Date: October 5, 2000

To: John Spotila
Administrator, OIRA

From: Jere Glover
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Subject: Draft Final Rule - Toxic Release Inventory – Lowering of Lead Reporting Threshold – Lead Designation as a Highly Persistent Bioaccumulative Toxic (PBT) Chemical

We have reviewed the U.S. Environmental Protection Agency's ("EPA") July 13th draft final rule, regarding the designation of lead as a highly persistent bioaccumulative toxic ("PBT") chemical and lowering of the lead reporting threshold for the Toxic Release Inventory ("TRI"), to be promulgated pursuant to § 313 of the Emergency Planning and Community Right-to-Know Act. As currently contemplated, the rule could impose substantial compliance costs on thousands of small businesses and other entities. EPA estimates the rule costs at $121 million in the first year. We are concerned 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 either 10 or 100 pounds under the TRI reporting requirement.

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. 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 TRI reports that are based on the current 10,000 and 25,000 pound reporting thresholds. 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. However, because the underlying bases 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 recommend that the scientific methodology, on which this rule is based, be referred to the Science Advisory Board (SAB).

Moreover, we question the factual basis for the certification of no significant small business impact. The entities that would have to report under this rule are dominated by small businesses, and the available information on the economic impacts of the rule indicate that the rule could have a significant impact on a substantial number of small businesses.

Lastly, the scientific basis of the rule is undermined by the peer-reviewed literature and international scientific consensus documents on lead. Because the science issues are of great significance for both this rulemaking and for other future PBT-related activities, the PBT methodology should be sent to the SAB for review and comment. There is considerable concern over the scientific issues and their potential regulatory impact, which extend far beyond this rulemaking. For example, a bipartisan House Science Committee has requested a formal SAB review of this issue. In addition, over fifty industry groups wrote a joint letter to EPA, also requesting SAB review. In light of the major concerns over the science underlying this rule, the most appropriate solution would be to defer this rule, pending SAB review.

Each of our major concerns is discussed further, below.

1. There are Unlikely to Be any Significant Benefits to Reporting Releases of Lead at a Ten Pound Threshold.

It is unlikely that more than a few of the over 15,000 new lead reports that would result from using a ten pound reporting threshold, would have any environmental significance. EPA has indicated 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 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 validity of EPA's view 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 pounds/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, draft Final Economic Analysis (EA)). Mobile sources, alone (not in TRI), accounted for over 1.0 million pounds/year. Hundreds of millions of pounds annually wash into streams from natural sources such as soil and rocks. In that context, releases in the order of 10, or even 100, pounds of lead per year are highly unlikely to have any environmental significance (note that releases are almost always a very small fraction of the reporting thresholds, which are based on chemical throughputs, not releases).

Approximately 900 printed circuit board manufacturers would report an average of five pounds released into the air annually (SBA/Advocacy estimate, using EPA draft EA), 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 fuel is combusted by homes, vehicles, and airplanes.

Is there any basis for the belief that lead releases at the ten pound threshold can be significant anywhere in the country? Historically, we have not observed anyone,

including EPA, using data involving 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, and the reduction of lead-based paint hazards. These plans were made with the knowledge of the national and local use of lead. New TRI reports for lead based on a 10 pound threshold are ill-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, and such a threshold may be appropriate. As discussed below, the 1,000 pound threshold would also provide a firm foundation for a certification decision. Thus, we support, as an alternative, a final rule threshold of 1,000 pounds.

2. <u>EPA's Certification Could Be Erroneous, and Subjects this Rule to Legal Challenge for Failure to Have a Small Business Panel.</u>

For a several reasons, the Agency appears to have underestimated the small business impacts of this rule. EPA acknowledged to GAO that it did not estimate any costs for firms in 33 Standard Industrial Code industries, which had at least five facilities reporting under the current, much higher, reporting thresholds. The GAO concluded that EPA could have easily missed hundreds of additional firms facing reporting costs in excess of 1% of sales. We also found at least one example of undercounting the number of impacted entities-- the heavily impacted petroleum wholesale industry. Even with EPA's low estimate of 369 firms with costs in excess of 1% of sales, the GAO noted, "some EPA program offices did not certify proposed rules that had at least a 1% economic impact on less than 100 companies." (GAO draft report, p. 33.) In short, this rule could easily have warranted an initial regulatory flexibility analysis, instead of a certification. As such, a Small Business Advocacy panel would have been required by the Small Business Regulatory Enforcement Fairness Act.

If the economic impacts of this rule are combined with the full PBT rule, the case against certification is even stronger. It was only due to an historical accident that the lead PBT (which accounts for about one half the total PBT costs) was separated from the PBT rule establishing the other PBT reporting requirements. Under the first PBT rule, the petroleum industry alone faced $18 million in first year costs. EPA estimates a cost of $4 million in first year costs for the petroleum wholesalers, although we believe, as already noted, the number of affected reporters in this industry is undercounted.

The new lead reporters are dominated by small businesses. This rule is very controversial within that community. The Agency was widely criticized by Senator Bond and the small business community for not implementing the SBREFA panel process and allowing small business input for this rule. In response to these protests, EPA twice extended the comment period to allow small businesses the opportunity to have more input into the process. This rule is subject to legal challenge by the affected small businesses, which face millions of dollars in costs for a rule with apparently little significant benefits. In addition, the scientific basis of the rule has been seriously questioned by a large variety of industry trade associations (mostly large businesses) in the metals industries, who are concerned about this regulation could lead to other costly Federal, state, and local requirements affecting metals generally. This rule faces serious legal hurdles from both the large and small business communities.

If EPA were to finalize the rule at 1,000 pounds, the number of lead reporters would decline from 14,612 to 4,960. This reduction in the number of affected small firms would reduce the costs significantly, and would permit EPA to certify the lead rule.

3. <u>SAB Review of the Scientific Methodology is Warranted.</u>

EPA faces a significant legal challenge to its view of the use of the bioconcentration factors ("BCF") factors alone to determine whether metals should be regulated as PBTs. The Agency's use of the science is not supported by any of the peer-reviewed literature. Further, the peer-reviewed literature supports the opposite view. Further, these contrary views are reflected in several international consensus documents dating back to 1996, and as recently as this month. The SAB, in a recent report, also cast doubt on the validity of using bioaccumulation as a factor in considering the hazards of metals, although the statement was made in a different context. There is considerable interest in this science issue among the metals community.

EPA's treatment of the bioaccumulation of metals is inappropriate, as a matter of science. The Agency assumes that, once a metal bioaccumulates, it will create a hazard. This is not the normal case 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 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 (Pullen & Rainbow, 1991). This finding of the lack of bioavailability 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).

EPA recently defended its point of view by stating that the most recent OECD report from the Task Force on the Hazard Classification of Metals "recognizes that it is appropriate to use bioconcentration factors in classifying the hazards of metals." This statement, although possibly technically correct, is misleading. The report clearly indicates that BCF factors should not be used alone as hazard indicators, but that BCFs should be used with "expert judgment", on a "case-by-case" basis. The OECD added that there might be a "number of complications in interpreting measured BCF values for metals and inorganic metal compounds." EPA's use here of a single BCF to classify a chemical as a "PBT" or "highly PBT" is not consistent with the OECD recommendations.

Conclusion.

We ask that the rule be deferred and that the scientific methodology be provided to the SAB for its review and comment.