



Background on the Rulemaking Process

V. Making Rules Work

Federal agency decision-making does not end with the publication of a final rule in the *Federal Register*. After all, once a regulation is issued an agency must administer or enforce it in order to fulfill the purposes of its statutory mission. A number of activities are critical to this process of implementation.

A. Guidance Documents

All regulations set forth policy and many of the details necessary for their implementation. However, they often do not provide all of the needed details. For example, they may not describe how an agency should coordinate the implementation of the new regulation with existing regulations, or who in the local or regional offices should approve exemption decisions.

As such questions arise, agencies often produce guidance documents to advise staff in national, regional, state, and local offices on regulatory implementation. These publications may not only become quite lengthy, but also are changed frequently to reflect regulatory revisions or new internal procedures.

Guidance documents are a broadly-defined class of information. They include any document which sets forth a policy, aids regulated bodies in complying with rules, or suggests action to the public or private sector on a matter the issuing agency feels it necessary to address. Guidance documents can take the form of memos, policy statements, brochures, and oral, written or visual communications.

Guidance documents do not have the force of law in the way regulations do. In some cases, agencies issue guidance documents to express a thought or opinion which may help the general health and welfare of the nation. Other times, agencies issue guidance to govern their own decision-making process. Regulated bodies may also ask for guidance in situations in which proper methods of compliance are unclear.

Beginning in July 2007, the Office of Information and Regulatory Affairs (OIRA) within the White House Office of Management and Budget (OMB) began reviewing guidance documents in the same way it does proposed regulations. (For more on OIRA's review process, see Sec. III.) OIRA subjects only "significant" guidance documents to its review process.

Significant guidance documents are those classified as affecting the economy by more than \$100 million, affecting the actions of other agencies, affecting non-discretionary programs, or raising new policy issues.

Due to the expanded review process, the public has easier access to agency guidance documents. Significant guidance documents are published in the *Federal Register* and made available on agency websites. In some situations, agencies will give the public an opportunity to comment on a proposed guidance document in the same way as proposed rules. (For more on commenting on proposed rules, see Sec. IV.)

B. Inspections and Enforcement

Once a regulation takes effect and agency personnel have integrated it into their program operations, the agency must ensure regulatory compliance.

The agency may require those individuals, companies or institutions subject to regulation to report to the agency on compliance or keep records to prove compliance. The agency may conduct surveys or scientific studies to determine if regulations are solving problems as intended. As discussed in Section IV, these information collection activities will require OMB clearance under the Paperwork Reduction Act.

Agencies also use inspectors to investigate how well laws and regulations are being followed. Inspectors for the Department of Labor's Occupational Safety and Health Administration check factories and work sites for proper equipment maintenance and worker safety measures and instruction. Nuclear Regulatory Commission inspectors monitor nuclear power plant operations. National Transportation Safety Board investigators sift through airplane wreckage to ascertain the cause of crashes. Securities and Exchange Commission officials monitor stock transactions to guard against insider trading. The Department of Agriculture Animal and Plant Health Inspection Service inspectors examine imported animals for disease.

Agency investigations can lead to adjudications or enforcement proceedings in which the agency may charge individuals with violating a regulation. Agency hearing examiners or administrative law judges may impose penalties ranging from further audits to suspension from federally-funded programs. In some situations, agencies will levy fines for failure to comply with a regulation.

If the matter is so serious as to suggest possible violations of criminal statutes, the case may be referred to the Department of Justice for criminal prosecution.

C. Program Management

For an agency to implement a regulation effectively it must be sure that its own operations are in order. This is a never ending task. Congress passes government improvement laws, agencies issue administrative regulations, and even the president, through OMB, instructs agencies on how to manage their programs, perform audits, distribute grant money, buy equipment, and investigate fraud, waste, and abuse.

Part of managing an agency is working to ensure that it is staffed with the needed experts and that the budget is sufficient to meet the mission the agency or program must carry out. Congress and the president, however, have the final say about the resources each agency receives. It isn't enough that Congress pass legislation authorizing regulatory policy; it needs to appropriate sufficient funding for an agency to implement the legislation.

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