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# WORKING PAPER

**IMPROVING THE REGULATORY PROCESS THROUGHOUT ITS  
LIFE CYCLE:  
Nine Recommendations to a New Administration**

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## **Improving the Regulatory Process Throughout its Life Cycle:**

### **Nine Recommendations to a New Administration**

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## Executive Summary

This paper sets out a life cycle view of the regulatory process with suggested changes for the near and longer term. The life cycle begins with the strategic goals that government hopes to achieve, continues through several steps to the implementation and monitoring the effects of a regulation, and continues to evolve over time. A total of nine distinct recommendations are presented, along with their purpose, background, reasons for adoption, and challenges to implementation.

The five short-term and four longer-term recommendations and a leading reason for adoption are listed below. One-page summaries on each of the recommendations provides more detail in the text as well as explanations of terms.

Table ES.1: Recommendations for Improving the Regulatory Process

<b>Recommendation name</b>	<b>Reason for recommendation</b>
<b>Near term</b>	
1. Integration of Government Performance and Results Act and the Regulatory Process	Establish performance criteria at the time of proposal for future evaluation of the regulation
2. Public Scorecard of Regulatory Analyses	Identifies to the public and to agencies requirements for and achievement of compliance with guidance
3. Regulation-specific “Wiki”	Creates an online dialogue and record of the suggested comments that may reach a community consensus
4. Performance Audit Guidance from the GAO	Gives responsibility to a neutral and credible source in government for guidance
5. Public Financial Education Module	A better-informed citizenry may participate in more actions such as regulatory comments or be better informed to vote
<b>Longer term</b>	
1. Create Residual Risk Accounting Data and Reports	Creates new information regarding what to regulate and the performance of existing regulation
2. Congressional Approval for High-Cost Regulations	Incorporates triggers for congressional review that the cost burden may be inappropriate
3. Public Private Partnership to Improve Regulatory Analysis Methods	Agencies and OMB have missions to accomplish and a public private partnership may use the best skills of each to improve methods
4. Integrate OMB Annual Regulatory Reporting with National Income and Product Accounts	Links regulatory reporting with standard economic reporting

## **Improving the Regulatory Process Throughout its Life Cycle:**

### **Nine Recommendations to a New Administration**

#### **Statement of the problem**

This paper identifies regulation as a governmental tool for managing risk, and sets out a life cycle view of regulation with suggested changes for the near and longer term. The life cycle of regulation is the cycle that begins with the strategic goals that government hopes to achieve, continues through implementation and monitoring of the effects of a regulation, and evolves in a periodic manner over time. In general, U.S. laws begin the process, for instance by establishing standards for consumers and businesses. Some laws that Congress establishes are explicitly prescriptive and require agencies to act in a precise way. Other laws require further agency development and the impact on society results from federal administrative law, the enforceable part of the federal regulatory system. That system affects what we hear over the airwaves, the planes we fly in and the cars we drive, the air we breathe, how we act in the workplace, the food we eat, the drugs we take, the companies we buy from, the sports our children play in school, and more.

The total benefits and costs of the regulatory system are considerable but uncertain. Estimates of the benefits of recent regulations far exceed their costs in aggregate (OMB Reports to Congress on Benefits and Costs of Regulation, multiple years). One cost estimate puts the burden at about 10 percent of the economy (Crain, 2005). Other cost measures are direct government administrative costs, relatively low at about \$44 billion, but involving about 75,000 pages of *Federal Register* notices covering all areas of Government (Dudley and Warren, 2006). However, regulatory systems are thought by many to hinder development abroad and to be a source of periodic problems domestically. Examples of recent problems include regulatory aspects of new types of credit lending, responding to disasters, anti-terrorism efforts, and emerging markets for new types of commodities such as those related to energy or the environment.

The procedural steps to develop a regulation are many and complex. The existing process of regulatory development and review that involves numerous steps and agencies can be found in Dudley (2005; reproduced in Appendix). That description of the process starts with initiation from the agency and runs through about sixteen steps or decisions until the rule becomes final and the regulation has the force of law.

A new administration will have the option to change executive branch aspects of the regulatory process and may work with Congress to improve regulation. Unfortunately, there is no agreement on what “improving” means in regulatory improvement (Brown, et al., 2004) Some participants in the policy process are focused on improving the mission outcomes of agencies; of improving the efficacy of actions to reduce crime, improve health, and so on. Other participants focus on the efficiency of the actions, whether they are produced at least cost or designed to balance incremental benefits and costs. Still others focus on competing interests involving fairness across the income distribution, or race, or gender, or health status. Some aspects of the regulatory process are designed to bring information on these issues to the decision maker’s attention. Some other laws or aspects of the regulatory process go further and identify relatively more or less weight to place on different dimensions of improvement. The author’s perspective on improvement is that of a policy-oriented economist. There is an element suggesting that markets and economic information, broadly conceived, are useful and important, but recognition that there are multiple perspectives on the nature of “improvement.”

Noll (1996) describes an “incoherency” in regulation that is not unrelated to the challenge in identifying directions and tools for improvement. He describes attempts to discipline the regulatory process as attempting to bell the political cat as there are strong forces resisting such disciplining efforts. Attempts to improve the administrative law/regulatory process were reviewed by the GAO (2005a)<sup>1</sup>. The GAO concluded that attempts to

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<sup>1</sup> The reform attempts since 1980 included the: 1) Paperwork Reduction Act (PRA), 2) Regulatory Flexibility Act of 1980 (RFA), 3) Small Business Regulatory Enforcement Fairness Act (SBREFA), 4) Unfunded Mandates Reform Act of 1995 (UMRA), 5) Congressional Review Act (CRA), 6) Government

reform regulation had often been less effective than anticipated due to “(1) limited scope and coverage of various requirements, (2) lack of clarity regarding key terms and definitions, (3) uneven implementation of the initiatives’ requirements, and (4) a predominant focus on just one part of the regulatory process, agencies’ development of rules” (GAO, 2005a, p. 2). Consequently, many of the recommendations to be presented here will have aspects of broad scope and coverage across agencies, support the implementation of requirements, suggest processes that clarify terms or to create new information, and will be spread across a cycle of regulatory activities from conception to implementation and monitoring.

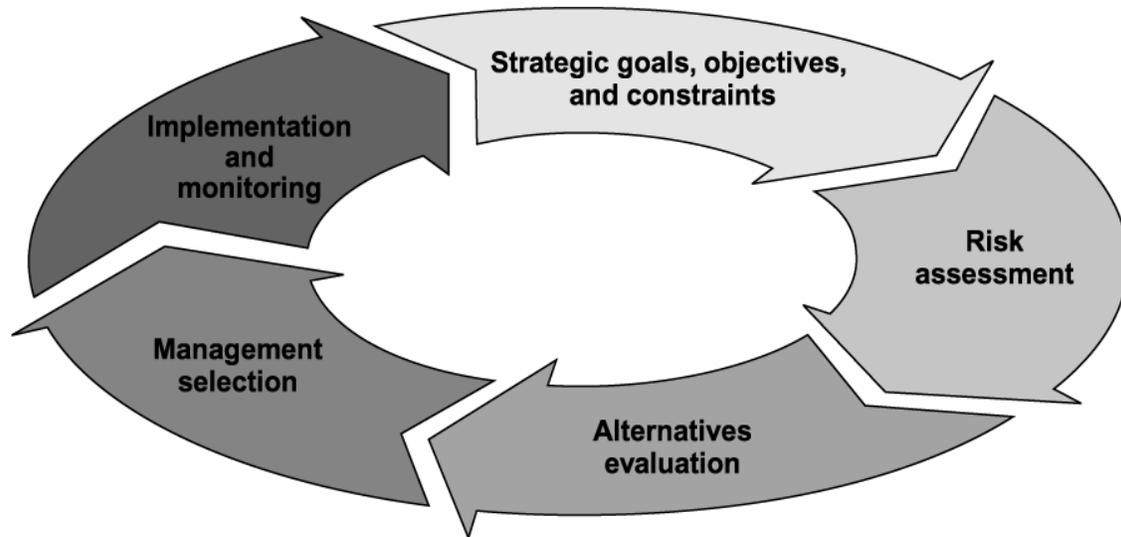
### *Regulation as a tool of risk management*

Regulation is one tool of government for managing risk. It is well understood that government has many tools at its disposal; tools such as direct expenditures, taxes, encouraging voluntary actions, and coercion—perhaps mutually agreed upon—through laws and regulation. In addition, most government actions can be viewed as working to reduce risk from someone’s perspective, whether that of a citizen, a company, an interest group, or governments. The risks may be related to health, employment, security, or finances, among others. Increasingly, risk management through any of the means available to government has been viewed as a cycle of activity that involves: (1) a strategic choice of direction and knowledge of constraints, (2) risk assessment, (3) evaluation of alternatives, (4) management selection—the choice by decision makers, and (5) implementation and monitoring; and the cycle repeats. Risk communication is sometimes viewed as a cross-cutting element (Presidential Commission, 1997). The GAO espoused this cycle most clearly in regard to Homeland Security but also applies it in a broader perspective (GAO, 2005c; Valverde and Farrow, 2008). Figure 1 below illustrates this risk-management cycle.

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Paperwork Elimination Act (GPEA), 7) Truth in Regulating Act (TIRA), 8) Information Quality Act (IQA), 9) E-Government Act, and 10) Executive Orders 12866 (Regulatory Review) and 13132 (Federalism).

Figure 1: GAO (2005c) risk management cycle



Source: GAO.

Nine near- and longer-term recommendations to improve the regulatory process are presented in this paper and linked to the risk management cycle. The recommendations are presented in the Executive Summary and further context to the cycle and organizational actions are provided in table 1. Following the table, each recommendation is presented in a one-page template that briefly describes the recommendation, the issue it is designed to address, how it improves the regulatory process, and challenges to its implementation. Each of the recommendations is relatively high level and could have further implications for additional recommendations. For instance, the recommendation for executive branch agencies and the Office of Management and Budget (OMB) to work with external professional groups to improve standards omits the many specific areas that such a partnership might investigate, although examples are discussed in the text. However, such a partnership could easily lead to a new source of specific recommendations for improvement.

Table 1: Risk Management, Institutional Actions, and Recommendation Summary

Risk Management Cycle	Illustrative Institutional Actions		Near Term Recommendations	Longer Term Recommendations
	Congress	Executive Branch		
Strategic Goals, Objectives, Constraints	What to regulate (yes, no, how much?)  What to fund	What to regulate within mission	GPRa Requirement	Congressional Approval for High Cost Regulations
Risk Assessment	Legislative develop.  Budgetary develop.	Agency development	GAO Performance-Audit Guidance	BEA: Residual Risk-Accounts  Public/Private Standards-Partnership
Evaluation		Management choice (Judicial review)	Public Scorecard  Regulatory Wikipedia  GAO Performance-Audit Guidance	Public/Private Standards-Partnership
Management selection				Congressional Approval for High-Cost Regulations
Implementation and Monitoring	Authorization & Appropriation  Oversight	Implementation and Monitoring  Budget	GPRa Requirement  Financial literacy-module	BEA/OMB Economic Reporting  Public/Private Standards-Partnership

## **Near-term recommendation 1**

### Integration of Government Performance and Results Act (GPRA) and Regulatory Process

#### ***Suggested Action:***

An agency must define at least two GPRA performance measures when a major regulation is proposed and at least one must be related to economic performance such as cost-effectiveness or benefit-cost assessment.

#### ***Background/issue addressed***

Although the regulatory process currently focuses on predicting the impacts of regulation, there is little retrospective assessment (GAO, 2005a; McGarity, 1991) of existing regulations, particularly related to their performance. Furthermore, GPRA measures produced by the agencies typically ignore economic performance (GAO, 2005b) although committee language for GPRA clearly includes at least cost-effectiveness measures and benefit-cost type measures appear consistent with intent. Finally, integrating GPRA with budget allocations has been an initiative of OMB through the program assessment and review procedures (the PART process). This recommendation brings regulation into the GPRA/budget connection by linking measures identified for regulatory review based on executive order with implementation and provides incentives for retrospective analysis.

#### ***How recommendation improves regulation and reasons for adoption***

- Establishes expectations for the retrospective assessment of a regulation based on its expected performance at the time of proposal
- The forecasting efforts of the agency and review by part of the OMB (Office of Information and Regulatory Affairs, OIRA) are integrated with performance based aspects of the Federal budget process that the budgetary part of OMB implements, most recently through PART (Program Assessment Rating Tool)
- The prior analysis of large regulations should provide benchmarks against which actual outcomes and performance measures can be addressed
- An established expectation can create incentives to design regulatory evaluation into the early stages
- Builds information for an adaptive approach to modify regulatory implementation depending on results

#### ***Challenges to improving regulation this way***

- Agency and OMB resources are scarce
- It is difficult to evaluate programs due to confounding factors

#### ***Step in risk-management process***

Monitoring and strategic review

## **Near-term recommendation 2**

### Public Scorecard of Regulatory Analyses

#### ***Suggested Action:***

The Office of Information and Regulatory Affairs (OIRA) in OMB should develop and make public a report/score card that identifies the actionable elements of their guidance, rates major proposals on each item, and explains any failures or inconsistencies that are below their standard.

#### ***Background/issue addressed***

Several non-governmental analysts have investigated the quality of Regulatory Impact Analyses based on their interpretation of OMB/OIRA guidance (Hahn and Tetlock, 2008; Belzer, 1999). Numerous weaknesses have been identified. However, neither agencies nor the public appear to know what the minimum or other standards are for acceptability. Having OMB be explicit about their criteria, and the agencies having to justify departures from those criteria, could improve quality through transparent and explicit attention to analytical practices.

#### ***How recommendation improves regulation and reasons for adoption***

- Identifies to the public and to agencies requirements and achievement of compliance with guidance
- Communicates more explicitly the basic analytical requirements in OMB guidance
- OMB guidance exists and no new executive order or legislation would be required
- External researchers have demonstrated feasibility

#### ***Challenges to improving regulation this way***

- Case specific issues may lead to a number of exemptions
- Defining a minimum threshold may drive agencies to achieve just the minimum

#### ***Step in risk-management process***

Quality control at the risk assessment and evaluation stage

### **Near-term recommendation 3**

Regulation specific “Wiki”

#### ***Suggested Action:***

At the time a regulatory proposal goes public, the agency shall create a public access, on-line and editable (wiki) version of the regulation on which multiple parties can make edits.

#### ***Background/issue addressed***

The public comment period is currently based on a non-computerized model of communication. In many cases it is difficult to determine exactly what changes parties are suggesting for the regulatory wording. Using newly created “Wikipedia”-type editing where multiple parties can enter changes, the agencies obtain a clearer understanding of what different groups are recommending and whether a community consensus emerges. In addition, a “wiki” approach can help to facilitate stakeholder understanding and communication with other stakeholders. While many details would remain to be worked out on shared editing; the “wiki” community on the web has developed a number of protocols (editing policy at [http://en.wikipedia.org/wiki/Wikipedia:Policies\\_and\\_guidelines](http://en.wikipedia.org/wiki/Wikipedia:Policies_and_guidelines)). Such policies may be modified for community commenting on a regulation in contrast to a neutral encyclopedia type entry. For instance, it may be that different editing communities could create an additional document and groups specialize in editing the one they most prefer. In addition to community editing of text, it may also be possible to provide the analytical summaries of regulations online in which different groups may edit assumptions.

#### ***How recommendation improves regulation and reasons for adoption***

- Creates an online dialogue and record of the suggested comments that may reach a community consensus
- Increases specificity and transparency of public comments on regulation
- Relatively low cost to implement and monitor (e.g., control “vandalism,” “reverting,” or excessive editing)

#### ***Challenges to improving regulation this way***

- Contradictory or other incorrect information may appear in the edited versions
- Documents evolve and can contain factual errors

#### ***Step in risk-management process***

Evaluation of alternatives/public comment

## **Near-term recommendation 4**

Performance Audit Guidance from the GAO

### ***Suggested Action:***

That GAO provides expanded government-wide guidance for the performance audit of regulatory programs.

### ***Background/issue addressed***

GAO produces “Government Auditing Standards,” known as the “Yellow Book” (GAO, 2007). An important part of that guidance distinguishes financial audits from performance audits where “Performance audits are defined as engagements that provide assurance or conclusions based on an evaluation of sufficient, appropriate evidence against stated criteria, such as specific requirements, measures, or defined business practices . . . Performance audit objectives may vary widely and include assessments of program effectiveness, economy, and efficiency; internal control; compliance; and prospective analyses.” (GAO, 2007, p.12)

The GAO has been considered for broader involvement in the regulatory process, as through the Truth in Regulating Act that involved pilot evaluations. GAO has resisted taking on a larger role in the absence of additional funding. However, GAO may be an appropriate source of government-wide guidance on specific types of performance audits given their expertise in evaluation, accounting, economics, and statistics and their credibility in convening third parties to assist in providing guidance.

### ***How recommendation improves regulation and reasons for adoption***

- Gives responsibility to a neutral and credible source in government for guidance
- As the source of GAGAS (Generally Accepted Government Auditing Standards), the GAO appears to have the authority to develop guidance related to performance audits
- GAO has an established advisory system that could be expanded
- GAO has a neutral, credible reputation suited to providing guidance
- GAO guidance is likely to be influential with Agency Inspector General offices

### ***Challenges to improving regulation this way***

- Guidance and convening advisory groups are costly activities
- Government agencies may not concur that they are conducting “performance audits” and avoid using guidance

### ***Step in risk-management process***

Prospective activity: Risk Assessment/Evaluation of alternatives

Retrospective auditing: monitoring

## **Near term recommendation 5**

Public Financial Education Module

### ***Suggested Action:***

Develop a public finance and regulation module as part of efforts to increase financial literacy in the citizenry.

### ***Background/issue addressed***

Concern for the financial literacy of the citizenry has led to the formation of the U.S. Financial Literacy and Education Commission and the President's Council on Financial Literacy. Members of the commission include the Departments of Treasury, Education, Health and Human Services, and the Social Security Administration, among others.

While an important part of financial education are personal finances, another part are issues at the intersection of governmental budgeting, taxation, and regulation. Topics such as retirement planning and social security are already a part of the commission web site (<http://www.mymoney.gov/>). That site includes topics on: (personal) budgeting and taxes, credit, financial planning, home ownership, kids, paying for education, privacy, retirement, saving and investing, and starting a small business.

Additional modules on a citizen's financial links to the government, including taxes, tax expenditures, and regulation should be an important if perhaps secondary part of personal financial literacy. Agencies such as those already listed but also including the Office of Information and Regulatory Affairs in the Office of Management and Budget could develop educational materials related to public finance and education for the commission web-site.

### ***How recommendation improves regulation and reasons for adoption***

- A better-informed citizenry may participate in more actions such as regulatory comments or be better informed to vote
- A commission and website exist with a purpose complementary to the recommendation
- Relatively low cost

### ***Challenges to improving regulation this way***

- Extends the concept of personal financial knowledge to knowledge of governmental finances and actions and their impact on an individual

### ***Step in risk-management process***

Risk communication that cuts across steps in the process; feedback from citizenry to strategic planning

## **Longer-term recommendation 1**

Create Residual Risk Accounting Data and Reports

### ***Suggested Action:***

The Bureau of Economic Analysis (BEA), in conjunction with other professional organizations, should develop time series data on actualized risks and their economic valuation that are the typical subject of regulation.

### ***Background/issue addressed***

How much and what to regulate could be better informed by risk data that cut across specific areas. Congress and agencies are often said to be reactive to the crisis of the moment, and regulation can follow that reaction. Information is not currently compiled in a way that illustrates the scale and monetized value of residual risks across various outcome issues, such as crime, health, education, environment, or natural hazards. Residual, actualized risks are those actual risks that occur even though citizens take their own avoidance actions and a regulatory system is in place for many events. Risk laws and regulations often result from high-profile risk events placing pressure on Congress and regulatory agencies to act. In many cases, there may not be easily obtainable data to place the new risks in context with existing risks, particularly in an actuarial sense—that is, measured injuries, illnesses, and deaths. Both the risks and their monetized value to society in a single could help legislators and regulators quickly place new risks in context.

The Bureau of Economic Research is the lead agency in the development of the National Income and Product Accounts (NIPA) which, for instance, lead to measures like Gross Domestic Product. New work combined with existing data could create information on both quantities of risks that occur (such as accidental deaths or high-school drop outs) and their value in dollar terms. These data would represent an upper bound on the historical benefits that a “perfect” regulation would have achieved, while also informing discussions on prioritizing and assessing the effectiveness of proposed laws and regulations. Measures of the variability in outcomes and values could also be addressed.

### ***How recommendation improves regulation and reasons for adoption***

- Creates new information regarding what to regulate and the performance of the regulation
- Structures information so that risks are both quantified in their natural units (e.g. drop-outs) and in common units, their dollar value
- Significant data and research has been done on component parts

### ***Challenges to improving regulation this way***

- The precision of estimates may vary by type of risk
- There are differences of opinion about values attached to outcomes

### ***Step in risk-management process***

Information for (1) strategic direction, (2) risk assessment, and (3) evaluation.

## **Longer-term recommendation 2**

### Congressional Approval for High Cost Regulations

#### ***Suggested Action:***

Regulations that impose costs of more than \$100 million per year in total should be approved by the relevant portion of Congress if the Congressional Budget Office (CBO) certifies that key regulatory performance measures, such as cost per statistical life, exceed a “pre-approved” cost level. An extension is that these high-cost regulations could be offset by cost reductions elsewhere under the agency’s control and so certified by the CBO, or the appropriate appropriations committee or other delegated body of Congress must vote to increase a newly created regulatory cost account of the agency by the appropriate amount.

#### ***Background/issue addressed***

Although Congress has the power to review regulations prior to their enactment (e.g., Congressional Review Act), this power is rarely invoked. Regulations that impose both costs and benefits on the economy are often based on broad delegation given to agencies from Congress. This recommendation establishes benchmarks for congressional approval of high cost regulations. Low-cost or cost-neutral regulations would not require such approval. The additional recommendation implements an incremental, regulatory budget check at the time of a proposed regulation in the spirit of PayGo legislation (Orszag, 2007). There is a history of suggestions to create a regulatory budget (e.g. DeMuth, 1980) that would limit agency and total regulatory spending. This proposal essentially implements an incremental and case by case regulatory budget for major regulations. The recommendation is also structured to follow general prescriptions for new laws under a PayGo system in which revenues to fund new programs are to be identified or offset by cost savings. This proposal provides some encouragement for agencies to find low cost alternatives or regulatory efficiencies elsewhere, or, failing that, to confirm approval from Congress to impose the regulatory cost.

#### ***How recommendation improves regulation and reasons for adoption***

- Incorporates triggers for congressional review when the cost burden may be inappropriate
- More efficiently implements retrospective review by creating constant incentives for agencies to find cost savings in their current activities
- Creates a parallel structure for regulations to that for direct government spending

#### ***Challenges to improving regulation this way***

- May encourage agencies to strategically game cost savings in other areas
- Imposes a new congressional review process for major regulations

#### ***Step in risk-management process***

Management selection and evaluation of alternatives

### **Longer-term recommendation 3**

#### Public Private Partnership to Improve Regulatory Analysis Methods<sup>2</sup>

##### ***Suggested Action:***

Create and fund an interagency, executive branch task force to work with professional organizations on cross-cutting principles and standards for regulatory analysis.

##### ***Background/issue addressed***

The Office of Information and Regulatory Affairs (OIRA) and some individual agencies have produced guidance on implementing some aspects of regulatory review. The most detailed guidance has generally been for benefit-cost analysis (OMB circulars A-94, and A-4 and from agencies such as EPA, DOT, and DHS). However, such guidance is relatively terse and may be improved with added detail in some areas and updating in others. Further, OIRA lacks an advisory group to assist in guidance development such that some issues, such as identifying some specific regulations as transfers, may not be consistent with professional standards. Academic economists and organizations such as the National Science Foundation, the National Bureau of Economic Research, the Society for Benefit-Cost Analysis, the Society for Risk Analysis may usefully inform analytical practice in a partnership with executive branch agencies.

Among issues that might be addressed include:

- The analytical integration of risk assessment and benefit-cost analysis
- Comparisons between benefit-cost analysis and multi-attribute utility
- Developing guidance on the quantification of risk and/or uncertainty
- Clarifying issues such as: transfers, default values (shadow prices), reporting quantities as well as individual values, and so on
- Developing benefit-cost electronic templates for classes of analysis, such as occupational safety, transportation regulations, air quality, water quality, etc.

##### ***How recommendation improves regulation and reasons for adoption***

- Public/private partnerships may produce more thorough, consistent and analytically grounded guidance with wider acceptance than currently exists.
- Guidance on methods and practice may come from a neutral source
- External groups could advise, but adoption up to OMB and the agencies

##### ***Challenges to improving regulation this way***

- Government (OMB and agencies) may give up some power to external groups
- Requires new monetary or time resources

##### ***Step in risk-management process***

Guidance for risk assessment and alternative evaluation.

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<sup>2</sup> This recommendation may be combined with development of GAO Guidance, near term recommendation 4 above.

## **Longer-term recommendation 4**

Integrate OMB Annual Regulatory Reporting with National Income and Product Accounts

### ***Suggested Action:***

OMB should work with the Bureau of Economic Analysis (BEA) to determine whether a supplemental account to the National Income and Product Accounts can be developed for regulatory impacts, costs, benefits, and other features of regulatory impacts.

### ***Background/issue addressed***

OMB produces an annual report on regulation (OMB, multiple years). That report now contains the start of a reporting form for annual regulatory impact. The Bureau of Economic Analysis, other data oriented agencies of the federal government, and scientific organizations have considered developing supplemental account to the National Income and Product Accounts in many areas. Although it is doubtful that a meaningful measure of total benefits and costs of cumulative regulations over all time could be constructed, the BEA is familiar with inventory adjustment and other methods that may increase the information content of OMB's reports. Further, the expansion of benefit-cost reporting to include quantitative and non-quantitative benefits and costs may help communicate underlying information that supports regulatory benefit-cost analysis.

### ***How recommendation improves regulation and reasons for adoption***

- Links regulatory reporting with standard economic reporting
- Congress has asked for an annual accounting for regulation but it is not clear that the major economic data generating agency has been brought into design discussions
- May improve a report requested by Congress

### ***Challenges to improving regulation this way***

- Supplemental accounts are time consuming and may be expensive to develop
- The BEA is not expert in regulations

### ***Step in risk-management process***

Information for monitoring and strategic review

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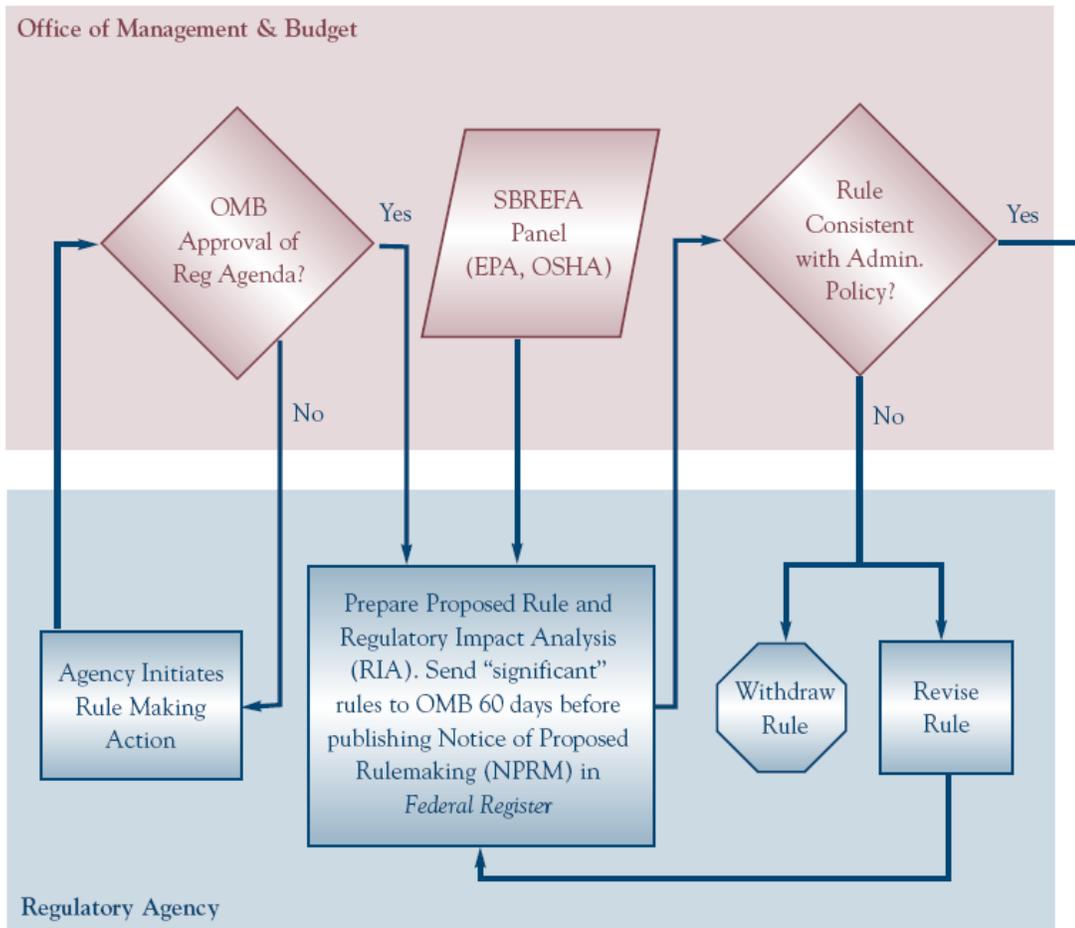
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**Appendix:  
The Regulatory Process: Part I (Dudley, 2005)**

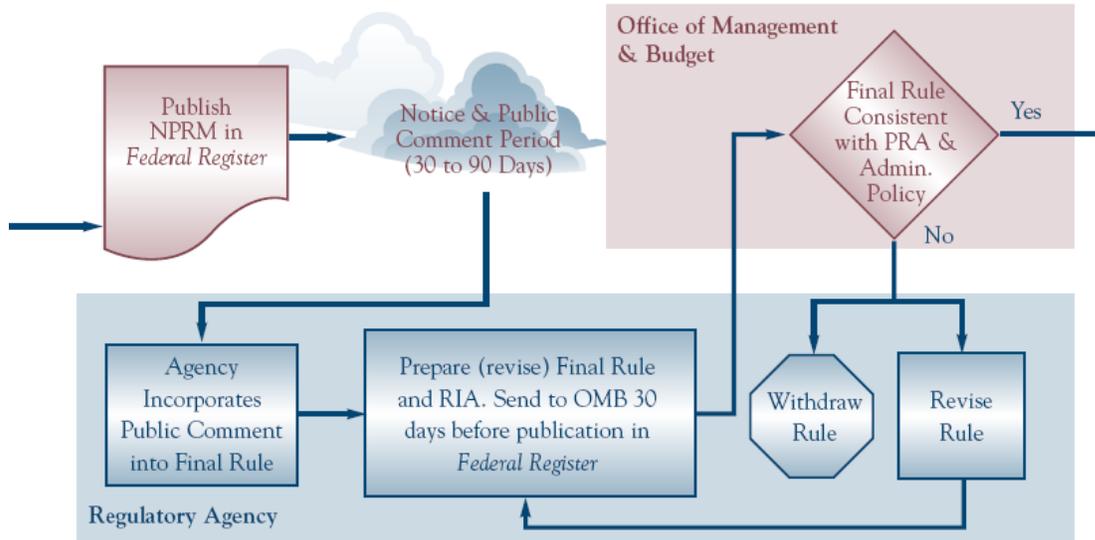
BIRTH OF A REGULATION, INITIATION PHASE



Figures 4-1 through 4-3 illustrate the regulatory development process. Agencies announce the initiation of a rule-making through the semi-annual Unified Agenda of Federal Regulations (a list of all forthcoming and ongoing regulatory actions). The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has a role in determining the content of the Unified Agenda. Agencies often spend years developing a regulation before beginning to draft a proposal. Once drafted, regulations that are considered significant must be reviewed by OIRA, and draft regulations of the EPA and OSHA are subject to a SBREFA review if they have the potential to affect small entities.

## Regulatory Process: Part II (Dudley, 2005)

### NOTICE, COMMENT, & FINALIZATION



Once a draft regulation has passed these reviews, it is published in the *Federal Register*, and the public has an opportunity to comment on it. After reviewing public comment, the agency must submit the draft final rule to OIRA once again before a final rule can be published in the *Federal Register*. Regulations do not take effect for at least 30 days after final publication. Congress has an opportunity to issue a joint resolution of disapproval after a final regulation has been published, and regulations are also subject to judicial review: affected parties can sue to have regulations overturned by the courts.

Figure 4.3  
PUBLICATION & POSSIBLE REVIEW

