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Report to the Chairman
Committee on Small Business
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REGULATORY FLEXIBILITY ACT

Implementation in EPA Program Offices and Proposed Lead Rule

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September 20, 2000

The Honorable Christopher S. Bond
Chairman, Committee on Small Business
United States Senate

Dear Mr. Chairman:

On August 3, 1999, the Environmental Protection Agency's (EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS) published a proposed rule in the Federal Register that would, upon implementation, lower certain reporting thresholds for lead and lead compounds under the Toxics Release Inventory (TRI) program from 25,000 pounds to 10 pounds.[1] OPPTS said the proposed lead rule would have positive effects on health, safety, and the natural environment, but it did not assign a dollar value to those benefits due to the lack of adequate methodologies. OPPTS estimated that the rule would cost businesses $116 million during the first year of implementation and that approximately 5,600 small businesses would be affected by the rule. However, OPPTS said that none of these small businesses would experience annual compliance costs above 1 percent of annual sales and that the proposed rule would, therefore, not impose significant compliance costs on any of these small businesses. As a result, OPPTS certified that the rule would not have a significant economic impact on a substantial number of small entities (SEISNSE) and did not trigger certain analytical and procedural requirements of the Regulatory Flexibility Act (RFA), as amended.[2] Concerns were subsequently raised regarding the methodologies that OPPTS used in its analysis and its conclusions about the impact of the rule on small businesses.

This report responds to your request that we review OPPTS' implementation of the RFA and certain aspects of OPPTS' economic analysis of its proposed lead rule. Specifically, you asked us to

[1] 64 Fed. Reg. 42222 (1999). In this report, the rule will be referred to as "the proposed lead rule."

[2] The RFA is codified at 5 U.S.C. 601-612. Section 601 of the RFA defines a "small entity" as including small businesses, small governmental jurisdictions, and other small organizations. The RFA incorporates the generally accepted meanings of small business as established by the Small Business Administration through size standards that define whether a business is small. For example, the size standard is 500 employees for about 75 percent of the manufacturing industries, and either 750, 1,000, or 1,500 for the remaining manufacturing industries.

- describe the guidance that OPPTS and EPA's three other major program offices have used during the past 10 years to determine whether their proposed rules could be certified as not having a SEISNSE;
- compare the rate at which OPPTS certified that its substantive proposed rules published during calendar years 1994 through 1999 would not have a SEISNSE with the rates in EPA's other major program offices; and
- review the methodology that OPPTS used in the economic analysis for the proposed lead rule and (1) describe key aspects of that methodology that may have contributed to the Office's conclusion that the rule would not have a SEISNSE, (2) determine whether and, if so, how OPPTS has changed its economic analysis since publication of the rule, and (3) determine whether additional data or analysis could have yielded a different conclusion about the rule's impact on small entities.

Results In Brief

Under the RFA, federal agencies have broad discretion regarding how key terms in the act should be defined and how RFA certification decisions should be made. Using that discretion, OPPTS and EPA's other major program offices have adopted three very different sets of guidance documents during the past 10 years to determine if their proposed rules could be certified as not having a SEISNSE. The current guidance was implemented because of the enactment of the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1996. The guidance includes specific numerical guidelines to assist EPA program offices in determining whether a rule should be certified as not having a SEISNSE. Those guidelines focus on the magnitude of a rule's impact (e.g., estimated annual compliance costs as a percentage of estimated annual revenues) and the number and percent of affected small entities that are expected to experience that impact. For example, the guidance indicates that a rule should be presumed eligible for certification if it does not impose a 1 percent economic impact on any number of small entities. However, this guidance and the two preceding sets of guidance also give agency personnel broad discretion in how they should be applied.

OPPTS certified 86 percent of the substantive proposed rules that it published during calendar years 1994 through 1999—about the same rate of rule certification as EPA's three other major program offices. The RFA certification rate in OPPTS and in each of the three other major program offices increased after the implementation of SBREFA in 1996. By the end of 1999, OPPTS and one other program office had certified all of their post-SBREFA proposed rules as not having a SEISNSE. Two other EPA program offices used the discretion afforded them in the guidance and did not certify at least four proposed rules published during this period that the numerical guidelines would have allowed them to certify.

OPPTS made a number of assumptions in the original economic analysis for the proposed lead rule that contributed to its determination that no small entities would experience significant economic effects. For example, to estimate the annual revenues of companies expected to file new reports for lead, OPPTS assumed that (1) the new filers would have employment and economic characteristics similar to current TRI filers, (2) different types of manufacturers would experience similar economic effects, and (3) the revenues of the smallest manufacturers covered by the proposed rule could be exemplified by the firm at the 25th percentile of the Office's projected revenue distribution for small manufacturers. As a result of these and other assumptions, OPPTS estimated that the smallest manufacturers affected by the proposed lead rule had annual revenues of $4 million. Using that and other information, OPPTS concluded that the rule would affect about 5,600 small businesses, but none of them would experience first-year compliance costs of 1 percent or more of their annual revenues. Therefore, OPPTS certified that the proposed lead rule would not have a SEISNSE.

OPPTS revised these and other parts of the economic analysis for the proposed lead rule before submitting it to the Office of Management and Budget (OMB) for final review in July 2000.[3] According to a summary of the draft revised economic analysis, OPPTS expected that the proposed lead rule would affect more than 8,600 small companies, and as many as 464 of them would experience first-year compliance costs of at least 1 percent of their annual revenues. Nevertheless, OPPTS again concluded that the rule would not have a SEISNSE. Using data that we obtained from the Bureau of the Census, we estimated that as many as 1,098 additional small manufacturing companies could experience compliance costs of at least 1 percent of their annual revenues, and as many as 78 small companies could experience a 3 percent economic impact. Therefore, if OPPTS had used this analytic approach and the discretion permitted in EPA's RFA guidance, it could have chosen not to certify the rule. However, the Office's initial and draft revised analyses and the conclusions that it based on those analyses were within the discretion permitted under the RFA and the EPA guidance.

Background

The RFA of 1980 requires federal agencies to examine the impact of their proposed and final rules on small entities and to solicit the ideas and comments of such entities for this purpose. Specifically, whenever agencies are required to publish a notice of proposed rulemaking (NPRM),

[3]Under Executive Order 12866, issued in September 1993, federal agencies must submit their significant draft proposed and final rules to OMB before publishing them in the Federal Register.

sections 603 and 604 of the RFA require agencies to prepare an initial and a final regulatory flexibility analysis (known as an IRFA and a FRFA, respectively) when publishing a proposed and final rule. However, subsection 605(b) of the RFA says that sections 603 and 604 do not apply to any proposed or final rule if the head of the agency certifies that the rule will not have a SEISNSE. The RFA took effect on January 1, 1981.

On March 29, 1996, Congress passed SBREFA to strengthen the RFA's protections for small entities. Among other things, SBREFA requires that before publishing an NPRM that may have a SEISNSE, EPA must convene a small business advocacy review panel for the draft rule.[4] Composed of representatives from EPA and OMB's Office of Information and Regulatory Affairs (OIRA) and the Small Business Administration's (SBA) Chief Counsel for Advocacy, the panel must collect the advice and recommendations of representatives of affected small entities about the potential impact of the draft rule. The panel must report on the comments that it receives from small entities and on the panel's recommendations no later than 60 days after the panel is convened. EPA then decides whether to change the rule pursuant to the panel's recommendations and to publish the NPRM. SBREFA also amended the RFA to allow small entities that are adversely affected by a rule to seek judicial review of the agency's compliance with certain provisions of the RFA, including the agency's certification determinations under subsection 605(b) of the act.

The RFA requires agencies to either certify that a proposed rule will not have a SEISNSE or conduct an IRFA. It does not specifically require agencies to determine whether or not the rule will have a SEISNSE. Therefore, EPA officials said that the agency never determines that a proposed rule will have a SEISNSE. The agency either certifies the rule will not have a SEISNSE or prepares an IRFA. EPA officials emphasized that preparing an IRFA does not mean that the agency has concluded that the rule will have a SEISNSE.

Previous Reports on the RFA and SBREFA

We have issued several reports in recent years on the implementation of the RFA and SBREFA.

- In our 1991 report on the RFA and small governments, we concluded that each of the four federal agencies we reviewed had a different

[4]These requirements are codified at 5 U.S.C. 609. The Occupational Safety and Health Administration within the Department of Labor is also required to convene advocacy review panels in these circumstances.

interpretation of key RFA provisions.[5] We said that the act allowed agencies to interpret when they believed their proposed regulations affected small governments. We recommended that Congress consider amending the RFA to require SBA to develop criteria regarding whether and how to conduct the required analyses.

- In our 1994 report on the RFA, we noted that the act required the SBA Chief Counsel for Advocacy to monitor agencies' compliance. However, we also said that one reason for agencies' lack of compliance with the RFA's requirements was that the act did not expressly authorize SBA to interpret key provisions in the statute and did not require SBA to develop criteria for agencies to follow in reviewing their rules.[6] We said that if Congress wanted to strengthen the implementation of the RFA, it should consider amending the act to (1) provide SBA with clearer authority and responsibility to interpret the RFA's provisions; and (2) require SBA, in consultation with OMB, to develop criteria as to whether and how federal agencies should conduct RFA analyses.
- In our 1998 report on the implementation of the small business advocacy review requirements in SBREFA, we said that the lack of clarity regarding whether EPA should have convened panels for two of its proposed rules was traceable to the lack of agreed-upon governmentwide criteria as to whether a rule has a SEISNSE.[7] We said that if Congress wished to clarify and strengthen the implementation of the RFA and SBREFA, it should consider (1) providing SBA or another entity with clearer authority and responsibility to interpret the RFA's provisions and (2) requiring SBA or some other entity to develop criteria defining a SEISNSE.
- In 1999, we noted a similar lack of clarity regarding the RFA's requirements for the review of existing rules under section 610 of the act, and we recommended that Congress and OIRA take action to clarify those issues.[8]

To date, Congress has not acted on any of our recommendations to clarify key terms in the RFA.

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[5] Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments (GAO/HRD-91-61, Jan. 11, 1991).

[6] Regulatory Flexibility Act: Status of Agencies' Compliance (GAO/GGD-94-105, Apr. 27, 1994). In this report, we noted that the SBA Chief Counsel for Advocacy had repeatedly considered EPA to be in compliance with the RFA.

[7] Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements (GAO/GGD-98-36, Mar. 18, 1998).

[8] Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary (GAO/GGD-99-55, Apr. 2, 1999).

EPA Program Offices

Although EPA has numerous headquarters and regional offices, its four major program offices issue most of the agency's regulations. Those offices are as follows:

- OPPTS, which develops national strategies for toxic substance control, promotes pollution prevention, and evaluates the safety of pesticides and chemicals;
- the Office of Air and Radiation, which oversees air and radiation protection activities;
- the Office of Solid Waste and Emergency Response, which provides policy, guidance, and direction for the land disposal of hazardous wastes, underground storage tanks, solid waste management, encouragement of innovative technologies, source reduction of wastes and the Superfund program; and
- the Office of Water, which is responsible for water quality activities including development of national programs, technical policies, and regulations relating to drinking water, water quality, ground water, pollution source standards, and the protection of wetlands, marine, and estuarine areas.

The TRI Program

Until October 1999, OPPTS was also primarily responsible for promoting the public's right to know about chemical risks.[9] One key element of this responsibility is the TRI program, which is a database created to inform the public about chemical hazards in their communities. TRI reporting is required by Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA),[10] which was enacted in response to serious chemical releases by plants in Bhopal, India, and West Virginia. Section 313 of the act generally requires facilities to report the amounts of various toxic chemicals that they release to the environment and requires EPA to make this information available to the public. EPCRA originally required that reports be filed by owners and operators of facilities that (1) had 10 or more full-time employees; (2) were in Standard Industrial Classification (SIC) codes 20 through 39 (manufacturing);[11] and (3) manufactured,

[9]In October 1999, this responsibility was given to EPA's new Office of Environmental Information. However, OPPTS officials and staff remained involved in the proposed lead rule. To simplify the presentation of this report, some of the actions taken after October 1999 by this new Office in relation to the proposed lead rule are described as OPPTS actions.

[10]42 U.S.C. 11001-11050, 11023. Reporting is also required under the Pollution Prevention Act of 1990 (42 U.S.C. 13101-13109, 13106), which added reporting requirements to EPCRA's reporting requirements beginning in 1991.

[11]The SIC code classification system was used by the federal and state governments, trade associations, and research organizations. On April 9, 1997, OMB decided to replace the SIC code system with the North American Industry Classification System. However, the TRI program still uses the SIC code

processed, or otherwise used any chemical listed in the act in quantities greater than the established thresholds in the course of a calendar year. EPCRA gave EPA the authority to add other industries that have to report, to add chemicals for which reports have to be filed, and to change reporting thresholds. Starting with reporting year 1998, EPA added seven nonmanufacturing industries to the program's coverage.[12] Previously, EPA had also added nearly 300 toxic substances to the more than 300 that were originally listed in EPCRA.[13]

The specific industries covered by the TRI program are identified by SIC code. In the SIC code system, major groups of industries are coded with 2 digits, and additional digits are used hierarchically to classify different industries within the major group. For example, SIC code 36 is for manufacturers of "electronic and other electrical equipment and components," which includes all companies in SIC codes starting with 36, such as SIC code 367 "electronic components and accessories." Correspondingly, SIC code 367 contains all companies in the more narrowly defined SIC code 3672 for "printed circuit boards."

The TRI report, known as a Form R, must be at least five pages in length, and consists of both facility identification information and chemical-specific information. The chemical-specific information that must be included in the report includes (1) the quantity of the chemical entering each environmental medium on-site (e.g., fugitive or nonpoint air emissions, discharges to each receiving stream or water body, underground injection on-site into wells, and disposing to land on-site); (2) transfers of the chemical in wastes to off-site locations (e.g., publicly owned treatment works); (3) on-site treatment methods and efficiency (e.g., waste treatment methods sequence and range of influent concentration); and (4) source reduction and recycling activities (e.g., the quantity released, used for energy recovery, recycled on-site, and treated off-site). Facilities must keep a copy of each report filed for at least 3 years from the date of submission and must also maintain those documents, calculations, worksheets, and other forms upon which they

categories because EPCRA specifically references SIC codes 20 through 39. All of the data in this report use the 1987 SIC code definitions.

[12]62 Fed. Reg. 23834 (1997). The added industries were metal mining (SIC 10), coal mining (SIC 12), electric services (SIC 4911), electric and other services combined (SIC 4931), combination utilities (not elsewhere classified) (SIC 4939), refuse systems (SIC 4953), chemicals and allied products (not elsewhere classified) (SIC 5169), petroleum bulk plants and terminals (SIC 5171), and solvent recovery services (SIC 7389). The TRI program covers only certain types of facilities in some of these SIC codes.

[13]59 Fed. Reg. 61432 (1994).

relied to gather information for prior reports. EPA may conduct data quality reviews of Form R submissions, and the agency said that a "partial list" of records, organized by year, that a facility should maintain includes

- previous years' reports,
- engineering calculations and worksheets,
- purchase records from suppliers,
- inventory data,
- monitoring records and flowmeter data,
- pretreatment reports filed with local governments,
- invoices from waste management companies,
- manufacturers' estimates of treatment efficiencies,
- process diagrams that indicate emissions and other releases,
- EPA permits and monitoring reports,
- hazardous waste generator's reports and manifests under the Resource Conservation and Recovery Act, and
- records for those EPCRA Section 313 chemicals for which they did not file TRI reports.

However, section 313(b) of EPCRA states that facilities "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." In 1994, EPA established a less burdensome substitute for reporting Form R information based on an alternate threshold for facilities with low amounts of EPCRA Section 313 chemicals in waste. However, EPA said that the Form A was not applicable to the proposed lead rule.

Objectives, Scope, and Methodology

The first objective of our review was to describe the guidance that OPPTS and EPA's other major program offices have used during the past 10 years to determine whether their proposed rules could be certified as not having a SEISNSE. To address this objective, we obtained and reviewed the three sets of guidance documents that EPA had in effect at different times during those 10 years. We also obtained explanations from EPA officials of how the guidance documents were used, why the guidance was changed, and whether the current guidance would be changed.

Our second objective was to compare the rate at which OPPTS certified that its substantive proposed rules published during calendar years 1994 through 1999 would not have a SEISNSE with the rates in EPA's other major program offices. To address this objective, we first developed a list of proposed rules published by each of the four major program offices from January 1, 1994, through December 31, 1999. We identified the

proposed rules for this list by searching the LEXIS-NEXIS database of the Federal Register for any notices involving proposed rules issued by these program offices during this period. EPA officials also identified some proposed rules that had not been identified by LEXIS-NEXIS. We excluded from our list of proposed rules a number of actions that were not substantive proposed rules. For example, we excluded advance notices of proposed rulemakings and notices that primarily announced meetings or the availability of data. We included proposals to add, streamline, or amend existing regulations and earlier proposed rules. We then reviewed the content of the Federal Register notices for each of the substantive proposed rules that we identified for the 1994 through 1999 period to determine whether the relevant EPA program office certified the rule as not having a SEISNSE. We considered a rule to be certified when the language in the notice either specifically stated that the program office was certifying the rule or more generally indicated that the rule would not have a SEISNSE.

Our third objective had multiple parts: (1) to describe key aspects of the methodology that OPPTS used in the economic analysis for the proposed lead rule that may have contributed to the Office's conclusion that the rule would not have a SEISNSE; (2) to determine whether and, if so, how OPPTS had changed its economic analysis since publication of the rule; and (3) to determine whether additional data or analysis could have yielded a different conclusion about the rule's impact on small entities. To address the first part of this objective, we reviewed the economic analysis that OPPTS prepared for the proposed lead rule and discussed the analysis with OPPTS officials and staff. To address the second part of this objective, we interviewed these officials and staff to determine how the economic analysis had changed since the publication of the proposed rule and obtained draft copies of documents summarizing those changes. However, neither OPPTS nor OIRA officials would provide us with the draft final rule or the revised economic analysis that OPPTS submitted to OIRA on July 13, 2000. An OIRA official cited section 6(b)(4)(D) of Executive Order 12866, which says that OIRA must make available to the public all documents exchanged between OIRA and the agency "(a)fter the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action." To address the third part of this objective, we obtained and analyzed unpublished data from the 1997 Census of Manufactures and reviewed OPPTS' initial economic analysis of the proposed lead rule and a summary of the draft revised economic analysis. The specific methodology and assumptions that we used in this part of our review are described later in this report.

We conducted this review from November 1999 until August 2000 in accordance with generally accepted government auditing standards. We provided a draft of this report to the OMB Director and the EPA Administrator for their review and comments. OMB said they had no comments on the report. EPA's comments are discussed at the end of this letter and reproduced in appendix I.

EPA's Guidance for RFA Certification Have Changed Over Time

Under the RFA, federal agencies have broad discretion regarding how key terms in the act should be defined and how certification decisions should be made. OPPTS and the other EPA program offices have adopted three very different sets of guidance documents during the past 10 years to determine if their proposed rules could be certified as not having a SEISNSE. The current guidance was implemented in 1996 because of the enactment of SBREFA. The guidance focuses on the magnitude of a rule's impact (e.g., estimated annual compliance costs as a percentage of estimated annual revenues) and the number and percent of affected small entities that are expected to experience that impact. However, this guidance (and its predecessors) gives agency personnel broad discretion in how it should be applied.

EPA Has Used Three Different Sets of RFA Guidance Documents

The RFA does not define what Congress meant by the terms "significant economic impact" or "substantial number of small entities" and does not give SBA, OMB, or any other entity the authority or responsibility to define these terms governmentwide. Neither does the act prescribe how federal agencies should determine whether a proposed or final rule could be certified as not having a SEISNSE. Subsection 605(b) of the act simply says that any certification must be published in the Federal Register with the rule "along with a statement providing the factual basis for such certification." Therefore, agencies have broad discretion to determine how these terms should be defined and how they should reach certification decisions. EPA has used that discretion to develop three different sets of RFA guidance documents.

EPA's 1982 RFA Guidance Document

EPA issued its first guidance document for assessing whether a proposed rule could be certified as not having a SEISNSE in 1982—the year after the RFA took effect. According to the guidance, a proposed rule was to be considered to have a "significant economic impact" on small entities whenever any of the following guidelines were satisfied:

- The annual cost of complying with the proposed rule would increase the total costs of production by more than 5 percent.

- The annual cost of complying with the proposed rule as a percentage of annual sales for small entities is at least 10 percent higher than compliance costs as a percentage of sales for large entities.
- Capital costs of compliance with the proposed rule represent a significant portion of capital available to small entities, considering internal cash flow plus external financing capabilities.
- The requirements of the proposed rule are likely to result in closures of small entities.

The 1982 guidance document generally defined "a substantial number of small entities" as more than 20 percent of all small entities affected by the proposed rule. Therefore, using the first of the "significant economic impact" guidelines above, if the relevant program office expected that a proposed rule would raise the cost of production by more than 5 percent for more than 20 percent of the small entities affected by the rule, the program office should not certify the rule and should conduct an IRFA.

However, the 1982 guidance document gave the program offices substantial discretion in how these guidelines should be applied. For example, the guidance document said that the program office could consider other, similar definitions for the term "significant economic impact" if the above guidelines were not appropriate. It also said that the program office should "use its best judgment on a case-by-case basis" in deciding whether to certify proposed rules that do not strictly meet the conditions shown in the guidance document.

EPA's 1992 "Any/Any" RFA Guidance Document

This flexibility notwithstanding, EPA said that applying this guidance was sometimes difficult and time consuming. Therefore, in April 1992, EPA issued a new guidance document instructing agency program offices that they should prepare an IRFA for any draft rule that the agency expected to have any impact on any small entities. According to EPA, the change to what was later referred to as the agency's "any/any" policy was intended to shift agency resources from determining whether a regulatory flexibility analysis was required to "the more productive consideration of regulatory options for small entities that are subject to the rule."

The 1992 guidance document stated that program offices "have wide latitude in determining the level of analysis that is appropriate for individual rulemakings." They also said that the offices could use factors, such as "the quality and quantity of available data" and "the severity of a rule's anticipated impacts on small entities," in deciding how much effort they needed to expend on the analysis. In addition, the 1992 guidance gave

program offices the option of continuing to follow the 1982 guidance for rulemakings that had been initiated before the 1992 guidance was issued.

EPA's 1997 and 1999 RFA Guidance Documents

When the advocacy review panel requirements in SBREFA became effective in June 1996, EPA instituted a new RFA policy that used the magnitude of the proposed rule's economic impact (e.g., estimated annual cost of compliance as a percentage of estimated annual revenues) and the number and percent of small entities expected to experience that impact to help the program offices determine whether rules could be certified. The new procedures were published as written agency guidance in 1997.

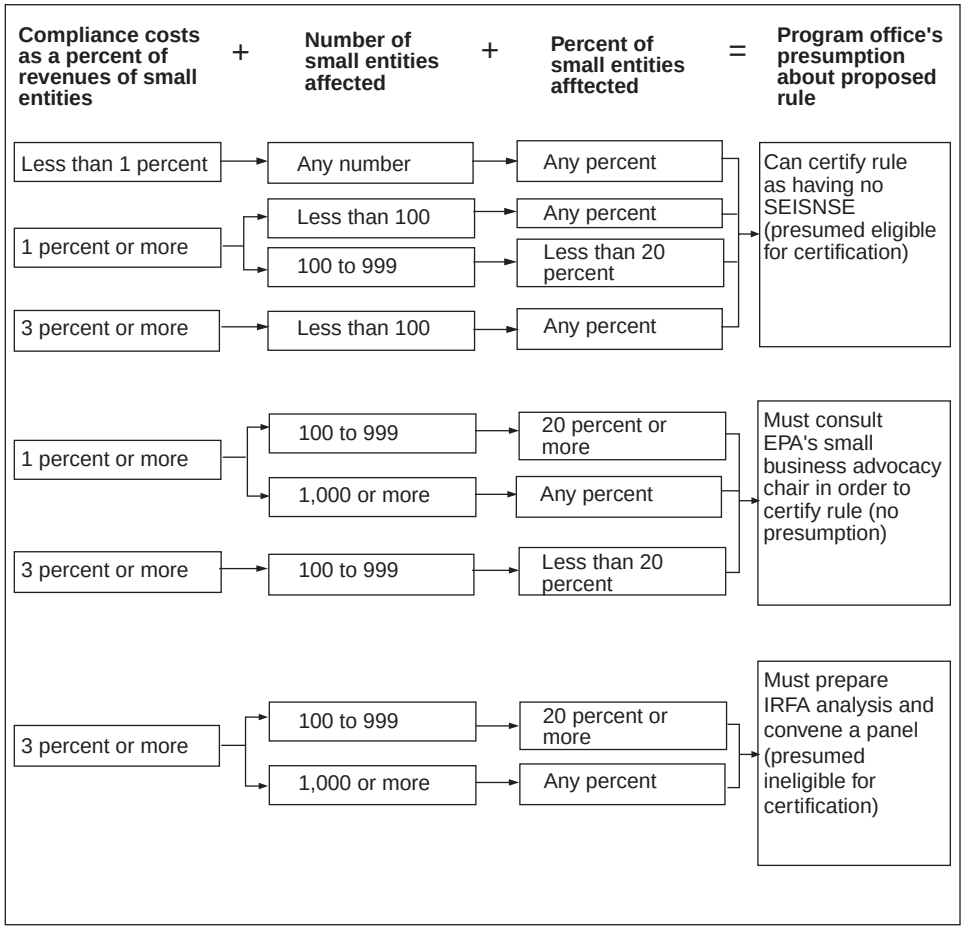
According to EPA officials, the agency changed its RFA guidance because the SBREFA requirement to convene an advocacy review panel for any proposed rule that was not certified made the continuation of the any/any policy too costly and impractical. One EPA official also said the SBREFA provision allowing judicial review of regulatory flexibility analyses meant that EPA would have to make sure that all of its IRFAs could withstand judicial scrutiny. Therefore, he said, EPA no longer had the option of doing a limited analysis on rules that it believed would have a minimal impact on small entities. The 1997 guidance document stated that the new approach would allow EPA to "manage its scarce resources such that the Agency can continue considering the potential small entity impacts of all its rules while preparing full regulatory flexibility analyses for those rules warranting such analyses under the RFA."

The 1997 guidance document was updated in 1999, but the numerical guidelines relating to the certification of rules as not having a SEISNSE were essentially unchanged**.** However, the 1999 guidance document emphasized that it "is not a binding agency procedural rule. In determining and mitigating impacts on small entities, we anticipate that there will be many situations in which agency staff and management must exercise considerable judgment." It also explicitly continued EPA's policy "that program offices should assess the direct impact of every rule on small entities and minimize any adverse impact to the extent feasible, regardless of the magnitude of the impact or the number of small entities affected." Nevertheless, the guidance document said that it was intended to provide agency staff and management with an "analytic and sequential structure that should be sufficient for most covered rulemakings."

As figure 1 illustrates, EPA's current guidance identifies different mixes of economic impacts and the number and percent of affected small entities. All of these factors are intended to help program offices determine when to certify a rule as not having a SEISNSE, when not to certify a rule, and

when to seek further guidance from EPA's small business advocacy chair (who is responsible for implementing the agency's SBREFA small business advocacy panel requirements).

Figure 1: EPA Numerical Guidelines to Help Determine Whether a Proposed Rule Has a SEISNSE



Source: GAO analysis of EPA's 1999 Revised Interim Guidance on the RFA as amended by SBREFA.

To illustrate how these numerical guidelines are applied, if a proposed rule is expected to affect 1,000 small entities, and for 200 of those small entities the rule's compliance costs represent 3 percent of their annual sales, the program office should presume that the rule cannot be certified. On the other hand, if the rule affects 10,000 small entities but their compliance costs never rise above 1 percent of their annual revenues, the guidance

indicates that the program office should presume that the rule can be certified as not having a SEISNSE.

Guidance Document Provides Discretion in How Numerical Guidelines Should be Applied

Although EPA's current guidance document provides specific numerical guidelines that program offices should use in determining whether a proposed rule should be certified under the RFA, the guidance also gives agency program offices substantial discretion regarding their application. For example, the guidance indicates that program offices should consider not certifying a rule if "the extent of the impact (measured in quantitative or qualitative terms) is particularly severe, even though the number of affected small entities totals fewer than 100 or 20% of all affected small entities." The guidance also says that "as the number of small entities that will be affected by a rule by more than 1% of sales or revenues approaches 1000 in number, the substantial number guidelines of 20% of affected small entities may become less relevant in determining whether a regulatory flexibility analysis or a certification should be prepared."

EPA's RFA Guidance May Be Revised Again

An EPA official told us that the agency is currently reevaluating its RFA guidance document because it is concerned about how the numerical guidelines could be viewed outside of the agency. For example, he said, the guidance makes it appear that EPA believes a rule that would cost 99 small entities 100 percent of their annual sales would not have a SEISNSE. He said that EPA is examining the feasibility of using compliance costs as a percentage of profit margins (instead of annual sales) to measure economic impacts on small businesses. However, he noted that EPA has not used profit margins to measure the economic impacts of its rules in the past because valid data on companies' profit margins are often not readily available.

RFA Certification Rates Increased After SBREFA Implementation

OPPTS certified 86 percent of the substantive proposed rules that it published during calendar years 1994 through 1999—about the same rate of rule certification as EPA's three other major program offices. The RFA certification rate in OPPTS and in each of the three other major program offices increased after the implementation of SBREFA in 1996. By the end of 1999, OPPTS and one other program office had certified all of their post-SBREFA proposed rules as not having a SEISNSE. Two other EPA program offices used the discretion afforded them in the guidance and did not certify at least four proposed rules published during this period that the numerical guidelines in EPA's guidance document would have allowed them to certify.

All EPA Program Offices Certified Most of Their Proposed Rules

EPA's four major program offices published at least 654 substantive proposed rules in the Federal Register during calendar years 1994 through 1999. Of these, 249 (38 percent) were tolerance actions or significant new use rules (SNURs) issued by OPPTS. Tolerance actions are rules that establish maximum levels for the amount of a pesticide residue that is allowed on food or feed crops, or establish an exemption from the statutory requirement for a tolerance. SNURs require anyone who intends to manufacture, import, or process a chemical substance in a manner designated in the SNUR as a "significant new use" to notify EPA before beginning those actions. OPPTS said that these types of rules are unlikely to have adverse economic impacts on entities (and may have positive economic impacts) because tolerance actions allow, instead of prohibit, the use of pesticides, and SNURs apply only when and if someone decides to engage in a significant new use. Both of these types of actions are issued on a chemical-by-chemical basis or for groups of chemicals. Because the impacts of each type of action are basically the same from chemical to chemical, EPA conducted a general analysis for each type and established, in consultation with SBA's Office of Advocacy, a generic certification for both types of actions.[14]

We excluded these 249 tolerance actions and SNURs from our analysis because we wanted to include only proposed rules that possibly could have had a SEISNSE. We also excluded nine rules from the Office of Solid Waste that proposed changes to EPA's National Priorities List for Uncontrolled Hazardous Waste Sites. EPA said that any economic impact that results from these rules would occur only indirectly through enforcement and cost-recovery actions, and case law indicates that the RFA applies only to direct regulatory impacts.[15] Therefore, our analysis focused on the remaining 396 substantive proposed rules that the 4 major program offices published during calendar years 1994 though 1999.

Table 1 shows the number and percent of these substantive rules that EPA's four major program offices proposed and certified between January 1, 1994, and the implementation of SBREFA (June 28, 1996); between implementation and December 31, 1999; and for the full 1994 through 1999 period.

[14]For the blanket certifications for tolerance actions and SNURs, see 46 Fed. Reg. 24950 (1981) and 62 Fed. Reg. 29684 (1997), respectively.

[15]For a discussion of these cases, see Clean Water Act: Proposed Revisions to EPA Regulations to Clean Up Polluted Waters (GAO/RCED-00-206R, June 21, 2000).

Table 1: Number and percentage of proposed rules certified as having no SEISNSE by four EPA program offices between 1994 and 1999

	Pre-SBREFA (Jan. 1, 1994 - June 27, 1996)			Post-SBREFA (June 28, 1996 - Dec. 31, 1999)			Total (Jan. 1, 1994 – Dec. 31, 1999)		
	Number of rules		Percentage of rules	Number of rules		Percentage of rules	Number of rules		Percentage of rules
EPA program office	Proposed	Certified	certified	Proposed	Certified	certified	Proposed	Certified	certified
OPPTS	30	22	73 %	26	26	100 %	56	48	86 %
Office of Air and Radiation	82	70	85	151	147	97	233	217	93
Office of Solid Waste	27	20	74	21	21	100	48	41	85
Office of Water	19	12	63	40	35	88	59	47	80
Total	**158**	**124**	**78**	**238**	**229**	**96**	**396**	**353**	**89**

Source: GAO analysis of EPA's proposed rules for calendar years 1994 through 1999.

Overall, the four program offices certified the vast majority (89 percent) of the proposed rules that they published during this period. OPPTS' rate of RFA certification throughout this period (86 percent) was within the range of certification rates in the three other EPA program offices (80 percent to 93 percent). Notably, the rate of RFA certification in all four program offices was substantially higher during the post-SBREFA period (96 percent) than before the act took effect (78 percent).[16] OPPTS and the Office of Solid Waste certified all of their proposed rules after the implementation of SBREFA. EPA officials told us that the change in the agency's certification guidelines (from the "any/any" policy to the policy adopted in 1996) led to the increase in the frequency of RFA certification from what they described as the "artificially low" levels during the pre-SBREFA period.

EPA Program Offices Could Have Certified More Post-SBREFA Rules

Two of EPA's program offices did not certify (i.e., they conducted an IRFA and held an advocacy review panel) 9 of the 191 proposed rules that they published during the post-SBREFA period of our review.[17] The Office of Water issued five of these nine rules, and the Office of Air and Radiation issued four of the rules. For at least 4 of these 9 rules, the relevant program

[16]Our review of the NPRMs indicated that the program offices made RFA determinations for at least 30 of the proposed rules published before SBREFA using EPA's 1982 guidelines rather than the 1992 guidelines. As noted previously, EPA's 1992 guidelines expressly allowed the use of this earlier guidance in rules that were under development before 1992.

[17]The Office of Air and Radiation and the Office of Water convened other advocacy review panels during this period but had either not published a proposed rule by the end of 1999 or certified that the rules would not have a SEISNSE.

offices estimated that fewer than 100 small entities would experience compliance costs of 1 or 3 percent of their annual revenues.[18]

- The Office of Air and Radiation published two proposed rules on October 21, 1998, dealing with the transport of ozone.[19] The Office estimated that one of these rules would impose at least a 1 percent economic impact on 42 of the 153 affected small entities, and 22 small entities would experience economic impacts of greater than 3 percent. The Office of Air and Radiation estimated that the other ozone transport rule would impose economic impacts of at least 1 percent on 39 of the 145 affected small entities, and 22 would experience greater than 3 percent economic impacts.
- The Office of Water published a proposed rule on June 25, 1998, dealing with transportation equipment cleaning.[20] The Office estimated that the rule would impose at least a 1 percent economic impact on 75 of the 87 affected small entities, and 64 of these small entities would experience at least a 3 percent economic impact. The Office of Water published another rule on January 13, 1999, dealing with centralized waste treatment.[21] The Office estimated that the rule would impose at least a 1 percent economic impact on 45 of the 63 affected small entities, and 23 of them would experience at least a 3-percent impact.

Applying EPA's numerical guidelines (1-percent or 3-percent impacts on fewer than 100 small entities) to each of these rules, the Office of Air and Radiation and the Office of Water could have presumed that the rules would not have a SEISNSE. Instead, the program offices used the discretion afforded them in the guidance documents, decided not to certify the rules, prepared IRFAs for the rules, and convened advocacy review panels. The preambles to the proposed rules did not indicate why these offices decided not to certify the rules, and the RFA does not require the offices to provide these explanations. However, EPA officials told us during this review that in making their certification decisions, the offices considered factors other than just the number of companies expected to

[18]One of the other five proposed rules met the numerical guidelines for being presumed ineligible for certification, and two other rules had impacts that fell into the guidelines' middle category—no presumption about whether they should be certified as not having a SEISNSE. The Federal Register notices for two rules did not contain enough information about the impacts of the proposed rules for us to determine whether the rules met the numerical guidelines for being presumed eligible for certification.

[19]63 Fed. Reg. 56292 (1998) and 63 Fed. Reg. 56394 (1998).

[20]63 Fed. Reg. 34686 (1998).

[21]64 Fed. Reg. 2280 (1999).

experience 1 percent and 3 percent economic impacts. For example, in the centralized waste treatment rule, EPA said that the range of impacts ran so high above 3 percent for a number of firms that the office considered the size of the impact more important than just the number of small firms affected.

Different Assumptions, Data, and Analysis Yield Different Estimates of Lead Rule's Effects

OPPTS made a number of assumptions in the original economic analysis for the proposed lead rule. As a result of those assumptions, OPPTS estimated that small manufacturers had annual revenues of $4 million. These and other assumptions and methods led OPPTS to conclude that although the rule would affect more than 5,600 small businesses, it would not have a SEISNSE. OPPTS recently revised some of the assumptions in its economic analysis, estimated that the rule would affect more than 8,600 small companies, and said that as many as 464 of them would experience first-year compliance costs of between 1 and 3 percent of their annual revenues. Nevertheless, OPPTS again concluded that the rule would not have a SEISNSE. Using data that we obtained from the Bureau of the Census, we estimated that as many as 1,098 additional small manufacturing companies could experience compliance costs of at least 1 percent of their annual revenues, and as many as 78 small companies could experience a 3 percent economic impact. If OPPTS had used this analytic approach and applied the flexibility afforded in EPA's RFA guidance, it could have chosen not to certify the rule and conducted an advocacy review panel. However, the Office's initial and draft revised analyses and the conclusions that it based on those studies were within the discretion permitted agencies under the RFA and the EPA guidance.

Development of the Proposed Lead Rule

In April 1998, the Vice President announced three initiatives designed to expand the amount of information available to the public about the health effects of chemicals. In one of those initiatives, he said that some chemicals accumulate in our bodies and that some substances linked to significant public health concerns were not subject to TRI reporting or are reported only at levels far exceeding those linked to health effects. Therefore, he said that EPA would review these "persistent bioaccumulative toxics" (PBTs) and determine if they should be subject to TRI reporting or lower reporting thresholds. The Vice President said any regulatory changes would be finalized by December 1999 and would be "fashioned in a way that minimizes cost and other burdens on business."

In January 1999, OPPTS published an NPRM adding a number of PBT chemicals to the TRI program and lowering the reporting thresholds for

other PBT chemicals already covered by the TRI program.[22] According to OPPTS, the rule had an expedited development schedule in order to meet the Vice President's committed final issuance date. OPPTS said that it received more than 35,000 public comments on its January 1999 PBT proposal, many of which requested that the Office include lead and lead compounds as PBT chemicals to be covered by the rule.

Rather than delay the issuance of the final PBT rule, OPPTS decided to publish a separate proposed rule covering lead and lead compounds. At the time of the proposal, a facility had to report under the TRI program if it manufactured or processed 25,000 pounds of lead, or if it "otherwise used" 10,000 pounds of lead. The NPRM, published in August 1999, proposed lowering the TRI reporting threshold for lead and lead compounds to 10 pounds. During the development of the rule OPPTS also considered reporting thresholds of 1,000 pounds, 100 pounds, and 1 pound.

A number of the public comments on the proposed lead rule questioned OPPTS' conclusion that the rule would not have a SEISNSE. On November 15, 1999, OPPTS announced three public meetings to obtain comments on issues relating to the proposed lead rule and requested comments on specific issues related to its RFA certification. OPPTS held those public meetings in November and December 1999, at which several of the participants questioned the Office's conclusions regarding the effect of the rule on small entities. On July 13, 2000, OPPTS sent the draft final lead rule and a revised economic analysis to OIRA for final review under Executive Order 12866. OPPTS officials told us that they hoped to publish the final rule in the Federal Register by the end of October 2000.

OPPTS' Economic Analysis for the Proposed Lead Rule

The methodology that OPPTS used to conclude that the proposed lead rule would not have a SEISNSE was extremely complicated, involving numerous steps and a variety of assumptions within each step. However, the overall process essentially involved (1) estimating the number of companies that would have to file new TRI reports at the new 10 pound reporting threshold, (2) estimating the cost of complying with the rule in the first year and in subsequent years, and (3) estimating the revenues of the companies that would have to file the new reports.

Estimating the Number of Companies Filing New Reports

Data are generally not available on the amount of lead and lead compounds that individual facilities and companies manufacture, process, or otherwise use each year. Therefore, OPPTS used six different methods

[22]64 Fed. Reg. 688 (1999). OPPTS published the final PBT rule on October 29, 1999, at 64 Fed. Reg. 58666 (1999).

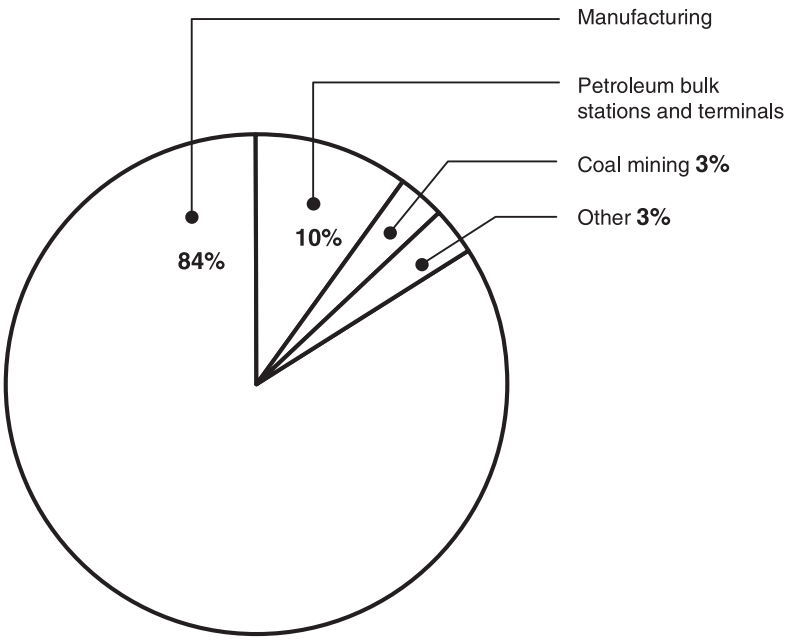
to develop SIC code-specific estimates of the number of facilities and companies that would have to file additional TRI reports for lead and lead compounds. Different methods were used in different industries. For example, in the "air emission factor" method, OPPTS used lead and lead compound air emissions as a proxy for minimum lead and lead compound use in the pulp mill, asphalt paving, iron foundry, and primary and secondary metals smelting industries.

Each of these estimation methods involved a number of assumptions. For example, in many of the methods, OPPTS used the number of employees to approximate a distribution of lead use within an industry. OPPTS also assumed that lead use was proportional to the cost of materials or the value of shipments and that certain facilities in each industry manufacture, process, or otherwise use lead in their operations. In three of the six methods, OPPTS used lead emissions as a proxy for minimum lead use—a process that OPPTS said in the economic analysis underestimates the total amount of lead used by a facility. However, OPPTS told us during this review that in practice, this method generally does not result in underestimates of the number of facilities that will use 10 pounds of lead. They said that affected facilities generally appear to emit more than 10 pounds of lead, so their lead use would be above that level.

As a result of these methods and assumptions, OPPTS estimated that 15,043 facilities from 27 SIC codes and SIC code groupings would have to file additional TRI reports at the proposed 10 pound reporting threshold—a nearly 800-percent increase from the 1,902 facilities that reported for lead and lead compounds in 1998 at the 25,000 and 10,000-pound thresholds.[23] OPPTS also estimated that these 15,043 facilities were in 8,175 parent companies, of which 6,874 (84 percent) were manufacturers (SIC codes 20 through 39). (See fig. 2.) The other 1,301 companies that OPPTS said would be affected by the rule were in 7 other SIC codes.

[23]Twenty-four individual SIC codes were at the 2, 3, and 4-digit levels, and three SIC code groupings were for coal, oil, and wood-fired combustion in SIC codes 20 through 39.

Figure 2: Most of the Parent Companies Affected by the Proposed Lead Rule Were Manufacturers



Note 1: OPPTS estimated that a total of 8,175 parent companies would be affected by the proposed lead rule at the 10 pound reporting threshold.

Note 2: The petroleum bulk stations and terminals sector is SIC code 5171, and coal mining is SIC code 12. "Other" includes electric services (SIC code 4911), electric and other services combined (SIC code 4931), combination utilities not elsewhere classified (SIC code 4939), refuse systems (SIC code 4953), and business services not elsewhere classified (SIC code 7389) .

Source: GAO analysis.

OPPTS also estimated that 5,620 (69 percent) of the 8,175 affected companies were small companies. Several of the public comments that OPPTS received on the proposed rule maintained that the Office's estimates of the number of affected facilities and companies, and the number of small entities affected, were too low.

In addition to the 15,043 new TRI reports that OPPTS estimated would come from companies in these 27 SIC codes and code groupings, the Office identified 42 other 4-digit SIC codes in the economic analysis that it said might also be affected by the proposed rule. Forty of these 42 SIC codes each had more than 5 facilities reporting lead or lead compounds at the current thresholds, which OPPTS said "may indicate that additional facilities in these SIC codes use lead or lead compounds at levels below current thresholds but above the proposed thresholds."[24] However, OPPTS

[24]The other two SIC codes were listed on the basis of lead consumption data from the U.S. Geological Survey (SIC code 3443—fabricated plate work) or because of the sector's potential for processing chemical products that contain lead as a trace constituent (SIC code 5169—wholesale distribution of chemicals).

did not estimate the number of additional lead TRI reports that it expected to be filed from facilities in these 42 SIC codes because of "lack of data on lead consumption or emissions at the facility and sector level."

Estimating the Cost of Complying With the Proposed Rule

OPPTS developed its estimate of the average annual cost of filing a TRI report for lead and lead compounds by multiplying an estimate of the average number of hours needed to complete the form (111 hours in the first year for new TRI filers) times an estimated average hourly wage rate (about $69 per hour across managerial, technical, and clerical occupational categories).[25] As a result, OPPTS estimated that first-year compliance costs for small manufacturers who had never filed a TRI report would be about $7,500.[26] OPPTS estimated that first-year reporting costs for companies currently filing TRI reports for other substances would be about $5,200, and that lead reporting costs in subsequent years would be about $3,600.

Estimating Company Revenues

OPPTS used a variety of methods and assumptions to estimate the annual revenues of the companies that would have to file the new TRI reports for lead and lead compounds. However, three of these methods and assumptions appeared to be key to this portion of the analysis and were the subject of several of the public comments.[27]

- OPPTS assumed that small manufacturing companies filing their first TRI reports under the proposed lead rule would be similar in terms of revenues and employment to small manufacturing companies that already filed TRI reports under other rules. OPPTS officials said that it used this assumption because (1) many small businesses that were expected to file under the proposed lead rule already filed other TRI reports; and (2) small businesses that did not already file TRI reports were likely to come from capital-intensive industries, which were the types of industries that already filed TRI reports. Therefore, OPPTS constructed revenue profiles for these new filers using revenue data from parent companies of existing filers who were manufacturers. Some of the comments on the proposed rule

[25]OPPTS estimated that for first time TRI filers, the paperwork burden associated with the first year of reporting for the PBT rule would be nearly 140 hours.

[26]In the original economic analysis for the proposed lead rule, OPPTS estimated small manufacturers' average first-year compliance costs at about $7,400, assuming that parent companies have some facilities that are current filers and some that are first-time filers. In its draft revised analysis, OPPTS estimated those costs at $7,700, assuming that the parent company has one facility that is a first-time filer. To simplify the presentation of this report, we used a uniform $7,500 reporting figure.

[27]OPPTS used similar assumptions in its economic analysis of the PBT rule and in earlier TRI rules. However, EPA officials said that the proposed lead rule was the first time EPA received significant adverse comments on these issues.

indicated that businesses that would have to report under the new 10-pound threshold were likely to be smaller than those filing for lead and other substances at the 25,000 and 10,000 pound reporting thresholds. As a result, they suggested that OPPTS had overestimated the annual revenues of new filers under the proposed lead rule and that OPPTS' certification that the rule would not have a SEISNSE may be incorrect.

- As noted in figure 2, OPPTS estimated that 84 percent of all companies affected by the proposed lead rule would be manufacturers (SIC codes 20-39), with the other 16 percent representing seven nonmanufacturing industries. Although OPPTS estimated the impact of the rule on each of these seven nonmanufacturing groups separately, it did not examine whether the rule would have different impacts on the different types of manufacturers that were expected to comprise the bulk of new filers. Some of the comments that were submitted to OPPTS on the proposed rule said that the various industries within the 20 major groups in the manufacturing sector are unrelated in most aspects and, therefore, should not have been analyzed as a group. Doing so, they said, may mask variation in small business impacts within the manufacturing industries.
- OPPTS modeled the revenues of affected small businesses on the basis of revenue quartiles for the manufacturing industries. To do so, OPPTS first arrayed from lowest to highest the revenues of all the small manufacturing companies currently filing TRI reports. It then selected the revenues of companies at the 25th, 50th, and 75th percentiles to represent the revenues of companies in the lowest third, middle third, and highest third revenue level, respectively. OPPTS officials said that prior economic analyses had used only one revenue level—averages or medians—to represent the revenues of expected TRI filers, and using three revenue levels was intended to better reflect the variation of revenues in the group. Nevertheless, in the November 15, 1999, announcement of the public meetings, OPPTS specifically asked for comments on whether the 25th revenue quartile was an appropriate revenue level for considering the potential impacts on the smallest of the small businesses affected by the proposed rule.

As a result of these and other methods and assumptions, OPPTS estimated that small manufacturing companies filing new TRI reports for lead would have annual revenues of $4 million. To determine whether the economic impact of the proposed lead rule on small businesses was significant, OPPTS divided the average annual cost of filing a TRI report (e.g., about $7,500 for first-time TRI filers in the manufacturing sector) by the estimated annual revenue level of filers (e.g., $4 million for the smallest manufacturers). The results of these calculations (0.2 percent for small manufacturers) caused OPPTS to conclude that no small entities would

experience a 1 percent economic impact from the rule. Using this information in concert with EPA's RFA guidance, OPPTS certified the rule as not having a SEISNSE.

OPPTS' Draft Revised Economic Analysis for the Lead Rule

OPPTS revised its economic analysis for the proposed lead rule earlier this year in response to the concerns raised in the public comments. In June 2000, we obtained a summary of the changes that OPPTS made in a draft of the revised analysis and a summary of the results of the draft revised analysis. On July 13, 2000, OPPTS sent the draft final lead rule and the revised economic analysis to OIRA for final review. OPPTS officials said they could not provide us with a copy of the economic analysis that they sent to OIRA because of restrictions on the distribution of documents related to a rule undergoing final review. OIRA officials also said that, under Executive Order 12866, they could not provide us with a copy of the revised economic analysis until the final rule was published in the Federal Register. OPPTS officials said that the results of the analysis that they provided to OIRA were only marginally different from the summary that they provided to us, but they cautioned that the results may change due to OIRA's review.

OPPTS Changed Key Assumptions to Estimate Companies' Annual Revenues

According to the summary of the draft revised analysis, OPPTS changed its analytic approach in a number of ways. For example, to determine the number of affected facilities, OPPTS contacted more trade organizations and potentially affected businesses and used additional information sources that had been identified as a result of public comments received on the proposed rule.

OPPTS also changed several of the key assumptions that it used in the initial analysis to estimate the annual revenues of filers. Those changes included the following:

- OPPTS did not assume that new filers under the lead rule would be similar to current TRI filers in terms of revenues and employment. Instead, OPPTS used the revenues of companies that did not already file under the TRI program to characterize the revenues of small manufacturing companies that would be required to file a TRI report for the first time under the proposed lead rule.
- OPPTS examined whether the rule would have different impacts on different types of manufacturers. Specifically, OPPTS developed revenue profiles for each of the 20 2-digit SIC code groupings within the manufacturing category (SIC codes 20 through 39) and used those SIC code-specific values to estimate the rule's impact.

- OPPTS used more revenue levels from the population of representative small entities to characterize the revenues of small manufacturing companies that will have to file under the lead rule. For the draft revised analysis, OPPTS used every 10th percentile level (10th through 90th) and the 95th percentile to represent 10 different levels of revenues. For example, it used the revenues at the 10th percentile to represent the revenues of the bottom 10 percent of the companies expected to file.

  Changes in these and other methods and assumptions resulted in very different data being used in the revised economic analysis. As previously noted, in the original economic analysis, OPPTS estimated that the smallest manufacturers (represented by companies at the 25th revenue percentile of current small manufacturing TRI reporters) had annual revenues of $4 million. However, as table 2 illustrates, revenues of small manufacturing companies not currently reporting were quite different from the revenues of those companies currently reporting at the 25th revenue percentile, and even more different at the 10th revenue percentile. There were also substantial differences in annual revenues among the different SIC codes within the manufacturing sector.

Table 2: Differences in Data Used in OPPTS Economic Analyses of Revenues of Small Manufacturing Companies

	Annual revenues of small manufacturing companies		
SIC codes	Reporting to TRI at the 25th revenue percentile	Not reporting to TRI at the 25th revenue percentile	Not reporting to TRI at the 10th revenue percentile
20	15,721,258	1,156,884	620,000
21	[a]	822,512	470,000
22	8,542,745	1,071,000	688,823
23	12,541,717	871,328	500,000
24	6,000,000	850,000	560,000
25	9,238,569	970,181	610,000
26	15,000,000	1,700,000	1,000,000
27	6,698,920	790,000	500,000
28	4,914,041	1,500,000	1,000,000
29	5,800,000	2,400,000	1,400,000
30	2,367,047	1,300,000	800,000
31	8,200,000	790,000	500,000
32	6,000,000	1,000,000	680,000
33	5,000,000	1,300,000	830,000
34	3,300,000	1,000,000	710,000
35	9,199,323	1,000,000	680,000
36	5,950,000	1,300,000	810,000
37	7,000,000	1,200,000	800,000
38	6,000,000	1,200,000	800,000
39	4,850,000	870,000	570,000

[a]Insufficient data.

Source: OPPTS.

OPPTS Revised Its Estimates of Rule's Impact

In the draft revised economic analysis, OPPTS estimated that the lead rule would affect 14,586 facilities in 10,133 companies. As table 3 illustrates, OPPTS said that 8,637 small companies—up from 5,620 in the initial analysis—would be affected by the proposed rule. OPPTS also said that as many as 464 of those small companies (about 5 percent of all affected small companies) could experience compliance costs of at least 1 percent of their annual revenues in the first year of implementation--up from zero in the initial analysis.[28] However, OPPTS said that no small company would experience compliance costs of 3 percent. After evaluation of the revised economic analysis, OPPTS officials said that they still believed the rule would not have a SEISNSE, and therefore they planned to certify that the final rule would not have a SEISNSE.

[28]OPPTS said that 273 (59 percent) of these 464 companies were in SIC Code 36 (electrical equipment).

Table 3: Comparison of the Results of OPPTS' Initial and Draft Revised Economic Analyses of the Proposed Lead Rule

Type of affected small companies	Number of small companies affected		Number of small companies with economic impacts of at least 1 percent of revenues in the first year[b]	
	Initial analysis	Draft revised analysis	Initial analysis	Draft revised analysis
Manufacturing	4,673	7,952	0	458
Other[a]	947	685	0	6
Total	**5,620**	**8,637**	**0**	**464**

[a]Other small companies include metal mining, coal mining, electrical utilities that combust coal and/or oil, hazardous waste treatment and disposal facilities, chemicals and allied products wholesale distributors, petroleum bulk plants and terminals, and solvent recovery services.

[b]In both the initial and draft revised economic analyses, OPPTS estimated that no companies would experience economic impacts of 1 percent of annual revenues in subsequent years of the rule's implementation.

Source: OPPTS.

OPPTS officials and staff said that their revised estimates of the number of small entities that would experience at least a 1 percent economic impact from the lead rule were probably higher than the number of entities that would actually experience those impacts. In particular, they said that first-year compliance costs in a small company could reasonably be expected to be less than the cost of reporting at a larger facility because (1) reporting in the smallest facilities may take only half as long as the average of all facilities (111 hours), and (2) wage rates in those facilities may be less than the $69 per hour average used. Therefore, OPPTS estimated that the first-year cost of compliance in small firms could be $3,360 (56 hours times $60 per hour)—well below the $7,500 estimate for all companies that was used to estimate the impacts on affected small entities. OPPTS officials and staff also noted that on the basis of a review of actual reporting, their estimates of the number of additional reports and affected facilities for previous TRI rules had been overestimates.

Hundreds of Other Small Manufacturers Could Experience a 1 Percent Economic Impact From the Lead Rule

The 464 small companies that OPPTS indicated in its draft revised economic analysis could experience compliance costs of at least 1 percent of their annual revenues were primarily in the 27 SIC codes and code groupings for which OPPTS developed estimates in the original economic analysis. In that analysis, OPPTS said that companies in 42 other 4-digit SIC codes could also be affected by the proposed rule, but lack of data prevented it from estimating how many additional TRI reports for lead would be filed by companies in those SIC codes. As previously noted, 40 of these 42 SIC codes each had more than 5 facilities reporting lead or lead compounds at the current thresholds. In the revised analysis, OPPTS developed estimates for 9 of these 42 SIC codes on the basis of information

received during the public comment period.[29] Therefore, OPPTS did not estimate the economic impact of the rule on companies in 33 SIC codes that it said could be affected.

All but 1 of the 33 SIC codes in which OPPTS did not estimate the lead rule's economic effects were in SIC codes 20 through 39—manufacturing. We attempted to provide a more complete picture of how the lead rule might affect small manufacturing companies by estimating how many companies in these 32 manufacturing SIC codes could experience a first-year economic impact of at least 1 percent of revenues. To do so, we first obtained unpublished data from the Bureau of the Census' 1997 Economic Census of Manufactures on the number of companies in SIC codes 20 through 39 that had 10 to 499 employees and annual revenues (shipments) of $750,000 or less.[30] We used the 10 to 499 employee size limitation because the TRI program applies only to facilities with at least 10 full-time employees, and any company with fewer than 500 employees is considered "small" according to SBA's size categories.[31] We selected the $750,000 revenue threshold because (1) OPPTS estimated that the proposed lead rule would impose average first-year compliance costs for new TRI filers of about $7,500, and (2) EPA's current RFA guidance indicates that a rule that imposes compliance costs of less than 1 percent of annual revenues on any number of companies should be presumed not to have a SEISNSE. In order for a company's cost of compliance with the lead rule in the first year to represent 1 percent of its revenues, the company would have to have annual revenues of $750,000 or less.

The Bureau of the Census data indicated that nearly 18,000 manufacturing companies had 10 to 499 employees and annual revenues of $750,000 or less.[32] Of these, 1,108 were in the 32 manufacturing SIC codes that OPPTS said might be affected by the rule but for which it did not provide an estimate of how many companies could be affected. OPPTS told us that 10 companies in the 32 SIC codes with 10 to 499 employees and annual

[29]OPPTS concluded that 85 small companies in these 9 SIC codes would experience a first-year economic impact of at least 1 percent of revenues.

[30]The Economic Census of Manufactures is conducted every 5 years on the universe of businesses in the manufacturing industry. It is to collect facts about the structure and functioning of the economy and features unique to this industry, such as materials consumed, inventories held, the number of establishments, payroll, and geographic location.

[31]The SBA size standard for "small" businesses is 500 for about 75 percent of manufacturing industries; and either 750, 1,000, or 1,500 for the other industries. Therefore, the use of the 500-employee limit is a conservative measure of the number of small manufacturing companies.

[32]About 99 percent of the nearly 18,000 companies had fewer than 50 employees, and about 84 percent had fewer than 20 employees.

revenues of $750,000 or less filed TRI reports in 1998. As previously noted, OPPTS estimated that first-year compliance costs for companies that already filed reports for some other TRI-covered substance would be about $5,200. Therefore, these companies would have to have annual revenues of $520,000 or less in order for the proposed lead rule to have a 1 percent economic impact on them in the first year. Although some of the 1,108 companies may have had annual revenues that low, we eliminated 10 companies from the total to ensure that all of the resultant 1,098 companies were first-time TRI reporters.[33]

Two other adjustments to the data may also be necessary before the rule's effects on small entities are estimated.

- As implemented by OPPTS, the TRI program covers companies with 10 or more "full-time equivalent" (FTE) employees, not just 10 employees.[34] Although the Bureau of the Census data reflects companies with at least 10 employees, some of those employees could be part-time workers. As a result, the number of employees in some of the smaller firms could fall below the 10 FTE threshold for the TRI program. For example, if a company had 12 employees but 6 of them worked only 20 hours per week, the company would have only 9 FTE employees. In order to account for this possibility, we also developed estimates of the number of companies that could experience a 1-percent impact assuming that three-quarters, one-half, and one-quarter of the companies in the 32 SIC codes met the 10 FTE threshold.
- Although OPPTS indicated that the companies in these 32 SIC codes may use lead in their manufacturing processes and could be affected by the proposed rule, it is not clear how many of these companies use at least 10 pounds of lead each year—the proposed reporting threshold. We were unable to locate any data identifying the amount of lead used by each company or within each SIC code. In order to account for the possibility that some of the companies in these 32 SIC codes use less than 10 pounds of lead each year, we developed estimates of the number of companies that could experience a 1 percent economic impact assuming that annual lead use in three-quarters, one-half, and one-quarter of the companies within these SIC codes met the 10-pound threshold.

[33]Therefore, we assumed that all 33 TRI filers in these 32 SIC codes had annual revenues of between $520,000 and $750,000.

[34]EPCRA (the statute creating the TRI program) states that the TRI program covers facilities with 10 or more full-time employees. OPPTS has defined the program as including facilities with 10 FTEs, even though some facilities with 10 FTEs may not have 10 full-time employees.

The results of these possible adjustments to the Census data are presented in table 4. If no adjustments are made to the Census data (i.e., assuming that all of the companies in the 32 manufacturing SIC codes have 10 FTE employees and all use 10 pounds of lead annually), then all 1,098 companies in these SIC codes with 10 to 499 employees and annual revenues of $750,000 or less could experience a 1-percent impact from the lead rule.[35] On the other hand, if we assume that half of the companies in these 32 SIC codes have 10 FTE employees and that half of those companies use 10 pounds of lead annually, we estimated that 275 additional companies could experience a 1-percent impact in the first year of implementation.

Table 4: Estimated Number of Small Companies Experiencing a 1 Percent Economic Impact From the Lead Rule in 32 Manufacturing SIC Codes During the First Year of Implementation

	All companies have 10 FTE employees	Three-quarters of companies have 10 FTE employees	One-half of companies have 10 FTE employees	One-quarter of companies have 10 FTE employees
All companies use 10 pounds of lead	1,098	824	549	275
Three-quarters of companies use 10 pounds of lead	824	618	412	206
One-half of companies use 10 pounds of lead	549	412	275	137
One-quarter of companies use 10 pounds of lead	275	206	137	69

Note: The estimates in this table were developed assuming no interrelationships between companies' lead usage and their FTEs. The estimates could be higher or lower depending on the strength or nature of any relationships.

Source: GAO analysis of Bureau of the Census data.

We also used Bureau of the Census data to estimate the number of companies in these 32 SIC codes that could experience first-year compliance costs equal to 3 percent of their annual revenues. To do so, we focused on companies with 10 to 499 employees and annual revenues of $250,000 or less. The data indicated that 78 companies in the 32 SIC codes met that employment and revenue profile. Because we could not presume that all 78 companies had 10 FTE employees or used 10 pounds of lead in the course of the year, we again adjusted the data assuming that three-quarters, one-half, and one-quarter of the companies met those

[35]Even this number could be an underestimate. As previously noted, EPA estimated that 85 companies in 9 other SIC codes could experience 1 percent economic impacts; however, the Bureau of the Census data indicated that up to 544 companies in those 9 SIC codes could experience 1 percent economic impacts.

parameters. The results, presented in table 5, indicate that between 5 and 78 companies in these 32 SIC codes could experience a 3 percent economic impact from the lead rule.[36]

Table 5: Estimated Number of Small Companies Experiencing a 3 Percent Economic Impact From the Lead Rule in 32 Manufacturing SIC Codes During the First Year of Implementation

	All companies have 10 FTE employees	Three-quarters of companies have 10 FTE employees	One-half of companies have 10 FTE employees	One-quarter of companies have 10 FTE employees
All companies use 10 pounds of lead	78	59	39	20
Three-quarters of companies use 10 pounds of lead	59	44	29	15
One-half of companies use 10 pounds of lead	39	29	20	10
One-quarter of companies use 10 pounds of lead	20	15	10	5

Note: The estimates in this table were developed assuming no interrelationships between companies' lead usage and their FTEs. The estimates could be higher or lower depending on the strength or nature of any relationships.

Source: GAO analysis of Bureau of the Census data.

Neither our estimates of the number of small companies that could be affected by the rule nor the estimates that OPPTS developed take into account behavioral changes that may occur as a result of the rule's implementation. For example, a company might change its manufacturing processes in order to reduce the amount of lead it manufactures, processes, or otherwise uses below the 10 pound reporting threshold. Also, a company might reduce its employment below the 10-FTE threshold and avoid the rule's requirements. We also did not attempt to determine the effects of the rule after the first year of implementation or to identify impacts above the 3 percent level.

Conclusions

The numerical guidelines in EPA's current RFA guidance document establish what appears to be a high threshold for what constitutes a SEISNSE. For example, an EPA rule can impose $10,000 in compliance costs on 10,000 small businesses, but the guidelines indicate that the program office issuing the rule can presume that the rule does not have a SEISNSE as long as those costs do not represent at least 1 percent of the businesses' annual revenues. The numerical guidelines also suggest that a

[36]We again assumed that all 33 TRI filers in these 32 SIC codes had annual revenues of between $520,000 and $750,000. Because table 5 only includes companies with revenues of $250,000 or less, no adjustments were made to this table for current filers.

rule can be presumed not to have a SEISNSE if as many as 99 small businesses experience compliance costs amounting to 100 percent of their annual revenues—essentially putting them out of business.

However, EPA's current RFA guidance document also gives the agency's program offices substantial discretion regarding how those numerical guidelines should be applied. The guidance suggests that those offices not certify proposed rules in which the extent of a rule's expected impact is severe or widespread, even if, according to the numerical guidelines, the rule can be presumed not to have a SEISNSE. Some EPA program offices have used that discretion and have conducted IRFAs and held advocacy review panels for proposed rules that met the conditions in the numerical guidelines for being presumed not to have a SEISNSE. However, by the end of 1999, OPPTS and the Office of Solid Waste had certified all 47 of the proposed rules that they published after the implementation of the SBREFA advocacy review panel requirements. It is impossible to determine with certainty whether EPA program offices are implementing RFA requirements in a consistent manner without a detailed examination of the circumstances surrounding each of the four offices' rules.

One of the 26 proposed rules that OPPTS certified after the implementation of SBREFA was its August 1999 lead rule. In both the original and draft revised economic analysis, the Office estimated that the lead rule would result in about 15,000 new TRI reports for lead and lead compounds—an increase of nearly 800 percent from reporting at the current 25,000 pound and 10,000 pound reporting thresholds. However, the actual increase in TRI lead reports as a result of the rule could be more than 800 percent. The Office's estimate of the number of new reports did not include any companies in 32 manufacturing SIC codes that OPPTS said might be affected by the rule. We did not estimate the total number of new TRI reports for lead that could come from companies in these 32 SIC codes. However, it is reasonable to presume that the number will be greater than zero—the number that OPPTS implicitly assumed in both its original economic analysis and its draft revised analysis.

OPPTS initially estimated that no small entities would experience 1 percent economic impacts from its proposed lead rule. However, using new assumptions and new data, OPPTS estimated in the draft revised analysis that as many as 464 small entities could experience those impacts. OPPTS believes that 464 is the maximum number of small companies that will experience 1 percent economic impacts and that 464 is likely to be an overestimate. However, that estimate—like the office's estimate of the number of additional reports—does not include companies in 32

manufacturing SIC codes that OPPTS said could be affected by the rule. Using data from the Bureau of the Census, we estimated that as many as 1,098 small manufacturing companies in these 32 SIC codes could face first-year compliance costs of at least 1 percent of their annual revenues. Although it is unclear exactly how many companies in these SIC codes will experience 1 percent economic impacts, it is reasonable to presume that the number will be greater than zero—the number that OPPTS implicitly assumed in both its original and its draft revised analysis. By combining the OPPTS estimate and our estimate, we believe that the lead rule could have a 1 percent economic impact on as many as 1,500 small companies. We also estimated that as many as 78 companies in these 32 manufacturing SIC codes could experience 3 percent economic impacts from the rule.

According to EPA's current guidance, if a proposed rule has a 1 percent economic impact on 1,000 or more small entities, the program office should consult with EPA's small business advocacy chair if the office wants to certify the rule. The guidance also indicates that a program office can conclude that a rule has a SEISNSE if it has a 1 percent economic impact on nearly 1,000 small entities—regardless of whether it has that impact on 20 percent of all affected small entities. As previously noted, some EPA program offices did not certify proposed rules that had at least a 1 percent economic impact on less than 100 companies. Therefore, if OPPTS had used our analytic approach and applied the flexibility allowed in the guidance (and that other EPA program offices have used), it could have concluded that the rule should not be certified, prepared an IRFA, and convened an advocacy review panel for the proposed lead rule.

Nevertheless, we believe that the analytic methods that OPPTS used in both the original economic analysis and the draft revised economic analysis, as well as the conclusions that the Office drew as a result of those analyses, were within the discretion provided by both the RFA and EPA's guidance. As we have said previously, concerns about the RFA compliance are often traceable to differences in those interpretations and the fact that no federal agency is responsible for developing uniform definitions. During the past 10 years we have recommended that Congress either define what it intended these key RFA terms to mean or consider giving some other entity the authority and responsibility to define them.[37]

[37] Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments (GAO/HRD-91-61, Jan. 11, 1991); Regulatory Flexibility Act: Status of Agencies' Compliance (GAO/GGD-94-105, Apr. 27, 1994); Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements (GAO/GGD-98-36, Mar. 18, 1998); and Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary (GAO/GGD-99-55, Apr. 2, 1999).

Congress has thus far not acted on those recommendations. We continue to believe that clarifying what Congress intends the term "significant economic impact on a substantial number of small entities" to mean would make the implementation of the RFA more consistent and help to prevent concerns about how agencies are implementing the act.

Agency Comments and Our Evaluation

We provided a draft of this report to the Director of OMB and the Administrator of EPA for their review and comments. OMB officials said they did not have any comments on the draft report. We obtained technical comments on the draft report from EPA officials and staff on August 30, 2000, and September 1, 2000, and we made changes to the report where appropriate. We also eliminated a section of the draft report in which we used information from Federal Register notices for proposed rules to conclude that the RFA had been inconsistently applied among EPA's four major program offices. EPA officials indicated that the program offices' RFA determinations were sometimes based on qualitative factors that were not always clearly reflected in the Federal Register notices. We therefore concluded that it was impossible to determine with certainty whether EPA program offices were implementing RFA requirements in a consistent manner without a detailed examination of the circumstances surrounding each of the four offices' rules. We will address the transparency of EPA's RFA determinations in separate correspondence with the Administrator of EPA.

On September 1, 2000, the Acting Assistant Administrator of OPPTS provided written comments on the draft report, which are reproduced in appendix I. The Acting Assistant Administrator said that EPA takes its responsibilities under the RFA very seriously, and that the agency appreciated the report's conclusion that its determinations were within the discretion permitted under the RFA. In addition, the Acting Assistant Administrator noted that EPA had twice extended the public comment period and conducted a series of public meetings on the proposed lead rule. She stated that this process allowed small business representatives to present their concerns directly to EPA and to submit information that EPA used to improve its assessment of potential small business impacts.

We agree that EPA's actions after the proposed lead rule was published helped the agency improve its estimate of the rule's impact on small businesses. However, if EPA had determined that the proposed lead rule could have a SEISNSE, it would have been required by SBREFA to convene a small business advocacy review panel. During the panel process, small businesses would have been afforded the opportunity to provide their views on the proposed lead rule before it was published in

the Federal Register. This early involvement of small businesses was what Congress envisioned when it enacted the advocacy review panel requirements in 1996. Nevertheless, EPA's determination that the lead rule did not have a SEISNSE (and thus was not required to convene an advocacy review panel) was within the broad discretion that federal agencies have under the RFA. EPA's revised economic analysis and the agency's exclusion of certain SIC codes from both its original and revised analysis demonstrate that choices made in exercising the discretion available to agencies can have a significant and even determinative effect on SEISNSE determinations.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after the date of this report. At that time, we will send copies of this report to Senator John F. Kerry, Ranking Minority Member of the Senate Committee on Small Business; Representatives James M. Talent and Nydia M. Velazquez, Chairman and Ranking Minority Member, respectively, of the House Committee on Small Business; the Honorable Jacob J. Lew, Director of OMB; and the Honorable Carol M. Browner, Administrator of EPA. We will make copies available to others on request.

If you have any questions regarding this report, please contact me or Curtis Copeland on (202) 512-8676. Key contributors to this assignment were Ellen Grady and Kathy Peyman.

Sincerely yours,

Michael Brostek
Associate Director, Federal Management
and Workforce Issues

Comments From the Environmental Protection Agency

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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U.S. General Accounting Office
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Washington, D.C. 20548

SEP - 1 2000

Dear Mr. Brostek:

Thank you for the opportunity to review a draft of your forthcoming report on EPA's compliance with the Regulatory Flexibility Act (RFA), with specific reference to its implementation within the Office of Prevention, Pesticides and Toxic Substances (OPPTS), and its application to the proposed rule to lower the reporting threshold for lead and lead compounds under the Toxics Release Inventory (TRI) program (proposed TRI lead rule). I am responding on behalf of the Agency.

We at EPA take our responsibilities under the RFA very seriously and have been gratified from time to time to see our efforts recognized. For instance, the 1994 GAO report on government-wide compliance with the RFA, cited early in your report, referenced a contemporary observation by the Small Business Administration that EPA was among the agencies "frequently characterized as satisfying the RFA's requirements." We therefore note with appreciation the basic conclusion of this report that in the case of the proposed TRI lead rule, as well as the other proposed rules reviewed by your staff, the determinations reached by EPA were within the discretion permitted agencies under the RFA.

I'd like to note that, in the case of the proposed TRI lead rule, we extended the public comment period not once, but twice, and conducted a series of public meetings to address concerns that were raised regarding the Agency's outreach to potentially affected small businesses. This process allowed small business representatives to present their concerns directly to EPA, and to submit information that would enable the Agency to improve its assessment of potential small business impacts. Since proposal, we have incorporated new information in our economic analysis from both formal public comment and additional small business outreach. As the report indicates, this rule is currently under Executive Order 12866 review by the Office of Management and Budget.

We certainly appreciate the professionalism and constructive approach your staff has displayed in the conduct of this review. Please feel free to contact me if you would like any additional information.

Sincerely,

Susan Wayland

Susan H. Wayland
Acting Assistant Administrator

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