



Report to the Chairman, Subcommittee
on Regulatory Affairs and Federal
Management, Committee on Homeland
Security and Governmental Affairs, U.S.
Senate

October 2017

FEDERAL REGULATIONS

Key Considerations for Agency Design and Enforcement Decisions

GAO Highlights

Highlights of [GAO-18-22](#), a report to the Chairman, Subcommittee on Regulatory Affairs and Federal Management, Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

Within the limits of their statutory authority, agencies may design their regulations in different ways to achieve intended policy outcomes. Agencies also decide how they will promote compliance with their regulations and ensure that regulated entities are informed of regulatory requirements.

GAO was asked to review how agencies make regulatory design and enforcement decisions. This report describes how selected agencies report (1) making decisions on regulatory designs among available options, (2) making decisions to designate resources among available compliance and enforcement activities, and (3) evaluating those decisions, and also identifies (4) key considerations for decision makers related to regulatory design and enforcement. To describe how agencies make and evaluate these decisions, GAO reviewed regulatory processes and spoke with officials at six executive departments—the Departments of Agriculture (USDA), Commerce, Health and Human Services (HHS), Labor (Labor), and Transportation and the Environmental Protection Agency (EPA)—based on volume of significant rulemaking, and 13 subcomponents within those departments. To identify key considerations for regulatory decision makers, GAO reviewed existing criteria, including statutory and Executive requirements, conducted a literature review, and obtained input on identified considerations with subject matter specialists.

GAO is not making any recommendations in this report. USDA, HHS, Labor, and the EPA provided technical comments that were incorporated as appropriate.

View [GAO-18-22](#). For more information, contact Heather Krause (202) 512-6806 or krauseh@gao.gov.

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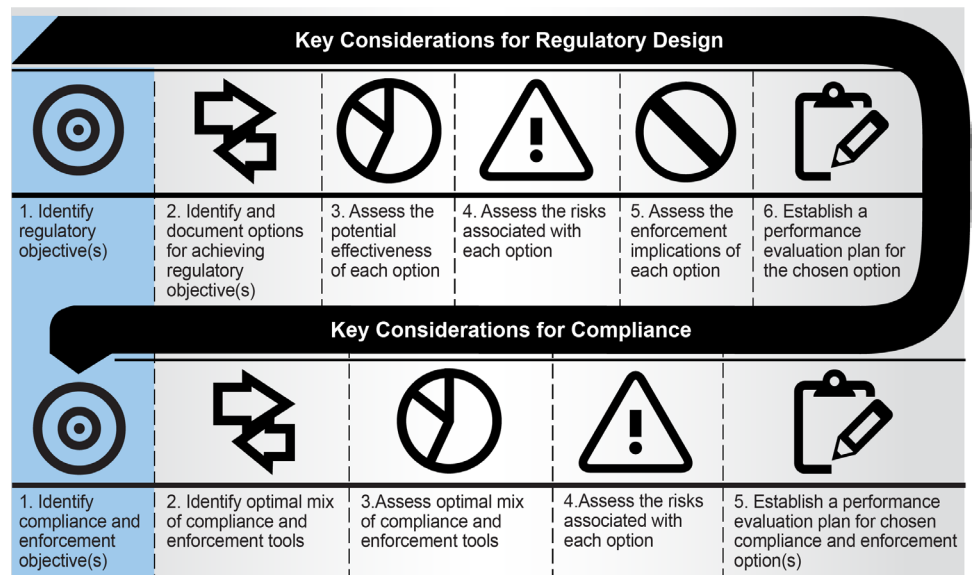
What GAO Found

Agencies have multiple available regulatory designs. Selected agency processes for choosing among them are informed by statutory and Executive requirements, regulatory objectives, and statutory discretion. Officials reported a preference for “performance” designs that establish an outcome but allow flexibility in how to achieve it, but stated that in some cases their objectives could require use of more prescriptive “design-based” regulations that specify a certain required technology or action. Officials at all selected agencies stated that they discuss potential regulatory designs internally, but some agency processes also included practices such as documentation of identified design options and assessments of the options’ risks and enforcement implications.

Selected agencies used multiple tools and approaches for allocating resources to elicit compliance. Agencies generally have flexibility to use a mix of tools, including providing compliance assistance to help regulated entities understand requirements, and monitoring and enforcement through inspections. Selected agency processes to allocate compliance resources vary, and agencies reported using collected data to target enforcement resources to address risks.

Selected agencies supplemented feedback on effectiveness of their regulatory design and enforcement approaches with evaluations, which agency officials said could prompt changes. When agencies identify noncompliance, selected agencies may update their regulation or their compliance strategy.

GAO identified key considerations to strengthen agency decisions related to regulatory design and enforcement (see figure). These build on current directives, academic research, and the experiences of selected agencies and are intended to serve as a resource for decision makers in designing—or redesigning—their regulations and determining how best to elicit compliance.



Sources: GAO analysis of academic literature and applicable internal controls, risk principles, and executive orders. | GAO-18-22

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Abbreviations

ADP	Action Development Process
APHIS	Animal and Plant Health Inspection Service
BIS	Bureau of Industry and Security
CMS	Centers for Medicare and Medicaid Services
Commerce	Department of Commerce
DOT	Department of Transportation
EBSA	Employee Benefits Security Administration
E.O.	executive order
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HACCP	Hazardous Analysis and Critical Control Point
HHS	Department of Health and Human Services
Labor	Department of Labor
MSHA	Mine Safety and Health Administration
OAR	Office of Air and Radiation
OCSP	Office of Chemical Safety and Pollution Prevention
OLEM	Office of Land and Emergency Management
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHMSA	Pipeline and Hazardous Materials Safety Administration
RFA	Regulatory Flexibility Act
USDA	Department of Agriculture

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October 19, 2017

The Honorable James Lankford
Chairman
Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs
United States Senate

Dear Mr. Chairman,

Federal regulations are one of the many tools that agencies use to achieve national goals, such as improving the economy and protecting the health and safety of the public and the environment. Within the limits of their statutory requirements and authority, agencies may design regulations in different ways to achieve intended policy outcomes. These regulatory designs range from designs that generally provide regulated entities with greater flexibility and options for compliance (“performance” regulations) to prescriptive designs that specify a certain technology or action regulated entities must adopt (“design-based” regulations). Each regulatory design has its advantages and disadvantages. For example, a regulation that provides flexibility on how to comply may leave regulated entities with less certainty on whether they are in compliance.

Agencies also decide how they will promote compliance with their regulations and deter noncompliance. Within available resources, agencies must tailor these efforts to encourage voluntary compliance and to inform regulated entities of regulatory requirements. While regulations can generate substantial benefits to society, they also have costs, and thus decisions agencies make about their regulatory designs and the way that they enforce those regulations are important. The Office of Management and Budget (OMB) estimated annual benefits from major federal regulations issued in fiscal years 2005 through 2015 to be from

\$208 billion to \$672 billion, and estimated annual costs from \$57 billion to \$85 billion.¹

You asked us to review how agencies make key decisions related to regulatory design, compliance and enforcement, and updating of regulations. This report describes how selected agencies report (1) making decisions on regulatory designs among available options, (2) making decisions to designate resources among available compliance and enforcement activities, and (3) evaluating those decisions, and also identifies (4) key considerations for decision makers related to regulatory design and enforcement.

To describe agency experiences and decisions regarding regulatory design and compliance and how they evaluate those decisions, we reviewed regulatory processes at six departments—the United States Departments of Agriculture (USDA), Commerce (Commerce), Health and Human Services (HHS), Labor (Labor), and Transportation (DOT), and the Environmental Protection Agency (EPA)—and 13 subcomponents within those departments. To illustrate a wide range of regulatory designs and resulting compliance activities, we selected the six executive branch departments (excluding the Department of Defense) that promulgated the

¹OMB, *2016 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act*, (Washington, D.C., 2016). In these estimates (reported in 2001 dollars), OMB included only the “major” regulations for which agencies estimated and monetized both benefits and costs. OMB noted that the estimates reflect uncertainty of the benefits and costs of each rule at the time it was evaluated. The Congressional Review Act defines “major rules” as those that are likely to result in an annual effect on the economy of \$100 million or more, among other criteria. 5 U.S.C. § 804(2). However, for purposes of the draft report, OMB defined major rules to include all final rules promulgated by an Executive Branch agency that meet at least one of the following three conditions: rules designated as major under 5 U.S.C. § 804(2); rules designated as meeting the analysis threshold under the Unfunded Mandates Reform Act of 1995; or rules designated as “economically significant” under section 3(f)(1) of Executive Order 12866.

most significant regulations² between September 1, 2011, and August 31, 2016.³

We used reginfo.gov data to identify the number of significant regulations. We assessed the reliability of those data by reviewing relevant documentation, interviewing knowledgeable agency officials, and electronically and manually testing the data for missing values, outliers, and invalid values, and we found the data to be sufficiently reliable for the purpose of identifying selected departments. The experiences of these selected executive branch departments are illustrative and nongeneralizable.

From these departments, we selected subcomponents for nongeneralizable case studies based on (1) information provided by department officials engaged in regulatory activities on their subcomponents' use of regulatory designs and on subcomponents that had amended or changed their regulatory design or compliance strategies or used compliance activities other than traditional compliance assistance and enforcement and (2) a review of past Inspector General (IG) and our own work on types of regulatory designs and compliance strategies. We excluded independent regulatory agencies in our scope as they are not subject to directives from OMB. In reviewing enforcement strategies used

²This included both "significant" and "economically significant" regulations. Under Executive Order 12866, OMB reviews significant proposed and final rules from agencies, other than independent regulatory agencies, before they are published in the *Federal Register*. The order defines significant regulatory actions as those that: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (these actions are commonly referred to as "economically significant" regulations); (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the executive order. Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

³This 5-year time period was chosen to ensure that the number of regulations over time was consistently reflected, as well as to ensure that our source, www.reginfo.gov, had been updated to reflect all regulations for our chosen time period when we conducted this analysis in late September 2016. We did not include Department of Defense regulations because those regulations often have unique characteristics—typically related to department administration or contracts—that are different from regulations addressed at outside entities and thus could make it difficult to identify broad regulatory designs and enforcement principles.

by agencies, we did not review federal regulatory programs for which enforcement has been delegated to states or localities. See table 1 below for our selected departments and subcomponents.

Table 1: Selected Departments and Subcomponents

Department	Subcomponent
United States Department of Agriculture	Animal and Plant Health Inspection Service (APHIS)
	Food Safety and Inspection Service (FSIS)
Department of Commerce	Bureau of Industry and Security (BIS)
Department of Health and Human Services	Food and Drug Administration (FDA)
	Centers for Medicare and Medicaid Services (CMS)
Department of Labor	Occupational Safety and Health Administration (OSHA)
	Mine Safety and Health Administration (MSHA)
	Employee Benefits Security Administration (EBSA)
Environmental Protection Agency	Office of Air and Radiation (OAR)
	Office of Chemical Safety and Pollution Prevention (OCSP)
	Office of Land and Emergency Management (OLEM)
Department of Transportation	Federal Aviation Administration (FAA)
	Pipeline and Hazardous Materials Safety Administration (PHMSA)

Source: GAO analysis | GAO-18-22

To illustrate how our selected agencies make decisions regarding regulatory design and compliance and how they evaluate those decisions, we reviewed agency written procedures and interviewed department and subcomponent officials on their practices for making these decisions. We analyzed information from those documents and interviews to identify and confirm common patterns as well as differences across selected agencies. These experiences illustrate how the selected agencies currently make these decisions, the outcomes of those decision-making processes, and their evaluation practices.

To identify key considerations for decision makers related to regulatory design and enforcement, we reviewed existing criteria, including statutory and Executive requirements as well as resources for managers, and conducted a literature review to ensure that our considerations incorporated applicable academic and government research and

findings.⁴ These considerations were also refined by the current practices and approaches of the selected agencies we reviewed. We obtained input on these considerations with subject matter specialists selected based on the results of our literature review and with officials from our selected agencies. Appendix I contains more information on our objectives, scope, and methodology.

We conducted this performance audit from August 2016 to October 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Statutory and Executive requirements assert broad principles and require agencies to consider alternative ways of regulating and preferred regulatory designs, such as performance standards rather than means-based design standards. Further, these requirements and directives urge agencies to consider alternative approaches to eliciting compliance, such as alternative reporting methods or delaying compliance dates.

- The **Regulatory Flexibility Act** (RFA) requires federal agencies to examine the impact of proposed, final, and existing rules on small businesses, small organizations, and small governmental jurisdictions, and to solicit the ideas and comments of such entities for this

⁴GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#), (Washington, D.C.: Sept. 10, 2014). Our literature review incorporated searches of several academic, literature, and government sources—including bibliographic databases such as ProQuest, Scopus, Academic OneFile, Public Affairs Information Service, and LexisNexis—for articles or studies published from January 2011 through August 2016. The team searched for articles using several combinations of relevant key words such as: “regulatory design,” “regulatory structure,” “regulatory compliance,” and “regulatory enforcement.” We then identified the articles that were relevant to our objectives based on the independent review of two team analysts. Two analysts independently reviewed each relevant record in the literature search results to document information that was relevant to our objectives and identify key themes to inform our key considerations. We also searched our own and selected federal IG websites for any reports relevant to our objectives. These searches were not meant to be a comprehensive search of all available literature on the topic, but rather were conducted to identify relevant work to inform our identification of key regulatory design and enforcement considerations for decision makers.

purpose.⁵ Among other requirements, the RFA requires that agencies consider regulatory alternatives that accomplish the stated objectives of a proposed rule while minimizing any significant impact on small entities. However, the RFA does not mandate any particular outcome in rulemaking.

- **Executive Order 12866** (E.O. 12866), issued in 1993, promotes a regulatory philosophy and set of principles that, to the extent permitted by law and where applicable, encourages agencies to assess costs and benefits of their proposed and final regulations.⁶ It also directs agencies to consider available regulatory alternatives in all regulations, including the alternative of not regulating, and generally select those alternatives that maximize net benefits, to the extent permitted by statute.⁷ Alternatives to direct regulation include providing economic incentives to encourage the desired behavior (such as user fees or marketable permits) or providing information upon which choices can be made by the public. If an agency determines that direct regulation is necessary, the Executive Order directs the agency, to the extent feasible, to specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt. Subsequent executive orders across administrations have reaffirmed this philosophy and these principles.
- **Circular A-4**, issued by OMB in 2003, provides guidance and best practices to federal agencies for determining the potential effects of new regulations.⁸ A-4 directs agencies to consider a number of regulatory alternatives, including market-oriented approaches rather than direct controls, performance standards rather than design

⁵U.S.C. §§ 601-612. Requirements to prepare regulatory flexibility analyses do not apply to any proposed or final rule if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

⁶Executive Orders 13563 and 13771 reaffirm this philosophy and these principles. Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993); Exec. Order No. 13563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3821 (Jan. 21, 2011); and Exec. Order. No. 13771, *Reducing Regulation and Controlling Regulatory Costs*, 82 Fed. Reg. 9339 (Feb. 3, 2017).

⁷Executive Order 12866 states that these benefits include potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity.

⁸Office of Management and Budget, *Circular A-4: Regulatory Analysis*, (Washington, D.C., 2003).

standards, informational measures, and different compliance dates and enforcement methods, among others.

The RFA, specific statutes, and multiple executive orders have also emphasized the importance of regulatory lookbacks, also referred to as retrospective reviews, in which agencies evaluate how existing regulations work in practice:

- **Statutory requirements:** The RFA's Section 610 requires agencies to review all regulations that have or will have a significant impact on small entities within 10 years of the publication of the rule 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 impacts on small entities. Congress also established other requirements for agencies to review the effects of regulations issued under specific statutes, such as the Clean Air Act.⁹
- **Executive Order 13771**, issued in January 2017, requires executive agencies to identify at least two existing regulations to be repealed whenever they publicly propose or otherwise promulgate a new regulation, unless prohibited by law.¹⁰ Agencies must also annually provide their best approximation of the total costs or savings associated with each new regulation or repealed regulation to OMB. Finally, the order requires that the total incremental cost of all new regulations, including the savings for regulations that have been repealed, be no greater than zero for fiscal year 2017, unless otherwise required by law or consistent with advice provided in writing by the OMB Director.
- **Executive Order 13777**, issued in February 2017, requires agencies to designate an agency official as its Regulatory Reform Officer.¹¹ Regulatory Reform Officers oversee the implementation of regulatory reform initiatives to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Agencies must also establish Regulatory Reform Task Forces to evaluate existing

⁹See, for example, 42 U.S.C. §§ 7411(b)(1)(B), 7412(d)(6).

¹⁰Exec. Order. No. 13771, *Reducing Regulation and Controlling Regulatory Costs*, 82 Fed. Reg. 9339 (Feb. 3, 2017).

¹¹Exec. Order. No. 13777, *Enforcing the Regulatory Reform Agenda*, 82 Fed. Reg. 12,285 (Mar. 1, 2017).

regulations and make recommendations regarding their repeal, replacement, or modification, consistent with applicable law.¹²

Selected Agencies Reported Using Statutory and Executive Requirements and Regulatory Objectives in Their Decision-Making Processes

Agencies Have Multiple Regulatory Design Options Available to Achieve Their Objectives Depending on Statutory Discretion

When agencies determine that they may need to regulate, they generally have multiple regulatory designs available to achieve their objectives. Agencies are directed by statute and Executive requirements to assess alternatives to regulatory action—including not issuing new regulations—and different ways of regulating. Available regulatory designs range from prescriptive regulations that specify the adoption of a certain technology or action to designs that generally provide regulated entities with more discretion and options for compliance, and in some instances hybrid designs that incorporate both prescriptive and less prescriptive elements. Alternatives to prescriptive regulations provide regulated entities with greater flexibility. For example, performance-based regulations require a certain outcome but allow regulated entities discretion to determine how

¹²Regulatory Task Forces are directed to be composed of: the agency Regulatory Reform Officer, the agency Regulatory Policy Officer designated under section 6(a)(2) of Executive Order 12866, a representative from the agency's central policy office or equivalent central office, and for agencies listed in section 901(b)(1) of title 31, United States Code, at least three additional senior agency officials as determined by the agency head. Among other things, each task force must attempt to identify regulations that eliminate jobs, or inhibit job creation; are outdated, unnecessary, or ineffective; impose costs that exceed benefits; or create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies.

they will achieve that outcome, while market-based regulations use tradeable permits or fees to influence behavior.¹³

Table 2 highlights the regulatory designs identified through our literature review and corroborated by subject matter specialists and agency officials. The table includes selected examples of applicable regulations implemented by our case study agency subcomponents.

Table 2: Examples of Regulatory Design Options at Selected Agencies

Type of regulatory design	Regulatory design options	Definition	Selected illustrative examples and corresponding agency
Prescriptive	Means-based (also referred to as design standards)	Specifies the means of achieving a certain requirement or outcome	Export licensing requirements allow or prohibit the sale of products exported from the United States to purchasers in foreign countries (Bureau of Industry and Security)
Hybrid	Hybrid standards	Uses combination of prescriptive and more flexible regulatory designs	Pathogen Reduction; Hazardous Analysis and Critical Control Point (HACCP) Systems Rule combines management-based requirements for meat and poultry facilities to develop and implement plans to mitigate hazardous bacterial contamination and performance-based standards mandating food safety outcomes (Food Safety and Inspection Service)
Generally more flexible	Performance	Specifies an outcome but allows flexibility in how to achieve it	Workplace health standards establish targets for healthful working conditions that employers are required to sustain while allowing discretion for how those targets are achieved (Occupational Safety and Health Administration)
	Market	Provides incentives through market signals (such as tradeable permits, taxes, and fees) to promote a desired outcome	Emissions trading programs distribute a finite number of emission allowances among regulated sources that can be monetized and traded as a means of incentivizing the reduction of overall emissions (Environmental Protection Agency, Office of Air and Radiation)
	Management	Mandates plans to identify and respond to hazards	Emergency Response Plans require mine operators to develop and gain approval for plans to prepare for emergency situations that put workers' lives and safety at risk (Mine Safety and Health Administration)

¹³In general, performance-based regulations can encourage innovation by allowing regulated entities to consider cheaper ways to meet the required outcome or standard. However, they generally do not provide incentives for regulated entities to do more than what is required to achieve the standard. Market-based regulations create an incentive for regulated entities to achieve a desired outcome and to innovate in such a way as to continually search for least cost solutions. In particular, market-based regulations may be more economically efficient than standards.

Type of regulatory design	Regulatory design options	Definition	Selected illustrative examples and corresponding agency
	Mandated information disclosure	Requires public disclosure of information	Toxic Release Inventory Program requires regulated facilities to provide toxic release information that the Environmental Protection Agency makes available through a publicly accessible database. (Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention)
Non-regulatory	Voluntary	Voluntary requirements or reporting	Aviation Safety Action Program encourages aviation employees to voluntarily report potential safety issues (Federal Aviation Administration)
	Deference to industry standards	Defers to requirements set by industry or standards-setting bodies	Industry consensus standards developed by nongovernmental Standards Development Organizations are adopted in some instances—such as with machinery and industrial equipment—in lieu of creating government-unique standards. (Occupational Safety and Health Administration)
	Deference to states and localities	Defers to the regulatory authority of state and local governments	(N/A – Outside the scope of this engagement)

Source: GAO analysis of agency case studies and academic literature, including Christopher Carrigan and Elise Harrington, "Choices in Regulatory Program Design and Enforcement," Research paper prepared for the Penn Program on Regulation's Best-in-Class Regulator Initiative, June 2015. | GAO-18-22

Statutes give agencies varying degrees of discretion to consider multiple designs as they develop regulations to meet their objectives. In some instances, Congress directs agencies by statute to implement specific regulatory designs. For example, the Occupational Safety and Health Act directs the Occupational Safety and Health Administration (OSHA), when promulgating a standard, to either (1) adopt existing scientific and industry consensus standards for workplace health and safety, or (2) explain why the standard adopted by the agency better protects workers than the national consensus standard. In addition, requirements dealing with exposures to toxic materials must be formulated in the terms of "objective criteria and the performance desired" whenever practicable.¹⁴ The Clean Air Act provides EPA's Office of Air and Radiation (OAR) with varying degrees of discretion to consider different regulatory designs when developing its regulatory programs.¹⁵ For example, the Clean Air Act gave the office broad authority to establish a tradable emissions allowance system—commonly referred to as cap and trade—with a market-based design for its Acid Rain Program, but to promulgate specific prescriptive regulations for the National Emission Standards for Hazardous Pollutants program.

¹⁴29 U.S.C. § 655(b).

¹⁵See 42 U.S.C. § 7651(b); 42 U.S.C. § 7651b; 42 U.S.C. § 7412 (c)(2).

Selected Agencies Stated a Preference for Less Prescriptive Designs to Achieve Regulatory Objectives

Officials at selected agencies reported a general preference for less prescriptive regulations in accordance with E.O. 12866, Circular A-4, and other Executive requirements, which encourage agencies to consider less prescriptive regulatory design options for achieving their objectives. For example, DOT officials told us that, when choosing among regulatory design options, they prefer performance-based regulations over means-based regulations. Officials from DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) told us that performance-based regulations—as implemented for classifying and packaging hazardous material—allow them to accommodate innovations among regulated entities, adapt to technological advances, and promote the competitiveness of U.S. firms in global markets without having to subsequently revise the regulations.

The following examples illustrate how some selected subcomponents have (1) encouraged the development of less prescriptive design options for new regulatory programs, and (2) updated or replaced existing regulations to incorporate more flexible designs.

- **Developing trainings to encourage less prescriptive designs:** Two selected subcomponents produced training materials to promote the consideration of all options for designing effective regulation, including less prescriptive regulations where appropriate. EPA's Office of Enforcement and Compliance Assurance developed a workbook and supplemental training course that present principles and tools to help rule drafters consider the relative effectiveness of different designs for achieving regulatory objectives, including how the degree of prescriptiveness can either promote or hinder compliance. The Federal Aviation Administration's (FAA) "Performance-Based Regulations Training" course uses real world examples and team exercises to teach rule drafters (1) the concepts that inform performance-based designs, (2) the relationship between prescriptive and less prescriptive regulatory approaches, and (3) considerations for developing and assessing performance-based regulations.
- **Updating or replacing existing regulations to incorporate flexible designs:** FAA's 2016 airworthiness standards for small airplanes replaced some prescriptive design requirements with more flexible performance-based standards.¹⁶ Agency officials told us that they

¹⁶81 Fed. Reg. 96,572.

expect the new regulation will improve safety and cost-effectiveness (such as by reducing compliance costs) while facilitating future technological innovations. Animal and Plant Health Inspection Service (APHIS) officials told us that increased international demand for cattle exports put pressure on their inspection infrastructure and prompted them to replace their formerly prescriptive standards with performance-based regulations that officials described as more flexible and easier to adapt to changing circumstances.¹⁷ Food Safety and Inspection Service (FSIS) officials told us that their Hazardous Analysis and Critical Control Points (HACCP) Rule represented a shift from FSIS's traditional means-based regulations (which mandated specific food production standards) to a mixed performance- and management-based regulatory program (which monitors food safety plans and production outcomes).¹⁸

Agencies Reported that Regulatory Objectives May Require Prescriptive Designs or Use of Multiple Designs

Despite a general preference for less prescriptive designs among selected agencies, officials from nine selected subcomponents told us that their regulatory objectives sometimes required a prescriptive regulation or that in some instances regulated entities expressed a preference for prescriptiveness.

- Mine Safety and Health Administration (MSHA) officials told us that their regulations were often necessarily prescriptive to implement and enforce the mine health and safety standards required by statute.¹⁹ For example, based on data from the National Institute for Occupational Safety and Health, MSHA determined that requiring more frequent respirable dust sampling for mining occupations known to have high dust levels and requiring the use of certain monitoring devices to measure respirable coal dust exposure are necessary to limit exposure to respirable coal mine dust and thus reduce occupational lung diseases.
- Bureau of Industry and Security (BIS) officials told us that their export licensing regulations are necessarily prescriptive to narrowly target specific items as unacceptable for export due to national security or commercial sanctions against certain countries.

¹⁷7 U.S.C. §§ 2131-2159; 15 U.S.C. §§ 1821-1831.

¹⁸61 Fed. Reg. 38,806 (July 25, 1996).

¹⁹30 U.S.C. §§ 801 et seq.

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- Food and Drug Administration (FDA) officials told us that, while they try to achieve a balance between prescriptive and less prescriptive regulatory designs, in some instances prescriptive regulations are the only means of ensuring public health and safety.
 - Officials from EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) told us that, when given non-prescriptive regulatory options, small businesses generally prefer prescriptive regulations with clear compliance requirements to minimize uncertainty.
 - An EPA OAR official told us that, during the update of a recent regulation on refrigerants, the agency considered including a provision allowing operators of pollutant-emitting facilities the option to either (1) set a corporate-wide budget for leaks covering all facilities, or (2) comply with a prescriptive regulation for individual appliances susceptible to leakage. Based on feedback from regulated entities and EPA enforcement officials, who voiced a need for predictability and ease of monitoring, EPA officials said that they ultimately chose to promulgate the more prescriptive regulation instead of the more flexible, but challenging to implement, corporate-wide approach.²⁰

Ten selected subcomponents incorporated multiple design elements into their regulations—what we refer to as hybrid designs—that offer more flexibility or, conversely, more clarity to meet the needs of different regulated entities.

- PHMSA officials told us that their special permits programs for hazardous materials and pipelines allow regulated entities the flexibility to determine their own means of satisfying transportation safety requirements if they achieve the same level of safety prescribed by regulation.
- FAA officials told us that most of their safety standards are necessarily prescriptive to ensure clarity and uniformity. However, they said that they often encourage the use of multiple designs in their rulemakings that allow for both performance-based and means-based regulations—as with the 2016 airworthiness standards for small airplanes.
- OSHA officials told us that they provide employers with multiple options for achieving regulatory compliance that incorporate both prescriptive and less prescriptive design elements. For example,

²⁰80 Fed. Reg. 69,458 (Nov. 9, 2015); 81 Fed. Reg. 82,272 (Nov. 18, 2016).

OSHA’s health standards regulating crystalline silica exposure among construction site workers provides employers both a performance-based option (which allows regulated entities discretion in determining how to meet permissible exposure limits), and a means-based option (in which regulated entities implement specified exposure mitigation measures for designated tasks).

- FDA and FSIS have both implemented voluntary programs to promote the adoption of practices among regulated entities that align with the agencies’ regulatory objectives. FSIS encourages regulated food facilities to develop voluntary food defense plans as a means of mitigating potential health hazards and strengthening food safety. FDA officials told us they issued voluntary food labeling standards for raw fruits and vegetables to assist in establishing an industry standard, and achieved 80 percent compliance among regulated entities.

Selected Agency Processes Included Practices for Considering and Assessing Regulatory Design Options

All selected agencies told us their processes for drafting regulations incorporated internal discussions to consider available regulatory design options. For example, Employee Benefits Security Administration (EBSA) officials told us that the agency’s process encourages rule drafters to solicit input from internal and external stakeholders to inform the consideration of all possible regulatory design options available to achieve statutory objectives. BIS officials told us that proposals for broadly applicable regulations—including available design options—are discussed and vetted with multiple stakeholders, including (1) BIS subcomponent officials, (2) Office of General Counsel staff, (3) agency engineers, and (4) external technical advisory committees.

However, some selected subcomponents’ processes for drafting proposed regulations also included documentation of identified design options for achieving objectives and assessments of risk or enforcement and compliance implications of identified design options. These practices for identifying and assessing regulatory designs are described in the following examples.

- **Documenting the assessment of design options for achieving regulatory objectives:** EPA uses an Analytical Blueprint to identify the range of regulatory design options considered throughout the Action Development Process (ADP)—the agency’s process for developing and responding to public comments on new regulatory proposals. FSIS officials told us that rule drafters develop an “options paper” to identify and assess alternative approaches to achieving

regulatory objectives based on multiple inputs, including (1) data analyses, (2) subject matter expertise, and (3) stakeholder feedback. FAA officials told us that rule-drafting groups discuss regulatory design options when developing a Rulemaking Action Plan and present these alternatives in briefing documents to the principal agency managers, referred to as “principals briefs.” FDA officials told us that rule-drafting groups generally develop a concept paper or other summary document to determine the optimal means of achieving a regulatory goal, including considerations of multiple design options.

- **Assessing the risk associated with identified regulatory design options:** Three selected subcomponents incorporated assessments of risk into their rule-drafting procedures. DOT’s Rulemaking Requirements direct agency officials to “consider, to the extent reasonable, the degree and nature of the risks posed [by agency action]” and “how the agency action will reduce risks to public health, safety, and the environment” per Executive Order 12866. EPA’s ADP specifies that Analytic Blueprints identify, assess, and discuss the risk management implications of proposed regulatory design options. USDA’s Regulatory Decisionmaking Requirements direct rule drafters to conduct a comparison of risks for regulatory design options and provide a description of the level of uncertainty and unknowns associated with each design.
- **Assessing the enforcement and compliance implications of identified regulatory design options:** An official from FSIS told us that representatives from its Office of Field Operations or Office of Investigation, Enforcement, and Audit often participate in rule-drafting groups to provide an enforcement perspective. A BIS official told us that rule drafters solicit informal feedback from enforcement officials to ensure the practicability of regulatory standards during both the development of prospective regulations and the initial implementation of new regulations.

EPA’s procedures require that enforcement officials participate in EPA’s ADP rule-drafting groups for rules involving “precedent-setting policy implications” and “extensive cross-agency participation,” and EPA officials told us that enforcement officials also are often involved in the drafting of other rules.²¹ Further, EPA Office of Enforcement

²¹EPA classifies these types of regulations as either “Tier 1” or “Tier 2.” These tiers are determined based on multiple considerations, including policy impacts and implications, the need for extensive cross-agency participation, and the use of precedent-setting application of new science or economic considerations.

and Compliance Assistance’s training and guidance materials encourage rule drafters to incorporate compliance principles—such as clarity, consistency, and transparency—into their decision making and consider how regulatory design choices can influence later compliance and need for enforcement.

Considering compliance and enforcement implications while making regulatory design decisions is important because agency officials stated that different design choices have implications for future compliance and enforcement resources. For example, PHMSA officials told us they create an implementation plan for any proposed regulation with an expected impact on enforcement resources. Officials from OSHA and EPA Office of Land and Emergency Management (OLEM) told us that management-based regulations—such as OSHA’s Process Safety Management requirements for oil refineries and chemical facilities and OLEM’s Risk Management Program for facilities that use hazardous chemical substances—can be resource-intensive to enforce because of the greater technical expertise needed to review highly individual and technical plans among heterogeneous regulated entities to ensure compliance. An EPA OAR official told us that the design of its cap-and-trade system—tradeable allowances that require regulated entities to monitor and report their emissions to EPA—limits the need for enforcement resources to only those entities that do not comply with monitoring, reporting, and allowance-holding requirements.

Selected Agencies Reported Using Multiple Tools and Approaches for Allocating Resources to Elicit Compliance

To Elicit Compliance, Agencies Generally Have Flexibility to Use a Mix of Available Tools

When regulations are promulgated, agency officials must determine how they will promote compliance with their regulations and deter noncompliance. Agencies generally have the flexibility to tailor their compliance and enforcement strategies to encourage voluntary compliance and inform regulated entities of regulatory requirements. Agency officials decide on the appropriate mix of compliance assistance

together with monitoring and enforcement efforts to achieve regulatory outcomes.

Based on our review of relevant academic literature, there are multiple tools available to agencies to elicit compliance, although agencies traditionally use two tools to achieve their objectives. The first, compliance assistance, helps regulated entities understand and meet regulatory requirements. For example, an agency may consider providing assistance through educational materials and outreach to promote compliance among regulated entities. The second, the use of monitoring, enforcement, and data reporting, ensures that regulations are followed and deters noncompliance. Agencies may also supplement these traditional approaches with options that provide more accommodating and flexible opportunities to promote compliance among regulated entities, such as developing cooperative programs or providing onsite consultation services. Table 3 identifies some of the options by which agency officials may accomplish their regulatory goals.

Table 3: Examples of Regulatory Compliance Options

Type of option	Regulatory compliance options	Definition
Traditional	Compliance assistance	Ensure regulated entities understand regulatory requirements and how to comply by providing guidance and other assistance to promote compliance
	Monitoring and enforcement	Identify and address noncompliance through inspections and monitoring of relevant data and information and deter future noncompliance through actions such as fines, penalties and targeting enforcement resources
Supplementary	Cooperative programs	Work with entities in the regulated community to address concerns and issues or recognize and reward entities that have gone beyond regulatory requirements
	Onsite consultation services	Promote compliance by providing on-site advice to regulated entities
	Voluntary disclosure	Encourage self-reporting or self-disclosure of data or regulatory violations from regulated entities by reducing penalties to promote compliance and improve agency monitoring and enforcement
	Third-party certification	Rely on independent third-party organizations to determine compliance with specific standards for safety, quality or performance

Source: GAO analysis of relevant academic literature and selected agency case studies. | GAO-18-22

As described in table 3, agencies use compliance assistance tools, such as education and consultation, to ensure that regulated entities understand regulatory requirements and provide examples of how to comply. One way that agencies do this is by providing regulatory guidance to regulated entities in the forms of Frequently Asked Questions, tools, or factsheets. We reported in 2015 that agencies used a

wide variety of guidance to interpret new regulations and clarify policies in response to questions or compliance findings.²² However, we have also recommended that selected agencies could further help regulated entities comply, and agencies have implemented those recommendations by offering further clarifications and guidance.²³ The selected subcomponents that we reviewed employed a variety of compliance assistance activities. For example:

- FSIS provides compliance guidance and makes training materials available to its regulated entities, such as meat, poultry, and egg product plants, and maintains help desks to provide technical assistance to its regulated community.
- BIS holds domestic and international seminars, provides online and in-person trainings, responds to inquiries submitted online, issues industry advisory opinions, and works with other federal agencies to provide immediate error alerts to filers using their Automated Export System.²⁴
- FDA provides web-based, in-person, and telephone education and outreach; hosts webinars, public meetings, and stakeholder meetings; and posts training videos and blogs. For example, the agency established a central source of information for questions related to its

²²GAO-15-368, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices* (Washington, D.C.: Apr. 16, 2015).

²³See for example GAO, *School Lunch: Implementing Nutrition Changes Was Challenging and Clarification of Oversight Requirements Is Needed*, GAO-14-104 (Washington, D.C.: Jan. 28, 2014). We concluded that timely and consistent guidance is vital to ensure successful implementation of program changes and achieve program goals. We recommended that USDA systematically assess all states' needs for information to improve their ability to oversee School Food Authorities' financial management and provide assistance to meet identified needs. USDA generally agreed and implemented the recommendations. *Fair Labor Standards Act: The Department of Labor Should Adopt a More Systematic Approach to Developing Its Guidance*, GAO-14-69, (Washington, D.C.: Dec. 18, 2013). We recommended that Labor's Wage and Hour Division develop a systematic approach for identifying and considering areas of confusion that contribute to possible Fair Labor Standards Act violations to help inform the development and assessment of its guidance. The Wage and Hour Division agreed with and implemented the recommendation.

²⁴The Automated Export System is an electronic export information gathering and processing system developed through cooperative efforts of the U.S. Customs and Border Protection, the U.S. Census Bureau, other federal agencies and the export community. The system collects export information electronically from participants approved to use it.

2011 Food Safety Modernization Act rules, programs, and implementation strategies.²⁵

Regulatory agencies also engage in enforcement activities such as inspections, monitoring reported data, and issuing fines when noncompliance is identified. The selected agencies we reviewed reported using criteria such as data, compliance history, and trends in noncompliance to identify risks and more efficiently target enforcement activities. For example:

- OSHA conducts two types of inspections—“un-programmed” and “programmed”—to target resources for the 8 million workplaces it regulates. Un-programmed inspections respond to specific complaints or injuries, while programmed inspections target resources towards specific high-risk industries and employers.
- FSIS officials analyze noncompliance trends for its food safety process control regulations at meat, poultry, and egg processing facilities and send inspection officials “early warning” alerts when the establishments they inspect reach certain noncompliance rates.
- APHIS’s Animal Care program uses its Risk Based Inspection System to conduct more frequent and in-depth inspections at facilities with a higher risk of animal welfare concerns, and fewer at those that are consistently compliant. The system uses criteria, such as past compliance history and the seriousness of documented noncompliance, to determine minimum inspection frequencies for licensed and registered facilities.

The selected agencies also reported supplementing traditional compliance assistance and enforcement approaches with other tools, including:

- **Cooperative programs:** OSHA uses multiple cooperative programs to recognize employers who have introduced health and safety initiatives at their worksites that exceed requirements. OSHA’s Voluntary Protection Program rewards employers that exceed worker safety requirements through an exemption from routine inspections while they maintain their status in the program. Participating employers are reevaluated every 3 to 5 years. OSHA uses its Challenge Program to partner successful employers as mentors for employers who are attempting to improve their safety and health

²⁵21 U.S.C §§ 2201-2252.

programs. The Centers for Medicare and Medicaid Services' (CMS) Skilled Nursing Home Facilities Value Based Purchasing Program is authorized to use incentive payments to recognize nursing homes that exceed minimum standards of quality.

- **Onsite consultation services:** OSHA works with state governments to provide onsite consultation services to small- and medium-sized businesses. These consultations assist employers to identify potential hazards and improve their injury and illness prevention programs. MSHA offers compliance assistance and outreach through “walk and talks” during which MSHA inspectors and education outreach staff provide mine operators and miners with information on hazardous tasks and conditions, as well as offer best practices to prevent accidents, injuries, and fatalities.
- **Voluntary disclosures:** FAA implements a number of voluntary reporting programs. For example, its Flight Operational Quality Assurance program allows commercial airlines and their employees to anonymously report incident information. The agency then uses this information to monitor trends and target resources. BIS encourages parties who believe they may have violated its export regulation to self-disclose. Officials then review the disclosure to determine if a violation has occurred and to identify the appropriate corrective action. BIS views a self-disclosure as an indicator of a party’s intent to comply with its requirements. EBSA’s Voluntary Fiduciary Correction Program and Delinquent Filer Voluntary Correction Program encourage voluntary compliance by allowing plans and plan fiduciaries to self-correct certain violations and by offering relief from higher civil penalty assessments.
- **Third-party certification:** EPA OCSP’s formaldehyde emissions rules require foreign and domestic wood mills to receive a third party certification that certain wood products meet defined standards. EPA must approve the third parties that certify the products.

Selected Agencies Reported Considering Multiple Factors and Take Different Approaches to Allocating Resources to a Mix of Compliance and Enforcement Tools

Agencies generally have flexibility in making decisions on and allocating resources for a mix of compliance assistance and enforcement strategies. However, some selected agencies reported that statutory requirements, programmatic constraints, and changing priorities affected how they allocated resources for compliance and enforcement activities. For example:

- MSHA must prioritize available resources to fund inspections because they are required by law to inspect every underground mine four times a year and every surface mine twice each year.²⁶ Once those resources have been allocated for inspection, any additional resources may then be used for compliance related activities.
- FSIS' allocation of resources is similarly constrained because it is statutorily required to be present at every meat, poultry, and egg product facility whose product enters into commerce in order for the facility to operate.²⁷
- APHIS is programmatically constrained in allocating resources between enforcement and compliance assistance because another federal department enforces some of their promulgated regulations, and thus determines compliance resources and approaches. The agency's Agricultural Quarantine Inspection program inspection activities are performed by Customs and Border Protection within the Department of Homeland Security.²⁸

The type and behavior of regulated entities also affects selected agency decisions on strategies to achieve compliance. The characteristics of regulated entities—such as the hetero- and homogeneity of the regulated community and frequency of interaction with agency officials—may inform agency compliance assistance and enforcement resource decisions. Some of the selected agencies described frequent interaction with regulated entities that were homogeneous or easily identified. As a result,

²⁶30 U.S.C. § 813(a).

²⁷21 U.S.C. §§ 601-683 and 21 U.S.C. §§ 451-472. The Federal Meat Inspection Act was originally enacted in 1907 as part of the USDA appropriations act, and the Poultry Products Inspection Act was enacted in 1957. Both pieces of legislation have been amended a number of times throughout the years.

²⁸The Homeland Security Act of 2002 transferred certain Agricultural Quarantine Inspection activities from APHIS to the then newly created Customs and Border Protection. Whenever USDA prescribes regulations, policies, or procedures for administering the activities transferred to Customs and Border Protection, USDA is to coordinate with the Department of Homeland Security (6 U.S.C. § 231(d)(2)).

officials said it is easier for their agencies to ensure that regulated entities are aware of applicable requirements, and that there may be less need to invest in compliance assistance. For example, the operators of the pipelines PHMSA regulates are a small and well known community. Similarly, FSIS inspectors must be present at each meat, poultry, or egg products facility, at frequencies determined by the type of operation being conducted, for it to function. MSHA inspects a fixed number of mines, and its inspectors are often onsite; however, MSHA officials stated that some mines are better at complying with health and safety standards than other mines.

In contrast, large and heterogeneous communities present different needs and considerations that may inform agencies' compliance assistance and enforcement resource decisions. When regulated entities are less likely to engage with inspectors or other federal officials, agencies' decisions on allocating resources to ensure all regulated entities understand requirements and to elicit voluntary compliance are important. As previously discussed, OSHA regulates and monitors a large and diverse community of regulated entities. EBSA monitors approximately 685,000 private retirement plans and 2.2 million health plans, and similar numbers of other welfare benefit plans. CMS regulates more than 15,000 large and small nursing home facilities across the country. In contrast to its pipeline-related regulations, PHMSA also regulates a broad spectrum of transportation operators and hazardous materials, requiring a different approach to disseminating information and providing outreach.

At the selected agencies we reviewed, agency officials told us that the main objective of their regulatory enforcement efforts is to achieve compliance with regulatory requirements. The selected agencies we reviewed took different approaches to achieve compliance, and used compliance and enforcement tools to escalate pressure to get regulated entities to comply. For example, FDA officials told us that when the agency identifies noncompliance, it may not immediately sanction a regulated entity. Rather, the agency may begin with a meeting or call with the regulated entity to address the noncompliance, and gradually implement more serious regulatory compliance measures (such as a negative inspection report or warning letter) or even seek an injunction from the relevant court(s) if it cannot resolve the noncompliance.

APHIS also uses a range of compliance assistance activities to promote compliance and reserves its enforcement authority for the most serious situations and noncompliance. For example, APHIS officials told us it

offers facilities struggling to maintain compliance the opportunity to work with trained compliance specialists to develop options and plans to promote future compliance. PHMSA officials told us the agency uses the Systems Integrity Safety Program as a non-adversarial tool that provides compliance assistance to regulated entities not currently in compliance. They said that the agency generally will not initiate enforcement actions against regulated entities enrolled in this program, but will pursue them if there are violations that PHMSA believes to be willful, and where a safety violation presents an imminent hazard.

Despite a common objective to elicit compliance, selected agency approaches to resource allocations for compliance and enforcement differ. While some agencies consider allocations for compliance and enforcement to implement each individual regulation, others allocate resources across regulations and regulatory programs. For example, Labor allocates compliance assistance and enforcement resources for individual regulations depending on multiple factors, such as the nature of the regulation and underlying subject matter. In contrast, EPA allocates resources across regulations, programs, and regions. Its Office of Enforcement and Compliance Assurance works with each regional office to allocate enforcement and compliance assistance resources for the various programs across EPA.

In addition, certain agencies we reviewed distinguish between compliance assistance and enforcement activities, while others view these activities as a joint effort. For example, EBSA allocates its resources between benefits advisors, who provide compliance assistance, and their enforcement staff. Conversely, OSHA inspectors provide compliance assistance to regulated entities in addition to their enforcement roles, supplementing onsite outreach and education provided by compliance assistance specialists located in regional offices.

To appropriately allocate their enforcement and compliance resources, selected agencies we reviewed also collect and review data to identify noncompliance trends. For example:

- OSHA uses collected data to identify national and local special emphasis programs to highlight specific workplace health and safety issues as the focus of targeted outreach and enforcement efforts.
- EBSA's national office annually establishes enforcement priorities—and shifts resources to respond with new emphases—through its guidance outlined in its Enforcement Program Operating Plan. In

preparing this guidance, EBSA assesses current enforcement activities, identifies recent enforcement trends, analyzes available information regarding industry activities and areas of noncompliance, and reviews current policy considerations to identify possible areas of potential risk within the employee benefit plan industry.

- EPA officials told us they use their National Enforcement Initiatives to prioritize resources to compliance concerns that are particularly entrenched or problematic. Further, EPA initiated its Next Generation Compliance (NextGen) strategy to structure regulations and permits with new monitoring and information technology, expanded transparency, and innovative enforcement activities. NextGen was designed to increase transparency and real time information made possible by electronic reporting and advanced monitoring, and allows the agency and its stakeholders the opportunity to experiment with innovative approaches. Furthermore, EPA stated that it and its stakeholders are better able to identify and solve environmental issues, and address large regulated communities with approaches that go beyond traditional single facility inspections and enforcement.

Selected Agencies Have Made Efforts to Make Compliance Data Transparent and Accessible

Transparency and availability of data are important to promoting compliance and achieving regulatory objectives. The selected agencies that we reviewed have made efforts to make compliance and enforcement information more transparent and accessible to the public, including:

- All the Labor subcomponents we reviewed made efforts to make data and information more publically accessible. MSHA developed online compliance tools that allow the public to monitor a mine’s compliance with key safety and health standards by providing a broad range of mine safety and health data, including information about mine inspections, accidents, injuries, illnesses, violations, employment, production totals, and air sampling. One of these tools is the “Rules to Live By Calculator,” which focuses on the 49 safety standards most often associated with fatal mining accidents and serious injuries.²⁹
- EPA’s Enforcement and Compliance History Online (ECHO) database provides integrated compliance and enforcement data for over 800,000 regulated facilities on air emissions, surface water discharges, hazardous waste, and drinking water systems.³⁰ The

²⁹<https://arlweb.msha.gov/drs/rlb-violations-calculator.asp> (accessed Aug. 2, 2017).

³⁰<https://echo.epa.gov/> (accessed Aug. 2, 2017).

database includes EPA, state, local, and tribal environmental agency compliance and enforcement records that are reported into national databases. ECHO also incorporates EPA environmental data sets to provide additional context for analyses.

- CMS created a “Nursing Home Compare” website to assist consumers in comparing information about nursing homes.³¹ The website contains detailed information on the quality of care and staffing information for more than 15,000 Medicare- and Medicaid-participating nursing homes including a five-star scale of quality ratings of overall and individual performance on health inspections, quality measures, and hours of care provided per resident by staff performing nursing care tasks.

³¹<https://www.medicare.gov/nursinghomecompare/search.html?> (accessed Aug. 2, 2017).

Selected Agencies Reported They Evaluated Regulatory Decisions by Collecting Feedback, and Responses to Identified Noncompliance Varied

Selected Agencies Supplement Feedback on Effectiveness of Regulatory Design and Enforcement Approaches with Evaluations

While agency officials receive feedback on their regulations during rulemaking, they also have opportunities to receive feedback during implementation of the regulation and as part of later retrospective review efforts.³² In 2007 and 2014, we reported on retrospective reviews of individual regulations, which agencies use to evaluate how existing regulations work in practice.³³ As mentioned previously, two executive orders issued in 2017 also emphasize the importance of retrospective review, and officials from two agencies told us that they are currently examining their regulatory evaluation processes in response to these directives. To supplement retrospective review efforts, officials told us that they collect feedback from both internal and external stakeholders on the effectiveness of their regulatory design and enforcement decisions. This feedback may occur during rulemaking or during implementation, and might prompt changes. For example:

³²The rulemaking process generally includes notice-and-comment rulemaking, which gives the public an opportunity to provide information to agencies on the potential effects of a rule or to suggest alternatives for agencies to consider.

³³GAO, *Reexamining Regulations: Agencies Often Made Regulatory Changes, but Could Strengthen Linkages to Performance Goals*, [GAO-14-268](#) (Washington, D.C.: Apr. 11, 2014), *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews*, [GAO-07-791](#) (Washington, D.C.: July 16, 2007). Retrospective reviews can be in response to, among other things, executive branch regulatory lookback initiatives or statutorily required either by an agency's authorizing statute or by Section 610 of the Regulatory Flexibility Act.

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- EPA officials told us they provide opportunities for regulated entities to give feedback, and that they may reconvene the initial Regulatory Working Group for a rule if they heard complaints or concerns.
 - At DOT, FAA officials told us they collect feedback about potential needs to update or change rules through requests for exemptions and through their various advisory committees. According to PHMSA officials, advisory committee inputs or petitions are two ways they evaluate the success of their regulations.
 - MSHA officials told us that in response to comments received during rulemaking, they changed their rule on proximity detection systems for continuous mining machines, which protects miners from being struck by such machines. MSHA initially proposed specifying certain requirements for a technology but used a performance-based approach in its final rule. This experience subsequently informed MSHA's proposed design for its new rule for proximity detection systems for mobile machines, in which the agency proposed a performance standard from the outset of the rulemaking.³⁴
 - A BIS enforcement official told us that his office requested a revision to an existing regulation that was difficult to enforce because it did not provide clear requirements for how companies could determine when a government-identified "red flag"—a party on BIS' Unverified List—could be resolved. BIS received similar feedback from advisory committees and revised the regulation for clarity.³⁵
 - According to APHIS officials, they evaluate the effectiveness of their compliance and enforcement activities by tracking compliance rates under the Animal Welfare Act and through feedback from their regulated entities. USDA officials also stated that interactions with inspectors and listening sessions provide the department's agencies with feedback.

Selected agency officials cited concerns about changing the design of established regulatory programs and the resources required for the

³⁴See 80 Fed. Reg. 2187 (Jan. 15, 2015), 80 Fed. Reg. 53,070 (Sept. 2, 2015). MSHA initially proposed that a proximity detection system must cause a machine to stop no closer than three feet from a miner. However, MSHA incorporated a recommendation from the National Institute for Occupational Safety and Health (NIOSH) in its final rule to use a performance-based approach, because the requirement to stop the machine no closer than three feet from a miner would have limited future technological innovations that could improve miner safety. This experience informed MSHA's proposed design for its new rule for proximity detection systems for mobile machines.

³⁵See 78 Fed. Reg. 76,741 (Dec. 19, 2013).

rulemaking process. Two of our selected agencies mitigated these concerns by piloting new regulatory designs. USDA implemented an ongoing project—the HACCP Inspection Models Project—to assess the viability of applying potential performance-based regulations to ensure food safety at hog and poultry processing facilities. After assessing inspection findings for the poultry pilot project and in response to public comments on the program, they ultimately determined that the regulation should be broadened to additional facilities.³⁶ FAA used feedback from pilot studies, in which more than 30 public-use airports participated, to inform a proposed rule for Airport Safety Management Systems.³⁷

Agencies also typically have flexibility to continue to change and adjust their compliance and enforcement strategies in response to feedback and evaluation without going through the rulemaking process to amend a final regulation. As previously mentioned, agencies assess the effectiveness of their enforcement and compliance efforts by collecting data to target their enforcement efforts. In addition, selected agencies identified evaluations of their enforcement and compliance efforts, including:³⁸

- DOL’s Chief Evaluation Office officials told us they work with Labor components to (1) develop and implement research studies, (2) address how collected information is used to assess effectiveness, and (3) support data analysis to inform management decision making. For example, the office worked with OSHA to pilot changes to issuing and following up citations to increase employer responsiveness. The study, which began in 2015, found that employers who were part of the new citation process, which included elements such as a handout

³⁶GAO, *Food Safety: More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, [GAO-13-775](#) (Washington, D.C.: Aug. 22, 2013). We noted concerns about the evaluations used to assess HACCP pilot programs. We recommended that FSIS clearly disclose the public limitations in the information used on the rulemaking for modernizing poultry slaughter inspections and, for its continuing evaluations for young hogs, collect and analyze the information necessary to determine whether the pilot project was meeting its purpose. USDA concurred with and implemented these recommendations.

³⁷75 Fed. Reg. 62,008 (Oct. 7, 2010), supplemented by 81 Fed. Reg. 45,872 (July 14, 2016).

³⁸In past work we have reported on opportunities for agencies to improve their evaluation of enforcement and compliance activities. See, for example, GAO, *Aviation Safety: FAA’s Risk-Based Oversight for Repair Stations Could Benefit from Additional Airline Data and Performance Metrics*, [GAO-16-679](#) (Washington, D.C.: July 28, 2016), and *Nursing Home Quality: CMS Should Continue to Improve Data and Oversight*, [GAO-16-33](#) (Washington, D.C.: Oct. 30, 2015).

during inspections, postcard reminders, and a follow-up call, were 3.9 percentage points more likely to engage with OSHA.³⁹

- EPA's Office of Enforcement and Compliance Assistance wrote a guide for EPA managers and staff on their integrated strategic approach to effectively eliciting compliance, focusing on compliance assistance, incentives, monitoring, enforcement, and other tools.⁴⁰ EPA has also conducted research on what makes a regulation more likely to be complied with and identified principles and tools to aid in writing more effective regulations. For example, EPA directs rule drafters to use clear and objective regulatory requirements and applicability criteria, to structure regulations to make compliance easier than noncompliance, and to leverage regulated entities and/or third parties to assess compliance and prevent noncompliance. It also encourages agency officials to leverage accountability and transparency through e-reporting to government and public access to data on websites.
- According to PHMSA officials, they developed formal enforcement goals, strategies, and metrics after reviewing leading practices for enforcement, including reviewing the compliance strategies at other DOT subcomponents. They analyzed data to identify commonalities between violations that are causal to incidents, as well as those that increased the severity of incidents. They also reviewed enforcement data to identify guidance that needs to be improved, provide feedback to inspectors, and ultimately provide ideas for improved rulemaking and regulatory design.

Selected Agency Responses to Continued Widespread Noncompliance Varied

Selected agencies responded differently when they identified continued widespread noncompliance through their evaluations or monitoring of compliance data. Some agencies told us they view a record of noncompliance as a fault in the regulation and may update their regulatory design, while others may change compliance strategies. FSIS officials told us they use enforcement data to analyze the effectiveness of

³⁹Mathematica and Ideas42, *Pilot OSHA Citation Process Increases Employer Responsiveness*, DOL Behavioral Interventions Project Brief. April 2016. The report found the difference to be statistically significant at the 0.01 level.

⁴⁰EPA, *Guide for Addressing Environmental Problems: Using an Integrated Strategic Approach*, EPA 305-R-07-001, March 2007. The 2007 guide reflected lessons learned from 10 pilot project case studies in eight EPA regions that tested past EPA research on integrated enforcement approaches. EPA, *A Workbook for Designing Effective Rules: Principles and Tools for Delivering Regulatory Benefits Through Built-in High Compliance*, June 2014.

their regulations, and may make changes to their regulations based on trends in noncompliance. According to PHMSA officials, they analyze enforcement data in several ways, including identifying regulations with the highest rates of noncompliance to understand weaknesses in individual regulations.

MSHA officials told us that when an Inspector General audit found that its enforcement actions were not strong enough for repeat violators, the agency updated its Pattern of Violations regulation to better attain compliance.⁴¹ Conversely, OSHA officials told us that they view persistent noncompliance or workplace injuries and illness as indicating a need to revisit and readdress how compliance assistance is being provided and enforcement applied, rather than as a reason to adjust the regulation. EPA officials told us that they will update an existing regulation to solve an ongoing compliance problem only as a last resort due to the large resource investment required and disruption to regulated entities to adapt to changes in regulatory design.












Key Considerations Could Strengthen Agency Regulatory Design and Enforcement Decisions

We built upon current statutory and executive requirements and selected agencies' current practices to identify key considerations to strengthen agency processes for regulatory design and enforcement decisions. As agency officials craft regulations, they are guided by high-level statutory requirements, economic principles in executive orders, and OMB directives and resources. In accordance with those directives, our selected agencies have implemented varied practices to facilitate their regulatory design and enforcement decisions. Based on our review of those directives and the selected agencies' processes, as well as academic and practitioner research, past IG work and our own past work, and existing criteria and resources for federal managers, we identified key considerations for regulatory design and compliance to aid decision makers in designing—or redesigning—their regulations and determining how best to elicit compliance.

⁴¹U.S. Department of Labor Office of Inspector General—Office of Audit, *In 32 Years MSHA Has Never Successfully Exercised its Pattern of Violations Authority*, 05-10-005-06-001, September 29, 2010. In response to this report, on January 23, 2013, MSHA revised its pattern of violations regulation in 30 CFR Part 104 to improve the agency's effectiveness in implementing its pattern of violations authority and to allow MSHA to timely focus on mine operators with a recurring pattern of significant and substantial violations at their mines.

The following key considerations for regulatory design and compliance in figure 1 are intended to serve as a resource to supplement existing directives and guidance. We identified these considerations to bridge the gap between high-level directives and current agency practices. These considerations can provide criteria for decision makers to identify, assess, and evaluate options for achieving their regulatory objectives. Further, we have offered elements for each consideration as concrete questions that agencies can ask themselves as they design their regulatory approaches to elicit compliance within statutory authority and available resources. Not all considerations are applicable in every instance. We recognize there are tradeoffs inherent in any choice, but we believe that these key considerations can strengthen agency decision making, resulting in more informed designs, plans for evaluations, and ongoing changes to compliance and enforcement approaches.

Figure 1: Key Considerations for Regulatory Design and Enforcement

Key Considerations for Regulatory Design					
					
<p>1. Identify regulatory objective(s) Establish clear outcome(s) intended from regulatory action based on:</p> <ul style="list-style-type: none"> • The nature of the problem to be addressed • Statutory authority or mandates • Executive directives and guidance • Agency priorities • Judicial mandates • External evaluations, including GAO/IG recommendations 	<p>2. Identify and document options for achieving regulatory objective(s) To the extent allowed by statute consider and document multiple approaches including:</p> <ul style="list-style-type: none"> • Not regulating at all • Deferring to state/local/private-sector authorities • Various regulatory design options 	<p>3. Assess the potential effectiveness of each option Examine the extent to which each option achieves:</p> <ul style="list-style-type: none"> • Economic efficiency – Maximizes net benefits • Equity – Assesses the distribution of benefits and costs across different groups in society • Adaptability – Accommodates future changes • Flexibility – Minimizes administrative burden • Clarity – Reduces uncertainty and ambiguity • Legitimacy – Promotes public engagement and procedural transparency • Certainty – Provides information to track compliance 	<p>4. Assess the risks associated with each option Consider and document each option within an enterprise risk management framework:</p> <ul style="list-style-type: none"> • Identify the opportunities and threats inherent in the risks associated with each option • Assess the likelihood and impact of the risks associated with each option • Develop potential actions to address identified risks 	<p>5. Assess the enforcement implications of each option Solicit the input of enforcement stakeholders and incorporate their considerations into the assessment of each option including:</p> <ul style="list-style-type: none"> • Establish metrics to assess compliance • Establish a monitoring approach • Identify and assess alternative means of compliance • Consider the compliance implications for regulated entities • Consider ways to maximize the efficiency/ease of compliance 	<p>6. Establish a performance evaluation plan for the chosen option Assess the operationalization of the chosen option including:</p> <ul style="list-style-type: none"> • Identify appropriate metrics to evaluate regulatory performance • Develop a regulatory performance evaluation plan • Determine a means of monitoring performance based on established metrics
Key Considerations for Compliance					
					
<p>1. Identify compliance and enforcement objective(s) Establish objective(s) for regulatory compliance and enforcement that:</p> <ul style="list-style-type: none"> • Clearly state the desired outcome • Link action to regulatory goal(s) 	<p>2. Identify optimal mix of compliance and enforcement tools To the extent allowed by statute consider and document the appropriate mix of tools that:</p> <ul style="list-style-type: none"> • Achieve objectives and respond to risks • Minimize burden on regulated entities to the extent practicable and appropriate • Maximize efficiency and effectiveness of compliance and enforcement 	<p>3. Assess optimal mix of compliance and enforcement tools Assess the mix of options for its potential to promote:</p> <ul style="list-style-type: none"> • Transparency and legitimacy of compliance and enforcement process • Independence from political influence • Clarity and predictability in the rules and processes for compliance and enforcement • Customer service to ensure that regulated entities and stakeholders understand their rights and obligations • Responsiveness to the actions of the regulated entities • Adaptability and flexibility to modulate depending on the profile and behavior of specific entities 	<p>4. Assess the risks associated with each option Consider and document the ways in which potential compliance and enforcement options are:</p> <ul style="list-style-type: none"> • Risk based and grounded in data and evidence. • Proportional to the level of risk aimed at reducing the actual risk posed by noncompliance • Use information and communication technologies to maximize risk-focus, coordination and information-sharing 	<p>5. Establish a performance evaluation plan for chosen compliance and enforcement option(s) Plan to evaluate the chosen option(s) including:</p> <ul style="list-style-type: none"> • Identify appropriate metrics to evaluate performance • Develop a performance evaluation plan to achieve outcomes based on established metrics • Coordinate and, where needed, consolidate activities to prevent duplication and overlap 	

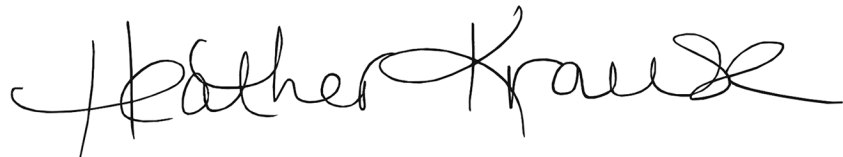
Sources: GAO analysis of academic literature and applicable internal controls, risk principles, and executive orders. | GAO-18-22

We provided a draft of this report to the Secretaries of Agriculture, Commerce, Health and Human Services, Labor, and Transportation, the Administrator of the Environmental Protection Agency and the Director of the Office of Management and Budget for comment. The Departments of Agriculture, Health and Human Services, and Labor and the Environmental Protection Agency provided technical comments that were incorporated as appropriate. The Departments of Commerce and Transportation and the Office of Management and Budget did not provide comments.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretaries of Agriculture, Commerce, Health and Human Services, Labor, and Transportation; the Administrator of the Environmental Protection Agency; the Director of the Office of Management and Budget; and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6806 or krauseh@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Sincerely yours,

A handwritten signature in black ink that reads "Heather Krause". The signature is written in a cursive, flowing style.

Heather Krause
Director
Strategic Issues

Appendix I: Objectives, Scope, and Methodology

You asked us to review how agencies make key decisions related to regulatory design, compliance and enforcement, and updating of regulations. This report describes how selected agencies report (1) making decisions on regulatory designs among available options, (2) making decisions to designate resources among available compliance and enforcement activities, and (3) evaluating those decisions, and also identifies (4) key considerations for decision makers related to regulatory design and enforcement.

To describe agency experiences and decisions regarding regulatory design and compliance and how they evaluate those decisions, we reviewed regulatory processes at 6 departments and 13 subcomponents within those departments. To illustrate a wide range of regulatory designs and resulting compliance activities, we selected the six executive branch departments—excluding the Department of Defense—that promulgated the most significant regulations¹ between September 1, 2011 and August 31, 2016.² These departments were the United States Departments of Agriculture (USDA), Commerce (Commerce), Health and Human Services (HHS), Labor (Labor), and Transportation (DOT), and the Environmental Protection Agency (EPA). Among other inputs, the selected departments were also among those that most often promulgated regulations that were anticipated to affect small entities

¹This included both “significant” and “economically significant” regulations. Under Executive Order 12866, OMB reviews significant proposed and final rules from agencies, other than independent regulatory agencies, before they are published in the Federal Register. The order defines significant regulatory actions as those that: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (these actions are commonly referred to as “economically significant” regulations); (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the executive order. Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

²This 5-year time period was chosen to ensure that the number of regulations over time was consistently reflected, as well as to ensure that our source, www.reginfo.gov, had been updated to reflect all regulations for our chosen time period when we conducted this analysis in late September 2016. We did not include Department of Defense regulations because those regulations often have unique characteristics—typically related to Department administration or contracts—that are different from regulations addressed at outside entities and thus could make it difficult to identify broad regulatory design and enforcement principles.

(such as small businesses, nonprofits, and governments) during the same time period.³ We used reginfo.gov to identify the number of significant regulations. We assessed the reliability of those data by reviewing relevant documentation, interviewing knowledgeable agency officials, and electronically and manually testing the data for missing values, outliers, and invalid values, and we found the data to be sufficiently reliable for the purpose of identifying selected departments. The experiences of these selected executive branch departments are illustrative and nongeneralizable.

From these departments, we selected subcomponents for nongeneralizable case studies. These subcomponents were selected based on information provided by department officials engaged in regulatory activities on their departmental subcomponents' use of a variety of regulatory designs and any experience making changes to their regulatory design or compliance strategies based on new information (such as evaluations) or new circumstances (such as evolving technologies or changes in agency resources for compliance). We also asked department officials about subcomponents' use of compliance activities other than traditional compliance assistance and enforcement. To further inform our selection of subcomponents, we reviewed past Inspector General and our own work on types of regulatory designs and compliance strategies. We did not include independent regulatory agencies in our scope as they are not subject to directives from the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs. Furthermore, many independent agencies promulgate and administrate financial regulations, which present different considerations and have been the focus of other work we performed.⁴ In reviewing enforcement strategies used by agencies, we did not review federal regulatory programs for which enforcement has been delegated to states or localities.

To illustrate how our selected agencies make decisions regarding regulatory design and compliance and how they evaluate those decisions, we reviewed agency written procedures and interviewed department and subcomponent officials on their practices for making these decisions. To

³Our six selected departments are all within the top 10 departments in frequency of promulgation of regulations during the same five year time period that are certified to affect small entities under the Regulatory Flexibility Act, which requires agencies to examine the impact of their rules on those small entities.

⁴http://www.gao.gov/key_issues/financial_system_stability_reform/issue_summary.

develop themes and examples from our documentary and testimonial evidence, we analyzed information from relevant documents and interviews to identify and confirm common patterns as well as differences across selected agencies. These experiences illustrate how the selected agencies currently make these decisions, the outcomes of those decision-making processes, and their evaluation practices.

To identify key considerations for decision makers related to regulatory design and enforcement, we reviewed existing criteria documents, including (1) elements of the Regulatory Flexibility Act; (2) applicable executive orders and guidance such as Executive Order 12866 and OMB Circulars A-4, A-11, and A-123; and (3) resources for federal managers, and leading practices we had previously reported on for enterprise risk management.⁵

To ensure that our considerations incorporated applicable academic and government research and findings we conducted a literature review. Our literature review incorporated searches of several academic, literature, and government sources—including bibliographic databases such as ProQuest, Scopus, Academic OneFile, Public Affairs Information Service, and LexisNexis—for articles or studies published from January 2011 through August 2016. The team searched for articles using several combinations of relevant key words such as: “regulatory design,” “regulatory structure,” “regulatory compliance,” and “regulatory enforcement.” We then identified the articles that were relevant to our objectives based on the independent review of two team analysts. In addition, we searched our own and selected federal Inspector General websites for any reports relevant to our objectives. These searches were not meant to be a comprehensive search of all available literature on the topic, but rather conducted to identify relevant work to inform our identification of key regulatory design and enforcement considerations for decision makers.

⁵Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993); OMB, *Circular A-4:Regulatory Analysis*, (Washington D.C., 2003); *Circular A-11:Preparation, Submission, and Execution of the Budget*, (Washington D.C., 2016); and *Circular A-123:Management’s Responsibility for Internal Control*, (Washington D.C., 2004). GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#), (Washington, D.C.: Sept. 10, 2014), *Enterprise Risk Management: Selected Agencies’ Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec. 1, 2017).

We developed a data collection instrument for each of the academic and government literature search sources and our own reports. To analyze and summarize the results of the academic literature search, two analysts independently reviewed each relevant record in the search results to document information that was relevant to our objectives and to identify key themes to inform our key considerations. We reviewed all relevant articles and reports and summarized information in the data collection instrument that related to the following topics: regulatory design; regulatory design principles; enforcement and compliance; enforcement and compliance principles; regulatory or subject matter area; and general observations that were relevant to the engagement's objectives. In addition, we reviewed the annotated citations and references in selected articles to identify additional articles to include in the literature review and ensure that we were not omitting key literature related to regulatory design and enforcement.

After applying identified criteria—including key practices and elements of those practices—to decision making about regulatory design and compliance, we obtained input on those considerations with officials from our selected agencies and with subject matter specialists. We initially selected and interviewed relevant specialists based on the results of our literature review (i.e., the authors of relevant articles or books included in our review). Based on suggestions from those individuals, we expanded our list of specialists and conducted a second round of interviews, ultimately speaking with 14 specialists. These considerations were also refined by the current practices and approaches of the selected agencies we reviewed.

We conducted this performance audit from August 2016 to October 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Heather Krause at (202) 512-6806 or krauseh@gao.gov.

Acknowledgments

In addition to the contact named above, key contributors to this report were Tim Bober, Assistant Director, Alexandra Edwards, Danny Berg, and Travis Hill. In addition, John Hussey, Timothy Guinane, Andrea Levine, Kayla Robinson, Robert Robinson, and Cynthia Saunders provided key assistance.

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