"THE TRI LEAD RULE: COSTS, COMPLIANCE AND SCIENCE"

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

WASHINGTON, DC, JUNE 13, 2002

Serial No. 107–62

Printed for the use of the Committee on Small Business

U.S. GOVERNMENT PRINTING OFFICE
80–876 WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
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HEARING ON THE TRI LEAD RULE: COSTS, COMPLIANCE, AND SCIENCE

THURSDAY, JUNE 13, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:07 a.m. in room 2360, Rayburn House Office Building, Hon. Mike Pence [Chairman of the Subcommittee] presiding.

Chairman PENCE. This Subcommittee on Regulatory Reform and Oversight of the House Committee on Small Business hearing entitled "The TRI Lead Rule: Costs, Compliance, and Science", is convened.

The Chair will recognize the gentleman from Pennsylvania for some brief opening remarks after a few remarks of my own.

I wish to thank all of our witnesses for their attendance today, but, most especially, the Environmental Protection Agency and the representative who joins us here today, with apologies for my tardiness. I am the victim this morning of having one too many Subcommittees in my life and appreciate the forbearance of our witnesses and my colleague from Pennsylvania.

I want to begin by giving the EPA my congratulations this morning. The threat of lead poisoning, especially to children, has been dramatically reduced in our country. Much of that, I would offer today, is due to the work of the good men and women at the EPA and other agencies of the federal government.

Former Health and Human Services Secretary Donna Shalala said in announcing the 1997 CDC results, "These lower lead levels for America's children constitute a public health achievement of the first importance. For our children as a whole, we have achieved average blood lead levels which would have been considered impossible just a few decades ago."

Governor Whitman's predecessor at the EPA had this to say. "The ongoing reduction in blood lead levels is a great American success story of environmental and public health protection. Years of aggressive action against lead exposure, particularly EPA's banning of lead in gasoline two decades ago, are yielding a brighter future for our children," and indeed they are.

The Center for Disease Control, in the same document, did go on to note that the job of lead exposure reduction is not complete, saying, "There are still close to one million children with a blood lead level that is associated with adverse effects on children. In addition, the survey showed that more than one-fifth of non-Hispanic

black children living in older homes had elevated blood lead levels. This pattern reflects the most serious remaining sources of lead exposure; deteriorating paint in older housing, dust and soil contaminated by paint and residues from past emissions of leaded gasoline."

Beyond those accolades and the kind of affection that this Chairman developed for the EPA when they spent three months decontaminating my anthrax-contaminated office with great professionalism and alacrity, I am disappointed today, though, that we are not maximizing the benefits of this great achievement. It seems we are not taking these results as a lesson for further progress on this public health issue.

Today, we are not talking about further reductions of children's exposure to lead in paint or other major remaining sources of concern that have been identified. Today, we are talking in this hearing about a paperwork regulation that will at best provide some new information about the uses of lead that present no real risk for human health at a significant cost to small businesses and to the EPA. At worst, one could argue, this rule will provide inaccurate information about lead usage and divert important resources away from more pressing public health and environmental needs.

I wish I had already completed a listing of the problems with this rule. In addition to it not addressing the most important public health aspects of lead and potentially providing no public right-to-know benefit, this rule, for instance, as we may well hear today, is based on questionable science and lacks independent peer review.

It eliminates burden reduction measures meant to make TRI reporting easier for small businesses, and it is the first retroactively applied TRI reporting rule, which will require companies to desperately search for data about lead usage prior to when the rule was promulgated and became effective.

It suffers from an EPA guidance document that was not available until 13 months after the retroactive date for data collection and was 200 plus pages that, candidly, no small business person, let alone any congressman, could decipher. It subjects upwards of 10,000 new filers to burdensome reporting obligations under an EPA rule that many may not even know about yet.

It is virtually guaranteed to produce poor quality data that will not well serve the public's right-to-know, creates a risk of enforcement actions or citizen suits against small businesses that may simply be unable to comply with the rule, despite doing their best, and, finally, I assume, in recognition of the questionable science underpinning this rule, the EPA has decided to submit to a Science Advisory Board review of the biggest questions, but is waiting three years after the final rule is published for a final report on some of these issues.

This is not the EPA's finest hour, I would argue, after a great and I think colossal achievement in the reduction of lead exposure to children in this country. It stands in stark contrast to those reductions. This paperwork rule is also estimated to cost businesses between $70 and $100 million in the first year of implementation. When our economy is hardly at its peak and small businesses account for a majority of job growth in this country, it is not time

right now for substantial new regulatory costs of questionable benefits to be imposed.

Now is the time to prioritize, time to focus all of our efforts on the environmental regulations which will provide us with the most bang for our buck, as we say in Indiana, with the greatest impact on human health and the environment. This Chair believes that this rule does not pass this test.

This hearing has garnered quite a bit of interest. In addition to the witnesses gathered today, we also have testimony submitted by the U.S. Small Business Administration, the National Association of Manufacturers and the Meractus Center. We look forward to the testimony of all of our witnesses.

I would like to now recognize the Ranking Member, the gentleman from Pennsylvania, Mr. Brady, for his opening statement.

[Mr. Pence's statement may be found in the appendix.]

Mr. BRADY. Thank you, Mr. Chairman. I am going to submit my statement for the record rather than read it all, but I would just like to also chime in and join in with your remarks about the EPA and what they have done with their paint and the safety of our children.

I come from the City of Philadelphia in the State of Pennsylvania, which it is a great city, but it is an old city. It has a lot of old houses and a lot of lead paint in a lot of our areas, and they have done an excellent job. It has been extremely helpful, and our children have been allowed to grow up in some much better environments and better safety.

I also was thrilled to find that the Honorable Kim Nelson is from the State of Pennsylvania, has been there for all her life, and now in the City of Washington. Do not worry about that. If you are from Pennsylvania, you have a great background. You will do fine here. I look forward to hearing your statement.

Thank you.

Chairman PENCE. Before we begin receiving testimony from witnesses, I want to remind everyone that we would like each witness to keep their oral testimony to just five minutes, and then in order the Chair and the Ranking Member and any other Members that arrive will be given an opportunity to pose questions thereafter.

As our first witness and no doubt veteran of Capitol Hill knows, but our other witnesses may not be as aware, you have a series of lights in front of you, and they mean just what traffic lights mean. The Chair will allow a certain amount of latitude once the red light appears, but then the gavel will eventually arrive.

You should know that your entire written statement will, without objection, be added to the record, so you might use the opportunity of your remarks here to amplify points in your written statement.

In our first panel we will hear from a single witness, the Honorable Kim T. Nelson, who is the Assistant Administrator for Environmental Information at the U.S. Environmental Protection Agency.

Having just had a private meeting in my congressional office with Secretary Whitman, I am grateful, despite our frustrations with this rule, for the EPA's willingness to attend this hearing, to participate in a dialogue with the Small Business Subcommittee

and am grateful for your participation, even though you are from Pennsylvania.

Ms. Nelson is recognized for five minutes.

STATEMENT OF THE HONORABLE KIM T. NELSON, ASSISTANT ADMINISTRATOR FOR ENVIRONMENTAL INFORMATION, U.S. ENVIRONMENTAL PROTECTION AGENCY

Ms. NELSON. Thank you. I am struggling for some connection I have with Indiana, but it is not coming to me at the moment.

Good morning, Congressman Pence and Congressman Brady. First, Chairman Pence, let me apologize since I was not at that meeting you had with Governor Whitman as I was out of town that day, but I am glad it went well.

I do appreciate the opportunity to be here today to discuss with you EPA's recent rule to expand the reporting on lead and lead compounds under EPA's Toxic Release Inventory Program. As you may recall, the new TRI lead rule was carefully reviewed by this Administration upon entering office and was eventually endorsed by the President and Governor Whitman and became effective, as you stated, in April of 2001.

The new rule requires any facility which is already subject to the Emergency Planning and Community Right-to-Know Act reporting provisions that also manufactures, processes or uses more than 100 pounds of lead or lead compounds annually to report to EPA their lead releases. This rule significantly expands the information available to the public about the presence and releases of lead in their communities.

Since its implementation in 1987, the TRI has been the centerpiece of EPA's right-to-know programs and has proven to be a very powerful tool for assisting communities in protecting their own environment and for making businesses more aware of their chemical releases. The basis of the TRI lead rule is EPA's determination that lead and lead compounds are persistent, bioaccumulative and toxic chemicals. These are also known as PBT chemicals.

These chemicals are of particular concern because they remain in the environment for long periods of time, they build up in the environment, and they accumulate in plants, animals and humans and may cause a range of very serious toxic effects.

In assessing the persistence of lead, EPA concluded that lead meets the PBT criterion for classification as highly persistent. Because lead is a PBT chemical and it is highly persistent, there is a greater potential for exposure to lead.

In assessing the bioaccumulation of lead, EPA considered bioaccumulation data in aquatic plants, animals and humans. In addition to the plant and animal data, there are extensive peer reviewed human data demonstrating that repeated exposure to low levels of lead results in a build up of lead in the bones of the human body where it can remain for many years. Numerous studies have shown that lead that has accumulated in bone can later move from the bone to blood, especially during pregnancy, breast feeding, menopause, old age, and serve as a source of exposure.

The toxicity of lead to humans is well documented and undisputed. Of particular concern is the effect lead has on fetuses, infants and children because they tend to be more susceptible to ex-

posures of lead and are more sensitive to the toxicity it causes. Their exposure to lead can cause permanent brain damage. Even at the very low dose levels, exposure can result in diminished IQ levels, impaired neurobehavioral development, decreased stature and growth and impaired hearing.

During the public comment period for the proposed rule, questions were raised challenging the sufficiency of the aquatic data to support the conclusion that lead and lead compounds are highly bioaccumulative. In addition, EPA recognized that it did not clearly indicate in the proposed TRI rule how the human data would be used to distinguish between bioaccumulative and highly bioaccumulative categories. Consequently, EPA determined that the data clearly supported a finding that lead and lead compounds are bioaccumulative and deferred on its determination as to whether lead and lead compounds are highly bioaccumulative.

In the final lead rule, EPA stated that before determining whether lead and lead compounds are bioaccumulative, EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA, as you mentioned, intends to do so. The date proposed for the peer review of the highly bioaccumulative issues pertaining to the lead rules is November, 2003.

This Administration believes that the preferred approach to achieving compliance with new rules is emphasizing compliance assistance during the first year rather than direct enforcement. EPA has worked hard in providing compliance assistance and outreach, especially for small businesses, for this first reporting year deadline.

For example, EPA issued a technical guidance document to assist facilities, as you mentioned, in complying with the new lead rule. Also, in the fall of 2001, EPA sponsored nine workshops specifically on the new lead rule. Both the workshops and the availability of the draft and final versions of the guidance document were extensively publicized.

In addition to these specific efforts, EPA continues to work hard to provide compliance assistance for facilities generally. For example, this spring EPA held more than 40 workshops. Also, EPA has many more TRI compliance assistance resources and tools available through the internet and telephone hotlines.

In conclusion, I would like to reiterate EPA's strong commitment to providing public access to environmental information and our firm belief that public access contributes positively to our citizens' ability to understand environmental issues and to make better decisions in their daily lives. An informed public can hold government and industry accountable for pollution control efforts.

Thank you, Mr. Chairman. Thank you, Congressman Brady. I would be happy to take any questions.

[Ms. Nelson's statement may be found in the appendix.]

Chairman PENCE. Thank you for that presentation. You mentioned a couple of different areas, and I may hit a few areas and then yield to Mr. Brady out of sensitivity to his schedule this morning.

First, I want to reiterate that you are here speaking for all of the EPA, including the Office of Enforcement and Compliance Assurance, according to our information.

Ms. NELSON. That is correct.

Chairman PENCE. You have described the EPA's policy as stressing compliance rather than enforcement in the first year. What does that specifically mean to a small business that is covered under this rule?

Ms. NELSON. Let me say I am new to EPA. I have been here since the fall, but I have spent 15 years in an environmental protection agency in Pennsylvania.

Like the experience I had in Pennsylvania, I believe EPA has a history, and particularly so now such as sensitivity, that the agency has the ability to exercise complete discretion over its enforcement actions.

What that means particularly when you are dealing with a new program is that we recognize that the first year of a program, even a second year, enforcement actions for a program that is new tend to be very low on the enforcement priority list.

Our emphasis is to bring facilities in compliance. I know of no one in this agency who is planning on taking enforcement actions against a facility where we show general goodwill in terms of complying with the requirements of the law and the regulations.

Chairman PENCE. Does that mean zero enforcement actions in the first year? If not, then when specifically would you choose to use enforcement?

Ms. NELSON. Let me say, you know, we all understand absolutes are something that can create problems in the long run. It is clearly a low enforcement priority. This is, as you mentioned, a paper reporting exercise.

Through this program, we are not asking people to implement new control technologies. We are not asking people to change effluent discharges or to limit effluent discharges in any way. This is a reporting exercise which is geared towards providing the agency and the American public with information.

Our goal will be to insure the highest quality of information, and that is where we want to focus our resources. I know of no one at this point in time that would see it appropriate to take what we would consider an "enforcement action" against someone who has filed inappropriately or incorrectly or incorrect data.

Chairman PENCE. The President has asked the EPA to provide special assistance to small businesses——

Ms. NELSON. Yes.

Chairman PENCE [continuing]. On this rule, tacitly recognizing the burden that it imposes on business.

Ms. NELSON. Right.

Chairman PENCE. What specifically did the EPA do to help prepare small businesses to comply with this rule?

Ms. NELSON. The agency first last summer held nine sessions throughout the country. Ten were scheduled, and, frankly, we canceled the one session that was scheduled in Region 2 because of the aftermath of September 11, but nine sessions were held across the country with over 700 people attending.

Seven hundred people does not sound like a lot when you talk about the numbers of facilities, potentially 5,000 facilities, give or take, that might be affected, but those sessions are really assigned to be a train the trainer session, to bring in the industry represent-

atives, the consultants and the others who actually provide support to industry. Seven hundred people attended those sessions.

In addition to that, we held a number of public meetings last summer on the guidance document. As you mentioned, it was EPA's plan to get the guidance document out in October. The meeting was held on September 10. We know we did not meet that deadline because of the aftermath of the events on September 11.

We extended the deadline, however, because of those events and because of certain concerns about the rule, which was one of the reasons the guidance document got out late. We provided more opportunity for public comment on the document. We could have gotten it out earlier, but we would have shortened the public comment input period.

This fall, we held our normal TRI sessions that had a special focus, as they normally do, on the new reporting requirements. Those sessions I believe totaled more than 40 throughout the country and were attended by thousands of people, in excess of maybe 3,000 people.

We also have our hotline that is available for people to call in any day on the document itself and the Q&As. It is, from my perspective, one of the most aggressive outreach programs EPA has ever done in the TRI program.

Chairman PENCE. This is the first TRI rule to be applied retroactively. I will say procedurally I want to see if I can get an answer to this question, and then we will recess while Mr. Brady and I go for what apparently will be about 20 minutes of votes and be back.

The final rule was not effective until April, 2001. The businesses are required to report releases starting January, 2001. EPA did not provide a final guidance document until the end of January of this year. What is the justification for applying this rule retroactively?

Ms. NELSON. Well, I guess we have to understand that the rule became effective on April, 2001, but the reports are not actually due until approximately 15 months later.

The justification for allowing a rule to go into effect in April when reports are not due for another 15 months is the fact that the TRI program has always allowed filers to estimate their releases. It is not like other programs, our NPDS program, for instance, where facilities have to submit monthly discharge monitoring reports where those reports are based on real monitoring of actual occurrences.

The TRI program has always allowed facilities to estimate, so it is easy or it is possible, based on formulas, for a facility to estimate their usage back for a period of a year.

Chairman PENCE. The Chair will ask the assistant administrator——

Ms. NELSON. Yes.

Chairman PENCE [continuing]. If she can stay here. We will return, I presume, by about ten minutes before the hour after a series of votes.

With that, we are in recess.

[Recess.]

Chairman PENCE. Kim Nelson, the Assistant Administrator for Environmental Information at the U.S. Environmental Protection Agency, is still with us. We are grateful for your patience and ev-

eryone else's patience. We do not anticipate another interruption prior to the end of the hearing.

The Chair has a great number of questions, but, in the interest of his time and schedule, wanted to yield to the gentleman from Pennsylvania, the Ranking Member, for any questions that he might have for our witness.

Mr. BRADY. Thank you, Mr. Chairman. I just have one that I do not understand.

What is the difference between the TRI Form A as to the one that we have now that is less burdensome? Do you know?

Ms. NELSON. The TRI Form A was a burden reduction effort that requires less information to be filed by a facility versus the full Form R.

Mr. BRADY. Was there a problem with that one, I mean, that it had to be changed to make it more burdensome? I mean, we are trying to make things less burdensome for small business.

Ms. NELSON. The Form A came after I believe the Form R. but I was not here at that particular time. I can get back to you on that particular sequence of events.

Mr. BRADY. Okay. Thanks.

No more questions, Mr. Chairman.

Chairman PENCE. Ms. Nelson, let me take a little different tact with the questions for the moment. I am going to read some statements from your confirmation hearing for the record and then ask you a couple of specific questions.

In your confirmation hearing, you said, quoting now, "The information that we provide must be of exceptional quality, supported with analytical tools which facilitate its use for assessing and managing risk and measuring environmental improvements."

You also said that it would be your intention to assist Administrator Whitman by helping to "sharpen the focus of the EPA's environmental information strategies, reduce burden on industries, promote intergovernmental cooperation and apply best practices to achieve internal efficiencies."

You also said, "I believe these activities will contribute significantly toward burden reduction, improved data quality and security, more informed environmental decision making and greater flexibility to manage environmental programs."

In light of the extensive evidence that without more time to get it right implementing this rule on June 30, 2002, will result, to put it bluntly, in extremely poor quality data, does this rule meet the goals expressed in your confirmation hearing for data quality and the right relationship between the EPA and small business America?

Ms. NELSON. I still believe everything I said on that day when I testified, which was October 17 of last fall.

This program I think has to be treated a little bit differently, as I mentioned before, from other programs in EPA. This program is not one where we are making individual, site specific risk assessment kinds of decisions.

What is important about the TRI program is that it provides the agency with an opportunity to collect information that it and others in the community and businesses can use hopefully to make better environmental decisions. We recognize that I think in any program

the first year is not going to be the highest performing year; that it always takes some experience under our belts to get to the level of high performance we would all like to see.

I think there are a number of things we are doing in the TRI program that can help improve the quality of the data, which is the ultimate goal that we all have, and reduce the burden. For instance, my primary focus with the TRI program is to focus on improved electronic reporting. The one thing we know as we move towards e-government is that the more we can get facilities and others to report electronically, the higher the quality of the data will be.

I do not know if you have used something like Turbo Tax before, but you know a software program like that, as we have with the newest versions of the TRI report, can help you calculate your answers and insure that the data submitted are accurate. It actually prevents you sometimes from putting in incorrect data, which often happens on the paper forms. Somebody gets a factor wrong by ten or more. We see an outlier way out here, and we recognize that cannot possibly be correct.

The more you can do electronic reporting, the more you can prevent that from happening, so that is my focus. With my goals of higher quality data and burden reduction, we can actually reduce that burden on companies if they begin to submit electronically because we can make it easier for them to submit, and we can get higher quality data.

Chairman PENCE. Let me change gears, if I can, to the whole issue of science and ask you first to maybe express what is your view of science at the EPA? Maybe more accurately, how should science inform policy at the EPA? Should it be controlling? Is it a factor in the development of environmental policy?

Ms. NELSON. As we look to new issues, there is one thing that I clearly have recognized the last couple years, and that is the issues we are going to face from an environmental protection perspective, regardless of where we sit in an organization, are issues that are getting far more complex.

The low hanging fruit, I think we can all agree, has been picked, so the issue we are faced with in the future will be of incredible complexity for many different reasons—impacts on communities, impacts on the regulated community, on people, as well as the science.

Governor Whitman I think has elevated in terms of stature within the organization the Office of Research and Development. Paul Gilman, Dr. Gilman, who is the assistant administrator for that particular office, has recently been named by her as her science advisor for the organization, and I think any good policy coming out of EPA is a policy that has to be based on teamwork across the organization. That teamwork includes the Office of Research and Development to insure that all of our decisions are based on sound science.

Chairman PENCE. So your view would be that all policy has to be based on teamwork and that essentially the researchers are part of that team. The science is a factor in the development of policy, but is it fair to say it should be the dominant factor in the development of policy?

Ms. NELSON. I do not think it can be because we have statutory and legislative requirements, so I do not think in any given situation or across the board you can make a statement that science has to be the dominant factor. I would not say that now.

I think in any given situation we have to balance and we have to look at all the particular drivers in any given situation. Some of them are statutory. Some of them are economic. Some of them are social. Some of them are science. It is our job as appointees there and as employees of the Environmental Protection Agency to balance those issues.

Chairman PENCE. Let me read you a quote from Governor Whitman in her confirmation hearing, which may be at odds with your prior statement. She said, "Scientific analysis should drive policy. Neither policy nor politics should drive scientific results. Good science is the basis for all the decisions that are made at the agency that is critical to the credibility of the agency and the implementation of the decisions made by the agency."

Again, her initial statement is there. "Scientific analysis should drive policy." Do you think that is a practice at the EPA, in your judgment?

Ms. NELSON. Well, that is what the governor said, and that is what I said in my first statement that the governor believes strongly in sound science. I believe she had heightened the visibility of the Office of Research and Development in appointing Dr. Gilman as her science advisor, and I believe we all within the organization have to make decisions based on sound science.

I do think that is the practice, yes, that we are all expected to abide by, but it is not the only one. We have to take other things into consideration.

Chairman PENCE. Let me see if I can get a quick yes or no on a series of questions, and then we can wrap up at least the Chair's portion of questions.

Number one, are you aware the EPA co-sponsored a workshop in January of 2000 on whether it was appropriate for metals to be considered as PBTs?

Ms. NELSON. I was not here at the time. I am aware that that did occur, yes.

Chairman PENCE. Okay. Are you aware that questions at that time were raised about the very characterization of lead as a PBT chemical in interagency reviews?

Ms. NELSON. I am aware there was discussion of that issue.

Chairman PENCE. Are you aware that the Small Business Administration, in its search, has yet to find any peer reviewed literature, journals or reports or scientists from government, industry or academia to support EPA's characterization of lead as a PBT?

Ms. NELSON. I am not aware of that.

Chairman PENCE. How about the fact that bipartisan leadership on the House Science Committee has requested SAB review of this issue and that the Committee has statutory authority to require SAB review?

Ms. NELSON. I am sorry. Could you repeat that?

Chairman PENCE. Are you aware that the House Science Committee has requested an SAB review of this issue in particular?

Ms. NELSON. I know prior to my coming here there was dialogue and discussion between various Members of Congress, but I am not sure of what you are specifically referring to.

If it is an earlier request that came out of the VA HUD appropriation a year or so ago, my understanding was we were urged to look at the issue and that as a result of some dialogue and discussion there was an agreement on an approach.

Chairman PENCE. Are you aware that the Small Business Administration, the Office of Science and Technology Policy, the Office of Management and Budget and the Department of Energy are all on record supporting peer review on the fundamental science question behind EPA's rule?

Ms. NELSON. I am aware this issue has been discussed by a number of organizations.

Chairman PENCE. Okay. Well, then let me ask. Is the question of whether or not lead or other metals are appropriately characterized as PBTs under this rule currently before the SAB, or will it be?

Ms. NELSON. The issue that we are putting before the SAB is whether lead and lead compounds are highly bioaccumulative. The agency has already made the decision that lead is considered a PBT, so that issue is not before the SAB. The issue before the SAB is whether lead should be considered and lead compounds highly bioaccumulative.

Chairman PENCE. So again, and I appreciate your clarity——

Ms. NELSON. Let me just say this. My understanding is also that issue is not before the SAB right now, but will be submitted to the SAB once the SAB reviews the action plan and the ultimate framework.

Once that framework has been reviewed by the SAB, then it is the intent to put the question before the SAB as to the highly bioaccumulative nature of lead and lead compounds.

Chairman PENCE. Maybe that explains it. In your written testimony you quote from the Federal Register notice of the final TRI lead rule in saying that, "The external peer review would address the question of whether lead or lead compounds should be classified as highly bioaccumulative." "The external peer review," and I am reading your testimony now, "would address the issue of how lead and other as yet unclassified metals such as cadmium should be evaluated using the PBT chemical framework, including the types of data and which species are most suitable for those determinations."

It is the last sentence I want to focus on. What is your understanding of that last sentence, and when will that question be before the Science Advisory Board?

Ms. NELSON. The schedule for the Science Advisory Board is that they will have the draft framework to review by June of 2003.

The draft guidance and issues based on that framework regarding the TRI lead rule and the highly bioaccumulative nature, whether lead and lead compounds are highly bioaccumulative, would be presented to the SAB in November of 2003 with the expectation that the SAB would release a report in March of 2004. That is based on the action plan that was recently published.

Chairman PENCE. Would that not represent the underpinning of this rule? It seems like, as we say in Indiana, we are putting the cart before the horse.

Ms. NELSON. I think at that point in time it would certainly be incumbent, based on the answers that come out of the SAB, for the program to evaluate the decisions and the implications on all of our current programs. I think it is also premature to change anything we are doing without that recommendation coming from the SAB.

Chairman PENCE. The Small Business Administration, and maybe we could have staff get this to you. The Small Business Administration has submitted written testimony——

Ms. NELSON. Okay.

Chairman PENCE [continuing]. For this hearing. They have shared with us some statements by scientists and other organizations that contradict your evaluation of the rule.

I am going to read to you some of these statements and try and get a reaction from you, and then we will wrap up and allow the Ranking Member to ask any follow up questions, and then we will move to our second panel. I will ask you to tell me if you think they support EPA's case or if they do not support EPA's case on the science behind this rule would be my main focus.

March 23, 1995, Great Lakes Water Quality Guidelines, "EPA's final rule establishing water quality guidelines for the Great Lakes examined whether ten metals, including lead, were bioaccumulative substances and found that none exceeded the BCF of 1,000, which is used as a cutoff. EPA is now apparently using the same set of pre–1995 data and found that BCF for lead exceeds at least 1,000."

Do you think that supports the EPA's case or does not support their case on the science behind the rule?

Ms. NELSON. Well, I think you have to be careful when you take a statement like this out of context that was intended for a specific situation.

The data that were used here are different data than we use for TRI, so I think it is inappropriate for me to suggest that it does or does not support our case. It is a completely different set of data for a different purpose and used in a different context.

Chairman PENCE. The Science Advisory Board report in May of 2000 was a draft case study analysis of the residual risk of secondary lead smelters. The quote is, "The classification of metals as PBTs is problematic since their environmental fate in transport cannot be adequately described using models for organic contaminants."

Without again confronting you with the same repetitive question about whether it supports EPA's case or not, and this is where I want to go with the next panel, but is there a sense within the EPA that this whole business of PBT chemicals was established around the idea of chemical agents like pesticides that are introduced into the environment, and now it seems like this classification has grown into even natural minerals like lead.

We can go through all of these, but all of them consistently challenge the very classification of lead and certain metallurgical natural minerals as PBTs. Is there any willingness at the EPA to

deeply rethink the whole move into minerals like lead as PBT chemicals?

Ms. NELSON. I think when we take issues like this in sort of chronological order and look at the history of PBT, we can see that these issues were dealt with, as the first one with the Great Lakes, for different purposes, for smaller audiences.

The most recent one you referred to with the Science Advisory Board and the lead smelters, my recollection is that analysis by the SAB was dealing primarily with different models that the agency uses and different risk assessment methods.

Again I would go back to the purpose of the TRI program. The TRI program is not a site specific program. The TRI program is not a risk assessment program. The TRI program is one in which we collect information that we can all use in government and outside of government hopefully in the future to make sounder decisions.

The PBT criteria that EPA published back in 1999 and the methodology was published as a rule, and we did receive comment on that rule. It became final. That methodology for applying the PBT criteria to chemicals was published as a rule. In that rule making, EPA did clearly state that it would apply to chemicals, not just certain chemicals, and in fact made a statement that it would apply to metals. This is an issue that EPA clearly stated several years ago.

While, like many issues, I believe there are different opinions, we have some statements here where people disagree with the use of PBT criteria. I think we could find an equal number of statements where people believe it is indeed very appropriate to apply the PBT criteria to metals.

One of the things we will all learn when the framework goes to the SAB is what they have to say about the issue. EPA believes it is entirely appropriate to apply PBT criteria to metals. What I think is important about the approach we are taking now is that with the administrator and with Linda Fisher we have leadership in the organization that recognizes you can often have what appear to be inconsistencies because every program has a different set of regulatory and statutory requirements.

I have been in government for 22 years. I have yet to find organizations that tend to be more diverse than environmental agencies with air programs, water programs, hazardous waste programs, radon programs. What I think we all know is that those individual silos often cause concern to people who are on the outside because they look at each individual program taking different actions.

The framework that we are looking for under Governor Whitman's leadership will help provide an overall framework for programs within EPA to take that framework and apply it to their individual situations because they still will have very different needs and situations as a result of their statutory and regulatory requirements.

Chairman PENCE. I am sure we cannot resolve this here today, but it seems to me that by your testimony today that the larger question is before the SAB, that it seems to me that this rule should be delayed until questions are answered from the science, from the people who are charged with determining the appropriate science.

Candidly, and I would ask you to convey back to Governor Whitman and to your colleagues at the EPA, I am just not prepared to sacrifice small businesses on a hunch that the EPA might be correct on major scientific questions related to this area.

There are conflicting facts, and we will hear more testimony today, but it appears that there is from my perspective overwhelming scientific consensus against EPA's view of this rule. If this qualifies as an occasion where, as Governor Whitman said, science should drive policy and not the other way around, then I am convinced that we will have a different outcome at the end of this process, and I am certainly convinced that we should.

Let me say, Ms. Nelson, we want to thank you for your testimony today. We are going to leave the record open so that we can submit some additional questions to you in writing and would appreciate if you can respond before the implementation date of this rule.

Ms. NELSON. Sure.

Chairman PENCE. Of course, any additional comments from you will be added to the record without objection.

With that, I will recognize the gentleman from Pennsylvania if he has additional questions.

Mr. BRADY. I am fine. Thank you.

Chairman PENCE. If there is nothing further, the witness is dismissed with our gratitude.

Ms. NELSON. Thank you very much.

Chairman PENCE. This hearing on the TRI Lead Rule: Costs, Compliance, and Science, will continue. Next, the Subcommittee will hear from a very distinguished panel.

Having heard from the EPA, and I believe most of you were in the room for most of that testimony, and, candidly, this panel I know would be grateful if you were to illuminate or respond to things you may have heard today. If our records are correct, things the EPA may have said for the first time on this issue were said in this hearing today. We would be anxious to know your reaction to those.

First, the Subcommittee will hear from Dennis McGuirk. Before I introduce him, I will remind you of the lights. Do not feel married to your written testimony. Those of you that are experienced at doing this know that we will enter your written testimony into the record without objection, and it is often more helpful for the Members if you will amplify the points that you want to make sure we make, as well as the requests that are made.

When you see the red light, try and wrap up your comments as quickly as possible. We will await questions until all of you have given your testimony and opening statements.

Dennis McGuirk is president of the IPC, the Association Connecting Electronics Industries. Mr. McGuirk's previous service includes over 24 years of active duty service in the United States Air Force. He holds degrees in Western European Affairs from the U.S. Air Force Academy and a Master's in Public Administration from the University of Colorado and is recognized for five minutes.

STATEMENT OF DENNIS MCGUIRK, PRESIDENT, IPC, ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES

Mr. MCGUIRK. Thank you, and good morning, Chairman Pence and Congressman Brady. I am the president of IPC, a trade association representing the electronic interconnection industries.

IPC's 2,500 members manufacture and assemble printed circuit boards, the backbone of our nation's high tech industries, including consumer, industrial and defense electronics. While some of our members are very large corporations, 60 percent of IPC members are small businesses. On behalf of the IPC and our member companies, I would like to thank you and your staff for organizing this important hearing.

As we have heard, EPA's TRI rule lowered the reporting threshold for lead and lead compounds from 25,000 pounds—that is over 12 tons of lead—down to just 100 pounds. The regulation took effect on April 17, 2001, and included the unprecedented retroactive application of the reporting requirements to January 1, 2001.

IPC members, along with many other industries, are concerned that the burden of this rule upon business has been significantly underestimated, and EPA has failed to provide effective compliance assistance, thereby further increasing the burdens on those least able to bear it.

During the development of the rule, EPA chose not to convene an advocacy review panel as required under the Small Business Regulatory Enforcement and Fairness Act, deciding instead to certify the proposed and final rules as having no significant economic impacts on businesses. Early outreach to small businesses could have helped EPA determine the number of small companies that would be significantly impacted by this rule.

Compliance with the lower reporting threshold also imposes a significant burden on IPC members. For a small business, the job of interpreting, and complying with the agency's instructions and guidance for TRI is substantial. To give you an idea of what I am talking about, we have already alluded to the mass amount of documents required. Before me I have the 746 pages of reporting forms, instructions and guidelines needed to fill out the TRI forms.

EPA's own estimates shows the cost of the compliance for the new reporters under TRI would be about $7,000 for the first year alone. We believe this grossly underestimates the actual cost, but, in any event, it is a significant amount for an industry that is going through decreasing consumer prices.

During the time the rule was under consideration and after its adoption, many concerns were raised about the enormous burdens it would impose. We were pleased back in April of 2001 when President Bush recognized this problem and directed EPA to help small businesses. In a May, 2001 letter to 71 concerned trade associations, EPA reiterated this point by promising to help reduce the burdens imposed on small businesses by developing final guidance by October, 2001.

As we have said, unfortunately EPA did not finalize the guidance until January of 2002, after the entire first reporting year had passed. The guidance is long, it is confusing, and often times it is conflicting.

In February of this year, IPC e-mailed 17 questions about the guidance document to EPA so that we could provide accurate assistance to our members. EPA took four months to respond to our e-mails, leaving IPC less than three weeks to respond back to our members with their appropriate guidance. The deadline, as I am sure you have heard, is June 30 of this year.

On February 22, 2002, 43 trade associations wrote the EPA asking for a one year delay of the reporting requirements so that they could work with them to insure the collection of accurate data without undue burden on small businesses. The need for this delay is supported by EPA's own words.

In response to a comment pointing out the confusion generated by EPA's inaccurate, out-of-date question and answer document, EPA states, "The TRI program can only update this guidance document once every several years." If EPA is unable to update the key guidance documents for such a significant rule, it should also delay the implementation until it is able to provide accurate guidance and compliance assistance.

Last month, a group of 30 trade associations met with EPA to further discuss concerns regarding the implementation of the rule and the need for the one year reporting delay. During the meeting, EPA acknowledged that there had been problems with the implementation, but noted that the first year, as we have heard, always serves as a road test. That may be EPA's perspective on the problem, but it is not shared by thousands of small businesses that will become the accident victims as EPA takes its test drive.

Moreover, such a cavalier disregard of major problems identified by small business suggest that they are at the risk of becoming the road kill of EPA's road test. This is in direct conflict with the intentions of the Small Business Regulatory Enforcement and Fairness Act.

Mr. Chairman, IPC members take their responsibility to environmental stewardship seriously. As small business owners, they and their families live, work and play in the communities where their businesses operate. Unfortunately, many of them are unable to fulfill their obligations to provide accurate information under the TRI program due to the lack of available information, inadequate outreach and assistance, and the impossibility of compiling data retroactively.

The environment and our public health depend upon good environmental information. America's families cannot benefit from the TRI program if EPA does not insure that small businesses have the tools to provide accurate information.

In conclusion, I ask you to consider whether it is reasonable to require thousands of small businesses to incur substantial regulatory burdens when EPA currently has underway a peer review of the very scientific framework upon which this expensive and burdensome regulation is based.

We believe that in the interest of good science and good data, EPA should suspend or otherwise delay the reporting thresholds for lead until small business concerns can be addressed properly and the results of EPA's Science Advisory Board's review can be completed and assessed.

Thank you, Mr. Chairman, for giving IPC and its members the opportunity to express our concerns, and I will await questions at the conclusion of this panel.

[Mr. McGuirk's statement may be found in the appendix.]

Chairman PENCE. Thank you, Mr. McGuirk.

The Subcommittee will now hear from Jim Mallory, the Executive Director of the Non-Ferrous Founder's Society. He is a board member of the American Metal Casting Consortium and serves on an EPA compliance assistance advisory committee.

We are grateful for his time and attendance. Mr. Mallory is recognized for five minutes.

STATEMENT OF JAMES MALLORY, EXECUTIVE DIRECTOR, NON-FERROUS FOUNDERS' SOCIETY

Mr. MALLORY. Thank you, Mr. Chairman. Good morning, and good morning, Congressman Brady. I am very pleased to appear here this morning representing aluminum and brass and bronze foundries.

I will let the importance of my industry be noted in the written comments that I have submitted, but let me just say that most of the people I am here to represent this morning are in fact small businesses. More than 50 percent of the non-ferrous foundry industry employs fewer than 50 people. Most are family run businesses.

Almost all of them are privately held, and in most cases in most foundries the person who is responsible for EPA reporting compliance is not a specialist or consultant, but is in fact the owner of the company, a family member or another principal executive of the company.

Non-ferrous foundries have several specific problems in compliance with the new TRI reporting requirements. If I can, I would like to use my time this morning to just summarize briefly the written comments that delineate those problems.

First of all, EPA's new TRI reporting rule has eliminated the de minimis exemption for TRI reporting. This fact alone will subject a number of non-ferrous foundries to the burdens of TRI reporting for the first time. Under the previous TRI rules, many of those companies fell within the purview of the de minimis exemption and, therefore, were exempt from the reporting requirement, but the burden and the elimination of the de minimis exemption occurs in that many foundries hold other state and federal permits that do not or shall I say that impose additional requirements once a company becomes subject to TRI reporting.

For example, NPDES storm water permitting requires companies that are subject to TRI reporting to do the actual outflow of source reporting under their storm water permitting rules, so if you can imagine for a moment that you are a small business owner, it is Saturday night, it is raining and you are standing in your parking lot measuring the outflow of rainwater only because you have now become subject to the TRI reporting rule for lead.

I think EPA ignored the domino effect that requiring a number of small businesses who have not previously been required to report to do so would have on the burdens that would be imposed.

Secondly, TRI is not supposed to require facilities to generate new data or to do additional research. We have heard this morning

that TRI allows people to use an estimate. The problem that most non-ferrous foundries have, and a lot of them aluminum foundries, is that there is no reliable source of data for the content of lead in the materials that they use, particularly in aluminum. I do not know if EPA was even aware that commercial aluminum alloys contain lead.

I have brought with me this morning a publication that we produced that lists all of the chemical specifications for aluminum alloys. There are 80 pages with two alloys on a page. Not one of those alloys indicates the amount of lead present in an aluminum alloy, typically only in trace elements, but the TRI reporting rule is going to require foundries to estimate the amount of lead in those alloys. Most aluminum foundries do not just pour one alloy. They may pour several dozen different alloys depending upon customer requirements.

Aluminum foundries are also, I think, somewhat arbitrarily subjected to this reporting requirement because within the TRI rule brass and bronze alloys and stainless steel alloys are exempt from inclusion in determining the threshold limit of the lead that they contain, even though the lead in those alloys exists in far higher quantities than it does in aluminum.

I think EPA was ignorant of the fact that aluminum alloys contain lead, and I think that at a minimum the aluminum alloys should have received the same exemption that was accorded to brass and bronze and stainless steel.

Lastly, to summarize my industry's problems with the rule, is the question of outreach. Most aluminum foundries, as I said before, have never had to file TRI reporting forms previously. Most were not sent copies of EPA's reports, were not informed of the hearings or the workshops that were being held on TRI reporting, did not receive copies of the guidance document and, frankly, even at this late date may be largely unaware of the fact that they are now subject to the reporting requirements for lead under the new TRI rule.

Mr. Chairman and Mr. Congressman, I appreciate the opportunity to be here this morning, and I await questions at the conclusion of this panel.

[Mr. Mallory's statement may be found in the appendix.]

Chairman PENCE. The Chair will now recognize a small business owner from Baltimore, Maryland, Nancy Klinefelter.

Ms. KLINEFELTER. Correct.

Chairman PENCE. Ms. Klinefelter is president of Baltimore Glassware Decorators and also serves as a member of the board of the Society of Glass and Ceramic Decorators.

As in the case of our last witness, we are especially grateful to be hearing from, for lack of a better term, ground zero of this type of a rule where it hits. I appreciated the passion of our last witness and recognize you for five minutes hopefully of the same.

STATEMENT OF NANCY KLINEFELTER, PRESIDENT, BALTIMORE GLASSWARE DECORATORS, FOR THE SOCIETY OF GLASS AND CERAMIC DECORATORS

Ms. KLINEFELTER. Thank you. I really appreciate the opportunity to be here today. Of course, you understand I am president of Bal-

timore Glassware Decorators, and it is a family operated business. Actually, my father has helped in growing the business, and he has been in this business for over 50 years.

We are a wholesale decorator, and we specialize in printing small quantities of custom glass and ceramic ware for special events, restaurants and for souvenir and novelty stores. As you see here in front of me, we do a number of glass and ceramic items for different government agencies.

When we print mugs or glasses for our customers, we sometimes use lead bearing colors on outside surfaces. These colors become part of the glass after they are fired. These colors are expensive, and we only use what is needed to print each job, so very little ends up as waste.

I am testifying today to point out major problems with EPA's new toxic release inventory lead rule. The greatest problem for my company, as well as other decorators, is the fact that EPA issued the rule April 17, 2001, and yet we are required to accurately report or account for lead usage from January 1, 2001.

For my company, it is impossible to compile precise lead use records as required by EPA unless we track our color use on a daily basis. Since every color contains a different amount of lead, we must make different calculations for each color used.

Companies such as mine cannot simply throw a switch and start to comply with the major environmental reporting rule overnight. Even when we were notified by SGCD that the rule had been imposed, we had no idea what it meant for the company. By the time we were able to review the reporting requirements and attend an SGCD seminar on the subject, half the reporting year had passed.

As we began to compile the data, problems emerged. We buy decals from small decal printers. They have fewer than ten employees, yet these companies have to provide me with lead content information so we can put it on the TRI report. These decal printers have no way of telling us how much lead is in each decal. We are still wrestling with this one, and the deadline is looming.

We have no experience at all with TRI. Our lead usage is minimal. We were never anywhere near the previous 10,000 pound annual reporting threshold. Now we do estimate that we exceed the new 100 pound threshold, although just barely. Please note that this is a usage threshold, not an emissions threshold, as many in the media and others have indicated. We almost have zero emissions.

For my company and every other small decorating shop, the most critical part of TRI compliance is tracking the lead usage. I do not know why EPA felt the need to make this a retroactive rule. It would seem only reasonable to issue rules in advance of when they must be applied, and that should have meant a January 1, 2002, start date. That would have given us adequate time to put a color tracking system in place. Would EPA not rather have accurate data than my best guess?

It is not as though EPA usually issues rules this way. This is the first time in the history of the TRI program that EPA has imposed a retroactive reporting requirement, which we heard earlier. I know that EPA publishes estimates that say it will take 124 hours

to track lead usage and complete TRI paperwork. That is already quite a large number, but it is a gross underestimate.

I have spent already 95 hours trying to understand and read the TRI forms and requirements. I am still nowhere near the point where I can complete the forms with confidence. In addition, I have spent an additional 60 hours or more trying to reconstruct retroactive color usage data. We are now spending about four to five hours a week tracking lead usage. Like I said, we only have 15 employees. I do not have any environmental engineers, and I do not employ any, so the responsibility is mine.

The time taken to reconstruct color usage data is time that is not spent managing my company or looking for new business. As we know, EPA has scads of paperwork you have to read. It is confusing. It provides little help in defining the calculations to determine the lead content of each color. The Try-Me software has been equally disappointing.

In conclusion, I urge the Committee to ask EPA to postpone the TRI lead rule for one year to enable me and other small businesses to provide reliable and accurate information on our lead use. There is no other way for EPA to address my problems short of using a time machine to take us back to January 1, 2001.

I thank you for your interest and the concerns of a small business such as mine and for the opportunity to testify here before you today.

[Ms. Klinefelter's statement may be found in the appendix.]

Chairman PENCE. Thank you, Ms. Klinefelter.

Our final witness is Hugh Morrow, president of the North American office of the International Cadmium Association. His previous services includes time at the Westinghouse Bettis Atomic Power Laboratory in Pittsburgh, IIT Research Institute in Chicago and the Zinc Institute.

He holds five patents related to high temperature alloys and cutting tool materials, has authored approximately 100 publications and presentations mostly on cadmium zinc, received his undergraduate and graduate degrees in Metallurgy and Materials Sciences from MIT.

We are grateful to have his expertise to close our panel today. Mr. Morrow is recognized for five minutes.

STATEMENT OF HUGH MORROW, PRESIDENT, NORTH AMERICAN OFFICE, INTERNATIONAL CADMIUM ASSOCIATION

Mr. MORROW. Thank you, Chairman Pence and Congressman Brady. As the Chairman mentioned, I am the president of the North American office of the International Cadmium Association, which is an association of organizations and companies producing, using and recycling cadmium, both here in the United States and throughout the world.

Cadmium is a key component of a number of important commercial and consumer products, including rechargeable and recyclable nickel cadmium batteries, which are used in cordless power tools and telephones, aircraft and railway applications, emergency lighting, and in remote area telecommunications.

I appreciate the opportunity this morning to testify on the science aspects of the TRI lead rule that is the subject of this hear-

ing. The scientific premise for this rule is that metals generally and lead and lead compounds in particular can appropriately be classified as persistent bioaccumulative and toxic or PBT chemicals using a methodology that was developed for application to pesticides and other synthetic organic compounds.

For more than three years, I have been involved, along with numerous academics and representatives of all the major metal sectors, including copper, zinc, nickel and lead, as well as cadmium, in expressing scientific concerns with EPA's plan to apply its PBT methodology to metals.

Those concerns are grounded in a solid body of peer reviewed scientific literature and the conclusions of international scientific experts that it is scientifically inappropriate to use the PBT criteria relied upon by EPA in order to asses the potential health and environmental hazards of metals.

Enough concerns had been expressed, as the Chairman previous mentioned, by January of 2000 that EPA co-sponsored with industry an experts' workshop entitled "Review of the State-of-the-Science Regarding PBT Concepts and Metals and Metal Compounds." The sessions of the workshop highlighted fundamental scientific problems with EPA's approach which industry hoped EPA would reconsider in the context of the TRI lead rule.

It also became clear at the experts' workshop that no independent scientific peer review had been conducted of EPA's plan to apply the PBT criteria to metals, a serious deficiency that should not have been allowed to occur.

These issues led the House Science Committee in a bipartisan letter signed by both the Committee and Subcommittee Chairmen and Ranking Members to write to EPA in July of 2000 noting that, "Questions have arisen regarding the scientific validity of applying the PBT criteria to metals and inorganic metal compounds and that this specific issue has not received the benefit of Science Advisory Board or other independent scientific peer review."

They went on to say, "We strongly encourage EPA as soon as possible to refer for SAB review the issue of the scientific soundness of applying PBT concepts to metals," and a copy of that letter from the Science Committee is attached.

Again, in November of 2000 when EPA had still not sought peer review, these concerns were echoed by the new Chairman of the Committee, Congressman Sherry Boehlert, who urged EPA, "To charge the SAB to undertake a broad review of the use of PBT, which would include the applicability of PBT to all metals and inorganic metal compounds as to which questions have arisen." Again, a copy of that letter is attached to my testimony.

The reasons for these concerns stem from the fact that PBT concepts were developed to assess hazard in synthetic organic compounds and do not work well, if at all, when applied to metals and inorganic metals compounds. In critical ways, metals are fundamentally different from organics.

Persistence, for example, may be a useful criterion for distinguishing among organic chemicals in terms of hazard, but all metals are deemed infinitely persistent under EPA's approach because, as naturally occurring elements, they cannot be destroyed. As we

all learned in high school chemistry, elements are neither created nor destroyed and, therefore, are infinitely persistent.

But, unless they are in a bioavailable form, this so-called "persistence" is not an indicator of environmental hazard. As applied by EPA, it is not a meaningful measure of hazard in metals. Moreover, since all metals are considered equally persistent under EPA's approach, persistence provides no basis for distinguishing among metals in terms of hazard.

In the same way, unlike the situation with organic chemicals, bioaccumulation or bioconcentration factors, which are commonly known as BAFs or BCFs, are not intrinsic properties of metals and do not provide useful indicators of hazard for them.

In fact, there is strong evidence that a high BAF or BCF value for a metal would most likely indicate a lower risk of toxicity, the very opposite result from what EPA's PBT methodology assumes for organic chemicals and a very good reason why we would not want to use this approach to try and identify metals of greater concern.

I am now happy to report that EPA has recognized the importance of these issues. In February, 2002, they announced that they were embarking on the development of a comprehensive cross-agency guidance for assessing the hazards and risks of metals and metals compounds and that the goal of this cross-agency guidance will be to articulate a consistent approach for assessing the hazards and risks of metals and metal compounds based on application of all available data to a uniform and expanded characterization framework.

Since February, the work has moved forward, and an SAB review schedule was recently announced that is expected to conclude by the end of 2003. Just last week, in a June 6 notice, the SAB reiterated the connection between this development of metals assessment guidance and the questions raised during the TRI lead rule making.

"Discussions between the agency and external stakeholders, as well as concerns expressed formally as part of the Toxics Release Inventory lead rule making, have demonstrated the need for a more comprehensive cross-agency approach to metals assessments that can be applied to human health and ecological assessments."

EPA expects to release for public comment this week its draft action plan—I have already seen it on the internet; it is available now—for the development of this metals assessment framework. I, along with my colleagues in the metals industry, will be involved in submitting comments on this action plan.

We applaud EPA's efforts to develop a scientifically sound metals assessment framework. We see this as a fulfillment of the commitment the agency made in the preamble to the final TRI lead rule in which it promised to "seek external peer review from its Science Advisory Board" on two issues. One, the question of whether lead and lead compounds should be classified as highly bioaccumulative, and, two, the issue of how lead and other as yet unclassified metals, such as cadmium, should be evaluated using the PBT chemical framework, including which types of data and which species are most suitable for these determinations.

I might add here that to me the first question of the highly bioaccumulative nature of lead is really a subset of the second question. The second question is the one which should be logically answered first, and then you consider the second question.

All of us who are interested in a sound, scientific approach to hazard assessment of metals and inorganic metal compounds look forward to EPA's and the SAB's responses to both these questions as the initiative to develop a cross-agency metals assessment framework review goes forward.

Thank you for your attention, and I look forward to answering any questions you may have.

[Mr. Morrow's statement may be found in the appendix.]

Chairman PENCE. Thank you, Mr. Morrow.

The Chair will yield to the Ranking Member for the first questions for our panel.

Mr. BRADY. Thank you, Mr. Chairman.

Mr. McGuirk, those forms are the forms that you now have to fill out?

Mr. MCGUIRK. No. These are the reporting instructions, the guidance on what we need to fill out the forms. This is the clarification of how to fill out the forms.

Mr. BRADY. That is going to clarify something?

Mr. MCGUIRK. Well, apparently.

Mr. BRADY. Do you know what the forms look like? I mean, do you have forms now that you have to fill out?

Mr. MCGUIRK. There are TRI forms that have to be filled out, but the concern we have now is so many more have come under this TRI rule, and they have had no exposure to this whatsoever.

As the lady was pointing out, they did not even know the rule existed until probably someone mentioned it to them and got their attention. Now they are trying to scramble to figure out how do we comply with this?

Mr. BRADY. Does anybody know what the TRI Form A is?

Ms. KLINEFELTER. Yes. It is actually TRI Form R, which is for lead reporting. The actual form is not long at all. It is actually short, but it is what goes behind it that you have to have all these calculations upon calculations upon calculations in order to put down a number in a certain spot.

The form itself is very unassuming. It is all the work that you have to do behind it.

Mr. BRADY. I just think that we want to protect everybody. We want to protect people, but I guess sometimes people make decisions that do not realize maybe the impact. The last thing we want to do is make a decision that does not protect people. I would like to make a decision that protects everybody.

There are people out there that could get hurt by the lead or whatever toxic could come out of it. We also want to keep people in business. I can appreciate what you said that you do not have an engineer and would have to hire an engineer just to fill out forms or find out whether you are complying, you know.

That is the only thing I am kind of concerned about and interested in and ready to follow my Chairman to track and find out where we are going to get to to try and solve this.

Thank you, Mr. Chairman.

Chairman PENCE. Thank you. I would like to just ask one question of each member of the panel. It is this Subcommittee's intention to have listened to what we hear today, particularly from our colleague from the EPA, and then we would make a decision as to whether there is much more to be done here.

Candidly, I think our minds are racing now with inherent contradictions built into this and the illogic of it. What the panel has said here has just been an extremely helpful commencement for what I can assure you the Subcommittee is going to be taking on in a very aggressive posture leaning forward.

It strikes me that from our testimony that we have heard today even from the administrator from the EPA, the assistant administrator, that this was truly a ready-fire-aim situation. I intend to go back over the written testimony, but it seems to me that we heard from the EPA that well, we do not have the science. We are pretty sure it will be good. It might not.

I guess I would just like a candid assessment from any of you. What did you think of Ms. Nelson's testimony today? Were you encouraged? Discouraged? Were there any aspects of her testimony that this Subcommittee should particularly focus on or representatives of the media that are in the room should be interested in?

I will begin with Dr. Morrow.

Mr. MORROW. Thank you, Mr. Chairman. I was a little bit concerned in her testimony about EPA and the SAB just considering the question of lead being highly bioaccumulative and being a little bit vague about considering the question of whether metals should be considered at all, and PBTs that is why I tried to emphasize the point in my testimony.

To me, we should not even be considering the first question if the answer to the second question is no. If lead and other metals cannot be considered as PBTs, then there is no question. Why consider lead as a PBT if the PBT concept is inapplicable to metals? It is a metal. To me, that was the most disturbing part of EPA's testimony.

Chairman PENCE. Pardon me for interrupting, Doctor, but according to her testimony today I thought she averred that they are considering whether or not minerals should even be classified in this way; that that is a part of the potential new framework.

Mr. MORROW. Yes. I got two sets of answers there. I felt a little ambiguous about exactly what she was saying. I know they are convening the SAB and that is going to move forward, but at the same time the TRI lead rule is moving forward, and it seems to me that it really should not be in place if its basis is in fact the concept that lead is a PBT.

If lead is not a PBT, then clearly if they want to establish a different basis for the lead TRI rule that is another matter, or if they want to change the level and so forth that is another matter. The premise right now is lead is a PBT, and it seems to me that that is a fairly indefensible position.

Chairman PENCE. But unless the testimony suggests otherwise, it seems to me that question is being considered now, which was unclear prior to this Subcommittee hearing as to whether or not that was an issue being considered by the SAB at this time. It is being considered and is being reviewed.

Ms. Klinefelter? Same question.

Ms. KLINEFELTER. Thank you. I wanted to ask a question. If the EPA, and I forget her name. I am sorry. I am nervous.

Chairman PENCE. That is all right. Nelson.

Ms. KLINEFELTER. Ms. Nelson. She mentioned something about the reporting for small businesses like mine. They are not looking for accurate data. Well, then my question is why file a report? I mean, if EPA does not want accurate data, then it is not worth the paper it is written on. I assume that that is what I got from her testimony or what she spoke about. I hope I am right.

Right now, just to give you one for instance, when we screen print mugs or glassware we keep paint in the screen, and it is done, you know, by hand on a machine. They use rags to wipe out the screen, to clean it out for imprints. I use regular Scot rags in a box that you buy from Home Depot, any place like that.

I am to a point right now where I had to weigh a rag with nothing on and weigh a rag that had some of the paint that they cleaned off, but I had to wait for the solvent to dissipate because that weighs part of it. Then I have to figure out what percentage in that rag is lead.

I have to know this information, or I feel that I have to know this information, in order to make my numbers correct. I cannot guess. I am really between a rock and a hard place at the moment.

Chairman PENCE. Thank you.

Mr. Mallory.

Mr. MALLORY. Yes. A couple of things came to mind as I was listening to the assistant administrator this morning. First of all, I heard her say on several occasions that this new TRI reporting rule would provide better information and more valid information to the local communities, to businesses and to the EPA.

I really have a question as to how that can happen when the rule says that if you do not have actual numbers make one up. Use an estimate. Come up with your own presumptive quantity of how much lead is going to be in the alloys that we are using and the reporting, how to use that in our calculations and just document where you got the numbers from.

Well, in the case of one of the alloys that we have tried to look at, we found that it can range anywhere from .1 percent lead to .5 percent lead in a range. Pick a number. Whatever number you are going to pick is going to be a supposition at best, and yet within the TRI rule it says that facilities are required to report their emissions to a level of accuracy of one-tenth of one pound.

Now, I cannot correlate the two statements. One, if you do not have a good number, make one up. Two, report your levels of emission to a level of accuracy of one-tenth of one pound. Those two just do not gel in any assessment that I have been able to make of the reporting requirements.

The second question that came to mind as I listened to the assistant administrator was when she was talking about the road test and the "non-enforcement" of the reporting for the first year that the rule is in effect, she made a statement this morning that said she was sure that no one within EPA was intending to seek enforcement actions against someone for erroneous reporting.

I have a question of EPA. What about the people who still do not get it that they are required to report and in fact may not file a report because they are not aware of the reporting requirement? If an EPA inspector is on premise doing an inspection and finds that this facility should have filed a TRI report and did not, do they intend to waive enforcement in that case, as well as for inaccuracy reporting?

I did not hear that from the administrator this morning, and that is a question that I think is one that needs to be answered.

Chairman PENCE. Mr. McGuirk?

Mr. MCGUIRK. Thank you, sir. I agree with the comments of my colleagues here on the panel, and I would just like to sum up by saying that we believe that, you know, sound scientific data would be absolutely necessary before you are going to go out and collect information from small businesses. They need to have the information. They need to have the guidance on how to do this.

For those who have not been exposed to it before, this is a significant burden to them. To make a rule that is retroactive where you are estimating or guesstimating or just filling in the blanks is absurd, so we would heartily recommend gathering the information on a sound scientific basis.

Thank you.

Chairman PENCE. Thank you. To Mr. McGuirk and Mr. Mallory, thank you very much for your broad expertise. To Dr. Morrow, it is enormously helpful to have your authoritative voice here in the wake of some weird science. To Ms. Klinefelter, you did not seem nervous at all.

Ms. KLINEFELTER. I was.

Chairman PENCE. I am very grateful for a very clear presentation——

Ms. KLINEFELTER. Thank you.

Chairman PENCE [continuing]. Of what you are dealing with as a successful entrepreneur. It is really about businesses like yours, a family business of 50 years, that we are thinking now as we go through this process.

Having only been in Congress a short period of time, I am growing more and more of the belief that we pay lip service to the people that employ America. We do not often put ourselves in your shoes and recognize what you are dealing with. This whole panel today has helped us on this Subcommittee now be able to do that more effectively.

You can anticipate that this will be the first of a series of hearings and actions that we will take, and we urge you to keep this Subcommittee informed as this issue develops and alert us of ways that we can be helpful.

It is our objective to either change the outcome, change the classifications or reorganize the timetable for enforcement here so that it simply has the least negative impact on small business America as possible, which is the broad mission of the Committee on Small Business in the House of Representatives.

This meeting of the Subcommittee on Regulatory Reform and Oversight is adjourned, and we thank you.

[Whereupon, at 12:15 p.m. the Subcommittee was adjourned.]

MIKE PENCE, INDIANA
CHAIRMAN

ROBERT BRADY, PENNSYLVANIA
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

107th Congress

Committee on Small Business

Subcommittee on Regulation Reform and Oversight
2361 Rayburn House Office Building
Washington, DC 20515–6315

Statement of Mike Pence
Chairman
Subcommittee on Regulatory Reform and Oversight
Committee on Small Business
United States House of Representatives
Washington, DC
June 13, 2002

I want to begin by giving the Environmental Protection Agency my congratulations. The threat of lead poisoning, especially to children, has been dramatically reduced in this country. And much of that is due to the work of the good men and women at the EPA and other agencies of government. Former Health and Human Services Secretary, Donna Shalala said, in announcing the 1997 CDC results, "These lower lead levels for America's children constitute a public health achievement of the first importance. For our children as a whole, we have achieved average blood lead levels which would have been considered impossible just a few decades ago." Governor Whitman's predecessor at the EPA had this to say, "The ongoing reduction in blood lead levels is a great American success story of environmental and public health protection. Years of aggressive action against lead exposure, particularly EPA's banning of lead in gasoline two decades ago, are yielding a brighter future for our children." The Center for Disease Control, in the same document, did go on to note that the job of lead exposure

reduction is not complete, "there are still close to 1 million children . . . [with] a blood lead level that is associated with adverse effects in children. In addition, the survey showed that more than one-fifth of non-Hispanic black children living in older homes have elevated blood lead levels. This pattern reflects the most serious remaining sources of lead exposure: deteriorated paint in older housing, and dust and soil contaminated by paint and residues from past emissions of leaded gasoline."

I am disappointed today, though, that we are not maximizing the benefits of this great achievement. We are not taking these results as a lesson for further progress on this public health issue or any other. Today, we are not talking about further reductions of children's exposure to lead in paint or any of the other major remaining sources of concern. Today, we are talking about a paperwork regulation that will at best, provide some new information about the uses of lead that present no real risk for human health at a significant cost to small businesses and to the EPA. At worst, this rule will provide inaccurate information about lead usage and divert important resources away from more pressing public health and environmental needs.

I wish that I had already completed a listing of the problems with this rule. In addition to it not addressing the most important public health aspects of lead and potentially providing no "public right to know" benefit this rule:

- is based on questionable science and lacked independent peer review
- eliminates burden reduction measures meant to make TRI reporting easier for small businesses

- is the first retroactively applied TRI reporting rule, which will require companies to desperately search for data about lead usage prior to when the rule was promulgated or became effective
- suffers from an EPA guidance document that was not available until 13 months after the retroactive date for data collection and was a 200+ page mess that no small business person, let alone congressman, could decipher
- subjects upwards of 10,000 new filers to burdensome reporting obligations under an EPA rule that many may not even know about yet
- is virtually guaranteed to produce poor quality data that will not well serve the public's "right to know"
- creates risks of enforcement actions or citizen suits against small businesses that may simply be unable to comply with this rule, despite doing their best
- and finally, I assume, in recognition of the questionable science underpinning this rule, EPA has decided to submit to a Science Advisory Board review of the biggest questions BUT is waiting until 3 years after the final rule was published for a final report on these questions.

This is not a record for which EPA should be particularly proud. And it stands in stark contrast to EPA's successes in lead exposure reduction. This paperwork rule is estimated to cost businesses $70 - $100 million in the first year of implementation. When our economy is not at its peak and small businesses account for a majority of job growth in this country, it is not a time when substantial new regulatory costs of questionable benefit should be imposed. Now is the time to prioritize. Now is the time to focus all of

our efforts on the environmental regulations which will provide us with the most "bang for our buck," with the greatest impact on human health and the environment. This rule does not pass this test.

This hearing has garnered quite a bit of interest. In addition to the witnesses gathered today, we also have testimony submitted by the U.S. Small Business Administration, the National Association of Manufacturers, and the Mercatus Center. We look forward to the testimony of all our witnesses.

STATEMENT OF
KIM T. NELSON
ASSISTANT ADMINISTRATOR
FOR ENVIRONMENTAL INFORMATION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT
OF THE
COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES

JUNE 13, 2002

INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. I appreciate this opportunity to discuss with you the Environmental Protection Agency's (EPA) recent rule to expand reporting on lead and lead compounds under EPA's Toxics Release Inventory (TRI) Program.

As you may recall, the new TRI lead rule was one of several regulations carefully reviewed by the Administration upon entering office. After a thorough review, the new lead regulation was endorsed by the President and Governor Whitman and became effective in April 2001. The new rule requires any facility, otherwise subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) reporting, that manufactures, processes, or otherwise uses 100 pounds or more of lead or lead compounds, to report annually to EPA its releases of lead. This rule significantly expands the information available to the public about the presence and releases of lead in our communities.

We believe that it is particularly important to provide the public with more information on lead releases given the well-documented hazards of lead, particularly to our Nation's children. Toxic effects from lead exposure can result years after releases and exposures occur because of lead's ability to remain in the environment, build up in the environment and bioaccumulate, particularly in humans. We firmly believe that public access to such information contributes positively to the public's ability to understand environmental issues and to its ability to make better "protection" decisions in daily life.

Before I discuss the rule, I would like to first provide a little background on the TRI program and the factors that led to the development of the rule. As you know, through Section 313 of EPCRA and the Pollution Prevention Act of 1990 (PPA), Congress mandated that information on toxic chemical releases and other waste management activities be collected in a publicly available database. Since its implementation in 1987, the TRI has been the centerpiece of the Agency's right-to-know programs and has proven to be a very powerful tool for assisting communities in protecting their own environment and for making businesses more aware of their chemical releases. Given the success of the program and its important contribution to the decrease in environmental releases of toxic chemicals, EPA has continued to expand the program to fill important data gaps in the public's right-to-know while working to reduce the reporting burden on affected businesses.

TRI BACKGROUND

Under the authority of EPCRA and PPA, the TRI program requires certain facilities with 10 or more employees in specific industry sectors to report to EPA and to the States their releases

and other waste management activities for over 650 chemicals. Chemicals on the TRI list must meet specific, Congressionally-mandated toxicity criteria. Generally, if a covered facility currently manufactures or processes more than 25,000 pounds of a listed chemical, or otherwise uses more than 10,000 pounds, it is required to report its annual chemical releases under TRI. The purpose of the program is to provide information to the public on releases and other waste management of toxic chemicals its communities. EPA accomplishes this by gathering data and making it accessible to the public through the Internet and other media. TRI data has proven to be a very valuable and useful source of information not only to communities but to businesses as well. Communities use TRI data to: learn about their local environment and potential exposures to toxic chemicals; begin dialogues with local facilities to encourage the reduction of emissions; develop pollution prevention plans thereby improving safety; and improve local environmental conditions. Businesses use TRI data to: identify opportunities for pollution prevention; increase efficiency in processes; demonstrate environmental progress; and improve local environmental conditions. These uses of the data are integral to the success of the TRI program in encouraging decreases in the release of toxic chemicals to the environment.

PERSISTENT AND BIOACCUMULATIVE TOXIC CHEMICALS

The basis of the TRI lead rule is EPA's determination that lead and lead compounds are persistent, bioaccumulative, and toxic chemicals, or PBT chemicals. PBT chemicals comprise a category of toxic chemicals that may pose an increased potential to cause harm to human health and the environment compared to chemicals that do not exhibit these properties. PBT chemicals are of particular concern because they remain in the environment for long periods of time (i.e.,

persistence), build up in the environment, accumulate in plants, animals, and humans (i.e., bioaccumulation), can be transferred within the food chain, and may cause a range of serious toxic effects such as neurological disorders, reproductive and developmental problems, genetic damage, cancer, and environmental toxicity (i.e., toxicity). All else being equal, PBT chemicals present a greater likelihood for exposure when compared to toxic chemicals that do not persist or bioaccumulate. As such, PBT chemicals have a greater potential to cause serious human health and environmental effects at relatively lower levels of release and exposure.

Over the years, PBT chemicals have been the focus of a great deal of public attention and concern due to the public health and environmental problems they have caused. EPA shares the public's concern regarding PBT chemicals and has made these chemicals a focus for Agency initiatives and actions. In 1998, faced with concerns that the current TRI reporting thresholds left significant data gaps for PBT chemicals, EPA began working on a proposal to add certain PBT chemicals to the list of TRI chemicals and to lower reporting thresholds for certain PBT chemicals. In October 1999, EPA published a final rule to lower the activity threshold quantity for reporting on PBT chemicals to 100 pounds and to 10 pounds for a subset of PBT chemicals that are highly persistent and highly bioaccumulative. This rulemaking, in conjunction with the subsequent 2001 TRI lead rulemaking, established the criteria EPA uses for identifying PBT chemicals for the TRI program. The criteria include:

- persistence of the toxic chemical in water, soil, or sediments; and
- bioaccumulation of the toxic chemical in plants, animals, and humans; and
- listing on the EPCRA Section 313 list of toxic chemicals.

The PBT rule is currently in effect, and last year, facilities reported their releases and other waste management data for PBT chemicals for the year 2000 – the first reporting year under the lower thresholds established by this rule. These data, which have recently been made available to the public, have contributed significantly to the public's knowledge about chemicals being used and released in their communities.

THE TRI LEAD RULE: LEAD AS A PBT CHEMICAL

After EPA published the proposed PBT rule in January 1999, the Agency received numerous comments requesting that lead and lead compounds be included as a PBT chemical under EPCRA Section 313 and that lower reporting activity thresholds be set. To address these comments, EPA applied its PBT criteria to lead and lead compounds to assess its persistence and bioaccumulation.

PERSISTENCE OF LEAD

EPA evaluated the persistence of lead in the environment and concluded that lead meets the PBT criterion for classification as highly persistent because lead is a metal and metals cannot be destroyed – they persist indefinitely. Lead is highly persistent and because it is a PBT chemical, there is a greater potential for exposure to lead.

BIOACCUMULATION OF LEAD

In assessing the bioaccumulation of lead , EPA considered bioaccumulation data both in aquatic plants and animals and humans. EPA determined that the data on oysters, snails, algae, phytoplankton, and blue mussels, as well as the human data, clearly support a conclusion that lead and lead compounds are bioaccumulative. There are extensive peer- reviewed human data

demonstrating that repeated exposure to low levels of lead results in a build-up (accumulation) of lead in the bones of the human body where it can remain for many years. Numerous studies have shown that lead that has accumulated in bone can later move from the bone to blood, especially during periods of increased bone mineral loss (such as occurs, for example, during pregnancy, breast feeding, menopause, old age). It can then reach organs and other tissues and cause toxicity to adults, fetuses, and infants.

TOXICITY OF LEAD

The toxicity of lead to humans is well documented and undisputed. In adults, exposure to lead can cause neurological toxicity, damage to the kidneys, and hypertension. Of particular concern is the effect lead has on fetuses, infants, and children because they tend to be more susceptible to exposures of lead and are more sensitive to the toxicity it causes. Their exposure to lead can lead to permanent brain damage. Even at very low dose levels, it can result in diminished IQ levels, impaired neurobehavioral development, decreased stature and growth, and impaired hearing.

SCIENCE ADVISORY BOARD (SAB) REVIEW

From its analysis of lead, EPA concluded that lead and lead compounds met the criteria for designation as persistent, bioaccumulative, and toxic chemicals. More specifically, EPA preliminarily concluded in its August 1999 proposal that lead and its compounds met the criteria for being classified as highly persistent, highly bioaccumulative toxic chemicals. EPA believes that the bioaccumulation data clearly show that lead and lead compounds significantly bioaccumulate in humans. EPA further believes that lead bioaccumulates in certain aquatic plants

and animals. However, during the public comment period, questions were raised challenging the sufficiency of the aquatic data to support the conclusion that lead and lead compounds are highly bioaccumulative. In addition, while there are extensive, high quality data in humans that clearly indicate that lead and lead compounds bioaccumulate in humans, EPA recognized that it did not clearly indicate in the proposed TRI rule how the data would be used to distinguish between bioaccumulative and highly bioaccumulative categories. Consequently, EPA determined that the data clearly supported a finding that lead and lead compounds are bioaccumulative and deferred on its determination as to whether lead and lead compounds are highly bioaccumulative. EPA finalized the rule in January 2001 and, based on the conclusion that lead and lead compounds are, at least, bioaccumulative, set the reporting thresholds at 100 pounds.

Before determining whether lead and lead compounds are highly bioaccumulative, EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA intends to do so. The external peer review would address the question of whether lead and lead compounds should be classified as highly bioaccumulative. The external peer review would address the issue of how lead and other, as yet unclassified metals, such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations.

SCHEDULE FOR SCIENCE ADVISORY BOARD REVIEW

Shortly after the lead rule was finalized, the Agency began to plan efforts to seek advice from its Science Advisory Board as discussed in the lead rule. To this end, the Agency convened a team of scientists under the auspices of the Agency's Risk Assessment Forum to develop a

"White Paper" that would serve as a summary of the bioaccumulation data available for lead and that would contain specific charge questions for the SAB to address.

EPA originally planned to have the SAB review take place last summer or fall. However, during the drafting of the SAB White Paper, discussions that EPA had with external stakeholders, as well as concerns expressed formally from Congress, led EPA to recognize the need to develop Agency- wide guidance for assessing the hazards and risks of metals and metal compounds. Last December, EPA's Deputy Administrator informed stakeholders of our intentions and charged the Agency's Science Policy Council (SPC) with the responsibility to prepare an Action Plan for identifying the primary elements that should be addressed in developing a cross-Agency metals assessment framework. The Action Plan is intended to propose a process that will culminate in the production of the framework and related guidance for characterizing and ranking the hazards and risks posed by metals. The development of the Action Plan has involved input from stakeholders and will include discussion of the issues that need to be addressed in the framework and how we intend to move forward.

Once developed, the Action Plan will be the subject of an SAB advisory. The SAB advisory will provide an opportunity for early input by the SAB on this proposed approach to developing broader-based guidance on the assessment of metals and metal compounds. Upon conclusion of the SAB's advisory, the Agency will develop a framework for the evaluation of metals and metal compounds and guidance on the characterization and ranking of metals. The Agency will submit the framework and guidance for peer review by the SAB. At that same time, EPA also plans to submit to the SAB for review the specific issue of whether the application of

the bioaccumulation data used in the TRI lead rulemaking would result in a classification of lead and lead compounds as highly bioaccumulative.

This week, EPA is announcing, through a Federal Register notice, the availability for public comment of the *Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals*, (EPA/630/P-02/003A), which was prepared by a cross-Agency workgroup under the auspices of the Science Policy Council. The draft Action Plan proposes that the development of both documents involve stakeholder workshops and SAB peer review and proposes dates for these workshops and SAB reviews. The date proposed for the SAB peer review of the draft metals framework is June 2003. The date proposed for the peer review of the draft metals guidance and the highly bioaccumulative issues pertaining to the lead rule is November 2003. The draft Action Plan proposes December 2003 as the date for completion of the metals framework document and May of 2004 as the date for completion of the metals guidance document.

COMPLIANCE AND ENFORCEMENT

EPA takes a problem-solving approach to addressing compliance issues and devising the best strategies for non-compliance. EPA uses many tools in achieving that mission. EPA's integrated approaches strategically use available tools – incentive programs, compliance assistance, investigations, settlements – in a manner targeted and tailored to particular problems and situations to produce the most benefit to the public and the environment.

To encourage self-monitoring and to reduce the need for direct enforcement, EPA's enforcement office created the "Policy on Compliance Incentives for Small Businesses" (also

known as the Small Business Policy) and a policy called "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations" (also known as the Audit Policy). These policies, the first directed specifically to account for small businesses concerns and the second directed toward all other businesses, provide for up to100 percent reduction in otherwise applicable gravity-based penalties for those violations that are voluntarily disclosed to the Agency in accordance with the terms of each policy. Thousands of businesses have self disclosed and successfully resolved violations under these policies without any penalty and long before it became necessary for the Agency to initiate any investigation.

Now I would like to discuss EPA's compliance assistance and outreach efforts for complying with the TRI lead rule. This Administration believes the preferred approach to achieving compliance with new rules is by emphasizing compliance assistance during the first year rather than direct enforcement. Indeed, for the lead rule, the President specifically directed EPA to provide compliance assistance to affected businesses, especially small businesses, to help them prepare their first release reports due by July 1 of this year under this new rule. EPA's direct enforcement priorities for existing TRI requirements focus on where we may see areas of noncompliance and the potential for significant environmental or public health harm.

For the first new TRI lead reports, EPA has worked hard in providing compliance assistance and outreach, especially for small businesses, for the first year reporting deadline. Within the past year, the Agency issued a technical guidance document to assist facilities in complying with the new lead rule. This document was developed through a public notice and comment process that included a meeting with interested stakeholders so that they could provide

feedback directly to EPA. Also in this first year, EPA sponsored workshops specifically on the new lead rule. These workshops were held in the Fall of 2001 in the northeast, mid-Atlantic, southeast, southern, central, and western geographic areas of the country. These workshops were developed specifically for the first time reporter. They provided an overview of the TRI program and the reporting requirements, an overview of PBT chemicals and the reporting requirements that apply to these chemicals, a detailed overview of the new reporting requirements for lead and lead compounds, including the use of emission factors for estimating quantities for activity thresholds and releases, and finally other sources to refer to for further information.

Both the workshops and the availability of the draft and final versions of the guidance document were extensively publicized, through announcements published in the Federal Register, the Agency's TRI web page, and e-mail announcements sent out by EPA's Small Business Ombudsman, to trade organizations and interested parties, including the Small Business Administration, as well as through other EPA efforts. EPA also provides TRI assistance through its Compliance Assistance Centers (http://www.assistancecenters.net/), which cover all applicable Federal, State, and local environmental requirements for specific sectors. These centers provide specific information on each environmental requirement or direct links to the agency or industry site which addresses the compliance issue of interest. In addition, EPA's Office of Enforcement and Compliance Assistance's (OECA) National Compliance Assistance Clearinghouse (http://cfpub.epa.gov/clearinghouse/) provides similar information for industries which do not have a dedicated center.

In addition to these specific efforts to address compliance with the lead rule, the Agency continues to work hard to provide compliance assistance for facilities generally. For example, EPA held more than forty workshops on compliance with the TRI reporting requirements, which also include the lead rule requirements, this spring throughout the country. More than 3000 people attended the workshops this spring. These annual spring workshops are especially helpful to those who will be responsible for reporting their releases and other waste management activities of lead and lead compounds for the first time. Also, the training materials used at these workshops are available on the Internet through the TRI web page. EPA has many more TRI compliance assistance resources and tools available through the Internet and telephone hotlines to assist small businesses with the reporting requirements.

I believe that our outreach to the small business community and our compliance assistance efforts to help small businesses comply with the new lead reporting requirements have been extensive. The Agency will continue to be diligent in our contacts with affected businesses to give them the assistance necessary to comply with the new regulation. Because the TRI program, which is in my office, has primary responsibility for compliance assistance efforts under TRI, OECA has a limited role to play in implementing the new TRI lead rule until after July 1, 2002, when the first reports are due. As with any new rule, EPA emphasizes compliance assistance during the first year of implementation rather than enforcement. For the new TRI lead reporting obligations, the Agency will devote most of its resources to outreach and education about the lead rule, ensuring that companies have the necessary information and assistance to

comply. EPA will continue to promote our incentive policies and compliance information, but it is incumbent upon the regulated facilities to take advantage of these offerings.

In conclusion, I would like to reiterate EPA's strong commitment to providing public access to environmental information and our firm belief that public access contributes positively to our citizens' ability to understand environmental issues and to make better decisions in their daily lives. An informed public can hold government and industry accountable for pollution control efforts.

Thank you, Mr. Chairman and Members of the Subcommittee for the opportunity to appear today. I would be glad to answer any questions you may have at this time.

Before the

UNITED STATES HOUSE OF REPRESENTATIVES

Committee on Small Business
Subcommittee on Regulatory Reform and Oversight

Testimony of

Dennis P. McGuirk

President
IPC - The Association Connecting Electronics Industries

2215 Sanders Rd
Northbrook, IL 60062

On

The TRI Lead Rule: Costs, Compliance and Science

June 13, 2002

Good morning Chairman Pence, Ranking Member Brady and members of the Committee. My name is Denny McGuirk and I am the President of the IPC, the trade association for the electronic interconnection industry. IPC's 2,500 members manufacture and assemble printed circuit boards, the backbone of our nation's high tech industries, including consumer, industrial, and defense electronics. On behalf of IPC and our member companies, I'd like to thank you and your staff for organizing this important hearing.

Sixty percent of IPC members are small businesses. As you know, the cost of regulatory compliance often has a disproportionate impact on small businesses. Environmental regulations must be based upon sound scientific and regulatory analysis so that they do not create unnecessary burdens while failing to achieve their goal of environmental protection.

The Environmental Protection Agency's (EPA's) rule lowered the reporting threshold for lead and lead compounds under the Toxic Release Inventory (TRI) from 25,000 lbs (over 12 tons) to 100 lbs. The regulation took effect on April 17, 2001, and included an unprecedented retroactive application of the reporting requirements to January 1, 2001. IPC members, along with many other industries affected by the rule, are concerned that the burden of this rule upon business, especially small businesses, has been significantly underestimated. To make matters worse, EPA has failed to provide effective, promised compliance assistance, thereby further increasing the burden on those least able to bear it.

EPA Failure to Conduct Appropriate SBREFA Outreach

During the development of the rule, EPA chose not to convene a Small Business Advocacy Review Panel as required under the Small Business Regulatory Enforcement and Fairness Act (SBREFA), deciding instead to certify the proposed and final rules as having no significant economic impacts on a substantial number of small entities. Yet, EPA admitted that its assessment was inadequate, stating that there were other industries "that may be affected by the rule, but for which existing data are inadequate to make a quantitative estimate of additional reporting," and thus excusing their omission from the cost

assessment.[1] Early outreach to small businesses could have helped the EPA determine the number of small companies that would be significantly impacted by the rule.

On April 9 2001 the Chief Counsel for Advocacy at the Small Business Administration wrote to EPA stating that, "advocacy disagrees with EPA's certification of this final rule under the Regulatory Flexibility Act that this rule does not impose a significant economic impact on a substantial number of small businesses."

On April 24, 2001, the Senate Committee on Small Business held a hearing on the effectiveness of SBREFA, with the GAO testifying that the EPA's assertion that the rule would not have a "significant impact" on small entities ignored more than 30 industry groups' concerns about the rule. Instead of investigating the validity and significance of these points, EPA's response was to turn the burden of proof on small businesses, challenging them to prove the impacts on their industries. This approach runs contrary to SBREFA, which was adopted in recognition that small businesses are not equipped to take on these kinds of obligations.

SBREFA represents more than a series of procedural hoops through which agencies must jump. SBREFA's small business outreach provisions are designed to ensure that federal agencies obtain crucial information from which they can assess a proposal's small business impact.

When EPA did not contact my organization prior to the proposal's release, our members were deprived of the opportunity to be involved during formative rulemaking stages – when regulatory options that might have lessened the enormous impact on small businesses should have been considered.

Compliance with the Rule will impose a significant burden on IPC members and many other small businesses

Compliance with the lowered reporting thresholds imposes a large and significant burden on IPC members. For a small business, the job of interpreting and complying with the agency's instructions and guidance for the TRI is a substantial source of burden. To give you an idea of what I am talking about, I have brought with me the reporting forms, instructions, and guidance for complying with the reporting

[1] Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting, 66 FR 4534 January 17, 2001.

requirements for lead and lead compounds. Together they total 746 pages, not including twelve industry specific guides, which have not been updated to include the lowered reporting thresholds. According to EPA's own estimates, the cost of compliance for new reporters in the electronics industry is $7,000 for the first year alone. We believe this underestimates the actual costs, but in any event it is a significant sum of money when you consider that it must come entirely from profits in an industry with ever decreasing customer prices.

EPA's failure to Provide Adequate Compliance Assistance

During the time the rule was under consideration and after its adoption, many concerns were raised about the enormous burdens it would impose on small businesses throughout the country. We were pleased when in April 2001 President Bush recognized this problem, and directed EPA to help small businesses.[2] In a May 2001 letter to 73 concerned trade associations, the EPA's Office of Environmental Information (OEI) reiterated this point by promising to help reduce the burdens imposed on small businesses by developing a final guidance document by October, 2001:

> "President Bush and Governor Whitman are also sensitive to the concerns expressed in your letter that this rule imposes regulatory burdens on to [sic] businesses, particularly small businesses. To address this concern, the President has asked Governor Whitman to provide technical assistance to affected small businesses to help them prepare their first release reports, which are due by July 1, 2002. EPA's Toxics Release Inventory Program is actively developing a guidance document that will assist regulated entities . . . to comply with the new lead rule. A primary objective of this guidance is to help reduce burdens imposed by the rule. Development of this guidance has been given high priority, and the guidance is expected to be finalized and made available by October of 2001.[3]

Unfortunately, EPA did not finalize the promised guidance document until the end of January 2002, after the entire first reporting year had passed.

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[2] Statement by the President, White House Office of the Press Secretary, April 17, 2001.

[3] Letter from Margaret N. Schneider, Acting Assistant Administrator, Office of Environmental Information, to Jane C. Luxton, King & Spalding, May 25, 2001. Ms. Schneider's letter responded to a letter sent to EPA by seventy-three associations, including many small business groups, that had written to the Agency expressing concerns about the rule.

Additionally, IPC members, along with thousands of other small businesses across the country, have found the EPA's guidance to be too long, confusing, and conflicting. In February of this year, my Director of Environmental Policy e-mailed 17 questions about the guidance document to EPA so that she could provide accurate assistance to our members. In its effort to help small businesses comply with the reporting requirements, EPA took four months to respond. IPC had less than 4 weeks to assist our members in complying with the July 1, 2002 reporting deadline.

On February 22, 2002, 43 trade association representing small businesses wrote to the EPA Administrator asking for a one-year delay of the reporting requirements so that they could work with EPA to augment and improve the EPA's assistance to small businesses needed to ensure the collection of accurate and useful data without placing undue burden on small businesses.

The need for this delay is supported by EPA's own words. In response to a comment pointing out the confusion generated by EPA's inaccurate, out-of-date Question and Answer document, EPA states, "The TRI Program can only update this guidance document once every several years."[4] If EPA is unable to update key guidance documents for such a significant rule, it should delay implementation until it is able to provide accurate guidance and compliance assistance.

Last month, a group of 30 trade associations met with the EPA Deputy Administrator to further discuss concerns regarding the EPA's implementation of the rule and the need for a one-year reporting delay. During the meeting, EPA acknowledged that there had been problems with the implementation, but noted that the first year of a regulation always serves as a 'road-test.' This cavalier disregard of small businesses' concerns suggests that they risk being turned into the road-kill of EPA's road test -- in direct conflict with the intentions of SBREFA (Small Business Regulatory Enforcement and Fairness Act).

While EPA has stated that it "does not believe that it would be likely to bring an enforcement case where a facility truly lacked any reason to suspect that lead was present in a product,"[5] and that, "In any enforcement action brought against a facility by EPA, it is the US government that bears the burden of

[4] Response to IPC Questions, E-mail from Elaine Stanley to Fern Abrams, June 6, 2002.
[5] Response to IPC Questions, E-mail from Elaine Stanley to Fern Abrams, June 6, 2002.

demonstrating that the facility has violated EPCRA Section 313,"[6] exactly the opposite happened two years ago. More than 600 facilities, including several IPC members, received "show cause" enforcement letters asking them to prove that they had not failed to report nitrates that may have been formed during wastewater treatment. Given an enforcement record like this, how can small businesses trust EPA when it says that TRI requires only that you make a report based on readily available information?

IPC members take their responsibility to environmental stewardship very seriously. As small business owners they and their families live, work and play in the communities where their businesses operate. Unfortunately, many of them are unable to fulfill their obligations to provide accurate information as required under the TRI program, due to lack of available information, inadequate outreach and assistance, and the impossibility of compiling data retroactively.

The environment and our public health depend upon good environmental information. When the public has only inaccurate information to work with, it cannot help but to misallocate resources to deal with imaginary problems, while overlooking real environmental dangers. America's families cannot benefit from the TRI program if EPA does not ensure accurate data filings. This includes providing small businesses with the necessary tools to meet their obligations.

In conclusion, I ask you to consider whether it is reasonable to require thousands of small businesses to incur substantial regulatory burdens, when EPA itself has underway a peer review of the very scientific framework upon which this expensive and burdensome regulation is based. We believe that in the interests of good science and good data EPA should suspend or otherwise delay the lowered reporting thresholds for lead until small business concerns can be addressed properly and until the results of EPA's Science Advisory Board's review can be completed and assessed. Taking such a step is the best way to ensure that the public's right to know is well served.

Thank you again, Mr. Chairman for giving IPC the opportunity to express our concerns and I welcome any questions.

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[6] Response to IPC Questions, E-mail from Elaine Stanley to Fern Abrams, June 6, 2002.

Responses To Fern Abrams Comments and Questions Regarding The Lead Rule[1]

Comment/Question: *To this date, EPA's TRI web site contains information referring to the 25,000 pound and 10,000 pound thresholds for lead reporting, including several references in the Revised 1998 Q & A document.*

Answer. EPA's TRI web site also contains a lot of information pertaining to the new 100 pound reporting threshold for lead and lead compounds. In fact, a specific portion of the TRI web site is devoted to the lead rule, and provides much detail on the new reporting requirements. The specific web site is http://www.epa.gov/tri/lawsandregs/lead . The revised guidance document for complying with the new reporting requirements for lead is also available from the TRI web site, and is prominently displayed.

Comment/Question: *EPA's final guidance for complying with the TRI Lead Rule [the Lead Guidance Document] refers readers to the Revised 1998 Q & A document. Yet the 1998 Q & A document contains many references to the 25,000 pound and 10,000 pound reporting thresholds for lead, in direct conflict with the current TRI regulations.*

Answer. The references the Lead Guidance Document makes to the Revised 1998 Q & A document pertain to information on general topics such as articles exemption, general reporting requirements, and the Form R release report, to name just a few. Given its limited resources, the TRI Program can only update this guidance document once every several years. The TRI Program is currently updating the document.

Comment/Question: *Compliance workshops held during Fall 2001 were not well publicized. No effort was made to reach the regulated community through trade associations, EPA's small business office, or the Small Business Administration.*

Answer. Extensive publicizing efforts of the workshops were made well before the workshops took place. These efforts include:

- EPA's Small Business Office sent out e-mail announcements to trade organizations and interested parties, including the Small Business Administration
- EPA published a Federal Register notice announcing the Workshops and sent flyers directly to interested parties via e-mail
- Some EPA regional offices also conducted local outreach

[1] Received from Elaine Stanley via e-mail to Fern Abrams, IPC Director of Environmental Policy, June 6, 2002.

Comment/Question: *Those who did attend the Fall 2001 workshops were only provided with Draft Guidance.*

Answer. The draft guidance was available during the period in which the fall workshops were being held, however the workshops did not focus on the lead guidance document. The final (revised) version of the guidance was made available in January 2002. Even though the guidance was draft at that time, the workshops provided valuable information about the TRI program and the lead rule. These workshops were developed specifically for the first time reporter. It provided an overview of the TRI program and the reporting requirements, an overview of PBT chemicals and the reporting requirements that apply to these chemicals, a detailed overview of the new reporting requirements for lead and lead compounds including the use of emission factors for estimating quantities for activity thresholds and releases, and finally other sources to refer to for further information.

Comment/Question: *Current reporting forms and instructions were not available during compliance workshops, were not posted on the EPA's website until the second week of February 2002. More alarmingly, EPA will not be mailing the forms until March 2001, and then only to facilities that filed TRI reports in 2001. This despite the fact that EPA acknowledges the large number of first time filers. A SBREFA review, had one been conducted, would have served to identify affected businesses. Since this was not done, outreach should be conducted to every potential filer, i.e., all businesses with 10 or more employees in the covered SIC codes.*

Answer. These extra compliance workshops were provided in October through December (i.e., fall) of 2001. EPA historically makes the most recent reporting instructions available early in the same year the reports are due. As with previous years, the reporting instructions were mailed out in March of this year. A SBREFA review would not have affected the distribution of the reporting instructions. To assist trade associations in their outreach efforts, EPA is always willing to accept addresses for businesses that may need to report to the TRI. Note, the only change from the previous reporting instructions was the new reporting requirements for lead: the primary subject matter of the fall, 2001 workshops.

Comment/Question: *EPA's final guidance, which leaves many questions unanswered, was not provided until after the entire reporting year passed, making data gathering more difficult and less accurate.*

Answer. EPA made a draft version of the guidance document on September 10. It held a public meeting to discuss the document on September 24, 2001. At that meeting commenters requested an extension of the comment period. EPA agreed and extended the comment period an additional week. EPA published the final version of the guidance in late January 2002.

Neither the guidance nor EPA regulations require the collection of new data. Instead, guidance is provided on what records or information may prove useful in completing the reporting form.

Comment/Question: *Unfortunately, many questions about complying with the new regulations remain unanswered. This is particularly troublesome for the legions of small businesses that have no experience in completing TRI reports.*

Answer. EPA provides assistance to all those who need to comply with TRI reporting requirements, including those in small businesses. EPA assistance is provided via:

- the TRI hotline;
- industry compliance assistance workshops are offered every spring in each EPA Region (approximately 3000 attendees for the spring 2001 workshops);
- TRI US, which is a mechanism by which individuals with questions or need or assistance can contact OIAA's TRI Division directly, and present their questions or assistance needs to the EPA headquarters TRI staff.

In addition to the usual TRI assistance provided to reporting facilities, EPA:

- developed a technical guidance document devoted specifically for complying with the lead rule, through a notice and comment process;
- conducted 9 lead rule workshops were held throughout the various regions of the country in the fall of 2001. These workshops were well attended.

Comment/Question: *The Lead TRI rule does not allow exclusion of de-minimis concentrations; range reporting; or rounding. How is it possible to obtain this level of precision with existing data sources?*

Answer: The determination to not allow the de minimis exemption for chemicals classified as PBT chemicals was made in the PBT chemicals rulemaking (64 FR 58666). The lead rule determined that lead and its compounds are PBTs. The lead rule does not allow for:

- an exclusion based on de minimis concentrations,
- use of range reporting; or
- use of the alternative reporting threshold for the Form A.

The TRI lead rule increased the data reporting precision to one-tenth (0.1) of a pound for lead. When reporting releases and other waste management activities of lead and lead compounds, facilities should round-off to the nearest one-tenth of a pound of lead. The

increased reporting precision, elimination of the deminimis exemption and range reporting options do not apply to lead when it is contained in stainless steel, brass or bronze alloys.

In determining whether thresholds for manufacturing, processing, or otherwise using a chemical listed on the EPCRA section 313 list of toxic chemicals has been exceeded and, hence, whether reporting of releases and other waste management quantities is required, EPCRA is very clear that EPA should not require facilities to conduct any monitoring or testing, but that facilities should use readily available information, such as monitoring data collected pursuant to other laws, or make a reasonable estimate of their release information. Therefore, the quality of the release and other waste management quantities submitted by a facility pursuant to EPCRA section 313 is dependent upon the quality of the data used to determine whether an activity threshold for reporting has been exceeded and, if so, the quality of the data used to make reasonable estimates of releases and other waste management quantities.

EPA recommends that facilities complete threshold determinations and release and other waste management quantity calculations using best readily available information applicable to their operations. In the absence of such information, EPCRA section 313 permits a reporting facility to make a reasonable estimate. EPA also recommends that facilities maintain documentation of the basis for making these estimates (see 40 CFR _ 372.10).

Comment/Question: *[With regard to the above question] will EPA enforce against facilities that followed EPA estimating procedures but are later found to have been inadequately precise?*

Answer: Guidance and recommendations provided by EPA for making threshold determinations, or calculating release or other waste management quantities is intended to assist industry with complying with EPCRA section 313 reporting requirements for lead and lead compounds. EPA guidance and recommendations do not supersede, however, any statutory or regulatory requirements, are subject to change, and are not independently binding on either EPA or covered facilities. Additionally, if a conflict exists between EPA guidance or recommendations and the statutory or regulatory requirements, the conflict must be resolved in favor of the statute or regulation. Although EPA encourages industry to consider the Agency's guidance and recommendations, industry should be aware that the Agency's guidance and recommendations usually pertain to common circumstances at typical facilities. The circumstances at a specific facility may significantly differ from those contemplated in EPA's guidance or recommendations. Thus, individual facilities may find that recommendations and guidance provided by EPA are inapplicable to their processes or circumstances, and that alternative approaches or information are more accurate and/or more appropriate for meeting the statutory and regulatory requirements of EPCRA section 313. To that end, industry should use readily available facility-specific information and process knowledge, where available, to meet the requirements of EPCRA section 313. EPCRA section 313 also provides that, in the absence

of such readily available data, a reporting facility may make reasonable estimates to meet those EPCRA section 313 requirements.

Comment/Question: *If a facility knows that lead is present but doesn't have idea of concentration, and their supplier is unable to provide specific information for each lead-containing product how should they calculate, to the level precision required by this rule?*

Answer: EPCRA 313 (g)(2) requires facilities to use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data is not readily available, reasonable estimate should be used of the amounts of the chemical involved. It is recommended that facilities document their efforts to comply with this provision of the law.

Comment/Question: *EPA's guidance document provides conflicting information on necessary data precision. The document states, "When estimating release and other waste management quantities of a listed chemical for purposes of reporting, facilities should base these determinations at a level of precision supported by available data and the estimation techniques used in determinations. The facility is required to make a reasonable estimate when it lacks readily available data." Yet, in the same paragraph, EPA goes on to state, "When expressing release and other waste management quantities of lead or lead compounds on a Form R, the level of precision one should use is one-tenth (0.1) of a pound." Which of these statements should be used to determine the appropriate level of precision?*

Answer: This quoted text in this question was taken from the first paragraph of section 1.4.4, Data Precision (page 1-11). It does not provide conflicting information on data precision. As stated in the document, the appropriate level of precision for reporting releases and other waste management quantities of lead or lead compounds is one-tenth (0.1) of a pound, except for lead contained in stainless steel, brass or bronze alloys.

Facilities should report releases and other waste management quantities to the level of accuracy that is supported by the underlying data on which the estimate is based. However, EPA stated it would not require greater 0.1 pound (except dioxins) level of precision, presuming that the data supports such a calculation. The Agency believes that, particularly for PBT chemicals, facilities should be able to calculate their estimates of releases and other waste management quantities to one-tenth of a pound and believes that such guidance is consistent with the reporting requirements of sections 313(g) and (h) of EPCRA, which requires facilities to use readily available information or make reasonable estimates as required by EPCRA section 313 (g)(2).

Comment/Question: *If EPA wishes facilities to report in one-tenth of a pound, despite the lack of available data and estimation methodologies to support this level of precision, how will EPA reconcile the deliberate gathering and publication of poor quality data with the Office of Management and Budget's data quality guidelines (67 FR 369).*

Answer: Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1991 requires the Environmental Protection Agency (EPA) to annually collect releases of and other waste management quantities for listed toxic chemicals from covered facilities. EPCRA section 313 also requires EPA to make this information available to the federal, state and local governments, researchers, and the public. EPCRA section 313 is very clear that EPA should not require facilities to conduct any additional monitoring or testing to comply, but that facilities should use readily available information, such as monitoring data collected pursuant to other laws, or make a reasonable estimate of their release information. Therefore, the quality of the release and other waste management quantities submitted by a facility pursuant to EPCRA section 313 is dependent upon the quality of the data used to determine whether an activity threshold for reporting has been exceeded and, if so, the quality of the data used to make reasonable estimates of releases and other waste management quantities.

EPA is developing Information Quality Guidelines to be issued by October 1, 2002, as specified in the guidelines published by the Office of Management and Budget (OMB). EPA's guidelines will build upon ongoing efforts to improve the quality of the information used to support Agency policy and regulatory decisions. Given existing Agency-wide systems and procedures and the TRI Program procedures, EPA is confident that the TRI Program will be consistent with OMB's Information Quality Guidelines.

Comment/Question: *In many products, different grades, items, colors, etc. contain varying levels of lead. For example: different grades of wire contain different amounts of lead; each of thousands of different electronic components contain differing lead levels; each color of decorative ceramic paint has a different lead content, etc. Often suppliers are unable to provide lead content for each variation of product. Given that rounding and range reporting are not permitted, how should facilities proceed? Also, how are facilities to identify and report de-minimis lead levels when EPA has upheld the applicability of de-minimis to the supplier notification requirements?*

Answer: EPA recommends that facilities complete threshold determinations and release and other waste management quantity calculations using best readily available information applicable to their operations. In the absence of such information, EPCRA section 313 permits a reporting facility to make a reasonable estimate. EPA also recommends that facilities maintain documentation of the basis for making these estimates (see 40 CFR _ 372.10).

Facilities may consult several types of sources for facilities for estimating the amount of a chemical in their raw materials and products. These include EPA guidance documents, trade associations, consultants, suppliers, monitoring data, technical references such as catalogues published by chemical companies, Kirk Othmer's Encyclopedia of Chemical Technology and others. The facility must determine what is the best information available to allow them to make a reasonable estimate of the quantities of chemicals that are processed, manufactured, or otherwise used. The information that is used for threshold calculations, which determine if they need to report, can be used to help make estimations of their reportable quantities. The use of range reporting and rounding relate to how the facility reports the estimates it has generated, not how the facility calculates its release and other waste management quantities. The lead rule does not preclude facilities from making reasonable estimates of the amounts involved, if facilities lack more precise information. EPA has previously provided guidance on how to report when the facility only knows that a listed chemical is present in a range of concentrations in a mixture, or in similar circumstances: see EPCRA Section 313 Questions and Answers, Revised 1998 Version, pages 31-32 (US EPA document number 745-B-98-004, December 1998)

Comment/Question: *In Appendix B of the guidance document, EPA states, "If the processing or otherwise use of all like manufactured items results in the release of 0.5 pounds of less of a toxic chemical, EPA will allow this quantity to be rounded to zero and the steel plates may be exempt as articles." This is in direct conflict from EPA's previous statement in Section 1.4.4, " When expressing, on a Form R, release and other waste management quantities for most listed chemicals EPA allows facilities to "round-off" release and other waste management estimates to zero if the estimates are 0.5 pounds or less., This option is not allowed, however, for PBT chemicals, including lead and the lead compound category." Is rounding allowed for lead and lead compounds?*

Answer. The two quotations are discussing two different things. The quoted statement "If the processing or otherwise use of all like manufactured items results in the release of 0.5 pounds of less of a toxic chemical, EPA will allow this quantity to be rounded to zero and the steel plates may be exempt as articles." from Appendix B of the lead guidance document is taken specifically from the answer to question 371, page B-12 of the document. This question and answer pertains to releases of listed chemicals, including lead, from articles. That is, if the release of lead is 0.5 pounds or less annually from processing or otherwise use of all like manufactured items (e.g., articles), this quantity can be rounded to zero for purposes of release reporting. The rounding to zero is only permissible, however, in situations in which the release of lead (or any other listed chemical) does not exceed 0.5 pounds annually from processing or otherwise use of all like manufactured items.

The quoted statement from question 371 (page B-12) does not conflict with the quoted statement from Section 1.4.4 of the document: " When expressing, on a Form R, release and other waste management quantities for most listed chemicals EPA allows facilities to "round-

off" release and other waste management estimates to zero if the estimates are 0.5 pounds or less, This option is **not** allowed, however, for PBT chemicals, including lead and the lead compound category." The rest of the paragraph in section 1.4.4 reads: "When expressing release and other waste management quantities of lead or lead compounds on a Form R, the level of precision one should use is one-tenth (0.1) of a pound. Thus, when reporting releases and other waste management quantities of lead and compounds, facilities should round-off to the nearest 0.1 pound." The statements in Section 1.4.4 do not pertain to releases of lead from all like-manufactured items.

Comment/Question: *In Section 1.4.1 of the guidance document, EPA states, "EPA eliminated the de minimis exemption for EPCRA section 313 chemicals that have been classified as PBT chemicals, including lead and the lead compounds category, except for lead contained in stainless steel, brass or bronze alloys," yet in Appendix B, Question 6, EPA states, "Lead is a PBT chemical, regardless of whether it is in an alloy…EPA has deferred on a decision to lower the 25,000 pound and 10,000 pound thresholds for lead when contaminated in stainless steel, brass, and bronze alloys." Is lead a PBT or not? Is it only a PBT some of the time?*

Answer. The statements quoted in the question above are correct. Lead is a PBT chemical all of the time: whether it is contained in stainless steel, brass, or bronze alloys does not determine whether lead is a PBT chemical. The 100 pound reporting threshold for processing, manufacturing or otherwise using lead does not pertain to lead when it is in stainless steel, brass, or bronze alloys: EPA has deferred on a decision to lower the 25,000 pound and 10,000 pound thresholds for lead when contained in stainless steel, brass, and bronze alloys. The reason for this deferral is discussed in the lead rule.

Comment/Question: *EPA doesn't require additional testing but instead encourages facilities to rely on existing data sources. Yet if a facility is wrong won't they violate RCRA at a $25,000/day fine?*

Answer: EPCRA 313 (g)(2) requires facilities to use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data is not readily available, to make reasonable estimate of the amounts of the chemical involved. Therefore, the TRI Program cannot require a facility to test for any chemicals. Facilities should refer to 40CFR§262 (generator standards) to determine compliance under the provisions of RCRA. The Office of Solid Waste should be consulted for further guidance on this issue.

Comment/Question: *If a facility doesn't have readily available information showing lead is present and they do not report and then there is an enforcement action against them, what type of data/information/backup would EPA require in order for the facility to prove that the information was not available?*

Answer: In any enforcement action brought against a facility by EPA, it is the US government that bears the burden of demonstrating that the facility has violated EPCRA section 313. In addition to the record keeping requirements under 40 CFR §372.10, EPA recommends that facilities document their efforts to demonstrate compliance with EPCRA section 313 (g)(2).

Comment/Question: *Would there be any type of enforcement against a company that doesn't report because there is no reason to suspect there is lead in the product and it is later found that there is lead in the product?*

Answer: EPCRA 313 (g)(2) requires facilities to use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data is not readily available, to make reasonable estimate of the amounts of the chemical involved. EPA recommends that facilities document their efforts to demonstrate compliance with EPCRA section 313 (g)(2). EPA does not believe that it would be likely to bring an enforcement case where a facility truly lacked any reason to suspect that lead was present in a product, and could not reasonably have obtained the information.

Comment/Question: *The emission factors provided by EPA in the index provide only a very limited subset of air emissions. What sources should facilities use to obtain emission factors solid waste? For water emissions?*

Answer: EPA guidance cannot substitute for all of the information and expertise available at the facility. It has been EPA's experience that facilities are often better able to make estimates of quantities involved, given that they know more about the specifics of their operation than the Agency. Facilities may wish to consider using the AP-42 handbook of emission factors, or other literature sources, such as government reports, trade journals, the open literature, or standard texts such as Kirk Othmer's Encyclopedia of Chemical Technology. Many of these and other literature sources can be accessed and searched from the Internet.

Comment/Question: *How should a facility, without testing, determine if the article status is voided through the release of greater that 0.5 pounds of lead from the cutting of items that contain trace lead, such as sheet metal, optical glass, PVC pipe, and copper pipe?*

Answer. As discussed in responses above, EPCRA is very clear that EPA should not require facilities to conduct any monitoring or testing, but that facilities should use readily available information, such as monitoring data collected pursuant to other laws, or make a reasonable estimate of their release information. EPA also recommends that facilities maintain documentation of the basis for making these estimates (see 40 CFR _ 372.10).

To determine without testing whether the release of lead from cutting of all like manufactured items (e.g., articles) is greater than 0.5 pounds annually, EPA recommends that one consider the conditions of the cutting. This includes, for example the annual quantities of the items being cut and temperature generated as a result of the cutting. Facilities may also want to consider available studies or reports that investigated releases of lead from cutting of items that contain lead. These studies may include studies published in government reports, trade journals, the open literature, or described in standard texts. Monitoring data (e.g., data collected or mandated by OSHA or NIOSH requirements) that pertain to these scenarios may also be available.

BEFORE THE

U. S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SMALL BUSINESS
Subcommittee on Regulatory Reform and Oversight

TESTIMONY OF

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on

The TRI Lead Rule: Costs, Compliance, and Science

June 13, 2002

I. INTRODUCTION

Good Morning Chairman Pence, Ranking Member Brady, and distinguished members of the Committee.

My name is Jim Mallory, Executive Director of the Non-Ferrous Founders' Society ("NFFS"), a not-for-profit trade association representing the aluminum and copper-based foundry industry. I am pleased to appear before the Subcommittee on Regulatory Reform and Oversight this morning to provide these comments on EPA's final TRI Reporting Rule for Lead, which has lowered the reporting thresholds for lead and lead compounds under the Toxics Release Inventory ("TRI") program from 10,000 pounds to 100 pounds. I am speaking here to represent all non-ferrous foundries that are subject to the TRI lead rule, and not just those companies that are members of the Society.

The foundry industry has played an important role in the history of American progress, invention, and innovation. Today, non-ferrous foundries operate in nearly every state of the union, producing component parts that are used in virtually every other manufacturing industry. The industry itself, while comprised mainly of small businesses, collectively employs more than 265,000 people, contributes in excess of $20 billion to the Gross National Product, and produces something over 100,000 distinct products.

Non-ferrous castings are found in everything from your kitchen sink and kitchen appliances to the engine, drive train, and dashboard of your automobile. Although the art of making castings is quite old, non-ferrous castings have been part of nearly every new technological development since the industrial revolution, and figure prominently in computers and digital scanners, and in medical devices from something as simple as an in-the-ear electronic thermometer to something as complex as a magnetic resonance imaging machine. There are non-ferrous castings all over your homes, in your backyard, in your office, and everywhere you go, whether you travel by land, by air or on the water.

The majority of non-ferrous foundries are small businesses. According to a census of the foundry industry compiled by Penton Publishing Company of Cleveland, Ohio, there are more than 2,000 non-ferrous foundries operating in the United States today. Of those, all but 1% meet the U.S. government definition of a small business. In fact, more than 1,800 of these companies have fewer than 100 employees. Of the total non-ferrous foundry population, more than 1,500 pour aluminum, a fact that I will come back to later in my comments.

Most non-ferrous foundries in business today are privately held companies - many family-run, some actually owned and run by the same family for several generations. In most of these companies, the person responsible for filing the TRI report is a principal of the company, usually the owner or another key executive. This person is not trained, or often even experienced, in completing and filing the TRI report. In fact, particularly among aluminum foundries, they may never have had to file a TRI report before. The changes to the TRI reporting rule will therefore have a very direct and profound affect on these companies. Moreover, the vagaries and difficulties of accurately completing the TRI report will place a significant new burden on these small business owners. I will expand on that statement later in my comments as well.

Non-ferrous foundries today are not the belching smokestack industrial polluters of years ago. Quite the opposite. Non-ferrous foundries are responsible neighbors and valued sources of employment in their local communities. Though they are already heavily regulated, these companies hold a healthy respect for – and commitment to – protecting the environment.

The foundry industry annually recycles millions of tons of scrap metal into useful components without which America's great production engine would come to a grinding halt. The reuse of these materials saves natural resources and decreases the amount of materials that would otherwise go to landfills. More than 95% of the feedstock for foundry production comes in the form of alloyed ingot derived from these recycled materials. But as I hope my comments will

also reveal, even this creates problems for some foundries in trying to comply with the new TRI reporting rule for lead.

II. A BRIEF HISTORY OF EPA'S TRI REPORTING RULE FOR LEAD

EPA originally proposed reducing the "manufacture/process" and "otherwise use" reporting thresholds for lead and lead compounds under its TRI Reporting Rule from 25,000 and 10,000 pounds per year, respectively, to 10 pounds per year. The rationale for this change was based on the agency's view that lead and lead compounds are toxic chemicals that persist and bioaccumulate in the environment.

To say that there is a lack of consensus as to the applicability of PBT criteria to metals would be an understatement. Nowhere was this confusion evidenced more clearly than in the fact that at the time this change was proposed there were no fewer than three distinct groups within the EPA itself working to develop appropriate PBT criteria.

As a trade association representing small businesses affected by the proposed reduction, NFFS directed comments to the Agency's urging the agency to conduct a proper impact assessment analysis as required under SBREFA. Responding to comments from affected parties, in April of 2001, EPA increased its proposed reduced reporting threshold limit from 10 to 100 pounds, but at the same time applied the rule retroactively covering releases beginning on January 1, 2001. The new lead reporting rule also eliminated both the exclusion of *de minimis* concentrations and the use of range reporting (or rounding). Under the new reporting rules, EPA requires facilities to provide data to a level of precision of 1/10 of a pound.

As a consequence of the rule having been made retroactive, affected facilities would be required to reconstruct data after the fact for the first four and a half months of the year 2001 without having any direct guidance from EPA. The agency promised to issue a final guidance document by October, 2001, but its' first draft wasn't issued until just before September 11. Almost

immediately, the draft was severely criticized by government agency representatives and by other stakeholders at a meeting EPA convened on September 24.

EPA did not make its final guidance document available until January, 2002. That effectively meant that small businesses were subject to substantial new data gathering and reporting obligations *for an entire calendar year* before they had any direct guidance from the Agency. Moreover, rather than providing the promised "clear, easy to follow guidance," the final document is more than 200 pages long, leaves many key questions unanswered, and provides confusing information on a number of important points.

It wasn't until February that compliance reporting forms and instructions were mailed to facilities that had filed TRI reports in 2001, and the materials were not posted on EPA's website until March. But despite their own internal delays and inefficiencies, EPA insists on holding to a June 30, 2002 reporting deadline for releases in Calendar year 2001.

III. NON-FERROUS FOUNDRIES HAVE SPECIFIC PROBLEMS TRYING TO COMPLY WITH THE NEW TRI REPORTING RULE

A. Eliminating the de minimis exemption triggered TRI reporting requirements for many small non-ferrous foundries for the first time.

EPA's elimination of the *de minimis* exemption for lead and lead compounds was not supported by any defensible justification. EPA had originally asserted that it adopted the *de minimis* exemption solely as a burden-reduction measure in its basic TRI rule. On the contrary, the preamble to the original rule clearly states that EPA added the *de minimis* exemption not just to reduce reporting burden, but mainly because the presence of chemicals below that level were felt to be unlikely to add significantly to thresholds or release reporting.

In the original TRI rule, EPA had stated that allowing a *de minimis* exemption was appropriate for two reasons. First, it was consistent with existing OSHA HCS requirements for development of MSDS information and with other requirements under Sections 311 and 312 of

Title III. Suppliers of products were familiar with these levels and users of these mixtures would be able to rely on the product MSDS for information about the content and percentage composition of covered toxic chemicals in the products. Second, EPA did not expect that the processing and use of mixtures containing less than the *de minimis* concentration would, in most instances, contribute significantly to the threshold determinations or releases of listed toxic chemicals from any given facility.

In eliminating the *de minimis* exemption in the revised rule, the Agency did nothing to demonstrate that the original justifications for the existence of the exemption had in fact lost their validity. The members of the Non-Ferrous Founders' Society, and indeed most other users of small quantities of numerous products and mixtures, use and rely on MSDS information as the most accurate and complete source of composition data on such products. But most MSDSs do not include the Rule's necessary information about content levels of lead, and there is currently no practical alternative for discovering information that an MSDS does not already provide.

Moreover, many foundries have environmental permits that require further action, at increased effort and expense, once they are required to file the SARA 313 TRI Form "R." For example, many general NPDES permits for stormwater runoff require monitoring only if the facility is required to file a SARA 313 TRI Form "R." Quarterly or semi-annual sampling of stormwater can be a burdensome requirement, especially for a small business. Imagine if you can that you are a small foundry owner, standing out in your parking lot on a Saturday night, hoping the predicted rain will be a "representative storm event" so you can get your required sample of runoff during this monitoring quarter.

EPA failed to take into account the "domino effect" that reducing the reporting threshold for lead would have on facilities like small businesses. The elimination of the *de minimis* exemption now requires many first-time facilities not only to submit the Form "R" but, as a consequence, but also to comply with other federal and/or state regulatory or permit requirements.

B. The new TRI Rule imposes new research burdens on reporting companies.

TRI reporters are supposed to be able to rely solely on existing information in completing their "R" form reports, but the Agency's new reporting rule for lead imposes additional requirements without providing users with any sources of reliable information from which to determine applicability. If accurate information is not available, EPA has suggested that users use "production records, monitoring, or analytical data, guidance documents provided by EPA and trade associations and reasonable judgment on the part of the facility's management" in determining the amount of lead processed or otherwise used in manufacturing. However, except for the judgment of its management (which may or may not be at all informed on such matters), users of products and mixtures simply do not have this information, besides what is provided in an MSDS. Nor, in point of fact, do EPA's guidance documents, or even industry trade associations. Accordingly, EPA's lead reporting rule forces users to take steps to develop additional information, and this result directly contravenes the statute's restriction against requiring development of new data. This is particularly true for aluminum foundries.

Commercial-grade aluminum does contain lead, though most often only in minor or trace quantities. Lead is typically added to aluminum casting alloys to increase machinability. The lead forms small insoluble spheres that act as chip breakers during machining. Lead is usually added in a concentration of less than 1%, however the actual content of lead may vary by alloy composition, by production lot, and indeed by producer.

The problem in determining the amount of lead that is present in an aluminum alloy arises from the fact that none of the standard chemical specifications for aluminum alloys indicate the amount of lead the alloy may contain. Similarly, aluminum ingot manufacturers are not required to provide this information to their customers. (Under the TRI reporting rules, companies that produce materials containing less than 1% lead by volume need not indicate the lead content of those materials on their MSDS sheets.)

Under the revised Rule, aluminum foundries in particular are being forced to determine how and/or where they can obtain information on constituents that may be present in concentrations below one percent, the method of analysis to obtain this information, and the accuracy of this information. This quest gives rise to numerous practical and technical issues of concern.

In attempting to assist its aluminum foundry members and the rest of the industry in complying with the TRI reporting rule, the Non-Ferrous Founders' Society has been trying to determine the range content for lead in the various aluminum alloys. However, as stated above, the accepted standard for chemical specification of aluminum alloys is the data complied and presented by the Aluminum Association. That organization's standards book (upon which most aluminum foundries and ingot manufacturers rely) lists more than 70 distinct alloy composition for aluminum, but NONE of those specifications indicate the percent content of lead. NFFS has begun working with aluminum ingot manufacturers to develop this data, but the task simply cannot be completed prior to the 7/1/02 reporting deadline for 2001 releases.

In its preliminary research, NFFS learned that one of the most common alloys, known as 319, can contain up to .5% (1/2 of 1%) lead. Simple mathematical calculations reveal that a foundry that processes 200,000 pounds of 319 alloy per year would trigger the reporting threshold (200,000# x .5% = 100 pounds), thus requiring the foundry to make an estimate, do the calculations, and file an "R" Form even if they have no emissions to report. The problem is compounded in that typical aluminum foundries cast several different alloys, perhaps even dozens, and each of those alloys will require the same investigation, estimate, and calculation.

As I stated earlier, if specific information on the lead content of the alloys is not available, EPA requires that aluminum foundries base their reporting on their "best educated estimate." Doing this, however, might easily result in significant over-reporting, with the net effect of presenting totally inaccurate information to the local community. That, in turn, may subject the

facility to unneeded scrutiny, and even the very real possibility of citizen suits based on the information contained in the company's "R" form.

When this was brought to EPA's attention in a May 10th meeting with Deputy Administrator Linda Fisher and key staff in charge of the TRI reporting program, the staff's response was that the TRI Reporting rule in fact allows a facility to file a corrected report if and when new information becomes available. NFFS was quick to point out, however, that EPA's own estimates of the paperwork burden imposed by the new lead reporting rule suggests that it will take an estimated 65 hours to research and prepare an "R" form report. Even assuming that only 1/3 of that time is needed to file a corrected report, it would still impose an additional 20+ hours on needless government paperwork on those facilities. In most small foundries, the TRI reporting is conducted not by an environmental consultant experienced in filing those documents, but instead by a principal of the firm – often the owner or another key executive – for whom EPA reporting is only a minor (though admittedly important) part of his or her day-to-day management responsibilities.

C. Aluminum foundries in particular have been arbitrarily subjected to requirements that other foundries are not.

The TRI reporting rule is intended to capture information on significant releases of hazardous materials to the environment, but EPA apparently recognized that lead in brass & bronze and stainless steel alloys did not present a significant risk of release. In fact, it is clear that this is why those foundries need not include the lead content of their alloy feedstocks in their calculations in order to determine whether or not they will trigger the TRI lead reporting requirement. However, though the percentage content of lead in aluminum is far less significant, aluminum foundries do not receive the same exemption for the lead content of their alloys, and thus are arbitrarily swept into having to make a plethora of estimates and calculations that other foundries need not make.

There is no logical reason why aluminum foundries should be required to include the lead content of their alloys in their threshold calculations when other foundries do not. This should not, however, be taken as suggesting that alloy exemption for brass & bronze and stainless steel foundries should be revoked. Most of the lead content of alloys remains relatively constant. The lead content of castings produced from a brass, bronze, or aluminum alloy is virtually identical with that of the primary or secondary ingot from which it is drawn. The same holds true for the grindings and turnings that are produced when these castings are machined. In fact, these materials are typically recycled into the furnace as additional charge material for subsequent production runs.

Of course, not all aluminum foundries grind or finish their castings. In many instances, these functions are performed by the foundry's customer, or by an independent machine shop. In those instances, under the new TRI reporting rule the aluminum foundry now becomes a provider of a lead-bearing material to its customers, but as in the case of the lead in ingot form, since the actual lead content of the castings is less than 1%, few if any aluminum foundries note the lead content of their castings on the MSDS sheets they give to their customers. Nor, frankly, are they required to under the TRI reporting rule, or should they be.

D. EPA's guidance to reporting facilities, and especially to first time reporters, has been woefully inadequate.

When EPA first proposed dropping the reporting threshold for lead, NFFS and other trade associations representing companies that would be affected by the rule were quick to object. Congress was also concerned with the agency's tactics in issuing the draft revision. Among others, Senator Christopher Bond objected so strongly to EPA's lack of small business outreach in developing the rule that he urged the agency to withdraw it until they had properly complied with the SBREFA requirements. The agency's final rule was adopted as a sort of compromise with Congress, but as noted earlier, once the rule was issued in its final form in April of 2001, the reporting requirements were made retroactive to January 1st.

As a consequence, affected facilities would be required to reconstruct data for the first four and a half months of the year after the fact with no direct guidance from EPA. The agency promised to issue a final guidance document by October, 2001, but its' first draft was not published until just early September and was almost immediately severely criticized by government agency representatives and by other stakeholders at a meeting EPA convened on September 24. The concerns raised at that meeting identified numerous internal inconsistencies, factual and arithmetic errors, confusing references to differing reporting levels and requirements, and other significant problems with the draft guidance.

EPA went to work rewriting the guidance document, but the *final* version was not made available until the end of January 2002. That meant that small businesses had been subject to the substantial new data gathering and reporting obligations *for an entire calendar year* without the assistance the Agency had from the beginning stated would be critical to reducing their burden and allowing them to comply with the rule. Moreover, the final document, which was "intended to provide clear, easy to follow guidance," ran to more than 200 pages, still left many questions unanswered, and provided confusing information on a number of key points.

It wasn't until February of 2002 that compliance reporting forms and instructions mailed – but even then only to facilities that had filed TRI reports in 2001. This procedure ignored most first time filers, most of whom were never even contacted and therefore were largely unaware of the new reporting requirements. These materials were also posted on EPA's website, but again, facilities that had never before file TRI reports – like most aluminum foundries - were not informed by the agency and therefore remained largely ignorant of the new reporting requirements they would now face.

Trade associations like NFFS have tried to inform these facilities both of the new rule and what they must do to comply. Since its introduction in proposed form, through the issuance of the final rule and the eventual guidance document, NFFS has included information on the new

reporting requirements in its magazine and environmental compliance newsletters. In April – one the guidance document became available, NFFS held a series of web-based teleconferences trying to explain what the rule now requires and how foundries should go about calculating both their threshold use and releases. But it is clear from both the participation in these conferences and the questions that we encountered that most of the participants – indeed most aluminum foundries – still do not appreciate nor understand the reporting requirements.

EPA has anecdotally stated that they do not intend to target enforcement actions based on the information present in the new "R" form reports, at least for now. They have suggested that they appreciate that there will be a "learning curve" for first-time reporting facilities, and that it would be "unfair" to penalize facilities that make a good-faith effort to comply with the rule for any inaccuracies that their reports may inadvertently contain. Responding to a questions at the May 10th meeting noted earlier as to why, if the agency knows that the information that will be gathered for calendar 2001 releases will be inaccurate the agency refuses to delay the effective date of the rule until more accurate reporting might be obtained, the agency's intimated "*That would only delay our effective enforcement capabilities even that much farther.*"

IV. CONCLUSION

The Non-Ferrous Founders' Society and other associations representing facilities that are affected by EPA's new Lead TRI Reporting Rule have long felt that the agency's action in lowering in the reporting threshold was neither justified nor necessary. More recently, and especially where aluminum foundries are concerned, it has become evident that the rule is indeed arbitrary in both its application and enforcement. Clearly, political motivations seem to have played more of a role than did science in the development of the agency's new TRI reporting rule for lead.

To respond to such criticisms, EPA has implemented a peer review of the scientific framework that the agency stated supports its action in the rule. But facilities such as non-ferrous foundries will be

forced to file their "R" Form reports based on largely presumptive estimates long before that review is to be completed. For the reasons I have cited today, NFFS believes that EPA should delay the implementation of the TRI reporting rule by at least a year. Of course, the Society and I have already repeatedly and directly expressed that opinion to the agency.

Mr. Chairman, thank you for providing me the opportunity to appear before the committee this morning to express the concerns of our members and of all non-ferrous foundries. I will welcome any questions you may have.

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United States House of Representatives
Committee on Small Business
Subcommittee on Regulatory Reform and Oversight

Testimony of

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on

Toxic Release Inventory Lead Rule & Small Business Compliance

June 13, 2002

Thank you for the opportunity to testify on the TRI lead rule. My name is Nancy Klinefelter, and I am President of Baltimore Glassware Decorators. I am also a member of the Board of the Society of Glass and Ceramic Decorators. The company was started in Baltimore by my brother in 1977 with the help of my father who has worked in glass decorating for more than 50 years. We have 15 employees including my Mom who works in the office, my Dad who acts as general manager and my two brothers who work in sales and production.

We are a wholesale decorator. We specialize in printing small quantities of custom glass and ceramicware for proms and weddings, restaurants and for souvenir and novelty stores. You may be familiar with the mugs that we decorated for sale here at the House gift shop. As you see here in front of me .. we do a number of glass and ceramic items for different government agencies.

When we print mugs or glasses for our customers .. we must sometimes use lead-bearing colors on outside surfaces. These colors become a part of the glass after they are fired. The lead does not leach out. Very little ends up as waste. The colors are expensive .. and we only use what is needed to print each job.

I am testifying today to point out major problems with EPA's new Toxic Release Inventory lead rule. The greatest problem for my company .. and for my fellow decorators .. is the fact that EPA didn't issue the rule until April 17, 2001 .. yet we are required to accurately account for lead usage from January 1 of 2001.

For my company .. it is impossible to compile precise lead use records as required by EPA unless we track our color use on a daily basis. Since every lead-bearing color contains a different amount of lead .. we must make different calculations for each color used. We cannot simply take an average of color usage from May through December of last year .. and claim that our usage was the same for January through April.

Even if the rule were not retroactive .. it still would not make sense for EPA to assume that companies such as mine can simply throw a switch and start to comply with a major environmental reporting rule overnight. Even when we were notified by SGCD that the rule had been imposed .. I still had no idea what it meant for my company. By the time we were able to review the reporting requirements and attend an SGCD seminar on the subject .. half of the reporting year had passed.

As we began to compile our lead use data .. unexpected problems emerged. We buy decals from small decal printers that have fewer than ten employees and yet these companies must still provide lead content details to us for our TRI report. These printers are so small that they have no practical way of telling us how much lead is in each decal. We are still wrestling with this one and the deadline is looming!

We have no experience at all with TRI. Our lead usage is so minimal that we never come anywhere near the old 10,000 pound annual reporting threshold. We do exceed the new 100 pound threshold .. although just barely. Please note that this is a usage threshold .. not an emissions threshold as many in the media and others have indicated. We have almost zero emissions.

For my company – and every other small decorating shop – the most critical part of TRI compliance is tracking lead usage on a daily basis. I do not know why EPA felt the need to make this a retroactive rule. It would seem only reasonable to issue rules in advance of when they must be applied .. and in this case .. that should have meant a January 1, 2002 start date. That would have given us adequate time to put a color tracking system in place. Wouldn't EPA rather have accurate data from my company rather than my best guess?

It is not as though EPA usually issues new rules this way. This is the first time in the history of the TRI program that EPA has imposed a retroactive reporting requirement.

I know that EPA has published estimates that say it will take 124 hours to track lead usage and complete the TRI paperwork. That is already quite a large number .. 3 full work weeks for one employee .. but sadly it is a gross underestimate.

I have already personally spent 95 hours trying to understand the TRI forms and requirements .. and I am still nowhere near the point where I can complete the forms with confidence. In addition .. I have spent 60 hours or more reconstructing retroactive color usage data. We are now spending about 4 to 5 hours per week tracking lead usage to enable us to have confidence in our 2002 TRI filing.

Like I said .. we have 15 employees. We have no environmental engineers .. actually .. we don't employ any engineers. So the responsibility is mine. The time taken to reconstruct color use data is time that is not spent managing the company and looking for new business.

EPA provides more than 700 pages of guidance and instruction on how to complete the TRI forms. The guidance is incredibly confusing .. and it provides no help in making the calculations that we must make to determine the lead content of each color. The guidance document wasn't even available until January 1, 2002 .. fully one year too late.

I have attempted to use EPA's TRI-ME software .. and I was expecting much more insight into how calculations for release are made. The software's help function sends you in circles to search for help and you inevitably end up back where you started with no information. The needle is still in the haystack.

In conclusion .. I urge the Committee to ask EPA to postpone the TRI lead rule for one year to enable me and other small businesses to provide reliable information on our lead use. There is no other way for EPA to address my problems and concerns without the use of a time machine to take us back to January 1, 2001.

I thank you for your interest in the concerns of a small business such as Baltimore Glassware. I only wish that EPA had showed the same concern when applying this rule retroactively and assuming that this would cause no problems for small businesses.

Thank you again for the opportunity to testify before you today.

UNITED STATES HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT
OF THE COMMITTEE ON SMALL BUSINESS

Testimony Of

Hugh Morrow
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on

THE TRI LEAD RULE: COSTS, COMPLIANCE AND SCIENCE

June 13, 2002

Good morning Chairman Pence, Ranking Member Brady, and members of the Committee. My name is Hugh Morrow, and I am the President of the North American Office of the International Cadmium Association, an association of organizations and companies producing, using, and recycling cadmium, both here in the United States and throughout the world. Cadmium is a key component of a number of important commercial and consumer products, including rechargeable and recyclable nickel cadmium batteries used in cordless power tools and telephones, aircraft and railway applications, and emergency lighting and remote area telecommunications. My background is in the sciences, with undergraduate and graduate degrees from MIT, research and teaching experience, and service on numerous technical committees. I have authored approximately 100 publications and presentations, primarily on cadmium and zinc, and hold five patents. My C.V. (attached) provides additional detail.

I appreciate the opportunity to testify on science aspects of the TRI lead rule that is the subject of this hearing. The scientific premise for this rule is that metals generally -- and lead and lead compounds in particular -- can appropriately be classified as persistent, bioaccumulative, and toxic ("PBT") chemicals, using a methodology that was developed for application to pesticides and other synthetic organic compounds. For more than three years, I have been involved -- along with numerous academics and representatives of all the major metals sectors, including copper, zinc, nickel, and lead, as well as cadmium -- in expressing scientific concerns with EPA's plan to apply its PBT methodology to metals. Those concerns are grounded in a solid body of peer-reviewed scientific literature and the conclusions of international scientific experts[1] that it is

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[1] To cite just a few examples, Margaret Cavanaugh, director of the inorganic, bioinorganic, and organometallic program at the National Science Foundation, and a member of an expert panel convened by the Canadian government to consider this question, summarized the state of the scientific evidence in September 2000, saying "the criteria for classifying organic chemicals are based on their persistence, bioaccumulation and inherent toxicity. However, the same criteria cannot be used for metals and

scientifically inappropriate to use the PBT criteria relied upon by EPA in order to assess the potential health and environmental hazards of metals.

Enough concerns had been expressed by January 2000 that EPA co-sponsored with industry an Experts Workshop entitled "Review of the State-of-the-Science Regarding PBT Concepts and Metals and Metal Compounds." The sessions at the workshop highlighted fundamental scientific problems with EPA's approach, which industry hoped EPA would reconsider in the context of the TRI lead rule. It also became clear at the Experts Workshop that no independent scientific peer review had been conducted of EPA's plan to apply PBT criteria to metals, a serious deficiency that should not have been allowed to occur.

These issues led the House Science Committee, in a bipartisan letter signed by both the Committee and Subcommittee Chairmen and Ranking Members, to write to EPA in July 2000 noting that "questions have arisen regarding the scientific validity of applying the PBT criteria to

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metalloids because the persistence and bioaccumulation criteria do not apply and do not provide a sound basis for discriminating benign and harmful substances." (Copy of letter attached.) This is consistent with such scientifically reported findings as: "[P]ersistence is not a useful measure for inorganic elements such as metals, because metals are intrinsically not degradable.... Bioaccumulation should not be used as an equivalent generic hazard evaluation measure for both organic and inorganic substances." P. Chapman, et al., International Harmonization Related to Persistence and Bioavailability, 2 *Human & Ecol. Risk Assessment* 393, 394-96 (Sept. 1996).

Similar conclusions have been expressed by international scientific and regulatory bodies: "Metals cannot be differentiated according to the PTB [PBT] approach." European Commission Directorate-General for Environment, Modified Proposal for a Procedure for the Identification of Priority Hazardous Substances in Accordance to Article 16(3) of the Water Framework Directive: Working Document, at 7 (Final Draft, Oct. 19, 2000). "The bioaccumulation of inorganic metal compounds is not a useful parameter for their hazard identification." Report of the Technical Workshop on Biodegradation/Persistence and Bioaccumulation/Biomagnification of Metals and Metal Compounds, held under the auspices of the Canada/European Union Metals and Minerals Working Group, Brussels, Belgium, Dec. 11-13, 1995, at x (Apr. 1996). Even EPA has acknowledged that "the persistence criteria [of the PBT methodology] are not themselves very helpful in screening or assessing metals and metal compounds with respect to the potential for risk, whether from direct exposure or through bioaccumulation. EPA Policy Statement on PBT, 64 Fed. Reg. 60194, 60202 (Nov. 4, 1999).

metals and inorganic metal compounds, and that this specific issue has not received the benefit of SAB [Science Advisory Board] or other independent scientific peer review." They went on to say: "[W]e strongly encourage EPA as soon as possible to refer for SAB review the issue of the scientific soundness of applying PBT concepts to metals." (Copy attached.) In November 2001, when EPA still had not sought peer review, these concerns were echoed by the new Chairman of the Committee, Congressman Sherry Boehlert, who urged EPA "to charge the SAB to undertake a broad review of the use of PBT, which would include the applicability of PBT to all metals and inorganic metal compounds as to which questions have arisen." (Copy attached.)

The reasons for these concerns stem from the fact that PBT concepts were developed to assess hazard in synthetic organic compounds and do not work well when applied to metals and inorganic metal compounds. In critical ways, metals are fundamentally different from organics. Persistence, for example, may be a useful criterion for distinguishing among organic chemicals in terms of hazard, but all metals are deemed infinitely persistent under EPA's approach -- because, as naturally occurring elements, they cannot be destroyed. But, unless they are in bioavailable form, this so-called "persistence" is not an indicator of environmental hazard. As applied by EPA, it is not a meaningful measure of hazard in metals. Moreover, since all metals are considered equally persistent under EPA's approach, persistence provides no basis for distinguishing among metals in terms of hazard.

In the same way, unlike the situation with organic chemicals, bioaccumulation or bioconcentration factors (which are commonly known as "BAFs or BCFs") are not intrinsic properties of metals and do not provide useful indicators of hazard for them. In fact, there is strong evidence that high BAF or BCF values for a metal would most likely indicate a lower risk

of toxicity -- the opposite result from what EPA's PBT methodology assumes for organic chemicals, and a very good reason why you would not want to use this approach to try and identify metals of greater concern.

I am happy to report that EPA has now recognized the importance of these issues. In February 2002 EPA announced it was embarking on the "development of comprehensive, cross-agency guidance for assessing the hazards and risks of metal[s] and metal compounds," and that "[t]he goal of this cross-agency guidance will be to articulate a consistent approach for assessing the hazards and risks of metals and metal compounds, based on application of all available data to a uniform and expanded characterization framework." 67 Fed. Reg. 5596 (Feb. 6, 2002). Since February, the work has moved forward, and an SAB review schedule was recently announced that is expected to conclude by the end of 2003. Just last week, in a June 6, 2002 notice, the SAB reiterated the connection between this development of metals assessment guidance and the questions raised during the TRI lead rulemaking. I quote: "Discussions between the Agency and external stakeholders, as well as concerns expressed formally as part of the Toxics Release Inventory (TRI) lead rulemaking have demonstrated the need for a more comprehensive, cross-Agency approach to metals assessments that can be applied to human health and ecological assessments." 67 Fed. Reg. 38957, 38958 (June 6, 2002). EPA expects to release for public comment this week its Draft Action Plan for the development of this metals assessment framework, and I will be involved in submitting comments.

We applaud EPA's efforts to develop a scientifically sound metals assessment framework. We see this as the fulfillment of the commitment the Agency made in the preamble to the final TRI lead rule, in which it promised to "seek external peer review from its Science Advisory Board"

on two issues: (1) "the question of whether lead and lead compounds should be classified as highly bioaccumulative" and (2) "the issue of how lead and other, as yet unclassified, metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations." 66 Fed. Reg. 4500, 4518 (Jan. 17, 2001). All of us who are interested in a sound scientific approach to hazard assessment of metals and inorganic metal compounds look forward to EPA's and the SAB's responses to both these questions as the initiative to develop a cross-agency metals assessment framework review goes forward.

I would be happy to answer any questions you may have.

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Thomas M. Sullivan
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Subcommittee on Regulatory Reform and Oversight

U.S. House of Representatives
Committee on Small Business

Date: June 13, 2002
Time: 10:00 A.M.
Location: 2360 Rayburn House Office Building
Topic: The Toxic Release Inventory Rule: Costs, Compliance and Science

Created by Congress in 1976, The Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. The Chief Counsel for Advocacy, who is appointed by the President and confirmed by the U.S. Senate, directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Issues are identified through economic research, policy analyses, and small business outreach. The Chief Counsel's efforts are supported by offices in Washington, D.C., and by Regional Advocates located across the United States. For more information on the Office of Advocacy, visit http://www.sba.gov/advo, or call (202) 205-6533.

I am pleased to provide this written testimony about the toxic release inventory (TRI) lead reporting rule for consideration by the Subcommittee on Regulatory Reform and Oversight. As Chief Counsel for Advocacy, I am charged with monitoring federal agencies' compliance with the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The Office of Advocacy is an independent office charged with representing the interests of small business before state and federal lawmakers. As such, these views are my own and do not necessarily reflect the views of the Administration or the U.S. Small Business Administration.

The Office of Advocacy has worked with the Environmental Protection Agency (EPA) in the development of toxic release inventory rules since the first rule was issued in 1988. In the past fifteen years, my office has developed substantial expertise in the TRI and other right-to-know programs, and has identified several opportunities for reducing paperwork burdens while preserving the right-to-know.

A. Introduction

The right-to-know provisions set forth by the Emergency Planning and Community Right-to-Know Act (EPCRA) are a cornerstone of modern day environmental protection. EPCRA requires facilities to provide information on toxic chemical releases, waste management activities and chemical inventories. Under the right circumstances, the information acquired through community right-to-know requirements can lead to environmental improvements without the need to resort to the traditional prescriptive regulatory approach. It is widely acknowledged that the toxic release inventory reporting requirements under section 313 of EPCRA are partially responsible for the decline in environmental releases since the first reports in 1987.

The Office of Advocacy strongly believes that the right-to-know can incorporate small-business friendly attributes. Two examples of where Advocacy helped EPA improve its right-to-know regulations, at no cost to environmental protection follow.

1) Advocacy worked with EPA to produce the short form for TRI reporting, the "Form A," which provides significant burden reduction. This form, adopted as a less burdensome alternative to the "Form R" by the Agency in 1994, saves small businesses millions of dollars annually.

2) In addition, at our suggestion, EPA eliminated in 1999, the right-to-know reporting requirement of reporting gasoline from hundreds of thousands of gasoline stations under sections 311 and 312 of EPCRA.

Not all of our efforts to improve EPA's consideration of small business in their right-to-know programs have been successful. Despite our opposition to the expansion of TRI to chemical and petroleum wholesalers on the grounds that the releases to the environment were insignificant, EPA did promulgate that requirement in 1997. The Office of Advocacy stands by its projections which were later verified by EPA's summary graph from the 2000 data release (Attachment A). The graph shows what we expected: that the reported releases are essentially zero for these industries for all three years – they make up less than six hundreds of one percent of the total reported releases. With these figures in mind, Advocacy is hopeful that EPA will re-examine the decision to expand TRI to these industries.

B. EPA Did Not Properly Evaluate Whether Lead Was a Persistent Bioaccumulative Substance Nor Did EPA Implement the Required Peer Review Process

We are concerned that EPA may once again be expanding the right-to-know requirements without appropriate consideration of the costs or benefits of the new paperwork requirements. (EPA now estimates TRI reporting to account for more than 7 million hours annually, one of the largest paperwork burdens imposed by EPA on businesses.)

In a rule published on January 17, 2001, pursuant to section 313 of EPCRA, the EPA designated lead as a persistent bioaccumulative toxic (PBT) chemical and lowered the

reporting threshold for lead for the TRI reporting requirement. The Office of Advocacy is concerned that the Agency did not establish an adequate factual basis either for designating lead as a PBT chemical or for lowering the reporting threshold for lead to 100 pounds under the TRI reporting requirement. According to the "Impact of Regulatory Costs on Small Firms," (SBA-HQ-00-R-0027; October 2001) a report prepared for the Office of Advocacy, small businesses pay 60% more than their larger counterparts in regulatory expenditures. Advocacy, therefore, has a direct interest in agencies making sound regulatory decisions because poorly made policy will disproportionately hurt small business.

At the January 2000 Metals EPA/industry workshop, Dr. Jerome Niragu, a scientist with the EPA Science Advisory Board (SAB) and two EPA scientists indicated that the PBT/metals methodology, which provides the basis for this rule, had not been reviewed by the Science Advisory Board. Under EPA's established protocol, all major scientific products, including scientific products underlying major rules, must udergo a peer review process. Thus, this major rule was promulgated without complying with EPA's own peer review procedures.

Advocacy provided our views on this issue in a letter dated April 9, 2001 to Governor Whitman (Attachment B). The letter articulated that the scientific basis of the rule was not borne out in the peer-reviewed literature and ran counter to international scientific consensus documents on lead. In short, Advocacy found that EPA's treatment of the bioaccumulation of metals was inappropriate, as a matter of science. As a result, we insisted, at a minimum, that the Agency submit the science issues underlying this rule for peer review before promulgation. To its credit, the Agency is now doing so in its effort to get a Science Advisory Board review of the Metals Assessment Framework (the Agency will address the metals hazard assessment issue in this document).

C. The Rule Will Impose Substantial Costs Without Significant Right-to-Know Benefits

This rule will impose substantial compliance costs on thousands of small businesses and other entities. EPA estimates the rule's costs at $80 million in the first year.

EPA has not demonstrated any significant right-to-know value for lowering the reporting threshold for lead to either 10 or 100 pounds per year under the TRI reporting requirement. Unlike the TRI reports that are based on the current 10,000 and 25,000 pound reporting thresholds, we do not expect that the new reports will lead to significant hazard reductions. We expect that these new requirements will result in mandated reporting of miniscule amounts of lead solder from junked computers or from ceramics that end up in the trash.

The Agency might be able to justify a 1,000 pound reporting threshold based on the greater right-to-know significance of releases at such a level of this substance, which is relatively more toxic than most TRI chemicals. Such a solution would significantly ameliorate the small business costs, and would be an appropriate threshold for right-to-know reporting.

D. The Agency Did Not Establish a Proper Scientific Basis for the 100-Pound Lead PBT Reporting Threshold

Advocacy's April 9th letter to Governor Whitman stated: "Unlike the arsenic drinking water final rule, which does have a significant, but contested, scientific regulatory basis, we cannot recall, in more than two decades of reviewing environmental regulations, a more egregious example of a total disregard of the science. In this case, despite the overwhelming scientific consensus on this issue, EPA failed to develop a PBT methodology that could be properly applied to metals, such as lead, in order to make the appropriate threshold determination for TRI reporting."

EPA claims that lead is a PBT substance, applying the same methodology for identifying PBTs as the methodology originally developed for organic substances. Despite the fact that this rule, as a major regulation, should have been peer reviewed, EPA failed to have this methodology reviewed for its application to metals. We are informed that, using the methodology used by EPA, other metals such as zinc, copper and iron would similarly be subject to the PBT reporting rule, although there is no evidence that lowering the reporting thresholds for those metals would contribute to the goals of the right-to-know program.

The Agency assumed that, once a metal bioaccumulates, it will create a hazard. This was a reasonable assumption for organic compounds, but is not for metals, and that is the source of the controversy. While metals can be accumulated by organisms, there is no one bioconcentration factor (BCF) that can be used to assess the bioaccumulation potential, as is done for organic chemicals. In organisms which have a greater potential to accumulate metals, such as in bivalves or mollusks, they are stored in a detoxified state. Organisms that feed on these species do not accumulate high levels of lead since the lead is generally in an insoluble form, and is typically excreted by the feeding organism.

For example, the storage of lead by bivalves is mainly in the granular form as calcium or orthosphosphate granules. Some bivalves also use metallothioneins as their detoxification mechanisms. Orthophosphate granules are generally considered to be a permanent storage/detoxification mechanism since they are extremely insoluble. This finding of the lack of bioavailability (ability of a substance to influence a target organ) of the accumulated lead is consistent with the low number of lead fish advisories, and the observation that lead generally does not biomagnify (increase in concentration in organisms higher in the food chain). Indeed, there is now growing evidence that metals normally do the exact opposite in aquatic environments - they biodilute. In addition, as many scientists acknowledge, there are extremely limited circumstances where metals are even bioavailable.

More specifically, it is clear that EPA's reliance on bioconcentration factors to classify metals hazards is inappropriate. First, all the relevant literature that we have found and provided to the Agency stated that BCF factors alone cannot be used as hazard indicators for metals. Second, we turned to scientists in industry, academia, and finally U.S. government scientists (from the U.S. Geologic Survey, the National Science Foundation and the Department of Energy). Every scientist that we contacted agreed that BCFs could not be used to classify the hazards of metals (see attachment C for the specific statements of those scientists). Attachment C also lists statements by international scientific and other organizations which conflict with the application of the PBT organics-derived methodology to metals. These statements contradict the EPA approach. Third, the December 2001 report from the Inorganics Working Group Report to Environment Canada on Hazard Categorization of Metals confirmed that BCFs would not be useful for metals classification, except when examined in combination with other factors.

Fourth, evidence available since the rule was promulgated suggests that BCFs are not an inherent property of metals, and cannot be determined for metals, because the measured BCF varies inversely with the concentration of the metal in the water. Thus, unlike organics, metals appear to have no defined BCF values which could be employed in a BCF-based methodology. Fifth, even the World Wildlife Federation, a leading environmental organization, has indicated that the "PTB [PBT] concept . . . is not fully applicable to metals. All metals are persistent, can accumulate and cause toxic effects. However, they are part of nature and many of them - but not all - are essential for living organisms. Thus the PTB concept does not really allow for priority setting..." Sixth, at the most recent EPA-sponsored meeting to gather scientific advice for its Metals Assessment Framework, not one person offered any support for EPA's BCF-based methodology.

The final rule's preamble attempts to bolster EPA's BCF-based lead determination by addressing its view of how lead bioaccumulates in humans (as opposed to the aquatic environment). The preamble, however, does not explain how such evidence would be

relevant to the bioaccumulation regulatory determination in the final rule. The stated methodology is based solely on BCF measurements in the aquatic environment. A substance is determined to be bioaccumulative simply if the BCF exceeds 1,000 (100 pound threshold) or 5,000 (10 pound threshold). At a minimum, EPA must re-evaluate its methodology to revise or eliminate its use of the BCF.

Given the nature of the hazards attendant to lead, using a methodology for metals based solely on the aquatic environment appears misguided. Stated in other terms, reporting very small or zero lead releases at thousands of reporting sites across the country does not appear relevant when hundreds of millions of pounds of lead wash into streams from natural sources, such as soil and rocks. By adding thousands of inconsequential reports to TRI, EPA undermines the value of the TRI database and diverts the country's attention from the real hazards of lead poisoning. To our knowledge, lead poisoning has not been associated with any pathway from the aquatic environment, which in turn means that a BCF-based methodology would not be expected to accurately predict lead hazards.

E. Peer Review of the Science Is Warranted and We Applaud the Plan for Science Advisory Board Review of the Metals Assessment Framework

Congress and the regulated industries expressed considerable concern over the scientific issues and their potential regulatory impact, which extends beyond this rulemaking to other programs and other metals. As stated earlier, EPA declined to seek such review before the rule was promulgated.

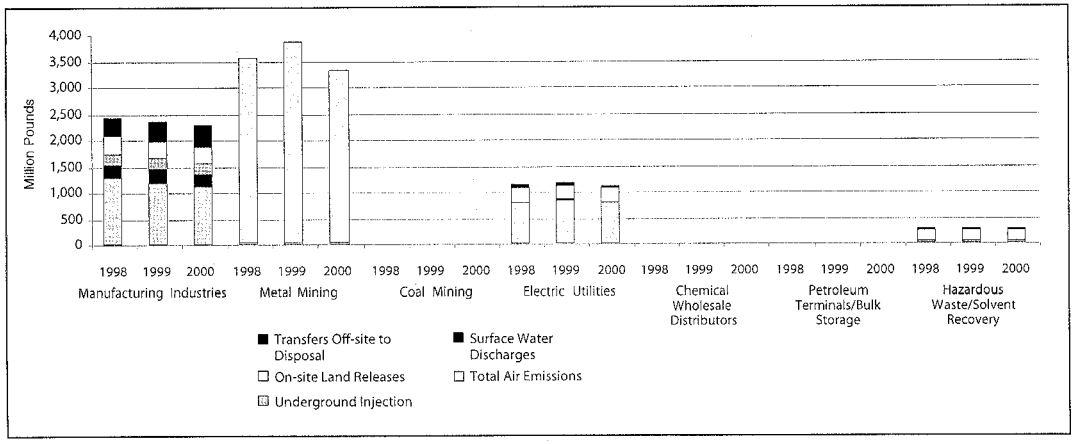
However, EPA acknowledged in the final rule's preamble that it was deciding the issue of whether lead was a PBT before an "external peer review [would address] the issue of how lead and other, as yet, unclassified metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations." 66 Fed. Reg. 4518 (January 17, 2001). Now, EPA is making good on the promise by initiating the Science Advisory Board review of a Metals Assessment Framework, and asking for a science review. That review

should explicitly address the legitimacy of the BCF-based methodology for any threshold determination (either highly bioaccumulative or bioaccumulative) and develop options for better methodologies that will be available to assist policymakers in the future.

F. Conclusion

The Office of Advocacy is pleased to present our views on this issue and compliments the EPA leadership for taking this opportunity to review its science. Advocacy hopes that EPA will take full advantage of this opportunity to reconcile a robust metals hazard classification methodology with its TRI regulatory methodology for lead and other metals. We want to assure EPA and Congress that Advocacy stands ready to assist EPA in any way that we can. Advocacy believes that good regulatory policy is based on sound science and the full understanding of how regulations will impact small business. Thank you for the opportunity to present this information to the Subcommittee.

Figure ES-3: TRI Total Releases, Original (Manufacturing) and New Industries, 1998-2000



Note: On-site Releases are from Section 5 of Form R. **Off-site Releases** are from Section 6 (transfers off-site to disposal) of Form R. **Off-site Releases** include metals and metal compounds transferred off-site for solidification/stabilization and for wastewater treatment, including to POTWs. **Off-site Releases** do not include transfers to disposal sent to other TRI facilities that reported the amount as an on-site release.

Source: U.S. EPA - 2000 TRI Public Data Release Executive Summary, accessed 06/12/02, at http://www.epa.gov/tri/tridata/tri00/press/execsummary_final.pdf

Attachment B

U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, DC 20416

OFFICE OF THE CHIEF COUNSEL FOR ADVOCACY

April 9, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: EPA Review of Lead Toxic Release Inventory Reporting Rule

Dear Administrator Whitman:

We are writing regarding the Environmental Protection Agency's (EPA) designation of lead as a highly persistent bioaccumulative toxic (PBT) chemical and lowering of the lead reporting threshold for the Toxic Release Inventory (TRI), pursuant to § 313 of the Emergency Planning and Community Right-to-Know Act in the rule published on January 17, 2001. The Office of Advocacy of the U.S. Small Business Administration was established by Congress pursuant to Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. One of the primary functions of the office is to measure the costs and other effects of Government regulation on small businesses and make recommendations for eliminating excessive or unnecessary regulation of small businesses.

Advocacy disagrees with EPA's certification of this final rule under the Regulatory Flexibility Act that this rule does not impose a significant economic impact on a substantial number of small businesses. We are convinced that the agency has not established an adequate factual basis either for designating lead as a highly persistent bioaccumulative toxic chemical, or for lowering the reporting threshold for lead to 100 pounds under the TRI reporting requirement.

This rule would impose substantial compliance costs on thousands of small businesses and other entities. EPA estimates the rule costs at $80 million in the first year, although others believe that the reporting costs alone would be much higher. Reporters also face related regulatory costs, such as state stormwater regulations and state TRI filing fees, which could considerably exceed the reporting costs.

EPA has not demonstrated any significant right-to-know value for lowering the reporting threshold for lead to 100 pounds per year under the TRI reporting requirement.

Such reports are unlikely to lead to any hazard reductions at any of the sites that would need to report under the rule, unlike the 2000 TRI reports that are based on the current 10,000 and 25,000 pound reporting thresholds. However, the agency might be able to justify a 1,000 pound reporting threshold based on the greater right-to-know significance of releases at such a level of this substance, which we believe is more toxic than most reported TRI chemicals. We and others suggested about ten years ago that the agency explore a two tier system of reporting, but EPA never acted on the suggestion. Such a common sense solution would significantly ameliorate the small business costs, and would be an appropriate threshold for lead right-to-know reporting. However, because the underlying basis for designating lead as a PBT chemical and lowering the reporting threshold are not supported or justified by the scientific information supporting the rule, we strongly recommend that the scientific analyses, on which this rule is based, be peer reviewed by the EPA Science Advisory Board (SAB), while the effective date of the rule is stayed pending review of the SAB advice.

A. The Agency Did Not Establish a Proper Scientific Basis for the Lead PBT Finding

Unlike the arsenic drinking water final rule, which does have a significant, but contested, scientific regulatory basis, we cannot recall, in more than two decades of reviewing environmental regulations, a more egregious example of a total disregard of the science. In this case, despite the overwhelming scientific consensus on this issue, EPA failed to develop a PBT methodology that could be properly applied to metals, such as lead, in order to make the appropriate threshold determination for TRI reporting.

The 1998 EPA Peer Review Handbook specifically requires peer review of all "major scientific and technical products," including products used to support major rulemakings. EPA apparently did not take the time to peer review the relevant regulatory documents in its haste to finalize this regulation for reporting year 2001. Indeed, as one EPA scientist told my staff, EPA did not send the EPA PBT/metals approach to the SAB because, "we [knew] that we would receive a 'no' from the SAB," which would have precluded EPA from issuing the lead rule. When my staff later attempted to verify the EPA scientific findings, we were unable to find any support in the published literature, peer-reviewed or otherwise for these findings. When we checked with other scientists from three different Federal agencies, they provided written statements contrary to the EPA views. The EPA Science Advisory Board and international scientific bodies have indicated that the PBT scheme, derived originally solely for organic compounds, not metals, would not be easily applied to metals. The EPA/Industry sponsored workshop on the issue in January 2000 offered only contrary views. No EPA scientist even attempted to defend its own approach. Even the World Wildlife Federation, a leading environmental organization, has indicated that the "PTB [PBT] concept . . . is not fully applicable to metals. All metals are persistent, can accumulate and cause toxic effects. However, they are part of nature and many of them - but not all - are essential for living organisms. Thus the PTB concept does not really

allow for priority setting...." [1] More astonishing, EPA offices do not appear to be in agreement with each other. In the most recent preceding EPA metals/PBT regulatory determination, which involved the Great Lakes in 1995, using the same or virtually the identical lead data, the EPA Office of Water found that no metals (including lead) were PBTs. We are forced to conclude that the position taken by the EPA Office of Environmental Information was driven by policy, and not science, and it is now time to correct this error.

Finally, even EPA acknowledged in the final rule preamble itself that it was deciding the issue of whether lead was a PBT before an "***external peer review [would address] the issue of how lead and other, as yet, unclassified metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations.***" 66 Fed. Reg. 4518 (January 17, 2001). EPA expected to send its request for Science Advisory Board review of the science underlying this rule in the near future. Why did it decide these science issues in advance of the peer review that even the agency admits was the appropriate procedure? This letter does not address the entire list of scientific criticisms, but this list should suffice to demonstrate that the rule should not go forward. Good public policy dictates that the scientific work inform the regulatory decision, and not that the regulatory agenda overwhelm the science.

B. There are Unlikely to Be any Significant Right-to-Know Benefits to Reporting Releases of Lead at a One Hundred Pound Threshold.

We strongly agree with EPA that the right-to-know is now a critical foundation of modern day environmental protection. We have seen it work. However, we part company with the agency because we would not spend hundreds of millions of dollars annually simply to report releases that are unlikely to pose significant environmental risks anywhere in America. This is in stark contrast to the same EPA that recently eliminated right-to-know reporting from hundreds of thousands of gasoline stations (under sections 311 and 312 of the Emergency Planning and Community Right-to-Know Act). In this rulemaking, the agency places no practical limit on its ability to require information because it failed to evaluate the benefits of receiving the required information in any meaningful fashion. EPA's position is not consistent with good public policy or common sense, let alone Executive Order 12866 (requiring consideration of costs and benefits), or the Regulatory Flexibility Act (requiring consideration of regulatory alternatives minimizing small business impacts).

It is unlikely that more than a few of the nearly 10,000 new lead reports (EPA estimate) that would result from using a hundred pound reporting threshold, would have any environmental significance. EPA has indicated on several occasions that it is "unable" to make statements about either the environmental significance, or the quantity of the releases. The agency relies on its statements in the final PBT rule that it is not

[1] World Wildlife Fund, Views on the List of Priority Substances for Pollution Reduction and on the Procedure for the Selection of Priority Hazardous Substances for Phase-out Under the EU Water Framework Directive (Oct. 6, 2000)

required to make any estimates or evaluations of these new reports. However, in the case of lead, we do know a substantial amount about this substance, which undermines the EPA's policy regarding this particular chemical.

Based on an examination of the current reporting industries, it is clear that thousands of the new reporters will be reporting releases well under ten, or even one pound per year into the air and water. In contrast, the total annual lead air releases are estimated at 7.8 million pounds annually. (EPA Table A-2, October 2000 Final Economic Analysis). Mobile sources, alone (not in TRI), accounted for over 1.0 million pounds/year. Hundreds of millions of pounds of lead annually wash into streams from natural sources such as soil and rocks. In this context, releases in the order of ten, or even 100, pounds of lead per year are highly unlikely to have any environmental significance (although this is widely misunderstood, releases are almost always a very small fraction of the reporting thresholds, which are based on chemical usage, not releases).

Here are two typical examples. Using EPA data, we estimate that approximately 900 printed circuit board manufacturers (almost entirely small businesses) would report an average of five pounds released into the air annually, at a reporting cost of approximately $5 million in the first reporting year. In addition, 1,000 or more petroleum wholesalers would report virtually no releases of lead at their fuel depots, at a cost of $4 million in the first year, because lead is only incidentally released when the fuel is combusted by homes, vehicles, and airplanes. Thus, all these reports involve no releases at the reporting depot.

Is there any basis for a belief that lead releases at the hundred pound threshold can be significant anywhere in the country? Historically, we have not observed anyone, including EPA, using data involving such small quantities of TRI chemicals as part of a risk reduction exercise. Logically, that is the expected result because there is no significant hazard to address. EPA declines to answer the questions posed above, relying on the community's apparently unlimited "right-to-know."

In contrast, to the credit of the agency and other Federal partners, EPA has already identified the significant lead hazards, and these are being addressed today. These actions include consideration of a reduction in the lead content of aviation gas, the reduction of lead-based paint hazards, and the identification of lead-based hazard levels. These plans were made with the knowledge of the national and local use of lead. New TRI reports for lead based on a 100-pound threshold are not designed to lead to any consideration of meaningful risk reductions.

We suggest that a threshold in the neighborhood of 1,000 pounds, or higher, per year, could be a more defensible reporting threshold. A 1,000 pound threshold likely would capture far more than 80% of the remaining releases (not already covered by the current 10,000/25,000 pound thresholds). EPA included a request for comment on the 1,000-pound threshold in its proposal, and such a threshold may be appropriate.

Thus, we support, as an alternative, that EPA examine the establishment of an alternate non-PBT based threshold of 1,000 pounds.

C. Conclusion

Advocacy recognizes that EPA faces two very unpopular courses of action here. On the one hand, EPA could stay the rule, send these science issues for review to the Science Advisory Board, and subject itself to criticism by environmental groups who are unlikely to examine these complex scientific issues here. Alternatively, the agency could do the right thing and admit that its staff failed to adhere to its own standards of scientific integrity in promulgating a rule that did not undergo the appropriate peer review, was not properly grounded in science and posed a considerable burden on small firms. The proper course is clear. This rule should not stand.

We welcome discussion of this issue with your staff. Kevin Bromberg of my staff can be reached at 202-205-6964.

Sincerely,

Susan M. Walthall
Acting Chief Counsel for Advocacy

Attachment C – June 13, 2002

Statements by Scientists, Scientific and Other Organizations Contradicting EPA's Use of PBT Methodology to Determine that Lead is a PBT (Including Use of Bioconcentration Factors)

March 23, 1995
Great Lakes Water Quality Guidelines
US EPA
EPA's final rule establishing water quality guidelines for the Great Lakes examined whether ten metals, including lead were bioaccumulative substances, and found that none exceeded the BCF of 1000, which it used as its cutoff. [EPA is now apparently using the same set of pre-1995 data and finds that the BCF for lead exceeds at least 1000.]

William J. Adams et al., *The Challenges of Hazard Identification and Classification of Insoluble Metals and Metal Substances for the Aquatic Environment*, 6 Hum. Ecol. Risk Assess. 1019 (2000)

"Persistence measurements typically used for organic substances (biodegradation) do not apply to metals. Alternative measurements such as complexation and precipitation are more appropriate. . . . Further, bioaccumulation and bioconcentration factors are often inversely related to exposure concentration for most metals and organisms, and hence are not reliable predictors of chronic toxicity or food chain accumulation."

May 2000
Science Advisory Board Report
An SAB Advisory on the US EPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters

The "classification of metals as PBTs is problematic, since their environmental fate and transport cannot be adequately described using models for organic contaminants."

September 22, 2000 Letter
Margaret Cavanaugh, National Science Foundation
to Kevin Bromberg, Office of Advocacy

The PBT methodology "is not consistent with the recommendations of inorganic chemists and other scientists who have considered this issue."

October 4, 2000 Letter
James Hickey, U.S. Geological Survey
to Kevin Bromberg, Office of Advocacy

The "criteria used for classifying organic chemicals (persistence, bioaccumulation and inherent toxicity) cannot be used for metal and metalloid compounds."

October 3, 2000 Email
Thomas Feeley, Department of Energy
to Kevin Bromberg, Office of Advocacy

The Department of Energy staff memo indicates that "the PBT criteria should not be used to establish the environmental hazard of metals."

October 6, 2000
World Wildlife Fund, Views on the List of Priority Substances for Pollution Reduction and on the Procedure for the Selection of Priority Hazardous Substances for Phase-out Under the EU Water Framework Directive

The "PTB [PBT] concept . . . is not fully applicable to metals. All metals are persistent, can accumulate and cause toxic effects. However, they are part of nature and many of them - but not all - are essential for living organisms. Thus the PTB concept does not really allow for priority setting."

January 16, 2001
Commission of the European Communities, Amended Proposal for a Decision of the European Parliament and of the Council Establishing the List of Priority Substances in the Field of Water Policy

"[I]t is not possible to apply toxic, persistent and bio-accumulative criteria to select those metals which should become 'priority hazardous substances'...."

December 2001

Inorganics Working Group Report to Environment Canada on Hazard Categorization of Metals

"Agreement was not achieved on the scientific relevance of B [bioaccumulation] within Environment Canada's regulatory framework, however, the IWG agreed that most published BCF (bioconcentration factor) and BAF (bioaccumulation factor) data for inorganics are, in practice, not useful for categorization. Thus, for the mechanical purposes of characterization, bioaccumulation based on BCF and BAF values can generally be ignored unless, based on best professional judgement, such data prove useful for some specific substances."

Questions to Supplement the Hearing Record of June 13, 2002
Subcommittee on Regulatory Reform and Oversight
House Committee on Small Business

Q1. In your testimony you state, "I know of no one in this agency who is planning on taking enforcement actions against a facility" where goodwill in complying is shown. This answer is frequently given as a defense against the problems with this rule including retroactivity, poor guidance, inconsistent outreach, and questionable science. What specifically do you and OECA plan to do differently when it comes to enforcing this specific rule given its unique problems? How will this rule be treated differently than other rules in their first or second year?

A1. The new TRI lead rule was carefully reviewed by this Administration. After a thorough review, the new lead regulation was endorsed by the President and Governor Whitman, becoming effective in April 2001. This rule significantly expands the information available to the public about the presence and releases of lead in their communities.

As our response to question number five, below, demonstrates, EPA's historical approach for achieving compliance with new TRI rules emphasizes compliance assistance during the first year of implementation rather than enforcement. We are continuing that practice for the new lead reporting rule. The compliance assistance provided by the TRI Program regarding the new reporting requirements for lead and lead compounds has been unusually extensive and robust, and EPA intends to continue promoting compliance by providing assistance with lead reporting to the TRI.

Q2. In your testimony you state, "I know of no one at this point in time that would see it appropriate to take what we would consider an 'enforcement action' against someone who has filed inappropriately or incorrectly or incorrect data." Does this mean that businesses should not fear submitting incorrect data? What is the standard of due diligence to prove goodwill in compliance?

A2. Businesses are required to use readily available data or, where such information is not available, reasonable estimates when reporting to the TRI. So long as businesses use data they have or provide reasonable estimates, EPA will not take enforcement action against them should the data later turn out to be incorrect in some fashion. EPA has long accepted corrections to TRI reports based on new information not available at the time the initial report was filed.

If a small business has no actual or constructive knowledge that it manufactures, processes, or otherwise uses lead above the threshold (100 pounds per year), then it has no reporting responsibility for lead under the TRI lead rule.

Q3. Can you guarantee small businesses that are unable to comply with this rule because of its numerous problems that they won't be subject to a citizen suit? How do you plan to help these businesses who have shown goodwill in compliance and are not subject to EPA enforcement, but are the targets of citizen lawsuits?

A3. The EPA cannot guarantee that a small business which is unable to comply with this rule will not be subject to a citizen suit. Historically, there have been few citizen's suits for TRI reporting, particularly since 1998 when the Supreme Court narrowed the circumstances under which citizens can file TRI cases. We are not aware of any TRI citizen's suits since 2000. The Agency is also working to assist small businesses with compliance; this will also serve to reduce the likelihood of action under the citizen's suit provision. EPA has conducted significant outreach efforts prior to finalization of this rule that focused primarily on small businesses, including conducting three public meetings with special emphasis on potential small business impacts of the lead rule in Los Angeles, Chicago and Washington, D.C. EPA distributed a Fact Sheet in August of 2001 that announced the new rule, and developed a technical assistance guidance document for complying with the lead rule. EPA also conducted numerous compliance assistance workshops. This Fact Sheet was distributed electronically by EPA's Small Business Office to businesses and trade associations that may be affected by the new rule.

EPA believes that its outreach efforts to small businesses have been effective. Every year TRI-training workshops are well attended by small businesses, and EPA responds to many compliance-related questions from small businesses in various industry sectors. During the public comment period of the proposed lead rule (published August 3, 1999), EPA received many comments from small businesses, and from trade associations that represent small businesses from diverse industry sectors. In addition, since promulgation of the final rule, EPA has responded to many inquiries from trade associations that represent small businesses, the Small Business Administration, and individuals (e.g., presidents, CEOs) from small businesses.

Q4. EPA officials have described the first year as a "road test" or as an opportunity for the EPA and the regulated community to learn. If you do not expect that 2001 data will be the most accurate, then will it always be "a low enforcement priority" or could it be part of an enforcement action in 2 or 3 years?

A4. When EPA describes the first reporting year as a "low enforcement priority," that priority is highly unlikely to change over time. Nevertheless, EPA would consider taking a case with first-year reporting violations where there was a continuing pattern of non-compliance extending past the first year. EPA intends to continue promoting compliance by providing assistance with lead and lead compound reporting to the TRI.

Q5. What is the EPA record on enforcement in the first year or two of a new rule? How many enforcements have occurred in the first year; what types, sizes, and numbers of enforcement fines have been issued; and what are the types of enforcement options available for TRI under this rule? (Please segregate TRI and non-TRI enforcement information).

A5. EPA examined enforcement activity subsequent to the issuance of the Facility Expansion Rule, ("Addition of Facilities in Certain Industry Sectors; Revised Interpretation of Otherwise Use; Toxic Release Inventory Reporting; Community Right-to-Know; Final Rule", 40 CFR Part 372, May 1, 1997), when 6,100 additional facilities were required to begin reporting to the TRI. As of this time, in that universe of 6,100 new facilities, only two enforcement actions are known to have been taken, both in fiscal year 2001, for reporting violations in the first year. The final penalty assessed in one of the cases was $45, 430. The other case is still open and pending.

Two recent non-TRI public right-to-know rules are the Lead Disclosure Rule and the Pre-Renovation Lead Information Rule. EPA phased-in enforcement of the Lead Disclosure Rule (Section 1018 of the Residential Lead-Based Paint Hazard Reduction Act). That rule was effective in September of 1996, but EPA did not take its first enforcement actions until July 1998, and then the actions were only based on conduct after September 1997.

The Pre-Renovation Lead Information Rule (Section 406(b) of the Toxic Substances Control Act) was published on June 1, 1998. To date, EPA has not taken any enforcement actions with penalties. For both of these rules, EPA engaged in extensive outreach and compliance assistance activities.

EPA has several enforcement options in response to violations of TRI reporting requirements. The 1992 "Enforcement Response Policy for Section 313 of the Emergency Planning and Community Right-to-Know Act" provides for different levels of action according to the level of severity for the violation. Enforcement alternatives provide for no action, notices of noncompliance, civil administrative penalties, civil judicial referrals, and criminal action under 18 U.S. Code 1001.

Additionally, EPA has two compliance incentive policies which companies can use to substantially reduce, or eliminate, penalties for TRI violations. The Small Business Compliance Policy provides for the elimination or significant reduction of penalties for small businesses (those with 100 or fewer employees) if the company discovers, discloses, and promptly corrects the violations. Those businesses with greater than 100 employees may be eligible for similar penalty elimination or reduction through the Agency's policy, "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations", 65 Fed. Reg. 19618 (April 11, 2000).

Q6. In your testimony you state that this is "one of the most aggressive outreach programs that EPA has ever done in the TRI program." What is the typical outreach performed in conjunction with a new rule and how does it differ from this one? What was the total cost of this outreach? (Please segregate the costs of this outreach from any normal or previously planned outreach on other TRI programs).

A6. The level of compliance assistance will vary for different rules. Typically, when EPA promulgates a new TRI rule, the TRI Program will provide guidance to the EPCRA Call Center (i.e., Hotline), highlight the changes at its annual industry training sessions, and conduct outreach to the reporting community. For the TRI lead rule, EPA provided additional compliance assistance which included nine training workshops in the fall of 2001 specific to the lead rulemaking, the development, with significant stakeholder input, of a guidance document, and outreach for both efforts (fact sheets, mailing announcements, Federal Register Notices, etc.). The costs for these additional efforts exceeded $200,000. In addition, a significant amount of EPA staff time was devoted to meeting requests for speakers and providing information over the telephone. The only other TRI rulemaking for which this level of compliance assistance was provided was the 1997 rulemaking adding seven industry sectors to the TRI.

Q7. You described these outreach sessions as "train the trainer" sessions. You acknowledged that it was your expectation that trade associations and consultants would report back to clients and members and would affect a larger group of the regulated community. What efforts have you made to do outreach to those businesses who are not members of a trade association or who have not hired a consultant to work with them?

A7. The "train the trainer" workshops that are presented each spring are targeted to those individuals at reporting facilities who are responsible for filling out the TRI forms, corporate environmental staff, consultants, and trade association representatives. These workshops are attended by a wide range of people. The nine training workshops in the fall of 2001 specific to the lead rulemaking were targeted to an audience of particular reporters, with a focus on small businesses.

In addition, EPA has been very active with outreach efforts during the entire development of the lead rule. This includes three public meetings that EPA conducted with special emphasis on potential small business impacts during the development of the final lead rule in Los Angeles, Chicago, and Washington, D.C. The notices announcing the meeting were reviewed by SBA. The meeting was also announced in a targeted mailing. EPA has been very active in announcing the final TRI lead rule, and informing those who may have to comply with the new reporting requirements for lead and lead compounds. In addition to the Federal Register notice (April 17, 2002), subsequent press releases and extensive media coverage announcing the final lead rule, EPA's TRI Program and regional offices have conducted extensive outreach efforts to inform those who may need to comply with the TRI lead rule of the new reporting requirements, and to provide compliance assistance, especially to those who are not familiar with TRI reporting. These outreach efforts are described briefly below.

- Fact Sheet: In August of 2001, the TRI Program developed a "Fact Sheet" that announces: 1) the new TRI lead rule; 2) the development of a guidance document to provide technical assistance for complying with the lead rule; and 3) compliance assistance workshops. This Fact Sheet was distributed electronically by EPA's Small Business Office to many individuals and organizations (i.e., businesses, including small businesses and trade associations) that may be affected by the new rule.

- Guidance Document: The TRI Program developed a technical guidance document through a public notice and comment process. A draft version was released on September 10, 2001, within five months after the lead rule became effective. A public (stakeholder) meeting was held on September 24, 2001, to discuss the draft version. A final version was released at the beginning of January 2002.

- Lead Rule Training Workshops: The TRI Program conducted nine lead rule workshops that were held throughout the various regions of the country in the fall of 2001. Approximately 730 people

registered for the fall 2001 workshops. In general, the feedback received by the TRI Program from the participants was positive.

- EPA's Small Business Ombudsman Office sent out e-mail announcements to trade organizations and interested parties, including the Small Business Administration, announcing the lead rule workshops.

- EPA published a Federal Register notice announcing the lead rule workshops and sent flyers directly to interested parties via e-mail.

- EPA spoke at conferences, attended meetings, and assisted in the development of outreach materials for trade associations upon request.

- EPA posted announcements of all of these efforts on the TRI Program's internet homepage, and EPA regional offices sent out mass mailing announcements to regulated entities and states. For example, Region 10 sent an announcement of the lead rule workshops to every business with eight or more employees that may potentially be subject to reporting under the lead rule. This included more than 19,000 mailings for this Region alone.

In addition to the above-mentioned special assistance for the lead rule, the TRI Program has established an extensive compliance assistance program to all those who need to comply with TRI reporting requirements (including the lead rule), including those in small businesses. The TRI Program provides this assistance through the:

- EPCRA hotline;

- TRI Industry Workshops: TRI Program sponsors compliance assistance workshops which are offered every spring in each EPA Region (approximately 3000 attended the spring 2001 workshops). This year, the TRI Program conducted forty-two workshops across the country. These workshops covered the new reporting requirements for lead and lead compounds as well as other aspects of TRI reporting (the training materials for the 2002 spring workshops are available from the TRI Program's internet homepage);

- TRI User Support: a mechanism by which individuals with questions who need assistance can contact EPA's TRI Program headquarters staff; and

- *TRI _ Made Easy* (*TRI_ME*): *TRI_ME* is an interactive, intelligent, user_friendly software tool that guides facilities through the TRI reporting requirements and contains a general information library on TRI assistance materials.

EPA believes that its outreach efforts to reach small businesses have been effective; this is supported by the fact that every year TRI-training workshops are well attended, and that the Agency has received many compliance-related questions from many individuals from different types of facilities, of different sizes, and of different industry sectors from the various venues provided. Also, during the public comment period of the proposed lead rule (published August 3, 1999) the Agency received many comments from small and large businesses, and from trade associations that represent small and large businesses from diverse industry sectors. In addition, since promulgation of the final rule, the Agency has received many inquiries from: trade associations that represent small businesses and large businesses; the Small Business Administration; and individuals (e.g., presidents, CEOs) from small and large businesses.

Q8. Is the 216-page guidance document that your office produced really supposed to help a small businessperson comply with the rule? How long would it take someone to read the document? Has any small businessperson commended you on the helpful guidance document? Has any complained about the document?

A8. The TRI Program has not evaluated how the final guidance document has been received by the "small business community" (i.e., the majority of all small businesses in the country). The TRI Program developed the guidance document through a public notice and comment process. A draft version was released on September 10, 2001, (which is within five months after the lead rule became effective). A public (stakeholder) meeting was held on September 24, 2001. This meeting provided the TRI Program with the opportunity to discuss the draft version with stakeholders, and listen to comments offered by stakeholders. The final version of the document incorporated, where appropriate, comments submitted to EPA in writing during the public comment period, and comments raised at the public meeting. The final version was released at the beginning of January 2002 - nearly seven months before the deadline for submitting the first year release reports.

The actual body of the lead rule guidance document is only 65 pages long. The remaining sections are the appendices. The appendices contain extensive and valuable information such as emission factors, thereby minimizing the time for facilities to search for this information elsewhere. The guidance document is well organized and easy to use. It contains a table of contents, a list of figures, a list of tables, and an index. The guidance document contains many real-world examples of scenarios likely to be encountered at facilities. Detailed explanations are provided on how facilities should deal with these scenarios with regard to the new reporting requirements for lead and lead compounds. In addition, Appendix B of the document "Selected Questions and Answers," provides EPA's answers to commonly asked questions regarding the new reporting requirements for lead and lead compounds.
The TRI Program has a policy for revising its guidance documents. Guidance documents will be revised as appropriate, based on changes in information, rules, or TRI Program policies and practices. The TRI Program always welcomes comments and additional information for all of their guidance documents, from all stakeholders. The TRI Program may choose to revise the lead guidance document at a future date if the Agency believes that such revision is needed based on comments received.

Q9. In an answer to my question about applying the rule retroactively you responded that the justification is "that the TRI program has always allowed filers to estimate their releases." Please describe your allowance of good faith estimation and your requirement that the data be reconstructed accurately to one-tenth of a pound. Should a facility just take a guess? What kind of information is required to back up an estimation to one-tenth of a pound?

A9. The TRI lead rule does not impose a "retroactive reporting obligation." A retroactive rule "alters the past legal consequences of past actions"; this rule does not affect a facility's liability for past conduct.

EPCRA section 313(g)(2) states that in reporting to TRI "the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or where such data are not readily available, reasonable estimates of the amounts involved."

It has been EPA's experience that facilities have knowledge, at a minimum, of the following: the facility's processes, EPA reporting instructions, EPA guidance documents, supplier notifications, trade association documents, the facility's air and water permits, and hazardous waste manifests. Regarding the issue of what constitutes a business' knowledge of the law, courts have long held that everyone possesses constructive knowledge of the laws passed by Congress and implementing rules and regulations published in the Federal Register.[1]

There is no "requirement that the data be reconstructed accurately to one-tenth of a pound." EPA has provided guidance that for PBT chemicals, all releases and other waste management quantities of a PBT chemical (except the dioxin and dioxin-like compounds chemical category) should be reported at a level of precision supported by the accuracy of the underlying data and estimation techniques on which the estimate is based. However, EPA does not require that facilities report their PBT chemical releases and other waste management quantities to greater than 0.1 pounds.

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[1] *See, e.g.*, 44 U.S.C. § 1507; Federal Crop Ins. Corp. v. Merrill, 332 U.S. 380 (1947).

EPA has engaged in outreach efforts to promote awareness among those required to report and to aid those required to report, including through a robust compliance assistance program. See answer to Q7 for details.

Q10. One of our witnesses is in the glass decorating business. Each colored dye contains a different quantity of lead. Her January – April data, without the benefit of a color tracking system that she is trying to implement, will be extremely difficult to reconstruct. How many hours must she spend to prove due diligence? How accurate must her estimate be? How do you reconcile your rather casual view of what is expected with the level of precision elsewhere required for these reports?

A10. The amount of time each facility spends on estimating their activity thresholds, and release and other waste management quantities will vary from facility to facility.

EPCRA section 313(g)(2) states that in reporting to TRI "the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or where such data are not readily available, reasonable estimates of the amounts involved."

EPA has provided guidance that for PBT chemicals, all releases and other waste management quantities of a PBT chemical (except the dioxin and dioxin-like compounds chemical category) should be reported at a level of precision supported by the accuracy of the underlying data and estimation techniques on which the estimate is based. However, EPA does not require that facilities report their PBT chemical releases and other waste management quantities to greater than 0.1 pounds.

Q11. Congressman Brady asked you about the Form A. In addition to your explanation of the history of the Form A, could you answer his question more directly? Why was a more burdensome Form R chosen for this rule? Why wouldn't it be appropriate to allow Form A for small businesses when the burden of this rule is extraordinary and from all accounts the data quality will be poor at best?

The Form A is a Certification Statement that was established in 1994. This form is based on an alternate threshold for facilities with small amounts of an EPCRA section 313 chemical in waste. The Form A serves to certify that a facility is not required to report the information specified in EPCRA section 313(g)(1) (collected on Form R) for a specific toxic chemical. The Form A provides facilities otherwise meeting EPCRA section 313 reporting thresholds the option of certifying on Form A that they are not required to report on a Form R because they meet certain criteria, i.e., they do not exceed 500 pounds for the total annual reportable amount for that chemical, and that their amounts manufactured or processed or otherwise used do not exceed one-million pounds. The Form A is not an alternate reporting form.

As part of the PBT final rule, EPA did not allow use of the existing alternate threshold and reportable quantity for Form A because it would be inconsistent with the intent of expanded PBT chemical reporting. The general information provided in the Form A certification statement on the quantities of the chemical that the facility manages as waste is insufficient for conducting analyses on PBT chemicals and would be less useless for communities interested in assessing risk from releases and other waste management of PBT chemicals. Therefore as part of the PBT final rule, EPA excluded all PBT chemicals from the alternate threshold of 1 million pounds. As lead and lead compounds are PBT chemicals, the alternate threshold of 1 million pounds and, thus, the Form A certification statement cannot be used (except for lead in alloys).

Q12. This Rule includes the elimination of several burden reduction measures meant to make it easier for small businesses to comply. Specifically, the *de minimis* exemption, range reporting, and the simplified Form A have all been removed as an option under this rule. What burden reduction measures do you have planned to replace these measures? Do you feel that you are complying with your obligations under the Paperwork Reduction Act?

A12. As indicated in the preambles to the proposed and final rules, the information collection activities contained in 40 CFR 372 are approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The preamble to the proposed and final rules, the economic analysis, and the Information Collection Request all specifically described EPA's proposal to lower reporting thresholds, and to change the reporting requirements so as not to allow use of the *de minimis* exemption, range

reporting, or Form A for reports submitted under the lowered thresholds. The Federal Register provided public notice and specifically solicited public comments on the changes to reporting and reporting instructions that were being considered, as well as on the Agency's associated burden estimates. The Agency provided a functional description of the changes in reporting that would result from this rule. Therefore, EPA has complied with the PRA and with OMB requirements.

The burden reduction goals of the PRA enumerated at 44 U.S.C. §3505(a)(l) are measured "Government wide." They are not intended to be applied identically to each individual agency, nor to individual regulations, programs, or Offices within EPA. Nevertheless, EPA continues to seek burden reduction for the TRI program through enhanced electronic reporting, industry- and chemical-specific guidance documents, chemical delistings, and the continued availability of an alternate reporting threshold that applies to non-PBT chemicals. EPA is always interested in opportunities to reduce reporting burden without damaging the informational content of the TRI program. For example, EPA has developed automated reporting software (*TRI-Made Easy*) that includes built-in calculation methodologies and error checking routines. Based on trial usage in reporting year 2000, facilities that used *TRI-ME* experienced a 25 percent reduction in per form burden. EPA is also developing a single facility identification program for facilities that report to EPA and developing guidance to facilitate more consistent use of chemical nomenclature, reporting units, and time frames across different programs. EPA continues to develop additional reporting guidance to simplify and ease reporting burdens.

44 U.S.C. §3505 requires that burden reduction goals be set that "improve information resources management in ways that increase the productivity, efficiency and effectiveness of Federal programs, including service delivery to the public." EPA believes that the additional information provided by lowering the TRI reporting thresholds for lead and lead compounds will be valuable to communities and will significantly enhance their knowledge about toxic chemical releases and other waste management activities that may be of concern to them. EPA believes that this action will increase the productivity, efficiency, and effectiveness of the TRI program by adding to the body of publicly available data on releases and other waste management of toxic chemicals. EPA does not believe that requiring additional reporting on lead and lead compounds is contrary to the statutory intent of the PRA.

Q13. One GAO Report estimates the burden at over 100 hours for each business to collect the information and fill out the forms. Numerous small business representatives have stated it is impossible for them to produce quality data on this rule by July 1, because of the retroactive reporting obligation and the inadequate and untimely guidance document, among other problems. If the information is not accurate and of little value, can you tell me why it is still a good idea to impose this enormous time burden on small business owners at this time?

A13. The purpose of this rule is to provide more information to the public about releases of lead and lead compounds in their communities. This information can also be used by local, state, and federal government agencies and others to identify problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Given the degree of compliance assistance that the Agency has provided, including training materials and training sessions, guidance documents and intelligent reporting software, EPA does not believe that the information will be inaccurate or of little value. Facilities are required to provide their best readily available information or if that is not available to make reasonable estimates. This is the same standard that applies to current TRI reporting.

Lead and lead compounds are persistent in the environment, bioaccumulative in humans and other organisms, and toxic in small amounts and concentrations. This action will provide the public with information on the releases and other waste management of lead and lead compounds at thousands of facilities that previously were not required to report this information. EPA has received hundreds of comments from private citizens, public interest groups, and local governments in support of lowering the reporting threshold for lead and lead compounds to capture additional reporting. EPA believes that TRI reporting is an important tool for better management of lead and lead compounds.

Q14. It is true that you made a determination that this rule would not significantly affect small businesses. On what basis did you make that determination? Based on the enormous outcry that has occurred, can you still maintain there is no significant impact on small business?

A14. EPA conducted an extensive economic analysis that included a quantitative small entity impact analysis. EPA made this analysis available as part of the public record for the rulemaking. The public comment process provided an opportunity for comment on this analysis, and to provide additional information to refine this analysis. Even though EPA extended the public comment period twice and held three public meetings with special small business emphasis, EPA did not receive additional information that would require changing the certification. EPA based its certification on careful, factual consideration of potential impacts of the rule on small entities. GAO found that "initial and draft revised analyses and the conclusions that [EPA] based on those analyses were within the discretion permitted under the RFA and the EPA guidance."

The factual basis for EPA's certification that the rule will not have a significant economic impact on a substantial number of small entities is found in the Federal Register notice for the final rule. At 66 FR 4543, EPA stated "EPA estimates that approximately 4,100 small businesses will be affected by the rule. The incremental burden of the additional reporting at the facility level is associated with labor that will be expended by facility staff to conduct reporting activities. Based on typical reporting burdens of approximately 110 hours (in the first year of reporting for a first-time TRI reporter) and 50 hours in subsequent years, the impact of this action ranges from 0.25 to 0.55 percent of available labor hours for the smallest affected facility. The impact would be even less for facilities with more than 10 full-time employees, or for those that take less than the average amount of time to report. EPA estimates that the final rule would have an annual cost impact between 1-3% of annual revenues on fewer than 250 small businesses (approximately 5% of all affected small businesses) in the first year only. After the first year of reporting, the annual cost impact as a percentage of annual revenues is estimated to be below 1% for all affected small entities."

Q15. Are you aware that the SBA's Office of Advocacy believes that your certification on this rule and its effect on small business was wrong? Are you aware that Dr. John Graham from OMB testified before this subcommittee June 6, 2002 and said that any rule that SBA identifies as not being properly certified as to its effect on small businesses will be sent back to the agency? Do you feel comfortable with a rule that under today's circumstances would not have passed muster?

A15. While SBA's Office of Advocacy asserted that EPA's certification was incorrect, they did not provide any analysis or other supporting factual basis to support this assertion. Presumably, OIRA would make the same demands on Advocacy for factual analysis as it does on EPA.

In the case of the TRI Lead rule, EPA considered the impact of the draft rule on small businesses, as required by the RFA. The rule was cleared by OIRA. Furthermore, according to GAO, "Initial and draft revised analyses and the conclusions that [EPA] based on those analyses were within the discretion permitted under the RFA and the EPA guidance."

Q16. Is there a public "right to know" benefit that can be derived from inaccurate information? If the information provided in this year's TRI reports under the new lead threshold provides completely inaccurate data, is there any benefit to that information?

A16. EPA does not expect this year's TRI data to result in inaccurate information. Many facilities reporting to TRI for the first time on lead and/or lead compounds report to TRI for other TRI chemicals. Further, EPA has conducted extensive compliance assistance and has provided tools such as *TRI Made Easy* and the TRI Lead Guidance Document that will help first time filers and small businesses reporting to TRI for the first time. In addition, EPA conducts a number of error checks on all submissions and conducts detailed data quality assessments which identify potential errors. EPA believes that these activities will minimize errors in the TRI data.

Q17. What new facilities do you expect will report under the new rule? Can you name a facility that you expect to report under the new rule that is causing a public health problem in its neighborhood?

A17. All industry sectors regulated under TRI will have to determine compliance with the lead rule. Those industry sectors that will provide the largest number of reports are primary metals, electronic equipment manufacturers and bulk petroleum.

The lack of existing publicly available data precludes the sort of risk assessment that is needed to respond to this question. If release data is provided then risk assessments can be attempted, but without such information they cannot. By lowering the reporting thresholds for lead and lead compounds, EPA will be able to provide communities with access to data that may help them in making risk determinations. This information could also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment.

Neither EPCRA section 313(h), nor its legislative history directs EPA to limit the collection of information on releases to those releases that, from the federal government perspective, pose significant local human and environmental exposure and human health and environmental risks. Congress stated in EPCRA section 313(h) that: "The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available. . . .to inform persons about releases of toxic chemicals to the environment; to assist government agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes."

Q18. In your testimony you state that, "I do not think in any given situation or across the board you can make a statement that science has to be the dominant factor [in the development of policy]. I would not say that now." Does that continue to be your opinion of the practices in your office and at the EPA?

A18. Sound sciences forms the basis for all our decisions. While our decisions are based on sound science, they must be guided by the laws that we are directed to implement. Additional considerations such as burden are also factored into these decisions.

Q19. When confronted with Governor Whitman's statement:

> Scientific analysis should drive policy. Neither policy nor politics should drive scientific results. . . . good science is the basis for all the decisions that are made at the Agency. That is critical to the credibility of the Agency and to the implementation of the decisions made by the Agency

your response was, "I do think that is the practice, yes, that we are all expected to abide by, but it is not the only one. We have to take other things into consideration." How can you abide by it and not abide by it at the same time? Is politics a legitimate consideration in policy development? Would Governor Whitman agree with your characterization of her policy on science?

A19. Sound sciences forms the basis for all our decisions. While our decisions are based on sound science, they must be guided by the laws that we are directed to implement. Additional considerations such as burden are also factored into these decisions.

Q20. At the hearing, you were unaware that the House Science Committee has requested an SAB review of lead and other metals characterization using PBT methodology. Are you now aware of this request? Is it being met by your Metals Framework Assessment and Metals Guidance documents that are being prepared by Science Advisory Boards? If so, is this not a question that underpins the current Lead TRI rule? If not, have you informed the House Science Committee that you will not be meeting their request?

A20. In a November 15, 2001 letter to Governor Whitman, Science Committee Chairman Boehlert urged EPA to "charge the SAB to undertake a broad review of the use of PBT." He stated that "[t]he PBT

methodology could underpin many EPA decisions in the future..." In her February 6, 2002 response to Chairman Boehlert, Governor Whitman stated that EPA "intends to submit to the Science Advisory Board an Action Plan that will identify the primary elements that should be addressed in a comprehensive cross-Agency metals assessment framework. The framework will establish guidance for EPA programs to use when considering the various environmental properties of metals, such as persistence, bioaccumulation and toxicity, in assessing the hazards and risks of metals and metal compounds." EPA also committed to submit for review "the specific issue of whether the application of the PBT chemical framework used in the TRI lead rulemaking would result in a classification of lead and lead compounds as highly bioaccumulative." As explained further in the answers to questions 21 and 25, EPA does not anticipate that this charge to the SAB will address the scientific questions that underpin the current TRI Lead rule.

Q21. After we asked specifically about your written testimony and the sentence in the Federal Register notice on the Lead TRI rule, "The external peer review would address the issue of how lead and other, as yet unclassified metals, such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations" you said that upon the completion of the SAB reviews "it would certainly be incumbent, based on the answers that come out of the SAB, for the program to evaluate the decisions and the implications on all of our current programs. I think it is also premature to change anything we are doing without that recommendation coming from the SAB." We appreciate your concession on the scientific matter. If the SAB might make a recommendation that you will be willing to use to change the current policy, then why not wait until after the review is complete to implement the current rule?

A21. To clarify the quoted language, EPA has not committed to send the scientific issues underlying the current TRI Lead rule to the SAB. The quoted sentence occurred in the context of a larger discussion of the Agency's decision to defer its finding that lead and lead compounds are highly bioaccumulative, pending SAB review. When read in context, it means only that EPA recognized that the guidance it would receive on the specific questions first raised during the rulemaking for lead, would potentially be relevant to any assessment of other, as yet unclassified metals. It does not commit the Agency to seek review of whether the PBT criteria can be applied to metals, nor whether lead and lead compounds are bioaccumulative.

To answer your question, EPA does not anticipate that the SAB will provide guidance that contradicts the science on which the TRI Lead rule is based. The accumulation data in humans is well documented, has been peer reviewed and was also reviewed as part of a 1999 SAB review of lead[2]. In addition, as discussed in the answers to questions 27 and 28, researchers have long measured the bioaccumulation of metals, including lead, in aquatic organisms. For these reasons, the Agency does not believe that it would be appropriate to delay implementation of the rule on the speculation of what the SAB might theoretically advise. EPA will review the advice provided by the SAB to the charges put forth by EPA, and make a determination on how to proceed.

Q22. One of the questions before the SAB is whether or not lead should be considered "highly bioaccumulative." If the SAB made a determination that lead was highly bioaccumulative, then what would EPA do?

A22. EPA will review the advice provided by the SAB to the charges put forth by EPA, and make a determination on how to proceed.

Q23. If the SAB presents a finding that lead and other metals should not be classified as PBTs, then what would EPA do and how would it affect the current TRI rule?

A23. EPA will review the advice provided by the SAB to the charges put forth by EPA, and make a determination on how to proceed.

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[2]"EPA-SAB-EHC-99-004, Technical Review of the Proposed TSCA Section 403 Regulation (Identification of Dangerous Levels of Lead)."

Q24. Isn't it possible that the SAB in these reviews may find that lead is not appropriately categorized using PBT methodology? So if it is possible that the SAB may say that the science behind this rule is not sound and lead should not be covered under the PBT rule, then how can you feel confident about implementing it?

A24. EPA does not anticipate that the SAB will provide guidance that contradicts the science on which the TRI Lead rule is based. For that reason, the Agency does not believe that it would be appropriate to delay implementation of the rule on the speculation of what the SAB might theoretically advise. EPA will review the advice provided by the SAB to the charges put forth by EPA, and make a determination on how to proceed.

Q25. You mentioned in your testimony that EPA has already determined that lead is a PBT. Based on the scientific questions before the SAB, wouldn't you have to say that EPA's determination is in question? Has EPA ever altered a policy that it had made a determination on after an SAB review recommended something to the contrary?

A25. In her February 6, 2002 response to Chairman Boehlert, Governor Whitman stated that EPA "intends to submit to the Science Advisory Board an Action Plan that will identify the primary elements that should be addressed in a comprehensive cross-Agency metals assessment framework. The framework will establish guidance for EPA programs to use when considering the various environmental properties of metals, such as persistence, bioaccumulation and toxicity, in assessing the hazards and risks of metals and metal compounds." EPA also will seek external advice from the SAB to address the specific question of whether the data cited in the lead rulemaking would support classifying lead and lead compounds as highly bioaccumulative rather than as bioaccumulative as EPA concluded in the final TRI lead rule. Thus, EPA's determination that lead is bioaccumulative is not in question.

EPA develops many science policies. When the Agency believes outside expert advice may be needed to develop a new science policy EPA will seek advice from the Science Advisory Board or other expert scientific bodies. EPA considers all advice provided by expert scientific bodies during the development of science policies or revision of existing policies when such advice has been solicited.

Q26. You stated in your testimony, "I think we could find an equal number of statements where people believe it is indeed very appropriate to apply PBT criteria to metals." Could you supply for the record any non-EPA statements endorsing the scientific appropriateness of applying PBT criteria to metals?

A26. In addition to comments submitted in support of both EPA's 1999 PBT rulemaking and the 2001 TRI lead rulemaking, EPA's application of concepts or criteria that pertain to persistence, bioaccumulation, and toxicity of metals is consistent with the positions of international organizations, developed by experts in the field. These organizations acknowledge that these concepts are important considerations for metals and can be applied to metals as long as they are applied appropriately. The Organization of Economic Cooperation and Development (OECD), for example, has developed schemes for classifying substances, including metals and metal compounds, that are hazardous to aquatic species. These classification schemes consider persistence, bioaccumulation, and toxicity.

Q27. Are there any non-EPA statements that indicate that BCFs can be used to characterize whether metals can bioaccumulate in the aquatic environment?

A27. Yes. BCFs are commonly used to characterize the bioconcentration of metals in the aquatic environment. There are many studies published in the open literature in which investigators have measured the bioconcentration of metals, including lead, by aquatic organisms and provide bioconcentration data. Some of these studies are listed below:

Borgmann, U., Kramer, O. and C. Loveridge. 1978. Rates of mortality, growth, and biomass production of *Lymnaea palustris* during chronic exposure to lead. J. Fish. Res. Board Canada 35:1109-1115.

Denny, P. And R.P. Welsh. 1979. Lead accumulation in plankton blooms from Ullswater, the English Lake District. Environ. Pollut. 18:1-9.

Eisler, R. 1988. Lead Hazards To Fish, Wildlife, and Invertebrates: A Synoptic Review. Contaminant Hazard Reviews Report No. 14, Biological Report 85(1.14), US Department of the Interior, Washington, D.C., 134 pp.

Eisler, R. 2000. Handbook of Chemical Risk Assessment, Health Hazards to Humans, Plants, and Animals. Volume 1, Metals. Lewis Publishers, CRC Press LLC, Boca Raton, FL, Chapter 4 Lead.

HSDB 2000a. Hazardous Substances Data Bank: record on lead (chemical abstracts # 7439- 92-1). National Library of Medicine, Bethesda, MD.

Jenkins, D.W. 1980. Biological monitoring of trace metals. Vol. 2. Toxic trace metals in plants and animals of the world. Part II. EPA 600/3-80-091, U.S. Environmental Protection Agency, Washington, DC., pp. 619-778.

Schulz-Baldes, M. 1972. Toxicity and accumulation of lead in the common mussel *Mytilus edulis* in laboratory experiment. Mar. Biol. 16:226-229.

Schulz-Baldes, M. 1974. Lead uptake from sea water and food, and lead loss in the common mussel, *Mytilus edulis*. Mar. Biol. 25:177-193.

Schulz-Baldes, M. and R.A. Lewin. 1976. Lead uptake in two marine phytoplankton organisms. Biol. Bull. 150:118-127.

Scoullos, M.J. 1986. Lead in coastal sediments: the case of the Elefsis Gulf, Greece. Sci. Total Environ. 49:199-219.

Seeliger, U. and P. Edwards. 1977. Correlation coefficients and concentration factors of copper and lead in seawater and benthic algae. Mar. Pollut. Bull. 8:16-19.

Shuster, C.N. and B.H. Pringle. 1969. Trace metal accumulation by the American Eastern oyster, *Crassostrea virginica*. Proc. Natl. Shellfish Assoc. 59:91.

Q28. In its draft action plan for metals, EPA cites 11 examples in the first 23 pages where metals are distinguished from organic chemicals for the purpose of assessing metal hazards. The quotes include:

> Hazard and risk assessments of metals and metal compounds raise issues not generally encountered with organic chemicals. (Exec. Summ.)
>
> While many of these same factors also affect the risk potential of organic chemicals, models for predicting fate, transport, and toxic properties are generally more robust for organic chemicals than for metals. (p. 2)
>
> While differing environmental conditions among specific locations can affect the risks posed by metals or organic substances released in these locations, this variability may more significantly affect the risk estimates for metals than for organic compounds. (p. 2)

> As has been mentioned before, these factors may have greater impacts on the estimates of risks for metals than for organic compounds. (p. 3)
>
> These correlations are often more complex and difficult to describe for metals than for organic compounds. (p. 3)
>
> While the Agency recognizes that there are always exceptions, the estimation process is generally more straightforward for organics than for metals. (p. 3)
>
> For metals, the assignment of indicator values is more complex . . . Its chemical form can change. (p. 4)
>
> Biomagnification appears to be restricted to certain types of organic chemicals with methylmercury being one notable exception. . .In general, most inorganic forms of metals tend to biodilute in aquatic food webs. (pp . 18-19)
>
> For nonionic organic chemicals, substantial progress has been made on identifying mechanisms and factors affecting the bioaccumulation process. . . For metals and metal compounds, such broadly applicable, mechanistically-based models for assessing bioaccumulation across metal compounds have generally failed to gain widespread regulatory application. (p. 19)
>
> This aspect combined with the lack of generalizable contstructs such as those commonly used for organics . . . makes national metal bioaccumulation assessments a challenging exercise. (p. 20)

EPA states in its September 13, 2000 analysis in an EPA document circulated during the interagency review process that "We do not believe that there is a scientific basis to distinguish the use of BCFs for organics and inorganic chemicals and metal and metal compounds." The September 13, 2000 analysis also states that "EPA does not believe that it has been shown that for metals there is an inverse relationship between metal concentration and the BCF values." Given the information in the new draft action plan which apparently assumes the "existence of the inverse relationship between BCF (BAF) and exposure concentrations (see page 23), does EPA believe that it can reasonably still rely on the published BCF values for lead?

A28. Yes. The quote in the draft Action Plan is "The existence of inverse relationships between BCF (BAF) and exposure concentrations for certain metal/species combinations has led to recommendations by some to abandon the current use of BCFs and BAFs for classifying metal hazards (Adams, 2000; Brix and Deforest, 2000)." However, as previously stated in the September 13, 2000, document "...BCFs have long been used as a measure of the bioaccumulation potential of chemicals. There is a large amount of data on the use of BCFs in the open literature including data for metals. Metal BCFs have been calculated for a number of years and all of these research papers have been peer reviewed. The BCF support document for the proposed rule cited a long list of references that deal with the bioaccumulation of lead in various organisms. We do not believe that there is a scientific basis to distinguish the use of BCFs for organics and inorganic chemicals and metals and metal compounds." EPA still maintains this position.

The metals action plan does not address the question of whether metals, including lead, are persistent, bioaccumulative, and toxic. Clearly, a number are, including lead. The draft Metals Action Plan addresses the issue of what factors and data should be considered in assessing the hazards and risks of metals.

Q29. You explained the inconsistency between lead not being a PBT in the Great Lakes Rule promulgated by the EPA water office and the lead rule promulgated by the EPA TRI office as being based on different set of data, and using the data for a different purpose. Could you explain the different use of the data, and the difference in the data used, as well as why the different data and methodology were employed?

A29. The TRI and the Water Quality Guidance for the Great Lakes System are two different systems that have different purposes, represent different constructs, and measure and classify different things. The

Water Quality Guidance considered potential exposure to humans and wildlife from the water and the plants and animals in the fresh water Great Lakes System. The focus was on chemicals that biomagnify and on species indigenous to the Great Lakes.

In the TRI lead rule the scope was not limited to a particular ecosystem. Thus, the species for which bioaccumulation data were considered included those that are indigenous to the Great Lakes and those that are not, such as blue mussels and oysters. Further, in the TRI lead rulemaking EPA considered available data on snails. The Agency was not aware of these data when the earlier rulemaking was conducted. In addition, the species considered in the Great Lakes rulemaking is not the definitive list of species that should be considered in all instances. For example, when assessing bioaccumulation in sediment dwellers, the Office of Water considered bioaccumulation data for sediment dwellers such as insect larvae, bivalves, crabs, and worms, a different group of organisms than it considered for the Great Lakes. Given the broad multi-environmental media scope of the TRI program, it is appropriate for EPA to consider a broader range of species than that considered in the Great Lakes rulemaking.

Finally, for both the PBT chemical rulemaking and the lead rulemaking, EPA assessed the degree of bioaccumulation, not the degree of biomagnification.

Q30. Should a facility lack any facility-specific, supplier-provided; or trade-association provided information regarding the level of lead in raw materials, what specific resources does EPA expect it to consult in order to demonstrate an appropriate level of inquiry? Some testimony given included that foundries that use aluminum alloys will have to test each of 50 different alloys for their lead concentration and no data is provided from suppliers because the lead content is below 1%. What must those facilities do to properly comply?

A30. EPCRA section 313(g)(2) states that in reporting to TRI "the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or where such data are not readily available, reasonable estimates of the amounts involved." EPCRA section 313 does not require that facilities conduct additional testing.

It has been EPA's experience that facilities have knowledge, at a minimum, of the following: the facility's processes, EPA reporting instructions, EPA guidance documents, supplier notifications, trade association documents, the facility's air and water permits, and hazardous waste manifests.

Suppliers are required to required to provide information on the concentration of lead and/or lead compounds contained in mixtures or other trade name products (including alloys) if lead is present at 0.1% or greater because lead is an OSHA carcinogen.

Q31. One of the witnesses (Dennis McGuirk, President of IPC) stated that it took EPA four months to answer a series of questions posed to them about how IPC members' facilities should comply. If EPA cannot answer compliance questions in a timely manner, then how can businesses be expected to report correctly?

A31. We regret the delay in the formal response to IPC's e-mailed questions. EPA has responded to IPC's previous telephone inquiries in a cooperative and timely manner. EPA provides a variety of avenues for facilities to receive compliance assistance, including:

- EPCRA Hotline
- TRI User Support - a mechanism by which individuals with questions who need assistance can contact EPA's TRI Program directly to the EPA headquarters TRI staff.
- Guidance Document: The TRI Program developed a technical guidance document through a public notice and comment process. A draft version was released on September 10, 2001, within five months after the lead rule became effective. A public (stakeholder) meeting was held on September 24, 2001, to discuss the draft version. A final version was released at the beginning of January 2002.

- Lead Rule Training Workshops: The TRI Program conducted nine lead rule workshops that were held throughout the various regions of the country in the fall of 2001. Approximately 730 people registered for the fall 2001 workshops. In general, the feedback received by the TRI Program from the participants was positive
- TRI Industry Workshops: TRI Program sponsors compliance assistance workshops which are offered every spring in each EPA Region (approximately 3000 attendees for the spring 2001 workshops). The TRI Program has conducted forty-two workshops across the country. These workshops covered the new reporting requirements for lead and lead compounds (the training materials for the 2002 spring workshops are available from the TRI Program's internet homepage);
- Interpretive Guidance. EPA routinely provides site-specific and situation-specific guidance for individual facilities.
- *TRI Made-Easy (TRI_ME)*: *TRI_ME* is an interactive, intelligent, user_friendly software tool that guides facilities through the TRI reporting requirements These materials are also accessible on EPA's TRI webpages.