



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Limited Public Comment on EPA's Regulatory Flexibility Act Section 610 Reviews

Report No. 12-P-0579

July 19, 2012



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Report Contributors:

Daniel Carroll
Jerri Dorsey
Heather Drayton
Gabby Fekete

Abbreviations

EPA	U.S. Environmental Protection Agency
GAO	U.S. Government Accountability Office
OP	Office of Policy
RAPIDS	Rule and Policy Information and Development System
RFA	Regulatory Flexibility Act
SISNOSE	Significant Economic Impact on a Substantial Number of Small Entities

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At a Glance

Why We Did This Review

The purpose of this review was to assess the reasons behind the lack of comment on Regulatory Flexibility Act (RFA) Section 610 reviews conducted by the U.S. Environmental Protection Agency (EPA).

Background

Under Section 610 of the RFA, agencies are required to review rules which have or will have a significant economic impact on a substantial number of small entities anytime within 10 years of promulgation. The purpose of these reviews is for the agency to determine whether such regulations should be continued as written or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize their impact on small entities.

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2012/20120719-12-P-0579.pdf

Limited Public Comment on EPA's Regulatory Flexibility Act Section 610 Reviews

What We Found

An essential aspect of Section 610 reviews is obtaining public comment on the impact of regulations. We found that EPA receives little to no public comment when Section 610 review notices are published in the Federal Register. This limited public comment can hinder the ability of the Agency to implement an effective Section 610 review process.

EPA's ability to conduct effective retrospective reviews is dependent on feedback from the public and the regulated community. We found that the shortage of comments may be the result of the following reasons:

- If small business concerns are identified, the Agency is mandated by the RFA to address these during the initial rulemaking process, which could result in concerns being addressed at the outset.
- EPA is required by a number of other statutes to conduct retrospective reviews; the Agency may have already reviewed and modified regulations before the 10-year mark for the Section 610 review. These other reviews are generally not coordinated with Section 610 reviews.
- Ten years after a rule is finalized may not be the optimal time to seek feedback; some rules may benefit from a review closer to issuance.
- Some of the stakeholders in the regulated community that we contacted were unaware of the purpose or execution of the Section 610 reviews.

Recommendations/Planned Agency Corrective Actions

We recommend that EPA's Associate Administrator for Policy coordinate the Section 610 review with other required retrospective reviews, and implement additional public outreach efforts to increase awareness of the Section 610 purpose and process.

The Agency indicated that it is committed to coordinating Section 610 reviews with other required reviews when appropriate. EPA agreed to implement additional public outreach to increase awareness of the Section 610 review purpose and process, including making changes to its Small Entities and Rulemaking website within 3 months.



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

THE INSPECTOR GENERAL

July 19, 2012

MEMORANDUM

SUBJECT: Limited Public Comment on EPA's Regulatory Flexibility Act
Section 610 Reviews
Report No. 12-P-0579

FROM: Arthur A. Elkins, Jr.

A handwritten signature in black ink, appearing to read "Arthur A. Elkins, Jr.", is written over the printed name.

TO: Michael Goo
Associate Administrator, Office of Policy

This is a report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed-upon actions, including milestone dates. Your response will be posted on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal. We have no objections to the further release of this report to the public. We will post this report to our website at <http://www.epa.gov/oig>.

If you or your staff have any questions regarding this report, please contact Carolyn Copper at (202) 566-0829 or copper.carolyn@epa.gov, or Jerri Dorsey at (919) 541-3601 or dorsey.jerri@epa.gov.

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Purpose

The purpose of this review was to identify the reasons for the lack of public comments and responses to the U.S. Environmental Protection Agency's (EPA's) Regulatory Flexibility Act (RFA) Section 610 retrospective reviews.¹

Background

The RFA requires agencies to examine the impact of their proposed and final regulations on small entities. The purpose of the RFA is:

to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.

In addition, under the 1996 amendments to the RFA, EPA is required to convene panels to address small business concerns when these are identified in the rulemaking process.²

Under Section 610 of the RFA, agencies are required to review rules that have or will have a significant economic impact on a substantial number of small entities (SISNOSE) within 10 years of promulgation. The purpose of these reviews is to determine whether such regulations should be continued without change or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize their impact on small entities.

A Section 610 review involves:

- Identifying a promulgated rule that was not certified (i.e., did not contain a finding that there was no SISNOSE)³
- Determining whether the rule should be amended, rescinded, or left unchanged based on five statutorily prescribed factors:

¹ The initial purpose of this review was to assess the efficiency and effectiveness of the EPA's policies and procedures in place for conducting Section 610 retrospective reviews and outcomes from past reviews. Our purpose was amended based on the lack of public comment received.

² The Small Business Regulatory Enforcement Fairness Act, enacted in 1996, added a judicial review provision to the RFA, which means the Agency can be challenged in court as to its compliance with the provisions of this section on a rule-by-rule basis.

³ This review did not include an assessment of the SISNOSE determination; our evaluation focused on those rules that met the criteria of the Agency, not on critiquing those criteria.

1. The continued need for the rule
2. The nature of complaints or comments received concerning the rule from the public
3. The complexity of the rule
4. The extent to which the rule overlaps, duplicates, or conflicts with other federal rules, and, to the extent feasible, with state and local governmental rules
5. The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

According to data provided by EPA's Office of Policy (OP), since 1996 EPA has completed 35 Section 610 reviews.⁴ In conducting a Section 610 review, EPA's guidance provides that the Agency must specifically address and ask the public for comment on the five factors outlined above. In addition to the Section 610 reviews, EPA conducts other mandatory reviews to comply with statutes that apply specifically to areas that program offices regulate.⁵

Scope and Methodology

We conducted this evaluation in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for the results reported based upon our objectives. We performed this evaluation from September 2011 through May 2012.

We reviewed EPA planning and implementation documents, federal documents and information related to the RFA, Section 610 reviews, and retrospective reviews in general. We reviewed EPA's internal Rule and Policy Information and Development System (RAPIDS) database. We conducted interviews with staff at EPA's OP, as well as with EPA's Office of Air and Radiation and Office of Water. We also reviewed the Agency's Regulatory Agendas for 2007–2010, which include the list of regulations to be reviewed under Section 610 each year. We conducted a detailed analysis of the universe of Section 610 reviews completed by EPA during the calendar year 2010 (see appendix A for the list of reviews and details⁶). In assessing the four reviews completed in 2010, we interviewed external stakeholder groups active in the Agency's rulemaking process but not specifically involved in

⁴ We found one Section 610 review that was scheduled to be conducted in 2009 that was not conducted within the 10-year timeframe: Heavy-Duty Engine Emission Standards & Diesel Fuel Sulfur Control Requirements (RIN: 2060-AI69; SAN: 4355). The Agency is currently executing this review.

⁵ According to the U.S. Government Accountability Office, some statutes that require EPA to conduct mandatory retrospective reviews include: Clean Air Act; Clean Water Act; Federal Food, Drug, and Cosmetic Act; Federal Insecticide, Fungicide, and Rodenticide Act; Comprehensive Environmental Response, Compensation and Liability Act; and Safe Drinking Water Act.

⁶ Appendix A lists the four reviews completed during calendar year 2010, as well as those done in 2008 and 2009. We completed a detailed review of those done in 2010 and a limited assessment of those from 2008 and 2009.

the Section 610 review process.⁷ We also did a cursory assessment to determine the number of comments received on and any changes made to Section 610 reviews conducted in calendar years 2008 and 2009.

Prior Audit Coverage

The U.S. Government Accountability Office (GAO) reviewed the RFA and EPA's work under Section 610 in at least five reports since the late 1990s.⁸ In general, GAO found that EPA used Section 610 as a notice and comment requirement. GAO noted the importance of EPA utilizing a systematic approach to conducting Section 610 retrospective reviews. GAO found that it was unclear if the Section 610 provision in the RFA had been consistently and effectively implemented. In a series of reports on agencies' compliance with Section 610, specifically in GAO-07-791, GAO identified important practices that can have an impact on the effectiveness and transparency of each phase of the review process and assessed the extent to which these three practices were a part of agencies' processes and standards. Important practices identified by GAO include: (1) use of a standards-based approach, (2) incorporation of public involvement, and (3) documentation of review processes and results. GAO found that, for the mandatory reviews completed within the timeframe for their evaluation, the most common result for a Section 610 review was that no changes were needed to the regulation. There were no previous OIG reviews of this subject matter.

Section 610 Reviews Receive Limited Public Comments

EPA receives little to no public comment on Section 610 reviews. During 2008 through 2010, EPA conducted eight Section 610 reviews. Specifically:

- In 2010, EPA conducted four Section 610 reviews. EPA received relevant comments on two of the four reviews.⁹ After reviewing these comments and posting them in the federal docket, the Agency concluded that revisions or amendments to minimize economic impacts on small entities were not warranted for these rules at that time.

⁷ These stakeholders were selected because they commented on draft EPA rulemakings but not on the Section 610 reviews related to these rules. During field work, we contacted seven stakeholders to determine their reasons for not participating in the Section 610 process and to obtain their perspectives; however, we were ultimately only able to discuss these reviews with four of the seven.

⁸ GAO/T-GGD-98-64, *Regulatory Reform: Agencies' Section 610 Review Notices Often Did Not Meet Statutory Requirements*, February 1998; GAO/RCED-99-250, *Environmental Protection: Assessing the Impacts of EPA's Regulations through Retrospective Studies*, September 1999; GAO/GGD-00-193, *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule*, September 2000; GAO-06-998T, *Regulatory Flexibility Act: Congress Should Revisit and Clarify Elements of the Act to Improve Its Effectiveness*, July 2006; and GAO-07-791, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews*, July 2007.

⁹ EPA received five comments on the Radionuclides Section 610 review and eight on the Arsenic review. See appendix A for specific details.

- In 2009, EPA conducted one review and received one comment supporting the continued need for the rule.¹⁰
- In 2008, EPA completed three reviews for which one received comment from a stakeholder. This comment suggested additional coverage for one of the rules; EPA considered this comment and provided a response in the Section 610 review decision document the Agency published and suggested an EPA contact person for the commenter.

None of the eight reviews conducted from 2008 to 2010 resulted in a change to a rule or regulation. According to Agency staff, it is typical that Section 610 reviews do not result in a revision.

External stakeholders and program office staff offered a number of reasons why EPA garners little to no response to these reviews. First, a Small Business Advocacy Review Panel would have been convened in the initial rule writing process if there were small business concerns. If the concerns are vetted by the public and addressed by the Agency during the rulemaking process, the frequency and amount of comments received during the Section 610 review process could be reduced.

Second, program office staff reiterated that EPA is required by other statutes to conduct mandatory retrospective reviews, including requirements in the Clean Air Act and the Clean Water Act. The frequency of these reviews ranges from every 2 years to every 10 years. For instance, the frequency of reviews conducted by the Office of Water ranges from every 2 years to every 6 years, depending on the review requirement. The Office of Air and Radiation is required to conduct reviews under the Clean Air Act ranging from every 5 years to every 8 years. These reviews are in addition to the Section 610 review requirement. Therefore, when reviews that have predetermined schedules and review factors (such as the Section 610 reviews) arise, the Agency might have already reviewed and potentially modified the regulation one or more times. We found this to be the case for two of the eight Section 610 reviews we assessed in our evaluation. The Agency, recognizing the potential for overlap, is assessing the potential for coordinating these reviews as part of its work under Executive Order 13563, “Improving Regulation and Regulatory Review.”

Third, Section 610 requires that EPA review the rule within 10 years of the date the rule became final.¹¹ According to the Agency’s guidance, conducting the review close to the 10-year anniversary allows for a more focused perspective on any changed impacts on small entities. However, external stakeholders and

¹⁰ According to EPA’s internal tracking system, there were two Section 610 reviews conducted in 2009. However, there is no record in the Federal Register or in www.regulations.gov indicating that the rule cited actually underwent a Section 610 review. EPA’s OP staff found that this rule never received the scheduled Section 610 review, and OP is currently executing it. This was the only error we found of this type in conducting our review.

¹¹ EPA adopted the practice of conducting the Section 610 reviews at the 10-year mark.

program staff expressed concerns surrounding the 10-year time frame. For example, one external stakeholder representative expressed that prior to the 10-year mark, entities were already in compliance and therefore lacked the incentive to provide comments. Additionally, regulated entities may be more concerned with what comes next rather than the “ten year old rule.”

Finally, there are external stakeholders in the regulated community who are unaware of the purpose or execution of the Section 610 reviews. Section 610 requires EPA to publish a plan semiannually in the Federal Register that lists the existing rules EPA plans to review, which it does as part of its semiannual Regulatory Agenda. We found that EPA issues notification of Section 610 reviews through the Agency’s normal notice and comment procedures in the Federal Register. In not conducting additional outreach, EPA may be missing affected external stakeholders who would otherwise participate in the process. Two of the four external stakeholder groups with whom we spoke stated that they had no knowledge of the Section 610 review process prior to our conversations. One of these two stakeholders was particularly concerned and indicated that it was a significant lost opportunity. External stakeholders expressed the concern that solely publishing a notice in the Federal Register of a regulation undergoing a review is not sufficient.

In EPA’s guidance on the RFA as a whole, public involvement is given substantial consideration, noting that “simply providing notice of EPA’s intent is not enough. Adequate outreach also requires that we seek opportunities for genuine engagement that places the Agency in a position to hear from and respond to small entities.” Furthermore, the Small Business Administration’s Office of Advocacy recommended that agencies additionally communicate information on Section 610 reviews via an agency website or other electronic media. Some external stakeholders said that EPA should attempt to disseminate information about the Section 610 review process and any upcoming reviews, particularly when already speaking to the regulated community.

Conclusion

Given that the 10-year review period for Section 610 reviews is a window and not a deadline, the possibility exists for consolidating the program offices’ review workload. Both EPA and the Small Business Administration’s Office of Advocacy recognize the potential to coordinate reviews wherever there is functional equivalency. As previously noted by GAO, Section 610 of the RFA is essentially a notification requirement that is designed to provide opportunities for the public to comment. EPA’s ability to conduct retrospective reviews is critically dependent on feedback from the public and the regulated community. EPA is receiving little to no comment when Section 610 review notices are published in the Federal Register. Limited public comment may hinder the ability of the Agency to implement an effective Section 610 review process. By making the public and stakeholder groups more aware of the Section 610 review process,

EPA may identify beneficial regulatory improvements for a broad representation of the public.

Recommendations

We recommend that the Associate Administrator for EPA's Office of Policy:

1. Coordinate the Section 610 reviews with other required retrospective reviews across regulated communities to the extent practicable.
2. Implement additional public outreach efforts to increase awareness of the Section 610 review purpose and process.

Agency Comments and OIG Evaluation

The Agency concurred with both recommendations as currently worded, and was in general agreement with the report's description of the Section 610 review process. EPA agreed that opportunities exist to enhance the Section 610 review process. The Agency acknowledged that the reviews studied did not result in changes to regulations, but disagreed with the OIG's characterization of the process as minimally effective. We revised the sentences of concern to better reflect the link between limited public comment and the Agency's ability to conduct effective Section 610 reviews. The Agency's detailed response with the OIG's evaluation is provided in appendix B.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in \$000s)	
Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	6	Coordinate the Section 610 reviews with other required retrospective reviews across regulated communities to the extent practicable.	O	Associate Administrator, Office of Policy			
2	6	Implement additional public outreach efforts to increase awareness of the Section 610 review purpose and process.	O	Associate Administrator, Office of Policy			

¹ O = recommendation is open with agreed-to corrective actions pending
 C = recommendation is closed with all agreed-to actions completed
 U = recommendation is unresolved with resolution efforts in progress

EPA's 2008–2010 Section 610 Reviews

Year	Rule Title and Docket Locator Information	Number of Relevant Comments Received	Rule Changed: Yes/No
2010	National Primary Drinking Water Regulations: Radionuclides (Section 610 Review) (RIN:2040-AF19; 2040-AC98; SAN:3992 SAN:5445)	5	No
2010	Effluent Guidelines and Standards for the Centralized Waste Treatment Industry (Section 610 Review) (RIN:2040-AF18; SAN:5444; RIN:2040-AB78; SAN:2805)	0	No
2010	Tier II Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Standards (Section 610 Review) (RIN:2060-AQ12; SAN:5432; (RIN:2060-AI23; SAN:4211)	0	No
2010	National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring (RIN: 2040-AF24; SAN:5487)	8	No
2009 ¹²	Revisions to the Underground Injection Control (UIC) Requirements for Class V Wells (RIN:2040-AF04; SAN:5332; RIN:2040-AB83; SAN:2778)	1	No
2008	Control of Emissions of Air Pollution From Nonroad Diesel Engines (Section 610 Review) (RIN:2060-AO82; SAN:5254;2060-AF76; SAN:3645)	0	No
2008	National Primary Drinking Water Regulations: Stage I Disinfectant/Disinfection By-Products Rule (Section 610 Review) (RIN:2040-AE97; SAN:5258; RIN:2040-AB82; SAN:2772)	0	No
2008	VOC Regulation for Architectural Coatings (Section 610 Review) (RIN:2060-AP09; SAN:5255; RIN:2060-AE55; SAN:3351)	1	No

Source: OIG analysis.

¹² There was one additional Section 610 review that should have been completed in 2009: Heavy-Duty Engine Emission Standards & Diesel Fuel Sulfur Control Requirements (RIN: 2060-AI69; SAN: 4355). The rule did not undergo its Section 610 review within the 10-year window. The Agency is currently executing this review.

Agency Response and OIG Comments

July 18, 2012

MEMORANDUM

SUBJECT: Response to Draft Report:
Limited Public Comment on EPA's Regulatory Flexibility Act Section 610
Project No: OPE-FY11-0024

FROM: Michael L. Goo, Associate Administrator

TO: Jeffrey Harris, Director for Program Evaluation, Cross Media Issues
Office of Inspector General

EPA appreciates the opportunity to comment on the Office of Inspector General's (OIG) draft evaluation report "Limited Public Comment on EPA's Regulatory Flexibility Act Section 610 Reviews."

We are in general agreement with the report's description of the Section 610 review process. However, we believe that there is insufficient information included in the report to conclude that the effectiveness of EPA's Section 610 reviews is "minimal." While we acknowledge that the reviews studied did not result in changes to regulations, we believe that our process is effective. As currently drafted the report implies that to be effective Section 610 reviews should result in changes to regulations, notwithstanding the merits of such changes. Additionally, as noted in the report there are a variety of reasons why the public may not respond to these reviews. As a result, we suggest that OIG delete the two sentences in the report that contain this characterization.

OIG Response: The OIG appreciates EPA's general concurrence with our description of the process. We revised the sentences of concern to better reflect the link between limited public comment and the Agency's ability to conduct effective Section 610 reviews.

We agree that opportunities exist to enhance our Section 610 review process and concur with the two recommendations offered in the report.

With respect to the first recommendation, as noted in the report, EPA is already committed to harmonizing Section 610 Reviews with other required reviews when appropriate. EPA committed to this in our Executive Order 13563 retrospective review plan and OP is working with the program offices on implementation of this.

With respect to the second recommendation, EPA agrees to implement additional public outreach to increase awareness of the Section 610 review purpose and process. We plan to make changes to our Small Entities and Rulemaking website (<http://www.epa.gov/rfa/>) within three months. Specifically we will be providing a list rules for which upcoming Section 610 reviews are required, the due date for the review, and any other retrospective reviews required for the rule. We will also be using our website to highlight any Section 610 reviews open for public comment. Finally, we intend to suggest to the Small Business Administration's Office of Advocacy that they include information about these reviews on their website and in their newsletters.

OIG Response: The OIG appreciates EPA's response and commitment to making these changes. In regard to the first recommendation, we acknowledge that the Agency has agreed to the first option afforded in the recommendation and was silent on the second option. We revised the recommendation to reflect the agreed-to recommendation as it meets the overall intent. In its 90-day response to the final report, EPA should provide estimated completion dates for all agreed-to actions and specific corrective action plans.

Again, thank you for the opportunity to comment on this report. If you or your staff has questions regarding this response, please contact Nathaniel Jutras at 202-564-0301.

cc: Nicole Owens
Alex Cristofaro

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