated discussion of the uncertainties of the analyses, there is no discussion following either Chapters 3 or 4 of Volume I as to the realities and or the limitations of the findings. This represents a major weakness of the approach, recognizing what may be difficulties in obtaining data for the most relevant parameters of the models.

Also with respect to issues of validating and understanding the model, there is little indication of how the actual default assumptions used alter the outcomes and any tests to look at how modifying these assumptions changes the outcomes, or drives the outcomes. Its not clear how the validity of the model can be established without understanding how its components work and influence outcomes.

The uncertainty analysis does little to provide additional reassurance with respect to the validity of the model. The description of the outcome of this analysis is presented but with little attention to its conclusions and to how these conclusions relate to the validity of the residual risk model, particularly the multipathway analysis. For example, the plots presented with respect to outcome are somewhat difficult to comprehend and do not provide a straightforward assessment of uncertainty. The analyses presented in Chapter 5 of Volume I are plotted in a manner that is not intuitively obvious and must be extracted. It is indicated, almost as an aside, that the range predicted for each cancer or non-cancer effect spans at least two orders of magnitude. How acceptable is this range? What would typically be an acceptable range of values from such an analysis?

Some of the predicted values from the residual risk assessment suggest problems with the default assumptions. For example, the residual risk assessment predicts

blood lead values from Facilities 3, 4 and 13 for infant blood lead levels of over 200 μg/dL. These are extraordinarily high, likely much higher than even encountered in an occupational context these days. Surely, if such blood lead values were being generated, they would result in obvious toxic effects and even lethality in infants and would be evident.

Similarly, the residual risk assessment derives exposure values for dioxins and furans were found to be considerably lower than those reported in breast milk in all of the facilities. The residual risk assessment concludes that this means that emissions of dioxinslfurans from secondary lead smelters are a minor contributor to overall dioxin/furan emissions nationwide. Not considered here is the alternative explanation that dioxinslfurans may be inadequately modeled. The comments suininarized in No.s 3 and 4 above suggest that by the simple potential mechanisms of validating the model, it does not work well.

Two major assumptions upon which the residual risk assessment is based are not adequately justified nor explained. The assumption that cancer as an endpoint has no threshold, whereas non-cancer endpoints do exhibit thresholds has no obvious biological basis. It also is not well supported by more recent reanalyses of data suggesting that Pb exposures below 10 μg/dL (a value used as a type of risk threshold) may actually produce larger effects than those above 10 μg/dl. It is also notably inconsistent with the rest of the document, since this is certainly not the most conservative approach. If this assumption is to remain in the residual risk assessment, then some type of rationale for it should be provided.

Another assumption that is problematic is that the effects of HAPs are considered to be additive. This may need to be a default assumption given the relative absence of a data base from which to conclude otherwise. Assumptions of synergistic or potentiated effects may be overly conservative and thus not appropriate in this case. Again, however, some rationale for the reliance on this assumption should be provided.

The focus on dioxin as a cancer risk really fails to embrace the fact that these compounds have marked effects on the immune system, the reproductive system, and perhaps the nervous system as well. This component of dioxin/furan effects should be included in the non-cancer effects.

Some of the distinctions between the subsistence farmer and the home gardener seem somewhat arbitrary. For example, why wouldn't the home gardener also be ingesting animal products, in fact those grown on the subsistence farm; local processing and distribution of these products certainly occurs.

One major component of the document that seems to be missing is any real discussion of the outcomes of the multipathway analysis with respect to known values as determined from other sources for emissions of the various metals and organics chosen as well as any exposure data for these compounds in smelter workers and or groups living around smelters. How do values computed relate to any known emission or exposure data?

A related point is that the document does not really put the risks generated into an adequate public health context. What do these derived risk estimates mean with respect to public health? The values generated are presented without really providing any discussion of their relationship to known toxicity levels for these compounds.

A minor point, but wouldn't chicken be a better choice than pork with respect to total human consumption in the category of animal product ingestion?

STATEMENT OF DR. THOMAS J. GENTILE, NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION, ALBANY

1. Overall: Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? Are the assumptions used in this risk assessment consistent with current methods and practices?

The risk assessment methodology presented in the case study is consistent with the framework described in the Report to Congress (RTC) with some significant exceptions. Overall, the case-study approaches incorporates the iterative approach (e.g. refine the risk assessment by reducing the conservatism by including site-specific detail). It carefully identifies the assumptions and impacts of the assumptions on the risk estimates presented. In addition, the public health risk assessment is consistent with current methods and practices. Although I have some concerns about the adequacy of the ecological assessment, these concerns may be due to my unfamiliarity with the current State of the science about ecological risk assessment practices.

However, the case study does not go far enough in providing site-specific information to make the important risk management decisions concerning the adequacy of the NESHAP to protect public health and the environment. There was an attempt to incorporate some site-specific information (e.g. facility compliance stack test, State stack test, receptor locations, ambient measurements and local blood lead levels), but more site specific information (e.g. the degree of partial or total fugitive emissions enclosures, specific terrain information for receptor modeling, soil sampling results for metals in the local areas) needs to be obtained by working with State and Local Public Health and Environmental Agencies and industry. This point is evident when a comparison is made between the screen and refined risk estimates for inhalation only exposure (Table 1).

Table 1.—A Comparison Between The Refined And Screen Inhalation Cancer Risk Estimates For The Facilities Selected For Refined Analysis

[All Risk Estimates Are Cases Per Million]

Facility	Initial Screen	Refined Screen w/o fugitives	Refined Screen w/fugitives	Risk Reduction w/o fugitives	Risk Reduction w/fugitives
2	6000	10	52	600	115
3	9000	5	2240	1800	4
4	6000	268	6950	22	risk increases
13	10000	16	130	625	7

The increase in risk for facility 4 as a result of the refined modeling raises concerns, which may go beyond the lack of refinement of the fugitive dust emission estimates in the refined analysis. This needs to be explored in greater detail in the case-study. The obvious differences which impact the risk assessment between facility 4 and the others is the size of the facility as determined by the number of emission points (n=13), the furnace type and the closer receptor impacts (Table 3.7 in case-study). However, the most troubling aspect is that Facility 4 had stack test data reported for all of the HAPs which were assessed in the refined screening exercise. It also had the smallest incremental reduction in risk (22 times) when just the process and process fugitive emissions impacts from inhalation exposure are considered. The other issue is that Facility 3 also had stack test data reported for all of the HAPs which were assessed in the refined screening analysis and had the largest incremental reduction in risk (1800 times). An in depth analysis of these large differences in risk reductions (1800 versus 22) needs to be examined more closely in the case study. In addition, they have probably been subject to stringent State air toxics requirements under the California Air Toxics Hot Spots Program. Is there a State Air Toxics Hot Spot Risk Assessment for these facilities? If it is available has OAQPS conducted an independent evaluation of the results and actions which were taken to reduce risk?

This is extremely important since the refined analysis for facilities 3 and 4 was based more site specific emissions information. The increased risk observed for facility 4 in the refined analysis indicates that the initial screening assumptions may not be overly conservative in all cases. The only way to check this would be to obtain some basic site-specific information to insure that the parameters used in the initial screen are always going to be conservative for all facilities.

In summary, a detailed site specific description of the four facilities selected for the refined analysis should be suininarized and included in volume 1. The brief discussion in section 3.1.1 is inadequate and should be expanded. This qualitative expansion should include cross references to other sections where site specific data is used in the refined analysis. For example, the use of actual stack characteristics for the refined analysis which is found in Table 3.3, the use of local met data which is found in Table 3.4 and the use of actual receptor locations which is found in Table 3.7. This would place all site specific or cross references to site-specific information into one important place and would help the reader conceptualize the differences between the facilities under evaluation.

In context of the framework presented in the RTC, it appears that the refined analysis can not answer the question: Is human health risk acceptable? The fugitive emissions issue (e.g. lack of refinement) and the lack of site-specific information clearly result in negative answer to the question: Are information and analysis sufficient to evaluate management options? This answer indicates that a further refinement of the case-study or another iterative step is needed before an evaluation of the risk management options can be considered.

The Agency is mandated under Section 112(f) to conduct the residual risk assessment and make a decision to implement further regulation or to make a decision that no further regulation is needed. In response to the previous SAB review of the RTC, the Agency responded that, "the decision made with the results of the screening analysis is no further action or refine the analysis, while the decision made with the results of the more refined analysis is no further action or consider additional emissions control." As discussed above, the results of the refined analysis provides the same answer as the initial inhalation screen, that a more refined analysis is needed. Therefore, the case study has not achieved the ultimate decision objective and another level of analysis or iteration is required. The case study should do a more in-depth refined analysis or an additional step-wise iteration to improve the case study for risk management decisionmaking.

An examination of the initial screen results indicates that it has provided important information about which hazardous air pollutants (HAPs) need to be considered in the multipathway and refined analysis. However, the results from the above Table are disconcerting. How can the refinement and the removal of conservative assumptions and HAPs from consideration result in an increased inhalation risk for receptors around facility 4? It is important to narrow the scope and refine the residual risk analysis in the first step, however, extreme caution must be exercised when eliminating HAPs and facilities from consideration as a result of the initial screening. It is clear that the use of post NESHAP emission rates in the initial screen would provide a better starting point for the case study.

The impact of consolidating emission points into a centroid emission point needs to be carefully considered and analyzed. The Office of Air Quality Planning and Standards (OAQPS) should evaluate the work that has been conducted with the Office of Pollution Prevention and Toxics (OPPT) on the Risk Screening Indicators Model concerning the use of centroid emissions locations versus the use of facility specific stack and location parameters. An analysis conducted by OPPT found that the impacts in the area close to the facility fence lines was underestimated by a factor of three to seven when the centroid was used to estimate emission impacts. As distance from the facility increased the centroid modeling provided more consistent predictions when compared with the model using actual stack emission parameters and location characteristics. Therefore, some of the conservatism of the initial screening and the refined screening exercises may be questionable if receptors are in close proximity to the facility fencelines.

The selection of facilities for the refined analysis needs to be placed into some type of risk management framework. These facilities were obviously selected since they represented the highest risk (e.g. cancer risk > 9000 in a million and HQ > 70). However, a defined process is needed for selecting which facilities will be included in the refined analysis. For example, if the 100 in a million cancer risk value was used only 2 of the 29 facilities would pass the screening criteria. The use of this cancer risk range would be consistent with the benzene decision and the Commission of Risk Assessment and Risk Management (CRARM) recommendations by having the total cancer risk from the facility being in the range of less than one to one hundred in a million for the screening assessment. In addition, if a hazard quotient of 10 is used as an action level for the screening assessment as recommended by CRARM, then a decision to eliminate facilities 6, 9, 12, 20, 25 and 29 for further analysis of noncanccr health effects can be made. One can construe from the selection of only four facilities that a decision of no further action may be made for the other 19 facilities based on the initial screening assessment.

In summary, there is a need to gather more site specific information for the initial and refined analyses than what was gathered and presented in the case-study.

The RTC discusses the need for including background risk and discusses the difficulty associated with this specific issue. The case study does not address background risk issues around any of the 23 facilities in the human health risk assessment. This is serious omission from the case-study and there is a need to attempt to address this issue at a minimum from a qualitative and quantitative point of view, well beyond the comparisons made in Chapter 6. No assessment of background risk seriously impacts statements about the conservative nature of the refined screening assessment.

I disagree with the statement on page 134 of the case-study that any attempt to include background concentrations in the ecological assessment ". . . were beyond the scope of this assessment." This is a critical part of the ecological risk assessment since these facilities have been probably impacting the local ecosystems for a long time prior to the addition of NESHAP controls. An assessment of background risk in addition to the screening level assessment is absolutely necessary before any decisions can be made about the significance or conservativeness of the ecological risk assessment.

The RTC also discusses the assessment of acute effects from short-term HAP exposure. The case study contains no discussion or assessment of acute effects from HAP emissions for this source category.

2. Model Inputs: Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

The methods used to estimate emission rates for the initial screen and refined analysis are clearly described. However, there is a concern that the emission rates used for the lead to metal HAP ratios in the initial screen are biased low based on the actual stack test results from facilities 3 and 4. A comparison of the lead/HAP metal ratios used in the initial screen and refined analysis are presented in Table 2.

Table 2.—A Comparison Of The Lead To HAP Metal Ratios Used In The Initial And Refined Screening Analysis

Metal HAP	Initial Screen (Process)	Refined (Process)	Initial Screen Process Fugitive	Refined Process Fugitive
Arsenic	0.09	0.31	0.03	0.035–0.098
Chromium	0.05(1)	0.00048	0.01	.00013–0.0014
Cadmium	0.02	0.031	0.01	0.02–0.045
Nickel	0.08	0.179	0.06	0.13–1.99

(1) The ratio for the initial screen is total chromium and for the refined analysis it is hexavalent chromium. An adjustment of the initial screen total chromium values using the 1 percent assumption as hexavalent provides almost the same value used for the refined process and process fugitive emissions.

The differences between the arsenic and nickel ratio values used in the initial screening analysis and the refined screen analysis clearly undermines the conservativeness of the initial screen risk results presented in Tables 2.4a and 2.4b. If the stack test results from facilities 3 and 4 are post NESHAP , then a decision should have been made to use those results in the initial screen versus the median values estimated from Background Information Document (Table B1.3—Appendix B).

The Agency should consider requesting stack emissions test for process and process fugitive at some of the facilities in order to obtain better emission estimates for use in the screening assessment case-study.

The Agency carefully needs to reevaluate the fugitive emissions rates since the modeled annual concentrations of lead with fugitives in Appendix C are unrealistically high for facilities 3 and 4. There is a need for site specific information on the effectiveness of fugitive emissions control after the implementation of the NESHAP housekeeping standards. Fugitive emissions from this source category are an issue and need to be carefully evaluated. In 1987, there were two exceedances of the National Ambient Air Quality Standard (NAAQS) for lead (1.5 μg/m3) in the vicinity of a secondary lead smelter. The elevated lead concentrations (2.46 and 1.61 μg/m3) at the monitor were the result of malfunctioning emissions control equipment and fugitive emissions from the plant. Monitoring of lead around the plant was increased by the addition of two downwind monitors. The plant upgraded the process emission controls, but the concentrations of lead were still elevated, but below the NAAQS when compared to other monitoring sites in the State. Further investigations concluded that fugitive emissions from the plant were a problem that needed to be addressed. The entire facility was enclosed and placed under negative pressure. HEPA filters were installed on all air exchange units and other housekeeping practices were required. This facility currently has 16 emission points. The annual geometric mean of lead at one monitoring site dropped from a high of 0.71 μg/m3 (1987) to 0.06 μg/m3 (1993) after all of the facility upgrades were in place. The highest quarterly average measured at the two remaining monitoring site in 1996 were 0.06 μg/m3. These two monitors are located 275 meters from the facility fence line. The third site was shutdown at the end of 1995.

The incorporation of this type of information into the case study and the refined screening analysis will result in a more informed risk management decision for this source category.

3. Models: Does the risk assessment use appropriate currently available dispersion models at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the State of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM–2M model, with some modifications. Is the IEM–2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did EPA appro-

priately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach, that is available at this time that EPA should consider?

The decision to use facilities 2,3,4, 13 because these represented facilities with the highest excess cancer rate and highest hazard index based on the initial screening produced a situation where only simple terrain would be used in the refined analysis. This process could have biased the modeling results to underestimate impacts at other facilities, with complex terrain, which were not designated for refined analysis. The Agency should reevaluate if any of the 29 facilities are in areas of complex terrain.

The exposure inputs into the IEM–2M and IEUBK model are conservative which is clearly acknowledged by the Agency throughout the case study. The Agency should continue refine the risk assessment using site specific information as discussed in many of my other comments. There is a strong need for another iteration to refine the case study which is acknowledged by the Agency in section 6.7. The case study should remain a Pre-Decisional Document until the next iterative refinement is conducted. OAQPS should work diligently with State and Local Health and Environmental Departments, the Agency for Toxics Substances and Disease Registry, Industry and the EPA Regions to further refine the case study. This step is absolutely necessary before any decision about unacceptable risk is made for the majority of the facilities identified in the case-study. The uncertainties associated with the fugitive emission parameters are the driver for a more detailed risk assessment within the source category. This need is discussed by CRARM on page 23 of the RTC.

4. Choice of Receptors: The Agency identifies the home gardener as the appropriate receptor to estimate risk to the residential population and the farmer to embody high end risk estimates. Are these receptors appropriate for this task?

The receptors identified by the Agency are appropriate and adequately represent the maximum individual risk (MIR) concept which is discussed in the RTC.

5. Ecological Risk Assessment: given the currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

The case study does not include a discussion of other ecological stressors (e.g. criteria pollutants) which may have an impact on the surrounding ecosystem. The effect of this omission on reducing the conservativeness of the ecological risk screen is mentioned on page 147. However, any refined analysis of ecological risk is going to have to account for these additional ecosystem stressors, especially the effects on terrestrial plants exposed via direct contact with criteria pollutants (in this case sulfur oxides) in the ambient air.

6. Health Risk Assessment: Given available dose-response information, is the hierarchy presented in the assessment appropriate (see especially footnote #6, section 2.21)?

The hierarchy presented in the assessment is appropriate. I agree with the use California Environmental Protection Agency values over HEAST values for all of the reasons outlined in footnote No. 6.

For each chemical included in the assessment is the choice of dose response assessment appropriate?

Overall, the choice of the available dose-response data used in the case study is appropriate. I have concerns about the elimination of HAPs from consideration in the case study if they have no available cancer or noncancer public health values. Seven organic HAPs are eliminated from consideration in the case study. It is difficult to assess the impact of the elimination of these organic HAPs from the case study. However, the effect may be negligible since emission rates in Appendix B for the organic HAP emissions omitted from consideration are low. The Agency should consider the development of default or surrogate values based on the available toxicity information or structure activity relationships with other HAPs which have dose response data.

Why is propanol identified as a HAP in the case study? I can not locate it on the list of 188 HAPs identified by the Clean Air Act.

The application of the use of risk ranges for benzene and 1,3-butadiene in the initial screen needs to be discussed. Do the cancer risk results presented in Table 2.3 use the high or low end of the range?

The use of only 25 percent of the inhalation unit risk estimate for nickel subsulfide needs to be explained in greater detail, since it will have a large impact on the total cancer risk estimates in the case-study.

Are the dose response assessments appropriately incorporated into the assessment?

Yes, the available dose response assessments are appropriately incorporated into the assessment, with a few exceptions as noted above.

7. Uncertainty and Variability Assessment: Did the assessment use the appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

8. Results Presentation: Does the document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

It is very difficult to present such a large amount of information in a clear and concise manner. The case study does a good job of presenting and interpreting the risk results. The discussion of the initial inhalation screening results should include a discussion of how the maximum and minimum risk values presented in Table 2.3 were defined. The Agency should indicate that they are simply the range of estimates determined for all 29 facilities.

The Agency should consider using a consistent cancer risk expressions in the narrative of the case study. The lay reader will be confused by the constant interchangeable expressions of cancer risk. For example, the use of the expression eight in a ten thousand should be changed to 800 in a million. This will allow the lay reader to place the results into the context of the less than one in one million expression which appears in the Act and throughout the case study.

The identification of the key issues and assumptions are clearly identified in the result sections of the the initial inhalation screen, the refined multipathway screen , the variability and uncertainty analysis, and the ecological screening assessment. The addition of a discussion about a few key issues concerning the lack of a background risk analysis and the effects of the adjustment of the nickel inhalation unit risk estimate could be added to the key issues identified in Section 3.3.2.

The tables and figures used throughout Section 4 provide a concise and well thought out approach for the presentation of variability and uncertainty for each scenario evaluated. They allow the reader to evaluate the broad spectrum of risk and the impacts of the various exposure parameters used in the refined multipathway risk assessment. These tables and figures significantly enhance the comprehendability of the variability and uncertainty assessment results. The inclusion of the point estimates in Tables 4.5 and 4.6 is an excellent way to concisely present information to the risk manager. The tables and figures provide the risk manager with the ability to view the broad spectrum of risk predictions, which includes the average exposed individual (AEI), the adjusted maximum individual risk and the maximum exposed individual (MEI).

Tables 6.1 and 6.2 provide a good overview summary of the final results for the refined multipathway risk assessment. I have some concerns about Section 6.2.1 Comparison of Modeled Concentrations with Measured Environmental Concentrations. As discussed through out my comments this section can be greatly enhanced and another iterative refined multipathway risk assessment step which relies on more site specific information should be added to the case study.

The effort which will be needed to gather the relevant information for this next step should not be considered overwhelming or beyond the scope of the case study. It should be considered as a necessary refinement which needs to be conducted before the case study becomes a public document. The discussion in section 6.2.1.1 needs to be expanded. The pre-NESHAP monitoring data from New York indicates that the NAAQS for lead can be exceeded and that the stringent control of fugitives can result in a dramatic lowering of ambient concentrations of lead and probably other metal HAPs in the vicinity of secondary lead smelters. Table 6.7 should be modified by locating the distance to the monitors and include a brief discussion of siting issues (e.g. predominate downwind or upwind monitoring location) before any comparisons are made. The same point can be made for the comparisons of the surface waters concentrations. However, the Agency does appropriately acknowledges that the comparisons in Table 6.8 are not meaningful.

Section 6.2.1.5 needs to be expanded since it provides information on an excellent biomarker for potential exposure (e.g., blood lead levels). The inclusion of this type of information would greatly enhance the case study. The CDC and State Health Departments should be consulted to find out if there is any other information on blood lead levels in children who reside in communities that are in close proximity to secondary lead smelters.

In summary, there is a strong need to gather and evaluate more site specific information using the risk assessment tools presented in the case study before any final risk management decisions can be made for this source category. The case study should undergo another iteration before being released to the public.

EDITORIAL NOTES

The overview presented in section one, the case study, is very good.

Section 2.2 needs to include the chemical abstract service registry numbers and the identity of the chemicals as they are primarily identified in Section 112 (b) of the Clean Air Act (e.g., 2-methyl phenol is identified by 112 (b) as o-creosol, iodomethane should be identified as methyl iodide, etc.)

Table 6.8—the units (μg/l) are missing.

STATEMENT OF DR. DALE HATTIS, CLARK UNIVERSITY, WORCESTER, MA

Below are my updated responses (following discussion at the meeting) to the questions posed to the Secondary Lead residual risk review Subcommittee:

Charge Question 1. Overall—Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? (EPA–453/R–99–001)? Are the assumptions used in this risk assessment consistent with current methods and practices?

Response. I have very considerable difficulty making an appropriate response to the first part of this question. I was not provided with a copy of the Report to Congress that is specifically referred to. Fairly recently, I was sent a copy of a substantial earlier SAB review of that document from which I can make some inferences about the risk assessment approach and methodology that was presented in the Report to Congress. However there does seem to be very significant commentary in the SAB review of the need to "validate" models, and to conduct appropriate analyses of the population variability of regulated risks and give a fair estimation of the uncertainty in the variable risk distributions. The current document, though very extensive in many ways, does not seem to reflect a serious effort to assemble and analyze a substantial body of post-MACT emissions and exposure (e.g., community blood lead) information that could be juxtaposed with the emissions estimates made in the early 1990's when the MACT standards were set. The documents do not appear to describe a systematic search for such information, do not present the specific emissions information that was collected, and do not document in nearly adequate detail the specific analyses that were done with the emissions information. There is no visible attempt to juxtapose model projections of either emissions or exposures (e.g., for blood lead) with such data and to form the bases for an updated set of distributional exposure and risk projections.

There is a great deal of discussion in the SAB review, and in the EPA residual risk assessment, of the need to conserve scarce EPA resources by limiting the analysis in various ways (by structuring the analysis in a series of tiers beginning with generic conservative assumptions, restricting the HAPs covered, the facilities examined in detail, etc.). Sadly the implementation of this approach does not seem to have lead to an economical analysis that can be said to have succeeded in producing meaningful insights into the likely level of risk posed to real people in the immediate vicinity of these facilities. There is no more expensive analysis than an analysis that does not produce results that can meaningfully inform public policy choices. The screening level analysis as it stands probably is adequate to focuses EPA's attention on lead and a few metallic HAP's, and away from the great majority of organic HAP's, but that result probably could have been foreseen with considerably less work than appears to have been devoted to this project. Certainly something is seriously amiss when the document can show projections of essentially lethal blood lead levels (200 μg/dL and above) for the case where fugitive emissions are included—and very significant blood lead levels (68 μg/dL) even without fugitives for one of four modeled facilities—without that leading to some attempt to pursue the issue with blood lead observations or some deeper conclusion than that the fugitive emissions estimates are probably "conservative". Maybe they are "conservative", but then to blithely exclude both the fugitive emissions and all exposures to lead entirely from the "variability/uncertainty analysis" without further reappraisal of the source of the apparent estimation problem seems to turn the screening results on their head. Any "tiered" analysis procedure that leads the investigators to exclude such a major source of concern as lead from important parts of the secondary lead smelter analysis has a serious fundamental problem, at least as implemented here. This is particularly true in the light of the fact that emissions of the other HAP's that are included in the variability/uncertainty analysis are estimated as ratios to lead.

The context of this residual risk analysis is a long term possible consideration of the need for emissions control measures that go beyond the available control technology-based standards that were mandated in the first round of controls following the passage of the 1990 iteration of the Clean Air Act. Almost by definition, when

you are building the informational basis for considering the need for technology-forcing measures, you need to have data that would be sufficient to support decisions that might involve very substantial technical and economic restructuring of an industry. At the same time, the context also involves considering the possibility that appreciable residual risks remain for people in communities surrounding these facilities that mean that the promise of the 1990 Act to provide an ample margin of safety for health protection is still not being fulfilled 10 years after the promise was made. This context demands that EPA take the time and devote the resources needed to fairly assess the current public health problem posed by these facilities. Otherwise no actions based on such an analysis are likely to survive Congressional and Judicial oversight.

Charge Question 2. Model Inputs—Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

Response. Briefly, no. The primary data should be provided in the document and the detailed analysis steps should be given in sufficient detail to allow an informed reader to reproduce the analysis. My understanding from the extra documents that have been provided to me in the context of the variability/uncertainty analysis is that the existing data base is not extensive—onsisting apparently of three "runs" (of undetermined duration) measuring Lead, Arsenic, Cadmium, and Nickel emissions from various stacks at two different facilities—constituting in all about 168 separate measurements if I have counted correctly. For a large number of other HAP's and other facilities my understanding is that there is some additional information available from recent (post 1990) measurements for four facilities, but that the primary sources of estimates of emissions is the 1994 Background Information Document for setting the MACT standards. The bases of these estimates and their applicability to current conditions is not discussed.

In addition, the authors should take a more creative approach to assembling other types of data relevant to emissions than they have apparently considered. For example, to estimate fugitive emissions, one clue might be air exposure levels measured for workers in this industry by OSHA industrial hygienists. [Some helpful background on the history of air and blood lead levels in the industry can be found in a couple of past reports I helped do for the Office of Technology Assessment—Goble et al., (1995, 1983)]. Such air levels, when combined with general ventilation assumptions and baghouse capture efficiencies, should provide some basis for new estimates of at least some process fugitive emissions, as should air measurements from environmental monitoring conducted near the facilities, and children's blood lead measurements that are routinely collected by agencies in several states, and which may therefore be available for communities near the facilities under study. In addition, it should allow some estimation of fugitive emissions from other parts of the process than the battery breaking and materials handling steps that are presently included as contributing fugitives in the current process flow diagram. What happens to the air around the workers working at other steps than the first two? Is it captured and treated to remove some dust? With what efficiency? Additionally, it would seem sensible to make systematic comparisons of observed community air levels with those predicted from the dispersion models.

Charge Question 3. Models—Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the State of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM–2M model, with some modifccations. Is the IEM–2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach, that is available at this time that EPA should consider?

Response. These questions cannot be fairly answered from the information provided. There was just not a sufficient presentation of the assumptions inherent in the IEM–2M model for me to evaluate it. I was provided with very large spreadsheets of the model, but without a great deal more time and appropriate documentation of the structure and assumptions built in to the model it is just impossible for me to make a sensible evaluation. I don't know and cannot easily infer, for example, how it differs from other multimedia models that are available, such as CALTOX.

Charge Question 4. Choice of Receptors—The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?

Response. I'm not at all convinced of this. My impression is that the chief pathway responsible for transferring gasoline air lead to children when gasoline lead was still allowed was a dust-hand-mouth pathway. It seems to me that this pathway, together with more recent information on the efficacy of community soil cleanups in reducing blood lead levels, needs to be evaluated as part of any fuller analysis of the issue. I understand EPA's desire to exercise its IEM–2M models, and this should certainly be one part of the analysis, but key issues need to be addressed, such as the persistence of dust contaminated with lead and other metallic HAP's in neighboring communities, rates of exchange between outdoor dust and indoor dust, and the magnitude and duration of exposures that result from emissions and deposition of indestructible metallic compounds in urban and other communities.

Charge Question 5. Ecological Risk Assessment Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

Response. This is not my area of expertise, and I have not evaluated this portion of the document.

Charge Question 6. Health Risk Assessment—Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose response information, is the hierarchy presented in this assessment appropriate (see especially footnote No. 6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose response assessment appropriate? Are the dose response assessments appropriately incorporated into the assessment?

Response. I do not have the cited Report to Congress, and I have not thoroughly evaluated this aspect of the document. However, I would suggest that at least for lead, where there are quantitative estimates of relationships between children's blood lead levels and IQ, that the results be taken to estimate likely individual and population aggregate impacts in quantitative terms—how much relative deficit for how many kids. Additionally, I believe that cancer impacts can and should be evaluated in population aggregate terms as well as in terms of risks to particular percentiles of the estimated exposure distributions. This would allow decisionmakers in Congress and EPA to assess the public health productivity of investments made under the residual risk provisions of the Clean Air Act.

Charge Question 7. Uncertainty and variability assessment—Did the assessment use appropriate currently available methods to identify the variables and pathways to address in the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

Response. Although there are some glimmers of creative analysis of data in the uncertainty/variability portion of the effort (e.g. the attempt to calculate metal HAP/lead ratios over a longer time period than covered by the directly observations), the current analysis is very disappointing in numerous ways. First, the scope and objectives of the analysis fall far short of what any sensible decisionmaker will wish to have in order to make informed choices under the residual risk mandate of the 1990 Clean Air Act. To fulfill the mandate of the Clean Air Act, EPA needs to not only be confident that it has addressed the most significant hazards posed by the industry under study, but to define what it means by an "ample" or "adequate margin of safety" in distributional terms, (e.g., X level of probability of harm of a particular type or severity for the Yth percentile of the exposed population with Z degree of confidence-See for example Hattis and Anderson, 1999; Hattis and Minkowitz, 1996). EPA then needs to develop an analysis that addresses the likely real variability and fairly appraised uncertainty for at least the HAP's and exposure pathways that are thought to pose the greatest potential for public health harm for the industries studied. In the present context, omission of the variability and uncertainty of lead exposures and risks, and omission of some analysis of the uncertainty in fugitive dust emissions and exposures means that the analysis is substantially irrelevant to some of the most important concerns that arise from the earlier screening and multipathway efforts.

The failure to distinguish variability from uncertainty in the present analysis almost guarantees confusion. Variability and uncertainty are different things and require different techniques for estimation. It is a shame that the individual variability in estimated exposures is essentially completely neglected even though existing dispersion modeling techniques, combined with data on the population distributions around the studied facilities, could readily produce such information. This information would seem central to the required analysis. The fact that it is not un-

dertaken, at least at this stage in the development of the project, suggests that the current variability/uncertainty analysis is largely a placeholder for some later effort that, it is hoped, will be planned as a more central part of some future analysis.

A second major problem is that the current analysis does not follow existing EPA guidelines on the documentation and presentation of distributional analysis. Those guidelines, drawn up in part at workshops that I attended, emphasize that the model itself and derivations of distributions used in the analysis must be transparently presented in sufficient detail that a reviewer can reproduce them. I have recently received several spreadsheets that contain portions of the model, but in the very limited time available I have not been able to get them running sufficiently to even examine the model structure, distributional assumptions, and correlation/dependency assumptions made. The document itself should have included as an appendix not the endless display of results for each stack, but the spreadsheet model equations, and the mathematical form of the distributional assumptions that were used.

In summary, in the present effort, the uncertainty/variability analysis appears to have been an afterthought, perhaps undertaken at a late stage in the development of the principal results. Unless analyses of variability and uncertainty are undertaken integrated into the warp and woof of the primary study, they will likely continue to be unsuccessful and unsatisfactory in illuminating the major issues involved in the evaluation of the real choices facing EPA decisionmakers, Congress, and the public.

Some more technical suggestions can be made for pursuing the probabilistic analysis in future work:

(a) In assessing the distribution of metal HAP to lead ratios, the analysts should explore the possibility that some air exhaust streams might be systematically different than others. In particular arsenic, which is more volatile than the lead and most other inorganic HAP's may appear in larger concentrations relative to lead in some air streams than others depending on the temperature of the process and exiting gas. The data should be examined to see if such mechanism-based expectations are borne out in the available observations. If so, then some metal HAP to lead ratios could be varied across process streams (and perhaps across facilities) to reflect the mechanism-based associations.

(b) In representing the interindividual variability of exposure factors such as consumption of different kinds of produce and fish, the analysts should seek data to quantify variability observed on different time scales than the 1–3 days that are typical for direct dietary studies. Some downward adjustment clearly needs to be made to calculate variability over longer time scales from shorter term data. However, because some dietary preferences are likely to be relatively consistent characteristics for individual people, it is not reasonable to estimate long term dietary exposure variability either by simply assuming that each separate 1- or 3-day period is a random draw from an observed population distribution of consumption. Some data bearing on the difference in effective variability in fish consumption inferred for longer vs. shorter timeframes is reviewed in Hattis et al. (1999).

(c) In Section 4.4 the document should clearly explain the implications of the assumptions that are being made. For example, the statement is made on p. 127 that because of data insufficiency, no analysis of correlation among emission parameters and exposure factors was undertaken. The statement should be clarified to say that the correlation could not be undertaken because the data wasn't available for it.

Charge Question 8. Results Presentation—Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

Response. As discussed above, the presentation of the basic inputs and methodology is very far from being adequate to provide a document that is even transparent enough for a thorough review, let alone a document that appropriately assess the uncertainty and variability for decisionmaker and the dependence of the results on key sets of assumptions. Without documentation of the derivation of the results and their uncertainties, the results cannot be appropriately conveyed to decisionmakers and the public. Moreover the neglect of real population variability in both exposures and risks deprives the reader of important information that is needed to arrive at risk management judgments.

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STATEMENT OF DR. MICHAEL J. MCFARLAND, ENGINEERING DEPARTMENT, UTAH STATE UNIVERSITY, RIVER HEIGHTS, UT

RESIDUAL RISK ASSESSMENT SECONDARY LEAD SMELTER SOURCE CATEGORY

SAB Charge Question No. 1. Are the methods used to estimate emission rates and the method used to estimate species at the stack appropriate and clearly described?

INITIAL INHALATION RISK SCREENING

Findings

The method used to estimate the HAP emission rates involve the use of several data sets from the Background Information Document from which the MACT standards were initially derived. The first data set (Table B.1.1) includes estimate emission rates (in metric tons/year) for each of the three emission sources including: (1) process stack emissions (both organic and metal HAPs), (2) process fugitive stack emissions and (3) fugitive emissions. The second data set (Table B.1.2) includes ratios of specific organic HAP emissions to total hydrocarbon emissions from the stacks of three (3) types of secondary lead smelter furnace types. The final data set includes the median metal specific HAP to lead ratios (Table B.1.3) as well as the total metal HAP to lead ratio for each of the three emission sources that include: (1) process stack emissions, (2) process fugitive stack emissions and (3) fugitive emissions.

Although Table B.1.3 indicated that the reported data were the *median* metal (total and specific) HAP to lead ratios, it is unclear whether Tables B.1.1 or B.1.2 were also reporting median values or another statistical measure (e.g., mean or average) of the sampling data. Moreover, since the purpose of the initial inhalation screening analysis was to employ a lower tier conservative approach to screen those HAPs that did not pose a significant human health risk, it would seem more appropriate to use the upper limit of a confidence interval (e.g., 95 percent) of the HAP ratios for estimating emission rates rather than mean (or median) values to estimate inhalation risk. Given the wide range in HAP ratios found in the data tables, use of an upper confidence limit would provide greater protection from deletion of species that may, in fact, represent a significant human health and/or ecological risk. The same argument can be applied to the use of a mean or median total HAP emission rate (Table B.1.1) for estimating specific HAP emission rates. The large range in reported data suggests that a more defensible risk screening evaluation would be achieved by selecting an upper limit of a prescribed confidence interval of emission rates for input into the general inhalation risk model rather than the use of an average emission rate.

Another concern regarding the inhalation risk model inputs was the specific management of the acid gas data. Both chlorine (Cl_2) and hydrogen chloride (HCl) emissions were included in Table B.1.2 and treated as organic HAPs in the emission rate calculations. The concern with regard to the acid gas data stems not only from the placing of the inorganic acid gas emissions in the table for organic HAPs (i.e., Table B.1.2) but, it is also unclear as to whether the total organic HAP process emission rate data (Table B.1.1) includes the contribution from the acid gases.

Although there are some concerns regarding the input data quality for the initial inhalation risk screening, the mathematical equations used to estimate the specific HAP emission rates are fundamentally sound. The specific metal HAP emission rates (E_{HAP}) from each of the three emission sources (i.e., process stack emissions, process fugitive stack emissions and fugitive emissions) were estimated by substituting the estimated total metal HAP emission rates (metric tons/yr) for each emission sources (E_{TMH}-Table B.1.1), the median metal HAP to lead ratio (R_{HAP}—Table B.1.3) and the total metal HAP to lead ratio (R_{TMH}-Table B.1.3) into Equation 1.

$$E_{HAP} = (E_{TMH})/R_{TMH})(R_{HAP})$$

where

E_{HAP} = Individual metal HAP emissions (i.e., antimony);
E_{TMH} = Total metal HEP emissions;
R_{TMH} = Ratio of total metal HAP emissions to lead emissions;
R_{HAP} = Ratio of individual metal HAP emissions from lead emissions.

The specific organic HAP emission rate (E_{VOC}) from the process stack emission source was estimated by substituting the estimated total hydrocarbon emission rate (metric tons/yr) from Table B.1.1 (E_{THC}) and the ratio of specific organic HAP to hydrocarbon emissions (R_{VOC}-Table B.1.2) into Equation 2.

$$E_{VOC} = (E_{THC})(R_{VOC})$$

where

E_{VOC} = Individual organ HAP emissions;
E_{THC} = Total hydrocarbon emissions;
E_{VOC} = Ratio of individual organic HAP emissions to total hydrocarbon emissions.

Recommendations

Although the data input descriptions were, in general, well written, there are several areas where significant improvement could be made. The specific recommendations for this section of the review include the following:

The data in Tables, B.1.1 and B.1.2 can be improved by explicitly stating the statistical measurement parameter being reported.

Consideration should be given to the use of upper confidence limits (of the HAP ratios) as inputs to the inhalation risk model.

The text should provide greater clarity as to how the acid gas data are being managed.

To provide clarity in the use of the mathematical relationships, quantitative examples should be inserted into the text that illustrate the use of Equations 1 and 2.

An example should be provided (perhaps in an appendix) illustrating how raw emission data from each emission source (i.e., process stack emissions, process fugitive stack emissions and fugitive emissions) is managed to generate final risk numbers.

MULTIPATHWAY ANALYSIS

Findings

The method used to estimate emission rates for the multipathway analysis included the use of compliance reports from stack tests for specific facilities (i.e., Facilities 2, 3, 4 and 13—Table C.1.1) as well as the EPA data base developed in the Background Information Document (BID). The MACT standards require that facilities report, at a minimum, both the total lead and total hydrocarbon emission rates. For Facilities 3 and 4, additional compliance testing was conducted that allowed specific organic and metal HAP emissions to be estimated. These facility-specific emission estimates were then used to generate specific emission ratios including: (1) organic HAP to total hydrocarbon ratio and (2) metal HAP to total lead ratio.

To estimate specific organic HAP emissions for Facility 2, the organic HAP to total hydrocarbon ratio generated from Facility 3 data was multiplied by the total hydrocarbon emission rate from Facility 2. Similarly, to estimate specific organic HAP emissions for Facility 13, the organic HAP to total hydrocarbon ratio generated from Facility 3 data was multiplied by the total hydrocarbon emission rate from Facility 13. Since diethylhexyl phthalate and naphthalene were not measured in Facility 3-stack test, EPA data base information was used to generate the organic HAP to total hydrocarbon ratio for these species for Facility 2 and 13.

To estimate specific organic HAP emissions for Facility 3 and 4, averages from three (3) stack test measurements for each facility were reported (adjusted for nondetects). Since diethylhexyl phthalate and naphthalene were not measured in Facil-

ity 3-stack test, EPA data base information was used to generate the organic HAP to total hydrocarbon ratio for these species. It was not possible to estimate diethylhexyl phthalate and naphthalene emissions in Facility 4 since the MACT standards do not require total hydrocarbon measurements for reverbatory furnaces.

To estimate specific metal HAPs for process emissions for Facility 2, the metal HAP to total lead ratio developed for Facility 3 was multiplied by the lead emission rate found in the Facility 2 compliance report. Similarly, for Facility 13, the metal HAP to total lead ratio developed for Facility 3 was multiplied by the lead emission rate found in the Facility 13 compliance report. Facilities 3 and 4 reported specific metal HAP emission rates for process emissions. It should be noted that Facility 3 did not test for antimony and Facility 4 did not test for manganese or mercury. The emissions of these metal species were estimated using EPA data base information to develop the metal to lead ratio, which was then multiplied by the lead emissionrate from the facility compliance report.

To estimate specific metal HAPs for process fugitive emissions for Facility 2, the *average* of the fugitive metal HAP emissions to total lead ratio developed for Facility 3 and 4 was multiplied by the lead emission rate found in the Facility 2 compliance report. Similarly, for Facility 13, the *average* of the fugitive metal HAP emissions to total lead ratio developed for Facility 3 and 4 was multiplied by the lead emission rate found in the Facility 13 compliance report. Facilities 3 and 4 reported specific metal HAP emission rates for fugitive process emissions. Finally, the Background Information Document (BID) estimates for fugitive emissions used in the initial inhalation screening were employed in the multipathway analysis.

With regard to metal speciation, 99 percent of the chromium emissions is assumed to be Chrome (III). This assumption was based on one furnace measurement and the fact that the secondary lead smelters operate under a reducing environment. For mercury speciation, it was assumed that all of the evaluated mercury was in the form of divalent particulate mercury (HgO).

Although the multipathway analysis employs site-specific data, it is unclear whether the comparability of the data been evaluated. In other words, in many cases, EPA data base information is used in conjunction with site specific data to generate specific HAP emission rates with no verification that the data sets contain elements of equivalent or similar quality. The absence of data quality evaluation leads to several fundamental questions that are summarized as follows:

What criteria were used to determine when Facility 3 data should be used for estimating organic HAP emissions from Facility 2 and 13 versus EPA data base information?

Are emission estimates provided in Table C.1.1 averages, median or upper limits of a confidence interval?

How many samples comprise the emission values reported in Table C.1.1? Can ranges or standard deviations be given?

Do the State compliance stack permits specify the number of samples to be taken? In other words, are all data of a known quality?

Descriptions of Facility 3 and 4 stack tests indicate that three stack test were conducted to estimate organic HAP emissions. Does this mean three samples?

It is unclear as to why the average of Facility 3 and 4 process fugitive metal HAP emissions were used to derive a specific metal HAP to total lead ratio for Facility 2 and 13.

Recommendations

Since HAP emission rates were generated using various facility data sets as well as the EPA data base, the most important general recommendation is that the Agency verifies the comparability of the data.In other words, use of data of varying quality in the risk assessment models would generate final risk numbers of questionable value. Therefore, the quality of each data set should be compared and documented prior to having its elements used in the risk assessment. Second, since there is no specific protocol employed for estimating the HAP emissions from each of the four facilities, it is strongly recommended that quantitative examples be inserted into the text that illustrate each unique approach. Finally, additional recommendations regarding data inputs to the multipathway model include the following:

a. Specify the type of statistical measurement being reported in Table C.1.1 (i.e., means, median, upper confidence limits, etc.).

b. Specify the number of samples that comprise the emission values reported in Table C.1.1 and provide *both* ranges and standard deviations.

c. Provide an explanation as to why the *average* of Facility 3 and 4 process fugitive metal HAP emissions were used to derive a specific metal HAP to total lead ratio for Facility 2 and 13 rather than some other statistical measurement.

STATEMENT OF DR. PAULETTE MIDDLETON, RAND CENTER FOR ENVIRONMENTAL SCIENCES & POLICY, BOULDER, CO

1. LINKS TO OTHER KEY EPA ACTIVITIES DEALING WITH HAPS

Other EPA activities that have direct bearing on the residual risk assessments should be noted in the document. These activities demonstrate that EPA is actively improving on the current framework. While the current approaches used in the document under review here are acceptable in the current timeframe, many of their shortcomings may be addressed as a result of these other ongoing efforts. Acknowledgment of this could be done upfront in the introduction where discussion of model appropriateness and future assessments are mentioned. They also could be placed at the end of the report where next steps are sited and where it is noted that SAB comments will be considered in next steps.

2. TRIM

In particular, it should be noted that EPA/OAQPS is developing TRIM as a flexible, state-of-the-art system for evaluating multimedia chemical fate, transport, exposure and risk of HAPs. The recent SAB/Environmental Models Subcommittee review of this effort found it to be effective and innovative and outlined a number of recommendations for improvement. When TRIM becomes available, it should provide an improvement over the modeling framework used in the current report.

3. SAB/EPA WORKSHOPS ON THE BENEFITS OF REDUCTIONS IN EXPOSURE TO HAZARDOUS AIR POLLUTANTS

As stated in the description of these up and coming workshops, "HAPs have been the focus of a number of EPA regulatory actions, which have resulted in significant reductions in emissions of HAPs. EPA has been unable to adequately assess the economic benefits associated with health improvements from these HAP reductions due to a lack of best estimate dose-response functions for health endpoints associated with exposure to HAPs and also due to a lack of adequate air quality and exposure models for HAPs. EPA is conducting two workshops to develop a proposed methodology to generate estimates of the quantified and monetized benefits of reductions in exposure to HAPs. The first workshop will focus on developing best estimates of dose-response functions that relate changes in HAP exposure to changes in health outcomes. The second workshop will focus on (1) integrating these dose-response functions with appropriate models of HAP concentrations and human exposure and (2) translating these into economic benefits that would estimate changes in health risks resulting from regulations that reduce HAP emissions." The results of these workshop discussions, in particular the reviews of models and methods, could well provide additional valuable input to this ongoing evaluation of the residual risk review and development of next steps.

4. QUESTIONS AND COMMENTS ON THE CURRENT STUDY

a. Missing HAPs

Have all of the potential important HAPs been included in the screening analysis? Can understanding of the processes be used to better substantiate the list of HAPs considered for screening?

Why are the acid gases not included in the analysis?

Organics are not considered beyond the screening. Can this screening result be better substantiated?

b. Emission rates

The development of emission rates for individual HAPs needs to be more clearly described. Here are some outstanding questions that need to be answered before providing a reasonable evaluation of appropriateness of the emissions estimates used in the modeling (both screening and multi-pathway).

What exactly was measured at the representative sites and how were the measurements done? How valid are the extrapolations of representative measurements to annual averages? How valid are the extrapolations to other facilities?

Are the processes leading to the emissions fairly constant throughout the year? How variable are the fugitive emissions at a given site?

5. MODELING

The model choices have been defended reasonably well. However, as noted above, improvements are needed and may be forthcoming with TRIM. Models seem to have

been applied appropriately. However, several concerns are noted below regarding the assumptions in the modeling that could have an impact on the overall analyses.

6. SCREENING

There needs to be more convincing discussion of the representativeness of the building and meteorology general parameters chosen.

Are the facilities being considered reasonably represented by the general building and stack configurations assumed? Stack height and building heights are particularly important variables.

Is the meteorology of the sites being screened adequately represented by the standard worst case meteorology? Wind speeds and directions relative to the selected receptor sites are particularly important variables.

7. MULTI-PATHWAY

Again, are the assumptions about standard building parameters reasonable? The assumptions about building parameters are retained in the multi-pathway analysis. This is probably reasonable provided the actual facilities are similar in construction.

What particle parameters and sizes are assumed in the modeling? This is very important to clarify since the ISCST3 does show different results for assumptions about larger particle sizes. If all of the particles considered are assumed to be less than 10 microns, then I doubt there is any difference in deposition and concentration patterns from those for the gases. This needs to be clarified since the exposures are sensitive to assumptions about particle size and particle versus gas.

8. RECEPTORS

A suggestion. The ISCST3 can produce patterns of concentrations and deposition at regular distances from the source. It might be helpful to provide these patterns as well as analysis at specific receptors. Patterns help provide an assessment of where risks might be important in the future. Is this type of analysis thought to be beneficial to the overall residual risk assessment?

9. MODEL/MEASUREMENT COMPARISONS

The results presented seem to be reasonable for the air models. However, the other comparisons are difficult to understand and are being discounted. The way that these comparison are being presented detracts from the work and tends to make one more skeptical of the findings.

10. UNCERTAINTY

It would be helpful to even more explicitly tie uncertainties to well-defined next steps.

STATEMENT OF DR. GEORGE E. TAYLOR, BIOLOGY DEPARTMENT, GEORGE MASON UNIVERSITY, FAIRFAX, VA

A CASE STUDY RESIDUAL RISK ASSESSMENT SECONDARY LEAD SMELTER SOURCE CATEGORY

The SAB review of the draft *Residual Risk Report to Congress* was a challenge in light of the report being framed in very general way. In my participation of that review, I was uneasy about the review solely because I was unable to see the trajectory for the analysis in a quantitative sense.

The *Secondary Lead Smelter Source Category* analysis is a giant step forward and helps me be more confident that the analyses will be quantitatively based and linked to the literature on human health and ecology. The Agency is commended for pursuing that tack.

There are a number of general issues that are of concern however in the draft document and the presentations at the meeting. These general issues are outlined. Collectively, these suggest to me that the current draft is well short of being scientifically defensible with respect to natural resources and ecology.

1. Attention to Ecology and Natural Resources

The attention to ecology and natural resources was a major concern in the *Residual Risk Report to Congress*, and I strongly encouraged the Agency to place ecology at parity with human health in this effort. Some assurances were made in that review exercise that ecology would be given more attention.

In the case of the *Secondary Smelters*, the case for ecology and natural resources is again diminished by the Agency. The effort is clearly well behind the analysis being conducted for human health and is not at a stage where this reviewer can be comfortable with a positive review. In short, while we have made some progress, there is insufficient analysis conducted to meet the legal mandate of the CAA.

This issue is a major one and warrants high visibility. My recommendation is for the committee to exhort the Agency to be more forthcoming with resources in order to get the task done in a scientifically sound manner.

2. Not a Risk Assessment But a Risk/Hazard Characterization

The title of the Agency's report is A Case *Study Residual Risk Assessment: Secondary Lead Smelter Source Category. Risk Characterization.* Following the original review of the draft *Residual Risk Report to Congress*, this reviewer was expecting an analysis that was more nearly a risk assessment. What was presented was a hazard characterization for ecology and natural resources, and the analysis was preliminary at best. Moreover, the Agency stated that no further work toward a risk assessment would be conducted for ecology and natural resources.

As a consequence, the current analysis does not meet the legal mandate of the CAA.

3. If this is the final product for this source category. . .

Because this report establishes a methodology for analyzing 179 source categories, it is very important that this report be done right. In light of the Agency's commitment to a preliminary hazard characterization *in lieu* of what is the legal mandate, I am concerned that this document will establish a precedent for all subsequent analyses so that ecology and natural resources are poorly addressed. As it now stands, the methodology produces a high number of false positives and fails to incorporate some pathways and receptors that are the most sensitive ones in an ecosystem with respect to persistent and bioacceumulated chemicals.

The proposed methodology is not likely to be of value in assessing the residual risk to ecology and natural resources and is likely to leave the risk manger with a formidable problem in handling the purported risks.

4. Linkage to Risk Manager

The shortcomings of the current report are presented above and are worthy of attention. Above and beyond these shortcomings is the linkage of the risk assessment to the task of the risk manager. There is no discussion of how the risk manager is likely to use this assessment.

It is recommended that a framework for the risk management be made a part of this report. The same recommendation was made for the previous report (*Residual Risk Report to Congress*) by the SAB.

5. Conclusion That the Analysis is Conservative

This assertion is stated throughout the report, and I am not in full agreement with that distinction with respect to ecology and natural resources. My rationale is twofold. Most importantly, the omission of fish eating birds (top carnivores) removes

one of the top predators in terrestrial/aquatic systems and one of the receptors that is highly valued (charismatic megafauna). In my analysis of the report, mercury would easily have been identified as a risk had this trophic level been included; it probably would have been the dominant risk. The argument that predatory fish are included does not suffice since predatory birds consume predatory fish, so there is an additional trophic level for bioaccumulation. The argument that data do not exist to evaluate this receptor is not accurate.

The second point is more tangential. The analysis for ecology identified a number of HAPs with concern in the screening exercise. Most, if not all, of these are likely to be "false positives". For example, antimony is screened as a risk, but I have never read a paper dealing with ecotoxicology to plants of antimony. The citation for the benchmark is an old paper published in an agricultural setting. The point is the false positives are almost to the point of being "silly" and can be easily discounted by the risk manager. This "silliness" might establish a precedent for ecology and natural resources that would permeate all 179 analyses.

I would much prefer to see a screening exercise that covers the potential serious risks (e.g., Bioaccumulated HAPs in top carnivores) than marginal risks, and I think that is the objective of the legal mandate.

6. HAPs That are Persistent and Bioaccumulated

The tenet is stated that any HAPs that is persistent *and* Bioaccumulated is automatically carried to the next level (multipathway not refined analysis?). I think those terms are confusing (e.g., if it is Bioaccumulated, by definition it is persistent; some persistent HAPs may not be Bioaccumulated). I am not certain what this statement means.

Most HAPs by definition are persistent. Lead, Ni, Hg, etc. . . . are elements and by definition are persistent. Most of the HAPs are also accumulated to some extent simply because many are lipophilic either as elements or in the complexes they form. So, there must be a threshold for bioaccumulation. Does that have to be a trophic enhancement factor of 2?

7. Background Concentrations

This issue was raised in the previous review and I encourage the Agency to rethink its position. While there may be some rationale for assuming a zero background concentration in the screening exercise, there are some major liabilities even at this level for pursuing this line of reasoning.

Even more difficult is the next level of analysis in which exposure-response functions might be generated. Given that many of the HAPs are elements and are common geochemical constituents in the crust, not addressing this issue is likely to undercut the conclusions significantly from a scientific basis.

SPECIFIC COMMENTS

This review supplements the forgoing analysis, which is more general. The comments herein are more specific and either supportive of the above or individualistic.

1. More refined analysis. The argument is presented often about the next iteration, which is a refined analysis. The structure and refinements to be done in that analysis are not presented. Is this to be a full risk assessment?

2. Screening for chronic effects protects for acute effects. While I can appreciate why shortcuts are used, I am not certain that this position is true. I can think of several cases where chronic exposures would not protect against acute exposures. For example, if you had a fugitive emission of a toxic chemical with a high 1 hour exposure, over the course of the season that exposure would not be significant but may very well compromise some receptors (e.g., radiochemicals, ozone). Can you provide a citation that supports the position?

3. Background concentration. This issue was raised in the previous review, and I am not in favor of the position being taken in the report. While the screening exercise may opt to assume that the background concentration is zero, this is NOT a conservative decision. In fact, it may significantly negate many HAPs (particularly those that are elements common in the earth's crust) from ever accumulating enough to exceed a threshold. I recommend that the Agency re-consider its position on background exposures, particularly as one moves on to more refined analyses. From my perspective, this omission negates the Agency's position that the analysis is conservative. Moreover, I do not think you can conduct a more refined analysis without including a background exposure for either human health or ecology. But, in the case of the latter, it is clearly critical.

4. Modifications to the multipathway model. It is noted that the analysis used the multipathway model in the *Mercury Report to Congress* for this modeling effort but

that the model was modified on a HAPs-specific basis. Those modifications are important to State since they could underpin the analysis.

5. Dispersion modeling. The report uses a dispersion model (Gaussian) to handle the offsite transport of HAPs. The guts of the model are not presented and key aspects are missing that might help skeptics relate to the code. Is deposition velocity (Vg) the operative parameters for driving deposition? If so, what nonlinear relationship is being used? Is particle size a part of the emission data? If not, then Vg cannot be used.

6. Figure 3.1 is missing but discussed in the text.

7. Plant Characteristics. Plants appear to be one of the critical parts of the model as the exposure to humans is preceded by deposition to leafy vegetable. This part of the code needs to be reviewed for such features as leaf area index, Vg, seasonality of phenology, yield, foliar leaching, etc. My suspicion is that none of these factors are part of the model, so it is unclear that the model handles the atmosphere-leaf transfer very well.

8. Figure 3.3. It is customary in compartment model diagrams to show compartments/state variables as boxes and transfers as ovals or some other geometric shape. They mean very different things. Also, is the half-life (T½) part of the model for HAPs? If so, a table of T½'s should be published. This is an important parameter.

9. The argument is presented that the mercury concentration in fish is a function of the mercury concentration in water. Is that true? I do not see how this could be coded into an aquatic model with multiple trophic levels? The mercury concentration in water must be processed through several intervening trophic levels before it gets to fish and thereafter it is bioaccumulated as a function of the trophic level.

10. The summary for all sections is not a summary. The summaries relate the methodology but not the summary of using the mythology for this exercise on lead smelters.

11. What are the endpoints in ecology and natural resources? In human health it is the farmer and his family. Clearly State the endpoints for this hazard characterization.

12. It is stated that the structure and function of the ecosystems is an endpoint. I have difficulty with that position.

13. It is stated that rare and endangered species are an endpoint. Again, I have trouble with that position.

14. Are receptors the same as assessment endpoints?

15. Why are carnivorous terrestrial wildlife omitted? These are likely to be the "charismatic megafauna" of most interest and the ones at greatest risk form HAPs that are bioaccumulated.

16. EC50 derivation. The argument is presented to derive some benchmarks from EC50's by dividing by a factor of 10. I am not certain that is justified. I would prefer to simply leave the benchmarks as stated in the literature rather than deriving some. This will eliminate a number of false positives and will help add credibility.

17. Summing HQ's. As noted above, this approach needs to be done with extreme caution.

18. Bioaccumulation. It is stated that bioaccumulation is assumed to be 100 percent. I am not sure what that means. Does that mean 100 percent of the HAP in the system is bioaccumulated to the next trophic level? If so, what BAF is used?

19. All chemicals without data are analyzed further. This is difficult to imagine. But, if there are insufficient data to conduct a screening analysis, how could there possibly be enough data to do a more refined analysis?

20. Fugitive Emissions. While I understand that fugitive emissions can be important, I am skeptical of the methodology that shows the entire assessment being driven by fugitive emissions. From my knowledge of ecology and human health, that simply does not compute.

21. False positives for ecology. This is where I think the methodology suffers, and I recommend that some remediation is in order. The ecology risk section concludes that several HAPs—antimony, chromium, and nickel—are a significant enough risk to warrant further study. I am not aware of any report for antimony in plants that would warrant that conclusion and probably the same for chromium and lead and nickel. The creation of many false positions that are unrealistic will be self defeating in the long run.

22. False negatives for ecology. In contrast to the above concern, there are some HAPs that are missing for methodological reasons. The most notable is mercury, which can be traced to the absence of top carnivores in terrestrial ecosystems.

23. Appendix F, Table F.2. The equation for calculating dry deposition simply does not work as portrayed. The units do not cancel out to arrive at the correct units.

24. Appendix E. The hazards with fugitive emissions are an order of magnitude higher than those without fugitive emissions. This seems inordinately high.

25. Distance for dispersion. The distance used for dispersion and assessment needs to be defined. Clearly it is not the distance traveled by the HAPs after emission, which for some of these (e.g., mercury) is global.

26. Air stagnation events. How are air stagnation events handled in the model?

27. Criteria pollutants. While I understand some of the legal mandate for this analysis, I suspect that some of the most significant residual risk from these categories will be the impact of the criteria pollutants, notably ozone and $PM_{2.5}$. This liability is best presented up front so the caveats are well articulated.

STATEMENT OF DR. RAE ZIMMERMAN, ROBERT WAGNER GRADUATE SCHOOL OF PUBLIC SERVICE, NEW YORK UNIVERSITY, NEW YORK, NY

BASIS FOR CASE STUDY SELECTION

The rationale for the choice of secondary lead smelters as a case that will become a prototype is only briefly described and should be expanded. Why is it significant and prototypical? Is it like other industrial emission sources?

The change in capacity or use of these smelters might be one reason for their being a significant case. The discussion on p. 5 alludes to a reduction in the number of lead smelters nationwide in 1999 over 1993–1994 levels. Capacity is really key, however. Has the capacity of the remaining smelters increased? Is the need for them changing, i.e., what is the quantity of lead-acid batteries needing recycling?

One very strong reason for its selection is that it is central to the debate over electric cars (see debate in Science, 1995). The contribution of lead smelters to air pollution in the course of recycling lead-acid batteries is part of the overall assessment of the relative environmental impact of electric cars over the conventional automobile. Thus, the relative risk associated with secondary lead smelters addresses a much broader health debate.

METHODOLOGICAL ISSUES

A number of methodological issues need greater explanation or some references to justify methodological approaches and choices.

a. p. 6—the expediency of using a surrogate standard for all metals is clear, but why was lead selected?

b. p. 9—what is the justification for using inhalation analysis for all HAPs rather than the ingestion route also, e.g., via soil deposition and subsequent entrainment in exposure areas? p. 14 also notes that inhalation pathway is the most important route of exposure, which needs a short explanation.

c. Decisions are made throughout the analysis, and should be explained. For example:

d. p. 9 How is the subset of facilities selected—just high emission rate rather than mix of HAPs? In other words a facility with a high emission rate may have low concentrations of HAPs.

e. p. 10 Receptor locations chosen as the point of maximum air concentration—was this regardless of the number and type of HAPs?

f. p. 10 How were the three HAPs and three pathways selected for the variability and uncertainty analyses?

g. Is there any way of identifying which of the HAPs present in the emission stream are likely to react with one another to increase or reduce residual risk?

h. The rationale behind the use of very numerous assumptions/defaults at any given point in the assessment is difficult to evaluate, e.g., p. 24, 32. On p. 24, for example, there are numerous simplifying assumptions for the inhalation screening analysis.

How do these assumptions interact with one another and affect the results?

i. In areas where information is not known, can't the Agency undertake some scenario building to at least identify some of the boundaries? For example:

(1) Geographic differences in the location of the smelters and the effects of this variation on exposure are not included, but need to be factored in somehow into the analyses. For example, p. 24–25 the building downwash or terrain options for SCREEN3 were not used because site specific information was not available. This is important, however, since the report specifically identifies that the use of such options can result in higher values for air pollutants. What about using locational scenarios?

(2) Where information on d/r for HAPs was not available the HAPs were excluded from the analysis (p. 33)—Does the uncertainty analysis at least include the fact

that "HAPs for which quantitative d/r assessments are not available" were excluded from the quantitative analysis?

j. p. 30 The technique for aggregating cancer risks is additivity. The drawbacks of this yet the need should be clearly stated, as well as how additivity is likely to affect the results.

APPENDIX B

A MORE DETAILED DESCRIPTION OF THE SAB PROCESS

The SAB Staff recruited Dr. Philip Hopke, Chair of the Chemistry Department at Clarkson University, to serve as Chair of the Subcommittee. Working with the Chair, other SAB Members and Consultants, Agency Staff, and submissions from the American Industrial Health Council (AIHC) and the Natural Resources Defense Council (NRDC), the SAB Staff compiled a list of over 30 scientists and engineers who were subsequently surveyed for their interest in and availability for participating in the review. The Chair and SAB Staff made the final selections for membership on the Subcommittee and assigned different members lead and associate responsibilities for each of the Charge Elements.

The Agency transmitted review materials to the Subcommittee members in late January. In mid-February SAB Staff convened a conference call with Agency staff to identify gaps in the information sent to the Subcommittee and to identify areas that the Agency should be prepared to clarify at the face-to-face meeting.

In addition, public comments were received from the following parties and distributed to the Subcommittee Members before the meeting:

a. Association of Battery Recyclers and the Lead Industries Association: Robert Steinsurtzel and Michael Wigmore—Swidler Berlin Shereff Friedman (Counsel for Association of Battery Recyclers), Jane Luxton and Cynthia A.M. Stroman—King and Spalding (Counsel for Lead Industries Association, Inc.), Dr. Teresa S. Bowers—Gradient Corporation, Russell S. Kemp—Lake Engineering.

b. Cambridge Environmental Inc: Dr. Edmund Crouch and Dr. Stephen Zemba.

c. Indiana Department of Environmental Management: Mr. Michael Brooks

d. Residual Risk Coalition: Dr. Elizabeth Anderson—Sciences International, Inc.

e. Sanders Lead Company, Inc.: Mr. Billy Nichols, Dames & Moore.

On March 1–2, 2000, the Subcommittee convened in the Main Auditorium of Environmental Research Center at the USEPA laboratory in Research Triangle Park, NC. Minutes of the meeting are available. Each member of the Subcommittee submitted written comments on the Charge questions for which he/she had lead responsibility. Two members of the public (Dr. Elizabeth Anderson and Dr. Teresa Bowers, see a and d above) provided comments on the technical issues under discussion. Following a full day of discussion, Subcommittee members drafted and reviewed responses to the Charge questions.

The Subcommittee members were given the opportunity to refine their pre-meeting comments for their inclusion in the Appendix A to the Advisory. These written materials formed the basis of this Subcommittee Advisory that was drafted by the Chair and the SAB Staff and subsequently modified/approved by the Subcommittee. [An SAB "Advisory" is a term-of-art used to denote review of an Agency document that is still undergoing development, in contrast to an SAB "Review" of a final Agency product.] The Subcommittee-approved draft was sent to the SAB Executive Committee (EC) for action during a publicly accessible conference call on May 1, 2000. At that meeting the EC approved the Advisory, subject to final approval by designated vettors, Dr. Kenneth Cummins and Dr. Linda Greer.

APPENDIX C

Glossary

AEI	Average exposed individual
ATSDR	Agency for Toxic Substances and Disease Registry
BID	Background Information Document
CalEPA	California Environmental Protection Agency
CAAA	Clean Air Acts Amendments of 1990
CDC	Centers for Disease Control and Prevention
CRARM	Commission on Risk Assessment and Risk Management

Glossary—Continued

HAPs	Hazardous air pollutants
HEAST	Health Effects Assessment Summary Tables
HI	Hazard index
HQ	Hazard quotient
IEM–2M	Indirect Exposure Methodology
IRIS	Integrated Risk Information System
ISCST3	Industrial Source Complex Short Term model
MACT	Maximum achievable control technology
MEI	Maximum exposed individual
MIR	Maximum individual risk
NAAQS	National Ambient Air Quality Standard
NATA	National Air Toxics Assessment
NESHAP	National Emission Standards for Hazardous Air Pollutants
NRC	National Research Council
OAQPS	Office Air Quality Planning and Standards
PAHs	Polyaromatic hydrocarbons
QSAR	Quantitative Structure-Activity Relationships
PBTs	Persistent bioaccumulative toxicants
RfD	Reference Dose
RTC	Agency's 1998 Report to Congress
SAB	Science Advisory Board
TRIM	Total Risk Integration Model
TRVs	Toxicity Reference Values
U&V	Uncertainty and variability
USEPA	United States Environmental Protection Agency