



# Office of Advocacy

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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 hundredths 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 undergo 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 orthophosphate 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.