



November 2, 2020

The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Re: Examination of Recent Trends in Regulation and Regulatory Reform

Dear Ranking Member Comer:

On behalf of the National Association of Manufacturers and the millions of men and women who make things in America, thank you for your interest in ensuring that the United States has a competitive regulatory system. This letter details commonsense regulatory compliance and enforcement relief that will support manufacturers as they respond to the COVID-19 pandemic and lead our economic recovery.

Manufacturers are making the products essential to supporting America during the crisis, and a strong economic recovery will simply not be possible without a robust manufacturing industry. Manufacturing has the highest multiplier effect of any economic sector, with every \$1.00 spent in manufacturing adding another \$2.74 to the economy.¹ In addition, for every one worker in manufacturing, there are another five employees hired elsewhere.² Taken alone, manufacturing's \$2 trillion value in the United States would constitute the eighth-largest economy in the world, built almost entirely on the backs of small businesses.³

The importance of a stable and tailored regulatory environment has become particularly clear during the COVID-19 crisis, as manufacturers across the country work around the clock (in some instances completely redesigning their shop floors) to produce critical materials like respirators and personal protective equipment. Yet, despite the immense value of the manufacturing sector, the cost of federal regulations falls disproportionately on manufacturers. On average, manufacturers pay \$19,564 per employee to comply with federal regulations, or nearly double the \$9,991 per employee costs borne by all firms as a whole.⁴ This burden falls heavily on small businesses; of the 248,039 firms in the manufacturing sector in 2017, all but 3,914 had fewer than 500 employees, with three-quarters of these firms having fewer than 20 employees.⁵ For the smallest firms (i.e., those with fewer than 50 employees), regulatory costs

¹ NAT'L ASS'N OF MFRS., FACTS ABOUT MANUFACTURING: TOP 18 FACTS YOU NEED TO KNOW, <https://www.nam.org/facts-about-manufacturing/> (last visited Oct. 30, 2020).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

equal \$34,671 per employee. This burden was last calculated in 2014.⁶ It is highly likely that tax and regulatory relief enacted in the intervening years has reduced the impact on manufacturers. Notwithstanding, it is clear that reforms to provide a stable, predictable regulatory regime would allow businesses small and large to thrive.

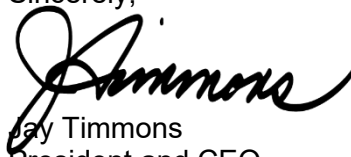
Our unique perspective informs the NAM's American Renewal Action Plan, which helps policymakers chart a path forward through the response, recovery and renewal phases of this crisis.⁷ One critical piece of that action plan is the need for Congress to produce an annual, comprehensive report on the relative competitiveness of the U.S. tax and regulatory regime with expedited congressional consideration of recommended actions to ensure that America is the most attractive place in the world to start and grow a business.

To this end, we are grateful for your leadership to develop such a report. Manufacturers also appreciate your leadership in introducing key legislation—such as H.R. 7922, the Pandemic Regulatory Cost Relief Act of 2020, and H.R. 8038, the Pandemic Preparedness, Response, and Recovery Act of 2020—that would provide manufacturers needed regulatory certainty and ensure Congress takes swift action to identify and address critical shortcomings in our regulatory system.

The NAM has long been a leader in the fight to improve our regulatory system and ensure the system works for consumers, manufacturers and importers alike. As part of the NAM's advocacy, we submitted suggested improvements to the White House in 2017.⁸ Since then 93% (66 of 71) of the NAM's suggestions involving rulemaking have been implemented, and 89% (118 of 132) items overall have been addressed. And as those regulations have been improved, manufacturers across the country have also kept our promises to protect our environment and keep our workplaces safe.

We hope that this submission can help inform Congress as you work to ensure that the U.S. regulatory system is credible, accountable and effective—and supports employee and consumer safety and economic growth

Sincerely,



Jay Timmons
President and CEO
National Association of Manufacturers

⁶ Crain and Crain, *The Cost of Federal Regulation to the U.S. Economy, Manufacturing and Small Business* (Sept. 10, 2014), available at <https://www.nam.org/wp-content/uploads/2019/05/Federal-Regulation-Full-Study.pdf>.

⁷ See NAT'L ASS'N OF MFRS., AMERICAN RENEWAL ACTION PLAN (April 22, 2020), <https://www.nam.org/wp-content/uploads/2020/04/v9-NAM-American-Renewal-Action-Plan.pdf>.

⁸ Comments of the Nat'l Ass'n of Manufacturers to the U.S. Dep't of Commerce re: Notice, Request for Information: Impact of Federal Regulations on Domestic Manufacturing (Docket No. 170302221-7221-01) (March 31, 2017), <https://documents.nam.org/tax/NAMRegulatoryDOCSubmissions03312017.pdf>.

1. Need to Modernize the Administrative Procedure Act

a. The Issue

In 1933, the federal government began the process of building the administrative state, enacting several statutes that created new federal agencies as part of the New Deal. Congress initially, and rightfully, recognized that a strong base was required to build this administrative state without it growing out of control and toppling over. Thus, in 1946 Congress passed the Administrative Procedure Act (APA), which established the basic procedural and definitional framework governing federal agencies' that remains the basis of the administrative law today.⁹

Unanimously passed by Congress in 1946, the APA first statutorily defined a "rule" and set forth mandatory procedures that *all* agencies must follow when promulgating substantive rules and issuing adjudicatory orders."¹⁰ The APA, however, never defines "general statements of policy" or even mentions the term "guidance," and defined "rule" so broadly that courts have said it "obviously could be read literally to encompass virtually any utterance by an agency."¹¹ Indeed, the APA does not even distinguish between rules and non-rules, but rather sets forth "the fundamental distinction in administrative law" between legislative rules, which must go through "notice and comment" rulemaking procedures and carry the force of law, and nonlegislative rules, which are exempt from rulemaking procedures but don't carry the force of law. The statute also provided an exemption from such procedures for "general statements of policy."

In the decades that followed, the federal government rapidly grew the administrative state built upon the APA framework, expanding both the number and power of federal agencies throughout the 1960s. In 1790, the federal government had just 1,000 nonmilitary workers. In 1962, there were 2,515,000 federal employees. As the administrative state grew, Congress neglected to periodically expand, modernize and fortify the structural framework upon which it was built. Instead, Congress addressed the procedural and jurisdictional cracks that appeared by simply piling procedural statutes on top of the APA's framework.

This failure to periodically reinforce and expand the administrative state's procedural base has resulted in a dizzying administrative law labyrinth of divergent, and often conflicting, procedural requirements and terminologies described by various courts as "fuzzy," "tenuous," "blurred," and "enshrouded in considerable smog."¹² So confounding is the modern procedural framework governing federal agencies that the seemingly simple question of whether an agency action is a rule or not has been described as possibly "the single most frequently litigated and important issue of rulemaking procedure before the federal courts today."¹³ Indeed, then-Circuit Court judge Brett Kavanaugh lamented in 2014 that "all relevant parties should instantly be able to tell whether an agency action is a legislative rule, an interpretive rule, or a general statement of

⁹ 5 U.S.C. §551 et seq.

¹⁰ *Id.*

¹¹ *Pacific Gas*, 506 F.2d 33, 37 (D.C. Cir. 1974). The APA defines a rule to mean "the whole or part of an agency statement of *general or particular applicability* and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency...." 5 U.S.C. § 551(4).

¹² *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (internal citations omitted); see also Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 266 (2018) [hereinafter Levin, *Guidance Exemption*].

¹³ Levin, *Guidance Exemption* at 265.

policy,” yet in practice “[t]hat inquiry turns out to be quite difficult and confused.”¹⁴ If the current framework perplexes a Supreme Court Justice, what hope is there for your average American business?

To this end, Congress should heed the American Bar Association’s (ABA)¹⁵ and the Department of Justice’s (DOJ) recent calls to amend and modernize the APA.¹⁶ Specifically, on December 6, 2019, the Department of Justice hosted a summit entitled *Modernizing the Administrative Procedure Act*. The summit brought together leading practitioners, scholars, and policymakers to discuss how the APA—largely unchanged since 1946—should be reformed to better serve the modern regulatory state.

As DOJ’s report states: “Put simply, the time has come to modernize the APA. Legislative reform of the APA is needed to meet the realities of today’s economy and regulatory state. And, perhaps as importantly, it is needed to restore constitutional norms.”¹⁷

b. The Solution

Amending the APA—and doing so with input from the regulated community, as well as other stakeholders—is the single most important step Congress can take to improve the regulatory process government-wide. Indeed, adopting the following proposals, which largely draw from DOJ and the ABA’s recommendations, would address many of the regulatory concerns identified by NAM members. These include ending regulatory ping pong, providing more clarity between rules and guidance and concerns with a lack of due process in regulatory enforcement and adjudication. It is important to note that manufacturers do not want *no* regulation, they simply want *good* regulation that follows a process that incorporates public input, provides strong controls, and ultimately promotes efficiency, growth, and safety.

As the DOJ report notes, there are numerous proposals already in existence that would go a long way towards ensuring the APA—the regulatory constitution—properly reflects the current size and power of the administrative state.

i. Pass the Bipartisan Regulatory Accountability Act

Congress should prioritize passing the Regulatory Accountability Act introduced in 2017 by Senators Rob Portman (R-OH) and Joe Manchin (D-WV), as well as then-Senators Orrin Hatch (R-UT) and Heidi Heitkamp (D-ND).¹⁸ This bipartisan proposal has been embraced by President Trump’s Deputy Attorney General and President Obama’s first “Regulatory Czar” Cass Sunstein.¹⁹ As DOJ noted in their report, the bill would institute a range of needed reforms and, of particular note, it incorporates at least parts of seven of the nine recommendations contained in the ABA’s 2016 resolution. Specifically, the bill would:

¹⁴ *Nat’l Minng Ass’n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014).

¹⁵ See Am. Bar Ass’n, House of Delegates Resolution 106B (adopted Feb. 8, 2016) [hereinafter ABA Resolution 106B] (urging “Congress to amend the rulemaking provisions of the APA,” and identifying nine ways the APA could be modernized).

¹⁶ See U.S. DEP’T OF JUSTICE, MODERNIZING THE ADMINISTRATIVE PROCEDURE ACT (2020), <https://www.justice.gov/file/1302321/download>.

¹⁷ DOJ Amending APA Report at 12 <https://www.justice.gov/file/1302321/download>.

¹⁸ Regulatory Accountability Act of 2017, S. 951, 115th Cong. (2017).

¹⁹ See, e.g., Cass R. Sunstein, *A Regulatory Reform Bill That Everyone Should Like*, BLOOMBERG (June 22, 2017), <https://www.bloomberg.com/opinion/articles/2017-06-22/a-regulatory-reform-bill-thateveryone-should-like>.

- Codify the *Portland Cement* doctrine that agencies must fully disclose data and other information used in rulemakings, establishing a minimum comment period for major rules and requiring agencies to adopt procedures to review rules retrospectively.
- Codify several procedures established in recent decades by executive orders, including cost-benefit analysis, consideration of a reasonable number of alternatives to an agency’s preferred course of action, and centralized review of *all* proposed rules by OIRA.
- Extend these best practices to independent agencies, which are currently not covered by the relevant executive orders—a measure multiple panelists recommended.
- Create a distinct set of more rigorous procedures for “high impact” and “major” rules. “High impact” rules are defined in the bill as rules likely to have an economic impact of \$1 billion or more, and “major” rules as those rules likely to have an economic impact of \$100 million or more or to significantly impact the economy in other ways. These are the rules it is most important to get right because they can shape the fate of entire industries. The Regulatory Accountability Act would therefore require agencies to undertake a rigorous cost-benefit analysis of all such rules and of reasonable alternatives. This cost-benefit analysis, moreover, would be judicially reviewable.

2. Need for Regulatory Certainty and Uniformity

a. Ensure Regulatory Uniformity

The issues caused by state-by-state regulations on interstate commerce are so significant that our founding fathers made sure to leave the regulation of commerce to the federal government. The courts have since continued to recognize the need for a uniform, federally controlled commercial regulatory regime in developing what is known as the “dormant commerce clause.”

The issues caused by piecemeal regulation across all levels of government have become acute in the COVID-19 era as manufacturers face a dizzying array of inconsistent and sometimes conflicting guidance while working to ensure Americans have everything they need to stay healthy and maintain their daily lives and protect their employees. Uniform regulations are critical for manufacturers to survive and thrive in competitive markets. Congress—whether through legislation or in their oversight role of regulatory agencies—should take all available steps to preempt state efforts to create a patchwork of regulations that burden interstate commerce, particularly where those state regulations conflict with federal ones.

A lack of uniformity in regulations not only hinders business, but it can also result in harm to the environment, consumers, employees, and other entities regulations intend to protect. Once again, manufacturers have been on the front lines throughout the COVID-19 crisis, providing the equipment and products to keep our country safe, healthy and fed. In doing so, manufacturers have also prioritized employee safety, complying with guidelines issued by the federal government, as well as the state and local governments of the jurisdictions in which they operate. Yet, manufacturers—particularly those that operate in multiple states—have made clear that complying with this patchwork of regulations is not only arduous and costly, it is sometimes impossible as different states and localities issue conflicting guidelines.

This issue has been, and continues to be, particularly difficult for seasonal manufacturers, such as those that manufacture the canned and frozen fruits and vegetables depended upon by hospitals and schools. A year’s supply of our nation’s canned and frozen corn is packed within a 60-day window. For canned and frozen peaches, the window is just 50 days. Tomatoes, green beans and peas are also packed within a short harvest window. However, inconsistent and

often contradictory guidelines put the nation's supply of these critical goods at risk. NAM members in the food industry have noted that some local and state authorities contradicted CDC guidelines on returning food industry workers who are asymptomatic within 72 hours, insisting on a 14-day quarantine in contravention of the CDC guidelines.

Similarly, the piecemeal adoption by states of federal energy efficiency standards for commercial buildings creates a multitude of issues for all parties.²⁰ Manufacturers incur additional costs to maintain products and product certifications that comply with the multiple codes and related product regulations; architects and design engineers incur additional educational and compliance costs to understand all of the piecemeal codes and related product regulations; and state and local building officials incur additional costs to train staff on various compliance requirements.

While these are but two examples of the innumerable examples to draw from, they nonetheless highlight the need for Congress to make clear that a state-by-state regulatory regime will hinder the free flow of commerce upon which manufacturers depend to meet the needs of consumers.

b. End “Regulatory Ping Pong”

Regulatory certainty and transparency is critical to manufacturers in order to plan for the future. Indeed, many NAM members have made clear that the only thing worse than a bad, burdensome regulation is an unpredictable regulation. Unfortunately, due to the politicization of many regulatory matters, this is becoming increasingly more difficult as regulations are passed and repealed repeatedly depending on which party controls the executive branch. The politicization of the regulatory state also means that, once one party undoes the other party's actions, it is almost inevitable that the action will be challenged in court, which only serves to create more regulatory uncertainty.

This “regulatory ping pong” can and must end. We urge Congress to pass legislation that will provide the certainty needed for American manufacturers to compete globally. Specifically, Congress should pass legislation that sets forth clear standards and prevents federal agencies from adopting and repealing regulations.

3. The Need for Broad Regulatory Reform

a. End Regulation Through guidance

Manufacturers believe that the appropriate use of agency guidance is both useful and in the public interest, particularly when providing clarity on complex matters.²¹ The improper use of guidance, however, can impose burdens on society when regulated parties struggle to differentiate between nonbinding guidance and binding rules. This problem is compounded when agencies issue guidance documents as a substitute for, or to avoid, rulemaking procedures that would otherwise ensure transparency and public participation in decision-making processes. For these reasons, the NAM urges Congress to ensure that agencies adopt clear and binding rules regarding the issuance of future guidance.

²⁰ See U.S. Dep't of Energy, Building Energy Codes Determinations: ANSI/ASHRAE/IES Standard 90.1-2016 (last visited Oct. 9, 2020), <https://www.energycodes.gov/development/determinations>.

²¹ Guidance here refers collectively to “informal interpretations, advice, statements of policy, and other forms of ‘guidance.’” See Regulations Prohibiting Issuance, Reliance, or Defense of Improper Agency Guidance, Notice of Petition for Rulemaking, 84 Fed. Reg. 50791, 50793 (Sept. 26, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-09-26/pdf/2019-20540.pdf>.

b. The Difficult Distinction Between Rules and Guidance

The distinction between binding rules and nonbinding guidance documents has been ambiguous for decades.²² While rules are binding norms that carry the force of law and guidance documents are not supposed to bind the public, courts often struggle to determine the difference between these seemingly separable forms of agency action. In recent cases, courts have found that while “all relevant parties should instantly be able to tell whether an agency action is a legislative rule, an interpretive rule, or a general statement of policy,” in practice “[t]hat inquiry turns out to be quite difficult and confused.”²³

A legal distinction that gives pause to tenured judges and talented lawyers alike is almost by definition unnecessarily complex—and regulated businesses must make these determinations on a daily basis. To add even more complexity, guidance may take the form of email exchanges with agency officials, conversations with an inspector about safety regulations, memoranda from agency leadership to front-line officials, and more.

c. Costs of Confusion

Manufacturers face a costly dilemma daily: should they adhere to a statement from a regulatory agency as if it is binding, or should they merely note it as a suggestion and derive their own answer from the broader range of permissible readings of the underlying rule? The potential costs are high regardless of the answer.²⁴ If manufacturers choose to comply only with agency policies issued through formal rulemaking procedures, they run the risk of being subject to an agency enforcement action, public ire or advocacy group litigation.²⁵ Manufacturers therefore often find agency guidance to be coercive as a practical matter, even if it is not legally binding.²⁶

Perhaps more concerning, agency guidance documents are seldom subject to public scrutiny or accountability. While the APA generally requires agencies to undertake a notice and comment process before issuing new binding rules, agencies may issue guidance documents without following any of this process. The resulting guidance often lacks notice or explanation and fails to provide the regulated public with recourse in the courts. Guidance documents are also often difficult to locate, and agencies need not publish them in the *Federal Register*, denying regulated parties the benefit of better understanding the agency’s thought process.

²² See e.g. *Pacific Gas & Elec. Co. v. Fed. Power Comm’n*, 506 F.2d 33 (1974).

²³ Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 266 (2018) (quoting *National Mining Ass’n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014)).

²⁴ See, e.g., Paul R. Noe & John D. Graham, *Due Process and Management for Guidance Documents: Good Governance Long Overdue*, 25 YALE J. ON REG. 103, 104 (2008) (“Each year, agencies issue on the order of 4000 regulations, and the number of guidance documents is orders of magnitude larger.”) (citing H.R. Rep. No. 106-1009 (2000) (noting that between March 1996 through 1999, NHTSA had issued 1225 guidance documents, EPA 2653, and OSHA 1641)).

²⁵ See *LabMD, Inc. v. Fed. Trade Comm’n*, 894 F.3d 1221 (11th Cir. 2018); see also Dune Lawrence, *A Leak Wounded This Company. Fighting the Feds Finished it Off*, Bloomberg (April 25, 2016), <https://www.bloomberg.com/features/2016-labmd-ftc-tiversal/>.

²⁶ Nicholas R. Parrillo & Lee Liberman Otis, *Understanding and Addressing Controversies About Agency Guidance*, THE REGULATORY REVIEW (Mar. 5, 2018), <https://www.theregreview.org/2018/03/05/parrillo-otis-understanding-addressing-controversies-agency-guidance/> (noting that a study by the Administrative Conference of the United States found that “regulated parties often ... have no practical choice but to follow a guidance document”).

d. Recommended Reforms

i. Amend the APA to Better Define Key Terms and Provide Opportunity to Comment on Guidance

While the Regulatory Accountability Act of 2017 would provide many of the needed APA reforms, one critical component to APA reform that is noticeably missing is ensuring the definitions of key regulatory terms are clear and consistent. The bill would finally define guidance and distinguishes between rules based on economic impact. As noted above, this is a critical step. However, manufacturers believe that Congress should go further and ensure all definitions correctly represent the action and consequences they carry, including rules themselves.

Despite legal scholars' consistent use of the term "rule" to solely refer to general agency actions akin to legislation that govern future conduct, under the APA the term includes essentially all possible agency actions. Section 551(4) of the APA defines a rule to mean "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency...."²⁷ Indeed, courts have said that the APA defines a rule so broadly it "obviously could be read literally to encompass virtually any utterance by an agency."²⁸

Thus, the confusion in differentiating between binding legislative rules and guidance began with the very first statutory definition of a rule. In fact, the APA does not distinguish between rules and non-rules, but rather sets forth "the fundamental distinction in administrative law between legislative rules," which carry the force of law, and "nonlegislative rules" (or guidance) which do not.²⁹ The APA then further distinguishes the types of rules, not by name, but by the process required to issue them by imposing a general obligation to use notice-and-comment in rulemaking but contains an exemption, § 553(b)(A), for "interpretative rules" and "general statements of policy."

Congress should therefore amend the APA to ensure that agency actions are accurately depicted definitionally, such as by:

- Ensuring "rule" is properly defined to only include agency actions with binding, broadly applicable future effect;
- Adding a definition for guidance, which should incorporate into it both the "interpretive rules" and "general statements of policy" components of § 553(b)(A) to avoid the current confusion between types of rules; and
- Removing the current exemption of § 553(b)(A) to require agencies to provide the affected public an opportunity to comment on guidance.

²⁷ 5 U.S.C. § 551(4).

²⁸ *Pacific Gas*, 506 F.2d at 37. The APA defines a rule to mean "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency...." 5 U.S.C. § 551(4).

²⁹ Levine, *Guidance Exemption* at 266.

ii. Extend Judicial Review to Cover Purportedly “Non-Binding” and “Draft” Guidance

Agencies are able to regulate through guidance by claiming that a guidance document is “non-binding” and a “draft” to avoid judicial review. As noted above, in many instances even putatively “non-binding” guidance is effectively binding for manufacturers. Moreover, because the APA requires an agency action to be final before it is ripe for judicial review, agencies can avoid having this practice challenged by stamping all guidance documents as “draft.”

Congress should therefore take actions to ensure guidance is judicially reviewable, such as by:

- More clearly defining “final agency action” for purposes of judicial review to ensure agencies cannot simply stamp “draft” on guidance to avoid judicial review; and
- Extending judicial review to cover putatively non-binding agency guidance that is effectively binding on the parties.³⁰

iii. Enact the GOOD Act to Codify Executive Order 13891, *Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents*

Manufacturers believe that agencies should make guidance easy to find by publishing all guidance documents in one location online. While much of this was accomplished through E.O. 13891,³¹ that order can be repealed and does not apply to independent agencies. To this end, Congress should prioritize passing H.R.7396, the Guidance Out of Darkness Act, sponsored by Rep. Walker (R-NC) and cosponsored by Ranking Member Comer (R-KY).

iv. Require Agencies to Afford the Public an Opportunity to Comment on Guidance

The landmark Food and Drug Modernization Act of 1997 was unanimously approved by the Senate before being signed into law by President Clinton. The legislation is notable because it expressly sought to improve collaboration between manufacturers and the FDA throughout the approval process.³² To achieve this goal, the statute required the FDA to seek public input in the development of their guidance, ensure that the documents are made available to the public in both electronic and written form, and ensure that the FDA does not deviate from guidance documents without appropriate justification.³³ Manufacturers believe that these policies should be extended to all federal agencies.

4. Need for Administrative Adjudication and Enforcement Reform

³⁰ This specific proposal was suggested by Helgi Walker, Chair of Gibson Dunn’s Administrative Law and Regulatory Practice Group, in comments made at DOJ’s 2019 Summit and incorporated into DOJ’s Report. See DOJ APA Report at 35-37.

³¹ Exec. Order No. 13,891, 84 Fed. Reg. 55235 (2019).

³² See Nick Littlefield & Sharon Webb, *FDA Modernization and Accountability Act of 1997: A Blueprint for Reform*, Federalist Society (Aug. 1, 1998), <https://fedsoc.org/commentary/publications/fda-modernization-and-accountability-act-of-1997-a-blueprint-for-reform>.

³³ 21 U.S.C. 371(h).

Federal agencies may apply arbitrary and inconsistent procedures during the regulatory enforcement process. In 2020, the White House Office of Management and Budget recognized the need to address the issues with federal agencies' administrative adjudication and enforcement practices by issuing a Request for Information asking the public to "identify additional reforms that will ensure adequate due process in regulatory enforcement and adjudication."³⁴

Manufacturers seized this rare opportunity and, along with a several other business groups, filed comments setting forth specific issues and opportunities for reform on all 11 topics identified by OMB. While a select sample of these proposals are set forth below, manufacturers believe Congress should act to address all of the issues identified and encourage the Committee to review the filed comments, which are attached to this response, in their entirety.³⁵

While the below recommendations provide a more detailed roadmap to reforming regulatory enforcement and adjudication practices, Congress can take significant strides simply by codifying the principles of fairness in administrative enforcement and adjudication set forth in key OMB documents.³⁶

a. Reforms to ensure speedy and fair investigations:

- Congress should require agencies to reform their investigation process by setting and following transparent procedures and allowing parties an opportunity to "show cause" for why an investigation should proceed. This could be done through an informal process in which the agency communicates information to the regulated party regarding its investigation, including the progress it is making or its bases for proceeding with the investigation, while also allowing for regulated parties to invoke a formal adjudication to allow for the resolution of issues of controversy and uncertainty through a process of declaratory relief.
- Congress should direct all federal agencies to review, and as necessary, revise current investigative procedures to reduce undue burdens, ensure transparency and provide measures to ensure investigations are concluded fairly and expeditiously. Timely decisions on enforcement matters are critical.
- Congress should require all agencies to follow clear, published procedures for site inspections to ensure fairer treatment during this essential aspect of an agency investigation.

b. Reforms to ensure fairness in regulatory proceedings:

- Congress should require agencies to enact policies to ensure the presumption of innocence is retained in regulatory/civil proceedings. Accordingly, agencies should be directed to review their regulatory enforcement practices and determine where respondents or defendants are subject to an impermissible *prima facie* presumption of liability so they may be corrected.

³⁴ Improving and Reforming Regulatory Enforcement and Adjudication, 85 Fed. Reg. 5483 (Jan. 30, 2020).

³⁵ See, *infra* Appendix A, Comments of the Nat'l Ass'n of Manufacturers, Am. Chem. Council, *et al* re: OMB-2019-0006 (March 16, 2020), https://documents.nam.org/tax/AFPM_API_ACC_NAM_NAHB_Comments_to_OMB_01302020.pdf.

³⁶ See, e.g., Executive Order 13924, *Executive Order on Regulatory Relief to Support Economic Recovery*, OMB Director Russell T. Vought's June 9, 2020 Memorandum M-20-25, *Implementation of Executive Order 13924*, and OIRA Administrator Paul J. Ray's August 31, 2020 Memorandum M-20-31, *Implementation of Section 6 of Executive Order 13924*.

- Congress should provide an opportunity for manufacturers to challenge or correct errors in press releases prior to release to avoid unfair reputational damage. This is particularly important at agencies such as the U.S. Consumer Product Safety Commission and the Occupational Safety and Health Administration who regularly issue press releases of alleged violations or unproven perceived dangers without notice, irrespective of factual disputes.

c. Reforms to ensure agencies are prohibited from relying on unwritten agency practice and/or unbinding guidance in enforcement proceeding

- Congress should require all agencies to adopt the DOJ policy that prohibits treating agency guidance documents as binding rules.³⁷ The policy should also extend to unwritten agency practice, as neither should impose legal obligations on private parties.

5. Need for Increased International Focus

Congress must be vigilant in ensuring that every administration uses appropriate channels—including World Trade Organization mechanisms, regional and bilateral trade agreements and direct bilateral negotiations—to address global trade barriers. Expanding manufacturers’ access to, and a level playing field in, global markets have been pivotal to improving U.S. manufacturing competitiveness—and has enabled businesses to raise wages and create more high-skilled U.S. jobs.

With more than 95 percent of the world’s consumers living outside the United States and the rise of new competitors, the United States needs a strong and multi-faceted trade policy to bolster U.S. manufacturing and grow well-paying jobs across America. Manufacturers need a more open, predictable, transparent and level playing field. Manufacturers believe that these objectives can best be achieved by pursuing, utilizing and enforcing a robust and revitalized rules-based international trading system that enhances the role of free market forces, promotes respect for the rule of law, raises standards and lowers costs, barriers and market-distorting government intervention.

Unfortunately, manufacturers in the United States face an array of barriers in major markets that prevent fair competition and access to global growth opportunities. These take a wide variety of forms, including traditional trade and investment restrictions, as well as forced localization that pressures companies to move manufacturing and operations overseas, intellectual property theft that undercuts manufacturing competitiveness, problematic import and export policies that distort global trade and discriminatory technical barriers to trade that block imports and create advantages for local country producers. The NAM’s October 2020 submission to the Office of the U.S. Trade Representative on global trade barriers provides a detailed accounting of priority trade barriers harming manufacturers around the world.³⁸

Efforts to set standards and regulatory policies through processes that do not align with good regulatory practices such as transparency, stakeholder engagement, and science and evidence-

³⁷ Memorandum from The Associate Attorney General, U.S. Dep’t of Justice, to Heads of Civil Litigating Components United States Attorneys (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>.

³⁸ Comments of the Nat’l Ass’n of Manufacturers to the Office of U.S. Trade Rep. re: Docket Number USTR-2020-0034: Request for Comments to Compile the National Trade Estimate Report on Foreign Trade Barriers (Oct. 28, 2020), http://documents.nam.org/IEA/NAM_NTE_Comments_2020_FINAL.pdf?_zs=WJNqd1&_zl=LlnC7.

based approaches are a particular concern for manufacturers, and can directly harm the competitiveness of manufacturers in the United States.³⁹ There are numerous examples of this:

- Manufacturers have noted an increase in regulatory policies targeting U.S. food and beverage manufacturers in countries such as Mexico, Chile, Ecuador, Israel, Peru, Saudi Arabia and Uruguay. Proposals are underway or being considered in additional markets such as Argentina, Brazil, Canada, Colombia, South Africa and the United Kingdom. Many of these proposals, which include package labeling, tax matters, advertising limitations and outright sales bans, have not been developed through transparent and non-discriminatory processes involving robust stakeholder engagement.
- Manufacturers have also seen an increase in national proposals for blanket bans or restrictions on manufactured products (such as plastics) as opposed to targeted, risk-based approaches that target core environmental concerns. These include new proposals in Canada to broadly label “plastic manufactured products” as toxic underneath the Canadian Environmental Protection Act and the European Union’s proposed addition of microplastics to its chemical management regime despite the lack of an EU determination of sufficient risk required to justify the addition.
- Manufacturers also remain highly concerned with regulatory approaches to management of chemicals in a wide range of manufactured products that do not align with U.S. risk-based approaches, but instead adopt a hazard-based approach based on the “precautionary principle.” This non-science-based approach, a frequent feature in EU regulations that impact trade and manufacturing, has been exported to other critical export markets, with EU-style chemical management regulations already adopted in countries from Korea to the United Arab Emirates and under active consideration in other countries such as Canada, India and Mexico.

In addition to trade barriers that appear first at the national level, manufacturers in the United States are increasingly confronting problematic initiatives from various global institutions, such as the World Health Organization, that similarly fail to reflect good regulatory practices but can promote the proliferation of trade barriers around the world. These concerns make it crucial for the United States remain engaged in these discussions to confront these trade barriers, using its voice and leverage to engage on behalf of U.S. economic and trade interests.

It is critical that Congress utilize its oversight powers to ensure that U.S. trade interests are protected. In particular, we urge this Committee to make clear to the U.S. Trade Representative, Secretary of State, Secretary of Commerce, and the Secretary of Agriculture that they should vigorously engage with their counterparts in countries that have adopted (or are considering) these measures to ensure that regulatory actions comply with all applicable trade requirements, are based on sound science and evidence, and do not unnecessarily burden U.S. exporters.

³⁹ For additional information on these issues, please see the NAM’s various comment letters. See Comments of the National Association of Manufacturers on Mexico’s Draft Amendment to NOM-051-SCFI/SSA1-2010 (Dec. 9, 2019), https://documents.nam.org/tax/NAM_Comments_on_MX_Amendment_NOM051_12092019.pdf (noting that, while manufacturers fully recognize and agree with the importance of science-based labels for food and beverages that inform consumers about nutritional choices they make, Mexico’s “proposals are out of step with the scientifically based global conversation taking place at the Codex Alimentarius Committee, where global food standards are set.”). See *also* Comments of the National Association of Manufacturers on the Codex Alimentarius Committee’s Proposed Draft Guidelines for Front-of-Pack Nutrition Labeling (April 9, 2019), http://documents.nam.org/LLRP/NAM_CODEX_FOPNL_Comments_040919.pdf.

Similarly, these agencies should look to work with likeminded countries to raise and address these issues in a comprehensive, strategic fashion.

6. Policymakers Must Address Trade of Counterfeits and Other Illicit Goods

The sale of dangerous counterfeits and unregulated goods is not a new problem; it has harmed manufacturers, American workers and consumers for years. But the problem is getting worse, and the COVID-19 pandemic has shown just how dangerous inaction can be. As part of the nation's critical response effort, manufacturers have been supplying health care workers and other Americans on the front lines of this crisis with vital goods, including personal protective equipment, hospital beds, ventilators, hand sanitizers, cleaning supplies and other critical health care and safety products. But counterfeiters have exploited the crisis to peddle fake tests, dangerous vaccines and ineffective protective gear. These counterfeits are harming American citizens and hindering manufacturers' efforts to protect their workers and communities.

The prevalence of counterfeits in the COVID-19 response has brought new urgency to this long-simmering issue, and the NAM is leading the charge against fake and counterfeit goods. In July, the NAM released a white paper detailing not only how fake products harm manufacturers, consumers and public health, but also setting forth specific policy solutions that Congress and the administration should adopt to address the issue.⁴⁰ Given the Committee's direct jurisdiction over postal matters, we draw your attention to the following regulatory issues that are specifically under the House Oversight Committee's jurisdiction which, if addressed, will go a long way towards stemming the tide of fake goods entering the United States.

The NAM's whitepaper contains dozens of recommended legislative and regulatory actions to address the issue of counterfeit goods. These items include the need for agencies to implement and monitor key matters that have already been approved that may merit Committee oversight. For example, Congress should ensure full implementation and enforcement of the Synthetics Trafficking and Overdose Prevention (STOP) Act of 2018 by U.S. Customs and Border Protection, including requirements for the U.S. Postal Service to collect advanced electronic data (AED) for 100% of packages to track counterfeits. In doing so, Congress should use its oversight authority to ensure CBP enforces current law and treats all importers the same, including shipments from foreign posts. The STOP Act addresses illicit imports by requiring AED on packages imported from foreign postal networks.⁴¹ Yet, to date, CBP has failed to comply with multiple benchmarks set forth by Congress, which has allowed counterfeiters to continue to get their dangerous products into the U.S. market. Congress should address these specific shortcomings:

- CBP has failed to issue regulations that were due a year ago to enforce the STOP Act.⁴²

⁴⁰ NAT'L ASS'N OF MANUFACTURERS, COUNTERING COUNTERFEITS: THE REAL THREAT OF FAKE PRODUCTS (2020), https://www.nam.org/wp-content/uploads/2020/07/CounteringCounterfeits.vF_.pdf.

⁴¹ STOP Act of 2018, Pub. L. 115-272, title VIII, section 8003 (October 24, 2018).

⁴² U.S. POSTAL SERVICE OFFICE OF INSPECTOR GENERAL, IMPLEMENTING ADVANCE ELECTRONIC DATA: CHALLENGES AND OPPORTUNITIES 6 (Sept. 30, 2020), <https://www.uspsoidg.gov/sites/default/files/document-library-files/2020/RISC-WP-20-010.pdf> (citing Synthetics Trafficking and Overdose Prevention (STOP) Act of 2018, S.3057, 115th Cong., 2D sess., §9(b)).

- CBP has failed to present any evidence that the USPS complies with initial STOP Act requirements and receives AED on 100% of packages imported from China and 70% of packages imported worldwide as of December 31, 2018.⁴³
- CBP has not provided any evidence that the USPS can submit AED on 100% of packages imported worldwide as of January 1, 2021, and will turn away any non-compliant packages, even though it will subject the USPS to potential civil penalties, as confirmed by the USPS Inspector General.⁴⁴

In addition, Congress should work with the State Department and the U.S. Ambassador to the United Nations to ensure that low terminal dues for foreign countries do not continue to allow counterfeiters to cheaply ship goods to consumers through the U.S. Postal Service.⁴⁵ To this end, Congress should closely monitor the global implementation of the September 2019 agreement by parties to the Universal Postal Union to allow countries to self-declare postal rates and work with the White House on further actions to take if that implementation is insufficient.

7. Conclusion

Smart regulation is critical to protecting worker safety, public health and our environment; yet overregulation will hold back our country's economic potential. A more competitive economy demands reforming the nation's broken regulatory systems. By addressing these regulatory burdens through the adoption of commonsense and bipartisan regulatory reform measures, Congress can ensure our regulatory structure is no longer a barrier to economic growth, hindering innovation and slowing productivity. Thank you for this opportunity to submit our views.

⁴³ 19 U.S.C §1415 (a)(3)(K)(v)(I) - (a)(3)(K)(vi)(I).

⁴⁴ USPS IG Report, *supra* n. 42, at 3.

⁴⁵ "Terminal dues is the system that posts use to pay one another for international deliveries of letters and small packages. The global terminal dues system, updated every four years by the Universal Postal Union (UPU), does not fully reflect actual domestic processing and delivery costs." U.S. POSTAL SERVICE OFFICE OF INSPECTOR GENERAL, TERMINAL DUES IN THE AGE OF E-COMMERCE (Dec. 14, 2015), <https://www.uspsig.gov/sites/default/files/document-library-files/2015/RARC-WP-16-003.pdf>.



March 16, 2020

Russell T. Vought
Acting Director
Office of Management and Budget
Executive Office of the President
725 17th Street, N.W.
Washington, D.C. 20503

Attention Docket ID No. OMB-2019-0006

Submitted electronically to regulations.gov

Re: AFPM, API, ACC, NAM, and NAHB Comments on Improving and Reforming Regulatory Enforcement and Adjudication, Request for Information, Docket ID No. OMB-2019-0006; 85 Fed. Reg. 5,483 (Jan. 30, 2020)

Dear Director Vought,

The American Fuel & Petrochemical Manufacturers (“AFPM”), American Petroleum Institute (“API”), American Chemistry Council (“ACC”), the National Association of Manufacturers (“NAM”), and National Association of Home Builders of the United States (“NAHB”) (collectively, the “Associations”) appreciate the opportunity to submit comments on the Office of Management and Budget’s (“OMB”) Request for Information (“RFI”) entitled, “Improving and Reforming Regulatory Enforcement and Adjudication” (hereinafter, the “Notice”).

INTRODUCTION

AFPM is a national trade association whose members comprise most U.S. refining and petrochemical manufacturing capacity. API represents all segments of America’s oil and natural gas industry with more than 600 members who produce, process, and distribute most of the nation’s energy. ACC represents the leading companies engaged in the business of chemistry, which is a \$553 billion enterprise. The NAM is the largest industrial association in the United States, representing manufacturers in every sector and in all 50 states. NAHB is a Washington, D.C.-based trade association that includes more than 700 state and local associations representing more than 140,000-member firms nationwide who are involved in home building, remodeling, multifamily construction, land development, property management and light commercial construction.

The Associations commend OMB for undertaking this important effort. The Notice is of particular interest, as the Associations and their members are subject to regulation by all manner of federal agencies, which can lead to interaction with agency enforcement and adjudication proceedings. Based on our experience, there is room for agencies to reform regulatory enforcement, but such reform should ensure agencies maintain core American precepts of due process, fairness, and equal treatment under the law.

OMB has framed its Notice by asking for feedback on 11 important topics. We discuss below selected topics that members have identified, and accept OMB's invitation to provide examples of due process failures and possible reforms to regulatory issues outside of the specific topics OMB has identified.

I. Prior to initiation of an adjudication, what would ensure a speedy and/or fair investigation? What reforms would avoid a prolonged investigation? Should investigated parties have an opportunity to require an agency to “show cause” to continue an investigation?

A. Agencies should reform their investigation process by setting and following transparent procedures — and allowing parties an opportunity to request an agency to “show cause” for why an investigation should proceed

The Associations have found that federal agencies apply arbitrary and inconsistent procedures during the regulatory enforcement process. OMB should direct all federal agencies to review, and as necessary, revise current investigative procedures to reduce undue burdens, ensure transparency and provide measures to ensure investigations are concluded fairly and expeditiously. Timely decisions on enforcement matters are critical.

One common problem is an inconsistent and arbitrary approach to site inspections. While some agencies have established guidelines to formalize their processes by outlining steps that every inspector is expected to follow — when they notify a company of an inspection, hold the closing conference and provide copies of an inspection report after the inspection,¹ — many do not. Having all agencies follow clear, published procedures would ensure fairer treatment during this essential aspect of an agency investigation.

An additional problem is that agencies generally do not allow regulated entities to request closure notices. Without an opportunity to request firm limits or deadlines, investigations can be unduly expansive and extend indefinitely without the regulated party having any closure. Information requests are often overly broad, requiring an enormous investment of time and resources — and on unreasonably short timelines. Agencies should be subject to reasonable but clear limits on the scope of the inquiry, while allowing reasonable timelines for responses by regulated parties.

Moreover, after information is submitted, there is typically no deadline for a response or feedback from the agency. As a result, it is common for extended time periods to pass without any further communication from the agency as to whether an inquiry remains open. This can

¹ See 85 Fed. Reg. 12,224 (Mar. 2, 2020) (EPA on-site civil inspection procedures).

disrupt operations significantly, leading to additional burdens on industry. The uncertainty alone can affect businesses, as long, ongoing investigations or outstanding notices of violation which remain unresolved must be reported, often publicly, and can interfere with contracts (such as by triggering automatic default provisions) or participation in important agency programs. Further, regulated parties need to know with certainty if operational changes are required to ensure compliance. The lack of closure can also mean unclear guidance on what is needed to move forward.

Given these burdens and the lengthy delays that often accompany these types of inquiries, the Notice's suggestion that parties have an opportunity to require an agency to "show cause" to continue an investigation is sound. This could be done through an informal process in which the agency communicates information to the regulated party regarding its investigation, including the progress it is making or its bases for proceeding with the investigation, while also allowing for regulated parties to invoke a formal adjudication to allow for the resolution of issues of controversy and uncertainty through a process of declaratory relief.

B. Specific examples of opportunities for reform

Members offered the following concrete examples of current due process shortfalls in individual agencies and possible reforms to the investigation process.

1. PHMSA should review and reform its inspection, investigation and audit procedures

The Pipeline and Hazardous Materials Safety Administration ("PHMSA") is one example of an agency that should reform how it conducts inspections, investigations and audits. Member companies that interact with PHMSA report that its inspection, investigation and audit processes can be unpredictable. Without clear, documented procedures on the frequency of or bases for inspections, certain facilities are targeted more than others merely due to ease of access for inspectors, as opposed to inspection or compliance history or other factors that contribute to public safety. Facilities also report that inspectors have acted arbitrarily by making requests for data or information without a legitimate foundation.

Clearer procedures would preserve the integrity of an agency's practices, while also providing a set of expectations for regulated entities. For example, as to PHMSA specifically and agencies more generally, the agency should communicate and define the scope of each scheduled inspection, investigation or audit. Significant changes to the scope should be formally decided and communicated. This will help to prevent "scope creep" without a justifiable cause, thereby allowing for a more efficient and effective investigation for both the agency and the regulated entity.

Where appropriate, agencies should also provide inspection, investigation and audit protocols to the regulated entity before any inspection, investigation or audit. Defined protocols allow for a more efficient and effective experience for both the agency and the regulated entity, including ensuring the safety of inspectors and workers and providing the regulated entity with some idea of how many workers must be pulled from their normal duties to aid agency inspectors. As an example, member companies report experience with multi-week PHMSA

inspections where several key operational personnel were requested to be present at all times during the inspection, despite not being needed for the full inspection. Taking these key personnel out of their normal duties for several weeks presents a significant operational burden and challenge to maintaining the normal operations of a business, without identifiable benefit to the inspection.

Agency procedures and training should make it clear to inspectors that they must stay within their legal authority in conducting an inspection. For example, PHMSA regulations² allow inspectors to “inspect, and examine ... the records and properties ... ” of the regulated entity to demonstrate compliance. The rule does not authorize inspectors to direct company personnel to perform specific actions on command (*e.g.*, take measurements, report readings, operate valves, locate pipelines, etc.); however, this is a common practice during PHMSA inspections, often disrupting operations. PHMSA should share clear procedures and identify necessary resources with the regulated entity to avoid disruptions.

2. Department of Labor’s Office of Federal Contract Compliance Programs should use clear and standardized investigative procedures

The Department of Labor’s Office of Federal Contract Compliance Programs (“OFCCP”) is a further example of the need for agencies to adopt clear, standardized and fair investigative procedures. OFCCP has significant power, as it has oversight over any company that does business with the federal government to hold them, “responsible for complying with the legal requirement to take affirmative action and not discriminate on the basis of race, color, sex, sexual orientation, gender identity, religion, national origin, disability, or status as a protected veteran.”³ To fulfill this responsibility, OFCCP may conduct off-site and on-site reviews of a company’s personnel policies, procedures and payroll. The agency also may interview a company’s workers as part of an investigation. With far-reaching effects, OFCCP’s enforcement mechanisms have become a system of complicated, inconsistent and unduly burdensome rules that often deprive contractors of legal protections.

OFCCP’s current practices demonstrate the need for agencies to adopt reforms that provide reasonable timelines for regulated parties to respond to an agency’s demands for information. Currently, while OFCCP is under no obligation to complete its audits, investigations or mediations within a specific time frame, contractors are under strict deadlines after receiving notice of an audit to submit the required information to OFCCP. For example, contractors are required to respond to desk audits within 30 days of receiving a notice.⁴ If there is a clerical error, or if the paper notice is not sent to the appropriate staff, the amount of time available to compile the necessary documents is shortened substantially. A reasonable reform

² 49 C.F.R. § 190.203.

³ U.S. Dep’t of Labor, Office of Fed. Contract Compliance Programs, *About OFCCP*, <https://www.dol.gov/ofccp/aboutof.html> (last visited Mar. 12, 2020).

⁴ U.S. Dep’t of Labor, Office of Fed. Contract Compliance Programs, *Federal Contract Compliance Manual* at 1C, <https://www.dol.gov/agencies/ofccp/manual/fccm/chapter-1-desk-audit/1c-receipt-aaps-and-itemized-listing-data-desk> (last updated Dec. 31, 2019).

would require the contractor to respond to an audit only after a designated staff member of the contractor has received the notice and confirmed receipt with OFCCP.

Further, the OFCCP process underscores the need for reforms that bring closure to agency investigations. Presently, contractors face great uncertainty once they submit the required audit information to OFCCP. Businesses often wait weeks and months before they are notified of OFCCP's findings of whether or not they have a violation. This delay strains a company's operations because it is not able to assign staff to new tasks or shift resources away from compliance mechanisms, and can result in additional ongoing legal costs.

In addition, the extended time during OFCCP audits likewise affirms the need for reforms that ensure agencies conducting investigations or audits are treating regulated parties fairly. For example, enhanced communication from OFCCP to contractors during audits would help to ease the burden businesses face by helping them plan ahead and make necessary staffing changes. It would also help to create records that can be reviewed to ensure that OFCCP is conducting its audits in a speedy manner, as expected by law. OFCCP should develop a mechanism to notify businesses routinely or allow them to check on the status of their audit. If a business waits weeks or months to receive a notice from OFCCP, they should be able to inquire about where in the process they stand. OFCCP should be able to tell contractors whether their review has not begun, is in progress or completed and waiting notification.

Member companies' experiences with inconsistent enforcement by OFCCP likewise confirm that reform of administrative investigations by agencies should include improved, timely training of agency investigators. OFCCP should conduct training for officers immediately after being hired and provide continuing education for tenured staff to ensure that all procedures are being followed and that requirements for contractors are uniform across the country. Contractors report that enforcement priorities, processes and procedures can vary based on OFCCP regional and district offices. Despite federal guidelines, regional offices differ in their primary enforcement targets and ways in which audits are conducted. Inconsistent procedures by enforcement staff make it difficult for companies that operate in multiple regions to maintain full compliance. It is unfair to require businesses to develop different internal policies for complying with OFCCP rules based on which region the review is taking place; this results in unnecessary costs and legal uncertainty for contractors trying to stay in compliance.

Finally, experience with OFCCP also demonstrates the need for agencies to justify and document the bases for prioritizing particular business for inquiry. OFCCP should focus its efforts and use the limited resources at their disposal to identify, investigate and hold responsible those companies or industries that pose the greatest risk of breaking the rules. When good actors are consistently audited and investigated, it takes resources away from finding and punishing bad actors. OFCCP should develop a mechanism for identifying the contractors that are the highest risk of discrimination and shift enforcement resources away from companies with established records of compliance and nondiscrimination practices.

3. Agencies, such as EPA, should tailor information requests — and then follow up after reviews of information requests and/or inspection reports are complete

As with OFCCP audits, member companies' experiences with information requests from the Environmental Protection Agency ("EPA") provide further support for reforming the regulatory investigation process. EPA often initiates the enforcement process by sending information requests that are authorized under one of the federal environmental laws. EPA has often sent detailed and lengthy requests asking for broad categories of information, seeking literally thousands of pages of material and extensive data in very short order. Often, these requests have cast an unduly wide net.

Agencies, like EPA, should be directed to reform the scope of these kinds of requests. EPA has made strides in issuing guidance to focus its information gathering efforts, which should serve as a meaningful framework for other agencies to improve their procedures.⁵ However, there remains opportunity to improve the process. Like the Federal Rules of Civil Procedure's limitation on interrogatory requests, Fed. R. Civ. P. 33, a reform of agency investigatory procedures should place some reasonable limit on the scope and burden imposed by its administrative inquiries. Likewise, while EPA in many instances does allow phased responses and due date extensions for responses to their requests, there should be reasonable timelines officially allowed for regulated parties to consider and respond to what can be exceptionally burdensome and broad requests.

Moreover, there should be a process for closing out an inquiry after an information request is made. Member companies frequently respond, but do not receive feedback from the agency for an extended period of time (if at all). This can be concerning because receipt of an EPA information request can in some instances indicate that an agency intends to initiate enforcement. Similarly, member companies experienced multiple instances where EPA conducted an extensive site inspection, issued an inspection report noting agency findings, engaged in discussions with these companies after the inspection regarding findings, but then communicated nothing further to these companies until they received a request for a tolling agreement (indicating that the agency is intending to pursue an enforcement action).

Just as EPA is now expected to provide regulated entities with an inspection report after it completes an inspection,⁶ the agency should notify the regulated party when it completes its information request review and explain whether it has concluded its inquiry or if it is still considering further action. Providing notice concerning the agency's present intentions will provide some degree of comfort to a regulated party.

In addition to being required to issue inspection reports after EPA inspections, EPA officials should be required to issue the report within a defined period (*e.g.*, three months).

⁵ Memorandum from Rosemarie Kelley, Dir., Office of Civil Enf't, to Reg'l Counsel, Reg'l Enf't Dirs. & Program Dirs., Reg'l Enf't Coordinators, Office of Civil Enf't Div. Dirs. (Nov. 21, 2018), <https://www.epa.gov/sites/production/files/2018-11/documents/bestpracticesforcomplianceandenforcementrelatedinformation.pdf>.

⁶ See note 1, *supra*.

There is general guidance on this, but requiring agencies to provide the report in a timely fashion will expedite resolution of any issues identified. Similarly, after EPA issues an inspection report, regulated parties should have the option of requesting the agency to issue a letter indicating that it is closing the investigation and no enforcement is forthcoming or to “show cause” why the investigation must remain open. The regulated community deserves to know where they stand after an inspection. This avoids staleness of facts and memories of participants, reduces rework caused by typical personnel turnover of the participants, improves the ability of all involved to timely resolve misunderstandings or misinterpretations made during inspections and facilitates the prompt resolution of alleged non-compliance. While regulated entities are not anxious to dive into enforcement actions, they deserve to have the ability to move these matters more swiftly to conclusion so they can get on with their business.

4. There should be a mechanism to close out agency notices of violation, such as those issued by EPA, if the agency decides not to pursue enforcement

Similar reforms are needed for the process by which agencies follow-up on a notice of violation (“NOV”). For example, member companies experienced instances where EPA issued an NOV, but then did not follow up further, leaving the NOV unresolved. This lack of resolution leaves regulated entities unable to discuss their compliance effectively in other transactions or legal communications and creates a stigma as a non-compliant company, even if they plan to contest any future enforcement action arising from an NOV.

This is a significant issue as EPA’s Enforcement and Compliance History Online (“ECHO”) database will list a facility that received an NOV as being in non-compliance or having a violation identified for every quarter that the NOV remains unresolved. An NOV is not a final agency determination of non-compliance, but rather an interim agency action that may not be challenged.⁷ It is highly inappropriate for EPA to label any company as violating the law based only on an NOV as it provides the public with the false notion that a company is adjudged liable. Moreover, so long as the courts find NOVs are not final agency action, there is no judicial mechanism for a company that receives an NOV to force EPA either to withdraw the NOV or to challenge it.

As at the inspection stage, a helpful reform would allow the regulated party the opportunity to require the agency to “show cause” as to why the NOV should be continued, by providing a written justification to the regulated party for extending the notice, subject to ALJ review. Having a mechanism for a regulated party to bring an NOV to closure would avoid staleness of facts and the memories of participants. This will allow regulated entities receiving an NOV at least some certainty in knowing that EPA either will undertake a formal enforcement action by a particular date or will deem the matter resolved. Further, under no circumstances should the issuance of an NOV result in any public statement or suggestion, in the ECHO database or elsewhere, that an entity that has merely received an NOV is non-compliant.

⁷ *Luminant Generation Co., LLC v. EPA*, 757 F.3d 439 (5th Cir. 2014).

5. Accident site preservation notices and orders should be addressed in a timely manner

Several of our members have received orders from the Chemical Safety and Hazard Investigation Board (“CSB”) or the Occupational Safety and Health Administration (“OSHA”) to preserve an accident site after an incident occurred at a facility. Preserving a site is, of course, important to ensure proper analysis is conducted and evidence is secured. However, these sites are part of active businesses, which are required to gather necessary information to conduct their own investigations, begin any necessary equipment repairs, and return to productive work. Yet, agency follow-up on such orders and notices often does not occur in a timely manner. If agency personnel do not communicate clear deadlines for how long a site preservation order should last, a company incurs lost production, delays in necessary repairs, and delays in its own internal investigations while waiting for the agency. Clear timelines should be set limiting how long an investigating agency may hold a site without documenting a sound basis for its order. For example, an administrative agency should not hold a site for more than three business days without articulating a clear reason in writing for doing so. Orders should be considered null after three business days unless the agency takes an affirmative step to extend for good cause.

6. The Endangered Species Act Incidental Take Permit program should have clear deadlines and timeframes

Timely investment in new projects and new productive capacity are important for economic growth. These types of projects require regulatory approvals, which will vary depending upon a range of factors, including where the investment is located. Timely review and action by regulators to conduct investigations and provide approvals is essential for investments to proceed.

In certain cases, investments are affected when regulators do not act in a timely way. For example, some of our members’ activities may result in habitat modification or have other potential effects on a listed species. In some cases, habitat modification and other impacts to federally listed species can rise to the level of a “take” under the Endangered Species Act (“ESA”) of 1973, 16 U.S.C. § 1531 et seq. In certain circumstances, this can be permitted under the ESA and implementing regulations. If there is no federal connection to a proposed activity, the Incidental Take Permit (“ITP”) program established in Section 10 of the ESA allows non-federal actors to obtain permits from the appropriate federal agency to authorize the activity. The program provides a process for agencies to conduct their review and grant the appropriate permit.

However, the ITP program lacks defined deadlines and timeframes. This uncertainty is antithetical to efficient agency decision-making and puts important investments at risk due to the delays and uncertainty. The agency guidance on this topic, such as recently adopted guidance on deadlines for conducting the National Environmental Policy Act (“NEPA”) process associated with ITPs,⁸ sets “targets,” but lacks concrete processing phases and associated deadlines. A series of appropriate deadlines and timeframes should be adopted by regulation.

⁸ See U.S. Fish & Wildlife Service, *Midwest Region, Endangered Species Permits, HCPs – Frequently asked Questions* (May 22, 2019), https://www.fws.gov/midwest/endangered/permits/hcp/hcp_faqs.html (establishing three

In addition, agencies that enforce the ESA should consider a routine program of reimbursable agreements with applicants so that staff or contractors can be dedicated to urgent projects without taking away from other, important efforts under the ESA. The Council on Environmental Quality (“CEQ”) has already proposed a similar procedure where contractors selected by the federal agency supplement agency resources by performing environmental review at the applicant’s expense.⁹

II. When do multiple agencies investigate the same (or related) conduct and then force Americans to contest liability in different proceedings across multiple agencies? What reforms would encourage agencies to adjudicate related conduct in a single proceeding before a single adjudicator?

Federal statutes often embody principles of federalism, authorizing federal agencies to authorize or delegate states to implement the federal law through a state program. In other instances, states have their own statutes and authorities to address the same issues. This is a common circumstance for environmental regulatory enforcement, where EPA has authority — but there are also delegations by EPA to state agencies and overlapping state regulatory authority. Federalism should not be used as a license for double enforcement of the same course of conduct by states and federal agencies. EPA has recognized this principle and the importance of deferring to its state partners,¹⁰ but there should be continued efforts at implementation. Moreover, it is an important principle that OMB should urge other federal agencies to advance in their enforcement efforts where appropriate.

More specifically, member companies reported visits from multiple levels of government and different agencies on single sites. There should be better coordination between state and federal agencies when it comes to enforcement and compliance assistance. Agencies should seek to restore the balance between enforcement obligations and compliance assurance assistance. To accomplish this, where states have delegated authority, they, not the federal agencies, should play a lead role in identifying educational gaps, driving innovation, and directing compliance assistance resources to those who need it most. Further, where multiple federal agencies are involved, there should be coordination among the agencies to ensure a company is not penalized more than once for the same conduct.

III. Would applying the principle of *res judicata* in the regulatory context reduce duplicative proceedings? How would agencies effectively apply *res judicata*?

OMB should offer clear direction to agencies on whether to apply *res judicata* in regulatory proceedings. In general, *res judicata* involves a matter that has been adjudicated by a

months as a target processing time for permits requiring “low-effect” habitat conservation plans, six months for those requiring an Environmental Assessment, and one year for those requiring an Environmental Impact Statement).

⁹ See 85 Fed. Reg. 1,684 (Jan. 10, 2020), Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act (proposed rulemaking).

¹⁰ Memorandum from Susan Parker Bodine, U.S. Env’tl. Prot. Agency Assistant Adm’r for Enforcement & Compliance Assurance, to Reg’l Adm’r (July 11, 2019), <https://www.epa.gov/sites/production/files/2019-07/documents/memoenhancingeffectivepartnerships.pdf>.

competent court and may not be pursued further by the same parties. In a typical enforcement context involving a standard adjudicatory proceeding, OMB should make clear that a respondent should be allowed to invoke *res judicata* as a defense to avoid duplicative enforcement actions by an agency against the same regulated party. Quite simply, if an agency has pursued an enforcement claim against the same party and the party has already been found not to be liable, then the same claim should not be pursued again. It likewise should be clearly allowed as a defense by the regulated party who has adjudicated the same matter before a state regulator. As noted, federal statutes often authorize federal agencies to authorize or delegate states to implement the federal law through a state program. In those circumstances, agencies, such as EPA, should also accept a finding of no liability after an adjudication by a state partner implementing a federal program to be *res judicata* to bar a subsequent action on the same matter by EPA.

IV. In the regulatory/civil context, when does an American have to prove an absence of legal liability? Put differently, need an American prove innocence in regulatory proceeding(s)? What reform(s) would ensure an American never has to prove the absence of liability? To the extent permissible, should the Administration address burdens of persuasion and/or production in regulatory proceedings? Or should the scope of this reform focus strictly on an initial presumption of innocence?

A. Agencies should be directed to ensure the presumption of innocence is retained in regulatory proceedings

The Associations believe it is a fundamental aspect of procedural due process protections that the enforcing agency must always carry the burden of proving liability, and the regulated party should not have to prove an absence of legal liability in a regulatory proceeding.¹¹ Any reform by OMB should focus on ensuring these core principles, including the rule of lenity, apply in regulatory proceedings. The regulated party should also not be required to carry the burden of persuasion or production in the proceeding, and a reform that applies across agencies to establish this core principle should be adopted. Accordingly, agencies should be directed to review their regulatory enforcement practices and determine where respondents or defendants are subject to an impermissible *prima facie* presumption of liability so they may be corrected.

Indeed, there are aspects of agency administrative liability schemes where a regulation or administrative practice presumes a company has violated a requirement, unless the company can disprove it. Those instances should be remedied, as such a practice violates due process protections, regardless of whether that practice has a statutory basis or is used in an attempt to enforce significant government interests. Such practices would be unfair enough in isolation, but they are often used in combination with other practices that erode the fairness of adjudications, such as in *Chevron*¹² or *Seminole Rock*¹³, where deference was paid to the prosecuting agency

¹¹ See, e.g., *Western & Atl. Ry. Co. v. Henderson*, 279 U.S. 639, 643-644 (1929) (creating rebuttable presumption of liability against defendant who violates the Due Process Clause); *Cleveland Bd. Of Ed. v. Loudermill*, 470 U.S. 532 (1985) (Due Process Clause applies to contested administrative matters).

¹² *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

¹³ *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945).

and frequent deference was paid to federal agents, respectively, on matters of contested facts and expert opinion.

B. Specific examples of opportunities for reforming existing presumptions to conform with basic due process principles

There are many examples in support of the proposition that existing presumptions should be reviewed and revised to conform with basic due process principles. In some cases, the presumptions applied by agencies are outside the typical adjudication, but can have just as far reaching effects. Here are three highlighted by members of the Associations:

1. Federal Railroad Administration tank car inspections should not use a strict or presumptive liability standard

The Federal Railroad Administration (“FRA”) tank car inspection standard¹⁴ is problematic both because it creates a presumptive liability standard, but also does not give appropriate weight to the pre-shipping inspection reports prepared by the tank car operator. Under the standard, when an inspector identifies a loose bolt or other closure after the tank car has left the shipper’s custody and control, the FRA cites the shipper for not properly inspecting the car before releasing it into transportation service. Thus, the regulation presumes a shipper failed to perform an inspection prior to transportation based solely on a loose bolt identified well after transportation began, sometimes hundreds of miles down the line. This establishes a de facto strict liability standard, as shippers can only avoid liability by proving how the bolt came loose after it left the shipper’s custody and control. This is all but impossible. Bolts can come loose in the course of transportation or be vandalized in other railyards once out of the shipper’s custody.

Further, the regulated entity is not afforded an opportunity to verify an inspector’s findings. Only a photo of the bolt is provided, and the photo does not reflect whether the bolt was “tool tight,” as the regulation requires. There is a longstanding D.C. Circuit case directly on this issue that cautions the FRA against applying a strict liability standard by precluding the FRA from refusing to consider “evidence of any type including evidence of a proper inspection” and noting that only this construction would avoid a constitutional violation by preventing the FRA from ““under the guise of regulating the presentation of evidence, operate to preclude the party from the right to present his defense to the main fact...presumed.””¹⁵ Yet, the FRA continues to apply strict liability. Absent compelling contrary evidence, records of pre-shipment inspections should be sufficient to prove that the shipper conducted a proper inspection.

2. PHMSA should offer opportunities to challenge written warnings

PHMSA warning letters are a further example of an existing practice using presumptions that should be reviewed. It is PHMSA’s practice to send companies warning letters alleging a “probable violation” of pipeline safety regulations. These letters are uncontestable, yet available to the public, providing a means to unfairly tarnish a recipient’s reputation without any means to

¹⁴ 49 C.F.R. § 173.31(d)(1)(iv).

¹⁵ *Chem. Mfrs. Ass’n v. Dep’t of Transp.*, 105 F.3d 702, 708 (D.C. Cir. 1997).

vindicate itself. Under 49 C.F.R. § 190.205, PHMSA may issue a written warning “upon determining that a probable violation ... has occurred.” PHMSA’s standard warning claims that “[f]ailure to [correct the items identified] will result in [the regulated entity] being subject to additional enforcement action.”¹⁶ Yet, when issuing these letters, PHMSA’s allegations have not been subject to any formal process allowing the recipient to dispute the charge, raise evidence, or obtain a finding in its favor. To the public, this language does not suggest the letter to be conditional in any way. Nor does it state that it is not an *actual* finding of violation. Instead, the letter suggests that it is an official finding that the recipient violated the law and, unless the recipient complies with the letter’s demands, the agency will pursue further enforcement. PHMSA should provide a fair and transparent mechanism for disputing such written warnings.

3. Agencies should provide an opportunity for companies to challenge or correct errors in press releases

Member companies have experienced situations where an agency issued a press release without providing a timely opportunity for a company to review the release and raise timely objections to the accuracy of representations. A useful reform would provide regulated entities to challenge or correct identified errors.

One example is OSHA, which typically issues several hundred enforcement press releases each year, which include proposed penalties based on allegations, even while the employer still has the opportunity to legally challenge and adjudicate the citations. Because there are no final orders of the Occupational Safety and Health Review Commission (“OSHRC”), this raises due process implications as many citations are ultimately downgraded, or even withdrawn completely. OSHA’s use of press releases to “name and shame” harms employers’ reputations among potential customers and employees.

The U.S. Consumer Product Safety Commission (“CPSC”) also has a growing practice of issuing unilateral press releases warning consumers of various perceived dangers for consumer products. This practice represents a troubling practice of agencies subjecting regulated entities to impermissible *prima facie* presumptions of liability.¹⁷ These public press releases unfairly tarnish a regulated entity’s reputation often without providing the company more than 24 hours’ notice — or, in certain instances, no notice — even when the company has a valid dispute with the information or disagrees with the CPSC’s conclusion.¹⁸ Companies face serious consequences when the CPSC discloses information about their products. Indeed, so steep are the consequences, that one court noted that, even when a disclosure is made in error, “[the

¹⁶ See e.g., U.S. Dep’t of Transp., Pipeline & Hazardous Materials Safety Admin., *Warning Letter Cases*, https://primis.phmsa.dot.gov/comm/reports/enforce/WL_opid_0.html (last updated Mar. 3, 2020).

¹⁷ See, e.g., Consumer Prod. Safety Comm’n, *Press Release: CPSC Warns Consumers of Serious Tip-Over Hazard Posed by Hodedah HI4DR 4-Drawer Dressers* (Jan. 8, 2020) (noting the CPSC “intends to continue pressing the case for a recall with” the manufacturer.); Consumer Prod. Safety Comm’n, *Press Release: CPSC Warns Consumers to Stop Using Summer Infant (USA), Inc.’s SwaddleMe By Your Bed Sleeper* (Jan. 16, 2020) (noting that, “[a]lthough CPSC is not aware of any incidents or deaths involving the Summer Infant SwaddleMe By Your Bed Sleeper, CPSC urges consumers to stop using the product immediately”).

¹⁸ See Mike Gentine, *CPSC Data Breach: Requirements for Handling Sensitive Information*, NAT’L L. REV. (May 29, 2019), <https://www.natlawreview.com/article/cpsc-data-breach-requirements-handling-sensitive-information>.

CPSC’s] denouncement may well be tantamount to an economic death knell” because “[w]here a product is once shrouded with suspicion, especially suspicion cast upon it by the government, the harm is irretractable [sic].”¹⁹

Under the Consumer Product Safety Act (“CPSA”), 15 U.S.C. § 2051 et seq., the CPSC is required to “take reasonable steps” to ensure information is fair and accurate before making it public.²⁰ Yet, while the CPSC’s statutes do require prior notice when the agency wants to talk about a particular company (no such notice is required when discussing a category of products, even when it may otherwise be obvious which company is being referred to, resulting in the same “economic death knell”), the CPSA offers only injunctive relief in instances where the CPSC insists on making a disclosure that the company believes is inaccurate or unfair. To obtain an injunction, the company must sue the CPSC in courts that frequently defer to agencies, and the litigation unfolds in public — “a cure that may be just as bad as the disease when a company’s brand is at stake.”²¹ Further, the law does not require the agency to make its case before any neutral arbiter either before or after making the press release public, only requiring it to retract any factual errors. Again, these errors can be retracted after the press release is already public and the damage to the company and product’s brand is irreparably tarnished. Finally, even where notice is required, the CPSC can — and regularly does — shrink the notice period, reducing the time available to a company to make what could be a bet-the-company decision. To remedy these issues, the CPSC, and other agencies that issue press releases, should allow the subject company an opportunity to contest claims made in the press release.

4. Resource agencies applying the Endangered Species Act should not presume that acts will constitute a taking under the law

With respect to the ESA, member companies report they frequently encounter field staff who adopt a presumption that an action will constitute a taking under the ESA if certain indices are present, such as in the case of clearing of potential habitat. While the courts and guidance documents do not encourage such a presumption, experience indicates that there needs to be more assurances that field staff are providing a fair and objective review and a clear path within each enforcing agency to seek redress when the agency’s determination of a taking is contested.

V. What evidentiary rules apply in regulatory proceedings to guard against hearsay and/or weigh reliability and relevance? Would the application of some of the Federal Rules of Evidence create a fairer evidentiary framework, and if so, which Rules?

A. OMB should allow agencies some measure of flexibility in regulatory adjudications in the admission of relevant, credible evidence

There is no one-size-fits-all set of evidentiary rules that should apply to regulatory proceedings. As such, it would be inappropriate to apply all of the Federal Rules of Evidence to

¹⁹ *Relco, Inc. v. Consumer Prod. Safety Comm’n*, 391 F.Supp. 841, 846 (S. D. Tex. 1975) (holding plaintiff not entitled to injunction against CPSC’s administrative recall process).

²⁰ 15 U.S.C. § 2055(b)(1)–(3).

²¹ See note 18, *supra*.

all regulatory proceedings. Instead, agencies should be directed to adopt those measures that are necessary to guard against reliance on evidence that is not reliable or credible.

With regard to specific provisions for more formal adjudications, the limitations imposed by Federal Rule of Evidence 404 should be applied. Agency adjudications should, for example, constrain introduction of evidence of past violations as evidence that the particular violation being adjudicated has occurred. Similarly, as NOV's are not evidence or final action by the agency, past (or current) NOV's should not be admissible as evidence that a violation occurred or as a factor in establishing a penalty, if liability were established. Likewise, agencies should have rules that follow the core principle of Federal Rule of Evidence 407 on subsequent remedial measures. Efforts by a regulated party to address alleged non-compliance should not be discouraged due to the risk of subsequent enforcement. Further, agency proceedings should follow Federal Rule of Evidence 408 and preclude admissibility of communications and proposals made during settlement negotiations. Efforts by a regulated party to resolve a dispute should be encouraged, and thus should not be admissible in an adjudication if the matter cannot be settled by the parties.

Agencies should likewise follow good practice protecting privileged attorney-client communications, as well as attorney work product. Moreover, agency administrative adjudications should allow regulated parties to invoke an audit privilege to protect matters identified during audits. The use of audits should be encouraged as a tool to improve compliance with regulatory requirements, without the risk of the gathered information being used against a respondent in an agency adjudication.

There are, however, certain proceedings that may warrant across the board formal evidentiary rules to ensure that the proceedings are conducted fairly. For example, in EPA administrative enforcement proceedings, both Administrative Law Judges ("ALJs") and the Environmental Appeals Board have appropriately adhered to the Federal Rules of Evidence and the Federal Rules of Civil Procedure.²² That practice is sound and should be continued.

Even beyond the conduct of the hearing itself, respondents in enforcement hearings should be afforded the opportunity to provide post-hearing submissions — and to reply to any submissions made by the government. Agencies should also allow full access to the recommended decision issued after a hearing and that such recommended decision and the agency order provide an adequate explanation of the decision with findings of facts and conclusions of law. It is a matter of fundamental due process to have these basic procedures apply. Moreover, there should be an opportunity for a regulated party to petition for reconsideration of an agency decision and for a timeline under which the request will be addressed.

Following these general parameters, we provide two examples, one in the context of the ESA and one in the context of enforcement hearings by the U.S. Department of Transportation ("DOT"), to show the need for continued flexibility on these issues.

²² See, e.g., *In re Euclid of Virginia, Inc.*, 13 E.A.D. 616 (EAB 2008).

B. Agencies should employ the *Daubert* Standard for evaluating expert opinions advanced in proceedings under the Endangered Species Act

As it relates to the ESA programs, enforcement proceedings should adopt a standard for evaluating the reliability of expert opinion akin to the *Daubert* standard applicable in judicial proceedings.²³ Under such a standard, expert opinions would be scrutinized for relevance, reliability, and sound methodology. Invoking the ESA can undermine a landowner's rights to develop and use their private property. Before that type of intrusion into fundamental property rights, the complex issues associated with determining whether a particular use would improperly take a species or its habitat under the ESA should demand a higher level of scientific scrutiny. The *Daubert* process provides a readily available framework.

C. DOT rules of evidence for enforcement hearings should not change

The current rules of evidence that apply in DOT enforcement hearings provide the appropriate level of formality for DOT regulatory proceedings. The informal rules of evidence used by DOT during an enforcement hearing²⁴ allow for a cost-efficient means of adjudication in which a regulated entity can challenge the application or interpretation of a regulation, or the validity of alleged facts. Implementing more formal rules of evidence in these DOT proceedings, such as those used by federal courts, would require a regulated party to expend more resources (such as additional legal resources). Increased costs may discourage regulated entities from making valid challenges to enforcement proceedings when the cost of adjudication may exceed the cost of acquiescence. Accordingly, the current evidentiary rules should remain in place for DOT enforcement hearings.

VI. Should agencies be required to produce all evidence favorable to the respondent? What rules and/or procedures would ensure the expedient production of all exculpatory evidence?

In criminal cases, the government must provide all exculpatory evidence (commonly referred to as "*Brady* material"),²⁵ and in civil enforcement cases, defendants are entitled to all of the discovery available under the Federal Rules of Civil Procedure. This should be mirrored in the administrative context by a regulation that would require each agency to provide regulated parties with *Brady*-like information in every enforcement matter and ensure full and fair access to all records pertinent to matters of fact and law asserted by the agency. It can easily be accomplished procedurally by making full disclosure to the regulated entity during the investigation phase — and by making the disclosure an essential and required element of an initial filing of a complaint or similar document by the regulatory agency, accompanied by a certification by the regulatory body that the disclosure is true and complete. This could be

²³ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

²⁴ 49 C.F.R. § 190.211.

²⁵ *See, Brady v. Maryland*, 373 U.S. 83 (1963).

accomplished by guidance in the first instance as some agencies have done²⁶ — but to be fully effective, agencies should establish these requirements by regulation.

Early sharing of agencies’ assessments of evidence would promote basic fairness in government proceedings, but will also facilitate settlements and compliance where appropriate. As an example, as noted, it is common agency practice for some agencies not to share their inspection reports, which agencies often claim are “enforcement confidential.” These inspection reports are often one of the most important documents for any enforcement proceeding and should be promptly shared with the regulated party in any proceeding.

Early sharing of information in this way will also promote confidence in government. Regulated entities often perceive agency staff as obscuring information that does not fit comfortably within preconceived notions of appropriate outcomes or the agency’s “mission,” or ignoring contradictory information altogether. That should not be the role of regulators. The best decisions are made only where agency staff take an unbiased and hard look at all available and relevant information, including information that does not comport with their initial inclinations to bring an enforcement action. The Supreme Court’s admonition to government agents seeking only victories is just as applicable to administrative enforcement as to criminal enforcement: government agents represent not “an ordinary party to a controversy, but ... a sovereignty whose obligation to govern impartially is as compelling as its obligation to govern at all; and whose interest, therefore, in a criminal prosecution is not that it shall win a case, but that justice shall be done.”²⁷ To engage in good faith and meaningful adjudication, an agency should divulge to the regulated entity all relevant evidence, regardless of whether it supports the agency’s position or not.

VII. Do adjudicators sometimes lack independence from the enforcement arm of the agency? What reform(s) would adequately separate functions and guarantee an adjudicator’s independence?

Member companies have experienced cases where the adjudicators appeared to lack impartiality at the ALJ and other levels, suggesting that adjudicators may lack complete independence from the enforcement arm of a relevant agency. Ensuring the decision-maker is truly neutral and independent is a core due process principle that agencies must uphold.²⁸ Effective reforms could remedy a lack of impartiality.

A. ALJ appointments should conform to *Lucia v. SEC*

To ensure independence, agencies should review ALJ appointments to ensure they conform with the U.S. Supreme Court’s 2018 decision in *Lucia v. SEC*, which held that

²⁶ Fed. Energy Regulatory Comm’n, *Policy Statement on Disclosure of Exculpatory Materials* (Dec. 17, 2009), <https://www.ferc.gov/whats-new/comm-meet/2009/121709/M-2.pdf>.

²⁷ *Berger v. United States*, 295 U.S. 78, 88 (1935).

²⁸ For example, commentators have observed that at least some agency adjudicators have ruled exclusively for the agency, suggesting a lack of true independence and impartiality. J. Wright, *Supreme Court Should Tell FTC To Listen To Economists, Not Competitors On Antitrust* (March 14, 2016) available at <https://www.forbes.com/sites/danielfisher/2016/03/14/supreme-court-should-tell-ftc-on-antitrust/#5f135dfd7c16>.

Securities and Exchange Commission (“SEC”) ALJs exercised significant authority without a proper appointment, in violation of the U.S. Constitution’s Appointments Clause.²⁹ There, the Supreme Court held that several factors determine whether an ALJ is an “Officer of the United States within the meaning of the Appointments Clause” or a mere employee. An officer has a continuing and permanent position, exercises significant discretion in their duties (such as discretion over discovery, evidence, and the enforcement of orders), and is vested with authority to bind the government and private parties (*i.e.*, their findings of facts and conclusions of law do not require approval from a higher officer for them to become effective).³⁰

For ALJs that are determined to be “Officers of the United States,” agencies should take immediate steps to have them appropriately appointed, if they are not already. Where agencies do not find their ALJs to be “Officers of the United States,” however, they should re-examine whether these ALJs may truly provide independent adjudications in enforcement proceedings. If an ALJ is an employee, that means that their terms of employment may be dependent on the approval of agency officers, providing incentives to produce findings for the agency and higher penalties. If they lack the authority to bind the government, such as by requiring the approval of their decisions by an agency officer, then there is no independence from the agency itself. The Associations cannot categorically state that non-officers are incapable of providing a fair and independent hearing, as each set of agency procedures may differ. However, in most circumstances, it would be difficult to understand how anyone, other than a duly appointed “Officer of the United States,” could provide a fair and independent hearing.

B. PHMSA should assure impartiality and separation of powers for all enforcement proceedings

The impartiality and separation of functions should be exercised throughout all the methods of enforcement and response. As an example, since PHMSA introduced a Presiding Official and prohibited *ex parte* communications, the agency’s administrative adjudication proceedings have exhibited more impartiality when a regulated entity exercises its right to a formal hearing. This should be expanded to ensure that in any enforcement proceeding, there should be an opportunity to request a formal hearing before a PHMSA ALJ.

Moreover, it remains unclear that the appropriate separation of functions, as required under 49 C.F.R. § 190.210, occurs during other enforcement proceedings, such as when a regulated entity provides only a written response to a notice of probable violation or notice of amendment, waiving a formal hearing. PHMSA has published its Pipeline Enforcement Procedures Manual; however, certain sections are still not available for review.³¹ To maintain transparency and assure that adjudicators have independence from the enforcement arm, the agency should make sure that all of these types of procedures are publicly accessible.

²⁹ *Lucia v. SEC*, 138 S. Ct. 2044 (2018).

³⁰ *Id.* at 2051–55.

³¹ U.S. Dep’t of Transp., Pipeline & Hazardous Materials Safety Admin., *Pipeline Enforcement Procedures Manual* § 4, <https://cms.phmsa.dot.gov/pipeline/enforcement/section-4-administrative-enforcement-processes-0> (last visited Mar. 12, 2020).

VIII. Do agencies provide enough transparency regarding penalties and fines? Are penalties generally fair and proportionate to the infractions for which they are assessed? What reform(s) would ensure consistency and transparency regarding regulatory penalties for a particular agency or the federal government as a whole?

Transparency regarding how penalties are calculated is inconsistent across agencies. Some agencies provide a great degree of transparency, while others provide substantially less information or do so inconsistently. As a general matter, consistency and transparency for regulatory agencies should be required across the federal government. Agencies should be required to explain the bases for their penalty demands — and provide an easy mechanism for stakeholders to review and compare penalties assessed to ensure transparency and fairness.

For example, at EPA, the level of detail provided by enforcement staff varies widely depending upon the program being enforced and the EPA regional office. While in some cases there may be a verbal explanation, it may be difficult if not impossible for regulated entities to recreate the penalty calculation from that explanation — even when it is founded upon an EPA penalty policy. Further, the broad parameters found in those policies can result in inexplicably disparate penalty amounts. For instance, we have seen examples where one company may be assessed a higher penalty for recordkeeping and reporting violations than another company that allegedly affected persons and the environment.

Regulated parties have also observed inconsistencies in the way PHMSA has asserted penalties, with numerous examples of seemingly identical circumstances where the same violations result in materially different penalty assessments. In many instances where a regulated entity provided additional information or mitigating factors in an effort to achieve a penalty reduction, PHMSA declined to consider that information when issuing the final order.

To reform this process and ensure appropriate transparency and fairness, there should be a clear approach across agencies. This would include (1) a written explanation of how an agency calculated a proposed penalty, (2) an accompanying worksheet (such as the attached example, Attachment A, of a penalty calculation worksheet from the Texas Commission on Environmental Quality), (3) references to appropriate documentation and policies, and (4) documented consideration of mitigating factors and other information the regulated entity provides describing the agency's analysis of each factor.³² A written explanation allows the regulated entity to review the calculation, address incorrect inputs, provide a substantive response based on the agency's approach, and otherwise ensure that the penalty is applied fairly. A written format based on existing regulations and policies can also provide guidelines to make sure that violations are appropriately penalized based on common sense factors, including whether harm actually occurred.

Further, providing documented access on an agency's website to final penalty assessments in a way that is accessible to the regulated community will provide helpful transparency and ensure better consistency across an agency. At present, administrative dockets are not uniformly maintained — and then are often difficult to navigate. A regulated entity

³² For example, PHMSA regulations direct the agency to evaluate specific “assessment considerations” when assessing penalties. 49 C.F.R. § 190.225. Those should be addressed and documented for the regulated party.

should have reasonable access to that information in a timely manner so it can evaluate if it is being treated the same as a similarly situated competitor.

IX. When do regulatory investigations and/or adjudications coerce Americans into resolutions/settlements? What safeguards would systematically prevent unfair and/or coercive resolutions?

The Associations have found a number of instances in which regulatory investigations or adjudications coerce regulated entities into resolutions or settlements. An essential safeguard would be to restrain the agency's ability to leverage its potentially expansive enforcement powers (*e.g.*, maximum administrative penalties) to coerce a party into a settlement, including settlements that provide relief beyond what the agency claims is necessary for compliance. There should likewise be policies that advance the goal of resolving disputes through fair and reasonable settlements.

A. Regulatory agencies should not be permitted to coerce settlements through use of penalties

Member companies found coerced resolutions and settlements in situations where the proposed penalty was reduced, but the cost of proceeding to an adjudicatory proceeding was substantially higher. This may be because the agency threatened to impose or seek the maximum penalties if the matter was not settled promptly or it may be simply because of the enormous costs associated with pursuing an administrative appeal, which often requires engaging outside legal counsel and ties up internal company resources for months. The rational decision in such a situation is to avoid the transaction costs of contesting the agency's claims and pay the proposed penalty, even where the company believes it has no real liability. Unfortunately, agency enforcement officials are aware of this and use it as leverage to extract penalties in settlement. While settlement can serve a useful purpose where there is a legitimate dispute as to the facts and/or the law, it should never be used to collect even reduced penalties in the absence of a good faith dispute as to whether there actually was a regulatory violation.³³ The power of this coercion is compounded should a regulated entity then face higher penalties in a subsequent dispute as a "repeat" offender. Having been coerced to settle once to avoid the transaction costs of proceeding, they then face enhanced burdens if there are any subsequent disputes. There should be reforms required of agencies that impose reasonable limits on these types of actions, including clearly defined limits in agency penalty policies in administrative matters and formal opportunities to elevate demands made by staff to agency management to ensure fair treatment. Agency enforcement officials should always bear in mind that their mission is to ensure compliance, within the boundaries of their jurisdiction and the law, and not to collect penalties.

Accordingly, agencies should avoid assessing a penalty against a company when another agency has already done so for the same activity. As an example, the U.S. Department of Housing and Urban Development ("HUD") recently proposed revisions to its Affirmatively

³³ Agency enforcement officials will occasionally refuse to engage in a reasonable debate regarding the merits of a particular proposed citation, offering instead a reduced penalty or willingness to drop other citations in the same action as a compromise to preserve a citation that is apparently factually groundless or indisputably contrary to the law. This is particularly true when a recent judicial decision has gone against the agency and the agency wishes to continue to enforce against the court's direction.

Furthering Fair Housing (“AFFH”) regulation that requires every recipient of HUD funding to reduce obstacles to fair housing choice.³⁴ The proposed rule would prevent municipalities that are found “in violation of civil rights law” from being considered an “outstanding AFFH performer.” By penalizing municipalities that have already been penalized by an ALJ or court, HUD is exceeding its authority under the Fair Housing Act (“FHA”), 42 U.S.C. 3601 et seq. The enforcement sections of the FHA provide specific penalties for those who violate the act, but none of these sections allow HUD to dispense additional penalties post-adjudication. Moreover, HUD recognizes that the ALJ and court processes allow for penalties after a hearing and full finding of the facts. Yet, the additional penalty imposed under the proposed rule (keeping a jurisdiction from being an outstanding AFFH performer) provides no such hearing. Furthermore, adding an AFFH penalty to an FHA case brought by the U.S. Department of Justice (“DOJ”) or HUD may force a municipality to settle a case it may want to defend because it cannot risk the AFFH penalty. This allows DOJ and HUD to put a thumb on the scale in a way that Congress did not anticipate.

B. Agencies should prioritize compliance education over enforcement, particularly when small businesses are involved

Faced with the prospect of significant civil penalties, attorney fees and public relations issues, many companies, particularly those that are small businesses, believe they must settle disputes and not challenge allegations, despite valid defenses and explanations. In addition to improving enforcement and investigation procedures, where there are opportunities, agencies should be directed to identify ways to prioritize compliance and education of regulated parties.

An example is the enforcement of the accessibility requirements of the FHA. A clear and urgent nationwide need exists to educate builders and their contractors in the field on the accessibility requirements of the FHA. A review of the current state of FHA accessibility litigation and member companies’ experiences reveals that builders are unfamiliar or often confused by, rather than intentionally skirting, their responsibilities under the law.

Rather than helping to reduce the confusion surrounding the FHA’s accessibility requirements, HUD and DOJ seem more interested in defining their success based on the number of enforcement actions filed. In 2017, HUD and its Fair Housing Assistance Program partners investigated, resolved or charged nearly 5,000 cases alleging discrimination based on disability.³⁵ Consistent with past years, complaints involving disability discrimination represented the single largest category of complaint filings at 59.4% of total complaints filed with HUD. From 2009 to 2015, DOJ’s Civil Rights Division filed 141 cases to enforce the FHA with 14% of those cases alleging discrimination based on a failure by developers, builders, architects, engineers and owners to design and construct multifamily housing in compliance with the FHA. It is important to note that the above-mentioned statistics do not reflect the fact that the vast majority of FHA

³⁴ 85 Fed. Reg. 2,041 (Jan. 14, 2020).

³⁵ U.S. Dep’t of Hous. & Urban Dev., Office of Fair Hous. & Equal Opportunity, *Office of Fair Housing and Equal Opportunity, Annual Report to Congress* (FY 2017), https://www.hud.gov/sites/dfiles/FHEO/images/FHEO_Annual_Report_2017-508c.pdf.

design and construction lawsuits are settled before they reach the courtroom, and therefore go undocumented.

HUD should devote greater attention to improving the quality of information available to homebuilders on federal accessibility requirements and place less emphasis on enforcement. In 2018, HUD, through its Fair Housing Initiatives Program (“FHIP”), awarded \$30,000,000 to organizations that conduct intake, testing, investigation and litigation for FHA complaints. In contrast, only \$7,450,000 million was provided to organizations that conduct FHA education and outreach efforts.³⁶

C. Regulatory agencies should not be permitted to coerce implementation of additional measures beyond what is necessary to achieve compliance

Relatedly, agencies, and EPA in particular, have historically used administrative investigations and threatened expanded enforcement to coerce a regulated party into accepting measures that go beyond straight compliance with the law. Specifically, agency enforcement staff assert that they can seek large penalties (in the many millions of dollars) due to the high daily maximum penalties provided by statute — or the regulated party can agree to implement measures that are effectively “beyond compliance,” as they exceed obligations otherwise required by existing law. Agencies, such as EPA, then use the agreement by one party to leverage similar concessions from others in the same industry, instead of through a new rulemaking.

To safeguard against this practice, agencies should be directed to limit enforcement to bringing regulated parties into compliance. Only requirements established by statute or by properly promulgated regulations should be imposed as part of enforcement proceedings. Enforcement should not be used to circumvent the notice and comment rulemaking process to advance an agenda and impose new industry obligations.

Another potential safeguard would be to require the agency to adopt policies that facilitate fair and reasonable settlements. One mechanism would be for the agency to sponsor mediation with an independent mediator for matters above a specified materiality level, if requested by the regulated party. In our experience, the right mediator can offset an agency’s refusal to engage on substantive issues and encourage compromise by the agency.

D. Regulatory agencies should not be permitted to use an existing enforcement dispute to deprive a regulated party of other rights under other agency programs

Agencies should also be directed not to use their enforcement authority to pressure a regulated entity to resolve a dispute or risk their ability to participate in agency programs, absent clear statutory authority to do so. A situation with the EPA ENERGY STAR Partner of the Year award offers an example. Each year, EPA honors a select group of organizations that have made outstanding contributions to protecting the environment through superior energy efficiency. This

³⁶ U.S. Dep’t of Hous. & Urban Dev., *HUD Awards \$37 million to fight housing discrimination* (Mar. 6, 2018), <https://archives.hud.gov/news/2018/pr18-004.cfm>.

is an award many member companies seek that helps both the bottom line and the environment. It is widely recognized by member companies, their customers, the public and consumers, and thus can affect company sales. We understand that after regulated entities submit their ENERGY STAR applications and EPA selects proposed winners, EPA ENERGY STAR representatives solicit feedback from EPA regional offices. However, this feedback process is informal, lacks clear criteria by which an entity is disqualified, and offers no opportunity for the entity to be heard.

In one particular circumstance, EPA regional office enforcement representatives objected to a member company's nomination as an ENERGY STAR Partner of the Year in what appears to be an effort to force them to settle an enforcement case. As a consequence, the EPA ENERGY STAR program declined to give this award to the member company without even an opportunity to hear the details of the objection or provide a response. The context was important. The last EPA inspection of the member company's subject facility had occurred over a year before, there were no outstanding notices of violation, and the entity had won this same award consecutively in the years leading up to this denial — including during years when the inspections at issue occurred. EPA should not attempt to force resolution of enforcements by disqualifying a regulated entity from participating in such programs. Moreover, EPA should not rely on undisclosed objections from regional offices in matters where there has been no final enforcement case resolution, and certainly not without providing the regulated entity the opportunity to refute the regional office's allegations.

E. OSHA currently uses practices to coerce resolutions that should be reformed

There are a number of reforms that should be considered by OSHA.

For example, OSHA should revise its Multi-Employer Citation Policy, Directive Number CPL 2-0.124, to provide clear guidance on the duty of care general contractors owe trade subcontractors for safety-related issues on the jobsite. The policy outlines agency procedures for allowing compliance officers to issue citations on work sites where there is more than one employer. As currently enforced on construction sites, this policy allows OSHA to issue citations to a general contractor for safety violations created by subcontractors, even if none of the general contractor's employees are exposed to the hazardous condition, and even if none of the general contractor's employees are on the construction site. The policy serves as a coercive enforcement tool that is not specifically included in the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq., limits OSHA's jurisdiction to the "employer-employee" relationship, and states that, "Each employer shall furnish to each of *his employees* employment and a place of employment which are free from recognized hazards."³⁷ The act does not impose a general duty on a general contractor to police the OSHA compliance activities of trade subcontractors, who are not direct employees. Accordingly, the Multi-Employer Citation Policy, Directive Number CPL 2-0.124 should be revised to better align with the Occupational Safety and Health Act's directive.

In addition, employers should have an opportunity to defend themselves against employee statements that are made during OSHA inspections and investigations. OSHA is

³⁷ 29 U.S.C. § 654 (emphasis added).

permitted to interview and take statements from employees, and these are memorialized in the case file and are often critical to OSHA making its case against an employer and issuing citations. OSHA essentially redacts entire statements from employees throughout almost the entire discovery and adjudication process, and employers have no real means to defend themselves against accusations that may or may not be true. This puts employers at a serious disadvantage, and also can be coercive to forcing them to settle. While it is appropriate to protect government informants, agencies should not simply redact all statements during the discovery process.

Further, agencies should engage in active oversight to ensure inspectors follow procedures and stay within the scope of their authority, as well as to guard against abuses of authority. Member companies reported experiences with some OSHA inspectors that use confrontational, abrasive, and harassing tactics when dealing with company employees, who may not be accustomed to dealing with regulators and may be easily intimidated by such tactics.

As part of their oversight of inspectors, agencies should ensure that certain facilities are not receiving undue attention of inspectors by clearly framing the maximum frequency of inspections at a particular facility. As noted above, member companies report that some facilities may be geographically convenient for an agency office or for a particular inspector, and thus, are subject to a disproportionate number of inspections, investigations and audits, as compared to their peers. Agencies should monitor inspection frequency and adjust accordingly.

X. Are agencies and agency staff accountable to the public in the context of enforcement and adjudications? If not, how can agencies create greater accountability?

Agency staff are often not accountable to the public in the context of enforcement and adjudications. Indeed, it is often the case that once a matter is “in enforcement,” the agency management will not engage — or is obligated not to engage — in a substantive discussion of the way in which enforcement may be interpreting and applying the agency’s regulations or facilitating a fair resolution of a dispute. That is a common experience for regulated parties who are subject to enforcement by EPA.

As a general matter, ensuring agencies adopt and implement safeguards already outlined here should improve accountability. For example: (1) enhanced sharing of information, including *Brady*-like material and inspection reports and related documents, (2) greater transparency detailing penalty demands, (3) enhanced availability of information concerning penalties assessed to improve fairness and comparability across industry, (4) improved procedures during proceedings, such as enhanced rigor with scientific requirements for ESA-related adjudications, and (5) providing for independent mediators in an effort to resolve matters fairly — and properly independent ALJs.

In the specific context of enforcement and adjudication under the ESA, regulated parties report concerns with agency staff accountability. ESA issues are often controversial and draw intense interest from various stakeholders and the public at large. Surprisingly, however, there is little regulation establishing the identities of the proper parties to these processes and when, and under what circumstances, an agency should entertain discussions with third parties not directly

involved. There is also no meaningful guidance on an agency's duty to disclose third-party contacts and information. Standards and guidance should be developed to provide adequate notice to regulated entities so they know when to expect third-party involvement.

There are, however, other efforts to increase accountability and transparency, which should be encouraged and enhanced. For instance, the ESA requires agencies to use "the best scientific and commercial data available" in rendering decisions.³⁸ Moreover, in its 2019 Guidance, OMB stressed to all federal agencies the importance of careful and transparent compliance with the Information Quality Act.³⁹ Still, much more could be done, as these requirements are followed inconsistently. The agencies that implement the ESA should improve and document training on these requirements, with clear lines of meaningful appeal established. Far too often, where a party believes that an agency's field staff are failing to meet applicable best science standards, the only practical route is a series of *ad hoc* communications to superiors or political appeals, which are highly disruptive, unpredictable, and elusive for smaller companies. For the benefit of both the agencies and the regulated community, there should be a standardized process for review of agency procedures and for regulated entities to submit complaints.

XI. Other regulatory areas for due process reform

In addition to providing examples and recommendations for the specific topics listed in the Notice, we would like to take this opportunity to provide our feedback on other issues where there are due process shortfalls.

A. EPA should reform its storm water pollution prevention compliance and enforcement procedures

Member companies experienced several inefficiencies related to EPA's storm water pollution prevention compliance and enforcement procedures. Improvements in these procedures will provide important assistance to the small business owners across the country that must comply with these construction-related requirements. Accordingly, we recommend OMB urge the agency to implement reforms to streamline these regulatory enforcement issues.

For example, the level of detail and work needed to develop and implement Stormwater Pollution Prevention Plans ("SWPPPs") under EPA's Construction General Permit ("CGP") is often overwhelming, complicated, and confusing for small entities. EPA's current 300-plus page CGP contains identical requirements for all sites, regardless of site size or risk.⁴⁰ Association member, NAHB, previously worked with EPA to develop a simplified compliance template for single-family homes on large subdivisions. We request that EPA turn this template into a streamlined single lot permit. Because a small lot permit will be short, better specify permit

³⁸ 16 U.S.C. § 1533(b)(1)(A).

³⁹ Memorandum from Russell T. Vought, Acting Dir., U.S. Office of Mgmt. & Budget, to Heads of Exec. Dep'ts & Agencies (Apr. 24, 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

⁴⁰ U.S. Evtl. Prot. Agency, *2017 Construction General Permit (CGP)*, <https://www.epa.gov/npdes/2017-construction-general-permit-cgp> (last updated Feb. 27, 2020).

requirements, and be more understandable, it will foster higher rates of compliance among these low-risk sites.

There should be a formal EPA policy clarifying the role of on-site compliance plans for construction storm water, confirming that they do not create or equate to permit limits. In February 2017, EPA's most recent CGP clarified SWPPPs are a flexible "external tool" to carry out permit responsibilities.⁴¹ However, builders continue to report violations for minor differences between compliance plans and actual site practices.

Regulated entities should have the opportunity to cure minor violations in the field without the threat of a monetary penalty. EPA's current storm water pollution prevention compliance and enforcement policies provide EPA site inspectors with the option to leave behind a preliminary inspection checklist that notifies the site operator (*i.e.*, developer or builder) of potential violations identified by the EPA inspector;⁴² however, our members report limited use of these checklists by EPA inspectors in the field. Furthermore, EPA's checklist does not provide developers or builders any assurance that even prompt correction of any deficiencies identified by an EPA inspector could avoid subsequent administrative fines and penalties. A missed opportunity exists during EPA's storm water inspection process to educate and provide assistance to operators trying to comply in good faith. Rather than assessing monetary penalties for every infraction, EPA inspectors could identify minor infractions to be corrected immediately or within a specific period of time without threat of further enforcement; provided those violations do not result in environmental harm. Such "right to cure" protection for first time violators would remove the fear factor associated with those trying to comply in good faith.

B. Agencies should not use interpretations that conflict with statutory and regulatory texts

Many agencies improperly go beyond statutes and regulations to impose legal obligations. As noted, an effective reform will provide clear direction to agencies to stay within the statutory framework to resolve administrative proceedings and not seek to use measures beyond compliance.

As an example, PHMSA continues to base enforcement on broad application of letters of interpretation, frequently asked questions ("FAQs"), guidance documents and similar materials. Use of these materials has resulted in approaches to enforcement that do not align with governing statutes and regulations. An example of this is enforcement under the Operator Qualification ("OQ") rule,⁴³ where recent orders and notices of probable violation against some companies suggest that PHMSA is using an interpretation of the OQ rule that invalidates the parameters of a four-part test in the regulatory text which specifies activities that qualify as covered tasks under 40 C.F.R. § 192.801. Suddenly, all operations and maintenance tasks that affect the integrity of a pipeline system are covered tasks. PHMSA's broad interpretation

⁴¹ *Id.*

⁴² U.S. Env'tl. Prot. Agency, *Protocol for Conducting Environmental Compliance Audits under the Stormwater Program* (Jan. 2005), <https://www.epa.gov/sites/production/files/documents/apcol-stormwater.pdf>.

⁴³ See 49 C.F.R. Part 192, Subpart N and 49 C.F.R. Part 195, Subpart G.

contradicts the regulatory language, creating inconsistency and uncertainty for regulated entities. There is growing concern among regulated entities that PHMSA may continue to regulate all operations, maintenance, and repair activities as covered tasks under the OQ rule. This would drastically alter qualification of personnel and outside contractors. Should this trend for broad interpretation continue, the reach of the OQ rule would expand so that 40 C.F.R. §§ 195.422 and 195.3 would become the standards for delineating OQ programs, rather than the original scope of 49 C.F.R. Part 195, Subpart G and particularly the four-part test.

To address concerns regarding the expansion of the OQ rule, we recommend PHMSA undertake a joint initiative to meet with local, state and federal regulators and regulated entities to discuss the four-part test and PHMSA's basis for its interpretation. PHMSA should also provide joint training sessions for regulators and regulated entities to help them interpret the four-part test based on an understanding developed from the joint initiative. While this process occurs, regulatory enforcement based on the four-part test should be suspended.

Another example is enforcement by HUD and DOJ of the agencies' own interpretation of the FHA and HUD's guidance for satisfying the accessibility requirements. HUD's guidelines are available through the agency's 1991 Fair Housing Accessibility Guidelines ("Guidelines"),⁴⁴ the 1996 and revised 1998 HUD Design Manual,⁴⁵ as well as through HUD's Questions and Answers about the Guidelines issued in 1994.⁴⁶ When HUD promulgated the Guidelines in 1991, it made clear that the FHA, not the Guidelines, set the minimum accessibility requirements.⁴⁷ With the release of its revised Design Manual in 1988, HUD again announced that the Guidelines "are not mandatory, but are intended to provide a safe harbor for compliance with the accessibility requirements of the Fair Housing Act."⁴⁸ Despite these statements, both HUD and DOJ continue to strictly enforce the Guidelines and their own interpretation of the law.

C. Agencies should be prohibited from relying on unwritten agency practice and guidance in enforcement proceedings

All agencies should adopt the DOJ policy that prohibits treating agency guidance documents as binding rules.⁴⁹ The policy should unquestionably extend to unwritten agency practice, as neither should impose legal obligations on private parties. Although the DOJ policy was issued on civil judicial matters, we believe many of the same principles and concerns exist in the context of regulatory enforcement. It is certainly inconsistent with both due process and the Administrative Procedure Act, 5 U.S.C. § 500 et seq., for regulated entities to be subject to

⁴⁴ See 56 Fed. Reg. 9,472 (Mar. 6, 1991).

⁴⁵ U.S. Dep't of Hous. & Urban Dev., *Fair Housing Act Design Manual: A Manual to Assist Designers and Builders in Meeting the Accessibility Requirements of the Fair Housing Act* (rev. Apr. 1998) ("*Fair Housing Act Design Manual*"), <https://www.huduser.gov/portal/publications/PDF/FAIRHOUSING/fairfull.pdf>.

⁴⁶ U.S. Dep't of Hous. & Urban Dev., *Questions and Answers About the Guidelines*, https://www.hud.gov/program_offices/fair_housing_equal_opp/disabilities/fhefhasp (last visited Mar. 12, 2020).

⁴⁷ 56 Fed. Reg. at 9,478.

⁴⁸ *Fair Housing Act Design Manual* at 2.

⁴⁹ Memorandum from The Associate Attorney General, U.S. Dep't of Justice, to Heads of Civil Litigating Components United States Attorneys (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>.

unwritten rules that are not only unofficial in character, but subject to arbitrary interpretation and re-interpretation without prior notice and opportunity to comment.

An example involves the Federal Trade Commission's ("FTC") oversight of data security and privacy practices. Although there is no comprehensive statutory framework, the FTC has stepped up to police the vast number of data security and privacy practices not covered by the few Internet privacy and cyber security statutes. Given the immensely broad language of its authorizing statute, which essentially grants the FTC enforcement powers over any business activity "in or affecting commerce," the FTC has extended its power to the cyber security practices of any company susceptible to cyber-attacks.⁵⁰ However, in filling this vacuum, the FTC has failed to provide companies with a framework that provides any "'ascertainable certainty' of the FTC's interpretation of what specific cyber security practices" are considered reasonable, resulting in confusion in both legal and business communities.⁵¹

With cyber-crime costs expected to reach \$6 trillion by 2021,⁵² business communities can ill afford to have to anticipate the approaches of both hackers and federal regulators simultaneously, and it would seem more practical for the agency to help guide businesses through regulations designed to better protect their consumers. Yet, rather than promulgate rules, the FTC has instead chosen to approach the issue through case-by-case enforcement actions, almost always ending in consent decrees.

Since 2002, the FTC has brought nearly 60 data security enforcement actions against companies whose computers and technological infrastructure were breached or compromised by hackers, with all but two of these suits not ending in consent decrees.⁵³ After one of those companies ultimately settled, only LabMD, a small, 30 employee medical testing company, remained as the sole company that stood up to the FTC and did not settle — a decision that led to the company's demise, despite its decision to challenge the FTC ultimately being vindicated by the Eleventh Circuit over a decade later.⁵⁴ That panel of three Eleventh Circuit judges decisively rejected the FTC's use of broad, vague consent decrees in *LabMD, Inc. v. FTC*, holding that the Commission may only bar specific practices, and cannot require a company "to overhaul and replace its data-security program to meet an indeterminable standard of reasonableness."⁵⁵

⁵⁰ According to a 2016 study, the top five U.S. industries susceptible of cyber-attacks are healthcare, manufacturing, financial services, government and transportation, although very few industries are not affected by cyber-risks. Steve Morgan, *Top 5 Industries At Risk of Cyber-Attacks*, *Forbes* (May 13, 2016), <https://www.forbes.com/sites/stevemorgan/2016/05/13/list-of-the-5-most-cyber-attacked-industries/#7ce3ebdf715e>.

⁵¹ *Fed. Trade Comm'n v. Wyndham Worldwide Corp.*, 799 F.3d 236, 256, n.21 (3d Cir. 2015).

⁵² Steve Morgan, *Cybercrime Damages \$6 Trillion By 2021*, *CYBERCRIME MAGAZINE* (Oct. 16, 2017), <https://cybersecurityventures.com/hackerpocalypse-cybercrime-report-2016/>.

⁵³ Justin (Gus) Hurwitz, *Data Security and the FTC's Uncommon Law*, 101 IOWA L. REV. 955, 972 (2016) ("To date the FTC has brought more than 50 data security actions; all but two of these actions have settled) [hereinafter Hurwitz, *Uncommon Law*].

⁵⁴ See Dune Lawrence, *A Leak Wounded This Company. Fighting the Feds Finished It Off*, *BLOOMBERG* (April 25, 2016), <https://www.bloomberg.com/features/2016-labmd-ftc-tiversa/>.

⁵⁵ *LabMD, Inc. v. FTC*, 776 F.3d 1275 (11th Cir. 2015).

As highlighted by *LabMD*, as well as *Wyndham*, the FTC’s use of consent decrees in enforcing data security and privacy practices has deprived the business community of the regulatory clarity necessary for our economy to grow.⁵⁶ The FTC’s practice is so troubling, in fact, that it led one court, despite being forced to ultimately deny the review on procedural grounds, to directly chastise the FTC’s counsel, stating:

No wonder you can’t get this resolved, because if [a 20-year consent order is] the opening salvo, even I would be outraged, or at least I wouldn’t be very receptive to it if that’s the opening bid ... You have been completely unreasonable about this. And even today you are not willing to accept any responsibility ... *I think that you will admit that there are no security standards from the FTC.* You kind of take them as they come and decide whether somebody’s practices were or were not within what’s permissible from your eyes. [H]ow does any company in the United States operate when ... [it] says, well, tell me exactly what we are supposed to do, and you say, well, all we can say is you are not supposed to do what you did ... *[Y]ou ought to give them some guidance as to what you do and do not expect, what is or is not required.* You are a regulatory agency. I suspect you can do that.⁵⁷

According to the FTC, “[t]he touchstone of the [FTC’s] approach [to data security] ... is reasonableness.” Yet, under this vague and highly subjective standard, and without more guidance, one can only question how a company would know that their policies are sufficient. Even to the extent the consent decrees provide companies with guidance, as both the courts and commentators have noted, “the standard language that the FTC uses is terse and offers little in the way of specifics about the components of a compliance program.”⁵⁸ Consequently, “aside from requiring the designation of an adequately trained chief data security or privacy officer and the undertaking of regular risk assessments,” anyone seeking to design a program that complies with FTC expectations must look to the complaints “to parse out what the FTC views as ‘unreasonable’—and, by negation, reasonable—privacy and data security procedures.” Unfortunately, given the Commission’s recent statement that “data security enforcement remains a critical FTC priority,” it seems like this trend is not only likely to continue, but may actually accelerate as the risk of cyber-attacks increases.⁵⁹ If the FTC intends to continue enforcement against data security and privacy practices, it should engage in a rulemaking to establish clear standards, not disparate enforcement actions that end in consent decrees.

⁵⁶ See *Nat’l Petroleum Refiners Ass’n v. F.T.C.*, 482 F.2d 672, 675 (D.C. Cir. 1973) (recognizing that “courts have stressed the advantages of efficiency and expedition which inhere in reliance on rule-making instead of adjudication alone,” including in providing businesses with greater certainty as to what business practices are not permissible).

⁵⁷ Transcript of Proceedings at 91, 94–95, *LabMD, Inc. v. Fed. Trade Comm’n*, No. 1:14-CV-810-WSD, 2014 WL 1908716 (N.D. Ga. May 7, 2014) (emphasis added).

⁵⁸ Patricia Bailin, *IAPP Westin Research Center, Study: What FTC Enforcement Actions Teach Us About the Features of Reasonable Privacy and Data Security Practices* 1 (2015), https://iapp.org/media/pdf/resource_center/FTC-WhitePaper_V4.pdf.

⁵⁹ Jessica Rich, *From Health Claims to Big Data: FTC Advertising and Privacy Priorities for Today’s Marketplace — Brand Activation Association Keynote* (Nov. 7, 2014), <https://www.ftc.gov/public-statements/2014/11/health-claims-big-data-ftc-advertising-privacy-priorities-todays>.

D. Agencies should be directed to narrowly frame demands for tolling agreements to toll the statute of limitations on claims

Member companies report that agencies requested regulated parties to enter into broad agreements to toll the applicable statute of limitations on claims well beyond the specific matters that may be at issue. This is often the case with EPA. In most instances, any tolling agreement should cover only the specific issues raised in an investigation, not every conceivable subject under the relevant statute. If the agency finds that a broader tolling agreement is warranted, then when the matter is ultimately resolved, the release should mirror the scope of the original tolling agreement. Moreover, tolling agreements should not be open-ended, but should have an end date. Along the same lines, if a settlement occurs, it should be standard practice to void the tolling agreement retroactively.

E. There should be reform of civil judicial enforcement

The Associations appreciate the opportunity to provide comments on due process issues regarding regulatory enforcement and adjudication; however, we also have concerns regarding due process in civil judicial enforcement. We believe there should be a set of due process considerations to guide DOJ civil judicial enforcement, as administrative enforcement tends to focus on smaller, less complex cases. Accordingly, we take this opportunity to recommend that OMB publish a separate RFI to address reforms for civil judicial enforcement.

* * *

In sum, the Associations believe many regulatory areas should be reformed to ensure better due process. In the past, reforms to environmental regulations were particularly slow. For instance, pre-enforcement judicial review under the Clean Water Act, 33 U.S.C. § 1251 et seq., was an issue that took nearly two decades and two Supreme Court cases to address.⁶⁰ The Associations appreciate that OMB is taking initiative now to correct issues in a timely and cost-effective manner. We look forward to continuing to engage with OMB on this important matter.

Respectfully submitted,

American Fuel & Petrochemical Manufacturers
American Petroleum Institute
American Chemistry Council
National Association of Manufacturers
National Association of Home Builders of the United States

⁶⁰ *Sackett v. EPA*, 132 S. Ct. 1367 (2012); *Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807 (2016).