

## Regulatory Consultation in the United States

Summary for Bertelsmann-GW Workshop on Regulatory Consultation

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This paper provides an overview of the U.S. regulatory process to facilitate discussion of stakeholder consultation at the joint Bertelsmann Stiftung and George Washington University Regulatory Studies Center workshop on December 1, 2010. U.S. procedures for developing regulations derive from the U.S. Constitution and the 1946 Administrative Procedure Act (APA). While more recent laws and executive orders provide for additional analytical requirements, review, and consultation, the APA has guided the regulatory process and the role for the public for almost 65 years. This paper summarizes the Constitutional framework and the APA requirements, and then reviews the stages of rulemaking and the role for public consultation at each stage.

### U.S. Constitutional Framework

The U.S. Constitution “divides power among sovereigns and among branches of government precisely so that we may resist the temptation to concentrate power in one location as an expedient solution to the crisis of the day.”<sup>1</sup> Under this “*separation of powers*” principle, power is divided among three branches of government—the legislative branch, the executive branch, and the judicial branch. The U.S. Constitution also includes *checks and balances*, through which the powers or decisions of one branch can be challenged by another branch.

The Constitution grants the **legislative branch** the power to pass laws. Article 1 of the Constitution establishes the Senate and House of Representatives and vests all federal legislative powers in these bodies. The most relevant section for regulatory purposes is the power “to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes,” often referred to as the “commerce clause.” Note that individual States regulate activities that do not involve interstate commerce, as clarified in the 10<sup>th</sup> amendment to the Constitution, which states, “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

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<sup>1</sup> Supreme Court in *New York v. United States*, 505 U.S. 144, 187 (1992).

To become law, a statute must pass both houses of Congress and be signed by the President. Some statutes, the Hazardous and Solid Waste Amendments, for example, prescribe in detail how regulatory standards should be designed. Others provide executive agencies more general guidance; for example, Section 109 of the Clean Air Act directs EPA to set standards to “protect public health... with an adequate margin of safety.”

The **executive branch** is tasked with the administration and enforcement of laws enacted by Congress. Article 2 vests all executive power in the President, and Section 3 of Article 2 specifies that the President “shall take Care that the Laws be faithfully executed.” Modern U.S. regulation is executed by federal agencies according to procedures established by the APA and described below.

The **judicial branch** is responsible for adjudication of conflicts arising from legislation or the executive’s execution of laws through regulation. Article 3 of the Constitution states that the “judicial Power of the United States shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.”

The first **ten amendments** to the Constitution further clarify the roles of the different branches and protect freedoms of religion, speech and press, security in people’s homes, weapons ownership, and the process of law.

## **Administrative Procedure Act of 1946 (APA)**

When writing regulations, agencies are constrained by the APA, as well as by enabling legislation. The APA established procedures an agency must follow to promulgate binding rules and regulations within the area delegated to it by statute. As long as an agency acts within the rulemaking authority delegated to it by Congress, and follows the procedures in the APA, courts have ruled that an agency is entitled to write and enforce regulations (subject to judicial checks).

The APA constrains executive rulemaking in three main ways:

- The agency can only act within the limits set by statutes.
- The agency actions must
  - Be reasonable (i.e., have sufficient factual support in the record)
  - Not be arbitrary or capricious
  - Not be an abuse of discretion.
- The agency must follow specified procedures. In particular, it must provide notice to the public of the proposed action and take into consideration public comment before issuing a final rule.

The APA describes two types of rulemaking – formal and informal. Formal rulemaking is typically used by agencies responsible for economic regulation of industries, and is only required when a statute other than the APA specifically states that rulemaking is to be done “on the record.” Formal rulemaking involves hearings and the presentation of formal documentation to support the rule in front a commission or judge. Generally speaking, formal regulation is rare except in cases of “ratemaking” by a regulatory commission (such as when the Federal Energy Regulatory Commission determines acceptable rates that electric utilities may charge customers).

Informal rulemaking, or notice and comment rulemaking, is the most common process used in the U.S. by agencies for writing, or “promulgating” regulations. In informal rulemaking, the agency or department first proposes a rule or standard and invites public comment through a Notice of Proposed Rulemaking (NOPR or NPRM). In some cases, the agency will even issue an Advance Notice of Proposed Rulemaking (ANPR or ANPRM) to gather information from the public in advance of issuing a proposed rule.

## **Public Involvement**

The chart at the end of this paper lists the steps involved in developing a new regulation, and highlights opportunities for public involvement at each step. We highlight key opportunities here.

## **Unified Agenda of Federal Regulatory and Deregulatory Actions**

Twice a year, the General Services Administration compiles the regulatory agendas of all executive branch agencies that have regulations under development. Fall editions of the Unified Agenda include the “Regulatory Plan,” which highlights agency regulatory priorities and provides additional information about the most significant regulatory activities planned for the coming year. These searchable on-line document may be the first notice the public receives about upcoming regulatory activity. Interested parties can search the Agenda for regulations that meet certain characteristics, including whether they are likely to have an effect on international trade or investment. Agencies classify upcoming regulations according to significance and a variety of other attributes. (See [RegInfo.gov](http://RegInfo.gov))

## **Public Notice and Comment**

While interested parties (e.g., lobbying organizations and those affected by the rule) are often aware of an agency’s regulatory plans and communicate with the agency during the drafting of a proposed rule, one of the distinguishing features of the U.S. regulatory development process is the APA requirement that agencies provide broad public notice of its intended actions by

publishing proposed rules in the [Federal Register](#). The *Federal Register* notice specifies a period for public comment that can range from 30 to 120 days or more, depending on the complexity of, and interest in, the proposal. The public is invited to submit comments on the rule during this period. These comments are collected in the “rulemaking record.”

After the comment period closes, the agency reviews the comments, and decides whether to publish a final rule if supported by comments. The preamble to the final rule provides the agency’s response to public comments. According to the APA, the final rule must be based on this rulemaking record. Otherwise the agency could be sued and the regulation overturned for being “arbitrary and capricious.”

The federal government’s e-rulemaking initiative is designed to improve the public’s ability to get involved in the rulemaking process. The website, [www.Regulations.gov](http://www.Regulations.gov), provides links to supporting document and allows visitors to view and comment electronically on regulations proposed by different agencies.

## **Interagency Coordination**

Regulatory agency coordination with other executive branch agencies, particularly the Small Business Office of Advocacy and the Office of Information & Regulatory Affairs in the Office of Management and Budget, offers other opportunities for the public to be heard on a developing regulation.<sup>2</sup>

## **Small Business Administration**

The Office of Advocacy in the Small Business Administration has emerged in recent years as a significant player in the regulatory development and oversight process. In 1976, Congress created the Office to provide an independent voice for small business within the federal government. The passage of the Regulatory Flexibility Act of 1980 (Reg Flex Act) (5 U.S.C. 601-612) gave the Office more clout. The Reg Flex Act requires agencies to consider the effects of their regulatory actions on small businesses and other small entities and to consider less burdensome alternatives. It puts the Office of Advocacy in charge of monitoring agency compliance with the Act and submitting annual reports to Congress.

The Small Business Regulatory Enforcement and Fairness Act (SBREFA), passed by Congress in 1996, reflects concerns that agencies were not always following the Reg Flex Act but that a lack of an enforcement mechanism left small businesses little recourse in the courts. SBREFA

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<sup>2</sup> Presidents have also directed agencies to consult with state and local governments before issuing regulations that may affect them. See [Executive Order 13132, “Federalism,”](#) dated August 4, 1999.

amends the Reg Flex Act by specifying the steps an agency must take to minimize the economic impact of a regulation on small businesses, and permitting judicial review of agencies' compliance. In 2003, SBA published a *Guide for Government Agencies on How to Comply with the Regulatory Flexibility Act*.

SBREFA also requires that two agencies—the Environmental Protection Agency (EPA) and the Occupational Health and Safety Administration (OSHA)—receive input from affected small business through the SBA's Office of Advocacy before publishing a proposed rule. (Recent financial legislation adds the new Consumer Financial Protection Agency to the agencies subject to SBREFA early consultation requirements.)

When a new proposal is expected to have a significant impact on a substantial number of small entities, SBREFA requires EPA, OSHA and the CFPA to convene a panel with representatives from the agency, the Office of Advocacy, and the Office of Management and Budget to review the draft proposed rule and related agency analyses under the Reg Flex Act. The panel also solicits advice from small business representatives and prepares a report to the regulating agency, which must consider the report in developing the proposal and include it in the public record of the rulemaking.

### *White House Office of Management and Budget*

The president of the United States is the chief executive responsible for executive branch agency actions, and for the last 40 years, presidents have established procedures for executive review of agency regulation. Since 1993, executive branch agencies have operated under procedures established by President Clinton in [Executive Order 12866](#) (E.O. 12866). The Order requires, among other things, that a regulatory analysis be performed on all rules deemed to be of significant economic impact (*i.e.* impose a cost burden of \$100 million or greater per year). The regulatory analysis must include a statement of need for the regulation, an assessment of alternative regulatory approaches, and a cost-benefit analysis.

E.O. 12866 also requires that significant rules be reviewed by the [Office of Information and Regulatory Affairs \(OIRA\)](#), in the Office of Management and Budget (OMB), before publication in the *Federal Register* in proposed or final form. Each proposed or final rule must meet specific informational requirements before it passes the OIRA review, providing a consistent format for regulations that is designed to reduce the costs to the public of obtaining this information.

OIRA posts on its Internet site a list of [rules under review](#) at any given time, and members of the public may request to meet with OIRA and the regulating agency while a draft regulation is under interagency review. OIRA posts on its websites any such meetings, names and affiliations of the attendees, and any materials provided. Once OIRA has completed its review of a rule,

the agency may then publish it in the *Federal Register* (either as a proposal for public comment or in final form).

## **Role of Congress**

As executive agencies exert the regulatory authority that Congress has delegated to them, Congress monitors the activities of the various agencies through oversight committees responsible for specific agencies. Through oversight hearings, oversight committee members can hear the testimony of agency representatives concerning the regulatory actions of their agency. If Congress is displeased with the manner in which an agency is implementing its mandates, it can attempt to guide the process through regulatory oversight, or it can pass another law with new directives. Through its appropriations committees, Congress can also reduce the agency's budget, or forbid agencies to use money in certain ways. Under the Congressional Review Act, both houses of Congress can issue a joint resolution of disapproval to overturn an agency final rule. Only one regulation has ever been overturned using this procedure, however.

## **Role of the Judiciary**

Parties affected by a regulation may challenge it in court. In the U.S., courts frequently rule that agencies have not followed statutory intent or the requirements of the APA. Thus, if agencies do not follow the required consultation procedures, their regulations may be overturned in court.

## **For more information on the U.S. regulatory process:**

Jeffrey S. Lubbers. "A Guide to Federal Agency Rulemaking." American Bar Association.

OMB/OIRA website: [www.omb.gov/infoereg](http://www.omb.gov/infoereg)

[www.RegInfo.gov](http://www.RegInfo.gov)

[www.Regulations.gov](http://www.Regulations.gov)

## Role for Public Consultation in the Development of Regulation

Step in Regulatory Development	Role for the Public
1. Authorizing legislation <i>Must pass both houses of Congress and be signed by the President</i>	Work with elected officials to influence legislation that will authorize regulatory action
2. Unified Agenda <i>Compendium of upcoming federal regulatory activity, published on-line twice a year</i>	Often first public notice of agency activity. Contains “flags” for regulations classified as having particular impacts, including international effects. Searchable electronic database allows public to identify upcoming regulations of interest.
3. Draft proposal <i>Depending on complexity of regulation, this phase can take years.</i>	Stakeholder and expert input on technical basis for regulatory approach is often sought at this stage. Expert panels may be convened, and states are consulted on regulations likely to affect state interests.
4. Executive review <ul style="list-style-type: none"> <li>○ SBREFA (small business)</li> <li>○ OIRA (interagency)</li> </ul>	Small entities can participate in panels organized by the Small Business Office of Advocacy to evaluate early draft proposals. Anyone may request a meeting with OIRA according to established procedures that ensure transparency.
5. Publication in Federal Register <i>Regulations.gov contains FR publication (including preamble and rule language) as well as other supporting materials.</i>	Agencies invite public comment on all aspects of regulation. Comment is not limited to stakeholders. To be considered in final regulation, comments must be filed on the public record. They may be filed through <a href="http://www.Regulations.gov">www.Regulations.gov</a> .
6. Revisions	Under the APA, agencies must consider public comments filed on the record during the comment period as it develops its final regulation. Agencies prepare response-to-comment documents addressing public input.
7. OIRA review	OIRA will meet with members of the public upon request while regulation is under interagency review.
8. Final rule published	Regulations are generally not binding until at least 30 days after publication in the Federal Register.
9. Congressional review (CRA)	Congress can issue a joint resolution of disapproval to overturn a final regulation (very rare).
10. Judicial review (lawsuits)	Parties affected by the rule may seek judicial review of final agency actions.