

PART I

**OVERVIEW OF FEDERAL AGENCY
RULEMAKING**

“The extent to which the administrative law of the national government is to be found in executive regulations is not ordinarily appreciated.”

Frank J. Goodnow
THE PRINCIPLES OF ADMINISTRATIVE LAW
IN THE UNITED STATES 87 (1905)

PART I

OVERVIEW OF FEDERAL AGENCY RULEMAKING

Passage of the Administrative Procedure Act (APA) in 1946¹ established the basic framework of administrative law governing federal agency action, including rulemaking. While the provisions of the APA continue to be central to the rulemaking process, a number of developments have, to some extent, undermined the original unifying effect of the APA. Beginning around 1970, Congress enacted a variety of specific regulatory statutes that mandated rulemaking procedures to supplement or supersede the APA's provisions.² In addition, many administrative agencies significantly modified their rulemaking procedures in response to court-mandated refinements and the increasing complexity and controversial nature of many rulemakings.³ Succeed-

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1. Pub. L. No. 404, 60 Stat. 237, ch. 324, §§ 1-12 (1946). Codified by Pub. L. No. 89-554 (1966) in 5 U.S.C. §§ 551-559, 701-706, 1305, 3105, 3344, 5372, 7521. See *The Administrative Procedure Act: A Fortieth Anniversary Symposium*, 72 VA. L. REV. 215 (1986) (discussing the history and contemporary impact of the APA on the Act's fortieth anniversary). This *Guide* refers to the sections in Title 5.
 2. See, e.g., Federal Trade Commission Improvement Act, 15 U.S.C. §§ 41-46, 50, 57a-58; Consumer Product Safety Act, 15 U.S.C. §§ 2051-2058, 2060-2061, 2063-2084; Occupational Safety and Health Act, 29 U.S.C. §§ 651-678; Mine Safety and Health Act, 30 U.S.C. §§ 801-804, 811-825, 841-846, 861-878, 901-931. These statutes are often referred to as "hybrid" rulemaking statutes, because they combine elements of both "formal" and "informal" rulemaking. Stephen F. Williams, "*Hybrid Rulemaking*" *Under the Administrative Procedure Act: A Legal and Empirical Analysis*, 42 U. CHI. L. REV. 401 (1975) (discussing creation of hybrid rulemaking). The term "hybrid rulemaking" was anticipated prior to publication of the Williams article. Bruce McAdoo Clagett, *Informal Action—Adjudication—Rule Making: Some Recent Developments in Federal Administrative Law*, 1971 DUKE L.J. 51, 70 (urging agencies to fashion "hybrid or conglomerate procedural devices"). See also *infra* subsec. (C) for a discussion of hybrid rulemaking.
 3. See, e.g., *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council*, 435 U.S. 519, 524 (1978) (reaffirming the principle that "[a]gencies are free to grant additional procedural rights in rulemaking in the exercise of their discretion

ing presidents, beginning with Nixon, have, by executive order, imposed procedural and analytical requirements on rulemaking by executive branch agencies that went beyond procedures required by the APA.⁴ Additional “regulatory reform” initiatives enacted by Congress have also prescribed procedural and analytical requirements for rulemaking. The combination of these add-ons to the rulemaking process has led numerous commentators to fret over the “ossification” of rulemaking.⁵ At the same time, a trend toward deregulation began in the late 1970s and has continued through the subsequent decades.⁶

. . .”). For an illuminating history of rulemaking’s “collision” “with vigorous judicial review” in the D.C. Circuit, see Reuel Schiller, *Rulemaking’s Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139, 1141 (2001).

4. The most important of these is Exec. Order 12,866, 3 C.F.R. 644 (1993 compilation), *reprinted in* 5 U.S.C. § 601 and Appendix B to this *Guide*. Its stated purpose is “to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decisionmaking process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public.” *Id.* Exec. Order 12,866 and other more recent executive orders governing agency rulemaking are discussed *infra* subsec. (D) and Part III, ch. 2(A), (G).
5. See, e.g., Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 Duke L.J. 1385 (1992); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995). One example of how rulemaking may be taking longer is recounted in a report by the Inspector General of the Department of Transportation, which found that the time taken to complete a rule increased from an average of 1.8 years and a median of 10 months in 1993, to an average of 3.8 years and a median of 2.8 years in 1999. Moreover, the number of significant rules issued fell from 45 in 1993 to 20 in 1999. DOT, OIG AUDIT REPORT: THE DEPARTMENT OF TRANSPORTATION’S RULEMAKING PROCESS 7, Report No. MH-2000-109 (July 20, 2000), *available at* <http://www.oig.dot.gov/StreamFile?file=/data/pdfdocs/mh2000109.pdf>. However, a follow-up report in 2004 found improvements in timeliness and conceded some problems with measurement with a small sample. See DOT, OIG AUDIT OF DOT’S RULEMAKING PROCESS AND TRACKING SYSTEM 2-3, Report No. SC-2004-035 (Mar. 2, 2004), *available at* <http://www.oig.dot.gov/StreamFile?file=/data/pdfdocs/0rm-f101.pdf>.
6. There is extensive literature on the subject of deregulation and its impact on agency rulemaking. See, e.g., Thomas O. McGarity, *Regulatory Reform in*

One of this *Guide's* major purposes is to provide agency rulemakers, participants, and others interested in agency rulemaking with an integrated view of the procedural requirements as they relate to each stage of the rulemaking process. Before embarking on a stage-by-stage discussion, however, the major events in the development of the federal rulemaking process will be summarized.

A. Rulemaking Under the Administrative Procedure Act

The APA was the product of a struggle between interests that supported the programs of the New Deal agencies and those that were afraid or suspicious of the power given those agencies.⁷ One of the APA's major accomplishments was the establishment of minimal procedural requirements for many types of agency proceedings. However, the APA did not require—as earlier bills would have—that all administrative action follow a single, rigid procedural model.⁸ Instead, the APA recognized and adopted various agency procedures that are

the Reagan Era, 45 MD. L. REV. 253 (1986); Robert R. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1315-26 (1986); Merrick B. Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505 (1985); Marianne K. Smythe, *Judicial Review of Rule Rescissions*, 84 COLUM. L. REV. 1928 (1984); ROBERT E. LITAN & WILLIAM D. NORDHAUS, REFORMING FEDERAL REGULATION (1983); STEPHEN BREYER, REGULATION AND ITS REFORM (1982).

7. See George B. Shepherd, *The Administrative Procedure Act Emerges from New Deal Politics*, 90 NW. U. L. REV. 1557 (1996); Jeffrey S. Lubbers, *APA Adjudication: Is the Quest for Uniformity Faltering?*, 10 ADMIN. L. J. AM. U. 65 (1996); Paul R. Verkuil, *The Emerging Concept of Administrative Procedure*, 78 COLUM. L. REV. 258, 268-74 (1978). See also Dennis R. Ernst, *Dacey's Disciple on the D.C. Circuit: Judge Harold Stephens and Administrative Law Reform, 1933-1949*, 90 GEO. L.J. 787 (2002) (detailing pre-APA history).
8. The need for procedural variety and flexibility was shown by the excellent empirical research conducted by the Attorney General's Committee on Administrative Procedure, in existence from 1939-1941 and chaired by Dean Acheson. See generally ATTORNEY GENERAL'S COMMITTEE ON ADMINISTRATIVE PROCEDURE, FINAL REPORT ON ADMINISTRATIVE PROCEDURE IN GOVERNMENT AGENCIES, S. Doc. No. 77-7 (1941).

commonly characterized as “formal adjudication,” “formal rulemaking,” “informal adjudication,” and “informal rulemaking.”

The emphasis in this *Guide* is on “informal” rather than “formal” rulemaking. Formal rulemaking is triggered only where a statute other than the APA requires a rule to “be made on the record after opportunity for an agency hearing.”⁹ Although formal rulemaking procedures are discussed in Part II, Chapter 1(B), they will not be analyzed in detail in this *Guide*, as they are seldom used except in some ratemaking and food additive proceedings.

Section 553 of Title 5, United States Code, is the APA’s general rulemaking section; rulemaking governed by it is commonly called “informal,” “APA,” or “notice-and-comment” rulemaking.¹⁰ The notice-and-comment label derives from the fact that section 553 requires (1) publication of a notice of proposed rulemaking, (2) opportunity for public participation in the rulemaking by submission of written comments, and (3) publication of a final rule and accompanying statement of basis and purpose not less than 30 days before the rule’s effective date. It is important to stress that these requirements are the procedural floor below which an agency may not go in prescribing procedures for a particular rulemaking. The APA’s drafters contemplated that “[m]atters of great import, or those where the public submission of facts will be either useful to the agency or the protection to the public, should naturally be accorded more elaborate public procedures.”¹¹

As discussed below,¹² however, even the procedural floor set in

9. 5 U.S.C. § 553(c).

10. Professor Herz has noted the increasing tendency of courts and commentators to blur the distinction between formal and informal rulemaking. He described the more frequent use of the oxymoronic phrase “formal notice-and-comment” and ascribed it to the facts that (1) traditional formal rulemaking has “virtually disappeared,” (2) agencies increasingly rely on policy statements, where the procedure is even less formal, and (3) the Supreme Court’s jurisprudence on the *Chevron* case (discussed in Part IV) has introduced different notions of “formality.” Michael Herz, *Rulemaking Chapter*, DEVELOPMENTS IN ADMINISTRATIVE LAW AND REGULATORY PRACTICE 2002-2003, at 144 (Jeffrey S. Lubbers ed., 2004).

11. REPORT ON THE ADMINISTRATIVE PROCEDURE ACT, S. REP. NO. 79-752, at 15 (1945).

12. See *infra* Part II, ch. 1(D).

section 553 does not apply to all rulemaking. Certain types of rules are exempted from some of these requirements, and entire classes of rules are totally exempted from APA notice-and-comment requirements. These exemptions reflect the APA drafters' cautious approach to imposing procedural requirements on a myriad of agency functions, as well as their willingness, in some situations, to permit agencies a measure of discretion in fashioning procedures appropriate to the particular rulemaking involved.

Congress's original willingness to leave to agency discretion rulemaking procedures exceeding the bare minimum required by section 553 partially eroded in the subsequent 60 years. Federal courts, Congress, and presidents have taken steps to require that agencies follow more rigorous procedures. While the Clinton Administration did take some steps to streamline presidential review of rules¹³ and the Supreme Court put the brakes on judicial supplementation of procedures in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council (Vermont Yankee)*,¹⁴ Congress has continued to require new procedural and substantive requirements, as has the Office of Management and Budget (OMB) under President George W. Bush.¹⁵ These developments are discussed below in greater detail.

B. Agency Rulemaking and the Courts

Under the APA, persons aggrieved or adversely affected by agency actions, including agency promulgation of rules, have the right to seek judicial review of those actions.¹⁶ Limited exceptions are provided—specifically, where another statute precludes judicial review or the action is committed to agency discretion.¹⁷ Most statutes establishing

13. See *infra* subsec. D.

14. *Supra* note 3.

15. OFFICE OF MGMT. & BUDGET, PEER REVIEW AND INFORMATION QUALITY PROPOSED BULLETIN (Aug. 29, 2003), available at http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf. See *infra* subsec. D(3).

16. 5 U.S.C. §§ 701-706. See generally *infra* Part IV (discussing judicial review of agency actions).

17. 5 U.S.C. § 701(a). The scope of these exceptions has been the subject of court decisions, particularly in the contexts of suits to compel agency action. See discussion *infra* Part IV, chs. 2, 3.

regulatory programs provide for court review of agency rules.¹⁸ Unless the enabling statute contains a controlling judicial review provision,¹⁹ reviewing courts generally follow section 706 of the APA in determining the scope of judicial review. Because the standards are stated in general terms, and the application of particular standards of review to specific types of proceedings is not defined clearly by the APA, the judicial review provisions have been the subject of much court interpretation. A number of landmark Supreme Court decisions have been important in explicating the relationship between the courts and administrative agencies in the rulemaking area.

The first of these major decisions, *Citizens to Preserve Overton Park, Inc. v. Volpe (Overton Park)*,²⁰ involved judicial review of the Secretary of Transportation's decision to authorize a road through a park. The Supreme Court first reaffirmed the presumptive reviewability of agency decisions by narrowly construing exceptions to the right to judicial review contained in section 701(a) of the APA.²¹ The Court then applied the "arbitrary and capricious" test of section 706(2)(A), concluding that it "must consider whether the [Secretary's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."²² The Supreme Court defined the reviewing court's obligation in the following language: "Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency."²³ Finally, the Court, refusing to accept as a basis for the agency decision "post hoc" rationalizations

18. *See infra* Part IV, ch. 1.

19. Thus, for example, the Occupational Safety and Health Act provides that the agency's determination shall be upheld if "supported by substantial evidence in the record considered as a whole." 29 U.S.C. § 655(f). The meaning of the "substantial evidence" test as applied to "informal" or "hybrid" rulemaking has been explicated in a number of court of appeals decisions. *See infra* Part IV, ch. 2(A)(6).

20. 401 U.S. 402 (1971).

21. *Id.* at 410 (relying on *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), and holding that there must be "clear and convincing evidence" of legislative intent to restrict judicial review).

22. *Id.* at 416.

23. *Id.*

contained in agency affidavits offered for purposes of litigation, stated that to perform its review responsibilities, it must have before it “an administrative record that allows the full, prompt review of the Secretary’s action.”²⁴

Overton Park has had a lasting impact on court review of rulemaking even though the proceeding in that case was not rulemaking.²⁵ The courts continue to apply the presumption of reviewability of agency action,²⁶ and the Supreme Court’s emphasis on the importance of the record to the review process has been extremely influential in the development of rulemaking procedures. The “searching and careful” standard of review described in the *Overton Park* decision, often called “hard look” review, has subsequently been applied by the courts to both substantive and procedural issues.²⁷

The application of hard look review to procedural issues in rulemaking resulted in a series of “hybrid rulemaking” decisions by the courts of appeals, principally the D.C. Circuit. These decisions mandated procedures in agency rulemaking that went beyond the minimum requirements of section 553.²⁸

Most of the early hybrid rulemaking judicial decisions involved rulemaking under statutes calling either for a decision after a hearing (but not on the record) or for “substantial evidence” review.²⁹ Although the courts refused to apply formal rulemaking procedures to these proceedings, they did remand final rules to the agencies for additional development of issues through cross-examination of witnesses or other unspecified procedural devices.³⁰

24. *Id.* at 419. The Secretary of Transportation’s determination was set aside and remanded to the district court for “plenary review.” *Id.* at 419-20.

25. The action, which involved approval of building a specific road, would more appropriately be characterized as informal adjudication.

26. *Cf. Heckler v. Chaney*, 470 U.S. 821 (1985), and related cases *infra* Part IV, ch. 3 (discussing the issue of reviewability of agency inaction).

27. *See infra* Part IV, ch. 2(A)(3).

28. *See Schiller, supra* note 3.

29. Review of informal rulemaking under the APA is under an “arbitrary or capricious” standard. 5 U.S.C. § 706(1). *See infra* Part IV, ch. 2, for discussion of these standards of review.

30. *See, e.g., Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974) (remanding rule on stationary source

In *Vermont Yankee*,³¹ the Supreme Court substantially halted the development of judge-made “common law” of rulemaking procedure. In criticizing the D.C. Circuit’s experimentation with hybrid procedure, the Court stated that

. . . generally speaking [§ 553 of the APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures. Agencies are free to grant additional procedural rights in the exercise of their discretion, but reviewing courts are generally not free to impose them if the agencies have not chosen to grant them.³²

Although *Vermont Yankee* precludes the invalidation of rules solely because an agency failed to use specific procedures not required by section 553, the decision did not overrule or overturn all the law of informal rulemaking that had been developed by the lower courts. And it did not affect continuing strict court review of agency adherence to the procedural requirements in the APA or in agency regulations.³³

The late 1970s began a rather sustained period of federal deregulation.³⁴ Deregulation was effected by legislation,³⁵ through administrative actions—including amendment and repeal of rules—and in

standards under Clean Air Act for failure to make available test results and procedures used in creating standards, as well as failure to respond to manufacturers’ comments); *International Harvester v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973) (remanding rule on emissions standards for light-duty vehicles for failure to properly consider availability of technology needed to meet standards). *See also* Symposium, *The Contribution of the D.C. Circuit to Administrative Law*, 40 ADMIN. L. REV. 507 (1988), for a discussion of these and related cases.

31. *Supra* note 3.

32. 435 U.S. at 524 (footnote omitted).

33. *See infra* Part IV, ch. 2(A)(5) (discussing judicial review of agency procedures in issuing rules).

34. *See* sources cited *supra* note 6 for a discussion of deregulation.

35. *See* Motor Carrier Act of 1980, Pub. L. No. 96-296, 94 Stat. 793 (codified in scattered sections of 49 U.S.C.); Airline Deregulation Act of 1978, Pub. L. No. 95-504, 92 Stat. 1705 (codified in scattered sections of 49 U.S.C.).

some cases through administrative inaction and delay.³⁶ In 1983, the Supreme Court, in *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co. (State Farm)*,³⁷ reversed a major deregulatory action by the Reagan Administration. The Court vacated the National Highway Traffic Safety Administration's rescission of a previously issued rule requiring passive restraints (air bags and passive safety belts) in new automobiles. The Supreme Court first rejected the manufacturers' argument that rescission of a rule should be treated on review as a refusal to promulgate standards, to which a very deferential standard of court review had traditionally been applied.³⁸ Concluding that "the forces of change do not always or necessarily point in the direction of deregulation," the Court decided that the regulatory direction in which the agency chooses to move "does not alter the standard of judicial review established by law."³⁹

Applying the "arbitrary and capricious" standard of review in *State Farm*, the Supreme Court asserted that the "agency must examine the relevant data and articulate a satisfactory explanation of its action, including a 'rational connection between the facts found and the choice made.'"⁴⁰ As the Court stated:

Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference of view or the product of agency expertise.⁴¹

36. The Occupational Safety and Health Administration's delay in issuing a field sanitation standard, which spanned several presidential administrations, is an example. See *Farmworker Justice Fund v. Brock*, 811 F.2d 613 (D.C. Cir. 1987) (decision ordering OSHA to issue standard within 30 days), *vacated as moot* after OSHA issued standard, 817 F.2d 890 (1987).

37. 463 U.S. 29 (1983).

38. See *id.* at 41.

39. *Id.* at 42.

40. *Id.* at 43 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

41. *Id.*

By insisting on taking a “hard look” at agency deregulatory decisions, and requiring rigorous justification for such actions, the Supreme Court limited the sweep of its earlier decision in *Vermont Yankee*. In *State Farm* the Supreme Court expressly distinguished the imposition of any “additional procedural requirements upon an agency” but, rather, required the agency to consider in its decisional process an available “technological alternative”—the use of air bags only—“within the ambit of the existing Standard.”⁴²

In a decision handed down a year after *State Farm*, the Supreme Court, in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc. (Chevron)*,⁴³ upheld an Environmental Protection Agency (EPA) rule under the Clean Air Act⁴⁴ allowing states to treat all pollution-emitting devices within the same industrial grouping as though they were encased in a single “bubble.” Having determined that Congress did not have a “specific intention” concerning the interpretive issue before the Court, the Supreme Court decided that the only question on review was whether the administrative agency’s view was a “reasonable one.” For a unanimous Court, Justice Stevens stated:

Judges are not experts in the field, and are not part of either political branch of the Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges’ personal policy preferences. In contrast, an agency to which Congress has delegated policy making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration’s views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intention-

42. *Id.* at 50, 51. On remand, the Department of Transportation issued a new rule relating to passive restraints, 49 Fed. Reg. 28,962 (1984), which was upheld by the D.C. Circuit in *State Farm Mutual Auto. Ins. Co. v. Dole*, 802 F.2d 474 (D.C. Cir. 1986), *cert. denied*, 480 U.S. 951 (1987).

43. 467 U.S. 837 (1984).

44. 42 U.S.C. § 7502(b)(6).

ally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.

When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges—who have no constituency—have a duty to respect legitimate policy choices made by those who do.⁴⁵

In adopting this highly deferential approach to agency legal interpretations in rulemaking, the Supreme Court in *Chevron* did not attempt to explain its somewhat different approach to factual review in the *State Farm* decision.⁴⁶

Although its relevance to agency rulemaking is somewhat limited, another Supreme Court decision of special significance to agencies in a period of deregulation is *Heckler v. Chaney*.⁴⁷ In that case, various petitioners challenged a decision of the Food and Drug Administration (FDA) not to investigate, under the Federal Food, Drug, and Cosmetic Act, the use by a state of lethal drugs to execute criminals. The Court upheld the FDA decision not to pursue the matter. In an opinion for a majority of the court, Justice Rehnquist stated that the presumption of reviewability of administrative agency action articulated in cases such as *Overton Park* did not apply to suits to force agency action. The Court concluded that decisions by agencies not to enforce or prosecute, whether by civil or criminal process, are “generally committed to an agency’s absolute discretion.” This “general unsuitability” for judicial review, the Court said, results largely from the fact that decisions not to enforce “often involve[] a complicated balancing of a number of factors which are particularly within [the agency’s] expertise.”⁴⁸

45. 467 U.S. at 865-66.

46. See Part IV, ch. 2(A), for a discussion of these cases.

47. 470 U.S. 821 (1985).

48. *Id.* at 831. These balancing factors include determining whether violations actually occurred, whether the agency’s resources should be spent on the particular case, and how the case fits the agency’s overall policies. *Id.* The

Although the Supreme Court expressly stated that it was not deciding the reviewability of agency decisions not to initiate rulemaking proceedings,⁴⁹ the decision has been cited by parties in challenges to agency decisions not to initiate, or failures to complete, rulemaking. Several courts of appeals have considered the relevance of *Heckler v. Chaney* to rulemaking and have determined that *Heckler v. Chaney* did not preclude court review. However, these and earlier decisions hold that the standard of review of agency inaction or decisions not to initiate rulemaking should be highly deferential.⁵⁰

C. Agency Rulemaking and the Congress

Congress has a pervasive influence on agency rulemaking activities.⁵¹ In the first place, Congress grants the fundamental authority to an administrative agency to engage in policy making through rulemaking. The enabling regulatory statute typically will, at least in general terms, define the scope of agency authority⁵² and describe any specific rulemaking procedures the agency must follow in addition to, or in lieu of, the minimum requirements of 5 U.S.C. § 553. In “hybrid” rulemaking statutes, Congress mandates additional rulemaking

other reasons for “unsuitability” mentioned by the Court are: (1) in refusing to enforce, the agency is not exercising its “coercive” power, and (2) refusals to enforce are analogous to decisions by a prosecutor not to indict, which have long been considered as the “special province” of the executive branch. *Id.* at 831-35.

49. *Id.* at 825 n.2.

50. On the other hand, *Heckler v. Chaney* does clearly affect the reviewability of agency rule enforcement (or lack thereof). See *infra* Part IV, ch. 3, for a discussion of these cases.

51. See JESSICA KORN, *THE POWER OF SEPARATION: AMERICAN CONSTITUTIONALISM AND THE MYTH OF THE LEGISLATIVE VETO* (1996) (presenting a comprehensive analysis of the many ways Congress exercises effective control over agency policymaking).

52. For example, in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988), discussed *infra* Part III, ch. 7(A)(6)(c), the Supreme Court held that the Medicare Act, 42 U.S.C. § 1395x(v)(1)(A), did not authorize the promulgation of retroactive cost-limit rules. The Court stated, “It is axiomatic that an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.” 488 U.S. at 208.

procedures normally reserved for adjudication, such as requirements for informal public hearings,⁵³ cross-examination of witnesses,⁵⁴ more extensive statements of justification for proposed and final rules,⁵⁵ or the application of the “substantial evidence” test to court review of agency rules.⁵⁶ The inclusion of these additional procedures in some regulatory statutes, most of which occurred in the 1970s, reflects in part the influence of pre-*Vermont Yankee* court decisions and the congressional view that the APA procedures, standing alone, did not necessarily ensure adequate public participation or accuracy in agency rulemaking decisions or provide an adequate basis for judicial review.

Congress has also sought to control and expedite agency rulemaking by imposing statutory deadlines for completing rulemaking actions. Congress has been particularly concerned about agency delay and inaction in the public health and environment areas. Thus, for example, the Asbestos Hazard Emergency Response Act of 1986⁵⁷ required the EPA to publish an advance notice of proposed rulemaking within 60 days of enactment, a proposed rule within 180 days, and final rules within 360 days for seven specific areas relating to asbestos-containing materials in school buildings.⁵⁸

Many other agency statutes have included deadlines for agency rulemaking action.⁵⁹ Typically, these statutory deadlines can be enforced

53. For example, under the Occupational Safety and Health Act, the agency is required to hold a public hearing if an interested person files written objections to a proposed rule and requests a public hearing “on such objections.” 29 U.S.C. § 655(b)(3). *See* 29 C.F.R. § 1911.11(d) (implementing 29 U.S.C. § 655(b)(3)).

54. *See, e.g.*, Federal Trade Commission Act, 15 U.S.C. § 57a(c)(2)(B).

55. *See, e.g.*, Consumer Product Safety Act, 15 U.S.C. § 2058(f)(3).

56. *See, e.g.*, FTC Act, 15 U.S.C. § 57a(e)(3); Occupational Safety and Health Act, 29 U.S.C. § 655(f). The “substantial evidence” test as applied to informal or “hybrid” rulemaking has been widely discussed in court decisions. *See also* discussion *infra* Part IV, ch. 2(A)(6).

57. Pub. L. No. 99-519, 100 Stat. 2970 (codified at 15 U.S.C. §§ 2641-2656). This Act amended the Toxic Substances Control Act.

58. 15 U.S.C. § 2643(a).

59. For example, the Federal Aviation Administration (FAA) Administrator is directed by statute to “issue a final regulation, or take other final action, not later than 16 months after the last day of the public comment period for the

only by court suits;⁶⁰ however, in some cases, Congress has added so-called hammers⁶¹ or other penalties if an agency fails to take timely action. An example of a statutory hammer is the provision in the 1984 amendments to the Resource Conservation and Recovery Act, providing the EPA with a specified period of time in which to issue regulations; if at the end of that time it had not acted, the hammer would fall—that is, a congressionally specified regulatory result would go into effect.⁶² The Nutrition Labeling and Education Act of 1990⁶³ contained a similar hammer specifying that the agency’s *proposed* rule would go into effect if the final rule were not issued within the statutory time limit.⁶⁴ New bioterrorism legislation gave the Department of Health & Human Services/FDA 18 months to issue proposed and final rules for registration of food imports, and included a hammer provision stipulating, in effect, that if the rules were not finalized by the deadline, import-

regulations or, in the case of an advanced notice of proposed rulemaking, if issued, not later than 24 months after the date of publication in the Federal Register of notice of the proposed rulemaking.” 49 U.S.C. § 106(f)(3)(A). *But see* U.S. GEN. ACCOUNTING OFFICE, AVIATION RULEMAKING: FURTHER REFORM IS NEEDED TO ADDRESS LONG-STANDING PROBLEMS 50-62 (GAO-01-821) (July 2001) (finding that the reforms did not improve rulemaking times). It was estimated that Congress imposed about 600 deadlines in various environmental statutes between 1970 and 1983 and added 60 more in the Hazardous and Solid Waste Amendments of 1984. Alden F. Abbott, *The Case Against Federal Statutory and Judicial Deadlines: A Cost-Benefit Appraisal*, 39 ADMIN. L. REV. 171, 173 (1987). *See also* Alden F. Abbott, *Case Studies in the Costs of Federal Statutory and Judicial Deadlines*, 39 ADMIN. L. REV. 467 (1987) (exploring wasted resource costs, agency resource misallocation costs, and regulatory inefficiency costs in context of 11 case studies of deadlines).

60. The issues of court enforcement of statutory deadlines and, more generally, of suits to compel agency action are discussed *infra* Part IV, ch. 3.
61. *See* Sidney A. Shapiro, *Congress’ New Direction in Administrative Law*, 13 ADMIN. L. NEWS 8 (Spring 1988).
62. 42 U.S.C. § 6924(d)(1-2).
63. Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).
64. *See* M. Elizabeth Magill, *Congressional Control over Agency Rulemaking: The Nutrition Labeling and Education Act’s Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 165-70 (1995) (describing FDA’s failure to meet strict congressional deadlines for issuance of final nutrition labeling regulations).

ers could register as they pleased.⁶⁵ And one memorable rider to an appropriations act withheld a portion of the budget of several agency offices until particular final rules were issued.⁶⁶

The Administrative Conference questioned the value of statutory rulemaking deadlines,⁶⁷ as have a number of commentators.⁶⁸ Congress continues to impose these deadlines, however, and they often are an important factor in court litigation to force agencies to initiate or complete rulemaking activity.⁶⁹

Congress also seeks to monitor agency rulemaking after its completion. Prior to 1983, Congress had incorporated “legislative veto” provisions into many statutes authorizing agency rules.⁷⁰ Such statutes typically provided for review of final agency rules by one or both houses of Congress. In 1983, however, the Supreme Court held in *Immigration and Naturalization Service v. Chadha*⁷¹ that a statutory

65. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No 107-188, § 305(e), 116 Stat. 594, 669 (June 12, 2002). Interim-final rules were issued October 10, 2003, 68 Fed. Reg. 58,893.

66. See Department of Transportation and Related Agencies Appropriations Act, 1988, Pub. L. No 100-202, Title 1, 101 Stat. 1329-358/359 (Dec. 22, 1987) (providing that 5% of appropriated funds be withheld from the Office of the Secretary and Office of General Counsel until several enumerated final rules are issued), cited in Neil R. Eisner, *Agency Delay in Informal Rulemaking*, 3 ADMIN. L.J. 7, 33 n.162 (1989). See also Department of Transportation and Related Agencies Appropriations Act, 1990, Pub. L. No. 102-388, 106 Stat. 1525 (Oct. 6, 1992) (providing that no funds can be used for pay raises for FAA employees responsible for preparing environmental impact statement until it is prepared).

67. Administrative Conference of the United States [hereinafter ACUS] Recommendation 78-3, *Time Limits on Agency Actions*, 43 Fed. Reg. 27,509 (1978). All ACUS Recommendations are available at <http://www.law.fsu.edu/library/admin/acus/acustoc.html>. See “Note on ACUS,” *supra* at xix.

68. See articles cited *supra* note 59.

69. See cases discussed *infra* Part IV, ch. 3.

70. An inventory of these statutes through 1983 appears as an appendix to the dissenting opinion of Justice White in *INS v. Chadha*, 462 U.S. 919, 1003-13 (1983). The appendix lists 56 statutes with provisions authorizing post-promulgation congressional review. *Id.*

71. 462 U.S. 919 (1983).

provision authorizing a one-house veto of the suspension of a deportation order by the Attorney General violated the separation of powers doctrine and was therefore unconstitutional.⁷² Subsequently, the Supreme Court applied *Chadha* to two-house vetoes and to vetoes of rules issued by administrative agencies.⁷³ Although the legislative veto in its classic sense no longer is an option for congressional control of rulemaking,⁷⁴ in 1995 a congressional review-of-rules procedure was enacted. The law delays the effective date of major rules for at least 60 days and provides expedited procedures for congressional consideration of resolutions of disapproval.⁷⁵ The overall scheme, while fraught with complexities,⁷⁶ appears to avoid *Chadha* problems because it requires bicameral passage of joint resolutions and presentation to the President for signature or veto. Only one rule has been “disapproved,”

72. The *Chadha* decision was the subject of extensive discussion. See, e.g., E. Donald Elliot, *INS v. Chadha: The Administrative Constitution, the Constitution, and the Legislative Veto*, 1983 SUP. CT. REV. 125.

73. *United States Senate v. FTC*, 463 U.S. 1216 (1983) (holding unconstitutional FTC Improvements Act provision authorizing two-house vetoes of FTC rules), *aff'g Consumers Union v. FTC*, 691 F.2d 575 (D.C. Cir. 1982); *Process Gas Consumers Group v. Consumers Energy Council of Am.*, 463 U.S. 1216 (1983) (mem.), *aff'g Consumer Energy Council of America v. FERC*, 673 F.2d 425 (D.C. Cir. 1982) (holding one-house legislative veto in Natural Gas Policy Act of 1978 unconstitutional).

74. See William F. Leahy, *The Fate of the Legislative Veto After Chadha*, 53 GEO. WASH. L. REV. 168 (1984). The impact of *Chadha* on existing legislative veto provisions remains an issue. Congress has amended several statutes to delete unconstitutional legislative vetoes. However, many statutes containing pre-*Chadha* legislative vetoes remain unchanged. The Supreme Court addressed the severability of such provisions in *Alaska Airlines v. Brock*, 480 U.S. 678, 692-97 (1987) (finding the legislative veto provision severable). See also *New Haven v. United States*, 809 F.2d 900 (D.C. Cir. 1987) (holding the legislative veto provision nonseverable).

75. The Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, Title II, subtitle E, 110 Stat. 856 (codified at 5 U.S.C. §§ 801-808). See *infra* Part II, ch. 3(J), for a detailed discussion of the congressional review-of-rules provision.

76. See *infra* Part III, ch. 7(A)(6)(b); Daniel Cohen & Peter L. Strauss, *Congressional Review of Agency Regulations*, 49 ADMIN. L. REV. 95 (1997) (discussing the Small Business Regulatory Enforcement Fairness Act of 1996).

and thus voided, under this process, but it, an ergonomics rule promulgated by the Occupational Safety and Health Administration (OSHA) at the end of the Clinton Administration, was a major one.⁷⁷

Even beyond this new congressional review process, however, Congress retains other means for overseeing agency rulemaking activity. Statutory requirements limiting agency rulemaking discretion, discussed above, continue to be an important method of congressional control, as are appropriations riders.⁷⁸ Another method is the exercise of congressional oversight authority, either by formal or by informal means.⁷⁹ Congressional committees frequently hold oversight hearings on rulemaking issues and, in some cases, file reports expressing strong views on agency performance on particular matters.⁸⁰

Informal contacts between agency rulemakers and members of Congress and congressional staff in connection with rulemaking are also frequent.⁸¹ In *Sierra Club v. Costle*,⁸² the D.C. Circuit held that it was “entirely proper for congressional representatives vigorously to represent the interests of their constituents before administrative agencies engaged in informal, general policy rulemaking, so long as the individual Members of Congress do not

77. Pub. L. No. 107-5 (Mar. 20, 2001), invalidating OSHA’s ergonomics program standard issued on Nov. 14, 2000 (65 Fed. Reg. 68,262).

78. *See, e.g.*, Pub. L. No. 105-78 § 104, 111 Stat. 1467 (1997), one of a series of riders prohibiting OSHA from using any appropriations “to promulgate or issue any proposed or final standard regarding ergonomic protection.”

79. There is an extensive literature on congressional oversight activity. *See, e.g.*, WALTER J. OLESZEK, CONGRESSIONAL PROCEDURES AND THE POLICY PROCESS (3d ed. 1989); R. DOUGLAS ARNOLD, CONGRESS AND THE BUREAUCRACY: A THEORY OF INFLUENCE (1979).

80. *See, e.g.*, House Comm. on Energy and Commerce; Subcommittee on Oversight and Investigations, Report on *EPA’s Asbestos Regulations: A Case Study on OMB Interference in Agency Rulemaking*, 99th Cong., 1st Sess. (Oct. 1985) (criticizing the EPA decision not to regulate asbestos under the Toxic Substances Control Act). EPA reversed its position and initiated a rulemaking. 51 Fed. Reg. 3738 (1986).

81. *See, e.g.*, JEFFREY M. BERRY, FEEDING HUNGRY PEOPLE: RULEMAKING IN THE FOOD STAMP PROGRAM (1984).

82. 657 F.2d 298 (D.C. Cir. 1981).

frustrate the intent of Congress as a whole as expressed in statute, nor undermine applicable rules of procedure.”⁸³

Congress also controls agency rulemaking procedure by enacting generic procedural statutes, such as the National Environmental Policy Act,⁸⁴ the Paperwork Reduction Act,⁸⁵ and the Regulatory Flexibility Act.⁸⁶ These statutes, which are designed to improve the quality of agency decisionmaking and further policy goals set forth in the statutes, have had a significant impact on the rulemaking process.⁸⁷

D. Agency Rulemaking and the President

Perhaps the most significant administrative law development during the last two decades has been the increased presidential involvement in federal agency rulemaking.⁸⁸ This presidential review, exercised by the Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs (OIRA) has been the result of numerous executive orders⁸⁹ as well as enactment of the Paperwork Reduction Act.⁹⁰ According to recent testimony of the OIRA Administrator,

83. *Id.* at 409. See discussion *infra* Part III, Ch. 6(D).

84. 42 U.S.C. §§ 4321-4370d.

85. 44 U.S.C. §§ 3501-3520.

86. 5 U.S.C. §§ 601-612.

87. See *infra* Part II, ch. 3, and Part III, ch. 2, for discussions of these and other generic statutes.

88. See the comprehensive review in Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001). See also the companion book published by the ABA Section on Administrative Law and Regulatory Practice, *A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES* 211-50, 275-82 (John F. Duffy & Michael Herz eds., 2005).

89. Exec. Order 12,291, 3 C.F.R. 127 (1981 compilation); Exec. Order 12,498, 3 C.F.R. 323 (1985 compilation) (providing guidance on regulatory planning process); Exec. Order 12,606, 3 C.F.R. 241 (1987 compilation); Exec. Order 12,612, 3 C.F.R. 252 (1987 compilation); Exec. Order 12,630, 3 C.F.R. 554 (1988 compilation); Exec. Order 12,866, 3 C.F.R. 644 (1993 compilation). All these executive orders are reprinted in 5 U.S.C. § 601 note. Exec. Order 12,866 is reprinted in the Appendix B to this *Guide*.

90. Pub. L. No. 104-13, 109 Stat. 163 (1995) (codified at 44 U.S.C. §§ 3501-3520). The Paperwork Reduction Act superseded the Federal Reports Act of 1942, Pub. L. No. 77-831, 56 Stat. 1078.

Since OMB began to keep records in 1981, there have been 109,710 final rules published in the *Federal Register* by federal agencies. Of these published rules, 20,029 were formally reviewed by OMB prior to publication. Of the OMB-reviewed rules, 1,073 were considered “major” or “economically significant” rules, primarily because they were estimated to have an economic impact greater than \$100 million in any one year.⁹¹

1. *The Development of Presidential Review*

Presidential oversight of regulation is not a recent innovation. It has been in effect, in one form or another, since 1971,⁹² and it accompanied a major expansion in the scope and complexity of federal regulation that occurred in the 1960s and 1970s when a number of important social and environmental regulatory statutes were enacted.⁹³

In June 1971, President Nixon established a “Quality of Life Review” program, under which all “significant” draft proposed and final rules were submitted to OMB, which circulated them to other agencies for comment.⁹⁴ Agencies were required to submit a summary of their proposals, a description of the alternatives that had been considered,

91. *Regulatory Reform, Hearing before the House Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs*, 108th Cong. (Nov. 17, 2004) (statement of John D. Graham, Administrator of OIRA), available at http://www.whitehouse.gov/omb/legislative/testimony/graham/111704_graham_reg_reform.html.

92. See Harold H. Bruff, *Presidential Management of Agency Rulemaking*, 57 GEO. WASH. L. REV. 533 (1989) (discussing evolution of presidential supervision); Caroline DeWitt, Comment, *The Council on Competitiveness: Undermining the Administrative Procedure Act with Regulatory Review*, 6 Admin. L.J. Am. U. 759 (1993).

93. See Robert. L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189 (1986) (providing an excellent history of government regulation).

94. See Memorandum to Heads of Departments and Agencies from George P. Schultz, Director, OMB, Agency Regulations, Standards and Guidelines Pertaining to Environmental Quality, Consumer Protection, Occupational and Public Health and Safety (Oct. 5, 1971), cited in William F. Pedersen, Jr., *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38, 52 n.61 (1975).

and a cost comparison of alternatives. In practice, this program applied to rules pertaining to environmental quality, consumer protection, and occupational health and safety.

In 1974, President Ford issued an executive order requiring executive branch agencies to prepare an “inflation impact statement” (IIS) for each “major” federal action.⁹⁵ The order empowered the director of OMB to administer the program, with authority to delegate functions to other agencies, including the Council on Wage and Price Stability (COWPS).⁹⁶ Under the IIS program, agencies were required to prepare an IIS for “major” rules⁹⁷ prior to publication of the notice of proposed rulemaking (NPRM) and then to forward a summary of the IIS to COWPS upon publication of the NPRM.⁹⁸ COWPS would review the IIS and, in its discretion, offer informal criticism of the proposal or participate in the public proceedings on the rule.⁹⁹

President Carter continued presidential review of agency rules by means of Executive Order (E.O.) 12,044, issued in 1978.¹⁰⁰ Under the order, executive agencies were required to (1) publish semiannual agendas describing and giving the legal bases for any “significant” regulations under development by the agency; (2) establish procedures to identify “significant” rules, to evaluate their need and to have the agency head ensure that the “least burdensome of the acceptable

95. Exec. Order 11,821, 3 C.F.R. 203 (1971-1975 compilation). When the executive order was later extended, the “inflation impact statement” was replaced by an “economic impact statement” to better reflect the required analysis, which could be characterized as a loose cost-benefit analysis. See OMB Circular No. A-107, § 4(d) (Jan. 28, 1975), cited in Charles W. Vernon III, Note, *The Inflation Impact Statement Program: An Assessment of the First Two Years*, 26 AM. U. L. REV. 1138, 1141 n.28 (1977).

96. See Vernon, *supra* note 95, at 1140.

97. Originally, agencies were left to develop their own criteria for determining what was a “major” proposal, subject to OMB approval; eventually, COWPS adopted a list of suggested criteria that essentially defined a “major” proposal as one entailing a cost of \$100 million or more in one year or \$150 million or more in two years. See Note, *Regulation Analyses and Judicial Review of Informal Rulemaking*, 91 YALE L.J. 739, 746 n.51 (1982).

98. Vernon, *supra* note 95, at 1142.

99. *Id.*

100. 3 C.F.R. § 152 (1978 compilation).

alternatives” was proposed; and (3) prepare a “regulatory analysis” that examined the cost-effectiveness of alternative regulatory approaches for “major rules.”

President Carter also established a Regulatory Analysis Review Group to review the regulatory analyses prepared for a limited number of proposed major rules and to submit comments on the proposed rules during the public comment period.¹⁰¹ He created another rulemaking review body, the Regulatory Council, which was charged with coordinating agency rulemaking to avoid duplication of effort or conflicting policy in regulation of any area.¹⁰² These efforts to coordinate agency rulemaking were challenged unsuccessfully in several lawsuits.¹⁰³

President Reagan acted quickly after taking office to increase control over executive branch rulemaking. On February 17, 1981, he issued an executive order on federal regulations designed “to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for Presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations.”¹⁰⁴ The new E.O. 12,291 replaced E.O. 12,044, which President Reagan said had “proven ineffective.”¹⁰⁵

E.O. 12,291 contained both substantive requirements and procedural steps to be followed in the development and promulgation of new rules.¹⁰⁶ The Office of Information and Regulatory Affairs in OMB

101. 43 Fed. Reg. 12,668 (1978).

102. Memorandum from President Carter to executive departments and agencies, “Strengthening Regulatory Management” (Oct. 13, 1978). The Regulatory Council included the heads of all executive branch agencies and the heads of any independent agencies that chose to participate on a voluntary basis.

103. See Michael S. Baram, *Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisionmaking*, 8 *ECOLOGY L.Q.* 473, 512-14 (1980) (discussing the controversy over use of cost-benefit analysis); Paul R. Verkuil, *Jawboning Administrative Agencies: Ex Parte Contacts by the White House*, 80 *COLUM. L. REV.* 943, 944-47 (1980).

104. Exec. Order 12,291, 3 *C.F.R.* 127 (1981 compilation).

105. OFFICE OF THE VICE PRESIDENT, FACT SHEET ACCOMPANYING EXECUTIVE ORDER ON REGULATORY MANAGEMENT 2 (1981).

106. See *infra* Part III, ch. 2(A) for a discussion of the order’s requirements.

was given responsibility for implementing E.O. 12,291. OMB's rulemaking review function is supplemented by the powers it was given in the Paperwork Reduction Act of 1980,¹⁰⁷ by which Congress statutorily established OIRA to, among other things, review and approve or disapprove agency "information collection requests."

The Office of Legal Counsel in the U.S. Department of Justice issued an opinion supporting the validity of E.O. 12,291.¹⁰⁸ The opinion stated that the President's authority to issue the order was based on his constitutional power to "take care that the laws be faithfully executed."¹⁰⁹ While concluding that any inquiry into congressional intent in enacting specific rulemaking statutes "will usually support the legality of Presidential supervision of rulemaking by Executive Branch agencies,"¹¹⁰ the opinion stated that presidential supervision of agency rulemaking "is more readily justified when it does not purport wholly to displace, but only to guide and limit, discretion which Congress had allocated to a particular subordinate official."¹¹¹

Despite criticism of this new form of presidential review, President Reagan began his second term by expanding the program through E.O. 12,498, which established a "regulatory planning process" with the purpose of helping to "ensure that each major step in the process of rule development is consistent with Administration policy."¹¹²

107. 44 U.S.C. §§ 3501-3520. It is important to note that OMB's power under the Paperwork Reduction Act extends to independent regulatory agencies in the executive branch. OMB has issued regulations setting forth procedures for clearance of informational requirements contained in agency rules, as well as procedures for collection requests not contained in rules. 5 C.F.R. pt. 1320. See *infra* Part III, ch. 2(B), for a discussion of the Paperwork Reduction Act.

108. Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12,291 and 12,498, Op. Off. of Legal Counsel, *reprinted in* OFFICE OF MGMT. & BUDGET, REGULATORY PROGRAM OF THE U.S. GOV'T 532-36 (1988-1989).

109. *Id.* at 532.

110. *Id.* at 533.

111. *Id.* at 533-34.

112. OFFICE OF MGMT. & BUDGET, REGULATORY PROGRAM OF THE U.S. GOV'T xiv (1987-1988).

According to OMB, the problem with regulatory review under E.O. 12,291 was that such review “often came late in the regulatory process, after huge investments of agency time and resources, and often after agency staff commitments to constituents had made it extremely difficult to consider any legally acceptable, but previously ignored, regulatory alternative.”¹¹³ This resulted, OMB said, in the “bureaucracy often present[ing] agency heads with *faits accompli*.”¹¹⁴

E.O. 12,498’s regulatory planning process was designed to avoid this problem.¹¹⁵ Under this procedure, the head of each agency was required to determine at the beginning of the regulatory process whether a proposed regulatory venture was “consistent with the goals of the Administration.”¹¹⁶ At the beginning of the year, agency heads were to develop a plan for managing the agency’s most significant regulatory actions. OMB then reviewed the plan for consistency with the administration’s program and published the coordinated agency plans in a government-wide document.¹¹⁷ This document, entitled *Regulatory Program of the United States Government*, governed more than twenty major rulemaking agencies and was published each year during the second Reagan term and the Bush I Administration to inform Congress and the public of the government’s regulatory plans.¹¹⁸

President Reagan, in 1987 and 1988, issued three additional executive orders, dealing with federalism,¹¹⁹ interference with property rights,¹²⁰ and the family.¹²¹ OMB was given a role in ensuring coordi-

113. *Id.* at xliii.

114. *Id.*

115. President’s Memorandum for the Heads of Executive Departments and Agencies, 21 WEEKLY COMP. PRES. DOC. 13 (1985).

116. *Id.*

117. Exec. Order 12,498, §§ 2, 3.

118. *See, e.g.*, OFFICE OF MGMT. & BUDGET, REGULATORY PROGRAM OF THE U.S. GOV’T (1990-1991).

119. Exec. Order 12,612, 3 C.F.R. 252 (1987 compilation) (ensuring that executive departments are guided by “principles of federalism”).

120. Exec. Order 12,630, 3 C.F.R. 554 (1988 compilation) (relating to “Governmental Actions and Interference with Constitutionally Protected Property Rights”).

121. Exec. Order 12,606, 3 C.F.R. 241 (1987 compilation) (intending to “ensure that the autonomy and rights of the family are considered” in formulation of

nation of regulatory policy in these areas.¹²² President George H.W. Bush basically continued the program of presidential review of agency rulemaking established by President Reagan, although due to congressional opposition to OIRA actions, President Bush's nominee to head OIRA was not confirmed.¹²³ To counter this weakening of OIRA's authority, President Bush created the Council on Competitiveness, headed by Vice President Quayle, and gave it authority to intervene in major agency rulemakings.¹²⁴ Several of the Council's interventions provoked intense criticisms leading up to the 1992 elections.¹²⁵

2. *Executive Order 12,866*

One of President Clinton's first actions was an attempt to reestablish some bipartisan consensus on rulemaking review. His nominee for OIRA Administrator was the first subcabinet nominee to be appointed.¹²⁶ Following the example of the Reagan Administration, the Clintonites then set out to redraft the extant executive order and produced E.O. 12,866 on September 30, 1993.¹²⁷ This order, which remains operative in 2005 under President George W. Bush,¹²⁸ carried

government policy). This order was repealed by Exec. Order 13,045, 62 Fed. Reg. 36,965 (1997). *See infra* Part III, ch. 2(G).

122. *See infra* Part III, Ch. 2(G) for further discussion of these executive orders.

123. *See* Delissa Ridgway et al., *The Council on Competitiveness and Regulatory Review: A "Kinder, Gentler" Approach to Regulation?*, 6 ADMIN. L.J. AM. U. 691, 698 & n.196 (1993) (comments by Jim Tozzi, former OIRA Administrator).

124. The Council was created by a press release from the Vice President's office. *See* DeWitt, *supra* note 92, at 760 n.3.

125. *See* Ridgway, *supra* note 123. *See also* David B. Rivkin, Jr., *The Unitary Executive and Presidential Control of Executive Branch Rulemaking*, 7 ADMIN. L.J. AM. U. 309 (1993); Thomas O. Sargentich, *The Supreme Court's Administrative Law Jurisprudence*, 7 ADMIN. L.J. AM. U. 273 (1993); Cass R. Sunstein, *The Myth of the Unitary Executive*, 7 ADMIN. L.J. AM. U. 299 (1993).

126. *See* *Clinton Regulation Will Be "Rational": Interview with Sally Katzen, the New OIRA Administrator*, 3 REGULATION MAG. 36 (1993), available at <http://www.cato.org/pubs/regulation/reg16n3b.html>.

127. Exec. Order 12,866, 3 C.F.R. 644 (1993 compilation). *See* Appendix B.

128. President Bush did amend the order to remove the Vice President from the process. Executive Order 13,258 (Feb. 26, 2002), 67 Fed. Reg. 9384 (Feb. 28, 2002). Appendix B contains the text of E.O. 12,866, as amended.

over many of the principles of E.O. 12,291 (and E.O. 12,498), which it superseded,¹²⁹ but it also made some significant modifications that simplified the process, made it more selective, and introduced more transparency into the OMB/agency consultations. In drafting this order, the Clinton Administration followed many of the suggestions of the Administrative Conference in its Recommendation 88-9, “Presidential Review of Agency Rulemaking.”¹³⁰

The order begins with a lengthy “Statement of Regulatory Philosophy and Principles,” which is quite similar to E.O. 12,291 except that it takes pains to specify that measurement of costs and benefits should include both quantifiable and qualitative measures. As with previous orders, E.O. 12,866 retains the traditional (since 1978) level of \$100 million annual effect on the economy for those major rules (now referred to as “economically significant” rules) that must be accompanied by cost-benefit assessments when forwarded to OIRA as proposed and final rules. It also provides the standard disclaimer that the order is not intended to create any enforceable rights in court.¹³¹

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129. Somewhat surprisingly, the order did not, however, supersede the other Reagan executive orders requiring various other impact statements in the rulemaking process—most of which remain in effect. *See supra* notes 119-21.
130. ACUS Recommendation 88-9, 54 Fed. Reg. 5207 (1989). The Conference recommended public disclosure of proposed and final agency rules and final agency agendas submitted to OMB, official written policy guidance from OMB, communications from OMB containing factual information relating to the substance of the rulemaking, and “conduit” communications (that is, communications containing the views, positions, or information from persons outside the government). The recommendation also suggests procedures to be followed by OMB reviewing officials to discourage such “conduit” communications. Finally, the recommendation states that presidential review “should be completed in a timely fashion” by both the reviewing office and the agencies, “with due regard for statutory and other relevant deadlines,” but a specific time limit on review was not recommended. The American Bar Association subsequently adopted a resolution urging OMB to complete review within 60 days. ABA Resolution (Feb. 12-13, 1990). The ABA also endorsed Recommendation 88-9 in its entirety. Report 302, Reports with Recommendations, 1990 ABA Annual Meeting, Chicago, Ill. (Aug. 7-8, 1990).
131. Exec. Order 12,866, § 10. *See generally* William Funk, in A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES, *supra* note 88, at 216-28.

E.O. 12,866 also retains the OIRA review process for other rules, although it only requires that “significant regulatory actions” be subject to review. This includes those \$100 million rules plus others that have material adverse effects on “the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.” It also includes rules that may materially alter the budgetary impact of benefit programs or the rights of recipients, that raise “novel legal or policy issues,” or are inconsistent or interfere with actions taken by another agency. The process established for identifying such “significant regulatory actions” relies on agency identification of them in the first instance, vetted by OIRA. Rules that are not so designated may be issued without OIRA review. This selectivity streamlined the review process considerably¹³² and made it possible to include, for the first time, a

132. The number of rules reviewed dropped considerably under E.O. 12,866—from an average of 2,080 in FY 1982-1993 to a low of 498 in FY 1996. *See infra* Part III, Ch 2(A)(1). Not surprisingly, the average review time per rule reviewed has increased, but it is well within the 90-day time limit. Under the previous executive order, reviews averaged 25 days; under E.O. 12,866, the average review times have been 35 days in FY 1994, 36 days in FY 1995, and 45 days in FY 1996. *See* OFFICE OF MANAGEMENT AND BUDGET, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, MORE BENEFITS FEWER BURDENS—CREATING A REGULATORY SYSTEM THAT WORKS FOR THE AMERICAN PEOPLE, A REPORT TO THE PRESIDENT ON THE THIRD ANNIVERSARY OF EXECUTIVE ORDER 12,866 A-3 (1996). On the other hand, critics of the OMB review process, while acknowledging some improvements, continued to maintain that “OIRA still reviews far too many [rules], and in so doing trivializes the review process and makes unneeded work for agencies.” Memorandum to author from David Vladeck, Director, Public Citizen Litigation Group (Oct. 7, 1997). Under President Bush II, the number of reviews increased again to 700 in 2001, and OIRA also returned significantly more rules to agencies for reconsideration than under the Clinton Administration. *See* OFFICE OF MGMT. & BUDGET, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, STIMULATING SMARTER REGULATION: 2002 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATION AND UNFUNDED MANDATES ON STATE, LOCAL AND TRIBAL ENTITIES (2002) at 14 http://www.whitehouse.gov/omb/info/2002_report_to_congress.pdf. Since then the number has leveled off. For the period from January 1, 2004 to January 1, 2005, the number of reviews was 627. *See* OIRA’s “counter,” available at <http://www.reginfo.gov/public/do/eoCountsSearch>.

firm deadline (of 90 days, with one 30-day extension allowed) for completion of OIRA review. In the event of an unresolved dispute between OIRA and the agency, the issue is submitted to the President, through the Chief of Staff.

The review process set forth in the order is intended to be quite transparent. It provides that after the agency has concluded its rulemaking, it should make available to the public all submissions to OIRA and identify all changes made in the rule, noting those made at the behest of OIRA.¹³³ In addition, OIRA, for its part, must regularize the way it receives any outside communications concerning an agency rule that is subject to review. Only the administrator or his or her designee may receive such communications. OIRA must forward any such communications to the agency within 10 days, invite agency officials to any meetings held with outsiders, and maintain a public log of all such contacts. At the end of the proceeding, OIRA must also make available all documents exchanged with the agency.¹³⁴

In place of the Reagan E.O. 12,498 on regulatory planning, E.O. 12,866 establishes its own yearly planning mechanism. It continues the semiannual publication of the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, which lists all proposed, pending, and completed regulatory and deregulatory actions. And it requires that the October *Agenda* contain each agency's annual regulatory plans, which have been approved by the OMB Director and the other regulatory advisors designated under the order. These plans must be for-

133. *But see* U.S. GEN. ACCOUNTING OFFICE, REGULATORY REFORM: CHANGES MADE TO AGENCIES' RULES ARE NOT ALWAYS CLEARLY DOCUMENTED (GAO/GGD-98-31) (Jan. 1998) (reporting a lack of complete transparency in a 1998 study of rules issued by four Departments) and U.S. GEN. ACCOUNTING OFFICE, RULEMAKING: OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS 110-15 (GAO-03-929) (Sept. 2003) (noting improvements but continuing deficiencies in the transparency of the review process, and detailing, in Appendix III, numerous "case studies on significantly affected rules with evidence that OIRA was contacted by external parties").

134. It should be noted, however, that the order does not address the participation of non-OMB White House entities in rulewriting; thus, the possibility of another "Quayle Council" is not foreclosed. See *supra* text accompanying note 124. Nor does it address contacts made prior to the issuance of the notice of proposed rulemaking.

warded to OIRA by June 1 of each year. The plans are also to include agency determinations on which existing rules are to be reviewed and reconsidered during the ensuing year. These actions do not represent any sharp break from the practices of previous administrations; however, the Clinton order was a departure in one regard—for the first time the *independent regulatory agencies* are specifically directed to comply with the planning and agenda provisions (though *not* with the rule-review process).¹³⁵

Executive Order 12,866 was generally well received by most observers of the regulatory scene, and in the thirteen years since its issuance, OIRA has worked out a stable and workable relationship with the agencies in administering it.¹³⁶ The once rather vibrant legal and policy debate over the pros and cons of presidential review¹³⁷ has

135. The Administrative Conference concluded that presidential review “can improve the coordination of agency actions and resolve conflicts among agency rules and assist in the implementation of national priorities” and that it should apply generally to federal rulemaking. ACUS Recommendation 88-9, *supra* note 130, ¶ 1. Thus, the Conference concluded that “[a]s a matter of principle, presidential review of rulemaking should apply to independent regulatory agencies to the same extent it applies to rulemaking of executive branch departments and other agencies.” *Id.*, ¶ 2. The National Academy of Public Administration also recommended that, “[a]s a matter of policy, Congress should consider extending presidential review to independent regulatory agencies on an agency-by-agency basis.” NATIONAL ACADEMY OF PUBLIC ADMINISTRATION, *PRESIDENTIAL MANAGEMENT OF RULEMAKING IN REGULATORY AGENCIES* 23 (1987). *See also* Thomas O. McGarity, *Presidential Control of Regulatory Agency Decisionmaking*, 36 AM. U. L. REV. 443, 454-62 (1987); Peter L. Strauss & Cass R. Sunstein, *The Role of the President and OMB in Informal Rulemaking*, 38 ADMIN. L. REV. 181, 202-05 (1986); Bruff, *supra* note 92, at 590-93.

136. Considering its wide influence, OIRA is still a remarkably small agency, with only 55 full-time equivalent employees as of 2003. *See* U.S. GEN. ACCOUNTING OFFICE, *RULEMAKING: OMB’S ROLE IN REVIEWS OF AGENCIES’ DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS*, *supra* note 133, at 3.

137. *See* Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075 (1986) and Alan B. Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way to Write a Regulation*, 99 HARV. L. REV. 1059 (1986) (debating the legality of OMB review). *See also* Strauss & Sunstein, *supra* note 135, at 189; Bruff, *supra* note 92; Erik D. Olson, *The Quiet Shift of Power: Office of Management & Budget*

gradually evolved into a fairly broad agreement that it is not only legal, but that if properly administered, it is essential to effective executive branch management.¹³⁸

This is not to say, however, that the debate over the need for further regulatory reform was quenched by the issuance of E.O. 12,866.

Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12,291, 4 VA. J. NAT. RESOURCES 1, 75-77 (1984); Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 MICH. L. REV. 193 (1981). Some critics argue that even if presidential oversight may be justified on a theoretical basis, the program has been implemented almost exclusively to achieve deregulatory goals, in contravention of enabling statutes. See McGarity, *supra* note 135, at 454-62.

138. For example, the legislative hearings on S. 981, "The Regulatory Improvement Act of 1997," 105th Cong., 1st Sess., which would have, among other things, codified the provisions of E.O. 12,866, were notable because that portion of the bill drew little criticism. On the other hand, the director of the Public Citizen Litigation Group contended that no empirical evidence exists supporting the premise that the cost of OIRA review is offset by the benefits, Vladeck memorandum, *supra* note 132. Academic writings now are generally accepting of OMB review. See, e.g., Kagan, *Presidential Administration*, *supra* note 88, at 2384 (concluding that the development of enhanced presidential control of regulatory administration "within broad but certain limits, both satisfies legal requirements and promotes the values of administrative accountability and effectiveness"). See also James F. Blumstein, *Regulatory Review by the Executive Office of the President: An Overview and Policy Analysis of Current Issues*, 51 DUKE L.J. 851, 899 (2001) (finding OIRA review to be "an important and constructive feature of the executive branch") and the empirical review in Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821 (2003). But see Robin Kundis Craig, *The Bush Administration's Use and Abuse of Rulemaking. Part I: The Rise of OIRA*, 28 ADMIN. & REG. L. NEWS 8 (Summer 2003) (finding OIRA to be an "unreviewable reviewer") and Scott Farrow, *Improving Regulatory Performance: Does Executive Office Oversight Matter?*, AEI Publication (Dec. 2001), available at <http://www.aei.brook.edu/admin/authorpdfs/page.php?id=123> (indicating that although Executive Office review has led to rejection of some regulations that would have been economically inefficient, such review appears to have no efficiency-improving impact on the difference between proposed and final regulations or on the cost-effectiveness of regulations that are implemented).

On the contrary, President Clinton's National Performance Review (also known as "Reinventing Government"), initiated in 1993, recommended additional actions to streamline rulemaking,¹³⁹ only to be overwhelmed by the seismic election of 1994, which produced a Republican-controlled 104th Congress and a resulting frenzy of proposed changes to the APA as a whole and to the rulemaking provisions in particular.¹⁴⁰ The most far-reaching "regulatory reform" bills did not pass—in part because of strong opposition from the Clinton Administration, although elements were enacted with bipartisan support in the Unfunded Mandates Reform Act of 1995¹⁴¹ and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).¹⁴² Moreover, President Clinton and his National Performance Review announced aggressive new initiatives to cut obsolete regulations; use more consensus-based techniques, such as negotiated rulemaking; and enhance public participation through more grassroots meetings and partnerships.¹⁴³

President Clinton also issued a presidential directive on plain language,¹⁴⁴ and number of other executive orders that remain in effect concerning environmental justice in minority populations and low-income populations (E.O. 12,898),¹⁴⁵ civil justice reform (E.O.

139. See OFFICE OF THE VICE PRESIDENT, CREATING A GOVERNMENT THAT WORKS BETTER AND COSTS LESS, NATIONAL PERFORMANCE REVIEW, IMPROVING REGULATORY SYSTEMS (1993).

140. See, e.g., Ronald M. Levin, *Administrative Procedure Legislation in 1946 and 1996: Should We Be Jubilant at This Jubilee?*, 10 ADMIN. L.J. AM. U. 55 (1996); Jerry L. Mashaw, *Reinventing Government and Regulatory Reform: Studies in the Neglect and Abuse of Administrative Law*, 57 U. PITT. L. REV. 405 (1996).

141. See discussion *infra* Part II, ch. 3(G).

142. See discussion *infra* Part II, ch. 3(C) & (J).

143. See OFFICE OF MGMT. & BUDGET, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, MORE BENEFITS, FEWER BURDENS—CREATING A REGULATORY SYSTEM THAT WORKS FOR THE AMERICAN PEOPLE, A REPORT TO THE PRESIDENT ON THE THIRD ANNIVERSARY OF EXECUTIVE ORDER 12,866 (1996).

144. White House Memorandum for the Heads of Executive Departments and Agencies, Plain Language in Government Writing (June 1, 1998), available at <http://govinfo.library.unt.edu/npr/library/direct/memos/memoeng.html>.

145. Issued Feb. 11, 1994, 59 Fed. Reg. 7629 (Feb. 16, 1994).

12,988),¹⁴⁶ protection of children from environmental risks (E.O. 13,045),¹⁴⁷ federalism (E.O. 13,132),¹⁴⁸ and consultation with Indian Tribal Governments (E.O. 13,175).¹⁴⁹ These are discussed in Part III, Chapter 2(G).

3. *Developments in the Bush II Administration*

When President George W. Bush took office on January 20, 2001, one of his first actions was to have his Chief of Staff issue a memorandum directing agencies to delay for 60 days all rules issued that had not yet gone into effect and to refrain from sending any additional rules (other than emergency rules) to the *Federal Register* until they were reviewed by an agency head appointed by President Bush.¹⁵⁰

The Bush II Administration ultimately decided to maintain E.O. 12,866 as the basis for its review, although the role of the Vice President, prominent in the Clinton Administration, was formally eliminated by an amendment to the executive order.¹⁵¹ OIRA did issue a memorandum in September 2001, putting the new Administration's own stamp on the E.O. 12,866 process.¹⁵² The memorandum describes the "general principles and procedures that will be applied by OMB in the implementation of E.O. 12,866 and related statutory and executive authority" and includes new "recommendations" that agencies engage in formal risk assessments and also subject their regulatory impact assessments and supporting technical documents to "independen-

146. Issued Feb. 5, 1996, 61 Fed. Reg. 4729 (Feb. 7, 1996).

147. Issued Apr. 21, 1997, 62 Fed. Reg. 19,885 (Apr. 23, 1997).

148. Issued Aug. 4, 1999, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

149. Issued Nov. 6, 2000, 64 Fed. Reg. 67,249 (Nov. 9, 2000).

150. Memorandum for the Heads and Acting Heads of Executive Agencies from Andrew Card, Assistant to the President and Chief of Staff (Jan. 20, 2001), available at http://www.whitehouse.gov/omb/inforeg/regreview_plan.pdf. For more discussion of the ramifications of the "Card Memorandum," see Part II, Ch. 1(D)(4)(f).

151. See Executive Order 13,258, *supra* note 128.

152. Memorandum for the President's Management Council from John D. Graham, OIRA Administrator, on Presidential Review of Agency Rulemaking by OIRA (Sept. 20, 2001), available at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html.

dent, external peer review by qualified specialists.”

Significantly, OIRA announced several new initiatives in its review process.¹⁵³ First, it made extensive use of its website¹⁵⁴ to publish its guidelines and other information pertaining to the process and to specific rule reviews. Second, it began the practice of issuing public “return letters” that send rules back to the agency for reconsideration, “post-review letters” that comment on aspects of a particular rule review, and “prompt letters,” which are sent on OMB’s initiative and contain suggestions for new or stronger regulations. For example, OMB sent prompt letters to the Department of Health and Human Services and OSHA on what OMB termed “two lifesaving issues.” One letter urged acceleration of an ongoing rulemaking concerning the labeling of trans-fatty acid content in foods while the other promoted use of automated external defibrillators in the workplace.¹⁵⁵ OIRA also maintains a website that provides the contents of all of its “return letters” from July 2001 to the present.¹⁵⁶ The site explains:

During the course of OIRA’s review of a draft regulation, the Administrator may decide to send a letter to the agency that returns the rule for reconsideration. Such a return may occur if the quality of the agency’s analyses is inadequate, if the regulatory standards adopted are not justified by the analyses, if the rule is not consistent with the regulatory principles stated in EO 12866 or with the President’s policies and priorities, or

153. For an illuminating article on the Bush Administration’s OIRA Administrator, see Rebecca Adams, *Regulating the Rule-Makers: John Graham at OIRA*, CQ WEEKLY 520 (Feb. 23, 2002). See also U.S. GEN. ACCOUNTING OFFICE, RULEMAKING: OMB’S ROLE IN REVIEWS OF AGENCIES’ DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS, *supra* note 133 (documenting OMB’s influence on agency rulemaking).

154. Office of Mgmt. & Budget, Regulatory Matters, <http://www.whitehouse.gov/omb/inforeg/regpol.html>.

155. News Release 2001-35, Office of Mgmt. & Budget, OMB Encourages Lifesaving Actions by Regulators (Sept. 18, 2001). See also <http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp> (listing 12 prompt letters as of Dec. 30, 2005).

156. OIRA Return Letters, <http://www.reginfo.gov/public/do/eoReturnLetters>. As of Dec. 30, 2005, there were 23 such letters.

if the rule is not compatible with other Executive Orders or statutes. Such a return does not necessarily imply that either OIRA or OMB is opposed to the draft rule. Rather, the return letter explains why OIRA believes that the rulemaking would benefit from further consideration by the agency.

Most of these activities are useful and largely uncontroversial supplements to the E.O. 12,866 review process. President Bush has also issued two executive orders concerning regulations that significantly affect energy supply, distribution, or use (E.O. 13,211)¹⁵⁷ and proper consideration of small entities in agency rulemaking (E.O. 13,272).¹⁵⁸ These are discussed in Part III, Chapter 2(G).

OMB also issued a more far-reaching and controversial “Peer Review Bulletin” on December 16, 2004.¹⁵⁹ OMB originally published the proposed Bulletin on September 15, 2003¹⁶⁰ and re-proposed it on April 28, 2004.¹⁶¹ It published its response to the 187 comments it received on the first proposal and the 56 comments it received on the second proposal.¹⁶² The Bulletin requires administrative agencies¹⁶³ to conduct

157. Issued May 18, 2001, 66 Fed. Reg. 28,355 (May 22, 2001).

158. Issued Aug. 13, 2002, 67 Fed. Reg. 53,461 (Aug. 16, 2002).

159. OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW, 70 Fed. Reg. 2664 (Jan 14, 2005).

160. PROPOSED BULLETIN ON PEER REVIEW AND INFORMATION QUALITY, 68 Fed. Reg. 54,023 (Sept. 15, 2003). See Jeffrey Lubbers, *OMB to Require Peer Review for Regulatory Science Documents*, 29 ADMIN. L. & REG. NEWS 3 (Fall 2003).

161. REVISED INFORMATION QUALITY BULLETIN ON PEER REVIEW, 69 Fed. Reg. 23,230 (Apr. 28, 2004). See Sidney A. Shapiro, *OMB's Revised Peer Review Bulletin*, 29 ADMIN. L. & REG. NEWS 10 (Summer 2004).

162. See Office of Mgmt. & Budget, Informational Policy, IT & E-gov, <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>.

163. The Bulletin applies to “agencies,” as defined in the Paperwork Reduction Act, 44 U.S.C. § 3502(1), which encompasses “any executive department, military department, Government corporation, Government-controlled corporation or other establishment in the executive branch (including the Executive Office of the President) or any independent regulatory agency [except the Federal Election Commission].” This clearly represents a broadening of White House management of the regulatory policies of independent regulatory boards and commissions (and of government corporations).

a peer review on all “influential regulatory information that the agency intends to disseminate.”¹⁶⁴ (And as this book went to press, OMB released for public comment a draft version of a potentially quite important new government-wide “Bulletin on Good Guidance Practices.”)¹⁶⁵

4. *Judicial Reaction to Presidential Review*

The D.C. Circuit’s opinion in *Sierra Club v. Costle*,¹⁶⁶ a case concerning the legality of presidential (and congressional) involvement in EPA rulemaking during the Carter Administration, is often quoted as being supportive of the policy underlying presidential review. The opinion, authored by Judge Patricia Wald, states:

The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in the making, and their contributions to policymaking considered. The executive power under our Constitution, after all, is not shared—it rests exclusively with the President. The idea of a “plural executive,” or a President with a council of state, was considered and rejected by the Constitutional Convention. Instead the Founders chose to risk the potential for tyranny inherent in placing power in one person, in order to gain the advantages of accountability fixed on a single source. To ensure the President’s control and supervision over the Executive Branch, the Constitution—and its judicial gloss—vests him with the powers of appointment and removal, the power to demand written opinions from executive officers, and the right to invoke executive privilege to protect consultative privacy. In the particular case of EPA, Presidential authority is clear since it has never been considered an “independent agency,” but always part of the Executive Branch.

164. See *infra* Part III, ch. 2(E) for a discussion of peer review.

165. See *infra* Part II, ch. 1(D)(3)(d), for a discussion of this draft bulletin.

166. 657 F.2d 298 (D.C. Cir. 1981). See *infra* Part III, ch. 6 for discussion of *Sierra Club*.

The authority of the President to control and supervise executive policymaking is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of administrative rulemaking. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policymakers in other agencies as well as in the White House.¹⁶⁷

Sierra Club involved the propriety of nonpublic executive communications in an EPA rulemaking and did not directly address the constitutionality of presidential review. No court has squarely addressed the constitutionality of the presidential review program.¹⁶⁸

167. 657 F.2d at 405-06 (footnotes omitted).

168. The constitutional issue was raised in *Pub. Citizen Health Res. Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986), where the petitioning public interest group asserted the invalidity of a portion of OSHA's ethylene oxide standard, in part on the ground that an important provision in the draft standard had been deleted by OSHA at OMB's direction, thus violating separation-of-powers principles. The challenge by petitioner Public Citizen was supported in an *amicus* brief filed by the chairs of several committees of the House of Representatives. The D.C. Circuit, however, reversed OSHA's decision on other grounds without deciding the separation-of-powers issue. *Id.* at 1507. See also *Nat'l Grain & Feed Ass'n v. OSHA*, 866 F.2d 717 (5th Cir. 1989) (rejecting argument that judicial review was obstructed by "alleged off-the-record coercion of OSHA," stating that "agency's final rule must stand or fall on the basis of the record before the agency, not on the basis of some 'secret record' of OMB's"; but remanding rule on other grounds); *Env'tl. Def. Fund v. Thomas*, 627 F. Supp. 566, 570 (D.D.C. 1986) (concluding that OMB, "by insisting on certain substantive changes," significantly delayed publication of proposed rules, thus causing EPA to miss a statutory deadline for promulgating regulations, and declaring that OMB did not have authority under Exec. Order 12,291 to delay promulgation of EPA regulations beyond date of statutory deadline and setting new deadline for final rule).

E. Overviews of Rulemaking—Other Views

1. The Administrative Conference’s Comprehensive Review of the “State” of Rulemaking

In 1993, the Administrative Conference’s Committee on Rulemaking undertook a comprehensive review of the state of rulemaking in the 1990s. The premise for the review was stated in the opening sentences of the eventual recommendation:

Informed observers generally agree that the rulemaking process has become both increasingly less effective and more time-consuming. The Administrative Procedure Act does not reflect many of the current realities of rulemaking [T]he APA’s simple “informal rulemaking procedures” (set forth in 5 USC § 553) have been overlain with an increasing number of constraints: outside constraints imposed by Congress, the President, and the courts, and internal constraints arising from increasingly complex agency management of the rulemaking process.¹⁶⁹

Given that premise, the recommendation sets out a “coordinated framework of proposals aimed at promoting efficient and effective rulemaking.” The recommendation addresses the impacts of presidential oversight and congressional structuring of rulemaking and the timing and scope of judicial review. It also suggests some amendments to the APA and agency management initiatives.

This recommendation represents the best thinking of the administrative law experts in the ACUS membership in 1993 on what should be done to remedy the perceived problems with rulemaking. Many of these recommendations seemingly run counter to the continued accretion of procedures and analytical requirements on the rulemaking

169. ACUS Recommendation 93-4, “Improving the Environment for Agency Rulemaking,” 58 Fed. Reg. 4670 (Feb. 1, 1994) (footnote omitted), *available at* <http://www.law.fsu.edu/library/admin/acus/305934.html>. This recommendation is also reprinted in Appendix C of this *Guide*.

process. Thus, from the perspective of Recommendation 93-4, the situation has gotten worse instead of better.¹⁷⁰ Moreover, the Administrative Conference's oversight of the process was terminated by the Congress in 1995. Thus, in one sense, Recommendation 93-4 represents ACUS's "last word" on the reform of agency rulemaking. It is hoped that the continued publication of the *Guide* by the American Bar Association can, however, continue to spread that word.

2. *The "Blackletter Statement" of the ABA Section of Administrative Law and Regulatory Practice*

In November 2001, the ABA Section of Administrative Law and Regulatory Practice, one of the co-sponsors of this *Guide*, completed its multiyear effort to produce *A Blackletter Statement of Federal Administrative Law*.¹⁷¹ The portion of the *Blackletter* that relates to informal rulemaking¹⁷² is reprinted after this Part. This *Guide* is intended to serve as the background report for that portion of the *Blackletter*.

3. *Other Overviews of Rulemaking*

I would be remiss not to mention some other excellent sources of information about the federal rulemaking process. Jim O'Reilly's 1983 comprehensive hardcover regulatory manual, kept up to date with annual cumulative supplements,¹⁷³ and Neil Kerwin's authoritative volume written from a public administration point of view¹⁷⁴ are worthy complements to this *Guide*. Shorter helpful treatments can be found

170. See Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 9 (1997) ("Indeed, one could argue that the increasing analytic requirements imposed on agencies and the reinvigoration of aggressive judicial review in recent appellate cases makes the ossification . . . even worse.") (footnote omitted).

171. 54 ADMIN. L. REV. 1-83 (2002).

172. *Id.* at 30-36.

173. JAMES T. O'REILLY, ADMINISTRATIVE RULEMAKING: STRUCTURING, OPPOSING, AND DEFENDING FEDERAL AGENCY RULEMAKING (1983) (annual supplements prepared by West Group).

174. CORNELIUS M. KERWIN, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY (3d ed. 2003).

in the 1993 National Performance Review report, *Improving Regulatory Systems*,¹⁷⁵ as well as Mark Seidenfeld's detailed "table of requirements" for federal rulemaking¹⁷⁶ and Neil Eisner's annual compendium of rulemaking requirements applicable to the U.S. Department of Transportation.¹⁷⁷ Useful agency guidance is provided by the Federal Trade Commission's staff manual.¹⁷⁸ Professor Stuart Shapiro has begun an extensive data-gathering project on agency rulemaking.¹⁷⁹ Finally, the ABA Administrative Law Section's six volumes of *Developments in Administrative Law and Regulatory Practice* beginning in 1998-1999 have been very helpful in updating this *Guide*,¹⁸⁰ and the Section's newly published guide to judicial and political review of federal agencies¹⁸¹ was especially helpful in revising and updating Part IV.

175. Office of the Vice President, *Improving Regulatory Systems, Accompanying Report of the National Performance Review* (Sept. 1993), available at <http://govinfo.library.unt.edu/npr/library/review.html>.

176. Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLA. ST. L. REV. 533 (2000).

177. Neil Eisner, *U.S. Department of Transportation Rulemaking Requirements* (May 2005), on file with author.

178. See FTC, ADMINISTRATIVE STAFF MANUAL: OPERATING MANUAL, RULEMAKING, ch. 7, available at <http://www.ftc.gov/foia/ch07rulemaking.pdf>.

179. See Stuart Shapiro, *Two Months in the Regulatory State*, 30 ADMIN. & REG. L. NEWS 12 (Spring 2005).

180. The chapters on rulemaking have been written by Mark Seidenfeld (1998-99), Daniel Cohen & Harold Walther (1999-2000), Marshall Breger (2000-01), Michael Herz (2001-02 & 2002-03) and Richard Stoll & Katherine Lazarski (2003-04). All volumes were edited by the author of this *Guide*.

181. See A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES, *supra* note 88.

**Excerpts from
“A Blackletter Statement of Federal Administrative Law”**

**PART TWO
INFORMAL RULEMAKING**

The following summarizes the procedural requirements that must precede the legally effective promulgation, amendment, or repeal of a rule by a federal agency, as imposed by the Administrative Procedure Act (APA), other procedural statutes, and judicial decisions. Certain additional requirements imposed by Executive Order (particularly economic impact analysis, as currently embodied in E.O. 12,866) are also included. Such requirements are not judicially enforceable, may be and often are waived by the relevant executive office, and are particularly subject to change. Economic impact analysis has been required for the last several presidencies in one form or another, and is assumed in much recent reform legislation.

I. APPLICABILITY

A. Definition of a Rule

A “rule” is an agency statement designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. Although the definition of “rule” in the APA refers to “an agency statement of general or particular applicability,” “rule” is usually understood to refer to a pronouncement that is intended to address a class of situations, rather than a named individual. Certain particularized actions, such as rate-setting or the approval of a corporate reorganization, are explicitly included within the statutory definition. A rule may be prospective, retroactive, or both, but an agency normally may not issue a retroactive rule that is intended to have the force of law unless it has express authorization from Congress.

B. Distinction Between Informal and Formal Rulemaking

The procedures described here apply to “informal” (also known as “notice-and-comment”) rulemaking. “Formal rulemaking” requires additional trial-type procedures, not described here but essentially the same as those described for initial licensing in Part One [of this

* Prepared by the Section of Administrative Law and Regulatory Practice of the American Bar Association, 54 ADMIN. L. REV. 1, 30-36 (2002).

Blackletter]. Unless a statute expressly provides for rulemaking “on the record after opportunity for a hearing,” or Congress otherwise unequivocally requires formal rulemaking, the requirements for informal rulemaking apply.

Agencies engaged in informal rulemaking may provide additional procedures beyond those established by the APA, other applicable statutes, and the agency’s own rules, but courts may not require them to do so.

C. Exemptions

The following types of rules are exempt from all the procedural requirements: rules relating to public property, loans, grants, benefits, and contracts; rules relating to agency management and personnel; and rules that involve a military or foreign affairs function of the United States. However, specific statutes may override these exemptions and agencies may voluntarily forswear them.

The following types of rules are subject to publication and petition requirements, but are exempt from the other procedural requirements set out below: rules regarding agency organization, procedure, and practice; staff manuals; interpretive rules; and general statements of policy. Failure to publish such a rule, either in the Federal Register or as described by 5 U.S.C. § 552(a)(2), denies to the agency any possibility of relying on it to the disadvantage of a private party, unless that party has had actual notice of the agency’s position.

An agency may also dispense with notice and comment, and/or may make a rule effective immediately, when it has good cause to do so and explains its reasons at the time of publication. Under time pressure, agencies occasionally adopt “interim final rules” that are both immediately effective and published with an invitation to comment and propose revisions; a subsequent agency revision will treat such a rule as if it were, also, a notice of proposed rulemaking.

II. INITIATING RULEMAKING

A. Means to Initiate Rulemaking

An agency may commence a rulemaking on its own initiative, pursuant to statutory mandate, or in response to an outside petition or to suggestions from other governmental actors. Any interested per-

son has the right to petition for the issuance, amendment, or repeal of any rule. The denial of a petition, which is a reviewable event, should be summarily explained.

B. Developing a Proposed Rule

In developing a proposed rule, and limited in some cases to economically significant rules and/or executive agencies, an agency may be required to evaluate the rule's impacts and prepare appropriate written analyses of (a) environmental impacts and alternatives, (b) overall economic costs and benefits, (c) the extent of new paperwork and information collection requirements, (d) impacts on small businesses, (e) impacts on state, local, and tribal governments and on the private sector, (f) impacts on families, (g) private property rights, (h) the civil justice system, (i) children's health and safety, (j) federalism, and (k) the supply, use, and distribution of energy. Requirements (a) through (e) are imposed by statute; requirements (f) through (k) are imposed exclusively by a series of executive orders. Requirement (b), although now also required by the Unfunded Mandates Reform Act, was first developed by executive orders—currently E.O. 12,866. In practice the administration of E.O. 12,866 appears to dominate executive branch implementation of all these requirements. Under that executive order, prior to issuing a Notice of Proposed Rulemaking, an executive agency proposing an economically significant rule must provide the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget with an assessment of the proposal's costs and benefits. This analysis may, and typically does, incorporate the analyses required by other statutes and executive orders.

Prior to issuing a Notice of Proposed Rulemaking, an agency may issue and take comments on an Advanced Notice of Proposed Rulemaking and/or establish a negotiated rulemaking committee to negotiate and develop a proposed rule. Under the Negotiated Rulemaking Act, agencies are encouraged to explore the development of consensus proposals for rulemaking with balanced, representative committees under the guidance of a convenor specially appointed for that purpose. Such proposals, if generated, serve as proposed rules under the normal procedure.

All agencies must obtain OIRA clearance of proposed information collection requirements, including those put in place by rulemaking.

C. Semi-Annual Agenda

All rulemaking agencies must semi-annually prepare and publish in the Federal Register a Regulatory Agenda listing all planned regulatory actions that are likely to have a significant economic impact on a substantial number of small entities. Under E.O. 12,866 all rulemaking agencies must prepare an agenda of all regulations under development or consideration. This agenda must include a Regulatory Plan identifying and justifying the most important “significant regulatory actions” the agency expects to issue in proposed or final form in the upcoming fiscal year and must be submitted to OIRA by June 1 each year. This plan is consolidated with the regulatory agenda for publication purposes.

III. NOTICE OF PROPOSED RULEMAKING AND OPPORTUNITY FOR COMMENT**A. Requirements for a Notice of Proposed Rulemaking**

An agency must publish in the Federal Register notice of its intent to promulgate, amend, or repeal a rule. Publication in the Federal Register is not necessary if all persons who will be subject to the rule, if adopted, are named and have actual notice.

The Notice of Proposed Rulemaking must include (1) a statement of the time, place, and nature of any public proceedings for consideration of the proposed rule, (2) a reference to the agency’s statutory authority for the rule, and (3) the proposed text of the rule, unless a description of the proposal or the subjects and issues involved will suffice to allow meaningful and informed public consideration and comment. Developing caselaw, in the wake of the Freedom of Information Act, has required the agency also to make available in time for comment thereon significant data and studies it knows to be relevant to the proposed rule, including any draft analyses previously made as under II above.

B. Public Comment on Proposed Rule

After publication of a Notice of Proposed Rulemaking, a reasonable time must be allowed for written comments from the public. An agency may, but, unless specifically required to do so by a relevant statute, need not, provide interested persons the opportunity to present oral comments or cross-examine witnesses.

IV. THE RULEMAKING RECORD AND DECISIONMAKING PROCESS

A. Record Requirements

The agency must maintain, and allow and facilitate public examination of, a rulemaking file consisting of (1) all notices pertaining to the rulemaking, (2) copies or an index of written factual material, studies, and reports relied on or seriously consulted by agency personnel in formulating the proposed or final rule, (3) all written comments received by the agency, and (4) any other material specifically required by statute, executive order, or agency rule to be made public in connection with the rulemaking.

The obligation to disclose written factual material, studies, and reports relied on or seriously consulted by agency personnel is limited to materials whose disclosure would be required under the Freedom of Information Act. Thus, neither a summary nor a record of predecisional internal agency policy discussions, or like contacts with government officials outside the agency or private consultants, need be included in the rulemaking file. Particular agency statutes or rules, however, may forbid or limit such communications or require that they be logged and made available to the public. The Executive Orders requiring economic impact analysis provoked concern about this issue, and E.O. 12,866 also includes such requirements.

B. Decisional Process

Subject to the obligation to disclose factual material, studies, and reports relied on or seriously consulted, decisionmakers within an agency may freely consult with other agency personnel, government officials outside the agency, and affected persons. Particular statutes or agency regulations may impose logging requirements or other restrictions. A decisionmaker will be disqualified for pre-judgment only where the person's mind is unalterably closed.

Under E.O. 12,866 (and the several other impact analysis requirements imposed by statute and/or executive order), a final analysis must be prepared in advance of the final rule; that analysis is generally a part of the rulemaking record. An executive agency may not publish a significant final rule until OIRA has completed, waived, or exceeded the time limit for its review of the rule under E.O. 12,866.

A rulemaking must be completed within a reasonable time, or within the time frame, if any, set by the relevant statute.

V. THE FINAL RULE

A. Publication of Final Rule and the Basis and Purpose of the Rule

The agency must publish the operative text of the final rule. The agency must also provide a statement of basis and purpose that adequately explains the justifications, purposes, and legal authority for the rule and indicates compliance with regulatory analysis requirements imposed by statute. The scope of this explanation depends on the importance and impact of the rule. The Administrative Procedure Act calls for only a “concise general statement of . . . basis and purpose.” However, courts have required that for rules likely to have major economic or other impacts the statement (a) must demonstrate that the agency fully considered significant alternatives to its final rule, important public comments, and relevant information and scientific data and (b) must explain the agency’s rejection of any of the foregoing.

After a rule subject to OIRA review has been published, E.O. 12,866 requires that the agency and OIRA disclose specified information pertaining to the review.

If the final rule is not a “logical outgrowth” of the proposed rule, a second round of notice and comment is required.

B. Effective Date

A substantive rule of general applicability is unenforceable unless published in the Federal Register, and cannot ordinarily become effective less than 30 days after its publication (unless it grants an exception or relieves a restriction).

No economically significant rule can take effect (a) until 60 calendar days after the agency has submitted a copy of the rule and a concise general statement relating thereto to both Houses of Congress and the Comptroller General and has submitted additional supporting material to the Comptroller General and made such material available to both Houses of Congress, or (b) if a joint resolution disapproving the rule is enacted. Rules relating to agency management or personnel or agency organization, procedure, or practice are exempt from this 60-day requirement.