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AGENDA ITEM D

Committee on Regulation

Proposed Recommendation
December 9-10, 1993

Procedures for Regulation of Pesticides

The Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without change and improvement in the Agency's regulatory procedures. The Conference recommends the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decisionmaking by EPA, and for effective public participation.

The Reregistration Process

The reregistration of existing pesticides under contemporary risk assessment standards, and the removal of unacceptable pesticides from the marketplace, are examples where procedures can hinder the agency's prospects for success in its substantive mission. Reregistration of existing pesticides, which Congress originally directed to be completed by 1976, became sufficiently delayed so that Congress in 1988 amended FIFRA specifically to force the completion of reregistration by 1998. Yet subsequent delays in the reregistration process may cause EPA to miss this congressional deadline. To some extent, the delay may reflect the underlying difficulty and resource-intensiveness of the risk assessment enterprise with which EPA has been charged. There are some 50,000 pesticide products that are separately formulated from 642 identified active ingredients. Although EPA has tried to expedite its task by focusing reregistration on some 402 "cases" (composed of single or related active ingredients), each case can require evaluation of 100-150 separate studies, every one of which may pose further questions of scientific protocol and interpretation. It may be that EPA's Office of Pesticide Programs needs more personnel to match its regulatory task.

Whatever the case for additional resources (a question not addressed by the Conference), there is a more basic need for timely and adequate data from registrants--all else in the reregistration process depends on this. Yet the reregistration process does not now provide sufficient procedural incentives to encourage timely and adequate data. In general, because registrants continue to market their products during reregistration, they have little to lose by regulatory decisions that are reached later rather than sooner. Although the 1988 FIFRA Amendments require registrants to identify data gaps, and commit to fill them, the 1988 Amendments do not provide the agency with sufficient tools to police tardy or inadequate data submissions.

As to tardiness, the 1988 Amendments authorized the agency to suspend registrations of those registrants who fail to submit data. But EPA must first provide nonsubmitters with 30-days' notice in response to which registrants can demand a limited hearing (which must be held within 75 days); the 1988 Amendments further provide that registrants suspended for not submitting data can have their registrations "reinstated" upon submission of the data. Some registrants, ironically, have used these suspension procedures as a means of obtaining penalty-free and self-awarded extensions of time. In the 7 months between August 1991 and February 1992, for example, EPA found it necessary to issue 70 Notices of Intent to Suspend for nonsubmittal of data, yet in the majority of these instances (53) the registrants merely submitted their data prior to exhausting their procedural rights and were no worse off for having missed their deadlines. To create an additional disincentive for untimely data submissions it is necessary to make lateness costly to the registrant. To this end, the Conference recommends that Congress authorize EPA to impose civil money penalties for untimely data.

As to the adequacy of data, EPA may now have the theoretical (but untested in court) capacity to suspend or cancel the registration of those pesticides for which inadequate data have been submitted. However, the more common response to inadequate data is a "data call-in," through which the agency demands that studies be redone--a source of additional delay that the agency has identified as significant.

Even with respect to its highest priority pesticides, EPA has in the recent past found 50 percent of studies to be either inadequate, "upgradable" or otherwise requiring supplementation. Although the cost of redoing studies should provide some incentive for registrants to ensure that their studies meet EPA's quality criteria, it does not seem to provide a sufficient incentive. In fairness to some registrants, there is evidence that EPA itself may be partially to blame for the high rates of data rejection. In 1992, an internal agency review found that misinterpretation of data requirements and poor guidance from EPA case managers were in part responsible for the inadequacy of data submissions. The Conference therefore recommends that EPA promulgate and communicate clear data standards and guidance on the adequacy of data expected from registrants. To help prevent the submission of inadequate data after sufficiently clear agency guidance is given, the Conference recommends that Congress authorize EPA to levy administrative civil money penalties for the submittal of data that fail to meet those standards. This will not only create incentives for registrants to take the extra steps necessary to ensure the adequacy of their submittals, but it will also create incentives for the agency to make clear its expectations.

Whatever the additional tactical advantages that the agency may gain by improving its own ability to enforce data timeliness and adequacy, the sheer number of studies and the innumerable decisions requiring agency discretion suggest that more global incentives are needed to ensure that registrants themselves have a stake in timely and adequate data. The danger is that the reregistration process now has become, even with the best of intentions, an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, submission of data that do not always meet EPA's standards for adequacy, and further data call-ins that restart the sequence. The Conference believes that the unique demands of the reregistration process justify congressional consideration of a "hammer" provision that would legislatively impose an automatic suspension of all List A pesticides (those high-priority pesticides to which there is greatest human exposure) for which there are still data gaps by a date certain, subject to a provision for registrants to petition for reinstatement. Such a provision would not only provide an overarching incentive for registrants to favor the completion rather than postponement of their data obligations, but it would also better align the reregistration process with FIFRA's central procedural presumption--that, in the face of uncertainty, applicants (especially those seeking to reregister pesticides with extensive human exposure) should bear the burden of proof in establishing that their pesticides do not pose unreasonable risks.

Suspension and Cancellation Hearings

Apart from improvements in the reregistration process, the Conference urges Congress to substitute a relatively informal decisionmaking process for the formal adjudicatory hearings that registrants can now demand in cancellation and suspension matters. In the past, formal hearings under FIFRA have averaged 1,000 days to complete. These hearings can directly impose on EPA significant resource costs and can also indirectly discourage the agency from aggressive prehearing negotiations with registrants (lest the registrant "take EPA to hearing"). It is not surprising that EPA has long sought alternatives to cancellation hearings. For years, it sought to identify problem pesticides for heightened regulatory attention in a "Special Review" process. There is little need for procedural formality in these types of decisions. At issue in most cancellation and suspension proceedings are scientific data on risks and benefits, disputes over which can generally be well-ventilated when EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. For those cases where oral testimony or cross-examination is justified, the benefits of more formal procedures can be preserved by providing registrants an opportunity to show cause why such procedures are warranted. Accordingly, the Conference recommends that Congress pattern cancellation and suspension proceedings on a basic notice-and-comment model, with more formal procedures available only upon a showing that such procedures are likely to improve significantly the accuracy of agency decisionmaking.

Labeling and Phase-down Procedures

Although the reregistration process and adjudicatory hearings are the most visible aspects of pesticide regulation in need of procedural improvement, they are not the only places where procedural reform is important. Since the late 1980's, EPA has in fact sought to reduce the risks of pesticides through private negotiations with registrants over label changes that impose restrictions on use. Such regulatory action has the potential to attain interim risk-reduction quickly when warranted by available data, without going through the cumbersome Special Review and cancellation procedures, even when complete reregistration may still be years away. But there are also disadvantages to relying so heavily on private negotiations with registrants--chief among them the lack of participation among the various interested publics in crafting label changes. In the early 1980's, similar concern for privately negotiated Special Review and pre-Special-Review decisions seriously undermined the agency's credibility and slowed regulatory progress. In 1985, EPA adopted procedures to open the door for information from, and participation by, the public in those processes.[1] The Conference recommends that EPA adopt analogous procedures to regularize and open the agency's negotiated label program. In addition, because label changes are effective in reducing risk only if they are actually implemented in the field, the Conference recommends procedures to facilitate feedback from registrants, pesticide users, and all other interested persons on the effectiveness or ineffectiveness of the interim risk-reduction measures EPA has adopted. Moreover, the Conference recommends that EPA's Office Of Pesticide Programs (OPP) establish regular channels of communication with EPA's Office of Enforcement and Compliance Assurance to inform that office of all label changes and of any material information received by OPP on noncompliance with such changes.

The Conference also urges Congress to consider providing EPA with a new procedural device designed to accommodate a safer pesticides policy: the ability by informal rulemaking to order the phase-down of existing pesticides when there are available for use safer, effective pest management products or practices.[2] There are several procedural advantages to empowering the agency with an informal phase-down mechanism. First, ordering the phase down of an existing pesticide on relative risk grounds will cause less stigmatization of an existing product than would a cancellation proceeding based on the traditional, more absolutist "unreasonable risk" judgment. Second, phase-down rulemaking provides for an incremental style of decisionmaking in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides in cancellation

[1] 40 CFR Part 154, Subpart B.

[2] Without taking any position on the substantive questions involved in determining the relative safety and effectiveness of pest control measures, the Conference notes EPA's interest in both the present and prior presidential administrations in developing such a substantive capability.

proceedings. Finally, phase-down rulemakings based on relative risk can reinforce and integrate EPA's pesticide programs under FIFRA with other federal environmental programs.

RECOMMENDATION

1. Because good data are central to the integrity of EPA's substantive decisions, and because the submission of such data is critical to the timeliness of agency action, EPA should promulgate, whenever possible, clear, written standards on the adequacy of data and communicate those standards to registrants.

2. Congress should provide EPA with the authority to impose administrative civil money penalties on registrants for the submittal of data after any applicable deadline, or for the submittal of data (even if timely) the inadequacy of which can be demonstrated by reference to clear data standards adopted by EPA.[3]

3. Congress should consider changing the incentives of registrants for reasonably expeditious reregistration by imposing an essentially automatic suspension of List A pesticides for which there still remain, by a date certain, outstanding significant data gaps within the registrant's control. Once suspended, pesticides could subsequently be reinstated through a petition process.

4. Congress should eliminate the provisions in FIFRA allowing for formal adjudicatory hearings and provide instead an informal procedure that affords registrants notice of the grounds on which EPA bases its proposed suspension or cancellation actions and reasonable opportunities to file written comments. Only upon cause being shown, would the agency grant the registrant the right to introduce oral testimony or to subpoena and cross-examine witnesses in individual cases.

5. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through pesticide label changes. EPA should inform the public, through a Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments

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[3]See Conference Recommendation 93-1 "Use of APA Formal Procedures in Civil Money Penalty Proceedings," 1 CFR §305.93-1.

they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

6. EPA should ensure compliance with label changes. After a label change, the agency should establish and publicize the availability of a "compliance docket," for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. In addition, EPA's Office of Pesticide Programs (OPP) should communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes and any material information received by OPP in its compliance docket.

7. Congress should consider providing EPA the authority to order a phase down in the use of any registered pesticide through an informal rulemaking procedure in which EPA considers such factors as the relative risks and benefits of the pesticide at issue when compared with alternative pest management products and practices.

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REGULATING PESTICIDES: FIFRA REGISTRATION, REREGISTRATION, SUSPENSION, & CANCELLATION PROCEDURES

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November 1993

This report was prepared for the consideration of the Administrative Conference of the United States. The views expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees except where formal recommendations of the Conference are cited.

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1-5:30
mark my calendar

Dear Mr. ~~Podesta:~~ John

Our December 9-10 plenary session is just around the corner and promises to be a productive and interesting meeting. As in the past, we will once again be holding a reception following the first day of the session. Your formal invitation to the reception will be sent shortly.

We appreciate these plenary receptions as an opportunity to visit with one another in an informal setting. Indeed, these occasions positively contribute to the collegial atmosphere upon which our business meetings are so dependent for their success. Traditionally, the Conference has invited selected members of the Administration, Congress, and the federal judiciary to attend as our guests. These invitations help us give recognition to those government officials who work with, and support, the Conference, and allow us all to become better acquainted professionally.

As you know, we are prohibited from using government funds for the costs of the reception. Thus, I must kindly ask for your financial support for the reception. Government members, members of the academic community, and public interest lawyers are asked to contribute $30 for themselves, plus $30 for each guest they may wish to bring. Other public members who are members of large law firms or corporations are asked to contribute $350. Those who contribute $350 are entitled to bring three guests. It is only through these larger contributions that we are able to hold this event at Anderson House, and to include our supporters and friends as guests.

We are proud that we have achieved outstanding support from our members in the past, and hope to do so again this year. Please make your check payable to "Renée Barnow, ACUS Reception," and send it to her at the above address.

Thank you in advance for your kind and generous assistance.

Sincerely,

Brian

Brian C. Griffin
Chairman

BCG/dkk

John - It's great to have you on the Council!

December 8, 1993

Sally Katzen, Acting Chairman

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<u>**December 10, 9:00 AM**</u>

9:00 AM

AGENDA ITEM C, **The Use of Audited Self-Regulation as a Regulatory Technique**

Committee on Regulation
John Golden, Chairman
Douglas C. Michael, Consultant
David Pritzker, Committee Liaison
(one hour and thirty minutes)

10:30 AM

AGENDA ITEM D, **Procedures for Regulation of Pesticides**

Committee on Regulation
John Golden, Chairman
Donald T. Hornstein, Consultant
David Pritzker, Committee Liaison
(one hour and fifteen minutes)

PRESENTATION - **Model Rules Working Group Report**

Model Rules Working Group
Alan Heifetz, Chairman

New Business

Adjournment, 12:00 PM

RESOLUTION GOVERNING THE ORDER OF BUSINESS

The time initially allotted to each proposed recommendation or other item is separately stated in the agenda. Individual comments from the floor shall not exceed five minutes (unless further time is authorized by unanimous consent). A majority of the members present and voting may extend debate on any proposed recommendation or other item for up to 30 additional minutes; thereafter, in the absence of unanimous consent to extend the time, the matter will go to the end of the agenda.

Amendments and substitutes that have been submitted in writing to the Executive Director before the meeting will receive priority in the discussion of a proposed recommendation or other item. Other amendments and substitutes will be entertained only to the extent that time permits. Notwithstanding Robert's Rules of Order, the Chair may allow up to five minutes for debate on any motion to lay on the table.

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OFFICE OF
THE CHAIRMAN

FORTY-NINTH PLENARY SESSION
The Amphitheater
Office of Thrift Supervision
Second Floor
1700 G Street, NW.
Washington, D.C.

Thursday, December 9, 1993 - 1:00 p.m.
Friday, December 10, 1993 - 9:00 a.m.

AGENDA

December 9th, 1:00 PM

1:00 PM Welcoming Remarks
Swearing in of new Council members
Adoption of the Resolution Governing the Order of Business

1:15 PM

AGENDA ITEM A, **Improving the Environment for Agency Rulemaking**

Committee on Rulemaking
Ernest Gellhorn, Chairman
Jeffrey S. Lubbers, Research Director
Nancy G. Miller, Committee Liaison
(Two hours and forty-five minutes - a fifteen minute break will be taken at 3:00 PM)

4:00 PM

AGENDA ITEM B, **Right to Consult with Counsel in Agency Investigations**

Committee on Governmental Processes Status Report
Neil R. Eisner, Chairman
(thirty minutes)

4:30 PM

ADR VIDEO - Produced by ACUS (18 minutes)

Committee on Rulemaking

Proposed Recommendation
December 9-10, 1993

Improving the Environment for Agency Rulemaking

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. The APA's cumbersome "formal rulemaking" procedures are rarely used except in some adjudicative-type rate proceedings. Meanwhile, the APA's simple "informal rulemaking" procedures (set forth in §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.[1] As a result, many federal agencies, faced with unsatisfactory rulemaking accomplishments in recent years, have turned to alternatives such as less formal policy statements or adjudicative orders to achieve regulatory compliance.[2]

The Conference believes that the environment for agency legislative rulemaking can be improved. This recommendation sets out a coordinated framework of proposals aimed at promoting efficient and effective rulemaking by addressing constraints on the current process that derive from a variety of sources. We present an integrated approach for improving the rulemaking environment in order to relieve agencies of unnecessary pressures and disincentives relating to rulemaking. We also identify

[1]See generally McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L. J. 1385 (1991).

[2]See Conference Recommendation 92-2, "Agency Policy Statements," which distinguished "legislative" rules, normally promulgated through notice-and-comment procedures, from interpretive rules and policy statements, which are exempt from such procedures. The present recommendation addresses legislative rulemaking.

desirable revisions to section 553 relating to legislative rulemaking. In doing so, this recommendation both presents new proposals and incorporates previous Conference recommendations.

Presidential Constraints

We continue to support presidential coordination of agency policymaking as beneficial and necessary.[3] We are concerned, however, that, unless properly focused, this additional review may impose unnecessary costs. All recent presidents have undertaken some level of review and coordination of agency rulemaking. Presidential review of rules, as undertaken under various executive orders applied by OMB and other White House entities, has often required agencies to submit nearly all proposed and final rules to a review process in which the rules are screened and analyzed for consistency with presidential objectives. Some of these objectives have been incorporated into analytical requirements found in separate executive orders.[4] This screening process can unduly slow the entire system of rulemaking; it can inhibit the growth of the promising consensus-based alternative of negotiated rulemaking;[5] and it can create undesirable tensions between the reviewing entities and agency policymakers. While these analytical emphases can be rationalized individually, in the aggregate, they can result in redundant requirements, boilerplate-laden documents, circumvention, delays, and clutter in the *Federal Register*. Although specific presidential review policies have varied among Administrations, these recommendations set forth principles that the Conference believes generally should govern presidential review of rules.

We therefore recommend that presidential oversight and review be reserved for the most important rules and that the agencies be given clear policy guidance in a directive, approved by the President, specifying what is required. In addition, the reviewing or oversight entity should avoid, to the extent

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[3]See Conference Recommendation 88-9, "Presidential Review of Agency Rulemaking" (applying Presidential oversight to both executive branch and independent agencies).

[4]Among the mandates reflected in these executive orders are requirements that agency rulemakers include cost-benefit estimates and analyses of the proposed and final rule's impact on federalism, family values, and future litigation, of whether it effects a "regulatory taking," and of other matters. The Conference of course takes no position on the merits of the values underlying these executive orders.

[5]See Conference Recommendations 82-4 and 85-5, "Procedures for Negotiating Proposed Regulations;" Negotiated Rulemaking Act of 1990, 5 U.S.C. §§561-69.

possible, extensive delays in the rulemaking process. The review process itself also should be open to public scrutiny--following guidelines previously developed by the Administrative Conference.[6] The President's policy should encourage planning and coordination of regulatory initiatives, and early dialogue between agencies and the reviewing entity. To this end, the concept of a unified agenda of regulations is a useful tool and should be preserved. We also believe that the number of extra-APA analytical requirements should be kept to a minimum. The cumulative impact of such requirements on the rulemaking process should be considered before existing requirements are continued or additional ones imposed. We also believe it is useful to periodically reassess the continued viability and relevance of the various presidential directives.[7]

Legislative Constraints

Congress should similarly review and rationalize legislatively-mandated rulemaking procedures. Specifically, we recommend that it refrain, as it generally has done since the 1970s, from imposing program-specific rulemaking requirements that go beyond the APA's basic notice-and-comment procedures.[8] Statutory "on-the-record" and "hybrid" rulemaking provisions that require adjudicative fact-finding techniques such as cross-examination, or more stringent provisions for judicial review (in particular, use of the "substantial evidence" test instead of the normal "arbitrary and capricious" test), can be unnecessarily burdensome or confusing and should be repealed.[9] Although additional procedures can sometimes be beneficial--see, e.g., §307 of the Clean Air Act (providing additional safeguards for rulemaking with significant economic and competitive effects),[10] they should be

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[6] See Conference Recommendation 88-9, "Presidential Review of Agency Rulemaking," at ¶4.

[7] While the most recent executive order of presidential review of rules generally reflects the views set forth in this recommendation, see Executive Order 12866, 58 Fed. Reg. 51735 (1993), the Conference takes no position on the specifics of that order.

[8] See Conference Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity to Comment in Informal Rulemaking."

[9] See Conference Recommendation 80-1, "Trade Regulation Rulemaking Under the Magnuson-Moss Warranty - Federal Trade Commission Improvement Act."

[10] 42 U.S.C. §7607.

imposed only after careful review and attention by Congress to possible unintended consequences. Otherwise, such additions generally should be left to the discretion of individual agencies.[11]

Similarly, legislatively-imposed time limits on rulemaking, while understandable, can be unrealistic, resulting in either hastily-imposed rules or missed deadlines that undermine respect for the rulemaking process.[12] Legislative deadlines backed by statutory or regulatory "hammers" (mandating, for example, that the *proposed* rule or some other policy change[13] automatically take effect upon expiration of the deadline) are particularly undesirable and often counter-productive;[14] they are generally less desirable than the alternative of judicial enforcement of deadlines. Finally, legislation ancillary to the APA that creates additional rulemaking impediments should be reconsidered. Statutes such as the Regulatory Flexibility Act, which requires a special analysis of virtually all rules' effects on small business, may have laudable intentions, but their requirements are often both too broadly applicable and not sufficiently effective in achieving their goals. If such requirements are imposed, Congress should focus them more narrowly, by, for example, confining their application to significant rules or particular categories of rules.

Judicial Constraints

Other constraints on rulemaking that warrant similar reconsideration have been imposed through judicial review. The APA, in section 706, provides that agency rules may be set aside if they are "arbitrary or capricious," represent an "abuse of discretion," or are "otherwise not in accordance with law." The evolving scope of judicial review of agency rules, along with the timing of much such review at the preenforcement stage, have contributed to what is sometimes an overly intrusive inquiry. This, in turn, has led agencies to take defensive measures against such review. While some tension is

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[11] See Conference Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking."

[12] See Conference Recommendation 78-3, "Time Limits on Agency Action."

[13] See, e.g., Conference Recommendation 90-8, "Rulemaking and Policymaking in the Medicaid Program."

[14] Where the "hammer" applied because of a failure to meet a deadline is that a proposed rule becomes effective, the anomalous result is that a policy that has withstood <u>no</u> public airing will be implemented.

an inevitable adjunct of the process of judicial review, we believe that steps can be taken to lessen some of the burdens without loss of effective outside scrutiny of agency rules.

The tendency of some courts to require extra-APA procedures in rulemaking was arrested by the Supreme Court's *Vermont Yankee* decision in 1978.[15] Nevertheless, while the prevailing judicial interpretation of the arbitrary-and-capricious standard of review (which became known as the "hard look doctrine") has promoted reasoned decisionmaking, courts have not infrequently remanded rules on the basis of agency failure to respond adequately to comments, consider relevant factors, or explain fully the bases for its rule. Courts should be sensitive not to require greater justification for rules than necessary; a reasoned statement that explains the basis and purpose of the rule and addresses significant issues raised in public comments should be adequate.

Preenforcement review, expanded by the Supreme Court in the 1967 *Abbott Laboratories* cases,[16] applauded by the Conference in various recommendations,[17] and codified in numerous rulemaking programs, has the virtue of settling legal issues early and definitively. When overused--particularly when coupled with legislatively-mandated preclusion of subsequent judicial review--it can have the negative effect of inducing precautionary challenges to most rules and the raising of as many objections to a rule as possible, including somewhat speculative challenges pertaining to the rule's potential application.

Under the *Abbott Laboratories* standard, challenges to a rule are permitted where issues are appropriate for judicial review and where the impact on a challenger is direct and immediate. The Conference believes that the *Abbott Laboratories* standard strikes a sensible balance, and that preenforcement challenges generally are appropriate where the administrative record provides a sufficient basis for the court to resolve the issues before it. Thus, a preenforcement challenge to a rule based on the procedures used in the rulemaking should normally be permitted. Preenforcement review

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[15] Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519 (1978).

[16] Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967).

[17] See Conference Recommendation 74-4, "Preenforcement Judicial Review of Rules of General Applicability;" Conference Recommendation 91-5, "Facilitating the Use of Rulemaking by the National Labor Relations Board."

that involves a facial challenge to a rule's substantive validity (whether because of a conflict with a statute or the Constitution, or because of the inadequacy of the facts or reasoning on which it is based) should also generally be heard.[18] In contrast, challenges to a rule because it might be applied in a particular way should normally be deferred until the rule has actually been applied.

Although prompt resolution of legal issues is to be encouraged, Congress should be cautious in coupling *mandated* time-limited preenforcement review with preclusion of review at the enforcement stage. Such time-limited review should be provided for only in the situations and conditions specified in Recommendation 82-7.[19] Where Congress does set time limits for preenforcement review, it should, in the interests of procedural consistency, generally specify that preenforcement review should occur within 90 days of a rule's issuance. In the past, the statutory specifications have varied. There does not seem to be any reason for variation that outweighs the benefits of uniformity in this context.

Congress should also amend any existing statutes that mandate use of the "substantial evidence" test for reviewing legislative rules, by replacing it with the "arbitrary and capricious" test. The occasional introduction of the substantial evidence test in the rulemaking context has created unnecessary confusion; some courts apply it in a manner identical to that of the "arbitrary and capricious" test, others believe that it sets a higher standard. The Conference believes that the arbitrary and capricious test provides sufficient review in the informal rulemaking context.

The intensity of judicial review directly affects the rulemaking process. For example, the scope of review of agency *statutory* interpretations is governed by the deferential *Chevron* test, which requires affirmance if the agency's interpretation of an ambiguous statute is permissible.[20] On the other hand, when reviewing the reasonableness of an agency's *policy and factual* justifications for its rules, courts apply the stricter "hard look" doctrine.[21] Deferential review of the legal issue of statutory

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[18]A challenge based on the facial invalidity of the rule, in this context, would normally be directed at a requirement or course of action to which the agency has clearly committed itself.

[19]Recommendation 82-7, "Judicial Review of Rules in Enforcement Proceedings," sets out criteria for when judicial review should be limited at the enforcement stage, and what kinds of issues should remain reviewable at that stage.

[20]Chevron USA Inc. v. NRDC, 467 U.S. 837 (1984).

[21]Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983) (State Farm).

interpretation, coupled with the rigorous review of a rule's factual and policy underpinnings that the "hard look" doctrine specifies, has been criticized as anomalous. The Conference believes, however, that the review standards can be harmonized by looking beyond the labels. That is, under both of these doctrines, courts are required to determine independently the limits of the agency's statutory authority and whether the factors the agency took into account in formulating the rule were permissible. Following that determination, courts properly defer to an agency's permissible reading of its statute and to its choice of inferences from the facts in making policy decisions. Courts would help make their review more consistent and predictable if they articulated more clearly this two-step approach. Both *the Chevron* and "hard look" doctrines would then be understood as including a searching review of the range of an agency's legally permissible choices (statutory, policy, and factual), combined with, in each instance, deference to the agency's reasonable selection among such choices, once the alternatives are determined to be within the permissible range.

Finally, in order to prevent additional litigation, courts should be encouraged to address certain issues that arise in many (if not most) reviews of rules. Reviewing courts should, for example, specify, to the extent feasible, which portions of the rule (if any) are to be set aside, vacated, stayed or otherwise affected by the decision in the case. They should seek to ensure that portions of a rule unaffected by a finding of illegality remain in effect, unless the rule expressly or impliedly indicates that the rule is inseverable. A reviewing court should also consider the extent to which its mandate will apply retroactively. In considering the effect to be given to its decision, the court should weigh the impact of the decision on parties not before the court, and recognize their interest in being heard or adequately represented prior to any ruling that adversely affects them.

Amendment of the APA

As we approach the fiftieth anniversary of the APA, some of its rulemaking provisions need to be updated. Section 553(c), which does not now specify a length of time for the comment period, should be amended to specify that a comment period of "at least 30 days" be provided (although the good cause exception for shorter periods should be retained). This would relieve agencies of the need to justify comment periods that were 30 days or longer. Agencies would still be encouraged to allow longer comment periods and to leave the record open for the receipt of late comments.[22] Section 553 should also specify that a second round of notice and comment is not required where the final rule is the "logical outgrowth" of the proposed rule, thus codifying generally accepted doctrine.[23] A provision requiring maintenance of a public rulemaking file should be incorporated into section 553, so that those who seek access to the file are not forced to rely on the Freedom of Information Act to obtain it.[24] The file should contain notices of the rulemaking, all written comments submitted to the agency, and copies or an index of all written[25] factual material, studies, or reports substantially relied on or seriously considered by the agency in formulating its proposed and final rule (unless the material is by law exempt from disclosure). Materials substantially relied on or seriously considered need not encompass every study, report, or other document that the agency may have in its files or has otherwise used, but they should include those that exerted a significant impact on the agency's thinking, even if they represent an approach that the agency ultimately did not accept.

In addition, the requirement in section 553(c) of a statement of basis and purpose for the rule should be rewritten to require a "reasoned statement"[26] (deleting the "conciseness" provision), which includes a response to significant issues raised in the public comments.[27] These changes essentially would codify the salutary aspects of the caselaw on rulemaking, discourage insubstantial arguments and objections on review, and stem the tendency to require additional, more burdensome justifications.

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[22]See Conference Statement #7, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act," 1 CFR §310.7 (para. 2).

[23]See South Terminal Corp. v. EPA, 504 F.2d 646, 659 (1st Cir. 1974), in which the 1st Circuit originated the "logical outgrowth" test. It was subsequently embraced by other circuits, particularly the D.C. Circuit. See Shell Oil Co. v. EPA, 950 F.2d 741 (D.C. Cir. 1991); International Union, United Auto, Aerospace and Agr. Implement Workers of America v. OSHA, 938 F.2d 1310 (D.C.Cir. 1991); American Medical Association, 887 F.2d 760 (7th Cir. 1989); NRDC v. USEPA, 824 F.2d 1258 (1st Cir. 1987); United Steelworkers v. Schuykill Metal Corp., 828 F.2d 314 (5th Cir. 1987); National Black Media Coalition v. FCC, 791 F.2d 1016 (2nd Cir. 1986); Chocolate Mfrs. Ass'n v. Block, 755 F.2d 1098 (4th Cir. 1985).

[24]Statement No. 7, supra n. 22, at ¶4.

[25]"Written" includes documents in electronic form. See Conference Recommendation 88-10, "Federal Agency Use of Computers in Acquiring and Releasing Information."

[26]*State Farm*, supra n. 21, 463 U.S. at 57 (quoting Greater Boston Television Corp. v, FCC, 444 F.2d 841, 852 (D.C. Cir. 1970).

[27]Conference Statement #7, supra n. 22, at ¶5.

Another long-overdue change in the Act is elimination of section 553(a)(2)'s exemption from notice-and-comment procedures for matters relating to "public property, loans, grants, benefits, or contracts." As the Conference recognized as early as 1969, this "proprietary exemption" is an anachronism.[28] The similar exemption for "military or foreign affairs function[s]" in section 553(a)(1) should be narrowed so that all but truly secret aspects of those functions are open to public comment.[29]

Internal Agency Management Initiatives

Rulemaking is not just a product of external constraints. The agency's own processes for developing rules and reviewing them internally affect the rulemaking environment. Thus, agency management initiatives can have a significant impact on the effectiveness and efficiency of rulemaking. The Conference recommends a number of steps agency managers can take to improve their internal processes.

Senior agency staff should develop management strategies to set priorities and track agency rulemaking initiatives.[30] Agencies should also seek to involve the presidential oversight entity in the rulemaking process as early as feasible, in order to reach agreement on the significance of rules in the developmental stage, to provide greater coordination, and to speed final oversight review. They should also seek to achieve more rapid internal clearances of proposed and final rules, to develop reasoned analyses[31] and responses to significant issues raised in public comments, and to manage the rulemaking file (and associated requests for access to it).[32] As part of this effort, agencies should review their existing systems for developing and reviewing regulations, to determine where problems and bottlenecks are occurring.

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[28] See Conference Recommendation 69-8, "Elimination of Certain Exemptions From the APA Rulemaking Requirements."

[29] See Conference Recommendation 73-5, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements."

[30] See Conference Recommendation 87-1, "Priority Setting and Management of Rulemaking by the Occupational Safety and Health Administration."

[31] See Conference Recommendation 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules; Conference Recommendation 88-7, "Valuation of Human Life in Regulatory Decisionmaking."

[32] Computerized access should be made available, preferably in a uniform system government-wide. See Conference Recommendation 88-10, "Federal Agency Use of Computers in Acquiring and Releasing Information."

Agencies should also consider innovative methods for developing and getting public input on rules. Agencies should use advisory or negotiated rulemaking committees where appropriate to improve the quality and acceptability of rules.[33] They should also consider the use of "direct final" rulemaking where appropriate to eliminate double review of noncontroversial rules. Direct final rulemaking involves issuing a rule for notice and comment, with an accompanying explanation that if the agency receives no notice during the comment period that any person intends to file an adverse comment, the rule will become effective 30 days (or some longer period) after the comment period closes.

* * *

We recognize that Congress will continue to delegate to federal agencies significant rulemaking responsibilities. However, it, along with the President and the courts, should carefully limit procedural demands on agency rulemakers to those necessary for open, reasoned rulemaking. The costs of any additional procedures that are imposed in response to particular problems should be assessed to ensure that they do not exceed likely benefits in improved rationality or fairness. Further, to facilitate this reform, the APA's rulemaking provisions should be updated and agencies should implement managerial reforms designed to make policymaking through rulemaking more effective and more efficient.

RECOMMENDATION

To improve the environment for agency legislative rulemaking, the President, Congress, and the courts should take steps to eliminate undue burdens on agency legislative rulemaking; Congress should update the Administrative Procedure Act's rulemaking provisions; and agencies should review their internal rulemaking environment and, where appropriate, implement internal management initiatives aimed at improving the effectiveness and efficiency of their efforts.

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[33] Any government-wide policy concerning the use of advisory committees should be consistent with their use as part of the process of negotiated rulemaking.

I. Presidential Oversight[34]

A. The President's program for coordination and review of agency rules should be set forth in a directive that is reviewed periodically. The program should be sensitive to the burdens being imposed on the rulemaking process, and implementation of the program should ensure that it does not unduly delay or constrain rulemaking. The President should consider the cumulative impact of existing analytical requirements on the rulemaking process before continuing these requirements or imposing new ones.[35]

B. The President's directive, as well as the explanations provided and the procedures followed by the presidential oversight entity, should, insofar as practicable:

1. Promote dialogue and coordination between the oversight entity and rulemaking agencies in the early identification and selection of rules warranting application of the review process;

2. Set forth the relevant analytical requirements that the oversight entity should apply to agency rulemaking, and provide interpretive guidance to assist agencies in complying with these requirements;

3. Ensure appropriate expedition and openness in the process, in accordance with Conference Recommendation 88-9;

4. Support a process for planning regulatory initiatives and tracking rule development; and

5. Encourage and support agency efforts to use consensual processes such as negotiated rulemaking.

II. Limiting Congressionally-Imposed Burdens

A. Congress should not require formal ("on-the-record") or other adjudicative fact-finding procedures in rulemaking, and should consider repeal of any existing statutes mandating such procedures.[36] Congress generally should refrain from creating program-specific rulemaking

[34]The recommendations contained in this section apply to oversight of both executive and independent agencies. The Conference has previously recommended that presidential review of rulemaking apply to the independent agencies to the same extent it applies to the rulemaking of the Executive Branch departments and agencies. See Conference Recommendation 88-9, "Presidential Review of Agency Rulemaking."

The term "presidential oversight entity," as used herein, is that part of the Executive Office of the President delegated responsibility for review and oversight of agency rulemaking.

[35]In recommending review of analytical requirements beyond those contained in the APA, we express no position on the substantive policies being mandated.

[36]Conference has recommended against the mandated use of cross-examination and other "adjudicative" procedures for agency fact-finding in rulemaking. See, e.g., Conference Recommendation 79-1, "Hybrid Rulemaking Procedures of the Federal Trade Commission." The Conference recognizes, however, that more formal procedures may be appropriate for ratemaking based on party-related facts. See United States v. Florida East Coast RR, 410 U.S. 224 (1973). Congress may also wish to consider whether less formal hybrid processes may be useful in contexts currently requiring formal rulemaking.

procedures or analytical requirements beyond those required by the APA. When Congress determines that additional procedures beyond those required by section 553 are justified by the nature of a particular program, such procedures should be focused on identified problems and, where possible, adopted incrementally or after experimentation.[37]

B. In general, Congress should not legislate time limits on rulemaking, but should instead rely on judicial enforcement of prompt agency action under §706(1) of the APA.[38] However, if Congress determines that a deadline is appropriate, it also should ensure that the agency has sufficient resources to support the required rulemaking effort without distorting the agency's other regulatory functions. If Congress further determines that a default rule is necessary where an agency does not meet a deadline, it should specify the terms of that rule and, in particular, should not impose "regulatory hammers" that would cause the agency's *proposed* rules to take effect automatically.

C. Congress should reconsider the need for continuing statutory analytical requirements that necessitate broadly applicable analyses or action to address narrowly-focused issues.[39] If Congress nonetheless determines that such analytical requirements are necessary, Congress should structure its requirements more narrowly (e.g., by confining their application to the most significant rules or to rules likely to be affected by the stated concern).

III. Timing and Scope of Judicial Review

Congress and the courts generally should be sensitive to the impact of judicial review on agency rulemaking and should seek to simplify, clarify, and harmonize provisions for judicial review of rules.

A. Congress and the Courts

In determining whether preenforcement challenges to rules are appropriate, courts have traditionally evaluated "both the fitness of the issues for judicial decision and the hardship to the parties of withholding its consideration."[40] Adherence to this standard benefits both

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[37]See, for example, the development of more specific, but not necessarily more burdensome, procedures for EPA rulemaking that has significant economic and competitive effects. See 42 U.S.C. §7607 (§307 of the Clean Air Act). See also Conference Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," which encourages agency experimentation with use of oral procedures beyond simple notice and comment in some circumstances.

[38]This is not a comment on the legitimacy of congressional directives in this regard, but on their impracticality. On the other hand, agency self-imposed deadlines are encouraged, see V(D), below. For more detailed advice on time limits, see paragraph 5 of Conference Recommendation 78-3, "Time Limits on Agency Action."

[39]See, e.g., the Regulatory Flexibility Act of 1980. The Conference takes no position on the substantive issues the Act seeks to address. Insofar as possible, however, such concerns are more appropriately included in the President's oversight guidelines. See I(B)(2) above.

[40]Abbott Laboratories v. Gardner, supra n. 16, 387 U.S. at 149.

agencies and those affected by agency rules. Congress generally should authorize and courts should allow preenforcement challenges where the administrative record is a sufficient basis for resolving the issues. Thus, preenforcement challenges to a rule based on the procedures used in the rulemaking, or on the asserted substantive invalidity of the rule, however it would be applied, should normally be permitted. The latter would include facial challenges based on statutory or constitutional grounds, or asserting the inadequacy of the facts or reasoning underlying the rule. Challenges to a rule on the basis that the rule might be applied in a particular way should normally be deferred until the application has occurred.

B. Congress

1. Congress should be cautious in mandating time-limited preenforcement review coupled with preclusion of review at the enforcement stage, and should rely on time limits only in the situations and conditions specified in Recommendation 82-7.[41] Congressional time limits on preenforcement review should be understood to bar later challenges in the enforcement context only to the extent specified by Congress. Where Congress mandates a time limit on preenforcement review, it generally should specify that such review be requested within 90 days of the issuance of the rule.[42] It should also provide that preenforcement review cases be directly reviewable in the courts of appeals, and that a stay or partial stay of the rule's effectiveness ordinarily be issued only on the demonstration of likelihood of success and the prospect of significant private harm if the rule is permitted to take effect.

2. The standards set out in §706(2)(A) of the APA's judicial review provisions should apply in all cases involving review of rules. Specifically, Congress should not provide for the use of the "substantial evidence" test for agency rules. It should conform existing statutes to this standard by deleting the use of the "substantial evidence" test for review of agency rules.

C. Courts

1. In articulating the doctrines used in the judicial review of rulemaking, reviewing courts should more clearly harmonize the deferential *Chevron* doctrine, applied in reviewing agency interpretation of its statutory authority, with the "hard look" doctrine, used in examining an agency's justification for its rule. Courts, in applying these doctrines, should recognize that both the *Chevron* and "hard look" tests call for a similarly searching review of the range of factors or permissible choices that may be considered by the agency, and require

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[41] See Conference Recommendation 82-7, "Judicial Review of Rules in Enforcement Proceedings."

[42] Congress should likewise reevaluate existing statutes for conformity with this approach.

a consistent degree of deference to agency application of those factors once they are shown to be legally appropriate.

2. When reviewing an agency's explanation for its rule, courts should consider the context of the entire proceeding and concern themselves principally with whether the agency's overall explanation and analysis is reasonable, including its response to the significant issues raised in public comments.

3. In reviewing challenges to agency rules, courts should, to the extent feasible and after taking into account the effect of the decision on affected persons not before the court, consider: (a) whether any portion of a rule unaffected by a finding of illegality should remain in full force and effect; (b) which portions of the challenged rule (if any) are to be set aside, vacated, stayed, or otherwise affected by the court's decision in a case; and (c) the extent to which the court's mandate should apply retroactively.

IV. Amendments to the APA's Legislative Rulemaking Provisions

Congress should update the APA and eliminate outmoded provisions. It should codify court decisions that have increased the effectiveness of public participation in the rulemaking process. In particular, Congress should amend section 553 of the APA to:

A. Eliminate the exemption (§553(a)(2)) for rules relating to public property, loans, grants, benefits or contracts, and delete the similar exemption (§553(a)(1)) of military and foreign affairs matters, except for secret matters;[43]

B. Specify a comment period of "at least 30 days" (§553(c)), provided that a good cause provision allowing shorter comment periods or no comment period is retained, and codify the doctrine holding that a second round of notice and comment is not required if the final rule is a "logical outgrowth" of the noticed proposed rule;

C. Require establishment of a public rulemaking file beginning no later than the date on which an agency publishes an advanced notice of proposed rulemaking or notice of proposed rulemaking, whichever is earlier. The rulemaking file should include (1) all notices pertaining to the

[43] See Conference Recommendation 69-8, "Elimination of Certain Exemptions From the APA Rulemaking Requirements" and Conference Recommendation 73-5, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements." The latter recommendation urged eliminating the APA's categorical exemption for matters pertaining to the military or foreign affairs function. It does recognize, however, that a modified exemption may be appropriate for matters "specifically required by executive order to be kept secret in the interest of national defense or foreign policy."

rulemaking, (2) copies or an index of all written factual material, studies, and reports substantially relied on or seriously considered by agency personnel in formulating the proposed or final rule (unless the material is by law exempt from disclosure), (3) all written comments submitted to the agency, and (4) any other material required by statute or agency rule to be made public in connection with the rulemaking;[44]

D. Restate the "concise" statement of basis and purpose requirement (§553(c)) by providing instead that a rule must be supported by a "reasoned statement," and that such statement respond to the significant issues raised in public comments.

V. Agency Management Initiatives

In order to improve their internal rulemaking environments, agencies should develop management techniques to ensure efficient and effective administration of rulemaking. Such techniques should include:

A. Systematically setting priorities at the highest agency levels and tracking rulemaking initiatives, including identifying clearly who has the authority to ensure that agency schedules and policies are followed;

B. Coordinating with the presidential oversight entity on the identification of rules warranting review as early in the process as is feasible, and establishing internal review procedures at the highest levels to ensure compliance with presidential analytical requirements;

C. Reviewing the agency's existing system for developing and reviewing regulations, to determine where problems and bottlenecks are occurring, and to improve and streamline the process;

D. Achieving timely internal clearances of proposed and final rules, using, where feasible, publicly announced schedules for particular rulemaking proceedings;

E. Managing rulemaking files, so that maximum disclosure to the public is achieved during the comment period and so that a usable and reliable file is available for purposes of judicial review;

F. Making use, where appropriate, of negotiated rulemaking and advisory committees;

[44]See Conference Statement 1 CFR §310.7, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act."

G. Considering innovative methods for reducing the time required to develop final rules without eliminating the opportunity for consideration and comment, (e.g., the use of "direct final" rulemaking to reduce double review of noncontroversial rules);

H. Taking steps to ensure that proposed rules are reviewed periodically and formally withdrawn when no future action is contemplated; and

I. Evaluating and reconsidering existing rules and initiating amendments and repeals where appropriate.

JONES DAY

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TO: ACUS COUNCIL MEMBERS

FROM: Ernest Gellhorn EG

DATE: November 12, 1993

The attached Recommendation of the Rulemaking Committee of the Administrative Conference of the United States will be considered at the Council Meeting on November 18 at 10:30 a.m.

It has been substantially revised since the recommendation considered at the last plenary session.

Thank you for your consideration.

Attachment

November 12, 1993

Committee on Rulemaking

Draft Recommendation

Improving the Environment for Agency Rulemaking

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. The APA's cumbersome "formal rulemaking" procedures are rarely used except in some adjudicative-type rate proceedings. Meanwhile, the APA's simple "informal rulemaking" procedures (set forth in §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.[1] As a result, many federal agencies, faced with unsatisfactory rulemaking accomplishments in recent years, have turned to alternatives such as less formal policy statements or adjudicative orders to achieve regulatory compliance.[2]

The Conference believes that the environment for agency legislative rulemaking can be improved. This recommendation sets out a coordinated framework of proposals aimed at promoting efficient and effective rulemaking by addressing constraints on the current process that derive from a variety of sources. We present an integrated approach for improving the rulemaking environment in order to relieve agencies of unnecessary pressures and disincentives relating to rulemaking. We also identify desirable revisions to section 553 relating to legislative rulemaking. In doing so, this recommendation both presents new proposals and incorporates previous Conference recommendations.

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[1] See generally McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L. J. 1385 (1991).

[2] See ACUS Recommendation 92-2, "Agency Policy Statements," which distinguished "legislative" rules, normally promulgated through notice-and-comment procedures, from interpretive rules and policy statements, which are exempt from such procedures. The present recommendation addresses legislative rulemaking.

Presidential Constraints

We continue to support Presidential coordination of agency policymaking as beneficial and necessary.[3] We are concerned, however, that, unless properly focused, this additional review may impose unnecessary costs. All recent Presidents have undertaken some level of review and coordination of agency rulemaking. Presidential review of rules, as undertaken under various executive orders applied by OMB and other White House entities, has often required agencies to submit nearly all proposed and final rules to a review process in which the rules are screened and analyzed for consistency with Presidential objectives. Some of these objectives have been incorporated into analytical requirements found in separate executive orders.[4] This screening process can unduly slow the entire system of rulemaking; it can inhibit the growth of the promising consensus-based alternative of negotiated rulemaking;[5] and it can create undesirable tensions between the reviewing entities and agency policymakers. While these analytical emphases can be rationalized individually, in the aggregate, they can result in redundant requirements, boilerplate-laden documents, circumvention, delays, and clutter in the *Federal Register*. Although specific presidential review policies have varied among Administrations, these recommendations set forth principles that the Conference believes generally should govern presidential review of rules.

We therefore recommend that Presidential oversight and review be reserved for the most significant rules and that the agencies be given clear policy guidance in a directive, approved by the President, specifying what is required. In addition, the reviewing or oversight entity should avoid, to the extent possible, extensive delays in the rulemaking process. The review process itself also should be open to public scrutiny--following guidelines previously developed by the Administrative Conference.[6] The President's policy should encourage planning and coordination of regulatory

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[3]See ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking" (applying Presidential oversight to both executive branch and independent agencies).

[4]Among the mandates reflected in these executive orders are requirements that agency rulemakers include cost-benefit estimates and analyses of the proposed and final rule's impact on federalism, family values, and future litigation, of whether it effects a "regulatory taking," and of other matters. The Conference of course takes no position on the merits of the values underlying these executive orders.

[5]See ACUS Recommendations 82-4 and 85-5, "Procedures for Negotiating Proposed Regulations;" Negotiated Rulemaking Act of 1990, 5 U.S.C. §§561-69.

[6]See ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking," at ¶ 4.

initiatives, and early dialogue between agencies and the reviewing entity. To this end, the concept of a unified agenda of regulations is a useful tool and should be preserved. We also believe that the number of extra-APA analytical requirements should be kept to a minimum. The cumulative impact of such requirements on the rulemaking process should be considered before existing requirements are continued or additional ones imposed. We also believe it is useful to periodically reassess the continued viability and relevance of the various Presidential directives.[7]

Legislative Constraints

Congress should similarly review and rationalize legislatively-mandated rulemaking procedures. Specifically, we recommend that it refrain, as it generally has done since the 1970s, from imposing program-specific rulemaking requirements that go beyond the APA's basic notice-and-comment procedures.[8] Statutory "on-the-record" and "hybrid" rulemaking provisions that require adjudicative fact-finding techniques such as cross-examination, or more stringent provisions for judicial review (in particular, use of the "substantial evidence" test instead of the normal "arbitrary and capricious" test), can be unnecessarily burdensome or confusing and should be repealed.[9] Although additional procedures can sometimes be beneficial--see, e.g., §307 of the Clean Air Act[10] (providing additional safeguards for rulemaking with significant economic and competitive effects), they should be imposed only after careful review and attention by Congress to possible unintended consequences. Otherwise, such additions generally should be left to the discretion of individual agencies.[11]

Similarly, legislatively-imposed time limits on rulemaking, while understandable, can be unrealistic, resulting in either hastily-imposed rules or missed deadlines that undermine respect for the

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[7]While the most recent executive order of presidential review of rules generally reflects the views set forth in this recommendation, see Executive Order 12866, 58 Fed. Reg. 51735 (1993), the Conference takes no position on the specifics of that order.

[8]See ACUS Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity to Comment in Informal Rulemaking."

[9]See ACUS Recommendation 80-1, "Trade Regulation Rulemaking Under the Magnuson-Moss Warranty - Federal Trade Commission Improvement Act."

[10]42 U.S.C. §7607.

[11]See ACUS Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking."

rulemaking process.[12] Legislative deadlines backed by statutory or regulatory "hammers" (mandating, for example, that the *proposed* rule or some other policy change[13] automatically take effect upon expiration of the deadline) are particularly undesirable and often counter-productive;[14] they are generally less desirable than the alternative of judicial enforcement of deadlines. Finally, legislation ancillary to the APA that creates additional rulemaking impediments should be reconsidered. Statutes such as the Regulatory Flexibility Act, which requires a special analysis of virtually all rules' effects on small business, may have laudable intentions, but their requirements are often both too broadly applicable and not sufficiently effective in achieving their goals. If such requirements are imposed, Congress should focus them more narrowly, by, for example, confining their application to significant rules or particular categories of rules.

Judicial Constraints

Other constraints on rulemaking that warrant similar reconsideration have been imposed through judicial review. The APA, in section 706, provides that agency rules may be set aside if they are "arbitrary or capricious," represent an "abuse of discretion," or are "otherwise not in accordance with law." The evolving scope of judicial review of agency rules, along with the timing of much such review at the preenforcement stage, have contributed to what is sometimes an overly intrusive inquiry. This, in turn, has led agencies to take defensive measures against such review. While some tension is an inevitable adjunct of the process of judicial review, we believe that steps can be taken to lessen some of the burdens without loss of effective outside scrutiny of agency rules.

The tendency of some courts to require extra-APA procedures in rulemaking was arrested by the Supreme Court's *Vermont Yankee* decision in 1978.[15] Nevertheless, while the prevailing judicial interpretation of the arbitrary-and-capricious standard of review (which became known as the "hard look doctrine") has promoted reasoned decisionmaking, courts have not infrequently remanded rules on

[12] See ACUS Recommendation 78-3, "Time Limits on Agency Action."

[13] See, e.g., ACUS Recommendation 90-8, "Rulemaking and Policymaking in the Medicaid Program."

[14] Where the "hammer" applied because of a failure to meet a deadline is that a proposed rule becomes effective, the anomalous result is that a policy that has withstood no public airing will be implemented.

[15] Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519 (1978).

the basis of agency failure to respond adequately to comments, consider relevant factors, or explain fully the bases for its rule. Courts should be sensitive not to require greater justification for rules than necessary; a reasoned statement that explains the basis and purpose of the rule and addresses significant issues raised in public comments should be adequate.

Preenforcement review, expanded by the Supreme Court in the 1967 *Abbott Laboratories* cases,[16] applauded by the Administrative Conference in various recommendations,[17] and codified in numerous rulemaking programs, has the virtue of settling legal issues early and definitively. When overused, however, it can have the negative effect of inducing affected interests to mount precautionary challenges to most rules and to raise as many objections to a rule as possible, including somewhat speculative challenges pertaining to the rule's potential application.

Under the *Abbott Laboratories* standard, challenges to a rule are permitted where issues are appropriate for judicial review and where the impact on a challenger is direct and immediate. The Conference believes that the *Abbott Laboratories* standard strikes a sensible balance, and that preenforcement challenges generally are appropriate where the administrative record provides a sufficient basis for the court to resolve the issues before it. Thus, a preenforcement challenge to a rule based on the procedures used in the rulemaking should normally be permitted. Preenforcement review that involves a facial challenge to a rule's substantive validity (whether because of a conflict with a statute or the Constitution, or because of the inadequacy of the facts or reasoning on which it is based,) should also generally be heard.[18] In contrast, challenges to a rule because it might be applied in a particular way should normally be deferred until the rule has actually been applied.

Although prompt resolution of legal issues is to be encouraged, Congress should be cautious in coupling *mandated* time limited preenforcement review with preclusion of review at the enforcement stage. Such time-limited review should be provided for only in the situations and conditions specified

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16 Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967).

17 See ACUS Recommendation 74-4, "Preenforcement Judicial Review of Rules of General Applicability;" ACUS Recommendation 91-5, "Facilitating the Use of Rulemaking by the National Labor Relations Board."

18 A challenge based on the facial invalidity of the rule, in this context, would normally be directed at a requirement or course of action to which the agency has clearly committed itself.

in Recommendation 82-7.[19] Where Congress does set time limits for preenforcement review, it should, in the interests of procedural consistency, generally specify that preenforcement review should occur within 90 days of a rule's issuance. In the past, the statutory specifications have varied. There does not seem to be any reason for variation that outweighs the benefits of uniformity in this context.

Congress should also amend any existing statutes that mandate use of the "substantial evidence" test for reviewing legislative rules, by replacing it with the "arbitrary and capricious" test. The occasional introduction of the substantial evidence test in the rulemaking context has created unnecessary confusion; some courts apply it in a manner identical to that of the "arbitrary and capricious" test, others believe that it sets a higher standard. The Conference believes that the arbitrary and capricious test provides sufficient review in the informal rulemaking context.

The intensity of judicial review directly affects the rulemaking process. For example, the scope of review of agency *statutory* interpretations is governed by the deferential *Chevron* test, which requires affirmance if the agency's interpretation of an ambiguous statute is permissible.[20] On the other hand, when reviewing the reasonableness of an agency's *policy and factual* justifications for its rules, courts apply the stricter "hard look" doctrine.[21] Deferential review of the legal issue of statutory interpretation, coupled with the rigorous review of a rule's factual and policy underpinnings that the "hard look" doctrine specifies, has been criticized as anomalous. The Conference believes, however, that the review standards can be harmonized by looking beyond the labels. That is, under both of these doctrines, courts are required to determine independently the limits of the agency's statutory authority and whether the factors the agency took into account in formulating the rule were permissible. Following that determination, courts properly defer to an agency's permissible reading of its statute and to its choice of inferences from the facts in making policy decisions. Courts would help make their review more consistent and predictable if they articulated more clearly this two-step

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[19] Recommendation 82-7, "Judicial Review of Rules in Enforcement Proceedings," sets out criteria for when judicial review should be limited at the enforcement stage, and what kinds of issues should remain reviewable at that stage.

[20] Chevron USA Inc. v. NRDC, 467 U.S. 837 (1984).

[21] Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983) (State Farm).

approach. Both *the Chevron* and "hard look" doctrines would then be understood as including a searching review of the range of an agency's legally permissible choices (statutory, policy, and factual), combined with, in each instance, deference to the agency's reasonable selection among such choices, once the alternatives are determined to be within the permissible range.

Finally, in order to prevent additional litigation, courts should be encouraged to address certain issues that arise in many (if not most) reviews of rules. Reviewing courts should, for example, specify, to the extent feasible, which portions of the rule (if any) are to be set aside, vacated, stayed or otherwise affected by the decision in the case. They should seek to ensure that portions of a rule unaffected by a finding of illegality remain in effect, unless the rule expressly or impliedly indicates that the rule is inseverable. A reviewing court should also consider the extent to which its mandate will apply retroactively. In considering the effect to be given to its decision, the court should weigh the impact of the decision on parties not before the court, and recognize their interest in being heard or adequately represented prior to any ruling that adversely affects them.

Amendment of the APA

As we approach the fiftieth anniversary of the APA, its rulemaking provisions need to be updated. Section 553(c), which does not now specify a length of time for the comment period, should be amended to specify that a comment period of "at least 30 days" be provided (although the good cause exception for shorter periods should be retained). Agencies would still be encouraged to allow longer comment periods and to leave the record open for the receipt of late comments.[22] A provision requiring maintenance of a public rulemaking file should be incorporated into section 553, so that those who seek access to the file are not forced to rely on the Freedom of Information Act to obtain it.[23] The file should contain notices of the rulemaking, all written comments submitted to the agency, and copies or an index of all written[24] factual material, studies, or reports substantially relied on or

[22] See ACUS Statement #7, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act," 1 CFR §310.7 (para. 2).

[23] *Id.*, para. 4.

[24] "Written" includes documents in electronic form. See ACUS Recommendation 88-10, "Federal Agency Use of Computers in Acquiring and Releasing Information."

seriously considered by the agency in formulating its proposed and final rule (unless the material is by law exempt from disclosure). Materials substantially relied on or seriously considered need not encompass every study, report, or other document that the agency may have in its files or has otherwise used, but they should include those that exerted a significant impact on the agency's thinking, even if they represent an approach that the agency ultimately did not accept.

In addition, the requirement in section 553(c) of a statement of basis and purpose for the rule should be rewritten to require a "reasoned statement" (deleting the "conciseness" provision), which includes a response to all significant issues raised in the public comments.[25] These changes essentially would codify the salutary aspects of the caselaw on rulemaking, discourage insubstantial arguments and objections on review, and stem the tendency to require additional, more burdensome justifications.

Another long-overdue change in the Act is elimination of section 553(a)(2)'s exemption from notice-and-comment procedures for matters relating to "public property, loans, grants, benefits, or contracts." As the Conference recognized as early as 1969, this "proprietary exemption" is an anachronism.[26] The similar exemption for "military or foreign affairs function[s]" in section 553(a)(1) should be narrowed so that all but truly secret aspects of those functions are open to public comment.[27]

Internal Agency Management Initiatives

Rulemaking is not just a product of external constants. The agency's own processes for developing rules and reviewing them internally affect the rulemaking environment. Thus, agency management initiatives can have a significant impact on the effectiveness and efficiency of rulemaking. The Conference recommends a number of steps agency managers can take to improve their internal processes.

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[25] ACUS Statement #7, para 5.

[26] See ACUS Recommendation 69-8, "Elimination of Certain Exemptions From the APA Rulemaking Requirements."

[27] See ACUS Recommendation 73-5, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements."

Senior agency staff should develop management strategies to set priorities and track agency rulemaking initiatives.[28] Agencies should also seek to involve the presidential oversight entity in the rulemaking process as early as feasible, in order to reach agreement on the significance of rules in the developmental stage, to provide greater coordination, and to speed final oversight review. They should also seek to achieve more rapid internal clearances of proposed and final rules, to develop reasoned analyses[29] and responses to significant issues raised in public comments, and to manage the rulemaking file (and associated requests for access to it).[30] As part of this effort, agencies should review their existing systems for developing and reviewing regulations, to determine where problems and bottlenecks are occurring.

Agencies should also consider innovative methods for developing and getting public input on rules. Agencies should use advisory or negotiated rulemaking committees where appropriate to improve the quality and acceptability of rules.[31] They should also consider the use of "direct final" rulemaking where appropriate to eliminate double review of noncontroversial rules. Direct final rulemaking involves issuing a rule for notice and comment, with an accompanying explanation that if the agency receives no notice during the comment period that any person intends to file an adverse comment, the rule will become effective 30 days (or some longer period) after the comment period closes.

* * *

We recognize that Congress will continue to delegate to federal agencies significant rulemaking responsibilities. However, it, along with the President and the courts, should carefully limit procedural demands on agency rulemakers to those necessary for open, reasoned rulemaking. The costs of any additional procedures that are imposed in response to particular problems should be

[28] See ACUS Recommendation 87-1, "Priority Setting and Management of Rulemaking by the Occupational Safety and Health Administration."

[29] See ACUS Recommendation 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules; ACUS Recommendation 88-7, "Valuation of Human Life in Regulatory Decisionmaking."

[30] Computerized access should be made available, preferably in a uniform system government-wide. See ACUS Recommendation 88-10, "Federal Agency Use of Computers in Acquiring and Releasing Information."

[31] Any government-wide policy concerning the use of advisory committees should be consistent with their use as part of the process of negotiated rulemaking.

assessed to ensure that they do not exceed likely benefits in improved rationality or fairness. Further, to facilitate this reform, the APA's rulemaking provisions should be updated and agencies should implement managerial reforms designed to make policymaking through rulemaking more effective and more efficient.

RECOMMENDATIONS

To improve the environment for agency legislative rulemaking, the President, Congress, and the courts should take steps to eliminate undue burdens on agency legislative rulemaking; Congress should update the Administrative Procedure Act's rulemaking provisions; and agencies should review their internal rulemaking environment and, where appropriate, implement internal management initiatives aimed at improving the effectiveness and efficiency of their efforts.

I. Presidential Oversight[32]

A. The President's program for coordination and review of agency rules should be set forth in a directive that is reviewed periodically. The program should be sensitive to the burdens being imposed on the rulemaking process, and implementation of the program should ensure that it does not unduly delay or constrain rulemaking. The President should consider the cumulative impact of existing analytical requirements on the rulemaking process before continuing these requirements or imposing new ones.[33]

B. The President's directive, as well as the explanations provided and the procedures followed by the presidential oversight entity should, insofar as practicable:

1. Promote dialogue and coordination between the oversight entity and rulemaking agencies in the early identification and selection of rules warranting application of the review process;

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[32] The recommendations contained in this section apply to oversight of both executive and independent agencies. The Conference has previously recommended that presidential review of rulemaking apply to the independent agencies to the same extent it applies to the rulemaking of the Executive Branch departments and agencies. See ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking."

The term "presidential oversight entity," as used herein, is that part of the Executive Office of the President delegated responsibility for review and oversight of agency rulemaking.

[33] In recommending review of analytical requirements beyond those contained in the APA, we express no position on the substantive policies being mandated.

2. Set forth the relevant analytical requirements that the oversight entity should apply to agency rulemaking, and provide interpretive guidance to assist agencies in complying with these requirements;

3. Ensure appropriate expedition and openness in the process, in accordance with ACUS Recommendation 88-9;

4. Support a process for planning regulatory initiatives and tracking rule development; and

5. Encourage and support agency efforts to use consensual processes such as negotiated rulemaking.

II. Limiting Congressionally-Imposed Burdens

A. Congress should not require formal ("on-the-record") or other adjudicative fact-finding procedures in rulemaking, and should consider repeal of any existing statutes mandating such procedures.[34] Congress generally should refrain from creating program-specific rulemaking procedures or analytical requirements beyond those required by the APA. When Congress determines that additional procedures beyond those required by section 553 are justified by the nature of a particular program, such procedures should be focused on identified problems and, where possible, adopted incrementally or after experimentation.[35]

B. In general, Congress should not legislate time limits on rulemaking, but should instead rely on judicial enforcement of prompt agency action under §706(1) of the APA.[36] However, if Congress determines that a deadline is appropriate, it also should ensure that the agency has sufficient resources to support the required rulemaking effort without distorting the agency's other regulatory functions. If Congress further determines that a default rule is necessary where an agency does not meet a deadline, it should specify the terms of that rule and, in particular, should not impose "regulatory hammers" that would cause the agency's *proposed* rules to take effect automatically.

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[34]ACUS has recommended against the mandated use of cross-examination and other "adjudicative" procedures for agency fact-finding in rulemaking. See, e.g., ACUS Recommendation 79-1, "Hybrid Rulemaking Procedures of the Federal Trade Commission." The Conference recognizes, however, that more formal procedures may be appropriate for ratemaking based on party-related facts. See United States v. Florida East Coast RR, 410 U.S. 224 (1973). Congress may also wish to consider whether less formal hybrid processes may be useful in contexts currently requiring formal rulemaking.

[35]See, for example, the development of more specific, but not necessarily more burdensome, procedures for EPA rulemaking that has significant economic and competitive effects. See 42 U.S.C. § 7607 (§307 of the Clean Air Act). See also ACUS Recommendation 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," which encourages agency experimentation with use of oral procedures beyond simple notice and comment in some circumstances.

[36]This is not a comment on the legitimacy of Congressional directives in this regard, but on their impracticality. On the other hand, agency self-imposed deadlines are encouraged, see V(D), below. For more detailed advice on time limits, see paragraph 5 of ACUS Recommendation 78-3, "Time Limits on Agency Action."

C. Congress should reconsider the need for continuing statutory analytical requirements that necessitate broadly applicable analyses or action to address narrowly-focused issues.[37] If Congress nonetheless determines that such analytical requirements are necessary, Congress should structure its requirements more narrowly (e.g., by confining their application to the most significant rules or to rules likely to be affected by the stated concern).

III. Timing and Scope of Judicial Review

Congress and the courts generally should be sensitive to the impact of judicial review on agency rulemaking and should seek to simplify, clarify, and harmonize provisions for judicial review of rules.

A. Congress and the Courts

In determining whether preenforcement challenges to rules are appropriate, courts have traditionally evaluated "both the fitness of the issues for judicial decision and the hardship to the parties of withholding its consideration."[38] Adherence to this standard benefits both agencies and those affected by agency rules. Congress generally should authorize and courts should allow preenforcement challenges where the administrative record is a sufficient basis for resolving the issues. Thus, preenforcement challenges to a rule based on the procedures used in the rulemaking, or on the asserted substantive invalidity of the rule, however it would be applied, should normally be permitted. The latter would include facial challenges based on statutory or constitutional grounds, or asserting the inadequacy of the facts or reasoning underlying the rule. Challenges to a rule on the basis that the rule might be applied in a particular way should normally be deferred until the application has occurred.

B. Congress

1. Congress should be cautious in mandating time-limited preenforcement review coupled with preclusion of review at the enforcement stage, and should rely on time limits only in the situations and conditions specified in Recommendation 82-7.[39] Congressional time limits on preenforcement review should be understood to bar later challenges in the enforcement context only to the extent specified by Congress. Where Congress mandates a time limit on preenforcement review, it generally should specify that such review be requested within 90

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[37] See, e.g., the Regulatory Flexibility Act of 1980. The Conference takes no position on the substantive issues the Act seeks to address. Insofar as possible, however, such concerns are more appropriately included in the President's oversight guidelines. See I(B)(2) above.

[38] Abbott Laboratories v. Gardner, supra n. 16, 387 U.S. at 149.

[39] See ACUS Recommendation 82-7, "Judicial Review of Rules in Enforcement Proceedings."

days of the issuance of the rule.[40] It should also provide that preenforcement review cases be directly reviewable in the courts of appeals, and that a stay or partial stay of the rule's effectiveness ordinarily be issued only on the demonstration of likelihood of success and the prospect of significant private harm if the rule is permitted to take effect.

2. The standards set out in §706(2)(A) of the APA's judicial review provisions should apply in all cases involving review of rules. Specifically, Congress should not provide for the use of the "substantial evidence" test for agency rules. It should conform existing statutes to this standard by deleting the use of the "substantial evidence" test for review of agency rules.

C. Courts

1. In articulating the doctrines used in the judicial review of rulemaking, reviewing courts should more clearly harmonize the deferential *Chevron* doctrine, applied in reviewing agency interpretation of its statutory authority, with the "hard look" doctrine, used in examining an agency's justification for its rule. Courts, in applying these doctrines, should recognize that both the *Chevron* and "hard look" tests call for a similarly searching review of the range of factors or permissible choices that may be considered by the agency, and require a consistent degree of deference to agency application of those factors once they are shown to be legally appropriate.

2. When reviewing an agency's explanation for its rule, courts should consider the context of the entire proceeding and concern themselves principally with whether the agency's overall explanation and analysis is reasonable, including its response to the significant issues raised in public comments.

3. In reviewing challenges to agency rules, courts should, to the extent feasible and after taking into account the effect of the decision on affected persons not before the court, consider: (a) whether any portion of a rule unaffected by a finding of illegality should remain in full force and effect; (b) which portions of the challenged rule (if any) are to be set aside, vacated, stayed, or otherwise affected by the court's decision in a case; and (c) the extent to which the court's mandate should apply retroactively.

[40] Congress should likewise reevaluate existing statutes for conformity with this approach.

IV. Amendments to the APA's Legislative Rulemaking Provisions

Congress should update the APA and eliminate outmoded provisions. It should codify court decisions that have increased the effectiveness of public participation in the rulemaking process. In particular, Congress should amend section 553 of the APA to:

A. Eliminate the exemption (§553(a)(2)) for rules relating to public property, loans, grants, benefits or contracts, and delete the similar exemption (§553(a)(1)) of military and foreign affairs matters, except for secret matters;[41]

B. Specify a comment period of "at least 30 days" (§553(c)), provided that a good cause provision allowing shorter comment periods or no comment period is retained, and codify the doctrine holding that a second round of notice and comment is not required if the final rule is a "logical outgrowth" of the noticed proposed rule;[42]

C. Require establishment of a public rulemaking file beginning no later than the date on which an agency publishes an advanced notice of proposed rulemaking or notice of proposed rulemaking, whichever is earlier. The rulemaking file should include (1) all notices pertaining to the rulemaking, (2) copies or an index of all written factual material, studies, and reports substantially relied on or seriously considered by agency personnel in formulating the proposed or final rule (unless the material is by law exempt from disclosure), (3) all written comments submitted to the agency, and (4) any other material required by statute or agency rule to be made public in connection with the rulemaking;[43]

D. Restate the "concise" statement of basis and purpose requirement (§553(c)) by providing instead that a rule must be supported by a "reasoned statement," and that such statement respond to the significant issues raised in public comments.

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[41] See ACUS Recommendation 69-8, "Elimination of Certain Exemptions From the APA Rulemaking Requirements" and ACUS Recommendation 73-5, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements." The latter recommendation urged eliminating the APA's categorical exemption for matters pertaining to the military or foreign affairs function. It does recognize, however, that a modified exemption may be appropriate for matters "specifically required by executive order to be kept secret in the interest of national defense or foreign policy."

[42] See South Terminal Corp. v. EPA, 504 F.2d 646, 659 (1st Cir. 1974), in which the 1st Circuit originated the "logical outgrowth" test. It was subsequently embraced by other circuits, particularly the D.C. Circuit. See Shell Oil Co. v. EPA, 950 F.2d 741 (D.C. Cir. 1991); International Union, United Auto, Aerospace and Agr. Implement Workers of America v. OSHA, 938 F.2d 1310 (D.C.Cir. 1991); American Medical Association, 887 F.2d 760 (7th Cir. 1989); NRDC v. USEPA, 824 F.2d 1258 (1st Cir. 1987); United Steelworkers v. Schuylkill Metal Corp., 828 F.2d 314 (5th Cir. 1987); National Black Media Coalition v. FCC, 791 F.2d 1016 (2nd Cir. 1986); Chocolate Mfrs. Ass'n v. Block, 755 F.2d 1098 (4th Cir. 1985).

[43] See ACUS Statement 1 C.F.R. §310.7, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act."

V. Agency Management Initiatives

In order to improve their internal rulemaking environments, agencies should develop management techniques to ensure efficient and effective administration of rulemaking. Such techniques should include:

A. Systematically setting priorities at the highest agency levels and tracking rulemaking initiatives, including identifying clearly who has the authority to ensure that agency schedules and policies are followed;

B. Coordinating with the presidential oversight entity on the identification of rules warranting review as early in the process as is feasible, and establishing internal review procedures at the highest levels to ensure compliance with presidential analytical requirements;

C. Reviewing the agency's existing system for developing and reviewing regulations, to determine where problems and bottlenecks are occurring, and to improve and streamline the process;

D. Achieving timely internal clearances of proposed and final rules, using, where feasible, publicly announced schedules for particular rulemaking proceedings;

E. Managing rulemaking files, so that maximum disclosure to the public is achieved during the comment period and so that a usable and reliable file is available for purposes of judicial review;

F. Making use, where appropriate, of negotiated rulemaking and advisory committees;

G. Considering innovative methods for reducing the time required to develop final rules without eliminating the opportunity for consideration and comment, (e.g., the use of "direct final" rulemaking to reduce double review of noncontroversial rules);

H. Taking steps to ensure that proposed rules are reviewed periodically and formally withdrawn when no future action is contemplated; and

I. Evaluating and reconsidering existing rules and initiating amendments and repeals where appropriate.

FY-1995 BUDGET HISTORY & PLANNING ASSUMPTIONS

REVISION DATE 11/17/93 11:42:32	ACTUAL FY 1993	CURRENT FY 1994	COUNCIL AUG 93 FY 1994	A11 FY 1995	COUNCIL FEB 93 FY-95	COUNCIL AUG 93 FY 1995
PERSONNEL COMPENSATION	$1,620,346.00	$1,371,014.94	$1,702,326.54	$1,432,979.41	$1,851,873.73	$1,790,814.08
11.1 FULL-TIME PERMANENT	$1,218,647.00	$1,030,975.77	$1,333,385.00	$1,217,138.51	$1,455,615.00	$1,393,689.00
11.3 OTHER THAN FULL-TIM	$92,556.00	$56,015.00	$53,749.00	$58,927.78	$77,052.00	$59,579.00
11.5 OTHER PERS. COMP. (AW	$28,000.00	$46,079.43	$19,733.00	$28,000.00	$28,000.00	$28,000.00
11.8 SPEC.PERS.SERVICES PM	S.(DETAILS)			$42,000.00		
11.9 TOTAL PERSONNEL CO	$1,339,203.00	$1,133,070.20	$1,406,867.00	$1,346,066.29	$1,560,667.00	$1,481,268.00
PERSONNEL BENEFITS						
12.1 CIVILIAN PERSONNEL BE	$281,143.00	$237,944.74	$295,459.54	$271,802.12	$291,206.73	$309,546.08
21.0 TRAVEL OF PERSONS	$51,008.25	$40,000.00	$71,500.00	$71,000.00	$86,500.00	$71,000.00
ACUS STAFF	$6,274.00	$5,000.00	$5,000.00	$3,000.00	$9,500.00	$3,000.00
COUNCIL	$2,923.00	$3,000.00	$3,000.00	$3,000.00	$5,000.00	$3,000.00
ASSEMBLY	$9,786.00	$12,000.00	$21,000.00	$22,000.00	$24,000.00	$22,000.00
PLENARY	$8,251.00	$20,000.00	$20,000.00	$20,000.00	$24,000.00	$20,000.00
RESEARCH	$23,774.25	$0.00	$22,500.00	$23,000.00	$24,000.00	$23,000.00
RENT, COMMUNICATIONS, &	$281,990.60	$271,145.00	$287,745.00	$238,709.00	$289,264.00	$301,159.00
23.1 RENTAL PMTS TO GSA (S	$222,750.00	$228,303.00	$228,303.00	$194,060.00	$228,203.00	$236,060.00
23.2 RENTAL PMTS TO OTHE	$12,960.00	$1,800.00	$12,900.00	$4,000.00	$12,769.00	$12,900.00
STORAGE	$2,160.00	$0.00	$2,100.00	$2,100.00	$1,311.00	$2,100.00
PARKING	$10,800.00	$1,800.00	$10,800.00	$1,900.00	$11,458.00	$10,800.00
XEROX						
23.3 COMMUNICATIONS	$46,280.60	$41,042.00	$46,542.00	$40,649.00	$48,292.00	$52,199.00
TELEPHONE:	$12,664.60	$13,478.00	$16,078.00	$12,500.00	$16,597.00	$16,739.00
GSA:						
1. LOCAL	$7,267.60	$7,358.00	$7,358.00	$7,500.00	$7,358.00	$7,500.00
2. FTS2000	$2,198.00	$5,120.00	$5,120.00	$4,000.00	$5,386.00	$5,386.00
C&P (LONG DISTANCE)	$3,199.00	$1,000.00	$3,600.00	$1,000.00	$3,853.00	$3,853.00
POSTAGE	$29,970.00	$26,364.00	$27,964.00	$26,949.00	$26,822.00	$31,460.00
1. REGULAR	$15,935.00	$16,343.00	$16,343.00	$16,343.00	$9,204.00	$18,500.00
2. EXPRESS	$1,383.00	$200.00	$1,800.00	$500.00	$2,845.00	$2,845.00
3. NEWSLETTER	$12,332.00	$9,490.00	$9,490.00	$9,775.00	$14,442.00	$9,775.00
4. INTERNATIONAL	$52.00	$55.00	$55.00	$55.00	$55.00	$55.00
5. FEES	$268.00	$276.00	$276.00	$276.00	$276.00	$285.00
MESSENGER $4,488.89	$3,646.00	$1,200.00	$2,500.00	$1,200.00	$4,873.00	$4,000.00
24.0 PRINTING AND REPRODU	$55,318.00	$23,103.57	$55,873.00	$42,037.00	$93,945.00	$65,337.00

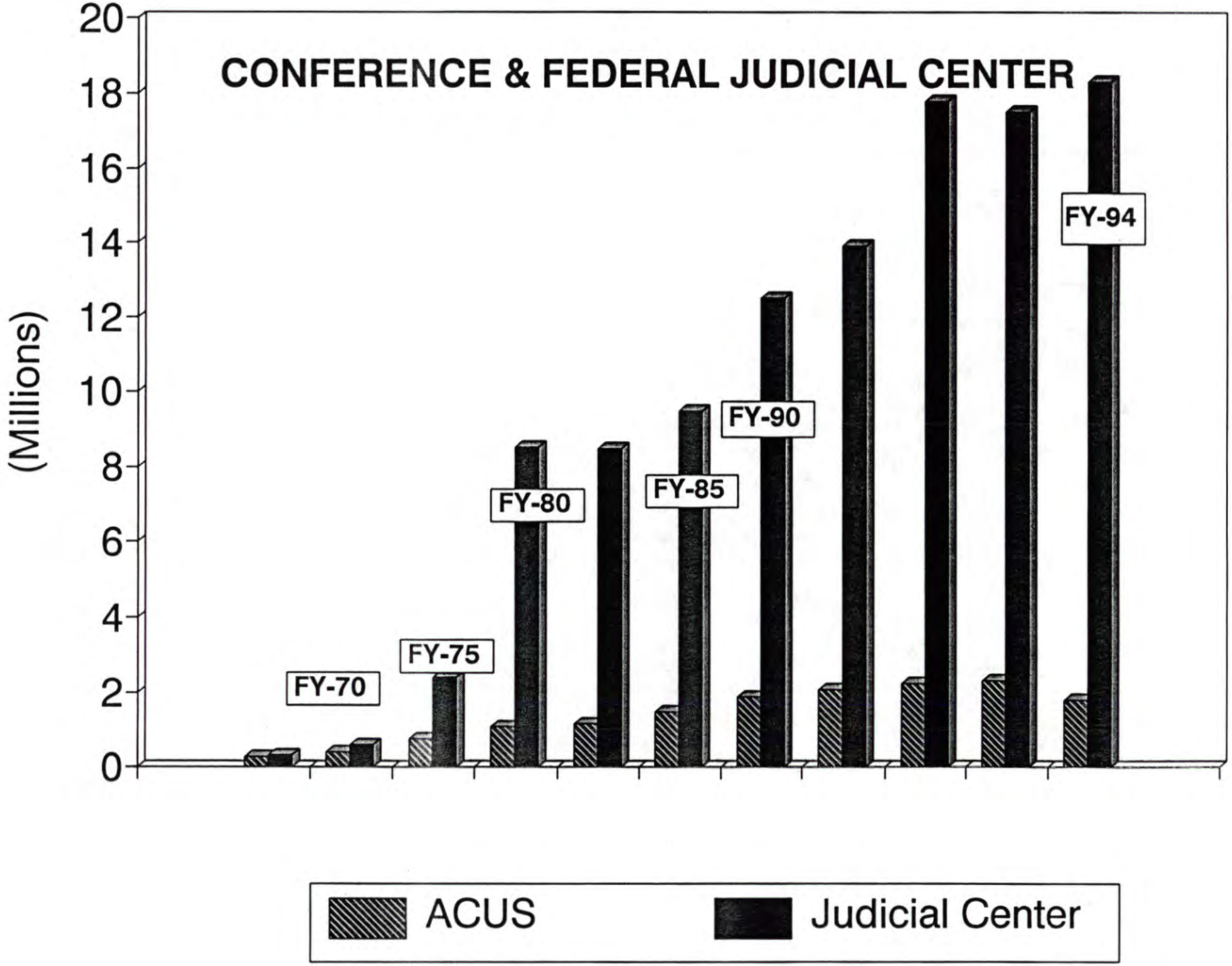
FY-1995 BUDGET HISTORY & PLANNING ASSUMPTIONS

REVISION DATE 11/17/93 11:42:32	ACTUAL FY 1993	CURRENT FY 1994	COUNCIL AUG 93 FY 1994	A11 FY 1995	COUNCIL FEB 93 FY-95	COUNCIL AUG 93 FY 1995
RECOMMENDATIONS & REP	$9,000.00	$6,000.00	$8,240.00	$8,240.00	$8,603.00	$8,240.00
ANNUAL REPORT	$3,101.00	$2,400.00	$3,195.00	$2,500.00	$3,797.00	$3,600.00
CODE FED REGS	$19,195.00	$3,203.57	$20,000.00	$15,000.00	$20,169.00	$20,000.00
FED REGISTER	$8,538.00	$10,000.00	$15,000.00	$9,000.00	$15,914.00	$15,000.00
CLRGHSE PUBS	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
NEWSLETTERS	$5,999.00	$0.00	$5,628.00	$5,797.00	$5,432.00	$5,797.00
1. NO.OF ISSUES						
2. NO. OF COPIES						
3. DISTRIBUTION NO.						
4. POSTAGE CHG. $9,874.0	$0.00					
OTHER PUBLICATIONS:						
1. Admin. Proce. Sourcebook					$25,809.00	
2. ALJ MANUAL	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
OTHER PRINTING (MISC.)	$6,664.00	$1,000.00	$1,640.00	$1,000.00	$10,670.00	$9,500.00
PHOTOGRAPHY	$2,821.00	$500.00	$2,170.00	$500.00	$3,551.00	$3,200.00
25.0 OTHER SERVICES	$150,508.40	$51,062.00	$104,480.00	$110,399.00	$171,119.00	$119,974.00
REPAIRS	$16,401.40	$16,028.00	$17,182.00	$16,443.00	$15,960.00	$17,468.00
1. ESI (COMPUTERS)	$8,592.00	$8,592.00	$8,820.00	$8,820.00	$8,422.00	$8,820.00
2. KODAK "	$1,215.00	$1,215.00	$1,116.00	$1,215.00	$1,194.00	$1,215.00
3. AT&T (TELEPHONES)	$0.00	$0.00	$100.00	$0.00	$160.00	$100.00
4. Typwr & Other	$892.00	$0.00	$925.00	$0.00	$186.00	$925.00
5. Xerox	$5,702.40	$6,221.00	$6,221.00	$6,408.00	$5,998.00	$6,408.00
INTERAGENCY	$33,524.00	$32,434.00	$33,109.00	$32,690.00	$26,469.00	$34,040.00
1. HEALTH UNIT	$3,456.00	$100.00	$2,375.00	$100.00	$2,239.00	$2,450.00
2. GSA ADMIN. SUPPORT	$20,000.00	$22,200.00	$20,600.00	$22,220.00	$17,294.00	$21,220.00
3. GSA IG AUDIT	$7,655.00	$7,690.00	$7,690.00	$7,920.00	$4,504.00	$7,920.00
4. OPM (PRINTING)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
5. TREASURY (AUTO REPO	$2,413.00	$2,444.00	$2,444.00	$2,450.00	$2,432.00	$2,450.00
SUPPORT CONTRACTS	$14,940.00	$1,600.00	$6,600.00	$8,266.00	$24,731.00	$15,466.00
1. TRAINING	$744.00	$0.00	$2,000.00	$1,000.00	$6,316.00	$2,700.00
2. ACCOUNTING	$5,624.00	$0.00	$3,000.00	$3,266.00	$3,200.00	$3,266.00
3. MISC. PURCHASE ORDE	$6,572.00	$1,600.00	$1,600.00	$4,000.00	$12,535.00	$7,500.00
4. COLLOQUYS	$2,000.00	$0.00	$0.00	$0.00	$2,680.00	$2,000.00
RESEARCH CONTRACTS	$85,643.00	$1,000.00	$47,589.00	$53,000.00	$103,959.00	$53,000.00
RES.ASSTS/SEC. $3000	$2,948.00	$1,000.00	$2,589.00	$3,000.00	$3,242.00	$3,000.00
RES. CONSULTANTS	$82,695.00	$0.00	$45,000.00	$50,000.00	$100,717.00	$50,000.00
26.0 SUPPLIES AND MATERIAL	$77,438.75	$44,000.00	$49,750.00	$50,000.00	$75,489.00	$73,704.01

FY-1995 BUDGET HISTORY & PLANNING ASSUMPTIONS

REVISION DATE 11/17/93 11:42:32	ACTUAL FY 1993	CURRENT FY 1994	COUNCIL AUG 93 FY 1994	A11 FY 1995	COUNCIL FEB 93 FY-95	COUNCIL AUG 93 FY 1995
1. OFFICE	$28,323.75	$18,000.00	$21,228.00	$18,000.00	$30,950.00	$29,870.00
2. LIBRARY	$49,115.00	$26,000.00	$28,522.00	$32,000.00	$44,539.00	$43,834.01
A. MEAD DATA (LEXIS)	$7,556.00	$0.00	$2,000.00	$6,000.00	$15,000.00	$12,000.00
B. SUBSCRIPTIONS	$35,935.00	$24,000.00	$24,000.00	$24,000.00		$26,334.01
C. BOOKS	$3,582.00	$1,500.00	$1,500.00	$1,500.00		$3,500.00
D. MISC.	$2,042.00	$500.00	$1,022.00	$500.00		$2,000.00
31.0 EQUIPMENT	$77,390.00	$0.00	$42,582.00	$18,000.00	$45,582.00	$40,000.00
1. COMPUTER	$35,460.00	$0.00	$21,000.00	$18,000.00	$25,000.00	$25,000.00
2. Xerox Lease to Purchase	$39,451.00	$0.00	$20,582.00	$0.00	$20,582.00	$0.00
3. OTHER OFFICE EQUIPME	$2,479.00	$0.00	$1,000.00	$0.00		$15,000.00
TOTALS:	$2,314,000.00	$1,800,325.51	$2,314,256.54	$1,963,124.41	$2,613,772.73	$2,461,988.09
Reimbursable	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
APPROPRIATION	$2,314,000.00	$1,800,000.00	$2,314,000.00	$2,456,000.00	$1,773,000.00	$2,456,000.00
BALANCE	$0.00	($325.51)	($256.54)	$492,875.59	($840,772.73)	($5,988.09)
				$1,908,000.00		
General Administration	$505,958.75	$370,207.00	$441,968.00	$367,108.00	$484,315.00	$482,837.01
Personnel Comp & Benefits	$1,620,346.00	$1,371,014.94	$1,702,326.54	$1,432,979.41	$1,851,873.73	$1,790,814.08
Formal Recommendations	$130,377.25	$36,000.00	$114,089.00	$121,000.00	$180,959.00	$121,000.00
Implementation & Advisory	$38,833.00	$15,603.57	$43,823.00	$32,297.00	$47,992.00	$46,397.00
Clearinghouse	$18,485.00	$7,500.00	$12,050.00	$9,740.00	$48,633.00	$20,940.00
TOTAL	$2,314,000.00	$1,800,325.51	$2,314,256.54	$1,963,124.41	$2,613,772.73	$2,461,988.09

BUDGET GROWTH OVER 25 YEARS



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES
2120 L STREET, N.W., SUITE 500
WASHINGTON, D.C. 20037-1568
(202) 254-7020

November 8, 1993

OFFICE OF
THE CHAIRMAN

The Honorable John D. Podesta
Assistant to the President and
Staff Secretary
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear Mr. Podesta:

Let me take this opportunity to welcome you as a new Council Member of the Administrative Conference. As you probably know, we have been anticipating your appointment by the President for some time. I am glad that we will now have our new Council Members on board in time for the December 9-10 plenary session of the Conference.

Please find enclosed a letter signed by Executive Director William Olmstead, along with materials in preparation for the upcoming Council meeting on November 18.

Again, let me welcome you to the Council, and say how delighted I am to have you with us. I shall look forward to seeing you November 18.

With all best wishes,

Sincerely,

Brian C. Griffin
Brian C. Griffin
Chairman

BCG/dkk

Nov. 18
9:30 - 12:00

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November 8, 1993

OFFICE OF
THE CHAIRMAN

The Honorable John Podesta
Assistant to the President
and Staff Secretary
The White House
1600 Pennsylvania Avenue, NW.
Washington, DC 20500

Dear Mr. Podesta:

The Council will meet Thursday, November 18, 1993 at 9:30 a.m. to set the agenda for the December plenary session (December 9th and 10th). A copy of the tentative agenda is attached. The Council should note that Ernie Gellhorn, Chairman of the Committee on Rulemaking is coming to give the Council a status report on changes the Committee has made to the draft rulemaking recommendation since the debate at the June Plenary.

Enclosed you will find two proposed recommendations and the associated research reports submitted by the Committee on Regulation. Also enclosed is a copy of the proposed bylaw amendment on conflicts of interest sent to the members by the Chairman on November 4. Also included is a memorandum from Walter Dellinger, Assistant Attorney General, to Gary Edles, General Counsel, clarifying the Deparment of Justice's view concerning the applicability of the Emoluments Clause to non-government members.

I look forward to seeing you Thursday, November 18.

Sincerely,

William J. Olmstead

William J. Olmstead
Executive Director

Enclosures

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES
COUNCIL AGENDA

November 18, 1993

9:30	*Swearing in of new Council members*
	John Podesta, Assistant to the President and Staff Secretary; Jack Quinn, Chief of Staff and Counselor to the Vice President; Sally Katzen, Administrator, Office of Information and Regulatory Affairs, OMB.
9:35	*Pesticide registration and cancellation*
	Presenters: John Golden, Chairman of the Committee on Regulation; Prof. Donald Hornstein, research consultant; David Pritzker, Staff Liaison.
10:00	*Use of audited self-regulation*
	Presenters: John Golden, Chairman of the Committee on Regulation; Prof. Douglas Michael, research consultant; David Pritzker, Staff Liaison.
10:30	*The rulemaking process -- has it become overburdened and underused?*
	Presenters: Ernest Gellhorn, Chairman of the Committee on Rulemkaing; Nancy G. Miller, Staff Liaison.
11:15	*Bylaw on Conflict of Interest* Gary Edles, General Counsel
11:30	Chairman's Business
	1. Reauthorization 2. FY-95 budget strategy 2. Reductions in Force, Furloughs (status) 3. Plenary Reception 4. New Member appointments
12:00	Adjourn

ACUS Committee on Regulation -- Working Draft Recommendation -- November 5, 1993

Procedures for Regulation of Pesticides

The Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without change and improvement in the Agency's regulatory procedures. The Conference recommends the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decisionmaking by EPA, and for effective public participation.

The reregistration of existing pesticides under contemporary risk assessment standards, and the removal of unacceptable pesticides from the marketplace, are examples where ~~poor~~ procedures can hinder the agency's prospects for success in its substantive mission. Reregistration of existing pesticides, which Congress originally directed to be completed by 1976, became sufficiently delayed that Congress in 1988 amended FIFRA specifically to force the completion of reregistration by 1998. Yet subsequent delays in the reregistration process may cause EPA to miss this congressional deadline. To some extent, the delay may reflect the underlying difficulty and resource-intensiveness of the risk assessment enterprise with which EPA has been charged. There are some 50,000 pesticide products that are separately formulated from 642 identified active ingredients. Although EPA has tried to expedite its task by focusing reregistration on some 402 "cases" (composed of single or related active ingredients), each case can require evaluation of 100-150 separate studies, every one of which may pose further questions of scientific protocol and interpretation. It may be that EPA's Office of Pesticide Programs needs more personnel to match its regulatory task.

Whatever the case for additional administrative resources (a question not addressed by the Conference), there is a more basic need for timely and adequate data from registrants -- all else in the reregistration process depends on this. Yet the reregistration process does not now provide sufficient procedural incentives to encourage timely and adequate data. In general, because registrants continue to market their products during reregistration, they have little to lose by regulatory decisions that are reached later rather than sooner. Although the 1988 FIFRA Amendments require registrants to identify data gaps, and commit to fill them, the 1988 Amendments do not prohibit registrants from seeking individualized data waivers and time extensions (which can require significant agency resources simply to process), and otherwise give the agency too few tools to police tardy or inadequate data submissions.

As to tardiness, the 1988 Amendments authorized the agency to suspend registrations of those registrants that fail to submit data. But EPA must first provide nonsubmitters with 30-days notice in

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NOTE: THIS WORKING DRAFT RECOMMENDATION HAS BEEN PREPARED BY THE CONSULTANT AND ACUS STAFF FOR APPROVAL BY THE COMMITTEE ON REGULATION; THE COMMITTEE HAS NOT YET APPROVED IT.

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response to which registrants can demand a limited hearing (which must be held within 75 days); the 1988 Amendments further provide that registrants suspended for not submitting data can have their registrations "reinstated" upon submission of the data. Some registrants, ironically, have used these suspension procedures as a means of obtaining penalty-free and self-awarded extensions of time. In the 7 months between August 1991 and February 1992, for example, EPA found it necessary to issue 70 Notices of Intent to Suspend for nonsubmittal of data, yet in the majority of these instances (53) the registrants merely submitted their data prior to exhausting their procedural rights and were no worse off for having missed their deadlines. To create an additional disincentive for untimely data it is necessary to make lateness costly to the registrant. To this end, the Conference recommends that Congress authorize EPA to impose civil money penalties for untimely data.

As to the adequacy of data, EPA may now have the theoretical (but untested in court) capacity to suspend or cancel the registration of those pesticides for which inadequate data have been submitted. However, the more common response to inadequate data is a "data call-in," through which the agency demands that studies be redone -- a source of additional delay that the agency has identified as significant. Even with respect to its highest priority pesticides, EPA has in the recent past found 50 percent of studies to be either inadequate, "upgradable" or otherwise requiring supplementation. Although the cost of redoing studies should provide some incentive for registrants to ensure that their studies meet EPA's quality criteria, it does not seem to provide a sufficient incentive. In fairness to some registrants, there is evidence that EPA itself may be partially (but only partially) to blame for the high rates of data rejection. In 1992, an internal agency review found that misinterpretation of data requirements and poor guidance from EPA case managers were in part responsible for the inadequacy of data submissions. The Conference therefore recommends that EPA promulgate and communicate clear data standards and guidance on the adequacy of data expected from registrants. To help prevent the submission of inadequate data after sufficiently clear agency guidance is given, the Conference recommends that Congress authorize EPA to levy administrative civil money penalties for the submittal of data that fail to meet those standards. This will not only create incentives for registrants to take the extra steps necessary to ensure the adequacy of their submittals, but it will also create incentives for the agency to make clear its expectations.

Whatever the additional tactical advantages that the agency may gain by improving its own ability to enforce data timeliness and adequacy, the sheer number of studies and the innumerable decisions requiring agency discretion suggest that more global incentives are needed to ensure that registrants themselves have a stake in timely and adequate data. The danger is that the reregistration process now has become, even with the best of intentions, an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, submission of data that do not always meet EPA's standards for adequacy, and further data call-ins that restart the sequence. The Conference believes that the unique demands of the reregistration process justify urging Congress to

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consider a "hammer" provision that would legislatively impose an automatic suspension of all List A pesticides (those high-priority pesticides to which there is greatest human exposure) for which there are still data gaps by a date certain, subject to a provision for registrants to petition for reinstatement. Such a provision would not only provide an overarching incentive for registrants to favor the completion rather than postponement of their data obligations, but it would also better align the reregistration process with FIFRA's central procedural presumption -- that, in the face of uncertainty, applicants (especially those seeking to reregister pesticides with extensive human exposure) should bear the burden of proof in establishing that their pesticides do not pose unreasonable risks.

Apart from improvements in the reregistration process, the Conference urges Congress to substitute a relatively informal decisionmaking process for the formal adjudicatory hearings which registrants can now demand in cancellation and suspension matters. Formal hearings under FIFRA in the past have averaged 1,000 days to complete. These hearings can directly impose on EPA significant resource costs and can also indirectly discourage the agency from aggressive pre-hearing negotiations with registrants (lest the registrant "take EPA to hearing"). It is not surprising that EPA has long sought alternatives to cancellation hearings. For years, it sought to identify problem pesticides for heightened regulatory attention in a "Special Review" process. There is little need for procedural formality in these types of decisions. At issue in most cancellation and suspension proceedings are scientific data on risks and benefits, disputes over which can generally be well-ventilated when EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. Although there may be exceptional cases where oral testimony or cross-examination is justified, the benefits of more formal procedures can be preserved by providing registrants an opportunity to show cause why such procedures are warranted in an individual case. Accordingly, the Conference recommends that Congress pattern cancellation and suspension proceedings on a basic notice-and-comment rulemaking model, with more formal procedures available only upon a showing that such procedures are likely to improve significantly the accuracy of agency decisionmaking.

Although the reregistration process and adjudicatory hearings are the most visible aspects of pesticide regulation in need of procedural improvement, they are not the only places where procedural reform is important. Since the late 1980's, EPA has in fact sought to reduce the risks of pesticides through private negotiations with registrants over label changes that impose restrictions on use. Such regulatory action has the potential to attain interim risk-reduction quickly when warranted by available data, without going through the cumbersome Special Review and cancellation procedures, even when complete reregistration may still be years away. But there are also disadvantages to relying so heavily on private negotiations with registrants -- chief among them the lack of participation among the various interested publics in crafting label changes. In the early 1980's, similar concern for privately negotiated Special Review and pre-Special-Review decisions seriously undermined the agency's

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credibility and slowed regulatory progress. In 1985, EPA adopted procedures to open the door for information from, and participation by, the public in those processes.[1] The Conference recommends that EPA adopt analogous procedures to regularize and open the agency's negotiated label program. Additionally, because label changes are effective in reducing risk only if they are actually implemented in the field, the Conference recommends procedures to facilitate feedback from registrants, pesticide users, and all other interested persons on the effectiveness or ineffectiveness of the interim risk-reduction measures EPA has adopted. Moreover, the Conference recommends that EPA's Office Of Pesticide Programs (OPP) establish regular channels of communication with EPA's Office of Enforcement and Compliance Assurance to inform that office of all label changes and of any material information received by OPP on noncompliance with such changes.

The Conference also urges Congress to consider providing EPA with a new procedural device designed to accommodate a safer pesticides policy: the ability by informal rulemaking to order the "phase-down" of existing pesticides when there are available for use safer, effective pest management products or practices.[2] There are several procedural advantages to empowering the agency with an informal phase-down mechanism. First, ordering the phase-down of an existing pesticide on relative risk grounds will cause less stigmatization of an existing product than would a cancellation proceeding based on the traditional, more absolutist "unreasonable risk" judgment. Second, phase-down rulemaking provides for an incremental style of decisionmaking in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides in cancellation proceedings. Third, phase-down rulemakings based on relative risk can reinforce and integrate EPA's pesticide programs under FIFRA with other federal environmental programs. Finally, phase-down rulemakings would tend to encourage efficient markets for pest management. By restricting a pesticide's use, the price of that pesticide can be expected to rise. This creates a more efficient market for reducing use of that pesticide than would outright cancellation. Under phase-down rulemaking, the pesticide would still be available but those farmers who can more cost-effectively switch will do so first, preserving the reduced-use pesticide for those who cannot switch as easily. Given the innumerable local differences that affect farmers' pest problems, a regulation-induced market for pest management will likely produce more efficient decisions than would have command-and-control regulation by EPA.

Recommendation

1. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through label changes. EPA should inform the public, through a

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[1] 40 CFR Part 154, Subpart B.

[2] Without taking any position on the substantive questions involved in determining the relative safety and effectiveness of pest control measures, the Conference notes EPA's interest in both the present and prior Presidential administrations in developing such a substantive capability.

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Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

2. EPA should assure compliance with label changes. The agency should establish and publicize the availability of a "compliance docket," after the agency has adopted a label change, for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. Additionally, EPA's Office of Pesticide Programs (OPP) should take special care to communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes, the importance of regulatory compliance to the actual attainment of interim risk reduction, and any material information received by OPP in its compliance docket.

3. EPA should promulgate and communicate clear data standards and guidance on the adequacy of data expected from registrants. Because good data are central to the integrity of EPA's substantive decisions, and because the submission of adequate data is critical to the timeliness of agency action, EPA should promulgate, whenever possible, clear, written data standards and otherwise take particular care to communicate data requirements carefully and conscientiously to registrants.

4. Congress should consider changing the incentives of registrants for reasonably expeditious reregistration by legislatively imposing an "automatic" suspension of List A pesticides for which there still remain outstanding data gaps by a date certain, subject to subsequent reinstatement through a petition process.

5. Congress should eliminate the provisions in FIFRA for formal adjudicatory hearings, providing instead an informal rulemaking procedure that affords registrants not only notice of the grounds on which EPA bases its proposed suspension or cancellation action, and a reasonable opportunity to file written comments, but also an opportunity to show cause in individual cases why the right should be granted to introduce oral testimony or to subpoena and cross-examine witnesses.

6. Congress should provide EPA with the authority to impose administrative civil money penalties on registrants for the submittal of data after any applicable deadline, or for the submittal of data (even if timely) the inadequacy of which can be demonstrated by reference to clear data standards.[3]

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[3] See Conference Recommendation 93-1 "Use of APA Formal Procedures in Civil Money Penalty Proceedings," 1 CFR §305.93-1.

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7. Congress should consider providing EPA with the authority to order a "phase-down" in the use of any registered pesticide through an informal rulemaking procedure in which EPA considers such factors as the relative risks and benefits of the pesticide(s) at issue when compared with alternative pest management products and practices.