ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Retrospective Review of Existing Regulations
Workshop Summary
March 10, 2011

WORKSHOP SYNOPSIS

Executive Order 13563 has given agencies 120 days to develop a preliminary plan for reviewing significant agency regulations. The impetus for the March 10 workshop was the EO and a subsequent Office of Information and Regulatory Affairs (OIRA) Memorandum containing guidance to agencies on the requirements. Workshop participants included over 50 federal officials representing 27 agencies. The following is a summary of the important ideas generated by the workshop. This summary will be posted at www.acus.gov.

This summary serves two purposes: to share actionable strategies and best practices gleaned from fellow regulatory subject matter experts, and to encourage an ongoing discussion regarding improving the regulatory process. This document will summarize the panelists' salient points, best practices and guidance from their respective agencies, as well as general comments regarding retrospective review of regulations.

Please direct comments, questions and feedback to David Pritzker at dpritzker@acus.gov or 202 . 480 . 2093.

CROSS-CUTTING THEMES

The following is a list of cross-cutting themes relevant to retrospective review of regulations.

Characteristics of successful processes:

- Involve high-level officials; garner executive support
- Conduct outreach beyond Federal Register notices to encourage public participation:
  - Unified Regulatory Agenda
  - Press Announcements
  - Mass Email Blasts
  - Social Media (Webcasts, conference calls and agency websites)
- Coordinate with federal, state, local and tribal agencies, relevant industries and their organizations.
- Solicit ideas from individuals throughout the agency - not just the rulemaking staff
- Emphasize that the review is addressing only existing rules, to minimize the likelihood that comments will be submitted on pending rules
- Focus on the quality of review versus the quantity of reviews conducted
- Balance the burdens of continuing on existing work with conducting ongoing, existing reviews.
- There is a great deal of difficulty in revising a rule: it might make sense to streamline the review process, and proceed with revising rules following review.
- Combine discretionary and mandatory reviews whenever there is overlap between requirements.
- Issue a report summarizing the agency's efforts at the end of the regulatory review, including an evaluation of whether regulations were changed in response and how long it took to implement changes.
- Work to make the process as transparent as possible by making a report complete and available to the public, even when the rule hasn't changed.
- Coordinate with legislative specialists to develop plain language explanations, help develop testimony, provide suggested language, and help make the public aware of the outcome of reviews.

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LEARNING FROM AGENCY EXPERIENCE

The workshop panel discussion was divided into Planning Issues and Implementation Issues. ACUS 1995 recommendation, 95-3, Review of Existing Agency Regulations, addressed both planning and implementation and emphasized that this is not a "one-size-fits-all" process. It stated that agencies should set priorities and for reviews, considering whether:

- the rule has been subjected to changed circumstances;
- the private sector or another level of government could be more effective;
- the public or the regulated community views modification or revocation as important; or
- there is overlap with other agencies' rules.

The following section provides the salient points from the panel discussion, as well as insightful tips for planning and conducting a review of agency regulations.

PLANNING

High-level lessons learned

Click on the Agency Name to View Lessons Learned

Department of Transportation - Neil Eisner
Environmental Protection Agency - Nicole Owens
Department of Labor - Kathleen Franks
Food and Drug Administration - Leslie Kux
Federal Deposit Insurance Corporation - Mindy West

IMPLEMENTATION

Guidance and Actionable Strategies

Click on the Agency Name to View Guidance

Government Accountability Office - Tim Bober
Department of Transportation - Neil Eisner
Occupational Safety and Health Administration - Jens Svenson
Federal Deposit Insurance Corporation - Ruth Amberg

GENERAL QUESTIONS AND ANSWERS

Discussions from the Audience

Click on the Topic to View Q&A

Revisiting Cost Benefit Analysis
Staff Resources During a Review
Base for Measuring Success
How Should the Preliminary Plan Look?

ACUS FOLLOW-UP ACTIVITIES

Participants in the workshop are invited to communicate to ACUS staff their ideas for potentially useful follow-up activities by ACUS.

Well-run agencies are always reviewing their rules after accidents or chemical releases, or tainted food incidents. They meet promptly to find out why existing rules did not prevent problems.

- Neil Eisner, DOT

Department of Transportation Perspective

- DOT's multi-year plan for review is published in the Unified Regulatory Agenda. Special reviews are one-time events, such as the EO. The agency also responds to public petitions for reviews, as well as performing reviews after significant events. Reviews vary significantly in their complexity.
- Solicit comments from those who cannot attend meetings in person, using both traditional and social media.
- Reports are due to OMB in April, so plan in advance. Decide which rules to review, what questions will be asked, and establish a time line.

CASE IN POINT

FAA undertook a review resulting in eight notices of proposed rulemaking asking for comments on 600 proposed changes, resulting in nine final rules adopting 500 changes. This gives a sense of how time-consuming this process can be.

- Neil Eisner, DOT

Environmental Protection Agency Perspective

- EPA writes many rules (second only to DOT) - about 400 final rules on an annual basis, though not all are significant rules. It typically takes about four years to adopt a rule from start to finish.
- It is not unusual to have 400 rules in the pipeline at any one time, which does not count rules assigned by regional administrators. Thus, EPA will have a massive volume of rules to review under the EO.
- EPA does not limit the review only to significant rules.
- EPA has created a permanent website with 15 different dockets focusing individuals on questions germane to the following process of reviewing rules:
  - Provide issues and impacts
  - Provide questions for each (e.g., ask whether rules impose a mandate on states and on how to reduce the costs of the rule to states; ask whether rules raise issues of "environmental justice"; etc.). EPA sometimes receives 100,000's of comments on its rules, so they are trying to emphasize usefulness of comments containing actual data in order to develop the plan and select an initial list of candidate regulations.

PLANNING | Lessons Learned

EPA, Continued

- EPA also plans to hold public meetings to discuss some of the issues, and each of 10 regions will host meetings and listening sessions as well. Issues that will be addressed are similar to the questions contained on EPA's website.

SAMPLE PUBLIC MEETING APPROACH:

- *Morning Session: How/what should be in the preliminary plan – how frequently should the Agency conduct reviews?*
- *Afternoon Session: Two sets of breakout sessions by program area – then presentations in each session, talking about discussions surrounding the issue/impacts provided on the website. Each of the 10 regions will host a session (video/townhall).*

Department of Labor Perspective

- DOL's representative from the Office of the Assistant Secretary for Policy (OASP) provided a historical perspective on required regulatory reviews. Building upon the Regulatory Flexibility Act's section 610 periodic review requirements, DOL agencies' Regulatory Agenda projects routinely reflect decisions to review their regulations, so there is some question as to what more the agencies can do under the new EO that they do not routinely do. OASP provides a coordinating role for DOL agencies in deciding what regulations to place on agendas, as well as for preparing the DOL Plan for retrospective review.
- Some DOL agencies follow a more structured approach than others (grant-making agencies tend to have less rigorous reviews). Much like other agencies, there's the added burden of continuing on existing work while the review is proceeding. The first step in such a review is public participation. It generally involves publishing a notice in the Federal Register and on the agency's website, as well as conducting face-to-face meetings and hearings.
- "Repeat players" in the regulatory process tend to use reviews as an opportunity to reiterate their general objections to an agency's policies. DOL is always seeking to broaden the sources of public input and in response to this EO, is expanding its efforts to reach a wider variety of stakeholders for their input.

Food and Drug Administration Perspective

- FDA already has existing mechanisms for reviewing rules (both regular and special). This began at least in the 1980s with the Regulatory Flexibility Act, EO 12866 and the Reinventing Government Initiative.
- FDA also has user-fee statutes that must be reauthorized every five years, which creates an opportunity for discussing needed changes.
- Some of FDA's practices include:
  - When one regulation is being revised, we consider whether any other related rules need to be changed.
  - Recognize citizens' petitions as a means of requesting reviews.
  - Also conduct Section 610 (c) reviews under the Regulatory Flexibility Act.
- It is difficult to issue rules and issuing revisions to a rule is no different. Thought could also be given to whether it is time to review and streamline all analyses that need to accompany proposed and final rules.
- As it implements the retrospective review process under EO 13563, FDA is considering how to marry up its strategic priorities, including globalization, supporting regulatory innovation, and improving regulatory science, with the EO's mandates.
- See FDA PowerPoint Presentation

CIRCUMSTANCES REQUIRING REVIEWS

- EO 13563
- §610 of the RFA
- Legislative Requirements

Formal retrospective reviews at FDA are often the result of changed circumstances (regulation no longer meets needs, changed international standards, etc.).

PLANNING | Lessons Learned

Federal Deposit Insurance Corporation Perspective

- FDIC representatives presented views regarding review of regulations. FDIC is an independent agency and therefore is not subject to the EO. Nevertheless, it is required to conduct reviews under its legislation. It completed a major regulatory review in 2006, and will focus comments on that in part. The agency is also implementing the Dodd-Frank Act under very tight time constraints.

INTERAGENCY OR PROGRAM COORDINATION

FDIC focused on Economic Growth and Regulatory Paperwork Reduction Act (EGRPRA) review requirement (enacted in 1996; review first conducted in 2006): Every 10 years, banking agencies must look at all of their rules. FDIC looked at 131 joint regulations and classified them into 12 categories. It then placed them on a 90-day comment period calendar and received approximately 1000 comments.

- Best Practice: In addition to Federal Register notices, FDIC developed a website for regulatory reviews and "branded" the project (with a logo, brochures, online comments, outreach events, etc.).
- In terms of planning, it is important to lead the project from the highest level of the organization.
- Look beyond possible rule revisions to other ways to reduce burden.

Government Accountability Office Perspective

- Among the objectives of GAO's 2007 report on reexamining regulations was identifying factors that helped or hindered conducting reviews, and whether those reviews were useful.
- GAO also looked at processes and standards agencies used, which were quite disparate. They looked at whether the process was standards based (systematic), the extent to which public participation was incorporated, and whether the review process was adequately documented.
- Barriers to conducting reviews: The major barriers that agencies identified were time, resources, and information. They suggested that it is best to get top management to buy into the process early. Agency officials also said that baseline and post-implementation data are key to assessing the effectiveness of existing regulations.
- Barriers to usefulness of reviews:
  - Agency officials highlighted the difference between discretionary v. mandatory (e.g., every set number of years) – the latter were generally considered less useful. Useful results from discretionary reviews were more likely because there was some particular impetus for conducting them. Of course, compliance with mandatory reviews is still required.
  - Agencies may lack discretion to modify some regulations, because of statutory constraints or requirements. (Suggestions to change such regulations might be flagged separately, so that Congress is informed that legislative changes are needed, and this could also be noted in an agency's report of its review.)
  - There's a danger of trying to scope reviews too broadly: For example, one review took 12 years because the scope kept expanding. Of course, it's often hard to tell in advance how broad the review will need to be.

IMPLEMENTATION | Guidance

GAO, Continued

- Lack of public participation: Agencies noted that they often try hard to solicit input and get very little; but nonfederal groups reported that they weren't contacted or were unaware of agencies' reviews. So there's some disconnect in communications.
- Lack of transparency: It's hard for people outside an agency to comprehend the full process, from start to finish. (Try to make the "string" visible to the public as much as possible.)

> *All in all, agencies are already doing a lot of this. The problem is more in reporting what is currently being done.*
>
> *- Tim Bober, GAO*

- Practices suggested by agencies and nonfederal parties for improving reviews:
  - Pre-planning data collection, prioritizing, and focusing your reviews are all important to do. Doing a few reviews well is better than doing many poorly.
  - Prioritizing reviews and obtaining high-level management support.
  - Nonfederal parties suggested using independent parties, in particular making sure that the same people who wrote and those who implement the rule are not the only people conducting the review.
  - Group related regulations. Try to find clusters of similar rules and focus on putting them together.
  - Tailor reporting to what different stakeholders need. Make the public aware of the outcome of your reviews so that they will gain a better understanding of the regulatory program.
  - Substantive, multi-purpose reviews are better than pro forma or single-purpose reviews.
- See GAO PowerPoint Presentation and GAO-07-791.

Department of Transportation Perspective

- On May 18, agencies are required to submit a preliminary plan for periodic review of their existing significant regulations. A draft is due at the end of April.
- Whether a rule is significant under the definition in EO 12866 may not be easy to determine.
- We need to focus limited resources on the most important rules, but DOT will look at all rules in the future.
- We must coordinate EO 13563 review with statutory reviews (e.g., Regulatory Flexibility Act), other EOs and administration requirements for reviewing paperwork burdens and state and local burdens.
- Yesterday (March 9), OMB circulated additional guidance on compliance with the review requirements, which includes a template for the plan.
- With regard to implementing your review plan, consider the following:
  - Basic elements Senior Level Involvement.
  - Process for identifying problems and priorities.
  - Questions to ask people who will work on the review and the public (e.g., has rule been difficult to enforce; have there been numerous requests for interpretation; requests for exemption; etc.).
  - Base for measuring success. Sources for information (e.g., census bureau reports).
  - Changes in technology (e.g., do you still require paper submissions; how often are reports required; etc.).
  - Independence of the office conducting the review. Consider having ombudsman or other agency contact point.
  - Rolling reviews (DOT lists each of its rules that are in the CFR and puts each on a schedule for review—asks for public input to help determine priorities.)
  - Possible categories for organizing reviews (may look at harmonization of standards; coordinating with other agencies; training rules; paperwork burden; types of entities affected; etc.).
- See DOT PowerPoint Presentation

IMPLEMENTATION | Guidance

Occupational Safety and Health Administration Perspective

- OSHA is part of Labor; they've conducted many types of reviews over the years. These include a few one-time reviews, updating existing standards, standards improvement project, etc. Also OSHA continuously conducts smaller, pro forma reviews.
- Paperwork Reduction Act (PRA) reviews are done regularly. OSHA has conducted more substantive reviews on specific regulations—about 1/year over past decade; would like to do more but cannot due to budget constraints.
- They do these reviews both because of specific requirements and because it's useful to their agency. Criteria for choosing rules for review include impact on small entities, size of rule, controversy, change of circumstances, likelihood of benefit or review, etc.
- Include an announcement of a planned review in the Unified Regulatory Agenda; also issue a Federal Register notice; work it into speeches, etc.
- Reviews are fairly resource intensive, often including economic analyses. Look at changes that have occurred. Legal and analytical review of regulatory requirements are included. Identify other applicable requirements. Coordinate with other agencies and state/local governments.
- The report is developed by a multi-disciplinary team.
- Once the report is complete, it is made available to the public. This is beneficial even if rules aren't changed. The agency may find it useful to change guidance materials, etc. to clarify rule.

Regulatory Reviews Conducted by OSHA
(Also posted on ACUS website)

- Cotton Dust
- Ethylene Oxide
- Excavations
- Grain Handling
- Lead in Construction
- Lockout/Tagout
- Presence Sensing Device Initiation
- Methylene Chloride

Federal Deposit Insurance Corporation Perspective

- FDIC representatives presented views regarding review of regulations. The last major review was a multi-year project involving significant resources over several years, interaction with other agencies and Congress, internal analysis, etc.
- Mechanics: Organization up front is key—need to dedicate sufficient staff, coordinate with other agencies, etc. Should be transparent to the public. FDIC assigned a team of internal subject matter experts to each project.
- They also designated legislative "point people" to coordinate with Congress.
- All analyses were discussed with agency leadership, leading to robust discussions on what to do with suggestions and which recommendations to pursue.
- FDIC coordinated with sister agencies when their regulations were identified. They learned the need for flexibility, based on current events (e.g., the agency received comments on flood insurance up until Katrina, when new issues were raised); events can change key issues and priorities.
- FDIC also worked with legislative specialists to develop plain language explanations and testimony.
- It is important to explain why suggestions from the review process were or were not recommended in the final report.

Q&A| Revisiting Cost Benefit Analysis

Since EO 12291 in 1981, agencies have had to conduct cost/benefit analyses. Once rules are in place, do agencies go back and re-check cost/benefit analysis in light of current conditions?

DOT: Answer is Yes. NHTSA did retrospective reviews on whether data they used turned out to be accurate. Businesses and public interest groups point this out.

EPA: They too have looked back to see if the initial cost-benefit analysis was accurate. Results have been mixed—sometimes right, sometimes not. Of course, EPA is sometimes precluded from doing cost-benefit analysis by statute.

Audience: The technical ability to do cost-benefit analysis has shifted dramatically over the last 5-10 years. As such, costs and benefits often change quite a bit from initial estimates. An agency economist suggested that a better approach might be to look at which regulations had a major impact that was not expected.

FDA: Cost-benefit analysis is not considered precedential—new data emerge, factors change, etc., so the analysis will almost certainly change. There's not much value in re-using tools you used originally to determine how well they worked; it makes more sense to run a new cost-benefit analysis.

DOT: Yes, always take later circumstances into account.

Unknown Agency: Always do a re-evaluation ten years after the fact to determine if the earlier assumptions are still accurate.

Q&A | Dealing with Staff Resources During a Review

To what extent do agencies have flexibility to shift around staff to perform such reviews?

EPA: Varies by program office and sub-program office. Some are dealing with quarterly deadlines, so they don't have as much time to dedicate.

FDA: Have user fee programs that have deadlines, and devote sufficient resources to that. An agency will likely not pull people off an ongoing rulemaking in order to comply with some new requirement.

Labor: Sometimes augment regulatory writing staff in program agencies. Can hire new writers if budget is generous, but there is a learning curve. So, basically, it's hard to dedicate resources immediately to a new requirement.

Q&A| Base for Measuring Success

How are agencies measuring the success of this effort? What measures will show whether an agency has complied with the EO?

DOT: It depends on how you define "success": Pages in CFR? Dollars saved? Improving benefits? Reducing paperwork burdens? Some of these are more useful than others.

Q&A| How Should the Preliminary Plan Look?

I'm trying to get a sense of how an agency's preliminary plan will look—will there be a need for consistency across agencies? How long should the document be?

DOT: OMB document circulated yesterday (March 9) that provided a template. Agencies will probably meet requirements fairly differently, in any event.

Resources

All materials are available at www.acus.gov

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27 Agencies . 53 Participants . 8 Panelists

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Background Materials

Background materials on retrospective reviews may be found on the ACUS website (www.acus.gov). (Click on the "Library" tab, and then on "Regulatory Review Materials" in the drop-down menu.) They are also listed below:

- Executive Order 13563: Improving Regulation and Regulatory Review
- Office of Information and Regulatory Affairs (OIRA) Memorandum
- Government Accountability Office (GAO) Report: GAO-07-791, REEXAMINING REGULATIONS: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews
- GAO Report – PowerPoint Summary
- EPA's Retrospective Review Web Page
- DOT's List of Regulatory Reviews (Appendix D to DOT's Fall 2010 Regulatory Agenda)
- FDA Plan for Periodic Review (Federal Register, Jan. 20, 1994)
- Regulatory Reviews by OSHA
  - Cotton Dust
  - Ethylene Oxide
  - Excavations
  - Grain Handling
  - Lead in Construction
  - Lockout/Tagout
  - PSDI
  - Methylene Chloride

ACUS Historical Studies

- Agency Review of Existing Agency Regulations – Report by Sidney Shapiro
- Recommendation 95-3 (1995)

Presentations

- DOT Presentation (Planning) . Eisner
- DOT Presentation (Implementation) . Eisner
- FDA Presentation . Kux
- GAO Presentation . Bober