Engaging Stakeholders in Designing Regulation

Draft Report for Public Comment

February 8, 2011

Please submit comments by February 25, 2011.
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On December 1, 2010, the George Washington University Regulatory Studies Center, in partnership with the Bertelsmann Stiftung, gathered twenty-seven European and American regulatory experts for a workshop on regulatory consultation. They compared information on how the public currently gets involved in developing regulations, and explored how more effective public consultation could improve regulatory policies and outcomes. Participants also explored applications of electronic rulemaking that can increase interaction between policy makers and the public.

The workshop launched one of four “workstreams” on regulatory reform that will feed into the International Regulatory Reform Conference (IRRC) to be held in Amsterdam on March 10-11, 2011. The Bertelsmann Stiftung organized the individual workstreams to provide a forum for evaluating specific topics of concern in regulatory reform, fostering deeper conversation from a wider audience than is feasible at a single conference alone.

This draft paper aims to contribute to IRRC Workstream 4 on “Engaging stakeholders in designing regulation” by (1) summarizing the key concepts discussed at the December 2010 workshop on regulatory consultation, (2) identifying questions for further discussion, and (3) serving as the basis for comment and continued dialogue. We welcome comments on all aspects of this draft, but particularly on the issues highlighted for further discussion. The draft and public reactions to it will be presented in March at the IRRC.

Workshop participants noted that structural differences between how legislation and regulation are developed in the EU and U.S. influence not only the procedures but the goals of public consultation, so a brief overview of the institutional frameworks relied on in the EU and U.S. can be found in Appendix B. Section I below provides a comparison of consultation approaches and discussion of issues and best practices. Section II examines the opportunities for new media to enhance public participation in rulemaking, as well as the challenges it brings. Section III offers a brief conclusion.

1 www.RegulatoryStudies.gwu.edu, e-mail: RegulatoryStudies@gwu.edu
2 www.bertelsmann-stiftung.de, e-mail: irr-network@bertelsmann-stiftung.de
3 Appendix A lists the December 1, 2010 workshop participants. Appendix B provides the agenda for the workshop.
Comments received before February 25, 2011 will be considered in preparing the presentation delivered at the IRRC in March.

I. Public Consultation in the U.S. and EU

This section provides an overview of the public consultation procedures in the EU and U.S., and then summarizes the discussion at the December 2010 workshop.

A. EU Public Consultation Practices

In the EU, regulations are usually proposed by the European Commission for consideration by the Council and Parliament. Prior to proposing a regulation, the Commission will usually have undertaken a lengthy public consultation. Its “minimum standards for consultation” have recently extended the opportunity for public comment to a 12 week consultation period. All consultations are published on a web-based register—Your Voice for Europe—and there are a number of tools available for the public to make sure their voices are heard in the policy-making process e.g. the European Business Test Panel.

Small- and medium-sized enterprises (SMEs) are often the largest business group to be affected by new EU policy. SMEs generally do not have the resources that large firms can dedicate to influencing policy-making or lobbying, meaning that they find it difficult to put their views across. To combat this, the Commission has appointed an SME Envoy and encourages an effective and wide-ranging consultation of SMEs as one of its elements of its “Think Small First” principle.

The Commission is committed to providing feedback on the results of the consultation and how these have been taken into account in the development of its proposal. As part of the Commission’s Smart Regulation Communication, published 8 October 2010, the Commission will carry out a review of its consultation policy this year to see whether it can further strengthen the voice of citizens and other stakeholders.

The Commission publishes its annual Legislative and Work Programme setting out its regulatory processes for the coming year and updates it periodically. It also publishes more detailed information on each of the proposals in ‘roadmaps’ thereby allowing citizens and other stakeholders’ to plan inputs into the policy process and to express their views at a much earlier stage than before. In addition, consultation about prospective EU regulation will often take place

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5 http://ec.europa.eu/enterprise/policies/sme/small-business-act/think-small-first/
at Member State level, with national governments consulting stakeholders to help inform their negotiating position once the regulation is discussed in the Council.

Once both the Council and Parliament pass legislation, the Commission is tasked with developing measures for an implementation plan down to the community level. Under the comitology system, committees created by the Commission oversee the review of regulatory measures (in “regulatory committees” or “regulatory committees with scrutiny”). Depending on whether the measures are approved by the committee, and/or other institutions if review is required, the Commission may need to amend or re-submit regulations before implementation. The Court of Justice and Court of Auditors serve as checks on the process once the regulations have been implemented to ensure they are in the best interest of citizens of the EU. It is yet to be seen how the Treaty of Lisbon’s introduction of delegated acts will affect the oversight of regulations.

One way public consultation is acquired through the comitology procedure, where committees gather opinions from interested parties on specific pieces of legislation. Committees are already composed of both public and private representatives from the Member State level, so the target of solicitations for comment are affected industry and other stakeholders who are already engaged in the regulatory process. Comitology procedure also occurs once the legislation has been passed and implementation decisions are being made, therefore major changes to the regulations are unlikely. It is unknown how the Commission will solicit public consultation without the direct involvement of committees, although many Member States have examples of public consultation use.

Since neither Parliament nor Council initiates legislation, they are not involved at this stage of public consultation, except when regulatory committees with scrutiny are called for. Even though EU citizens directly elect the Parliament, this body does not initiate regulatory priorities, therefore voting is not a form of public consultation in this system.

In addition to public consultation on the development of Commission proposals, consultation also occurs when the Commission evaluates whether the legislation has done what it set out to do. The increased availability of ex-post evaluation work plans has helped the public to express their views earlier in the process.

B. U.S. Public Consultation Practices

Table 1 lists the steps involved in developing a new regulation, and identifies opportunities for public involvement at each step. We highlight key opportunities here.6

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6 This section is based on “Regulatory Consultation in the United States,” by Susan E. Dudley, Director, GW Regulatory Studies Center, prepared as background reading for the December 1, 2010 workshop.
Table 1. Public Involvement in the Development of U.S. Regulation

<table>
<thead>
<tr>
<th>Step in Regulatory Development</th>
<th>Role for Public</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Authorizing legislation</strong></td>
<td>Work with elected officials to influence legislation that will authorize regulatory action</td>
</tr>
<tr>
<td>Passes both houses of Congress and is signed by the President</td>
<td></td>
</tr>
<tr>
<td><strong>Unified Agenda</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Compendium of upcoming federal regulatory activity, published on-line twice a year</td>
<td></td>
</tr>
<tr>
<td><strong>Draft proposed regulation</strong></td>
<td>Stakeholder and expert input on technical basis for regulatory approach is often sought at this stage.</td>
</tr>
<tr>
<td>Depending on complexity of regulation, this phase can take years.</td>
<td></td>
</tr>
<tr>
<td><strong>Interagency review of significant proposed regulation</strong></td>
<td>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.</td>
</tr>
<tr>
<td>SBREFA (small business) OIRA (interagency)</td>
<td></td>
</tr>
<tr>
<td><strong>Publication in Federal Register</strong></td>
<td>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>.</td>
</tr>
<tr>
<td>Regulations.gov contains regulations published in the FR (which includes preamble and rule language) as well as other supporting documentation.</td>
<td></td>
</tr>
<tr>
<td><strong>Revisions</strong></td>
<td>Under the APA, agencies must consider public comments filed on the record during the comment period as it develops its final regulation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OIRA review of significant final regulation</strong></td>
<td>OIRA will meet with members of the public upon request while regulation is under interagency review.</td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Final rule published</strong></td>
<td>Regulations are generally not binding until at least 30 days after publication in the Federal Register.</td>
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<tr>
<td><strong>Congressional review (CRA)</strong></td>
<td>Congress can issue a joint resolution of disapproval to overturn a final regulation (very rare).</td>
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<td></td>
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<tr>
<td><strong>Judicial review (lawsuits)</strong></td>
<td>Parties affected by the rule may seek judicial review of final agency actions.</td>
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1. **Unified Agenda of Federal Regulatory and Deregulatory Actions**

Twice a year, the General Services Administration (GSA) 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 documents 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)

2. 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 their 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. 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, provides links to supporting document and allows visitors to view and comment electronically on regulations proposed by different agencies.

3. Interagency Coordination

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

a) Small Business Administration

The Office of Advocacy in the Small Business Administration works with regulatory agencies to ensure they both consider the effects of their regulatory actions on small businesses and other small entities and consider less burdensome alternatives. The Regulatory Flexibility Act of 1980 (RFA), as amended by the Small Business Regulatory Enforcement and Fairness Act (SBREFA) of 1996 specifies the steps an agency must take to minimize the economic impact of a regulation on small businesses, and permits judicial review of agencies’ compliance.
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 Bureau 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 CFPB to convene a panel with representatives from the agency, the Office of Advocacy, and OIRA to review the draft proposed rule and related agency analyses under the RFA. 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.

\[b] \quad \textit{White House Office of Management and Budget}\]

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. an effect on the economy of $100 million or more in any one 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 OIRA before publication in the Federal Register in proposed or final form. Each proposed or final rule must meet specific informational requirements before it passes OIRA review, providing a consistent format for regulations that is designed to reduce the costs to the public of obtaining this information.

On January 18, 2011, President Obama issued Executive Order 13563, which affirmed and reinforced the principles and procedures in E.O. 12866, and called for a review of existing regulations.\footnote{Available at: \url{http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/EO_13563_01182011.pdf}} According to a memorandum to U.S. departments and agencies,

Section 2 of Executive Order 13563 emphasizes the importance of public participation. It requires agencies to “afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days.” This section complements a corresponding provision in Executive Order 12866, while also emphasizing the importance of public comment through the Internet. Section 2 aims to promote agencies’ continuing efforts to use online technologies to facilitate greater
participation in the rulemaking process, thus making that process simpler and more accessible—and less burdensome and costly—for all stakeholders.8

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). Note however, that this review process does not apply to about twenty “independent regulatory boards and commissions” such as the Federal Communications Commission and the Consumer Product Safety Commission.

4. 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, elected 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, (enacted as part of SBREFA), both houses of Congress can issue a joint resolution of disapproval to overturn an agency final rule. Perhaps because such resolutions must then be sent to the President for signature or veto, only one regulation has ever been overturned using this procedure, however.

5. Role of 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.

C. Discussion

At the December 2010 workshop, one European and one American provided very brief introductory remarks that served as a catalyst for discussion. This section summarizes the discussion, with footnotes referencing the workshop participant who raised certain points.

1. Motivation for seeking public comment

Modern democratic governments are interested in transparent, evidence-based regulatory policies that lead to better, more effective outcomes, addressing the needs of the broader public, rather than catering to special interests. Public consultation can contribute to these goals in several ways:

- **Evidence**: Public consultation not only shares government officials’ evidence supporting draft regulations, but solicits information from key stakeholders—important when assessing what impact a proposal may have if implemented.

- **Legitimacy**: Allowing all parties to be heard and explain the effect that the regulation will have on them increases the legitimacy of the chosen policy.

- **Level playing field**: Public consultation serves to level the playing field among the government, public, and interest groups by providing all interested stakeholders with a voice in decision making and balancing asymmetries.

- **Control of bureaucracy**: Public consultation can serve as a check on bureaucracies that may not be attuned to the effect their regulations may have in a broader context.  

While endorsing this characterization of the different motivations for consulting the public during rulemaking, participants debated whether some of these motivations were more important in Europe or the U.S. In Europe, the Council of the European Union, which may better reflect member state interests than the European Commission, must approve legislation proposed by the Commission before it becomes law. It may be that, because elected officials have the final say in regulatory policy, direct public consultation is considered less important for controlling the bureaucracy than in the U.S., where regulatory agencies in the executive branch issue final regulations (with authority delegated in advance from Congress).

American participants objected to an overly broad characterization, however. They argued that the judicial branch, as well as internal executive branch procedures (such as centralized review of regulations in the Office of Information and Regulatory Affairs), also guard against uncontrolled bureaucracy. Somewhat unique to the U.S. is the role of judicial oversight in achieving both legitimacy and bureaucratic control by ensuring regulations are based on the rulemaking record—including public comment. Courts frequently overturn or remand

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9 Kai Wegrich, Professor of Public Administration and Public Policy at the Hertie School of Governance, introduced these four categories for discussion.

10 Jeffrey Lubbers, Professor of Practice in Administrative Law at American University, introduced the discussion for the U.S. and stressed this point.

11 Gray. Dudley & Gray illustrated this point with the U.S. Occupational Safety & Health Administration’s rulemaking notice on whether to require third-party testing of electronic devices in the workplace. The vast
regulatory decisions that do not reflect public comment or otherwise conform to the rulemaking record.\textsuperscript{12}

Both European and U.S. participants suggested that regulatory impact analysis, or impact assessment, played a key role in controlling the bureaucracy as well as providing evidence in support of rulemaking. A topic for further discussion thus may be the interaction between impact assessment and public consultation.\textsuperscript{13}

One key test of the effectiveness of consultation may be whether the final action contains any surprises—elements that interested parties did not expect based on the evidence presented during consultation. A successful consultation practice would minimize such surprises and ensure that regulatory policies reflect robust public engagement.\textsuperscript{14}

2. \textbf{The Timing of Public consultation}

Apparent differences in emphasis on the motivations outlined above likely reflect differences in the timing of consultation, which in turn are influenced by institutional differences.\textsuperscript{15} In Europe, the Commission generally seeks comment during the legislative stage, when it is developing a proposal for Parliament and the Council.\textsuperscript{16} It may also seek comment, once regulations are passed, on how they should be implemented. It also consults the public when evaluating whether regulations have done what they set out to do. In the United States, the executive branch seeks public notice and comment later in the process, as agencies develop particular rulemakings to implement legislative directives. Each has advantages and disadvantages. Public involvement early in the process can identify problems or suggest alternatives before government officials become too wedded to particular policies. There are also advantages of consultation later in the process when more information is available and proposals are more well-developed.

This timing issue is crucial. It affects who participates, the quality of the input, and the value of that input for the rulemaking.\textsuperscript{17} Should a goal be to engage the public in a transparent way at more points in the process?

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\textsuperscript{12} Gray. Europeans note that there are some examples of judicial review in the UK – for instance, in 2009-an IA was used in court to challenge a regulation issued by Her Majesty’s Revenue and Customs (HMRC).

\textsuperscript{13} Cordes

\textsuperscript{14} Hunt

\textsuperscript{15} Smookler

\textsuperscript{16} Merkel

\textsuperscript{17} Balla
3. Consultation at different levels of government

Most of the discussion centered on the more formal public consultation that occurs at the Commission level in Europe, and at the executive branch level in the U.S., but participants pointed out that stakeholders are engaged at other points in the process, as well. The European Parliament (EP) represents the interests of member states, and often determines the priorities for the Commission. Direct lobbying (by NGOs and civil society as well as corporate interests) contributes to a large fraction of Parliamentary decisions. Some Committees in the EP consider the Commission’s impact assessment before discussing the proposal and also conduct impact assessment on their substantive amendments to Commission proposals. However this is not a consistent practice.

While the legislative branch in the U.S. delegates rulemaking authority to executive branch agencies, it retains oversight over how that authority is implemented through staff contact, letters, and hearings in which agency officials must testify. Moreover, as U.S. legislators develop enabling laws, they work closely with the public, including constituents and lobbyists for affected parties, NGOs and civil society. They make political judgments regarding policies.

4. Who is invited to participate?

On both continents, different consultation procedures may be applied for interactions with (1) stakeholders, (2) other institutions (e.g., member states), and (3) other countries (e.g., trading partners).

Consultation with stakeholders: In Europe, consultation often involves identifying specific stakeholders (including NGOs and civil society). Members of the public are also invited to comment, but their comments are likely to be weighted less heavily than those by member states, unions, businesses and other inside stakeholders, who will be consulted first, invited to regular meetings, etc. In the U.S., agencies may also reach out to specific stakeholders when developing regulations, but during the public comment period (required by the APA), anyone can file comments on a regulation and the final regulation must be based on the information available in the public record. This is not to suggest that all comments are treated equally; those with more technical content or from commenters with whom the regulators agree are likely to be given greater deference. Occasionally, a U.S. agency will engage in “negotiated rulemaking,”

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18 Kaczyński
19 Eisner
20 Heather. For example, legislation required that 100 percent of imported cargo be screened, even though some members knew it would be prohibitively expensive, because it was a political judgment.
21 Meneghini
22 Merkel,Kaczyński
23 Otis
to bring different stakeholders to the table to jointly draft a proposed regulation, similar to EU stakeholder consultation. OIRA has resisted these negotiations because of concerns that they could diminish its ability to hold agencies accountable for meeting analytical requirements, and that the broader public interest might be undervalued if the participating stakeholders are not representative. However, the Department of Transportation has found negotiated rulemakings to be very helpful, and in its experience, if structured properly these problems do not arise.

Consultation with other levels of government: This is generally a higher priority in Europe than in the U.S. The EU is a multilevel institution made up of twenty-seven sovereign member states, each of which has a role in developing union-wide regulations. The relative roles for the different levels are defined by comitology procedures and Council legislation. Pursuant to the recent Treaty of Lisbon these roles and procedures are changing. The federal government in the U.S. tends to be more uniform, though federalism principles embodied in the U.S. Constitution do require it to consult with state and local governments, and to defer to them in some areas. Within the executive branch, interagency consultation is coordinated through OIRA, and this also provides opportunities for communication with the outside world.

Consultation with trading partners: From a trade partner perspective, EU regulations are developed in a less transparent manner than in many other countries, and the EU appears to be less responsive to comments from other countries. Often, comments from WTO Members are sought only after policies have been negotiated to the satisfaction of EU member states and stakeholders. EU standard setting bodies exclude non-EU persons from voting and the standards these bodies develop are often de facto mandatory if a supplier wants to demonstrate compliance with EU legislation. Internationally, sharing regulatory agendas and notifying the WTO of proposals when changes can still be made can enable greater U.S.-EU cooperation and potentially head off conflicting standards later.

Some stakeholders have advantages in the consultation. Can we improve how governments inform other interests in society, and give them a greater voice?

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24 Lubbers, Eisner
25 Morrall
26 Eisner, Lubbers
27 Otis
28 Fitzpatrick
29 Weiss. He estimates that, since 2007, 35-40 percent of the concerns raised by WTO Members in the WTO Committee on Technical Barriers to Trade have involved EU and Member State measures.
30 Weiss
31 Cordes
D. Issues for further discussion

- To what extent do the four dimensions of public consultation discussed above accurately describe the motivations for public consultation in regulatory process? Can these dimensions be maximized in parallel or are there tensions and trade-offs between them?

- What is the effect of participation on outcomes? Does wider public consultation improve outcomes and make policies more responsive to broad objectives?

- What input should be considered? What is the relationship between impact analysis (expert evaluation) and consultation (public feedback)? For example, at the impact assessment stage, should comment be sought from selected experts or a broader range of perspectives?

- When is the best time to seek input, i.e. at early stages of the regulatory design process or once mature proposals have been developed? How does timing influence who participates, the quality of input, and responsiveness of the policy outcome? Should a goal be to engage public in a transparent way at more points in the process?

- Given that some stakeholders have advantages in the consultation, how should other interests in society (both domestically and internationally) be informed and give a voice?

- To what extent should EU and U.S. public consultation procedures align? Would this yield more effective practices and outcomes?

- Are lobbying or special interest perspectives legitimate forms of public consultation? How should these interests be factored into regulatory decision-making in comparison to citizen input? Is transparency enough? How do different forms of participation—public consultation and lobbying—interact? Does public consultation serve to reinforce imbalances in lobbying power or level them out?

II. New Media

New media offers the potential to transform the process and the use of regulatory information by improving internal government operations, enhancing transparency and public engagement, creating more productive deliberation and collaboration mechanisms, and improving regulatory outcomes. It also offers potential for coordinating related statutes, regulations, legal reviews, compliance, enforcement, and programmatic evaluation.
A. U.S. Experience with Electronic Rulemaking

Over the past 15 years, various efforts have been undertaken by the U.S. government, think tanks, interest groups, and academia to advance eRulemaking. These include a research effort by the National Science Foundation, small and large scale use of software by individual federal agencies to manage their internal regulatory processes, a federal government-wide on-line regulatory docket and public commenting system, and academic research papers and forums.

In 2003, the U.S. government launched Regulations.gov to provide an online source for documents associated with rulemaking at most federal regulatory agencies. It enhances the public’s ability to participate by providing access to a searchable database of proposed rules, public comments, background studies and analyses, final rules, etc. It also allows users to submit a comment, application, petition, or adjudication document on a regulation, access popular, newly posted, or closing-soon regulations from the homepage, sign up for e-mail alerts about a specific regulation, and subscribe to RSS feed by agency. As described on the Regulations.gov website, the eRulemaking Program manages Regulations.gov with the assistance of 25 partnering federal agencies.

While eRulemaking has evolved, it has not yet reached its potential. Many federal agencies continue to employ complex, time consuming, and manual work processes. Public understanding, access, and engagement in e-rulemaking remains limited. Related activities (such as developing laws and regulations) remain distinct processes. Congressional interest is limited. Little effort seems to be dedicated to developing an overall vision for eRulemaking and putting in place the steps necessary to address these and other challenges.

B. EU Experience with Electronic Rulemaking

The Your Voice in Europe web portal is the Commission’s single access point for public consultations. It provides a central on-line location that allows people to track regulations that are open for consultation, provide input on open consultations, and review other comments. The European Business Test Panel is another online facility that focuses on consultation responses from business. In addition, Pre-Lex allows the public to follow draft EU laws through the policy-making cycle.

32 This section is based on “eRulemaking Challenges in the United States,” by Rick Otis, prepared as background reading for the December 1, 2010 workshop, as well as his introductory remarks on this topic at the workshop.
33 Otis
34 Otis
35 This section is based on introductory remarks by Jennifer Smookler, Assistant Director in the UK Better Regulation Executive, at the December 1, 2010 workshop.
Member states are experimenting with other forms of on-line consultation. In July 2010, the UK government launched **Your Freedom**, an “unpredictable forum” that it called “part of the most radical shake up of our politics for decades.” The site asked citizens to identify

laws and regulations you think we should get rid of. Your feedback will inform
government policy and some of your proposals could end up making it into bills
we bring before Parliament to change the law.

The site ran for three months, receiving 15,000 individual ideas and 95,000 comments. These were distilled into 900 discrete ideas for policy change. Thirty-six per cent of the suggestions related to regulatory areas already identified for review by the government and fed into this existing work. An additional four per cent were identified where changes had not been planned but could be taken forward on the basis of the public’s suggestions.

The initial response was successful in generating a considerable volume of responses. However, while wide in volume they were often shallow in detail. Some comments did not contain enough information to direct officials to where the problem actually lay or were based on an incorrect understanding of particular policies. Where questions to the public were more specific—asking for views about regulations that affected particular sections of society, for instance—suggestions were correspondingly more detailed and their viability easier to pinpoint and assess. The effort was labor-intensive, involving tens of people to moderate and consider the comments. It raised useful questions about how to get the best out of such a forum and how to manage expectations of respondents about how their views will be considered and responded to.

### C. Discussion

In both governments, eRulemaking initiatives have evolved, and continue to do so. In the U.S., efforts have depended on the vision and tenacity of individuals, rather than a statutory driver. Initially aimed at increasing efficiency and reducing government costs, eRulemaking has emerged as a forum not only for greater access, but for give-and-take among different interested parties. The UK experience showed that by reducing transaction costs associated with filing public comments, it increases participation, but can also increase government costs. It can provide new opportunities for richer exchange among commenters, facilitating comments on comments.

38 Smookler
39 Otis
40 Eisner
1. **How do we measure success?**

New media clearly has the potential to increase accessibility and transparency, but whether eRulemaking is always better than alternative forums for getting feedback is an open question. Information technology offers improved efficiency in the flow of documents and creates workspaces for teams to engage, but greater access will not necessarily improve the quality of public comment received. Will it ever replace face-to-face discussions, or should it be considered a complement? How would one measure whether it is better?\(^{41}\)

In terms of the four motivating factors for consultation identified above – improving evidence, enhancing legitimacy, leveling the playing field among commenters, and controlling the bureaucracy, how does e-Rulemaking measure up?

**a) Evidence**

By lowering transaction costs to commenters, e-Rulemaking can elicit new evidence, but increasing access does not guarantee that. It can be costly for policymakers to sift through large numbers of comments to elicit valuable information on benefits and costs of regulatory alternatives that can help inform government decisions.\(^{42}\) Yet, engaging the “wisdom of crowds” can be very valuable. Facilitators will need to evaluate the quality of evidence, but new media offers superior opportunities for getting input from unexpected sources.\(^{43}\) Technology is helping manage the information in comments received, by creating a general format for comment and sorting tools.\(^{44}\) For example, working with Cornell University, web 2.0 technology allows agencies to use blogs for facilitating discussions, where facilitators can follow up to elicit more data etc.\(^{45}\) eRulemaking can help segment rules so those interested in commenting on the same parts can find each other.\(^{46}\)

**b) Legitimacy**

Engaging the public broadly through portals like Your Voice in Europe and Regulations.gov does improve democratic legitimacy. Feedback is essential, however.\(^{47}\) It is important to manage the expectations of contributors as to the timing of responses to suggestions.\(^{48}\)

To what extent should on-line facilitators filter comments?\(^{49}\) Is there a fine line between filtering and censorship? Is that an appropriate role for government\(^{50}\) or might third parties—including

\(^{41}\) Otis, Wegrich  
\(^{42}\) Tonevsky  
\(^{43}\) Cordes  
\(^{44}\) Otis  
\(^{45}\) Eisner  
\(^{46}\) Lubbers  
\(^{47}\) Kaczyński  
\(^{48}\) Smookler
non-profits or civil society—develop mechanisms for aggregating and moderating diverse inputs?  

How can agencies address the problem of bad comments driving out good ones, so that the quality of the discussion does not deteriorate? The White House Open Government Initiative has used the Wikipedia model of enlisting the public to collaborate on the development of recommendations and flag unhelpful, inappropriate, and off-topic comments for deletion by government moderators. (An MIT study found that an obscenity randomly inserted on Wikipedia is removed in an average of 1.7 minutes.)

A threshold test of legitimacy could be that participants are not surprised by the final policy decision. U.S. procedures, particularly judicial review under the APA, ensure fair notice because policies that are not supported by the rulemaking record can be sent back to the agency. New media, while expanding the dialogue on developing regulations, poses new challenges that U.S. courts have not dealt with yet. How will courts rule if an agency bases its regulatory decision on information provided through electronic comments, and on which people had ample opportunity for discourse, but was not provided in the initial proposal?

c) Level playing field

Electronic mechanisms expand participation beyond organizations that have a direct lobbying presence, and are engaging people who could not engage before. Regulations are not developed through referendum, so the number of comments supporting or opposing a particular policy won’t necessarily determine the outcome. There will always be commenters with greater knowledge or stake in a policy outcome, and better informed comments will receive more deference. “Your Voice In Europe” invites two types of consultation, those from all citizens and those from registered users. We need to understand the effect of eRulemaking on the flow of comments, and how they are used in the context of the institutions, legal environments, norms, standard procedures and behavior, so that we can build opportunities for constructive, informed participation.

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49 Rigby
50 Eisner
51 Otis
52 Farrell
53 Hunt
55 Hunt
56 Lubbers
57 Melberth
58 Lubbers, Merkel
59 Balla
An added complexity in the European Parliament is that all documents must be translated into twenty-three different official EU languages, and efforts are made to ensure translations accurately reflect the legal and original meaning. Other documents and studies produced by external contractors for the European Parliament on technical and scientific issues carry a disclaimer as they do not represent the official position of the European Parliament on the issue.60

d) Control bureaucracy

As discussed above, both in Europe and the U.S., analysis plays an important role in developing regulations. A key question is how well comments, and the evidence they provide, inform the analysis conducted by civil servants, since a better understanding of alternative policies’ likely effects before-the-fact should lead to better regulatory outcomes. Public comment cannot substitute for mechanisms to ensure the quality of analysis supporting regulations.61 On the other hand, impact assessment and analysis alone can’t substitute for political decision-making.62

Ex post evaluation of regulations once they are in place has traditionally been secondary to ex ante evaluations, at least in the U.S. In Europe, policies are generally reviewed every 4 to 5 years,63 where the default is that regulations sunset. New media, like the UK’s “Your Freedom” initiative, offer vehicles for identifying existing policies that should be reconsidered.64 New media may thus be a valuable vehicle for challenge existing policies that may be outmoded or result in unintended consequences.

D. Issues for further discussion

- Are there overall cost savings from using new media, or does the increase in volume of comments offset cost savings?

- Has eRulemaking improved regulatory outcomes? Can we address this question empirically?

- What is the appropriate role for government and other parties in collating and filtering comment?

- Which platforms work best for consulting with the public on regulations? Can blogs be a successful mechanism for sharing information between the government and interested public?

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60 Meneghini
61 Morrall
62 Meneghini
63 Merkel
64 Smookler
• Does limited public participation in U.S. and EU politics provide any insight into the potential role for participation in rulemaking? What does behavioral research indicate about the value of increased opportunities for public involvement?

III. Concluding thoughts on best practices for public consultation

Opportunities for the public to get involved in regulatory policy are increasing and new media is playing a role. The timing and format of public engagement can influence the quality and value of public input. Both the EU and U.S. need to evaluate the potential value of soliciting public input at different stages of the regulatory process and how best to involve different participants at each stage. The EU is reviewing its consultation process in 2011, and recent directives the U.S. have emphasized the role for public participation, particularly through electronic media. Governments are utilizing new media tools to gather input from the public, and innovation continues to test current procedures for public consultation. The ability to comment on comments, and remove time and space constraints from public dialog is a powerful asset that the Internet offers to the realm of regulatory reform.
Appendix A: December 1, 2010 Workshop Participants

**Steven J. Balla** is Associate Professor of Political Science, Public Policy and Public Administration, and International Affairs at George Washington University.

**Erin Bankey** is a research associate at the George Washington University Regulatory Studies Center and Master of Public Policy candidate at the Trachtenberg School of Public Policy and Public Administration.

**Joseph Cordes** is the Co-Director of the George Washington University Regulatory Studies Center and Professor at the Trachtenberg School of Public Policy and Public Administration.

**Susan Dudley** is the Director of the George Washington University Regulatory Studies Center and Research Professor at the Trachtenberg School of Public Policy and Public Administration.

**Amy Edwards** is a performance budget specialist for the U.S. Senate Budget Committee. She supports Senator Mark Warner’s (D-VA) bipartisan Task Force on Government Performance for the Committee.

**Neil Eisner** is currently the assistant general counsel for regulation and enforcement at the U.S. Department of Transportation.

**Henry Farrell** is associate professor of political science and international affairs at the George Washington University.

**Michael Fitzpatrick** currently serves as the Associate Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA).

**Boyden Gray** is the former Ambassador to the European Union from the United States.

**Sean Heather** is the Executive Director for Global Regulatory Cooperation. The Global Regulatory Cooperation (GRC) Project seeks to align trade, regulatory, and competition policy around the world in support of open and competitive markets.

**Alexander Hunt** is a Branch Chief in the Office of Information and Regulatory Affairs (OIRA) within the U.S. Office of Management and Budget (OMB).

**Piotr Maciej Kaczyński** is a research fellow at the Centre for European Policy Studies (CEPS), where he is responsible for the unit dealing with the EU institutional and political issues.

**Barbara Kunz** is Project Manager with the Bertelsmann Stiftung's "Modern Regulation" project.

**Wendy Liberante** is a Policy Analyst in the Office of Information and Regulatory Affairs at the Office Management and Budget (OMB), Executive Office of the President.
Jeffrey S. Lubbers was appointed Professor of Practice in Administrative Law at American University’s Washington College of Law in 2009, after being a Fellow in Law and Government since 1996.

Shawne C. McGibbon currently serves as the General Counsel for the Administrative Conference of the United States.

Rick Melberth joined OMB Watch in November 2006 as the Director of Federal Regulatory Policy, where he directs all activities related to policy advocacy, analysis, research, monitoring, and public education.

Gian Paolo Meneghini is a Liaison Officer since 2005 as part of the Secretariat of the Coordination Group on the Lisbon Strategy and the interinstitutional work platform on Better regulation and impact assessment.

Bernard Merkel is the Head of the Food Safety, Health and Consumer Affairs section of the Delegation of the European Union (EU) in Washington.

John F. Morrall III is an economic consultant and Affiliated Senior Scholar with the Mercatus Center of George Mason University, is an expert in the area of regulatory reform and oversight, benefit-cost analysis.

Joroen Nijland is Director of the Regulatory Reform Group at Ministry Finance & Ministry of Economic Affairs in the Netherlands. He also serves as Chair of Regulatory Policy Committee at OECD, and Co-Chair of OECD’s group on Public Service Delivery, PPPs and Regulatory Reform at OECD-program on Middle East and North Africa (MENA).

Rick Otis is the former Deputy Associate Administrator for the Environmental Protection Agency’s Office of Policy, Economics, and Innovation.

Elizabeth Rigby is an Assistant Professor in the Trachtenberg School of Public Policy and Public Administration at George Washington University.

Jennifer Smookler is an Assistant Director in the UK Better Regulation Executive.

Tsvetelin M. Tsonevski is Editor at the Foundation for Economic Education where he is responsible for New Media communications.

Kai Wegrich teaches Public Administration and Public Policy at the Hertie School of Governance.

Jeff Weiss is the Senior Director for Technical Barriers to Trade (TBT) at the Office of the U.S. Trade Representative (USTR).
Appendix B: December 1, 2010 Workshop Agenda

The George Washington University Regulatory Studies Center & Bertelsmann Stiftung
The George Washington University, Washington, DC

Objective: Explore how the public currently gets involved in regulatory development in Europe and the U.S., and how more effective public consultation could improve regulatory policies and outcomes. The Workshop will generate a report to be presented at the annual International Regulatory Reform Conference held in Amsterdam on March 10-11, 2011.

8:30 – 8:50 Continental breakfast

8:50 – 9:00 Welcome

Susan Dudley (the George Washington University), Joseph Cordes (the George Washington University, and Barbara Kunz (Bertelsmann Stiftung)

9:00 – 10:30 Topic 1: Comparison of consultation procedures

Brief introduction to the topic by Jeff Lubbers (American University) and Kai Wegrich (Hertie School of Governance, Berlin)

• What can we learn from a comparison of different countries’ consultation procedures?
• Who actually gets involved under different approaches?
• Do different methods lead to different regulatory outcomes and different public perceptions?

10:30 – 11:00 Coffee Break

11:00 – 12:30 Topic 2: How are new media opportunities affecting consultation?

Brief introduction to the topic by Richard Otis (former Regulations.gov official) and Jennifer Smookler (UK Better Regulation Executive)

• What e-rulemaking initiatives have been undertaken by different countries?
• Has the Web increased public involvement in the regulatory process, or public understanding of regulatory effects and the role of regulations (including better regulation initiatives)?
• Has it affected the outcomes of regulations?
• What new media opportunities might improve public involvement and understanding?

12:30 – 2:00 Lunch Discussion
Appendix C: Overview of EU and U.S. Approaches to Regulation

The assembled experts agreed that many of the differences in EU and U.S. regulatory practices stem from differences in our constitutions and governing institutions. As background for the more targeted discussion, this appendix provides a brief overview of these institutional frameworks.

A. The European Union’s Parliamentary System

Five institutions created by the Treaty of Rome govern the European Union: European Parliament, Council of the European Union, European Commission, Court of Justice, and Court of Auditors. These institutions operate within a single institutional framework and act within the decisional process of three pillars: (1) Commission, (2) Council & Parliament, and (3) Member States.

European Parliament is the assembly of representatives directly elected by the 492 million EU citizens, and with the Council it forms the bicameral legislative branch of the EU. The main functions of this body are legislative power, budgetary power, and power over EU institutions, especially the Commission. Both legislative and budgetary powers are shared with the Council under co-decision procedure. Co-decision procedure aims to facilitate increased dialogue between the Parliament, Council and Commission and increase the democratic nature of Community action. Recent treaties have continued to enhance the Parliament’s powers by extending co-decision procedure and granting it rights to bring actions before the Court of Justice.

The Council of the European Union (“Council” or “Council of Ministers”) is the EU’s main decision-making body; it is the institution that represents the Member States. Since January 2007, the Council Presidency is held for an 18-month period by three Presidents simultaneously, who prepare a common agenda. The key issue areas of the Council are common foreign and security policy, coordination of economic policies, and holder of executive power, which it generally delegates to the Commission. Council’s decisions are based on proposals from the Commission, and are made jointly with the European Parliament under co-decision procedure. Although the Parliament and the Council form the highest legislative body within the EU, their

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65 Erin Bankey drafted this section based on publicly available information.
66 http://europa.eu/scadplus/glossary/eu_institutions_en.htm
powers are limited to specific competencies conferred by the European Community and have no control over policy areas held by the other two pillars.69

The European Commission is a politically independent institution with virtually exclusive right to initiate legislation.70 It also prepares and implements the legislative instruments adopted by the Council and Parliament. The Commission is appointed for a five-year term by the Council by qualified majority in agreement with the Member States, and subject to a vote of appointment by the Parliament. Two representatives of nations from each Member State with larger populations, and one per nation from each of the others comprised the Commission until the Treaty of Nice, which entered in force February 1, 2003 and limited the number of Commission Members to one per Member State.71 Currently in the ratification process, the Constitution would provide for a Commission in which only two-thirds of the Member States would be represented at a given time after 2014, with members selected in accordance with a rotation system, based on the principle of equality.72

The Commission is also in charge of implementing law on the community level, and before the Treaty of Lisbon, committees have been used to assist in the implementation process. The committee, or “comitology” process was replaced by “delegated acts” under the Treaty of Lisbon on December 1, 2009.73 Criticized for lack of transparency and democratic oversight, comitology aimed not to overburden legislators due to practical issues of adapting legislation, but provided little information to the public about meetings.74

Although the Treaty has been adopted, the precise legal framework of delegated acts is still under discussion and not expected until April 2011.75 Delegated acts are a new category of law in addition to regulations and EU directives that law-makers can give the Commission to supplement or amend certain non-essential elements of the EU law or framework by delegating authority; these also have supreme authority over national laws and national constitutions although they must be approved by an institution where all member states will not be represented if the new organization of Parliament is approved.76 Until that framework is in place, the

69 http://www.newworldencyclopedia.org/entry/European_Parliament
70 http://europa.eu/scadplus/glossary/european_commission_en.htm
72 http://europa.eu/scadplus/constitution/commission_en.htm
73 http://europa.eu/lisbon_treaty/index_en.htm
76 http://en.euabc.com/word/271
comitology procedure still guides implementation of legislation, and will apply to legislation adopted before the treaty came into force.\textsuperscript{77}

Under comitology, like most national systems of government, the legislature delegates implementing powers to the executive, the Parliament and Council delegate the development of the detailed measures to the Commission from the legal framework of objectives and timelines outlined in the legislation.\textsuperscript{78} Committees are composed of representatives from private sector and national experts from Member States and chaired by the Commission to facilitate dialogue between national administrators.\textsuperscript{79} The comitology procedure outlined a framework for interactions between the Commission, committees, and approval process by other EU institutions.\textsuperscript{80} Four main categories of committees exist: advisory, management, regulatory, and regulatory committees with scrutiny.

Measures designed by the Commission that do not match regulatory committee opinion are referred to the Council, as well as for informational purposes to the Parliament. The Council may then give agreement, or introduce an amendment within a three-month period. If the time lapses and the Council does not oppose, the Commission may draw up implementing measures, but if Council is in opposition, the Commission must amend or re-submit to the Council before implementation. “Regulatory committees with scrutiny” require Council and the European Parliament consideration prior to adoption of measures by co-decision. If one the institutions opposes the measure, the Commission may not adopt it without amendment (or it may submit a new proposal).\textsuperscript{81} There are about 300 committees in the fields of industry, social affairs, agriculture, environment, internal market, research and development, consumer protection, and food safety.\textsuperscript{82}

The European Court of Justice (ECJ) ensures compliance with the law in the interpretations and application of the founding Treaties.\textsuperscript{83} It is composed of the same number of judges as there are Member States and at present has 27 judges with partial replacement every three years. Judges select one of themselves as President of the Court for a renewable three-year term, and the court may sit in chambers (3-5 judges), Grand Chamber (13 judges), or as a Full Court. The main functions of the ECJ are to check whether instruments of the European institution of government are compatible with the Treaties, and give rulings at the request of a national court on the

\begin{footnotes}
\item[77] \url{http://www.europarl.europa.eu/sides/getDoc.do?language=EN\&type=IM-PRESS\&reference=20100406STO72095}
\item[78] \url{http://www.europarl.europa.eu/sides/getDoc.do?language=EN\&type=IM-PRESS\&reference=20100406STO72095}
\item[79] \url{http://europa.eu/scadplus/glossary/experts_committees_en.htm}
\item[80] \url{http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1999D0468:20060723:EN:PDF}
\item[81] \url{http://europa.eu/scadplus/glossary/comitology_en.htm}
\item[82] \url{http://europa.eu/scadplus/glossary/experts_committees_en.htm}
\item[83] \url{http://europa.eu/scadplus/glossary/eu_court_justice_en.htm}
\end{footnotes}
interpretation or the validity of provisions contained in Community law. The Court of First Instance (CFI) was created in 1989 as a second tier of judicial authority to relieve ECJ workload.

The European Court of Auditors is composed of one national from each Member State appointed for six-year renewable terms by qualified majority of the Council after consulting the European Parliament. This body acts independently to check the revenue and expenditure of the EU and any body created by the Community for legality, regularity, and sound financial management. Under the Treaty of Amsterdam, it has the power to report any irregularities to the European Parliament and the Council, but does not have the power to impose penalties.

B. The United States’ Representative Democracy

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.

1. U.S. Constitutional Framework

A key principle of the U.S. government is the “separation of powers” established by the Constitution, whereby 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 10th 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.”

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

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85 This section is based on “Regulatory Consultation in the United States,” by Susan E. Dudley, prepared as background reading for the December 1, 2010 workshop.
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 them 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. Of particular note with respect to federal regulation is the 10th amendment, 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.”

### 2. Administrative Procedure Act of 1946

The legislative branch frequently “delegates” rulemaking power to executive branch agencies. When writing regulations to implement legislation, agencies are constrained by the Administrative Procedure Act (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 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:

1. The agency can only act within the limits set by statutes.
2. 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.
3. 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 courts frequently are asked to evaluate the legality of regulations issued by the executive branch, and they rely on the language of the Constitution, the APA, and enabling statutes, as well as precedent from previous judicial decisions.

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 (NPRM or NOPR). In some cases, the agency will even issue an Advance Notice of Proposed Rulemaking (ANPRM) to gather information from the public in advance of issuing a proposed rule. The APA exempts some rules from the notice and comment requirements due to subject matter (e.g., military or foreign affairs, or internal organizational matters) or when comment would be “impractical, unnecessary, or contrary to the public interest.”