PART I

OVERVIEW OF FEDERAL AGENCY RULEMAKING

Passage of the Administrative Procedure Act (APA) in 19461 established the basic framework of administrative law governing 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, agencies have had to significantly modify their rulemaking procedures in response to court-mandated refinements and the increasing complexity and controversial nature of many rulemakings.3 Succeeding Presidents, beginning with Nixon, have, by executive order, imposed procedural requirements on rulemaking by executive branch agencies that went beyond procedures required by the APA.4

4. The most important of these is President Clinton’s Executive Order 12,866, 3 C.F.R. 644 (1993 compilation), reprinted in 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
Additional “regulatory reform” initiatives enacted by Congress have also prescribed procedural 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

One of this Guide’s major purposes is to provide agency rulemakers, participants, and others interested in agency rulemaking 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. One of the APA’s major accomplishments was the establishment of minimum 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. Instead, the APA recognized and adopted various agency procedures that are 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.” 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, agriculture marketing order, 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. 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.


7. The need for procedural variety and flexibility was shown by the path-breaking empirical research conducted by the Attorney General’s Committee on Administrative Procedure in existence from 1939 to 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. 77-8 (1941).

8. 5 U.S.C. § 553(e).

9. 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 oxymoron “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, ch.2) has introduced different notions of “formality.” Michael Herz, Rulemaking Chapter, in DEVELOPMENTS IN ADMINISTRATIVE LAW AND REGULATORY PRACTICE 2002-2003, at 144 (Jeffrey S. Lubbers ed., 2004). Even the Supreme Court has mislabeled informal rulemaking as formal. See, e.g., Wyeth v. Levine, 555 U.S. 555, 580 (2009); Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 1004 (2005); Wash. State Dept. of Social and Health Servs. v. Guardianship Estate of Keffeler, 537 U.S. 371, 385 (2003). According to a Westlaw Search of “allfeds,” the term “formal rulemaking” appeared in more federal cases (304) from May 2008 to May 2018 than it did in the previous two decades, although there are very few formal rulemaking statutes on the books.
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 a protection to the public, should naturally be accorded more elaborate public procedures.”\textsuperscript{10}

As discussed below, however, even the procedural floor set in section 553 does not apply to all rulemaking.\textsuperscript{11} 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 has eroded significantly in the subsequent 72 years. Federal courts, Congress, and Presidents have taken steps to require that agencies follow more rigorous procedures. While the Clinton Administration did, to some extent, streamline presidential review of rules\textsuperscript{12} and the Supreme Court put the brakes on judicial supplementation of procedures in \textit{Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council (Vermont Yankee)},\textsuperscript{13} Congress has continued to require new procedural and substantive requirements, as has the Office of Management and Budget (OMB) under Presidents Bush II and Obama. President Trump has imposed some new stringent requirements and Congress is considering even more. These developments are discussed below in greater detail.

\section*{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.\textsuperscript{14} Limited exceptions are provided—specifically, where another statute precludes judicial review or the action is committed to agency discretion.\textsuperscript{15} Most statutes establishing regulatory programs provide for court review of agency rules.\textsuperscript{16} Unless

\begin{itemize}
  \item \textbf{10.} Report on the Administrative Procedure Act, S. REP. No. 79-752, at 15 (1945).
  \item \textbf{11.} See infra Part II, ch. 1(D).
  \item \textbf{12.} See infra subsec. D.
  \item \textbf{13.} Supra note 3.
  \item \textbf{14.} 5 U.S.C. §§ 701-706. See generally infra Part IV (discussing judicial review of agency actions).
  \item \textbf{15.} 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.
  \item \textbf{16.} See infra Part IV, ch. 1.
\end{itemize}
the enabling statute contains a controlling judicial review provision, 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)*, 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. 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.”

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.” Finally, the Court, refusing to accept as a basis for the agency decision “post hoc” rationalizations 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.”

*Overton Park* had a lasting impact on court review of rulemaking even though the proceeding in that case was not rulemaking. The courts continue to apply the presumption of reviewability of agency action, 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

---

17. 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).


19. *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).

20. *Id.* at 416.

21. *Id.*

22. *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.

23. The action, which involved approval of building a specific road, is more appropriately characterized as “informal adjudication.”

A Guide to Federal Agency Rulemaking

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.25

The application of hard-look review to procedural issues in rulemaking resulted in a series of decisions by the courts of appeals, principally the D.C. Circuit, which mandated procedures in agency rulemaking that went beyond the minimum requirements of section 553.26

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.27 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.28

In Vermont Yankee,29 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.30

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.31 And it did not affect continuing strict court review of

25. See infra Part IV, ch. 2(A)(2).
26. See Schiller, supra note 3.
27. Review of informal rulemaking under the APA is under the “arbitrary or capricious” standard. 5 U.S.C. § 706(1). See infra Part IV, ch. 2(A), for discussion of these standards of review.
28. 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 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); Int’l 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), and the articles cited in note 3, supra, for a discussion of these and related cases.
30. Id. at 524 (footnote omitted).
31. See Scalia, supra note 3, at 395 (“In sum, it would seem that Vermont Yankee’s demand for fealty to the APA must be taken with a grain of salt.”). See also Jack M. Beermann & Gary Lawson, Reprocessing Vermont Yankee, 75 GEO. WASH. L. REV. 856, 860 (2007) (“The decision can be read in at least three different ways: broadly to require strict fidelity to the text of the APA in all
agency adherence to the procedural requirements in the APA or in agency regulations.\textsuperscript{32}

The late 1970s began a rather sustained period of federal deregulation.\textsuperscript{33} Deregulation was effected by legislation,\textsuperscript{34} through administrative actions—including amendment and repeal of rules—and in some cases through administrative inaction and delay.\textsuperscript{35} In 1983, the Supreme Court, in \textit{Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co. (State Farm)},\textsuperscript{36} 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.\textsuperscript{37} 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.”\textsuperscript{38}

Applying the “arbitrary and capricious” standard of review in \textit{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.’”\textsuperscript{39} As the Court stated:

\begin{quote}
respects, narrowly to forbid only the very specific practices rejected in the case, or naturally
(so we claim) to forbid imposition of any administrative procedures not firmly grounded in
some source of positive statutory, regulatory, or constitutional law.”).
\end{quote}

\begin{thebibliography}{9}
\bibitem{32} See infra Part IV, ch. 2(A)(5) (discussing judicial review of agency procedures in issuing rules).
\bibitem{33} There is extensive classical literature on the subject of deregulation and its impact on agency rulemaking. See, e.g., \textsc{Robert E. Litan & William D. Nordhaus}, Reforming Federal Regulation (1983); \textsc{Stephen Breyer}, Regulation and its Reform (1982); \textsc{Robert L. Rabin}, Federal Regulation in Historical Perspective, 38 \textsc{Stan. L. Rev.} 1189, 1315–26 (1986); \textsc{Thomas O. McGarity}, Regulatory Reform in the Reagan Era, 45 \textsc{Md. L. Rev.} 253 (1986); \textsc{Merrick B. Garland}, De-regulation and Judicial Review, 98 \textsc{Harv. L. Rev.} 505 (1985); \textsc{Marianne K. Smythe}, Judicial Review of Rule Rescissions, 84 \textsc{Colum. L. Rev.} 1928 (1984).
\bibitem{35} The Occupational Safety and Health Administration’s delay in issuing a field sanitation standard, which spanned several presidential administrations, is an example. See \textit{Farmworker Justice Fund v. Brock}, 811 F.2d 613 (D.C. Cir. 1987) (ordering OSHA to issue standard; ultimately vacated after OSHA issued standard), \textit{vacated as moot}, 817 F.2d 890 (1987).
\bibitem{36} 463 U.S. 29 (1983).
\bibitem{37} Id. at 41.
\bibitem{38} Id. at 42.
\bibitem{39} Id. at 43 (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).
\end{thebibliography}
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.\(^{40}\)

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 \textit{Vermont Yankee}. In \textit{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.”\(^{41}\) Not until 2009, in the case of \textit{FCC v. Fox Television Stations, Inc.},\(^{42}\) did the Court return to the issue of how to apply the arbitrary and capricious test to agency change of policy.

In a decision handed down a year after \textit{State Farm}, the Supreme Court, in \textit{Chevron U.S.A. Inc. v. Natural Resources Defense Council (Chevron)},\(^{43}\) upheld an Environmental Protection Agency (EPA) rule under the Clean Air Act\(^{44}\) 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 statutory interpretation 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 intentionally left to be resolved

\(^{40}\) Id.

\(^{41}\) 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 \textit{State Farm Mutual Automobile Insurance Co. v. Dole}, 802 F.2d 474 (D.C. Cir. 1986), cert. denied, 480 U.S. 951 (1987).

\(^{42}\) 556 U.S. 502 (2009), discussed in greater detail in Part IV, ch. 2(A)(2)(c).


\(^{44}\) 42 U.S.C. § 7502(b)(6).
by the agency charged with the administration of the statute in light of every-
day 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 Con-
gress, 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.\textsuperscript{45}

In adopting this highly deferential approach to agency legal interpretations in
rulemaking, the Supreme Court in \textit{Chevron} did not attempt to explain its somewhat
different approach to factual review in the \textit{State Farm} decision.\textsuperscript{46} Nevertheless, \textit{Chev-
ron} has spawned a huge volume of cases and articles interpreting both its methodology and application to cases beyond the notice-and-comment rulemaking involved in the \textit{Chevron} case itself.

Although its relevance to agency rulemaking is somewhat limited, another Supreme
Court decision of special significance to agencies in a period of deregulation is \textit{Heckler v. Chaney}.\textsuperscript{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 the majority, Justice Rehnquist stated that the presumption of reviewability of administrative agency action articulated in cases such as \textit{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 peculiarly within [the agency’s] expertise.”\textsuperscript{48}

Although the Supreme Court expressly stated that it was not deciding the review-
ability of agency decisions declining to initiate rulemaking proceedings,\textsuperscript{49} the decision was cited by the government in challenges to agency decisions not to initiate, or failures to complete, rulemaking. However, the Supreme Court firmly buried that concern in \textit{Massachusetts v. EPA},\textsuperscript{50} which reviewed EPA’s denial of a rulemaking

\textsuperscript{45} 467 U.S. at 865–66.
\textsuperscript{46} See Part IV, ch. 2(A), for a discussion of these cases.
\textsuperscript{47} 470 U.S. 821 (1985).
\textsuperscript{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. at 831. The 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.
\textsuperscript{49} Id. at 825 n.2.
\textsuperscript{50} 549 U.S. 497 (2007).
petition asking the agency to regulate greenhouse gas emissions from new motor vehicles. In so doing the Court distinguished *Heckler* and said, “There are key differences between a denial of a petition for rulemaking and an agency’s decision not to initiate an enforcement action.” It reaffirmed that its review was a “narrow” one under the arbitrary and capricious standard, but found that the agency had “offered no reasoned explanation” for its denial.

On the other hand, *Heckler v. Chaney* does clearly affect the reviewability of agency rule enforcement (or lack thereof).

### C. Agency Rulemaking and the Congress

Congress has a pervasive influence on agency rulemaking activities. In the first place, Congress decides whether to grant 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 authority 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 procedures normally reserved for adjudication, such as requirements for informal public hearings, cross-examination of witnesses, more extensive statements of justification

---

51. *Id.* at 527. The four dissenting justices did not disagree that EPA’s action was reviewable.
52. *Id.* at 527–28.
53. *Id.* at 534.
54. See infra Part IV, ch. 3, for a discussion of these cases.
56. For example, in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988), discussed infra Part III, ch. 8(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.
57. *But see* section 559 of the APA, which states that a “[s]ubsequent statute may not be held to supersede or modify [the APA] . . . except to the extent that it does so expressly.” 5 U.S.C. § 559. *Discussed in* Coal. for Parity, Inc. v. Sebelius, 709 F. Supp. 2d 10, 18 (D.D.C. 2010).
58. 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)).