

April 2022

Report on the Regulatory Flexibility Act, FY2021

Annual Report of the Chief Counsel
for Advocacy on Implementation of
the Regulatory Flexibility Act and
Executive Order 13272



Created by Congress in 1976, the Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. Appointed by the President and confirmed by the U.S. Senate, the Chief Counsel for Advocacy directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Economic research, policy analyses, and small business outreach help identify issues of concern. Regional advocates and an office in Washington, DC, support the Chief Counsel's efforts.

The views expressed by Advocacy here do not necessarily reflect the position of the Administration or the SBA because Advocacy is an independent entity within the U.S. Small Business Administration.



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April 2022

To: The White House
The Senate Committee on Small Business and Entrepreneurship
The House Committee on Small Business

The Regulatory Flexibility Act (RFA) is the statutory basis of small entity consideration in federal rulemaking. The RFA assigns the Office of Advocacy official responsibility in rulemaking. Advocacy monitors whether regulations take small entities into account and informs agencies of small businesses' concerns to improve regulations.

The RFA directs the Chief Counsel for Advocacy to monitor and report on federal agencies' compliance with the law. This report fulfills that mandate, covering fiscal year 2021, from October 1, 2020, to September 30, 2021. Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," also imposes certain requirements on federal agency rulemaking and requires Advocacy to report on agency compliance with that executive order. Chapter 2 reports on their compliance in FY 2021.

FY 2021 was a difficult year for small businesses in the United States. The COVID-19 pandemic continued to hurt small businesses, who struggled to keep employees and customers safe, with regulations surrounding COVID-19 mitigation strategies, and supply chain issues. Throughout the pandemic, the Office of Advocacy has maintained its mission of being an independent voice for small businesses within the federal government by continuing to focus on regulatory solutions that can help struggling businesses and educating regulators who craft rules and regulations that could disproportionately impact small business. Advocacy and federal agencies continued practices developed in 2020 to ensure that, despite being unable to meet small businesses face-to-face, stakeholders were involved in the regulatory process.

Advocacy has enforced the RFA for over 40 years. However, in these unprecedented times, safeguards on the regulatory process are even more important for small businesses. Advocacy has remained attuned to regulatory changes and continues to monitor new rules and regulations for impacts on small business.

Advocacy's overall efforts to promote federal agency compliance with the RFA resulted in nine rule changes that led to \$3.277 billion in quantifiable regulatory cost savings for small entities in FY 2021.

- One of this year's cost savings included the Occupational Safety and Hazard Administration (OSHA) COVID-19 Emergency Temporary Standard. After President Biden issued an Executive Order on Protecting Worker Health and Safety, OSHA held a series of interagency meetings with stakeholders across the federal government. Advocacy participated in every meeting, conveying the interest of small businesses to all participants. The final standard was limited to employers with ten or more employees

in the health care sector where suspected or confirmed coronavirus patients are treated. The standard led to aggregate cost savings of \$3.2 billion, which represents most of Advocacy's cost savings for FY 2021.

- Another cost savings included the Environmental Protection Agency (EPA) Multi-Sector General Permit. Advocacy worked with the EPA to eliminate a series of unnecessary universal monitoring and benchmark tests and encouraged EPA to add other flexibilities for small entities. The changes led to \$22.8 million in estimated cost savings.

Advocacy also won other, less quantifiable, battles for small businesses:

- In one case, EPA responded to Advocacy's concerns surrounding a lack of clarity on worker protection standards for agricultural workers. After meeting with stakeholders, Advocacy proposed revisions to EPA's application exclusion zone standards to help reduce the compliance burden for small entities.
- In another case, Advocacy encouraged the Department of Energy (DOE) to swiftly finalize a rule on the energy efficiency test-procedure interim waiver process. The DOE lengthened its response time for waiver applications, but also changed the procedure so that applications not responded to were assumed to be granted.

Chapter 2 reports on agencies' compliance with Executive Order 13272. In FY 2021, Advocacy provided training in RFA compliance in nine training sessions for 290 federal officials. While RFA training is normally held in person, the pandemic caused Advocacy to move its sessions online. Additionally, Advocacy confirmed whether agencies had posted their RFA procedures on their websites, information that can be found in Table 2.2.

Also of note in FY 2021:

- Advocacy submitted 17 formal comment letters to 9 regulatory agencies. These letters expressed Advocacy's concerns about how new rules and regulations would harm small businesses.
- Advocacy held 20 issue roundtables. These roundtables are helpful tools to mediate conversations between small business owners and representatives and federal regulators and allow Advocacy to participate in conversations about federal rulemaking. During the pandemic, these roundtables were moved online for safety and convenience.

I am pleased to present you this report on federal agency compliance with the Regulatory Flexibility Act. Advocacy looks forward to further achievements in reducing small businesses' regulatory burdens.



Major L. Clark, III
Deputy Chief Counsel

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Chapter 1

The Regulatory Flexibility Act, Small Business, and Regulation During the Pandemic

FY 2021 was a difficult year for small businesses in the United States. The COVID-19 pandemic continued to dramatically impact the U.S. economy. Small businesses were hit particularly hard, with federal aid in the form of the Paycheck Protection Program and Economic Injury Disaster Loan program necessary to keep them afloat. Small businesses struggled under the weight of lockdown orders, regulations surrounding COVID-19 mitigation strategies, and supply chain issues.

Throughout the pandemic, the Office of Advocacy maintained its mission of being an independent voice for small businesses within the federal government by producing timely research on the impact of the pandemic and continuing to focus on both regulatory reform that can help struggling businesses and educating regulators who craft rules and regulations that could disproportionately impact small business. Advocacy and federal agencies continued processes developed in 2020 to ensure that, despite being unable to meet small businesses face-to-face, stakeholders were involved in the regulatory process. As a result, Advocacy produced important gains for American small businesses.

This chapter documents the Regulatory Flexibility Act (RFA) and the other laws Advocacy uses to help protect small businesses against burdensome regulatory action. While Advocacy has enforced the RFA for over 40 years, safeguards on the regulatory process are even more important for small businesses in these unprecedented times. While the pandemic has harmed small businesses, Advocacy has remained attuned to regulatory changes and continues to monitor new rules and regulations for impacts on small business. In the case of deregulatory

actions, Advocacy monitored potential outcomes to ensure maximum benefits for small entities.

The Regulatory Flexibility Act

Advocacy has pursued regulatory solutions since its inception. No law after Advocacy's basic charter has had more influence on the office's activities than the RFA, first enacted in 1980¹ and strengthened in 1996² and 2010.³ It established into law the principle that government agencies must consider the effects of their regulatory actions on small entities and mitigate them where possible. The RFA arose from years of frustration with ever-increasing federal regulations that disproportionately harmed large numbers of smaller entities. From the RFA's section titled "Congressional Findings and Declaration of Purpose":

It is the purpose of this Act 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.⁴

1. Public Law 96-354 (September 19, 1980), 5 U.S.C. § 601 et seq.

2. The Small Business Regulatory Enforcement Fairness Act, Public Law 104-121, Title II (March 29, 1996).

3. The Small Business Jobs Act of 2010, Public Law 111-240, title I, § 1601 (September 27, 2010) and the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203, title X, § 1100G(a) (July 21, 2010).

4. 5 U.S.C. § 601 note.

The RFA includes procedures for agencies to accomplish this purpose and provides Advocacy, whom a Florida federal court called the “watchdog of the RFA,” with tools to help promote compliance. The 1996 amendments to the RFA provided judicial review for many of its provisions, and since then a significant body of RFA case law has developed, including instances in which rules or their impact analyses have been remanded by the courts due to RFA problems.⁵

In addition to RFA legislation, several executive orders have given Advocacy additional responsibilities to assist agencies in meeting their RFA obligations. One of these, Executive Order 13272, Proper Consideration of Small Entities in Agency Rulemaking,⁶ requires Advocacy to report annually on agencies’ compliance with the RFA. That report is included in this Annual Report on the RFA.

Executive Order 13272 also requires Advocacy to provide RFA compliance training to federal regulatory officials, which ordinarily occurs through live classroom training. Because of the pandemic and the resulting widespread use of telework arrangements, training during FY 2021 was conducted online through meeting software. Advocacy continues to customize RFA training to each individual agency or multi-agency group receiving the training. Better-trained regulatory and policy staff can better assess the potential need for both deregulation and regulation, and when regulation is necessary, develop smarter rules that have reduced impacts on small entities. Additionally, RFA training provides federal regulators with a better understanding of how the RFA is a positive tool for regulatory compliance. Fully RFA-compliant rules can result in better rules, better small business compliance, and reduced litigation.

Since the enactment of the RFA in 1980, Advocacy has sought to help agencies develop a regulatory culture that internalizes the Act’s purposes. Advocacy shows

5. E.g., *Southern Offshore Fishing Association v. Daley*, 55 F. Supp. 2d 1336 (M.D. Fla. 1999), and *Northwest Mining Assoc. v. Babbitt*, 5 F. Supp. 2d 9 (D.D.C. 1998), in which Advocacy filed an amicus brief.

6. Executive Order 13272 (August 13, 2002), 67 Fed. Reg. 53461.

regulatory and policy officials how considering the potential effects of their proposals on small entities and adopting mitigation strategies can improve their regulations, both by reducing costs to small entities and the broader economy, and by improving compliance by those regulated. Since 2003, when Advocacy began its ongoing RFA compliance training program, through 2021, training has been provided to officials in 18 cabinet-level departments and agencies, 80 separate component agencies and offices within these departments, 24 independent agencies, and various special groups including congressional staff, business organizations, and trade associations.

On January 20, 2021, President Biden issued Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation,⁷ citing the need “to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID-19) pandemic, economic recovery, racial justice, and climate change.” President Trump’s Executive Orders 13771, Reducing Regulation and Controlling Regulatory Costs, and 13777, Enforcing the Regulatory Agenda, were among those revoked.

At the same time, President Biden issued a Memorandum for the Heads of Executive Departments and Agencies on Modernizing Regulatory Review,⁸ setting as a goal the modernization of regulatory review and reaffirming previous executive orders establishing a process for review of pending regulations by the Office of Management and Budget. These presidential actions set the ground rules for the agencies that engage in rulemaking and for Advocacy as it pursues its statutory goals. This report includes descriptions of success stories of small business burden reduction achieved by federal agencies and Advocacy working together under the RFA.

Since its passage in 1980, the RFA has helped establish small business consideration as a necessary part of federal rulemaking. In the past, Advocacy has

7. Executive Order 13992, 86 Fed.Reg. 7049.

8. Modernizing Regulatory Review, 86 Fed.Reg. 7223.

made regulatory reform recommendations directly to agencies based on a review of rules subject to the requirements of Section 610 of the RFA and based on outreach to small entity representatives. In addition to recommendations under Section 610, and after agencies had designated Regulatory Reform Officers and established the Regulatory Reform Task Forces required under Executive Order 13777, Advocacy offered its recommendations and other assistance and views to agencies, as suggested by that order. Since then, Advocacy has continued to engage in a longer-term effort to make specific recommendations to agencies and the Office of Management and Budget about regulations and regulatory policies that could be modified to lower small entities' compliance costs.

The RFA, Its Requirements, and Efforts to Strengthen It

Congress passed the RFA in 1980 to address the disproportionate impact of federal regulations on small businesses. Under the RFA, when an agency proposes a rule that would have a “significant economic impact on a substantial number of small entities,” the rule must be accompanied by an impact analysis, known as an initial regulatory flexibility analysis (IRFA), when it is published for public comment.⁹ When the final rule is published, it must be accompanied by a final regulatory flexibility analysis (FRFA).¹⁰ Alternatively, if a federal agency determines that a proposed rule would not have a significant impact on small entities, the head of that agency may “certify” the rule and bypass the IRFA and FRFA requirements.¹¹

In an IRFA, the agency must consider less burdensome alternatives to its own rule, and in the FRFA the agency must explain why it was chosen among the alternatives in the IRFA.¹²

9. 5 U.S.C. § 603.

10. 5 U.S.C. § 604.

11. 5 U.S.C. §605(b).

12. 5 U.S.C. § 604.

In 1996, Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA). The amendments to the RFA under SBREFA emphasized federal agency compliance with the RFA, imposing specific procedures addressing small business concerns regarding environmental and occupational safety and health regulations. Additionally, the amendments made compliance with certain sections of the RFA judicially reviewable, meaning small entities could challenge regulations based on the agency's failure to comply with those sections of the statute.

The Small Business Jobs Act of 2010 codified some of the procedures introduced in Executive Order 13272. That same year, the Dodd-Frank Wall Street Reform and Consumer Protection Act created the Consumer Financial Protection Bureau and made the agency's rules subject to the RFA's SBREFA panel provisions.

In 2011, President Obama issued Executive Order 13563, Improving Regulation and Regulatory Review,¹³ which directed agencies to heighten public participation in rulemaking, consider overlapping regulatory requirements and flexible approaches, and conduct ongoing regulatory review. Concurrently, the president issued a memorandum to all federal agencies, reminding them of the importance of the RFA and of reducing the regulatory burden on small businesses through regulatory flexibility. In this memorandum, the president directed agencies to increase transparency by providing written explanations of any decision not to adopt flexible approaches in their regulations.

In 2012, Executive Order 13610, Identifying and Reducing Regulatory Burdens,¹⁴ provided that “... further steps should be taken...to promote public participation in retrospective review, to modernize our regulatory system, and to institutionalize regular assessment of significant regulations.” This aligns with the RFA's Section 610 “look-back” provision mandating the periodic review of existing regulations. The executive order also called for greater focus on

13. Executive Order 13563 (January 18, 2011), 76 Fed. Reg. 3821.

14. Executive Order 13610 (May 10, 2012), 77 Fed. Reg. 28469.

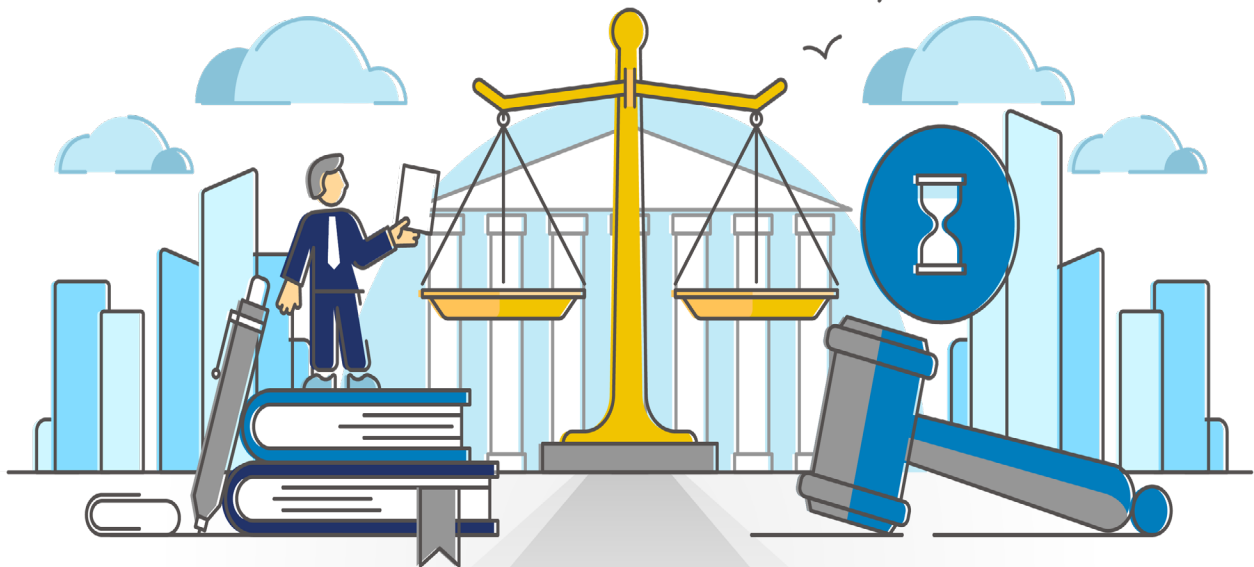
initiatives aimed at reducing unnecessary regulatory burdens, simplifying regulations, and harmonizing regulatory requirements imposed on small businesses.

Conclusion

Since its passage in 1980, the RFA has demonstrated remarkable results. It has helped establish small business consideration as a necessary part of federal rulemaking. The careful tailoring of regulation to business size has made better regulations with improved compliance in pursuit of safety, health, and other public goods. The subsequent regulatory and legislative improvements have solidified Advocacy's

participation in rulemakings affecting small businesses. What these regulatory reform initiatives all have in common is agreement that the regulatory burden on small businesses must be minimized. Over its 41-year history, the RFA has provided federal agencies with the framework to accomplish this goal, which is especially important in times of disruption like the COVID-19 pandemic. With Advocacy's ongoing monitoring, this important tool will continue to remind agencies that are writing new rules or reviewing existing ones to identify or minimize "significant economic impacts on a substantial number of small entities."¹⁵

15. 5 U.S.C. § 601.



Chapter 2

Compliance with Executive Order 13272 and the Small Business JOBS Act of 2010

Federal agencies' compliance with the Regulatory Flexibility Act improved after President Bush signed Executive Order 13272, Proper Consideration of Small Entities in Agency Rulemaking, in 2002. The executive order established new responsibilities for Advocacy and federal agencies to facilitate greater consideration of small businesses in regulatory development. Portions of it have been codified in the Small Business Jobs Act of 2010.¹

Executive Order 13272 requires Advocacy to educate federal agency officials on compliance with the Regulatory Flexibility Act (RFA), to provide resources to facilitate continued compliance, and to report to the Office of Management and Budget on agency compliance with the executive order.

RFA Training

Advocacy launched its RFA training program in 2003. Since then, the office has offered RFA training sessions to every rule-writing agency in the federal government. These training sessions are attended by the agencies' attorneys, economists, and policymakers. While RFA training is normally held in person, the COVID-19 pandemic caused Advocacy to move its sessions online. In FY 2021, Advocacy held nine training sessions for 290 federal officials (see Table 2.1). The entire list of agencies trained since FY 2003 appears in Appendix D.

1. Small Business Jobs Act, Pub. L. No. 111-240, 124 Stat. 2504 (2010).

Table 2.1: RFA Training at Federal Agencies in FY 2021

Date	Agency	Number Trained
01/22/21	Department of Transportation, Federal Motor Carrier Safety Administration	9
04/20/21	Centers for Medicare and Medicaid Services	55
04/22/21	Department of the Treasury	27
05/11/21	Department of Energy	19
05/13/21	Federal Aviation Administration	38
06/16/21	Department of Labor, Wage and Hour Division	47
06/24/21	Nuclear Regulatory Commission	56
07/14/21	Department of Housing and Urban Development	27
08/25/21	Department of Justice, Civil Rights Division	12
	Total	290

RFA Compliance Guide

To provide clear directions on RFA compliance, Advocacy publishes a manual called “A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act.” The manual can be found on the Advocacy website and are provided to agencies during training.²

Agency Compliance with Executive Order 13272

Executive Order 13272 requires federal agencies to take certain steps to boost transparency and ensure small business concerns are represented in the rulemaking process. These steps include the following:

- *Written RFA Procedures.* Agencies are required to show publicly how they take small business concerns and the RFA into account when creating regulations. Most agencies have posted their RFA policies and procedures on their websites.

2. The most recent edition can be found at <https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/>

- *Notify Advocacy.* Agencies are required to engage Advocacy during the rulemaking process to ensure small business voices are being heard. If a draft regulation may have a significant impact on a substantial number of small entities, the agency must send copies of the draft notification to Advocacy.
- *Respond to Comments.* If Advocacy submits written comments on a proposed rule, the agency must consider them and provide a response to them in the final rule published in the Federal Register. The Small Business Jobs Act of 2010 codified this as an amendment to the RFA.

A summary of federal agencies' compliance with these three requirements is shown in Table 2.2.

As federal agencies have become more familiar with the RFA and have established cooperative relationships with Advocacy, the regulatory environment under Executive Order 13272 and the Small Business Jobs Act has led to less burdensome federal regulation. In addition to improving compliance with the RFA, Advocacy finds that Executive Order 13272 has improved the office's overall relationship with federal agencies.



Table 2.2 Federal Agency Compliance with Rule-Writing Requirements under Executive Order 13272 and the JOBS Act, FY 2021

Agency	Written Procedures on Website	URL of Agency's RFA Procedures	Notifies Advocacy	Responds to Comments
Cabinet Agencies				
Department of Agriculture	√	www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory	√	√
Department of Commerce (a)	√	www.fisheries.noaa.gov/national/laws-and-policies/guidance-conducting-economic-and-social-analyses-regulatory-actions	√	√
Department of Defense	X	https://www.acquisition.gov/node/28713/printable/print	√	√
Department of Education	X		√	n.a.
Department of Energy	√	www.energy.gov/sites/prod/files/gcprod/documents/eo13272.pdf	√	√
Department of Health and Human Services	√	FDA: www.fda.gov/ForIndustry/SmallBusinessAssistance/ucm167644.htm CMS: https://www.cms.gov/Regulations-and-Guidance/Guidance/CMSSmallBusAdminOmbuds	√	√
Department of Homeland Security	√	www.dhs.gov/publication/signed-regulatory-flexibility-act-executive-order-13272-memo-2004	√	n.a.
Department of Housing and Urban Development	n.a.	www.hud.gov/program_offices/sdb/policy/sbrefa	n.a.	n.a.
Department of the Interior	√	https://www.fws.gov/policy/library/rgeo12372.pdf	√	n.a.
Department of Justice	X		√	n.a.
Department of Labor	√	www.dol.gov/general/regs/guidelines	√	√
Department of State	X		√	n.a.
Department of Transportation	√	www.transportation.gov/sites/dot.dev/files/docs/1979%20Regulatory%20Policies%20and%20Procedures.doc	√	n.a.
Department of the Treasury (b)	√	Treasury: www.treasury.gov/about/role-of-treasury/orders-directives/Pages/td28-03.aspx Internal Revenue Service: www.irs.gov/irm/part32/irm_32-001-005#idm140712272166000	√	n.a.
Department of Veterans Affairs	√	www.va.gov/ORPM/Regulatory_Flexibility_Act_EO_13272_Compliance.asp	√	n.a.

Agency	Written Procedures on Website	URL of Agency's RFA Procedures	Notifies Advocacy	Responds to Comments
Environmental Protection Agency	√	www.epa.gov/sites/production/files/2015-06/documents/guidance-regflexact.pdf	√	√
Small Business Administration	n.a.	n.a.	√	n.a.
Noncabinet Agencies				
Commodity Futures Trading Commission	n.a.	n.a.	X	n.a.
Consumer Financial Protection Bureau (c)	n.a.	n.a.	√	n.a.
Consumer Product Safety Commission	√	https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking	√	n.a.
Equal Employment Opportunity Commission	√	www.eeoc.gov/eeoc/plan/regflexibilityact.cfm	√	n.a.
Federal Acquisition Regulation Council	X	https://www.acquisition.gov/node/28713/printable/print	√	n.a.
Federal Communications Commission	√	www.fcc.gov/sites/default/files/fcc-directive-1158.2.pdf	√	n.a.
Federal Reserve Board (c)	n.a.	n.a.		n.a.
Federal Retirement Thrift Investment Board	n.a.	n.a.	√	n.a.
General Services Administration	X		√	n.a.
National Labor Relations Board (c)	n.a.	n.a.	√	n.a.
Pension Benefit Guarantee Corporation	n.a.	n.a.	√	n.a.
Securities and Exchange Commission (c)	n.a.	n.a.	√	n.a.
<p>Notes: √ = Agency complied with the requirement. X = Agency did not comply with the requirement. n.a. = Not applicable because Advocacy did not publish a comment letter in response to an agency rule in FY 2021 or because the agency is not required to do so. a. NOAA drafts most regulations the Commerce Department releases. b. On April 11, 2018, Treasury and the Office of Management and Budget signed a Memorandum of Agreement stating that tax regulations would be reviewed under Executive Order 12866. c. Independent agencies are not subject to the E.O. requiring written procedures.</p>				

Chapter 3

Communication With Small Business and Federal Agencies

Communication with Federal Agencies

The principal goal of the Regulatory Flexibility Act (RFA) is to communicate small business concerns to federal agencies as they craft regulations. The RFA requires federal agencies to engage with small businesses in specific ways. These communications form the basis of federal small business regulatory analysis and regulatory burden reduction.

Direct Communications

Advocacy uses numerous methods of communication to present the concerns of small businesses and other small entities to federal officials promulgating new regulations. Meetings with officials, comment letters to agency directors, and training sessions on RFA compliance provide meaningful participation by all interested parties and produce more effective federal regulation. In FY 2021, Advocacy’s communications with federal agencies included 17 public comment letters and 9 RFA compliance training sessions for 290 federal officials. Table 2.1 lists the agencies where training was held this year, and Appendix D contains a list of all agencies that have participated in RFA training since 2003.

Additionally, Advocacy’s regional advocates participate in the regulatory process. By reaching out to local businesses, the regional advocates obtain valuable input directly from small businesses across the country. In turn, the regional advocates refer regulatory issues to Advocacy attorneys for review.

Executive Order 12866 and Interagency Review of Upcoming Rules

Executive Order 12866, Regulatory Planning and Review, celebrated its 28th anniversary in FY 2021.¹ The executive order’s goals are to enhance planning and coordination of new and existing regulations, reaffirm the primacy of federal agencies in the regulatory decision-making process, maintain the integrity and legitimacy of regulatory review and oversight, and make the process more accessible and open to the public.

Under Executive Order 12866, the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA) reviews all significant executive agency regulations. OIRA will also meet with interested parties to discuss any issues with a rule under its review in what are called “12866 meetings.” Advocacy attends these meetings when the regulation will affect small businesses.

SBREFA Panels

In 1996, the Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the RFA to require certain agencies to convene review panels whenever a potential regulation is expected to have a significant economic impact on a substantial number of small entities. These are commonly called SBREFA or Small Business Advocacy Review (SBAR) panels. These panels provide for small business input at the earliest stage of rulemaking—when a topic is still being studied, before a proposed rule sees the light of day. The list of SBREFA panels convened since 1996 can be found in Appendix D.

1. Executive Order 12866, Regulatory Planning and Review, September 30, 1993. https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

Three agencies are covered by this requirement: the Consumer Financial Protection Bureau (CFPB), Environmental Protection Agency (EPA), and Occupational Safety and Health Administration (OSHA). 5 panels were convened in FY 2021:

- CFPB convened a panel on small business lending data collection in October 2020.
- EPA convened a panel on Ethylene Oxide Commercial Sterilization and Fumigation Operations in November 2021.
- EPA convened a panel on Methylene Chloride in January 2021.
- EPA convened a panel on 1- Bromopropane in April 2021.
- EPA convened a panel on the oil and natural gas sector in July 2021.

Regulatory Agendas

Each spring and fall, federal agencies, including independent regulatory agencies, prepare an agenda of all the regulatory actions under development or review for the fiscal year. Each agency, including independent regulatory agencies, must also create a regulatory plan containing the most important proposed or final regulations the agency expects to release that fiscal year or thereafter. In addition to the regulatory agendas, agencies are also required by Section 602 of the RFA to publish a regulatory flexibility agenda that specifically addresses regulatory actions that will affect small businesses. These also must be published in the Federal Register each spring and fall.

The agendas facilitate public participation, specify the subjects of upcoming proposed rules, and indicate whether these rules are likely to have a significant economic impact on a substantial number of small entities. Agencies are specifically required to both provide these agendas to the Chief Counsel for Advocacy and make them available to small businesses and their representatives. Often, the agendas alert Advocacy and other interested parties to forthcoming regulations of interest.

OIRA then publishes these as the Unified Regulatory Agenda. The Fall 2019 regulatory agendas were published on March 31, 2020, and the Spring 2021 agendas were published on July 30, 2021. The Unified Regulatory Agendas are a key component of the regulatory planning mechanism prescribed in Executive Order 12866, Regulatory Planning and Review. The full regulatory agendas can be found on [reginfo.gov](https://www.reginfo.gov), while the introductions to the regulatory agendas can be found here:

- Fall 2020: <https://www.federalregister.gov/documents/2021/03/31/2021-04348/introduction-to-the-unified-agenda-of-federal-regulatory-and-deregulatory-actions-fall-2020>
- Spring 2021: <https://www.federalregister.gov/documents/2021/07/30/2021-14882/spring-2021-unified-agenda-of-regulatory-and-deregulatory-actions>

Retrospective Review of Existing Regulations

Under Section 610 of the RFA, agencies are required to conduct a retrospective review of existing regulations that have a significant economic impact on small entities. Executive Orders 13563 and 13610, which require all executive agencies to conduct periodic retrospective reviews of all existing regulations, bolster the mandate of RFA Section 610. As a result of Section 610, agencies publish retrospective review plans in the Unified Agenda of Regulatory and Deregulatory Actions semiannually.

The Department of Transportation's regulatory review process is one useful example of how agencies can incorporate Section 610 reviews into their semiannual retrospective reviews of all existing regulations.² Advocacy continues to monitor retrospective review plans and their implementation and accepts feedback

2. DOT divides its rules into ten groups and analyzes one group each year, checking to determine whether any rule has a significant economic impact on a substantial number of small entities. If a rule is found to do so, DOT reviews it in accordance with Section 610. U.S. Department of Transportation's Review Process (Jan. 20, 2015). www.transportation.gov/regulations/dots-review-process.

from small entities regarding any rules needing review.

Outreach to Small Business

In the Congressional Findings and Declaration of Purpose section of the RFA, Congress states, “The process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions...”³

To help fulfill this purpose, Advocacy assists governmental agencies by conducting outreach to small entities, relaying information from one to the other. In most instances, Advocacy encourages agencies to participate in these outreach efforts, and most agencies are receptive to the invitation.

Advocacy engages with small business stakeholders through a variety of mechanisms, ensuring that lines of communication remain open and that small business concerns are heard by the appropriate contacts within the federal agencies. For example, Advocacy publishes regulatory alerts that are emailed to lists of small entities. In addition, Advocacy directs targeted email notices to stakeholders who may be affected by rulemaking. These alerts allow small businesses to stay informed of regulatory developments without having to conduct searches

3. Regulatory Flexibility Act, Pub. L. No. 96-3554, 94 Stat. 1164 (codified at 5 U.S.C. § 601).

of their own. Regional advocates serve as a daily point of contact for small businesses throughout the country.

Throughout its history, Advocacy has met regularly with small entities, both informally through in-person meetings and teleconferences, and at more structured events. Those events have included stakeholder conferences to present specific regulatory topics, where Advocacy can work to inform small business stakeholders about the federal rulemaking process and how to write effective comment letters. One of Advocacy’s most effective outreach strategies has been roundtable events in Washington, DC. In these roundtables, specific regulatory issues are discussed by small businesses and their representatives, in almost all cases with the federal agency present. As a result of the COVID-19 pandemic, Advocacy staff have moved these roundtables online. The result has been greater participation by stakeholders, including participation by those from distant locations.

In recent years, Advocacy has hosted roundtables around the country as needed. These roundtables are often Advocacy’s principal means of gathering extensive small business input. During the pandemic, Advocacy staff have moved roundtables online for safety and convenience. As online communication has become more prevalent, Advocacy has been able to include stakeholders that otherwise may have gone unnoticed.



Table 3.1 Regulatory Roundtables Hosted by the Office of Advocacy

Agency	Purpose	Date
Department of Energy	Small Business Energy Teleconference	04/27/21
Department of Labor	Small Business Labor Roundtable on DOL's Proposed Rule on Tip Credits	08/03/21
Department of Labor Occupational Safety and Health Administration/ Mine Safety and Health Administration	Regulatory Flexibility Act, Open Discussion	01/29/21
	House Education and Labor Committee, COVID-19 Pandemic	03/19/21
	OSHA's Hazard Communication Standard	04/23/21
	COVID-19 Pandemic, OSHA COVID-19 ETS	05/21/21
	OSHA's ETS for Health Care Settings, General Industry Guidance	06/24/21
	OSHA and MSHA Regulatory Agendas, Total Worker Health	07/16/21
	SBREFA Panel on Emergency Response, MSDs, and COVID-19	09/17/21
Department of the Treasury/ Internal Revenue Service	Department of Treasury/IRS Paycheck Protection Program Tax Issues	12/04/20
	Department of Treasury/IRS Paycheck Protection Program (PPP) Tax Issues & Employee Retention Credit (ERC) Update	02/19/21
Environmental Protection Agency	EPA's Final Risk Evaluations for Cyclic Aliphatic Bromide Cluster (HBCD)	10/16/20
	EPA's Final Risk Evaluation for Carbon Tetrachloride	12/04/20
	EPA's Final Risk Evaluation for Trichloroethylene (TCE) and Draft Scope of Risk Evaluations for DIDP and DINP	12/18/20
	EPA's Final Risk Evaluations for Perchloroethylene and EPA's Office of Research and Development Staff Handbook for Developing Integrated Risk Information System Assessments	01/15/21
	EPA's Final Risk Evaluations for 1,4 Dioxane and Asbestos and EPA's Proposed Fees Rule	02/05/21
	EPA's Final Risk Evaluation for Pigment Violet 29 and N-Methyl-2-pyrrolidone (NMP) and HFC Phase-Down under the American Innovation and Manufacturing Act	02/26/21
	Environmental Roundtable on 2021 Multi Sector General Permit	04/09/21
	Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program under the AIM Act	06/04/21
	EPA's Proposed TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances	08/13/21

Roundtables by Agency and Date

Department of Energy

Small Business Energy Teleconference

April 27, 2021

On April 12, 2021, the U.S. Department of Energy issued a proposed rule that would revise processes and procedures the agency follows in developing energy conservation standards and test procedures for consumer products and commercial and industrial equipment. During this teleconference, small entities presented data, information, and public comments on the rule. The small entities made specific suggestions for policies that the agency should not rescind or should otherwise modify. The agency attended the teleconference but did not present.

Department of Labor

Small Business Labor Roundtable on Department of Labor's Proposed Rule on Tip Credits

August 3, 2021

On August 3, 2021, Advocacy held a small business roundtable on the Department of Labor's proposed rule revising the tip credit under the Fair Labor Standards Act, which allows an employer to count a limited amount of tips earned by tipped employees as a credit towards its minimum wage obligation. The roundtable was attended by small business representatives from more than 20 states and Puerto Rico. Small businesses told Advocacy that the proposed rule will be costly and burdensome to implement in their busy restaurants, hotels, nail salons and other workplaces because it will require businesses to track their workers' tasks minute to minute to utilize the tip credit wage. On October 29, 2021, the Department of Labor released a final rule with minimal changes.

Department of Labor, Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA)

Regulatory Flexibility Act, Open Discussion

January 29, 2021

On January 29, 2021, Advocacy hosted a small business labor safety roundtable. The roundtable began with an abbreviated version of the RFA/SBREFA training that Advocacy provides to federal agencies. This overview was designed to explain the regulatory process to small entities. Following the RFA/SBREFA training overview, participants engaged in an open discussion of several key regulatory issues. These issues included the incoming White House's new "Regulatory Freeze" memorandum and OMB guidance to agencies, the Congressional Review Act, OSHA/MSHA revised penalties, COVID-19 enforcement policy and guidance, and the OSHA injury and illness electronic reporting deadline.

House Education and Labor Committee, COVID-19 Pandemic

March 19, 2021

This roundtable began with an update from the Senior Labor Policy Advisor to the House Education and Labor Committee, including the structure of the Committee, its priorities, and possible legislation on items such as workplace violence in healthcare and social service settings, injury and illness reporting, and workers' rights to organize for action. The Senior Advisor then discussed the Committee's recent hearing, "Clearing the Air: Science-Based Strategies to Protect Workers from COVID-19 Infections." Next, a panel of small business representatives from the construction and manufacturing sectors discussed the myriad of challenges that small businesses face in implementing COVID-19 guidance and controls to protect their employees and workplaces. These challenges included both technical and economic

feasibility concerns of implementing a possible OSHA COVID-19 Emergency Temporary Standard.

OSHA's Hazard Communication Standard

April 23, 2021

This small business roundtable focused exclusively on OSHA's proposed Hazard Communication Standard rule, which would modify OSHA's Hazard Communication Standard to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals. The change would address issues that arose during the implementation of OSHA's 2012 rule and would provide better alignment with other U.S. agencies and international trading partners without lowering overall protections. The acting director of OSHA and a senior scientist from OSHA's Directorate of Standards and Guidance provided an overview of the proposed rule. Two small business industry representatives then discussed concerns involving proposed revisions and the inclusion of language requiring chemical manufacturers or importers to determine the hazard classes, and, where appropriate, the category of each class that applies to the chemical being classified as "under normal conditions of use and foreseeable emergencies."

COVID-19 Pandemic, OSHA COVID-19 ETS

May 21, 2021

This small business roundtable focused on the COVID-19 pandemic. First, the Director of the National Institutes of Occupational Safety and Health (NIOSH) discussed the state of COVID-19 science and public health precautions that should be taken in response to the pandemic. The director also discussed specific guidance and assistance from NIOSH tailored to high-risk industries. Next, Advocacy provided an update on the President's Executive Order on Protecting Worker Health and Safety, including updated guidance, increased enforcement, and a possible OSHA Emergency Temporary Standard on COVID-19. Finally, there was a recap of the American Bar Association's

recent occupational safety and health law committee meeting.

OSHA's Emergency Temporary Standard for Health Care Settings, General Industry Guidance

June 24, 2021

On June 24, 2021, Advocacy hosted a small business labor safety roundtable focused exclusively on OSHA's new Emergency Temporary Standard to protect healthcare workers from contracting COVID-19. The standard focuses on protecting workers in health care settings with 10 or more employees where suspected or confirmed coronavirus patients are treated. These settings include employees in hospitals, nursing homes, and assisted living facilities, as well as emergency responders, home health care workers, and employees in ambulatory care settings where suspected or confirmed coronavirus patients are treated. The standard requires non-exempt facilities to conduct a hazard assessment and have a written plan to mitigate virus spread. It also requires healthcare employers to provide some employees with N95 respirators or other personal protective equipment.

OSHA and MSHA Regulatory Agendas, Total Worker Health

July 16, 2021

This small business roundtable focused primarily on OSHA and MSHA's Spring 2021 Regulatory Agendas. These agendas track future regulatory and policy actions that the agencies plan to pursue. First, the Acting Director of OSHA's Directorate of Standards and Guidance discussed OSHA's latest Regulatory Agenda, including COVID-19, indoor and outdoor heat stress, and safety and health programs. OSHA also addressed its National Advisory Council for Occupational Safety and Health agenda going forward. Next, the Deputy Assistant Secretary of Labor for Operations at MSHA discussed the agency's regulatory priorities, including respirable crystalline

silica. Finally, a small business representative discussed the new NIOSH “Total Worker Health” program and its implications for small business.

SBREFA Panel on Emergency Response, MSDs, and COVID-19

September 17, 2021

This small business roundtable centered on OSHA’s Small Business Advisory Review Panel on “Emergency Response.” OSHA’s potential Emergency Response standard could lead to regulations that impact small employers in firefighting, fire rescue, and emergency medical service, as well as general industry, construction, and maritime industry employers that provide “skilled support” at an emergency incident. Next, a representative from the National Safety Council discussed innovative solutions to prevent musculoskeletal disorders. Finally, a small business representative discussed the legal and regulatory landscape facing the business community in light of COVID-19 mandates.

Department of the Treasury/Internal Revenue Service (IRS)

Department of Treasury/IRS Paycheck Protection Program Tax Issues

December 4, 2020

Participants in this roundtable discussed the federal and state tax issues surrounding Paycheck Protection Program (PPP) Loans. The CARES Act created the PPP to provide loans to small businesses impacted by the COVID-19 pandemic. The Small Business Administration and Treasury implemented the PPP, and as of August 2020 provided over five million loans of over \$525 billion. Although the CARES Act provides that forgiven PPP loans are not included in gross income at the federal level, there are still federal and state tax issues surrounding PPP loans, including the impact of IRS Notice 2020-32, the tax treatment of an Economic Injury Disaster Loan advance, and whether states will tax forgiven PPP loans. Speakers

included Tom West, Principal, Passthroughs Group KPMG US; and Jared Walczak, Vice President of State Projects with the Center for State Tax Policy at the Tax Foundation.

Department of Treasury/IRS Paycheck Protection Program Tax Issues & Employee Retention Credit Update

February 19, 2021

Participants at this roundtable discussed updates on PPP tax issues and the Employee Retention Credit (ERC). The Consolidated Appropriations Act of 2021 brought about needed tax relief for small businesses. For example, it included an allowance of the deduction of business expenses paid with forgiven or forgivable PPP loans and updates to the ERC. The ERC could be used for 2020 and 2021 and could be claimed even if the employer received a PPP loan. Participants discussed the tax updates for the PPP, the eligibility requirements for the ERC and how



the ERC works in conjunction with the PPP. Speakers included Deborah Walker, National Director of Cherry Bekaert's Compensation & Benefits Solutions group; and Andrew W. McLaughlin, shareholder with Stearns Weaver Miller.

Environmental Protection Agency

EPA's Final Risk Evaluations for Cyclic Aliphatic Bromide Cluster

October 16, 2020

Advocacy held a roundtable on the third of the EPA's 10 high-priority chemicals under the amended Toxic Substance Control Act (TSCA). On September 25, 2020, the EPA published a risk evaluation for Cyclic Aliphatic Bromide Cluster (HBCD), finalizing determinations of unreasonable risk for 6 out of 12 evaluated conditions of uses. The EPA found the import, processing, recycling, commercial use, consumer use, and disposal of HBCD present unreasonable risks to the environment, and the use of HBCD in building and construction materials as well as exposure through demolition also present an unreasonable risk to workers and occupational non-users.

At this roundtable, the EPA presented an overview on its final risk evaluation, discussed its regulatory options for the risk management of HBCD, and expressed interest in stakeholder engagement including consultations with small businesses.

EPA's Final Risk Evaluation for Carbon Tetrachloride

December 4, 2020

Advocacy held a roundtable on the fourth of the EPA's 10 high-priority chemicals under the amended TSCA. The EPA completed the final risk evaluation for carbon tetrachloride in October 2020. Carbon tetrachloride is used in commercial settings as a raw material for producing other chemicals like refrigerants, chlorinated compounds, and agricultural

products in accordance with the Clean Air Act and Montreal Protocol. The final risk evaluation shows that there are unreasonable risks to workers and occupational non-users for 13 of the 15 conditions of use the EPA evaluated. This includes unreasonable risks when manufacturing the chemical, processing the chemical as a reactant or intermediate and into formulation of other products, laboratory uses, recycling, uses in a variety of industrial and commercial applications, and disposal.

At this roundtable, the EPA presented an overview on its final risk evaluation, discussed its regulatory options for the risk management of carbon tetrachloride, and expressed interest in stakeholder engagement including consultations with small businesses. W. Caffey Norman, an attorney who focuses on the regulation of hazardous chemicals, also presented on implications of carbon tetrachloride risk evaluation for feedstock and laboratory uses.

EPA's Final Risk Evaluation for Trichloroethylene (TCE) and Draft Scope of Risk Evaluations for DIDP and DINP

December 18, 2020

Advocacy held a roundtable on the fifth of the EPA's 10 high-priority chemicals under the amended TSCA and on the draft scope for two



manufacturer-requested risk evaluations. The EPA completed the final risk evaluation for trichloroethylene (TCE) in November 2020. After evaluating 54 conditions of use of TCE, the EPA has determined that TCE presents an unreasonable risk under 52 conditions of use. This includes an unreasonable risk to workers and occupational nonusers when manufacturing the chemical, processing the chemical for a variety of uses, when used in a variety of industrial and commercial applications, and disposal.

DIDP and DINP are common chemical names for categories of chemicals primarily used as plasticizers in plastic and rubber products. In 2019, manufacturers requested that the EPA conduct a risk evaluation for these chemicals. As a first step toward those risk evaluations, on November 27, 2020, the EPA published a draft scope, which include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects the risk evaluations will cover.

At this roundtable, the EPA presented an overview on its final risk evaluation, discussed its regulatory options for the risk management of TCE, and expressed interest in stakeholder engagement including consultations with small businesses. The Halogenated Solvents Industry Alliance also presented its view of final risk evaluation and the implications on small businesses. The EPA also presented on the draft scoping documents for the risk evaluation of DIDP and DINP and sought input on conditions of use, life cycle, conceptual model, analysis plan, and exposure pathways.

EPA's Final Risk Evaluations for Perchloroethylene and EPA's Office of Research and Development Staff Handbook for Developing Integrated Risk Information System Assessments

January 15, 2021

Advocacy held a roundtable on the EPA's final risk evaluation for perchloroethylene (PCE), the sixth of the first ten high-priority chemicals under the

amended TSCA. In December 2020, the EPA published a risk evaluation for PCE, finalizing determinations of unreasonable risk for 59 out of 61 evaluated conditions of uses. These uses include consumer and occupational uses. The EPA presented an overview on its final risk evaluation, discussed its regulatory options for the risk management of PCE, and expressed interest in stakeholder engagement including consultations with small businesses.

This roundtable also included a discussion of the EPA's Office of Research and Development's Staff Handbook for Developing Integrated Risk Information System Assessments (IRIS Handbook), for which the agency sought public comments. The IRIS Handbook provides operating procedures for developing assessments to the scientists in the IRIS Program, including operating procedures for developing assessments including problem formulation approaches and methods for conducting systematic review, dose response analysis, and developing toxicity values. IRIS chemical assessments are an important source of toxicity information used by the EPA and other agencies to characterize potential public health risk. One of the IRIS presenters was Kevin Bromberg, a former Advocacy staffer.

EPA's Final Risk Evaluations for 1,4 Dioxane and Asbestos and EPA's Proposed Fees Rule

February 5, 2021

Advocacy held a roundtable on the EPA's final risk evaluations for 1,4, dioxane and asbestos, the seventh and eighth of the first ten high-priority chemicals under the amended TSCA. In December 2020, the EPA published a risk evaluation for 1,4, dioxane, finalizing unreasonable risks to workers and occupational non-users from 13 conditions of use. The EPA also published the risk evaluation for asbestos in December 2020 finalizing unreasonable risks to workers, occupational non-users, consumers, and bystanders from 16 out of 32 conditions of use. At this roundtable, the EPA presented an overview on its final risk evaluation, discussed its regulatory options

for the risk management of 1,4, dioxane and asbestos, and expressed interest in stakeholder engagement including consultations with small businesses.

The EPA also presented on its proposed fees rule. On January 11, 2021, the EPA proposed revisions for its 2018 fees rule. The EPA is required to review and adjust the fees, if necessary, every three years. Among the proposed changes, the EPA proposed to add new fee categories while providing exemptions for some fee-triggering activities. The EPA also proposed various changes to adjust its fees including a new production volume-based allocation for EPA-initiated risk evaluation fees. The EPA acknowledged that the incorporation of a production volume fee calculation may result in some small businesses paying higher fees if they produce more than other manufacturers. As a result, the EPA's proposal specifically requested comments on its new cost methodology, its impact on small businesses, and whether caps for fees should be considered for small businesses.

EPA's Final Risk Evaluation for Pigment Violet 29 and N-Methyl-2-pyrrolidone (NMP) and HFC Phase-Down under the American Innovation and Manufacturing Act

February 26, 2021

Advocacy held a roundtable on the EPA's final risk evaluations for pigment violet 29 (PV29) and n-methyl-2-pyrrolidone (NMP), the ninth and tenth of the first ten high-priority chemicals under the amended TSCA. In December 2020, the EPA published a risk evaluation for PV29, finalizing unreasonable risks to workers and occupational non-users from 10 out of 14 conditions of use. In January 2021, the EPA published the risk evaluation for NMP, finalizing unreasonable risks to workers and consumers from 26 out of 37 conditions of use. At this roundtable, the EPA presented an overview on its final risk evaluation, discussed its regulatory options for the risk management of PV29 and NMP, and expressed interest in stakeholder engagement including consultations with small businesses.

This roundtable also included a discussion of the American Innovation and Manufacturing Act of 2020. The Act directs the EPA to establish a regulatory framework for phasing down the production and consumption of hydrofluorocarbons (HFCs) over a fifteen-year period. HFCs are targeted because they are a highly potent greenhouse gas. New regulations will have a significant effect on the marketplace, including reopening some EPA regulations finalized over the last four years.

Environmental Roundtable on 2021 Multi-Sector General Permit

April 9, 2021

Advocacy held a roundtable with the EPA to discuss its final 2021 Multi-Sector General Permit (MSGP) implemented under the Clean Water Act. This roundtable began with a detailed summary of the EPA's 2021 MSGP and a small entity response by the Federal StormWater Association. The roundtable also included a robust Q&A period where small entity representatives were able to ask the EPA about the 2021 MSGP. Participants also asked about how the EPA plans to use data collected under the 2021 MSGP for its next revisions to the MSGP, expected in 2026.

Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program under the American Innovation and Manufacturing Act of 2020

June 4, 2021

Advocacy held a roundtable on the EPA's proposed rule to implement the American Innovation and Manufacturing Act of 2020. This rule would set the hydrofluorocarbon production and consumption baseline levels from which reductions would be made, establish an initial methodology for allocating and trading hydrofluorocarbon allowances for 2022 and 2023, and create a new compliance and enforcement system. At this roundtable, the EPA presented on this proposal and request for

comments, including the proposed set-aside of allowances for small businesses.

EPA's Proposed TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances

August 13, 2021

Advocacy held a roundtable on the EPA's proposed reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances (PFAS) under the TSCA. The proposal requires any person who manufactures or has manufactured PFAS chemical substances since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. The proposed rule does not include an exemption for small manufacturers. Unlike section 8(a)(1), which provides a specific exemption for

small manufacturers and processors from reporting and recordkeeping requirements for chemical substances, section 8(a)(7) does not specify an exemption for small manufacturers from reporting and recordkeeping for PFAS chemical substances. The proposed rule would also apply to importers of PFAS chemical substances and of articles containing PFAS chemical substances. The agency sought comments on whether imported articles containing PFAS should be included within the scope of its proposed rule. At this roundtable, the EPA presented an overview on the proposed rule including impacts of the rule, the EPA's plans to use the data collected, and its timeline for implementation of the final rule.



Regional Advocate Outreach

Advocacy's regional advocates reach out directly to small businesses in their respective regions to inform them of the role of Advocacy in the regulatory process and to hear directly from them on issues affecting their business operations. The regional advocates also receive information from small businesses concerning the enforcement of agency actions. Advocacy forwards this information to the Office of the National Ombudsman (ONO). ONO is primarily concerned with helping small businesses when they experience excessive or unfair federal regulatory enforcement actions.

Chapter 4

Advocacy's Public Comments to Federal Agencies in FY 2021

In FY 2021, Advocacy submitted 17 formal comment letters to regulatory agencies. The most frequent concerns were that agencies did not adequately analyze small business impacts (seven letters), that agencies failed to consider significant alternatives (five letters), and that agencies needed to reach out to small entities (five letters). Several letters (ten)

referenced other issues not categorized. In one case, Advocacy commended an agency for their consideration of small business concerns. Figure 4.1 summarizes Advocacy's issues of concern. Table 4.1 lists all the comment letters submitted in FY 2021 in chronological order. Each letter is summarized in the following section, arranged by agency.

Figure 4.1 Number of Specific Issues of Concern in Agency Comment Letters, FY 2021

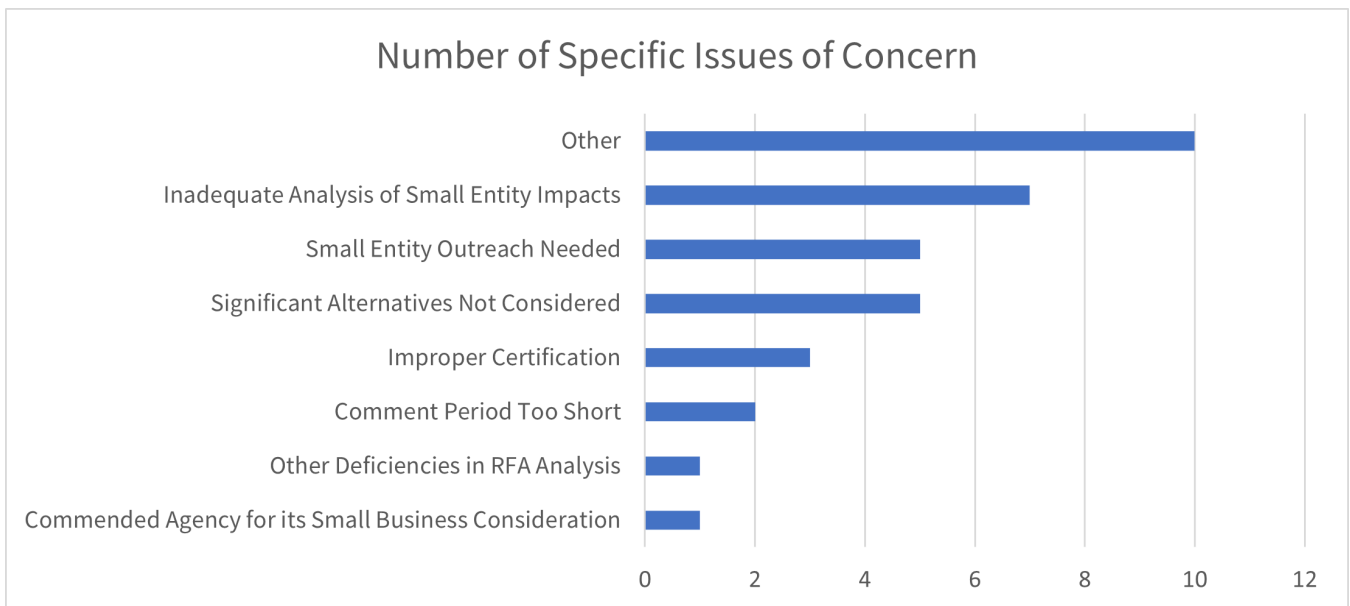


Table 4.1 Regulatory Comment Letters Filed by the Office of Advocacy, FY 2021

Date Filed	Agency*	Topic	Citation to Rule
10/08/20	USDA	Establishment of a Domestic Hemp Production Program; Comment Period Reopened	85 Fed. Reg. 55363
10/13/20	FDA	Citizen Petition for Extension of Premarket Tobacco Product Application Filing Deadline Due to the COVID-19 Pandemic	Docket Number FDA- 2020-P-1797
11/06/20	CORPS	Proposal to Reissue and Modify Nationwide Permits	85 Fed. Reg. 57298
11/09/20	DOL	Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States	85 Fed. Reg. 63872
11/16/20	CORPS	Proposal to Reissue and Modify Nationwide Permits	85 Fed. Reg. 57298
12/31/20	OMB	Guidance for Grants and Agreements	85 Fed. Reg. 49506
04/28/21	DOC	Securing the Information and Communications Technology and Services Supply Chain: Licensing Procedures	86 Fed. Reg. 16312
05/10/21	EPA	Revisions to the Unregulated Contaminant Monitoring Rule for Public Water Systems	86 Fed. Reg. 13846
05/25/21	DOE	Energy Conservation Program for Appliance Standards	86 Fed. Reg. 18901
06/07/21	FDA	Extension of One-Year Moratorium on FDA Enforcement Actions Against ENDS Manufacturers with Timely Submitted Premarket Tobacco Product Applications and the FDA's Policy to Review Premarket Tobacco Product Applications by Market Share	84 Fed. Reg. 50566
06/23/21	DOC	Cyber Supply Chain Risk Management Practices for Systems and Organizations	SP 800-161 Rev. 1 (Draft)
07/06/21	EPA	Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act	86 Fed. Reg. 27150
07/12/21	EPA	2022 Construction General Permit Under the National Pollution Discharge Elimination System Permit Program of the Clean Water Act	86 Fed. Reg. 26023
07/26/21	EPA	Addition of 1-Bromopropane to Clean Air Act Section 112 HAP List	86 Fed. Reg. 31225
08/20/21	DOL	Tip Regulations Under the Fair Labor Standards Act (FLSA); Partial Withdrawal	86 Fed. Reg. 32818
08/27/21	DOL	Increasing the Minimum Wage for Federal Contractors	86 Fed. Reg. 38816
09/28/21	EPA	EPA's Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances	86 Fed. Reg. 33926

*Abbreviations:

CORPS Army Corps of Engineers
 DOC Department of Commerce
 DOE Department of Energy
 DOL Department of Labor

EPA Environmental Protection Agency
 FDA Food and Drug Administration
 OMB Office of Management and Budget
 USDA Department of Agriculture

Summaries of Advocacy's Public Comments to Federal Agencies

Department of Agriculture

Issue: Establishment of a Domestic Hemp Production Program

On October 31, 2019, the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) published an interim final rule outlining the policies and procedures by which States, Indian tribes, and the AMS itself will administer programs for hemp production in the United States. The interim final rule outlined several requirements that plan administrators and producers alike must meet to engage in approved production activities. Advocacy expressed concerns that several of the provisions of the rule imposed unnecessary burdens on small entities as written. Many of the sampling and testing requirements needed revision, and the agency should have considered alternatives to minimize the burden on small producers. First, Advocacy urged the AMS to allow for remediation and on-farm disposal of non-compliant crops so that farmers would not experience a total revenue loss. Second, Advocacy asked the AMS to lengthen the 15-day harvest window, which was too narrow for farmers. Third, Advocacy suggested that testing procedures include more than just the top one-third of the plant, a test that better reflects how the plant will be used and ensures that there will not be an inflated number of non-compliant crops. Finally, Advocacy encouraged the AMS to reconsider its measurement of uncertainty for sampling to account for variables in pre-sampling activities and reconsider the requirement that labs be DEA-registered.

Department of Commerce

Issue: Cyber Supply Chain Risk Management Practices for Systems and Organizations

In April 2021, the National Institute of Standards and Technology (NIST) issued a draft revision to its publication Cyber Supply Chain Risk Management Practices for Systems and Organizations. The updates were designed to provide organizations with ways to better identify and respond to cyber threats while aligning with other federal cybersecurity guidelines.

Advocacy encouraged NIST to address the risk that their new guidance could become a set of de facto requirements for contractors, which would disproportionately harm small businesses. Additionally, Advocacy recommended that NIST describe small businesses in the cyber supply chain, explain how the guidance pertains to them, and provide summary information for small businesses to understand the new recommendations. Finally, Advocacy recommended NIST discuss how its new guidelines related to policies from other agencies and broader cybersecurity concerns facing small businesses.

Issue: Securing the Information and Communications Technology and Services Supply Chain: Licensing Procedures

On January 19, 2021, the Department of Commerce published an interim final rule on the implementation of Executive Order 13873, Securing the Information and Communications Technology and Services Supply Chain. The rule, which became effective March 22, 2021, would allow the Secretary of Commerce to address national security threats by prohibiting certain information and communications technology and services transactions. Commerce announced it would implement a licensing process for small entities seeking pre-approval.

On March 29, 2021, Commerce published an advance notice of proposed rulemaking seeking additional input on a voluntary licensing or pre-clearance

process. Advocacy commented on the notice, encouraging Commerce to extend the public comment period for a minimum of 30 days. Advocacy argued that doing so would allow small businesses and their representatives ample time to participate in the rulemaking.

Department of Defense, U.S. Army Corps of Engineers

Issue: Proposal to Reissue and Modify Nationwide Permits

On September 15, 2020, the U.S. Army Corps of Engineers published a proposed rule to reissue 52 nationwide permits (NWP) and issue five new permits. Under Section 1344 of the Clean Water Act, the Secretary of the Army has the authority to issue nationwide permits for categories of activities involving dredged or fill material if they determine that those activities will have a minimal adverse effect on the environment. Similar nationwide permits may be issued to authorize activities pursuant to Section 10 of the Rivers and Harbors Act. This authority has been delegated to the Chief of Engineers. Nationwide permits can be issued for a period of no more than five years.

Executive Order 13783, signed in March 2017, directed federal agency heads to review existing regulations that burden the development of domestically produced energy resources. The agency identified nine NWPs that could be modified to reduce the regulatory burdens on entities that develop or use domestically produced energy resources. This proposed rule provided modifications to those nine NWPs, as well as reissuing and modifying the remaining NWPs so they remain on the same five-year schedule.

The new permits were to cover electric and telecommunications utility lines not covered by other permits, construction and maintenance of water reuse and reclamation facilities, and seaweed and finfish mariculture activities.

Advocacy urged the agency to consider additional comments and data sources provided by small businesses in bolstering its environmental impact analyses for the rulemaking. Advocacy also suggested that the agency retain the term aquaculture and not implement the proposed change to the term “mariculture,” reconsider classifying certain seeding activities and equipment as “structures” subject to permitting requirements, and refrain from categorizing aquaculture harvest activities as “dredge and fill” activities.

Department of Energy

Issue: Energy Conservation Program for Appliance Standards

On April 12, 2021, the Department of Energy (DOE) published a proposed rule to revise its 2020 final rule that set forth processes for determining test procedures and finalizing energy conservation standards for industrial and consumer products. The proposed rule eliminated the binding nature of the 2020 final rule, including the requirement to conduct early engagement through a request for information or advance notice of proposed rulemaking. Rather than being the default procedure for proposed rulemakings, the agency would return to discretionary use of these tools.

Advocacy filed a comment letter encouraging the DOE to reconsider eliminating large portions of the 2020 final Process Rule because it would create regulatory uncertainty and burdens for small businesses. Advocacy urged the DOE to maintain the binding early engagement requirement while allowing for exceptions in certain instances. The proposed rule also removed the significant energy savings threshold set forth in the 2020 final rule, which created a numerical threshold requiring that an energy conservation standard result in a specified reduction in energy use. Advocacy encouraged the DOE to retain the significant energy savings threshold because it provides certainty to small businesses and meets the agency’s statutory objectives. The

rule also eliminated a requirement that the DOE establish and finalize test procedures for a particular product at least 180 days prior to publication of a proposed energy conservation standard. Advocacy strongly recommended that this requirement not be eliminated because small businesses need time to test the feasibility of new procedures. Finally, the proposal eliminated the requirement to conduct a comparative analysis when determining whether a specific conservation threshold is economically justified. Advocacy requested that the DOE not remove the comparative analysis requirement from the rulemaking and that the DOE use the comparative analysis to ensure compliance with the RFA.

The DOE finalized most portions of its proposal without any changes. However, the agency left the 180-day publication requirement in place for new product classes only.

Department of Labor

Issue: Increasing the Minimum Wage for Federal Contractors

On April 27, 2021, President Biden issued Executive Order 14026, which increased the hourly minimum wage paid to employees of federal contractors and subcontractors to \$15.00 per hour beginning January 30, 2022. The Department of Labor (DOL) released a proposed rule implementing Executive Order 14026 on July 22, 2021. On August 27, 2021, Advocacy submitted a comment letter to the DOL based on small business feedback, citing concern that the proposed rule will result in financial hardship for affected small businesses that are not normally considered government contractors, such as concessionaires, lease holders, and seasonal recreational businesses who have contracts and permits on Federal property or lands. Many of these small businesses will be unable to pass on these increased wage costs to the federal government like traditional federal contractors. Advocacy also commented that the DOL improperly certified that this rule would not have a significant economic

impact on a substantial number of small entities. Advocacy recommended that the DOL prepare and make available for public comment a supplemental initial regulatory flexibility analysis that adequately assesses the small business compliance costs from this regulation and consider significant alternatives that would accomplish the objectives of the statute while minimizing the economic impacts to small entities.

Issue: Tip Credit Regulations Under the Fair Labor Standards Act; Partial Withdrawal

On June 23, 2021, the DOL released a proposed rule modifying the tip credit under the Fair Labor Standards Act. The tip credit allows an employer to count a limited amount of tips earned by tipped employees as a credit towards its minimum wage obligation. The proposed rule focused on the “dual jobs” portion of the tip credit, which addresses a situation where an employee performs multiple jobs, both tip and non-tip related. The proposed rule adopts a version of the prior “80/20” guidance, subject to an additional restriction of a 30- minute time limit. As proposed, an employer can utilize the tip credit if the employee works 80 percent of their job on tip-producing work and completes directly supporting work if it does not exceed 20 percent of hours worked or any continuous periods of time that exceeds 30 minutes during the workweek. The DOL certified that the proposed rule will not have a significant economic impact on a substantial number of small entities.



On August 20, 2021, Advocacy submitted a comment letter to the DOL, cautioning the agency that its certification was improper and lacked a factual basis. The agency omitted and underestimated compliance costs of this rule. Small businesses told Advocacy that the proposed rule will be costly and burdensome to implement because it will require businesses to track their workers' tasks minute to minute to utilize the tip credit wage. Advocacy recommended that the DOL prepare and make available for public comment an initial regulatory flexibility analysis that adequately assesses the small business compliance costs from this regulation and consider significant alternatives that would accomplish the objectives of the statute while minimizing the economic impacts to small entities.

Issue: Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States

On October 8, 2020, the DOL issued an Interim Final Rule amending the prevailing wage methodology and increased the prevailing wages immediately for certain employment-based immigrant visas and non-immigrant visas in the H-1B, H-1B1, E-3, EB-2, and EB-3 categories. In a comment letter to the DOL on November 9, 2020, Advocacy expressed concern that this rule will cost employers over \$198 billion dollars over a 10-year period according to the DOL's analysis, which will have a disproportionate impact on small businesses. Small businesses have told Advocacy that they cannot pay the high wage increases in the Interim Final Rule. In addition, they may lose their current skilled workers and be shut out of the visa program, harming innovation and business growth. Advocacy recommended that the DOL delay implementation of this Interim Final Rule by a minimum of 30 days to receive comments from small businesses on any negative economic impacts of this regulation and to develop less burdensome regulatory alternatives.

On January 14, 2021, the DOL published a final rule which adopted the changes but extended the

effective date to March 15, 2021. This proposal has undergone multiple delays in effective date in response to a Presidential directive on January 20, 2021, entitled Regulatory Freeze Pending Review. The DOL has announced the delays of the effective dates to May 14, 2021, and later to November 14, 2022. The DOL also released a Request for Information on April 2, 2021, seeking information about potential sources and methods for determining prevailing wage levels. The DOL has noted that the delay will provide the agency with sufficient time to consider the final rule's legal and policy issues thoroughly and review the public comments received in response to the Request for Information.

Environmental Protection Agency

Issue: Construction General Permits

On May 12, 2021, the Environmental Protection Agency (EPA) published its proposed 2022 Construction General Permits (CGP) under the Clean Water Act. The CGP, utilized by operators of construction activities that disturb at least one acre of land, requires the regulated entities to take certain preventive and corrective actions in relation to stormwater discharges at these construction sites.

On July 12, 2021, Advocacy filed public comments on the proposed 2022 CGP. Advocacy commented that the EPA must fully comply with the Regulatory Flexibility Act when promulgating the CGP and better evaluate the economic impacts of the proposed revisions to the CGP on small entities. To move forward without convening a Small Business Regulatory Enforcement Fairness Act panel or IRFA, EPA would need to reconsider the elements of the proposed 2022 CGP that create new burdens for small entities. Advocacy also commented that EPA had not identified affected small entities, although Advocacy estimated that 25,000 of the 26,000 affected entities would be classified as small. In addition, Advocacy commented that EPA failed to fully account for the

cost to small entities from the regulation. Finally, Advocacy recommended against the following:

- Extending the waiting period from 14 calendar days from notice of intent to 30 calendar days from notice of intent for when entities are covered under the CGP.
- An unreasonable delineation between what constitutes “routine maintenance” compared to “corrective actions.”
- The classification of activity as “corrective action” triggering additional paperwork obligations and the possibility of civil fines.
- Reducing the amount of time operators have to stabilize construction sites if the construction site is larger than five acres.
- Eliminating the clarification that uncontaminated, non-turbid water does not need to be treated for turbidity.
- Requiring operators to inspect property beyond their ownership and control for signs of erosion and sedimentation.
- Requiring operators to complete EPA’s yet-to-be-developed or an EPA yet-to-be-approved construction inspection course.

Issue: Unregulated Contaminant Monitoring Rule 5

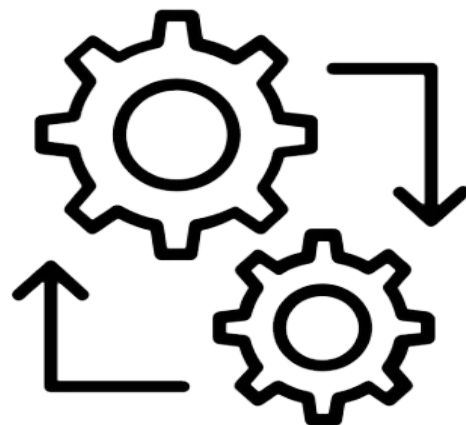
On March 11, 2021, the EPA published its proposed Revisions to the Unregulated Contaminant Monitoring Rule 5 for Public Water Systems (UCMR 5) under the Safe Drinking Water Act (SDWA). The UCMR 5 is the fifth revision to the list of contaminants not subject to any proposed or promulgated national primary drinking water regulations which are known or anticipated to occur in Public Water Systems (PWSs) and which may require regulation under the SDWA. The UCMR 5 proposed adding 29 perfluoroalkyl and polyfluoroalkyl substances (PFAS) chemicals and lithium to the list.

On May 10, 2021, Advocacy filed public comments on the proposed UCMR 5. Advocacy commented that the EPA must fully comply with the Safe Drinking Water

Act as amended by the America’s Water Infrastructure Act of 2018. Advocacy commented that these laws expressly provide that small PWSs must comply with UCMR 5 sample collection and analysis obligations only if appropriations were available to pay for such costs. Advocacy also commented that wholesale and consecutive PWSs that purchase water from other PWSs subject to UCMR 5 sample collection and analysis obligations should be exempt from re-testing the same water under UCMR 5. Similarly, Advocacy commented that PWSs that are required by other federal, state, or local law to collect samples and analyze for the 29 PFAS chemicals and lithium should be exempted from UCMR 5 obligations.

Issue: Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act

The American Innovation and Manufacturing Act (AIM Act), which became law on December 27, 2020, mandated a phase-down of hydrofluorocarbons (HFCs) domestic production and net imports to 15 percent of a 2011-2013 baseline, weighted by global warming potentials (GWPs). It grants EPA new authorities in three main areas: implementing the phase-down of production and net imports of listed HFCs, managing these HFCs and their substitutes, and facilitating the transition to next-generation technologies by restricting use of these HFCs. The AIM Act requires the EPA to have most of this



system in place for calendar year 2022. On May 19, 2021, the EPA published a proposed rule partially implementing the AIM Act.

On July 6, 2021, Advocacy filed a public comment letter on this proposed rule. Because small businesses are integral to the entire market and supply chain of HFCs, Advocacy argued that the EPA should be evaluating alternatives for the long-term health of the market, including minimizing transaction costs and encouraging innovation that furthers the goals of the AIM Act. Advocacy expressed support for the proposed set aside for small businesses and suggested the following:

- The EPA should maintain maximum flexibility in sale and transfer of allowances.
- The EPA should set aside allowances for reclaimers and environmentally beneficial innovations.
- The EPA should not ban disposable cylinders.
- The EPA should delay its proposed certification and labeling system.
- The EPA should reduce the burden of the audit requirement.
- The EPA should consider whether it should require AHRI purity standards for some imports.

Issue: Addition of 1-Bromopropane to Clean Air Act Section 112 HAP List

On July 26, 2021, the Office of Advocacy submitted comments to the Environmental Protection Agency (EPA) on an advance notice of proposed rulemaking on listing 1-bromopropane (1-BP) as a Hazardous Air Pollutant (HAP). In 2020, the EPA had announced it would add 1-BP to the Clean Air Act list of HAPs. On June 11, 2021, the EPA published an advance notice of proposed rulemaking to solicit information to identify and evaluate the regulatory impacts of adding 1-BP to the HAP list, including the information necessary to develop National Emission Standards for Hazardous Air Pollutants amendments. The EPA is simultaneously considering regulation of 1-BP under the Toxic Substances Control Act. Advocacy

recommended that the EPA engage in a single rulemaking that would satisfy the requirements of both the Clean Air Act and Toxic Substances Control Act. A single rulemaking would ensure coordination between the rulemakings, minimize the risk of confusion and inconsistencies between the rules, and reduce uncertainty.

Issue: EPA's Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Under the Toxic Substance Control Act

On June 28, 2021, the EPA published a proposed rule to require reporting and recordkeeping for PFAS. This proposed rule would require any person who manufactures or has manufactured PFAS since January 1, 2011 to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. On September 28, 2021, Advocacy submitted a public comment letter recommending that the EPA conduct a small business advocacy review panel, as required by Section 609 of the RFA, to assess the impact of the proposed rule on small entities, and to consider less burdensome alternatives. Advocacy said that the agency improperly certified that the rule will not have a significant economic impact on a substantial number of small entities under the RFA. Based on stakeholder outreach, Advocacy also expressed concerns about small businesses' ability to comply with the rule due to its broad scope and applicability, which includes importers of articles.

Food and Drug Administration

Issue: Extension of One-Year Moratorium on FDA Enforcement Actions Against ENDS Manufacturers with Timely Submitted Premarket Tobacco Product Applications and the FDA's Policy to Review Premarket Tobacco Product Applications by Market Share

On June 7, 2021, the Office of Advocacy sent a letter to the Food and Drug Administration (FDA)

encouraging the agency to seek an extension of the one-year moratorium of FDA enforcement actions against manufacturers of timely filed premarket tobacco product applications (PMTA). The one-year moratorium on FDA enforcement actions against manufacturers that timely filed PMTAs expired on September 9, 2021. As of May 2021, there were timely submitted PMTAs for over 6 million electronic nicotine delivery systems (ENDS) products. The FDA Center for Tobacco Products prioritized review of timely submitted PMTAs by market share, reviewing the products of large ENDS manufacturers first. In its comment letter, Advocacy encouraged the FDA to seek an extension of the court-ordered moratorium of FDA enforcement actions. Advocacy also encouraged the FDA to reverse its order of review of PMTAs so that more small ENDS manufacturers can keep their products on the market, as waiting longer for approval may result in these small businesses closing permanently.

Issue: Citizen Petition for Extension of Premarket Tobacco Product Application Filing Deadline Due to the COVID-19 Pandemic

The FDA’s final Deeming Rule required manufacturers of deemed tobacco products to submit their products to the agency for approval before they can be introduced into the market. For most ENDS products, the only approval pathway available is the PMTA. On March 30, 2020, the U.S. Government requested an extension of the PMTA compliance date deadline because of the “exceptional and unforeseen” circumstances of the COVID-19 pandemic. On April 22, 2020, the United States District Court for the District of Maryland granted the Government’s request, setting September 9, 2020, as the new PMTA compliance date.

On August 24, 2020, several small ENDS manufacturers, retailers, and trade associations submitted a citizen petition with the FDA to further extend the PMTA compliance date. In support of the citizen petition, Advocacy sent a comment letter to the FDA on October 13, 2020. In the letter, Advocacy

argued that many small businesses in the vaping industry will be forced to close without a further extension of the PMTA deadline and that many of the issues the FDA cited as reasons for an extension in March 2020 were still present.

Office of Management and Budget

System For Award Management (SAM) Exemption for Small Entities

On August 13, 2020, the Office of Management and Budget (OMB) published a Guidance for Grants and Agreements in the Federal Register. Among other things, the guidance requires a small entity to obtain a number on the System for Award Management (SAM) to apply for a loan. Advocacy responded to the guidance on December 31, 2020, encouraging OMB to exempt small entities from a requirement to obtain a SAM number to apply for a loan.

Advocacy argued that an exemption would help small businesses devastated by the COVID-19 pandemic, allowing them to get Paycheck Protection Program funding without having to fulfil another requirement. Additionally, Advocacy encouraged OMB to exempt all Small Business Administration (SBA) disaster programs from the SAM registration requirement, noting the burden of requiring devastated small entities to file an application and wait for approval was unreasonable.



Legislative Comment Letter

One of the primary responsibilities of the Office of Advocacy is listening to small businesses and ensuring that their views and concerns are heard by Congress, both formally and informally. Advocacy is frequently asked by members and committees of Congress for its views on legislation and policy issues of importance to small business. Formal responses may be delivered either as legislative comment letters or as testimony before a congressional committee. In FY 2021, Advocacy submitted one formal legislative comment letter regarding the deductibility of business expenses paid with forgiven Paycheck Protection Program (PPP) loans.

Department of the Treasury/Internal Revenue Service (IRS)

Issue: The Deductibility of Business Expenses Paid with Forgiven Paycheck Protection Program Loans

On December 4, 2020, Advocacy held a tax roundtable regarding SBA's Paycheck Protection Program (PPP). Participants in this roundtable discussed the federal and state tax issues surrounding PPP loans. The CARES Act created the PPP to provide loans to small businesses impacted by the COVID-19 pandemic. The SBA and Treasury implemented the PPP.

Although the CARES Act provided that forgiven PPP loans are not included in gross income at the federal level, there were still federal and state tax issues surrounding PPP loans, including the impact of IRS Notice 2020-32. The Notice announced the agency's position that otherwise deductible business expenses paid with forgiven PPP loans are not deductible. Small business taxpayers could have faced unplanned and unbudgeted increases in federal income tax liabilities of up to 37 percent for 2020.

On December 15, 2020, Advocacy sent a letter to the Senate Committee on Small Business and Entrepreneurship and the House Small Business Committee. In the letter, Advocacy urged Congress to pass legislation to amend the CARES Act to state that otherwise deductible business expenses paid with a forgiven PPP loan are still deductible business expenses.

On December 27, 2020, the Consolidated Appropriations Act, 2021, was signed into law. This legislation overturned IRS Notice 2020-32 and made clear that expenses paid with forgiven PPP loans are deductible and the forgiveness of indebtedness remains nontaxable.



Chapter 5

Small Business Regulatory Cost Savings and Success Stories

In FY 2021, small businesses saved \$3.277 billion in measurable estimated forgone regulatory cost savings because of the Regulatory Flexibility Act (RFA) and Advocacy's efforts to promote federal agency compliance. There were additional regulatory successes whose impacts are not quantifiable. These are described in the Small Business Regulatory Success Stories section of this chapter.

Small businesses benefited from Advocacy's RFA activities through nine quantifiable regulatory actions.

One of this year's cost savings surrounded the Occupational Safety and Hazard Administration (OSHA) COVID-19 Emergency Temporary Standard. After President Biden issued an Executive Order on Protecting Worker Health and Safety, OSHA held a series of interagency meetings with stakeholders across the federal government. Advocacy participated in every meeting, conveying the interest of small businesses to all participants. The final standard was limited to employers with ten or more employees in the health care sector where suspected or confirmed coronavirus patients are treated. The standard led to aggregate cost savings of \$3.2 billion, the vast majority of savings in FY 2021.

Another cost savings surrounded the Environmental Protection Agency (EPA) Multi-Sector General Permit. Advocacy worked with the EPA to eliminate a series of unnecessary universal monitoring and benchmark tests and encouraged EPA to add other flexibilities for small entities. The changes led to \$22.8 million in estimated cost savings.

Table 5.1 summarizes the cost savings from nine final actions at five federal agencies in FY 2021.

There were also successes throughout FY 2021 that were not quantifiable. In one case, EPA responded to Advocacy's concerns surrounding a lack of clarity of worker protection standards for agricultural worker. After meeting with stakeholders, Advocacy proposed revisions to EPA's application exclusion zone standards to help reduce the compliance burden for small entities.

In another case, Advocacy encouraged the Department of Energy (DOE) to swiftly finalize a rule on the energy efficiency test-procedure interim waiver process. The DOE lengthened its response time for waiver applications, but also changed the procedure so that applications not responded to were assumed to be granted.

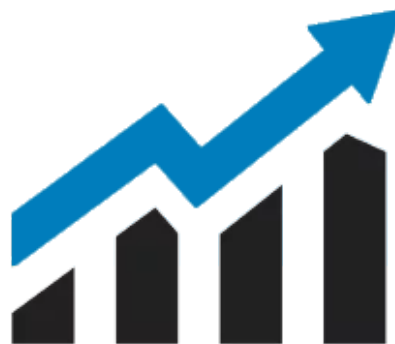


Table 5.1 Summary of Small Business Regulatory Cost Savings, FY 2021

Agency	Rule	Initial cost savings (\$million)	Recurring cost savings (\$million)
Department of Agriculture	Lacey Act Inspection Requirements ¹	0.6	0.6
Department of Commerce	Turtle Excluder Devices ²	1.4	1.4
Department of Defense	Nationwide Permits ³	2.8	2.8
Department of Labor	COVID-19 Emergency Temporary Standard ⁴	3,200.0	
Environmental Protection Agency	Disposal of Coal Combustion Residuals from Electric Utilities ⁵	8.9	8.9
	Final Action on Perchlorate ⁶	5.5	5.5
	Lead and Copper Rule Revisions ⁷	14.4	14.4
	Multisector General Permits ⁸	22.1	22.1
	Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)) ⁹	21.2	21.2
Total Foregone Regulatory Cost Savings, FY 2021		3,277	

Note: Advocacy generally bases its cost savings estimates on agency estimates. Cost savings estimates are derived independently for each rule from the agency’s analysis, and accounting methods and analytical assumptions for calculating costs may vary by agency. Cost savings for a given rule are captured in the fiscal year in which the agency finalizes changes in the rule as a result of Advocacy’s intervention. These are best estimates to illustrate reductions in regulatory costs to small businesses. Initial cost savings consist of capital or recurring costs foregone that may have been incurred in the rule’s first year of implementation by small businesses. Recurring cost savings are listed where applicable as annual or annualized values as presented by the agency. The actions listed in this table include deregulatory actions such as delays and rule withdrawals.

Sources:

1. 86 Fed. Reg. 35259 (July 2, 2021).
2. 85 Fed. Reg. 59198 (September 21, 2020).
3. 86 Fed. Reg. 2744 (January 13, 2021).
4. 86 Fed. Reg. 32376 (June 21, 2021).
5. 85 Fed. Reg. 53516 (August 28, 2020).
6. 85 Fed. Reg. 43990 (July 21, 2020).
7. 86 Fed. Reg. 4198 (January 15, 2021).
8. 86 Fed. Reg. 4198 (January 15, 2021).
9. 86 Fed. Reg. 894 (January 6, 2021).

Descriptions of Cost Savings

Department of Agriculture

Issue: Lacey Act Inspection Requirements

On March 31, 2020, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) published a notice of enforcement schedule for Phase VI of the import declaration requirements under the Lacey Act. The schedule requires those importing certain plants and plant products produce an import declaration. The declaration must contain the scientific name of the plant including genus and species, the value of the importation, the quantity of the plant, and the name of the country from which the plant was harvested. Enforcement, set to begin on October 1, 2020, contained five categories of products covered by the notice: essential oils; trunks, cases, and suitcases; wood and articles of wood; musical instruments; and miscellaneous manufactured articles.

On July 1, 2020, Advocacy filed a public comment letter asking APHIS to delay the implementation date, to exempt products covered under other statutes, and to clarify that once inspected the products would not need to be further inspected. On July 2, 2021, APHIS published a notice stating that implementation of Phase VI would occur on October 1, 2021, a delay of one year. The delay postponed costs for importers of some wood products. APHIS had previously estimated that costs of this phase of implementation were \$5-\$18.2 million annually. To estimate cost savings from the delay, Advocacy took the midpoint of these costs and discounted them over 10 years at a 7% discount rate, comparing costs without delay to costs with a one-year delay.

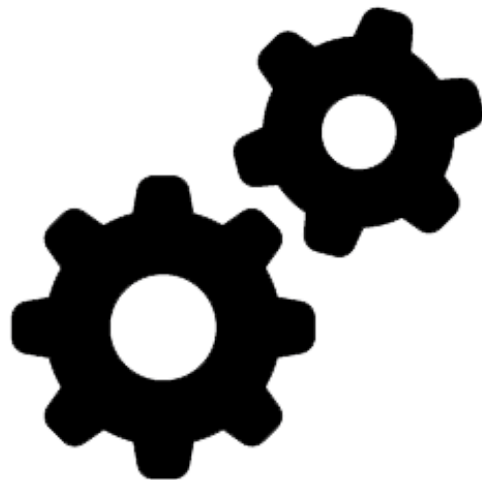
Affected small entities exist across a range of NAICS categories, so for simplicity Advocacy used the fraction of entities in NAICS 423310 (Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers), to estimate annualized cost savings of \$0.6 million for small entities.

Department of Commerce

Issue: Turtle Excluder Devices

On December 20, 2019, the National Oceanic and Atmospheric Administration (NOAA) published a final rule requiring all skimmer trawl vessels 40 feet and greater in length to use turtle excluder devices designed to exclude small sea turtles from their nets to reduce incidental bycatch and mortality of sea turtles in the southeastern U.S. shrimp fisheries. Advocacy engaged in this rulemaking through the interagency Executive Order 12866 process and encouraged the agency to look for less burdensome alternatives for small businesses. Between the proposed and final rule, NOAA reduced the number of vessels required to use turtle excluder devices. Advocacy did not receive cost savings data on this rule until December 2020, and therefore savings are being scored in FY 2021.

Using figures supplied by NOAA, the exemption of vessels up to 40 feet in length reduced costs for small



entities by \$1.4 million in 2018 dollars, annualized over 10 years at a 7 percent discount rate.

Department of Defense

Issue: Nationwide Permits

On January 13, 2021, the Army Corps of Engineers (Corps) published its final 2021 Nationwide Permits (NWP) issued under the Clean Water Act and the Rivers and Harbors Act of 1899. NWPs authorize certain discharges of dredged and fill materials into waters of the United States as well as the use of certain structures in waters of the United States. Advocacy encouraged the agency to reissue only a portion of the 52 existing NWPs that required immediate reissuance because of statutory or court deadlines. Advocacy also asked the EPA to clarify that NWP 48 coverage was not required under certain conditions. 40 of the existing NWPs could be utilized by permittees until March 18, 2022. Consequently, the Corps issued 4 new NWPs and only reissued 12 of the existing NWPs, allowing 40 of the existing NWPs to continue to be utilized by permittees until March 18, 2022. The Corps also clarified that NWP 48 was required when mechanical harvesting activity deposited captured sediment in a different location of the water of the United States.

The Corps' decision not to reissue all 52 nationwide permits saved small businesses an estimated \$2.8 million, annualized over ten years.

Department of Labor

Issue: COVID-19 Emergency Temporary Standard (Healthcare Facilities)

On January 21, 2021, President Biden issued an Executive Order, Protecting Worker Health and Safety. The President called for swift action by OSHA to issue updated guidance on worker safety, consider issuing an Emergency Temporary Standard (ETS) for COVID-19, and increase enforcement related to COVID-19. In response, OSHA hosted several stakeholder listening sessions to obtain public input

on how it should proceed. It was widely understood by the public that the OSHA COVID-19 ETS would apply to most or all employers. OSHA sent its draft COVID-19 ETS to the Office of Management and Budget (OMB) for interagency review (including Advocacy) under Executive Order 12866 on April 26, 2021. During its review, OMB hosted dozens of Executive Order 12866 meetings with interested stakeholders. Advocacy participated in all these meetings and discussed the status of the COVID-19 ETS at its small business labor safety roundtable on May 21, 2021.

On June 21, 2021, OSHA published its COVID-19 ETS. However, rather than applying to most or all employers as expected, the ETS was limited to employers with ten or more employees in the health care sector where suspected or confirmed coronavirus patients are treated. This included employees in hospitals, nursing homes, and assisted living facilities, as well as emergency responders, home health care workers, and employees in ambulatory care settings where suspected or confirmed coronavirus patients are treated. The standard requires non-exempt facilities to conduct a hazard assessment and have a written plan to mitigate virus spread. It also requires healthcare employers to provide some employees with N95 respirators or other personal protective equipment. OSHA also announced new general industry guidance for the coronavirus that is aligned with Centers for Disease Control and Prevention guidance.

Based on OSHA's analysis, the cost savings from limiting the COVID-19 ETS to healthcare facilities where suspected or confirmed coronavirus patients are treated (rather than applying it to most or all employers) resulted in estimated cost savings of \$2,902.04 for more than 1.1 million small businesses. This resulted in potential aggregate cost savings to small businesses of \$3.2 billion.

Environmental Protection Agency

Issue: Disposal of Coal Combustion Residuals from Electric Utilities

On August 28, 2020, the EPA issued final regulations to implement a court order to vacate provisions that allowed unlined impoundments to continue receiving coal combustion residuals (CCR). Related to this change, the EPA's final rule includes revisions to extend the deadline for the initiation of closure for unlined CCR surface impoundments and for units that failed the aquifer location restriction from October 31, 2020 to April 11, 2021. The agency also included additional time under its alternate closure provisions of a CCR surface impoundment to allow for the development of alternate capacity in managing both CCR and non-CCR waste streams to cease receipt of waste and initiate closure. Advocacy's efforts to promote the agency's compliance with the RFA in considering small business impacts supported these modifications. Advocacy did not finalize its cost savings estimate on this rule until December 2020, and therefore savings are being scored in FY 2021.

As a result of these actions, the total cost savings for small businesses is approximately \$8.9 million annualized.

Issue: Final Action on Perchlorate

On July 21, 2020, the EPA withdrew its determination to regulate perchlorate, effectively rescinding its proposed national primary drinking water regulation for perchlorate. The EPA's proposal would have imposed monitoring and administrative costs on 58,325 small water systems. Advocacy, on behalf of small entities, recommended that the EPA make a negative regulatory determination to not regulate perchlorate. Advocacy argued that the costs to the small systems outweighed the benefits of the proposed regulation. Advocacy did not finalize its cost savings estimate on this rule until December 2020, and therefore savings are being scored in FY 2021.

As a result of Advocacy's work on this rule, the EPA's determination not to regulate perchlorate saved small systems an estimated \$5.5 million annualized.

Issue: Lead and Copper Rule Revisions

On January 15, 2021, the EPA issued the final revisions to its lead and copper rules under the Safe Drinking Water Act. The EPA reduced the cost of sampling between the proposed and final rule by reducing the number of required scheduled school samples. In developing the final rule, the EPA set a threshold for small system flexibilities at systems serving 3,300 people or fewer. The EPA's final decision to set the threshold at systems serving 10,000 people or fewer resulted in cost savings for small systems. Advocacy's efforts to promote agency's compliance with the RFA in considering small business impacts supported these modifications.

Based on data supplied by the EPA, the total cost savings for small water systems is approximately \$14.4 million annualized.

Issue: Multi Sector General Permits

On March 2, 2020, the EPA published its proposed 2021 Multi Sector General Permits (MSGP) issued under the Clean Water Act in the Federal Register. The MSGP, utilized for stormwater discharges by industrial facilities, contains provisions requiring the implementation of control measures and development of site-specific stormwater pollution prevention plans to comply with the National Pollutant Discharge Elimination System program. In the proposed MSGP, the agency proposed the following:

- Requiring universal monitoring and data collection of pH, COD, and TSS.
- Universal benchmark levels for pH, COD, and TSS.
- Requiring specific corrective action to be taken in strict compliance with Appendix Q actions upon any benchmark exceedance of any pollutant.

- Prohibiting any user of coal tar sealants from claiming coverage under MSGP (5).
- Requiring signage to be posted detailing permittee and agency information.

Advocacy engaged with the agency on behalf of small entities to identify universal monitoring and data collection of pH, COD, and TSS; the universal benchmark levels for pH, COD, and TSS; required corrective actions as outlined in Appendix Q; the prohibition on coverage of coal tar sealants; and the signage requirements as particularly onerous to small businesses. In addition, Advocacy encouraged the agency to expand flexibilities offered to permittees to correct any benchmark exceedances as well as to ensure the agency timely analyzed any data collected to prevent unnecessary future data collection or compliance requirements.

On January 15, 2021, the EPA published its final MSGP. The final permit exempted 11 of the 30 sectors from monitoring and data collection requirements of pH, COD, and TSS and eliminated universal benchmark levels for pH, COD, and TSS. The EPA also agreed to analyze data collected on pH, COD, and TSS on a timely basis to determine whether such criteria required any future regulation and allowed coal tar sealant users to claim coverage under MSGP. The final permit also reduced the character count information required on signage, required permittees with benchmark exceedances to take only action that was “feasible” if they were in Tier 1 or Tier 2 of the three-tier benchmark framework, and allowed permittees with benchmark exceedances caused naturally not to be required to take any corrective actions.

As a result, the EPA’s revisions to the final MSGP potentially saved small businesses an estimated \$22.1 million, annualized over five years at a discount rate of 7%. Cost savings are based on a reduction in stormwater control measures between the proposed and final permits. As the EPA did not provide estimates for the costs of these stormwater control measures, Advocacy based its estimates on specific costs of stormwater control measures provided by trade associations in comments on the proposed permit.

Issue: Phenol, Isopropylated Phosphate (3:1) (PIP (3:1))

On January 6, 2021, the EPA finalized its regulation of phenol, isopropylated phosphate (3:1) (PIP (3:1)) as a persistent, bioaccumulative, and toxic chemical under the Toxic Substance Control Act. The final rule prohibits the processing and distribution of PIP (3:1) and PIP (3:1)-containing products, with some exclusions, and prohibits the release of PIP (3:1) to water during manufacturing, processing, and distribution. In the final rule, the EPA provided additional exclusions and compliance delays which reduced the number of small businesses subject to the regulation. Advocacy’s efforts to promote agency compliance with the RFA in considering small business impacts supported these modifications.

Based on data supplied by the EPA, the total cost savings for small businesses is approximately \$21.2 million.



Table 5.2 Summary of Small Business Regulatory Success Stories, FY 2021

Agency	Rule
Department of Agriculture	Establishment of a Domestic Hemp Production Program ¹
Department of Defense	Cybersecurity Maturity Model Certification ²
Department of Energy	Test Procedure Interim Waiver Process ³
Department of the Interior	Fish and Wildlife Service/National Marine Fisheries Service Definition of Habitat ⁴
Environmental Protection Agency	EPA’s Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements ⁵
	Hazardous and Solid Waste Management System: Disposal of CCR; A Holistic Approach to Closure Part B: Alternate Demonstration for Unlined Surface Impoundments ⁶
<p>Sources:</p> <ol style="list-style-type: none"> 1. 86 Fed Reg. 5596 (January 19, 2021). 2. 85 Fed. Reg. 61,505 (September 29, 2020). 3. 86 Fed Reg. 70945 (December 14, 2021). 4. 85 Fed Reg. 81411 (December 16, 2020). 5. 85 Fed. Reg. 68760 (October 30, 2020). 6. 85 Fed Reg. 72506 (November 12, 2020). 	

Success Story Descriptions

Department of Agriculture

Establishment of a Domestic Hemp Production Program

On January 19, 2021, the U.S. Department of Agriculture’s Agricultural Marketing Service (AMS) published a final rule outlining policies for domestic hemp production. This rule follows and replaces an interim final rule published by the agency on October 31, 2019, and addresses comments raised during two public comment periods for that rule. Following extensive outreach to businesses, Advocacy filed three public comment letters on the interim final rule on January 29, 2020, September 11, 2020, and October 8, 2020. The letters outlined several

policies that were overly burdensome to small hemp producers.

In its final rule, the AMS modified some of its policies to make them less burdensome. The policies modified included the following:

- Delaying the requirement that labs be DEA certified until 2022, allowing more time for labs to apply and receive certification.
- Lengthening the testing window from 15 days to 30 days, which allows farmers to account for uncontrollable variables when harvesting, such as weather events and labor and equipment shortages.
- Allowing for on-site remediation which offers at least one avenue for a non-compliant crop to still be sold into commerce, provided it does not test non-compliant once it has been remediated.

- Allowing for additional disposal methods beyond burning non-compliant crops.
- Allowing for performance-based sampling methodologies, which will reduce the overall sampling burdens.

All these modifications result in additional clarity for small producers and a reduction in the overall compliance burden.

Department of Defense

Cybersecurity Maturity Model Certification

In September 2019, the Department of Defense released its new Cybersecurity Maturity Model Certification (CMMC), designed to bring its entire industrial base up to date with the latest cybersecurity protections. Advocacy responded to the DOD on September 25, 2019, with three concerns about the draft model. First, the model lacked clarity as to how small businesses would be reimbursed for compliance. Second, Advocacy expressed concerns that lower levels of certification under the model would hurt small businesses trying to stay competitive in the federal space. Third, there was risk that the model would create a tremendous negative impact on DOD’s small business statutory annual goal requirements.

On September 29, 2020, the Defense Acquisition Regulations System issued an interim final rule to implement the DOD’s CMMC. In turn, Advocacy staffers met with DOD regulators regarding how to conduct regulatory analysis on this rule, how to accurately calculate the impact of the rule on small businesses, and how they could potentially minimize costs to small businesses while maintaining statutory objectives.

Ultimately, the DOD agreed with Advocacy that the CMMC adversely impacted small businesses and that DOD needed to revisit the impact the rule would have on small businesses. The conversations helped DOD improve its compliance with the Regulatory Flexibility Act and gave it a better understanding

of how to draft a more thorough analysis in future rulemakings. The interim rule is currently on hold pending the finalization of the revisions, and a new or amended interim rule is anticipated once the review is complete.

Department of Energy

Test Procedure Interim Waiver Process

On December 11, 2020, the U.S. Department of Energy (DOE) finalized a rule streamlining its approach to the energy efficiency test procedure interim waiver process. The Energy Policy and Conservation Act of 1975 authorizes the DOE to regulate energy efficiency of consumer and commercial products. Advocacy submitted a comment letter on the proposed rule on July 15, 2019, urging the DOE to swiftly finalize the rule to address delays small businesses face in receiving a decision on their waiver application. While the final rule lengthened the time within which the agency must respond from 30 to 45 business days, it also states that if the agency does not respond within those 45 days, the interim waiver is deemed granted until such time as the agency renders a decision on the application. Furthermore, the agency is required to post the application on its website upon receipt and post a decision on the application when it is rendered, thus providing increased transparency to applicants. The final rule provides much-needed measures to address the application backlog and ensures that small businesses receive a decision in a timely manner.

Department of the Interior

Fish and Wildlife Service/National Marine Fisheries Service Definition of Habitat

On November 27, 2018, the U.S. Supreme Court in *Weyerhaeuser v. U.S. Fish & Wildlife Serv.* ruled that, to be eligible for critical habitat designation, an area must be “habitat” for the listed species. In this case, the Court also ruled that a decision of whether to exclude areas from critical habitat is subject to judicial review. On December 16, 2020, in response

to the Court's decision, the Services finalized a rule to add a definition of "habitat" to regulations implementing Section 4 of the Endangered Species Act. This final action followed a public comment period in which Advocacy and various small entity stakeholders commented on the proposed rule indicating the necessity for the rule in adding regulatory certainty to critical habitat designations.

Environmental Protection Agency

EPA's Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements

On October 30, 2020, the EPA finalized its revision of the application exclusion zone (AEZ) requirements in its agricultural worker protection standard. In 2015, the EPA issued a final rule revising its existing worker protection standard. The rule included a requirement to keep workers and other persons out of certain areas defined as AEZ during pesticide application without much clarity on enforcement. In 2014, Advocacy submitted a public comment, which noted that this requirement may cause regulatory confusion. The agency did not address this concern in the final rule. After the final rule was published, small businesses and their representatives identified this issue during the agency's regulatory reform activities as one that should be addressed to reduce compliance burden. To further amplify the small businesses' concerns, Advocacy also raised them with the EPA. In response to this feedback, the EPA revised the AEZ requirements to limit the applicability to the employer's property, clarify when the application can be resumed, provide an exemption for areas subject to easements and for immediate family members sheltering in place, and to simplify the criteria and factors for determining AEZ distances.

Hazardous and Solid Waste Management System: Disposal of CCR; A Holistic Approach to Closure Part B: Alternate Demonstration for Unlined Surface Impoundments

On November 12, 2020, the EPA issued a finalized portion of regulations proposed on March 3, 2020, including procedures to allow facilities to request approval to operate an existing coal combustion residual (CCR) surface impoundment with an alternate liner, among other things. In 2015, the EPA published a final rule to regulate existing and new CCR landfills and existing and new CCR surface impoundments. Under these requirements, any existing unlined CCR surface impoundment that cause groundwater concentrations to exceed a groundwater protection standard must stop receiving waste within six months of making an exceedance determination. In addition, these surface impoundments would also be required to initiate either unit retrofit or closure activities. On the other hand, lined surfaces that impact groundwater above the specified groundwater protection standard are not required to close and could continue to operate while corrective action is performed and the source of the groundwater contamination is addressed. Small businesses and their representatives identified this issue as one that should be addressed during the agency's regulatory reform activities to allow for the consideration of alternative liners as lined surfaces.

Advocacy also raised these concerns to the agency. As a result, in the final rule, the agency allowed facilities to demonstrate that, based on ongoing groundwater monitoring data and the design of the surface impoundment unit, the surface impoundment with an alternative liner has had no negative impact on groundwater and will continue to have no reasonable probability of adverse effects to human health and the environment.

Appendix A

The Regulatory Flexibility Act

The following text of the Regulatory Flexibility Act of 1980, as amended, is taken from Title 5 of the United States Code, sections 601–612. The Regulatory Flexibility Act was originally passed in 1980 (P.L. 96-354). The Act was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121), the Dodd-Frank Wall Street Reform and Consumer Protection Act (P.L. 111-203), and the Small Business JOBS Act of 2010 (P.L. 111-240).

Congressional Findings and Declaration of Purpose

(a) The Congress finds and declares that —

(1) when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public;

(2) laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities;

(3) uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting and consulting costs upon small businesses, small organizations, and small governmental jurisdictions with limited resources;

(4) the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;

(5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;

(6) the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation;

(7) alternative regulatory approaches which do not conflict with the stated objectives of applicable statutes may be available which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions;

(8) the process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions to examine the impact of proposed and existing rules on such entities, and to review the continued need for existing rules.

(b) It is the purpose of this Act [enacting this chapter and provisions set out as notes under this section] 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.

Regulatory Flexibility Act

- § 601 Definitions
- § 602 Regulatory agenda
- § 603 Initial regulatory flexibility analysis
- § 604 Final regulatory flexibility analysis
- § 605 Avoidance of duplicative or unnecessary analyses
- § 606 Effect on other law
- § 607 Preparation of analyses
- § 608 Procedure for waiver or delay of completion
- § 609 Procedures for gathering comments
- § 610 Periodic review of rules
- § 611 Judicial review
- § 612 Reports and intervention rights

§ 601. Definitions

For purposes of this chapter—

(1) the term “agency” means an agency as defined in section 551(1) of this title;

(2) the term “rule” means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term “rule” does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

(3) the term “small business” has the same meaning as the term “small business concern” under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(4) the term “small organization” means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(5) the term “small governmental jurisdiction” means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

(6) the term “small entity” shall have the same meaning as the terms “small business,” “small organization” and “small governmental jurisdiction” defined in paragraphs (3), (4) and (5) of this section; and

(7) the term “collection of information” —

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either —

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies,

instrumentalities, or employees of the United States;
or

(ii) answers to questions posed to agencies,
instrumentalities, or employees of the United States
which are to be used for general statistical purposes;
and

(B) shall not include a collection of information
described under section 3518(c)(1) of title 44, United
States Code.

(8) Recordkeeping requirement — The term
“recordkeeping requirement” means a requirement
imposed by an agency on persons to maintain
specified records.

§ 602. Regulatory agenda

(a) During the months of October and April of each
year, each agency shall publish in the Federal Register
a regulatory flexibility agenda which shall contain —

(1) a brief description of the subject area of any rule
which the agency expects to propose or promulgate
which is likely to have a significant economic impact
on a substantial number of small entities;

(2) a summary of the nature of any such rule under
consideration for each subject area listed in the
agenda pursuant to paragraph (1), the objectives
and legal basis for the issuance of the rule, and an
approximate schedule for completing action on any
rule for which the agency has issued a general notice
of proposed rulemaking, and

(3) the name and telephone number of an agency
official knowledgeable concerning the items listed in
paragraph (1).

(b) Each regulatory flexibility agenda shall be
transmitted to the Chief Counsel for Advocacy of the
Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of
each regulatory flexibility agenda to small entities
or their representatives through direct notification
or publication of the agenda in publications likely to

be obtained by such small entities and shall invite
comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from
considering or acting on any matter not included in a
regulatory flexibility agenda, or requires an agency to
consider or act on any matter listed in such agenda.

§ 603. Initial regulatory flexibility analysis

(a) Whenever an agency is required by section 553 of
this title, or any other law, to publish general notice
of proposed rulemaking for any proposed rule, or
publishes a notice of proposed rulemaking for an
interpretative rule involving the internal revenue
laws of the United States, the agency shall prepare
and make available for public comment an initial
regulatory flexibility analysis. Such analysis shall
describe the impact of the proposed rule on small
entities. The initial regulatory flexibility analysis or a
summary shall be published in the Federal Register
at the time of the publication of general notice of
proposed rulemaking for the rule. The agency shall
transmit a copy of the initial regulatory flexibility
analysis to the Chief Counsel for Advocacy of the
Small Business Administration. In the case of an
interpretative rule involving the internal revenue
laws of the United States, this chapter applies to
interpretative rules published in the Federal Register
for codification in the Code of Federal Regulations,
but only to the extent that such interpretative rules
impose on small entities a collection of information
requirement.

(b) Each initial regulatory flexibility analysis required
under this section shall contain —

(1) a description of the reasons why action by the
agency is being considered;

(2) a succinct statement of the objectives of, and legal
basis for, the proposed rule;

(3) a description of and, where feasible, an estimate
of the number of small entities to which the proposed
rule will apply;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as —

(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(3) the use of performance rather than design standards; and

(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

(d)

(1) For a covered agency, as defined in section 609(d)

(2), each initial regulatory flexibility analysis shall include a description of—

(A) any projected increase in the cost of credit for small entities;

(B) any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities; and

(C) advice and recommendations of representatives of small entities relating to issues described in subparagraphs (A) and (B) and subsection (b).

(2) A covered agency, as defined in section 609(d)(2), shall, for purposes of complying with paragraph (1) (C)—

(A) identify representatives of small entities in consultation with the Chief Counsel for Advocacy of the Small Business Administration; and

(B) collect advice and recommendations from the representatives identified under subparagraph (A) relating to issues described in subparagraphs (A) and (B) of paragraph (1) and subsection (b).

§ 604. Final regulatory flexibility analysis

(a) When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain —

(1) a statement of the need for, and objectives of, the rule;

(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected;

(6)¹ for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

§ 605. Avoidance of duplicative or unnecessary analyses

(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number

1. So in original. Two paragraphs (6) were enacted.

of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

§ 606. Effect on other law

The requirements of sections 603 and 604 of this title do not alter in any manner standards otherwise applicable by law to agency action.

§ 607. Preparation of analyses

In complying with the provisions of sections 603 and 604 of this title, an agency may provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.

§ 608. Procedure for waiver or delay of completion

(a) An agency head may waive or delay the completion of some or all of the requirements of section 603 of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of section 603 of this title impracticable.

(b) Except as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title. An agency head may delay the

completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

§ 609. Procedures for gathering comments

(a) When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as—

- (1) the inclusion in an advance notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;
- (2) the publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;
- (3) the direct notification of interested small entities;
- (4) the conduct of open conferences or public hearings concerning the rule for small entities including soliciting and receiving comments over computer networks; and

(5) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.

(b) Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter—

- (1) a covered agency shall notify the Chief Counsel for Advocacy of the Small Business Administration and provide the Chief Counsel with information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected;
- (2) not later than 15 days after the date of receipt of the materials described in paragraph (1), the Chief Counsel shall identify individuals representative of affected small entities for the purpose of obtaining advice and recommendations from those individuals about the potential impacts of the proposed rule;
- (3) the agency shall convene a review panel for such rule consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel;
- (4) the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule, collect advice and recommendations of each individual small entity representative identified by the agency after consultation with the Chief Counsel, on issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c);
- (5) not later than 60 days after the date a covered agency convenes a review panel pursuant to paragraph (3), the review panel shall report on the comments of the small entity representatives and its findings as to issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c), provided that such report shall be made public as part of the rulemaking record; and

(6) where appropriate, the agency shall modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required.

(c) An agency may in its discretion apply subsection (b) to rules that the agency intends to certify under subsection 605(b), but the agency believes may have a greater than de minimis impact on a substantial number of small entities.

(d) For purposes of this section, the term “covered agency” means

(1) the Environmental Protection Agency,

(2) the Consumer Financial Protection Bureau of the Federal Reserve System, and

(3) the Occupational Safety and Health Administration of the Department of Labor.

(e) The Chief Counsel for Advocacy, in consultation with the individuals identified in subsection (b) (2), and with the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, may waive the requirements of subsections (b)(3), (b)(4), and (b)(5) by including in the rulemaking record a written finding, with reasons therefor, that those requirements would not advance the effective participation of small entities in the rulemaking process. For purposes of this subsection, the factors to be considered in making such a finding are as follows:

(1) In developing a proposed rule, the extent to which the covered agency consulted with individuals representative of affected small entities with respect to the potential impacts of the rule and took such concerns into consideration.

(2) Special circumstances requiring prompt issuance of the rule.

(3) Whether the requirements of subsection (b) would provide the individuals identified in subsection (b)(2)

with a competitive advantage relative to other small entities.

§ 610. Periodic review of rules

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors—

(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; and

(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.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.

§ 611. Judicial review

(a)

(1) For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(2) Each court having jurisdiction to review such rule for compliance with section 553, or under any other provision of law, shall have jurisdiction to review any claims of noncompliance with sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(3)

(A) A small entity may seek such review during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply to an action for judicial review under this section.

(B) In the case where an agency delays the issuance of a final regulatory flexibility analysis pursuant to

section 608(b) of this chapter, an action for judicial review under this section shall be filed not later than—

(i) one year after the date the analysis is made available to the public, or

(ii) where a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period, the number of days specified in such provision of law that is after the date the analysis is made available to the public.

(4) In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with this chapter and chapter 7, including, but not limited to —

(A) remanding the rule to the agency, and

(B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

(5) Nothing in this subsection shall be construed to limit the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law or to grant any other relief in addition to the requirements of this section.

(b) In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule, including an analysis prepared or corrected pursuant to paragraph (a)(4), shall constitute part of the entire record of agency action in connection with such review.

(c) Compliance or noncompliance by an agency with the provisions of this chapter shall be subject to judicial review only in accordance with this section.

(d) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise permitted by law.

§ 612. Reports and intervention rights

(a) The Chief Counsel for Advocacy of the Small Business Administration shall monitor agency compliance with this chapter and shall report at least annually thereon to the President and to the Committees on the Judiciary and Small Business of the Senate and House of Representatives.

(b) The Chief Counsel for Advocacy of the Small Business Administration is authorized to appear as amicus curiae in any action brought in a court of the United States to review a rule. In any such action, the Chief Counsel is authorized to present his or her views with respect to compliance with this chapter, the adequacy of the rulemaking record with respect to small entities and the effect of the rule on small entities.

(c) A court of the United States shall grant the application of the Chief Counsel for Advocacy of the Small Business Administration to appear in any such action for the purposes described in subsection (b).

Appendix B

Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

Executive Order of August 13, 2002

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:²

Section 1. General Requirements. Each agency shall establish procedures and policies to promote compliance with the Regulatory Flexibility Act, as amended (5 U.S.C. 601 et seq.) (the “Act”). Agencies shall thoroughly review draft rules to assess and take appropriate account of the potential impact on small businesses, small governmental jurisdictions, and small organizations, as provided by the Act. The Chief Counsel for Advocacy of the Small Business Administration (Advocacy) shall remain available to advise agencies in performing that review consistent with the provisions of the Act.

Sec. 2. Responsibilities of Advocacy. Consistent with the requirements of the Act, other applicable law, and Executive Order 12866 of September 30, 1993, as amended, Advocacy:

(a) shall notify agency heads from time to time of the requirements of the Act, including by issuing notifications with respect to the basic requirements of the Act within 90 days of the date of this order;

(b) shall provide training to agencies on compliance with the Act; and

(c) may provide comment on draft rules to the agency that has proposed or intends to propose the rules and

2. Executive Order 13272 (August 13, 2002), 67 Fed. Reg. 53461.

to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA).

Sec. 3. Responsibilities of Federal Agencies. Consistent with the requirements of the Act and applicable law, agencies shall:

(a) Within 180 days of the date of this order, issue written procedures and policies, consistent with the Act, to ensure that the potential impacts of agencies’ draft rules on small businesses, small governmental jurisdictions, and small organizations are properly considered during the rulemaking process. Agency heads shall submit, no later than 90 days from the date of this order, their written procedures and policies to Advocacy for comment. Prior to issuing final procedures and policies, agencies shall consider any such comments received within 60 days from the date of the submission of the agencies’ procedures and policies to Advocacy. Except to the extent otherwise specifically provided by statute or Executive Order, agencies shall make the final procedures and policies available to the public through the Internet or other easily accessible means;

(b) Notify Advocacy of any draft rules that may have a significant economic impact on a substantial number of small entities under the Act. Such notifications shall be made (i) when the agency submits a draft rule to OIRA under Executive Order 12866 if that order requires such submission, or (ii) if no submission to OIRA is so required, at a reasonable time prior to publication of the rule by the agency; and

(c) Give every appropriate consideration to any comments provided by Advocacy regarding a draft rule. Consistent with applicable law and appropriate

protection of executive deliberations and legal privileges, an agency shall include, in any explanation or discussion accompanying publication in the Federal Register of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule that preceded the final rule; provided, however, that such inclusion is not required if the head of the agency certifies that the public interest is not served thereby.

Agencies and Advocacy may, to the extent permitted by law, engage in an exchange of data and research, as appropriate, to foster the purposes of the Act.

Sec. 4. Definitions. Terms defined in section 601 of title 5, United States Code, including the term "agency," shall have the same meaning in this order.

Sec. 5. Preservation of Authority. Nothing in this order shall be construed to impair or affect the authority of the Administrator of the Small Business Administration to supervise the Small Business Administration as provided in the first sentence of section 2(b)(1) of Public Law 85-536 (15 U.S.C. 633(b)(1)).

Sec. 6. Reporting. For the purpose of promoting compliance with this order, Advocacy shall submit a report not less than annually to the Director of the Office of Management and Budget on the extent of compliance with this order by agencies.

Sec. 7. Confidentiality. Consistent with existing law, Advocacy may publicly disclose information that it receives from the agencies in the course of carrying out this order only to the extent that such information already has been lawfully and publicly disclosed by OIRA or the relevant rulemaking agency.

Sec. 8. Judicial Review. This order is intended only to improve the internal management of the Federal Government. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

George W. Bush
THE WHITE HOUSE,
August 13, 2002.
Filed 08-15-02; 8:45 am]
[FR Doc. 02-21056
Billing code 3195-01-P

Appendix C

Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered that:

Section 1. Policy. It is the policy of my Administration to use available tools to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID-19) pandemic, economic recovery, racial justice, and climate change. To tackle these challenges effectively, executive departments and agencies (agencies) must be equipped with the flexibility to use robust regulatory action to address national priorities. This order revokes harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems, and empowers agencies to use appropriate regulatory tools to achieve these goals.

Sec. 2. Revocation of Orders. Executive Order 13771 of January 30, 2017 (Reducing Regulation and Controlling Regulatory Costs), Executive Order 13777 of February 24, 2017 (Enforcing the Regulatory Reform Agenda), Executive Order 13875 of June 14, 2019 (Evaluating and Improving the Utility of Federal Advisory Committees), Executive Order 13891 of October 9, 2019 (Promoting the Rule of Law Through Improved Agency Guidance Documents), Executive Order 13892 of October 9, 2019 (Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication), and Executive Order 13893 of October 10, 2019 (Increasing Government Accountability for Administrative Actions by Reinventing Administrative PAYGO), are hereby revoked.

Sec. 3. Implementation. The Director of the Office of Management and Budget and the heads of agencies shall promptly take steps to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing the Executive Orders identified in section 2 of this order, as appropriate and consistent with applicable law, including the Administrative Procedure Act, 5 U.S.C. 551 et seq. If in any case such rescission cannot be finalized immediately, the Director and the heads of agencies shall promptly take steps to provide all available exemptions authorized by any such orders, rules, regulations, guidelines, or policies, as appropriate and consistent with applicable law. In addition, any personnel positions, committees, task forces, or other entities established pursuant to the Executive Orders identified in section 2 of this order, including the regulatory reform officer positions and regulatory reform task forces established by sections 2 and 3 of Executive Order 13777, shall be abolished, as appropriate and consistent with applicable law.

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented in a manner consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,

January 20, 2021.

Memorandum for the Heads of Executive Departments and Agencies on Modernizing Regulatory Review

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Modernizing Regulatory Review

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Background. For nearly four decades, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has been charged by Presidents of both parties with reviewing significant executive branch regulatory actions. This process is largely governed by Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), as amended. This memorandum reaffirms the basic principles set forth in that order and in Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review), which took important steps towards modernizing the regulatory review process. When carried out properly, that process can help to advance regulatory policies that improve the lives of the American people.

Our Nation today faces serious challenges, including a massive global pandemic; a major economic downturn; systemic racial inequality; and the undeniable reality and accelerating threat of climate change. It is the policy of my Administration to mobilize the power of the Federal Government to rebuild our Nation and address these and other challenges. As we do so, it is important that we evaluate the processes and principles that govern regulatory review to ensure swift and effective Federal action. Regulations that promote the public interest are vital for tackling national priorities.

Sec. 2. Implementation. (a) I therefore direct the Director of OMB, in consultation with representatives of executive departments and agencies (agencies), as appropriate and as soon as practicable, to begin a process with the goal of producing a set of recommendations for improving and modernizing regulatory review. These recommendations should provide concrete suggestions on how the regulatory review process can promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations. The recommendations should also include proposals that would ensure that regulatory review serves as a tool to affirmatively promote regulations that advance these values. These recommendations should be informed by public engagement with relevant stakeholders.

(b) In particular, the recommendations should:

(i) identify ways to modernize and improve the regulatory review process, including through revisions to OMB's Circular A-4, Regulatory Analysis, 68 Fed. Reg. 58,366 (Oct. 9, 2003), to ensure that the review process promotes policies that reflect new developments in scientific and economic understanding, fully accounts for regulatory benefits that are difficult or impossible to quantify, and does not have harmful anti-regulatory or deregulatory effects;

(ii) propose procedures that take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not

inappropriately burden disadvantaged, vulnerable, or marginalized communities;

(iii) consider ways that OIRA can play a more proactive role in partnering with agencies to explore, promote, and undertake regulatory initiatives that are likely to yield significant benefits; and

(iv) identify reforms that will promote the efficiency, transparency, and inclusiveness of the interagency review process, and determine an appropriate approach with respect to the review of guidance documents.

Sec. 3. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Director of OMB is authorized and directed to publish this memorandum in the Federal Register.

JOSEPH R. BIDEN JR.

Appendix D

RFA Training, Case Law, and SBREFA Panels

Federal Agencies Trained in RFA Compliance, 2003-2020

Executive Order 13272 directed the Office of Advocacy to provide training to federal agencies in RFA compliance. RFA training began in 2003, and since that time Advocacy has conducted training for every cabinet level agency, 84 separate component agencies and offices within these departments, 24 independent agencies, and various special groups including congressional staff, business organizations and trade associations. The following agencies have participated in RFA training since its inception in 2003.

Cabinet Agencies

Department of Agriculture	Office of Special Education and Rehabilitative Services
Animal and Plant Health Inspection Service	Office of the General Counsel
Agricultural Marketing Service	Department of Energy
Food Safety and Inspection Service	Department of Health and Human Services
Forest Service	Center for Disease Control and Prevention
Grain Inspection, Packers, and Stockyards Administration	Center for Medicare and Medicaid Services
Livestock, Poultry, and Seed Program	Center for Tobacco Products
National Organic Program	Food and Drug Administration
Rural Utilities Service	Indian Health Service
Office of Budget and Program Analysis	Office of Policy
Office of the General Counsel	Office of Regulations
Department of Commerce	Department of Homeland Security
Bureau of Industry and Security	Federal Emergency Management Agency
National Oceanic and Atmospheric Administration	National Protection and Programs Directorate
National Telecommunications and Information Administration	Office of the Chief Procurement Officer
Office of Manufacturing Services	Office of the General Counsel
Patent and Trademark Office	Office of Small and Disadvantaged Business Utilization
Department of Defense	Transportation Security Administration
Defense Acquisition Regulations System	U.S. Citizenship and Immigration Service
Defense Logistics Agency	U.S. Coast Guard
Department of the Air Force	U.S. Customs and Border Protection
Department of the Army, Training and Doctrine Command	U.S. Immigration and Customs Enforcement
U.S. Strategic Command	Department of Housing and Urban Development
Department of Education	Office of Community Planning and Development
Office of Elementary and Secondary Education	Office of Fair Housing and Equal Opportunity
Office of Post-Secondary Education	Office of Manufactured Housing
	Office of Public and Indian Housing
	Department of the Interior
	Bureau of Indian Affairs

Bureau of Land Management	Federal Railroad Administration
Bureau of Ocean Energy Management, Regulation and Enforcement	Federal Transit Administration
Fish and Wildlife Service	Maritime Administration
National Park Service	National Highway Traffic Safety Administration
Office of Surface Mining Reclamation and Enforcement	Pipeline and Hazardous Materials Safety Administration
Department of Justice	Research and Special Programs Administration
Bureau of Alcohol, Tobacco, and Firearms	Department of the Treasury
Civil Rights Division	Alcohol, Tobacco, Tax, and Trade Bureau
Drug Enforcement Administration	Bureau of Fiscal Services
Federal Bureau of Prisons	Financial Crimes Enforcement Network
Department of Labor	Financial Management Service
Employee Benefits Security Administration	Internal Revenue Service
Employment and Training Administration	Office of the Comptroller of the Currency
Employment Standards Administration	Office of the General Counsel
Mine Safety and Health Administration	Surface Transportation Board
Occupational Safety and Health Administration	Department of Veterans Affairs
Office of Federal Contract Compliance Programs	National Cemetery Administration
Wage and Hour Division	Office of the Director of National Intelligence
Department of State	Office of Management and Budget
Department of Transportation	Office of Federal Procurement Policy
Federal Aviation Administration	Small Business Administration
Federal Highway Administration	Office of the General Counsel
Federal Motor Carrier Safety Administration	

Independent Federal Agencies

Access Board	Federal Maritime Commission
Chemical Safety and Hazard Investigation Board	Federal Reserve System
Consumer Financial Protection Bureau	Federal Trade Commission
Consumer Product Safety Commission	General Services Administration / FAR Council
Commodity Futures Trading Commission	National Aeronautics and Space Administration
Environmental Protection Agency	National Credit Union Administration
Farm Credit Administration	National Endowment for the Arts
Federal Communications Commission	National Endowment for the Humanities
Federal Deposit Insurance Corporation	Nuclear Regulatory Commission
Federal Election Commission	Pension Benefit Guaranty Corporation
Federal Energy Regulatory Commission	Securities and Exchange Commission
Federal Housing Finance Agency	Trade and Development Agency

RFA Case Law, FY 2021

Courts across the country have decided various issues regarding the Regulatory Flexibility Act through litigation. This section notes pertinent cases in which the courts discussed the RFA. This section does not reflect the Office of Advocacy's opinion of the cases and is intended to provide the reader with information on what the courts have held regarding agency compliance with the RFA in FY 2021.

Centro Legal de la Raza v. Executive Office for Immigration Review

This case concerned four non-profit immigration legal services organizations: Centro Legal de la Raza, Tahiri Justice Center, Immigrant Legal Resource Center, and Immigration Center for Education and Legal Services. The organizations sought a motion for preliminary injunction enjoining the Department of Justice's Executive Office for Immigration Review from implementing Appellate Procedure and Decisional Finality in Immigration Proceedings; Administrative Closure, 85 Fed. Reg. 81,588 (Dec. 16, 2020). The rules in this case affected the ability to appeal and were created as final rules without adequate opportunity to comment. Among the plaintiff's complaints, was a challenge that the rules were improperly marked as not having a significant economic impact on a substantial number of small entities.

While analyzing the RFA claim, the Court relied on the case *U.S. Citrus Science Council v. U.S. Department of Agriculture*, 314 F. Supp. 3d 884 (E.D. Cal. 2018), where domestic lemon growers were found to be indirectly regulated small entities affected by a rule allowing imports of lemons from Argentina and therefore unable to make an RFA challenge. The Court used the standard from *All For The Wild Rockies v. Cottrell*, 632 F.3d 1127 (9th Cir. 2011), and found the plaintiff showed sufficient facts to conclude there were "serious questions going to the merits" of the plaintiff's claim that the defendant failed to comply with the RFA. Ultimately, the Court granted the plaintiff's motion for a nationwide preliminary injunction on numerous grounds.

Silver v. Internal Revenue Service

The Plaintiffs, Monte Silver and his business Monte Silver, Limited, claim that small entities are unduly burdened by tax regulations promulgated under section 965 of the 2017 Tax Cuts and Jobs Act. However, the Secretary of Treasury certified "that the proposed regulations would not 'have a significant economic impact on a substantial number of small entities'" and therefore no RFA analysis was performed. The Plaintiff sued the Internal Revenue Service and the Department of Treasury, challenging their alleged failure to assess the economic impact of the regulation on small businesses as required by the RFA. The court held that the plaintiffs lacked constitutional standing for their claims and even if they had Article III standing, the plaintiffs did not have a cause of action under the RFA.

Regarding Article III standing, the plaintiffs failed "to show that they face ongoing or imminent future injury" and therefore lack standing to seek injunctive relief. In addition, they also lack standing for declaratory relief because the plaintiffs must demonstrate ongoing or imminent future injury to satisfy the redressability requirement for retrospective relief. Therefore, the court lacks jurisdiction over the plaintiffs' claims. Regarding the statutory standing of the plaintiffs, there are two questions the court considered while determining whether the plaintiffs had a cause for action under the RFA: first, whether the plaintiffs are "subject to" transition tax regulations, and second, whether the plaintiffs are "small entities" under the RFA. Neither the plaintiff nor his business satisfied both requirements. First, only Silver and not the business was "subject to" the transition tax regulations.

Second, Silver as an individual did not qualify as a “small entity” under the RFA because he was not “independently owned and operated.” Thus, the court granted the defendant’s cross-motion for summary judgment.

Loper Bright Enters. v. Raimondo

The Plaintiffs, “a collection of commercial fishing firms headquartered in southern New Jersey that participate regularly in the Atlantic herring fishery,” challenged a final rule “which establish[es] a process for administering future industry-funded monitoring in Fishery Management Plans governing certain New England fisheries and implement[s] a required industry-funded monitoring program in the Atlantic herring fishery.” The Plaintiffs argued that the government failed to comply with the RFA because the final rule contained “conclusory findings” regarding the economic effects of the Omnibus Amendment that are “facially unreasonable.” The plaintiffs contended that the government failed to consider three things: first, the “economic impacts associated with the omnibus alternatives,” second, “the full set of costs,” and third, an “ explanation for their conclusion that certain businesses ‘were more likely to exit the fishery if the cost of monitoring [were] perceived as too expensive.’” T

he court quickly dispensed with this argument because the Plaintiff’s motion only pointed “to alleged compliance failures within the IRFA and d[id] not point to any alleged deficiencies within the FRFA. . . . Pursuant to section 611(a) of the RFA, the adequacy of an agency’s IRFA is not reviewable.” Additionally, the court held that the substantive challenge would have failed anyways because, despite the Plaintiff’s claims to the contrary, the secretary did make relevant findings and his conclusion was reasonable.

Behring Regional Center. LLC v. Wolf

The plaintiff alleged that the Department of Homeland Security failed to follow

the requirements of the RFA, among other allegations. However, the RFA is only mentioned once throughout the case.

Wellness Pharmacy, Inc. v. Becerra

The complaint alleged that the Food and Drug Administration, in developing the Final Standard Memorandum of Understanding (MOU), failed to conduct an analysis of the MOU’s impact on small pharmacies. The court concluded that the plaintiffs have standing, and the Final Standard MOU is a legislative rule and thus subject to the RFA procedural requirements. The court granted the plaintiff’s motion for summary judgement and remanded the MOU to the agency to certify that it will not have a significant economic effect on small business (note the court misstates the RFA language) or prepare a RFA analysis.

Notably, defendants did not contend that they conducted a regulatory flexibility analysis or certified an analysis to be unnecessary. Rather they allege that the MOU is an interpretive rule and therefore not subject to the requirements of the Act. The plaintiff countered that the MOU fell within the RFA because it was a legislative rule and the court agreed. The court found that the plaintiff’s allegation under the RFA was connected to the financial injuries stemming from compliance with the Final Standard MOU.

Pangea Legal Services. v. United States Department of Homeland Security.

Four non-profit organizations serving immigrants sued the Department of Homeland Security alleging, inter alia, that the agency failed to perform an analysis of the potential impact on small entities as required by the Regulatory Flexibility Act when it passed a final rule entitled “Procedures for Asylum and Bars to Asylum Eligibility.” However, the court declined to rule on this issue but specified that it “may revisit the Regulatory Flexibility Act question at the preliminary injunction stage.” There

is no indication that this issue has been raised again in the relevant decisions on this case thus far.

National Mining Association v. U.S.W.

The Petitioners, mining associations and companies, sought review of the United States Secretary of Labor and Mine Safety and Health Administration’s final rule entitled “Examinations of Working Places in Metal and Nonmetal Mines.” In the statement of issues, and an included footnote, the petitioners argued that the rule was promulgated in a “perfunctory and conclusory manner” and was thus not created properly under the RFA. The Court emphasized in a footnote that the Court will not consider an argument raised in a footnote only.

Table D.1 SBREFA Panels Convened Through FY 2021

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
Consumer Financial Protection Bureau				
Small Business Lending Data Collection	10/15/20	12/14/20		
Debt Collection	08/25/16	10/19/16	05/21/19. Supplemental rule published 03/03/20.	11/30/20
Arbitration Clauses	10/20/15	12/11/15	05/24/16	Rule published 07/19/17. Repealed via Congr. Review Act, 10/24/17.
Limit Certain Practices for Payday, Vehicle Title, and Similar Loans	04/27/15	06/25/15	07/22/16	11/17/17
Home Mortgage Disclosure Act	02/27/14	04/24/14	08/29/14	10/15/15
Loan Originator Compensation Requirements under Regulation Z	05/09/12	07/12/12	09/07/12	02/15/13
Mortgage Servicing under the Real Estate Settlement Procedures Act (RESPA or Regulation X) and Truth in Lending Act (TILA or Regulation Z)	04/09/12	06/11/12	09/17/12	02/14/13
Integrated Mortgage Disclosures under the Real Estate Settlement Procedures Act (RESPA or Regulation X) and Truth in Lending Act (TILA or Regulation Z)	02/21/12	04/23/12	08/23/12	12/31/13
Department of Labor, Occupational Safety and Health Administration				
Tree Care Operations	03/23/20	05/22/20		
Telecommunications Towers	08/15/18	10/11/18		
Process Safety Management Standard	06/02/16	08/01/16		
Occupational Exposure to Infectious Diseases in Healthcare and Other Related Work Settings	10/14/14	12/22/14		

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl	05/05/09	07/02/09		
Occupational Exposure to Beryllium	09/17/07	01/15/08	08/07/15	
Cranes and Derricks in Construction	08/18/06	10/17/06	10/09/08	08/09/10
Occupational Exposure to Hexavalent Chromium	01/30/04	04/20/04	10/04/04	02/28/06
Occupational Exposure to Crystalline Silica	10/20/03	12/19/03	09/12/13	03/25/16
Confined Spaces in Construction	09/26/03	11/24/03	11/28/07	
Electric Power Generation, Transmission, and Distribution	04/01/03	06/30/03	06/15/05	04/11/14
Ergonomics Program Standard	03/02/99	04/30/99	11/23/99	11/14/00
Safety and Health Program Rule	10/20/98	12/19/98		
Tuberculosis	09/10/96	11/12/96	10/17/97	Withdrawn 12/31/03
Environmental Protection Agency				
Standards of Performance for New, Reconstituted, and Modified Sources: Oil and Natural Gas Sector Review	07/15/21	09/20/21		
1-Bromopropane; Rulemaking under TSCA §6(a)	04/27/21			
Methylene Chloride; Rulemaking under TSCA §6(a)	01/07/21			
National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations	11/25/20	04/26/21		
Financial Responsibility Requirements for Hard Rock Mining	08/24/16	12/01/16	12/01/16	Withdrawn 02/21/18
Regulation of Trichloroethylene for Vapor Degreasers under Section 6(a) of the Toxic Substances Control Act	06/01/16	09/26/16	01/19/17	

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
Regulation of N-Methylpyrrolidone and Methylene Chloride in Paint and Coating Removal under Section 6(a) of the Toxic Substances Control Act	06/01/16	09/26/16	01/19/17	03/27/19
Risk Management Program Modernization	11/04/15	02/19/16	03/14/16	01/13/17
Emission Standards for New and Modified Sources in the Oil and Natural Gas Sector	06/16/15	08/13/15	09/18/15	06/3/16
Federal Plan for Regulating Greenhouse Gas Emissions from Electric Generating Units	04/30/15	07/28/15	10/23/15	Withdrawn 04/03/17
Greenhouse Gas Emissions Standards for Medium- and Heavy-Duty Vehicles	10/22/14	01/15/15	07/13/15	10/25/2016
PCB (Polychlorinated Biphenyls) Use Authorizations Update Rule	02/07/14	04/07/14		
Review of New Source Performance Standards and Amendments to Emission Guidelines for Municipal Solid Waste Landfills	12/05/13	07/21/15	07/17/14 08/27/15	08/29/16
National Emissions Standards for Hazardous Air Pollutants (NESHAP): Brick and Structural Clay Products and Clay Products	06/12/13	01/16/14	12/18/14	10/26/15
Long Term Revisions to the Lead and Copper Rule	08/14/12	08/16/13	-	-
Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards	08/04/11	Rule proposed rule w/o completion of SBREFA panel report	06/30/14	12/01/15
Control of Air Pollution from Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards	08/04/11	10/14/11	05/21/13	04/28/14
Greenhouse Gas Emissions from Electric Utility Steam Generating Units	06/09/11	Rule proposed rule w/o completion of SBREFA panel report	04/14/13	04/13/12 01/08/14 06/02/14

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
National Emission Standards for Hazardous Air Pollutants (NESHAP) Risk and Technology Review for the Mineral Wool and Wool Fiberglass Industries	06/02/11	10/26/11	11/12/11	07/29/15
Formaldehyde Emissions from Pressed Wood Products	02/03/11	04/04/11	06/10/13	12/16/16
Stormwater Regulations Revision to Address Discharges from Developed Sites	12/06/10	10/04/11	-	Withdrawn 06/06/17
National Emission Standards for Hazardous Air Pollutants for Coal- and Oil-fired Electric Utility Steam Generating Units	10/27/10	03/02/11	05/03/11	02/16/12
Revision of New Source Performance Standards for New Residential Wood Heaters	08/04/10	10/26/11	02/03/14	03/16/15
Pesticides; Reconsideration of Exemptions for Insect Repellents	11/16/09	01/15/10		
National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers: Major and Area Sources	01/22/09	03/23/09	06/04/10	03/21/11
Pesticides; Certification of Pesticide Applicators (Revisions)	09/04/08	11/03/08	08/24/15	01/04/17
Pesticides; Agricultural Worker Protection Standard Revisions	09/04/08	11/03/08	03/19/14	11/02/15
Renewable Fuel Standards 2	07/09/08	09/05/08	05/26/09	03/26/10
Total Coliform Monitoring	01/31/08	01/31/08	07/14/10	
Non-Road Spark-Ignition Engines/ Equipment	08/17/06	10/17/06	05/18/07	10/08/08
Mobile Source Air Toxics	09/07/05	11/08/05	03/29/06	02/26/07
Federal Action Plan for Regional Nitrogen Oxide/Sulfur Dioxide (2005 Clean Air Interstate Rule)	04/27/05	06/27/05	08/24/05	04/28/06

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
Section 126 Petition (2005 Clean Air Interstate Rule)	04/27/05	06/27/05	08/24/05	04/28/06
Cooling Water Intake Structures Phase III Facilities	02/27/04	04/27/04	11/24/04	06/16/06
Nonroad Diesel Engines – Tier IV	10/24/02	12/23/02	05/23/03	06/29/04
Lime Industry – Air Pollution	01/22/02	03/25/02	12/20/02	01/05/04
Aquatic Animal Production Industry	01/22/02	06/19/02	09/12/02	08/23/04
Construction and Development Effluent Limitations Guidelines	07/16/01	10/12/01	06/24/02	Withdrawn 04/26/04
Nonroad Large Spark Ignition Engines, Recreation Land Engines, Recreation Marine Gas Tanks and Highway Motorcycles	05/03/01	07/17/01	10/05/01 08/14/02	11/08/02
Stage 2 Disinfectant Byproducts; Long Term 2 Enhanced Surface Water Treatment	04/25/00	06/23/00	08/18/03	01/04/06
Reinforced Plastics Composites	04/06/00	06/02/00	08/02/01	04/21/03
Concentrated Animal Feedlots	12/16/99	04/07/00	01/12/01	02/12/03
Metals Products and Machinery	12/09/99	03/03/00	01/03/01	05/13/03
Lead Renovation and Remodeling Rule	11/23/99	03/03/00	01/10/06	04/22/08
Diesel Fuel Sulfur Control Requirements	11/12/99	03/24/00	06/02/00	01/18/01
Recreational Marine Engines	06/07/99	08/25/99	10/05/01 08/14/02	11/08/02
Arsenic in Drinking Water	03/30/99	06/04/99	06/22/00	01/22/01
Light Duty Vehicles/Light Duty Trucks Emissions and Sulfur in Gas	08/27/98	10/26/98	05/13/99	02/10/00
Filter Backwash Recycling	08/21/98	10/19/98	04/10/00	06/08/01
Long Term 1 Enhanced Surface Water Treatment	08/21/98	10/19/98	04/10/00	01/14/02
Radon in Drinking Water	07/09/98	09/18/98	11/02/99	
Section 126 Petitions	06/23/98	08/21/98	09/30/98	05/25/99

SBREFA Panel Rule	Date Convened	Date Completed	Notice of Proposed Rulemaking	Final Rule Published
Phase I (FIP) To Reduce the Regional Transport of Ozone in the Eastern United States	06/23/98	08/21/98	10/21/98	05/06/05
Ground Water	04/10/98	06/09/98	05/10/00	11/08/06
Underground Injection Control (UIC) Class V Wells	02/17/98	04/17/98	07/29/98	12/07/99
Centralized Waste Treatment Effluent Guideline	11/06/97	01/23/98	09/10/03 01/13/99	12/22/00
Transportation Equipment Cleaning Effluent Guidelines	07/16/97	09/23/97	06/25/98	08/14/00
Stormwater Phase II	06/19/97	08/07/97	01/09/98	12/08/99
Industrial Laundries Effluent Guidelines	06/06/97	08/08/97	12/17/97	Withdrawn 08/18/99
Nonroad Diesel Engines	03/25/97	05/23/97	09/24/97	10/23/98
See Appendix F for abbreviations.				

Appendix E

History of the Regulatory Flexibility Act

Shortly after the Office of Advocacy was founded in 1976, the first White House Conference on Small Business engaged small business representatives from across the United States in national brainstorming sessions. One recurring concern was the difficulty that “one-size-fits-all” regulations created for small businesses trying to compete in U.S. markets. President Jimmy Carter, a one-time small business owner himself, understood the necessity for greater protections for small businesses in the regulatory process and helped facilitate administrative and legislative changes. In 1979, President Carter issued a memorandum to the heads of all executive agencies, instructing them to “make sure that federal regulations [would] not place unnecessary burdens on small businesses and organizations,” and more specifically, to apply regulations “in a flexible manner, taking into account the size and nature of the regulated businesses.”¹² He asked Advocacy to ensure that the agencies’ implementation would be consistent with government-wide regulatory reform.

In 1980, Congress enacted the Regulatory Flexibility Act (RFA), which elevated aspects of this memorandum to the level of federal statute.¹³ The new law mandated that agencies consider the impact of their regulatory proposals on small businesses, analyze proposed regulations for equally effective alternatives, and make their analyses of equally effective alternatives available for public comment. This new approach to federal rulemaking was viewed as a remedy for the disproportionate burden placed

12. Jimmy Carter, Memorandum on Regulation of Small Businesses and Organizations, II Pub. Papers 2142 (Nov. 16, 1979), available at <https://www.presidency.ucsb.edu/documents/memorandum-from-the-president-regulation-small-businesses-and-organizations>

13. 5 U.S.C. § 601 et seq.

on small businesses by one-size-fits-all regulation, “without undermining the goals of our social and economic programs.”¹⁴

RFA Requirements

Under the RFA, when an agency proposes a rule that would have a “significant economic impact on a substantial number of small entities,” the rule must be accompanied by an impact analysis (an initial regulatory flexibility analysis, or IRFA) when it is published for public comment.¹⁵ Following that, should the agency publish a final rule, that agency must publish a final regulatory flexibility analysis (FRFA) as well.¹⁶ If a federal agency determines that a proposed rule would not have a “significant economic impact on a substantial number of small entities,” the head of that agency may “certify” the rule and bypass the IRFA and FRFA requirements.¹⁷

During a November 2015 interview, Frank Swain, chief counsel for advocacy from 1981 to 1989, noted that “the RFA is the only regulatory reform that is statutorily required. Most of the regulatory reforms are largely executive orders.” Executive orders frequently expire at the end of a president’s term. “The RFA, because of its statutory basis, is going to be around indefinitely,” Swain said. As such, the RFA continues to be an important check on burdensome regulation.

Interpreting and Strengthening the RFA

During the first half of the 1980s, the federal courts were influential in developing the RFA’s role in the

14. Carter, supra note 12..

15. 5 U.S.C. § 603.

16. 5 U.S.C. § 604.

17. 5 U.S.C. § 605(b).

regulatory process. One question that required the courts' intervention was whether a federal agency had to consider a proposed rule's indirect effects on small businesses, in addition to its direct effects. In *Mid-Tex Electric Cooperative, Inc. v. Federal Energy Regulatory Commission (FERC)*, the D.C. Circuit found that "Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy."¹⁸ This interpretation—that federal agencies must only consider the direct effects on small businesses within the jurisdiction of the rule—has continued to be the judicial interpretation of the RFA, even after subsequent amendments.¹⁹

The following year, in the run-up to the second White House Conference on Small Business in 1986, conference planners noted that "the effectiveness of the RFA largely depends on small business' awareness of proposed regulations and [their] ability to effectively voice [their] concerns to regulatory agencies."²⁰ They also voiced concern that at the time "the courts' ability to review agency compliance with the law is limited." Eight years later, the Government Accounting Office reported that agency compliance with the RFA varied widely across the federal government, a condition that likely impaired efforts to address the disproportionate effect of federal regulation on small business.

Advocacy was statutorily required to report annually on federal agency compliance, but given that compliance with the RFA was not itself reviewable by the courts at the time, the effectiveness of such reporting was limited. The RFA did allow the chief counsel for advocacy to appear as *amicus curiae* (friend of the court) in any action to review a rule, expanding the chief counsel's role in representing small business interests in policy development. However, given that courts did not review compliance

18. *Mid-Tex Elec. Coop. v. FERC*, 773 F.2d 327, 341 (D.C. Cir. 1985).

19. See *American Trucking Ass'ns v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999).

20. The Small Business Advocate newsletter, U.S. Small Business Administration, Office of Advocacy, September 2005.

with the RFA, any challenge to regulation would need to be primarily under the Administrative Procedure Act.

After the third White House Conference on Small Business in 1995 renewed the call for strengthening the RFA, Congress and President Bill Clinton did so by enacting the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). SBREFA provided new checks on federal agency compliance with the RFA's requirements, as well as additional procedures specifically addressing small business concerns regarding environmental and occupational safety and health regulations. The SBREFA amendments also made a federal agency's compliance with certain sections of the RFA judicially reviewable, allowing challenges to regulations based on the agency's failure to supply a FRFA or sufficient reason for certification.

After amending the RFA to allow for judicial review of agency compliance, the courts again provided guidance regarding the RFA's requirements for federal agencies. In *Southern Offshore Fishing Associations v. Daley*, the court held that the National Marine Fisheries Service failed to make a "reasonable, good-faith effort" to inform the public about the potential impacts of a proposed rule imposing fishing quotas and to consider less harmful alternatives.²¹ The agency had published a FRFA with its final rule, but had not published an IRFA when the rule was proposed. The court's holding established that an IRFA must precede a FRFA for an agency to have "undertak[en] a rational consideration of the economic effects and potential [regulatory] alternatives."²²

SBREFA Panels

The SBREFA amendments also required the Environmental Protection Agency and the Occupational Safety and Health Administration to convene small business advocacy review panels

21. *Southern Offshore Fishing Ass'ns v. Daley*, 995 F.Supp 1411, 1437 (M.D. Fla. 1998).

22. *Id.*

whenever the agency proposes a rule that may have a significant impact on a substantial number of small entities. These panels consist of officials from the promulgating agency, the Office of Information and Regulatory Affairs, and the Office of Advocacy. Their task is to consult with small business representatives on the agency's regulatory proposals to ensure that the agency has identified and considered regulatory alternatives that could attain the policy objectives while minimizing the impacts on small businesses. After each collaborative panel has concluded, the panel issues a report of its findings and any recommendations for providing flexibility for small entities.

The innovation of SBREFA panels has allowed for greater consideration of small business alternatives for federal rules. Jere W. Glover, chief counsel for advocacy during the passage of SBREFA, made two key observations about the rulemaking process. First, "if you get to the agency early in the process, they are more likely to change their mind." And second, the mission of these efforts is to "make the regulation work for the industry," not to "kill the regulation." Glover's perspective comes not only from his tenure as chief counsel from 1994 to 2001; he was also present at the creation of the RFA as deputy to Milton Stewart, the first chief counsel for advocacy.

Executive Order 13272

As President George W. Bush's administration began to consider small business priorities, improved RFA compliance was one key goal. To this end, President Bush issued Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking" in 2002.²³ This order tasked Advocacy with training federal agencies and other stakeholders on the RFA. The training sessions helped apprise agencies of their responsibilities under the RFA and educated agency officials on the best RFA compliance

23. Executive Order 13272 (August 13, 2002), 67 Fed. Reg. 53461.

practices. In addition, E.O. 13272 required Advocacy to track agency compliance with these education requirements and report on them annually to the White House Office of Management and Budget.

E.O. 13272 also instituted new procedures to help facilitate a collaborative relationship between agencies and the Office of Advocacy. First, it required agencies to notify Advocacy of any draft proposed rule that would impose a significant impact on a substantial number of small entities. Second, it required agencies to provide a response in the Federal Register to any written comment on the proposed rule from the Office of Advocacy when the final rule was published.

Thomas M. Sullivan, chief counsel for advocacy during the Bush administration, discussed E.O. 13272's pivotal role in furthering RFA compliance. He noted that, because of the executive order, "Advocacy became a part of the fabric of federal rulemaking." The aspect most responsible for this evolution in Sullivan's view was federal agency training. "Training really helped accomplish this," he said. "The goal is to create regulations that meet the regulatory purpose and are sensitive to small business requirements." Sullivan added that "The biggest misperception is how hard it is to work with an agency for a win-win solution as opposed to just being critical of regulation."

Eight years and one presidential administration later, Congress and President Barack Obama enacted the Small Business Jobs Act of 2010,²⁴ which codified some of the procedures introduced in E.O. 13272. That same year, the Dodd-Frank Wall Street Reform and Consumer Protection Act became law.²⁵ The new law created the Consumer Financial Protection Bureau and required that the new agency's major rules come under the SBREFA panel provisions of the RFA.

24. Small Business Jobs Act, Pub. L. 111-240 (2010).

25. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111-203 (2010).

The Obama administration looked to Advocacy for ways of encouraging economic activity. Again, the RFA was an important part of the answer. Executive Order 13563, “Improving Regulation and Regulatory Review,”²⁶ signed in 2011, directed agencies to heighten public participation in rulemaking, consider overlapping regulatory requirements and flexible approaches, and conduct ongoing regulatory review. President Obama concurrently issued a memorandum to all federal agencies, reminding them of the importance of the RFA and of reducing the regulatory burden on small businesses through regulatory flexibility. In this memorandum, President Obama directed agencies to increase transparency by providing written explanations of any decision not to adopt flexible approaches in their regulations. The following year, President Obama further attempted to reduce regulatory burdens with Executive Order 13610, “Identifying and Reducing Regulatory Burdens,”²⁷ which placed greater focus on initiatives aimed at reducing unnecessary regulatory burdens, simplifying regulations, and harmonizing regulatory requirements imposed on small businesses.

Executive Orders 13563 and 13610 bolstered the retrospective review requirements of the RFA by requiring all executive agencies to conduct periodic retrospective review of existing rules. President Obama also issued an administrative action, Executive Order 13579, which recommended that all independent agencies do the same.²⁸ This emphasis on the principles of regulatory review and the sensitivity to small business concerns in the federal rulemaking process further increased federal agency compliance.

Dr. Winslow Sargeant, chief counsel for advocacy from 2010 to 2015, stressed that these executive orders sought to “make federal regulation more clear, predictable, and transparent.” Sargeant identified two key areas, “retrospective review of existing regulation and deregulation when rules are no

26. Executive Order 13563 (January 18, 2011), 76 Fed. Reg. 3821.

27. Executive Order 13610 (May 10, 2012), 77 Fed. Reg. 28467.

28. Executive Order 13579 (July 11, 2011), 76 Fed. Reg. 41585.

longer needed,” as important future challenges for regulatory improvement.

New Horizons: Small Business and International Trade

With the enactment of the Trade Facilitation and Trade Enforcement Act of 2015, Advocacy’s duties to small business expanded beyond our borders. Under the Act, the chief counsel for advocacy must convene an interagency working group whenever the president notifies Congress that the administration intends to enter into trade negotiations with another country. The working group conducts small business outreach in manufacturing, services, and agriculture sectors and gather input on the trade agreement’s potential economic effects. Informed by these efforts, the working group is charged with identifying the most important priorities, opportunities, and challenges affecting these industry sectors in a report to Congress. In December of 2018, pursuant to section 502 of the Trade Facilitation and Trade Enforcement Act (TFTEA), Advocacy released the Section 502 Small Business Report on the Modernization of the North American Free Trade Agreement (NAFTA): Prepared for the Consideration of the United States-Mexico-Canada Agreement (USMCA).²⁹

Deregulation and Executive Orders 13771 and 13777

With the inauguration of President Donald J. Trump in January 2017, the regulatory process would see dramatic reform. Shortly after the beginning of his administration, President Trump issued two executive orders aimed at substantially ameliorating the regulatory burden faced by the private sector. The first, E.O. 13771, “Reducing Regulation and Controlling Regulatory Costs,” commonly known as

29. U.S. Small Business Administration, Office of Advocacy, Section 503 Small Business Report on the Modernization of the North American Free Trade Agreement (NAFTA): Prepared for Consideration of the United States-Mexico-Canada Agreement (USMCA) (Dec. 2018), available at <https://cdn.advocacy.sba.gov/wp-content/uploads/2018/12/20094150/Section-502-Small-Business-Report-on-the-Modernization-of-the-North-American-Free-Trade-Agreement-NAFTA.pdf>

“one-in, two-out,” required that any new regulations be balanced by the reduction of at least two other regulations—and that the incremental cost of new regulations be entirely offset by elimination of existing costs of other regulations. The second, E.O. 13777, “Enforcing the Regulatory Reform Agenda,” set a framework for implementing this vision of regulatory reform, requiring inter alia each agency appoint a Regulatory Reform Officer to supervise the process of regulatory reform. These measures were another opportunity for small business regulatory reform. Agency implementation of these executive orders offered significant opportunities for regulatory relief targeted to small businesses.

Since its passage in 1980, the RFA has demonstrated remarkable staying power. It has helped establish small business consideration as a necessary part of federal rulemaking.

Appendix E

Abbreviations

RFA	Regulatory Flexibility Act	IRS	Internal Revenue Service
SBREFA	Small Business Regulatory Enforcement Fairness Act	MSHA	Mine Safety and Health Administration
SBAR	small business advocacy review	MSGP	Multi Sector General Permit
IRFA	initial regulatory flexibility analysis	NAICS	North American Industry Classification System
FRFA	final regulatory flexibility analysis	NIOSH	National Institutes of Occupational Safety and Health
1-BP	1-bromopropane	NIST	National Institute of Standards and Technology
AEZ	Application Exclusion Zone	NMP	N-Methyl-2-pyrrolidone
AIM Act	American Innovation and Manufacturing Act	NOAA	National Oceanic and Atmospheric Administration
AMS	Agricultural Marketing Service	NWP	Nationwide Permits
APHIS	Animal and Plant Health Inspection Service	OIRA	Office of Information and Regulatory Affairs
CCR	Coal Combustion Residuals	OMB	Office of Management and Budget
CFPB	Consumer Financial Protection Bureau	ONO	Office of the National Ombudsman
CGP	Construction General Permits	OSHA	Occupational Safety and Health Administration
CMMC	Cybersecurity Maturity Model Certification	PCE	Perchloroethylene
CORPS	Army Corps of Engineers	PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
DEA	Drug Enforcement Administration	PMTA	Premarket Tobacco Product Applications
DOC	Department of Commerce	PPP	Paycheck Protection Program
DOD	Department of Defense	PV29	Pigment Violet 29
DOE	Department of Energy	PWS	Public Water Systems
DOL	Department of Labor	SAM	System for Award Management
EPA	Environmental Protection Agency	SBA	Small Business Administration
ENDS	Electronic Nicotine Delivery Systems	SDWA	Safe Drinking Water Act
EO	Executive Order	TCE	Trichloroethylene
ERC	Employee Retention Credit	TSCA	Toxic Substance Control Act
ETS	Emergency Temporary Standard	UCMR 5	Unregulated Contaminant Monitoring Rule 5
FDA	Food and Drug Administration	USDA	Department of Agriculture
FLSA	Fair Labor Standards Act		
GWP	Global Warming Potentials		
HAP	Hazardous Air Pollutant		
HBCD	Cyclic Aliphatic Bromide Cluster		
HFC	Hydrofluorocarbon		
IFR	Initial Final Rule		
IRIS	Integrated Risk Information System Assessments		