ADAPTATION AND ANTICIPATION:
LEARNING FROM POLICY EXPERIENCE

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June 29. 2007

A Working Paper of the Political Economy and Technology Policy Program
Center for International Studies, Massachusetts Institute of Technology

Note: Versions of this paper were presented at the NSF-EPA Trans-Atlantic Uncertainty Colloquium, Washington, DC October 10-11, 2006; and Milieu-en Natuurplanbureau, Seminar Omgaan met Onzerkerheid in Beleid, Bilthoven NL June 29, 2007. The authors acknowledge with gratitude NSF support for research and conferences. This is a draft paper, subject to revision. Suggestions to oye@mit.edu and lmccray@mit.edu are most welcome.

I. INTRODUCTION

This paper attempts to take a long view of domestic and international regulatory decision making, posing two sets of questions on the interaction of new knowledge and old policies.

- Do domestic regulatory systems and international regulatory regimes routinely self-correct, adjusting to changing knowledge and conditions over time? Or do regulatory systems lock in on existing policies, failing to recognize and act on changing knowledge and conditions?
- What domestic and international pathologies may block or distort access to relevant information and impede adjustments of policies? Conversely, what concrete measures may improve the adaptive capacity of domestic regulations and international regulatory regimes?

Only a handful of students of regulation have taken this viewpoint. Regulatory economists have spent much more thinking about expected efficiency – asking if *new* regulatory decisions are made with satisfactory understanding of their expected benefits and costs. Students of administrative law have spent more time thinking about regulatory processes and who participates in the decision process. Both are, of course, important matters. Sustained attention to "getting-it-right up front" has led to productive methodological innovations and reforms of the regulatory process. The front end conventional advice of the box below is not wrong. However, given the importance of new science and evolving conditions to so much of health-and-safety regulation, and given that so many domestic regulations and international regimes were written decades ago, we also need to ask how well knowledge and policy are linked over the long run.

FRONT END CONVENTIONAL ADVICE: FOCUS ON GETTING IT RIGHT INITIALLY
INTEGRATED ASSESSMENT makes best use of limited initial information BEFORE decisions
-- given irreversibility of public policies (and business strategies) in the face of revealed info . .
-- technocratic emphasis on formal integrated assessment, cost benefit, and risk assessment
BUT anticipation is difficult and early warning signs and models are not taken seriously
SUGGESTIONS. . .
-- improve quality of data, analytic methods, and models
-- strengthen institutions for credible assessment of early warnings and models

Accordingly, this paper focuses on how and whether domestic regulations and international regimes adapt in light of new knowledge and circumstances. For while many things about regulation are debated, all sides agree on at least this: regulators nowadays have to reach their decisions amid much uncertainty – reflecting scientific, economic, and behavioral unknowns - about near-term and long-term costs and benefits. It is not unusual, in fact, for uncertainty in compliance costs to amount to a factor of two, and for uncertainty in health/safety benefits to amount to factors of ten or a hundred. In such conditions, it is not sensible for us in 2006 to leave unexamined a rule written in 1980 based on knowledge and assumptions available in 1980. Scientific knowledge about the benefits of a rule change, relevant technologies change, patterns of exposure change, and public priorities change. In fact, old policies often spur the development of new technologies, alter compliance costs, and foster the development of new understandings of environmental conditions. As a consequence, the benefits and costs of a rule evolve, with fewer benefits to show for the costs incurred or with diminished costs that imply that more benefits to health and safety could be easily gained.

BACK END UNCONVENTIONAL ADVICE: FOCUS ON IMPROVING ADAPTIVE CAPACITY
INTEGRATED RE-ASSESSMENT commits to use information revealed AFTER decisions
-- improve quality of decision making
-- reduce the intensity of up front fights
BUT policies tend to lock in.
SUGGESTIONS
-- reduce interests in status quo through judicious use of overt and covert compensation
-- mobilize bureaucratic, business and NGO interests in adaptation
-- strengthen incentives for surfacing and using information revealed after initial decisions
-- use proxies for ultimate goals to limit lock in on wrong intervening and behavioral indicators

Maladaptive regulatory systems and organisms do not fare well in environments characterized by turbulence. Because changes in knowledge, relevant technologies, exposure patterns, and public priorities are often pervasive and typically cannot be known in advance, the capacity of regulatory systems to adapt and self correct is perhaps the key to effective long term performance. Policies are, in our view, properly viewed as experiments that elicit information and alter conditions. The "back end" of adaptive capacity, treated in the box above, is the key to making good use of information produced by policy experience.

The main line of argument offered here reduces to the following. Where uncertainty is substantial, the norms, rules and procedures embodied in an international regime or domestic regulatory system will inevitably be wrong. If understandings of underlying causal structures are imperfect, then domestic and international regulatory systems based on those understandings will be flawed, not necessarily out of stupidity or carelessness. But flawed because knowledge needed to make informed decisions is lacking at the outset. Under such conditions, domestic regulations and international regimes may be properly viewed as experiments that generate information on political, economic, biological, or engineering assumptions that may in turn be used to update causal beliefs and policies. Properly designed regulatory systems harvest information generated by policy experience, and use that information to revise and update policies.

II. EXISTING LITERATURES ON ANTICIPATION AND ADAPTATION

Our core argument for emphasizing adaptation is based on pessimism with respect to anticipation. The findings of the existing literature on the weaknesses of anticipation underscore the need for more effective adaptation in domestic public policy and international regulatory affairs. But policy adaptation is not a subject with a rich literature. Experience with planned adaptation within the US government are limited, and after-the-fact academic ruminations on adaptation are of limited value. Experience with adaptation in international regulatory regimes are a bit more common, with literatures that engage more self-consciously with problems of updating and correction.

A. Some Studies and Experiments on Anticipation

Scholarly studies rarely offer conclusions without caveats and qualifications. Studies on anticipation in public affairs represent an exception. The National Academy of Public Administration (NAPA) completed two representative studies on applications of forecasting methods in government and business. "Remembering the Future: Applying Foresight Techniques to Research Planning at EPA" and on "Foresight Methods and Their Application

to Scientific Research Planning: A Survey of the Field" reviewed methodologies and assessed a wide range of forecasting cases. These included USAF scenario building in the 2025 exercise on technology and strategic planning, NIEHS use of lookout panels to evaluate research priorities in light of expected technical advance, an EPA "Foresight Methods" exercise comparing methods of assessing environmental implications of technological change, and Shell and Electric Power Research Institute technological and economic scenario building (NAPA, 1998 and 1999).

The NAPA studies suggested that the record of forecasting is less than sterling, noting that problems with foresight were caused in part by limited knowledge at the time forecasts were made, in part by technical and methodological deficiencies, in part by pervasive difficulties integrating knowledge across disciplinary lines and in part by a reluctance of policy makers to engage directly with many elements of uncertainty. Intrinsic and extrinsic limitations of foresight underscore the need for more effective adaptation and self correction. As noted above, the tasks of revising domestic regulations and updating international regimes take on greater importance if the projections of costs, benefits and consequences on which policies are based are weak.

The intrinsic difficulty of anticipating changes in technology, evolving environmental conditions, shifting costs of compliance, and swings in public priorities is compounded by what could be termed a credibility problem. Anticipation entails more than forecasting. It entails acting on early warnings or committing resources on the basis of the results of models. Leading indicators and early warning signs are vulnerable to criticism as unrepresentative false alarms, while the methods, structure and parameter values of models are arcane objects of debate. Knowledge claims associated with the selection of an indicator or the construction of a model can be controversial . As Sheila Jasanoff suggests:

> Knowledge claims are deconstructed during the rulemaking process, exposing areas of weakness or uncertainty and threatening the cognitive authority of science. At the same time, the legitimacy of the final regulatory decision depends on the regulator's ability to reconstruct a plausible scientific rationale for the proposed action. The processes of deconstructing and reconstructing knowledge claims give rise to competition among scientists, public officials, and political interest groups all of whom have a stake in determining how policy-relevant science should be interpreted and by whom. [1]

What Jasanoff terms “processes of deconstructing knowledge claims” during rule making undercut the credibility of the early warnings and models and weaken anticipatory responses. But the consequences of deconstruction of knowledge claims - of moves toward what Europeans call post normal science - do not stop there. What Jasanoff terms the “reconstruction” and defense of “plausible rationales” for actions once rules are formed reduces adaptive capacity once a policy is in place. The defense of existing knowledge claims can impede learning, making it more difficult to update a model, to displace a received truth, to revise a standard, or to replace one variety of canary with another better suited to detecting gas in the mine. Ironically, actions taken to improve the plausibility of rationales and bolster anticipation can have the effect of limiting adaptation.

Some Studies and Experiments on Adaptation in US Domestic Regulation

Only a few domestic and international regulatory analysts have explicitly addressed adaptation. The most thorough set of readings has come from the legal community;

[1] Sheila Jasanoff, “Contested Boundaries in Policy Relevant Science,” Social Studies of Science 17, 1987, pp 195-230.

economists[2] and other social scientists seem to have, in contrast, shown scant interest in the subject.[3] One of the most interesting discussions came from the technologists. Using internal funding, the National Academy of Engineering [NAE] organized a workshop leading to the 1993 NAE report, Keeping Pace with Science and Engineering: Case Studies in Environmental Regulation.[4] The symposium examined seven regulatory cases, asking in each case how well the policy decisions took account of the latest scientific information. In reviewing the results of the exercise, NAE President Robert M. White concluded that the key issue was less a matter of *supplying* new science than a matter of getting the regulatory community to *demand* it: "We need to build into the structure of the regulatory system means for reconsidering earlier decisions if and when our understanding changes sufficiently to call our earlier decision into question."[5] However, this insight was not pursued further within or outside NAE.

Meanwhile, those legal scholars who concern themselves with administrative law became interested in what were then termed "look-back" provisions in regulatory policy. The apparent stimulus for this was President George H. W. Bush's 1992 moratorium and its breath-taking edict that *all* existing federal regulations be reviewed immediately. The results of this effort may have been thin, but the idea certainly did intrigue some administrative lawyers. In 1993, the American Bar Association's Section of Administrative Law and Regulatory Practice decided to find out what twenty federal agencies had learned from the Bush initiative.

The ABA report, Federal Agency Review of Existing Regulation,[6] catalogs how the federal regulatory agencies responded to the 1992 Bush mandate. It provides only fragmentary details concerning specific agency initiatives, and it reflects a lack of enthusiasm among most federal regulators – even amid the energetic Republican revolution of 1994 -- for opening existing rules to new public discussion. One agency objection, which the report saw as "the major stumbling block,"[7] was that agencies lacked adequate budgets to both write new rules and to reconsider old ones. "Who can afford such a luxury?" one DOT official replied.[8] The ABA report concludes with a long list of sensible, but very general,

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[2] While most regulatory economists express avid interest in assessing the projected costs and benefits of prospective rules, the possibility that past decisions represent excessive costs or inadequate benefits does not appear to animate them. We need to explore this further.

[3] The dearth of practical work on adaptation in the fields of political science and public administration may seem surprising to those who recall the interest in incrementalism and in cybernetic models of policy formation a few decades ago; Karl Deutsch's Nerves of Government [1966], Herbert Simon's work on "satisficing" and "bounded rationality," and Charles Lindblom's popular work on "muddling through" [1959] as a preferred decision-making style all seemed to presage a time when rational incrementalism was to be broadly discussed, and perhaps would become the source of reform ideas. A focus on adaptable government seemed a short step away. However, I have found no recent political science work that addresses regulatory adaptation. Most recently, a group at Rand has begun to write thematically of adaptive policy processes, and their work may in the coming years find practical application in regulatory or other policy spheres. Examples of this new strain include Warren E. Walker *et al.*, "Adaptive Policies, Policy Analysis, and Policy-making," European Journal of Operational Research, number 128 [2001], pp. 282-289, and Warren E. Walker *et al.*, "Adaptive Policies: An Approach for Dealing with Structural Uncertainty in Public Policymaking," May 2004 [discussion draft]. As this work becomes specific it may put new ideas on the table.

[4] National Academy Press, 1993.

[5] Ibid., p. 5

[6] American Bar Association, 1994. This report finds that "Agencies agree that they cannot ignore the need to review their regulations and that, as a general proposition, mandatory or discretionary periodic review of existing regulations is a sound idea." [Section IV.A]

[7] Ibid., p. 21.

[8] Ibid., p. 17.

"suggestions" for federal agencies to consider. There is no record that the agencies considered them.

In 1995 the Administrative Conference of the United States [ACUS],[9] stimulated in part by the Clinton Administration initiative to look at existing regulations[10], commissioned what stands as the definitive summary of regulatory adaptation.[11] It was written by University of Kansas Law School Professor Sidney Shapiro. The Shapiro paper later led to ACUS Recommendation 95-3. ACUS stated that:

> ". . . agencies have an obligation to develop systematic processes for reviewing existing rules regulations, and regulatory programs on an ongoing basis."[12]

To make clear its view that such reviews should be substantive, and not just superficial attempts to reduce paperwork, the recommendation said:

> "As part of the review process, agencies should review information in their files as well as other available information on the impact and the effectiveness of regulations and, where appropriate, should engage in risk assessment and cost-benefit analysis of specific regulations.[13]

It concluded, however, that "there are relatively few successful well-developed models available, and no widely accepted methodologies,"[14] ACUS called for further experimentation before a universal requirement would be adopted. That hasn't happened, and any impetus to change seems to have been buried with ACUS itself.

C. Studies and Experience on Adaptation in International Regimes

Several important bodies of scholarship on international regulatory arrangements have sought to take account of learning and planned adaptation. Seminal works on international regimes, including Robert Keohane's *After Hegemony*, Stephen D. Krasner's (editor) *International Regime,* and more recent literatures on international legal conventions by Abram and Antonia Chayes, Judith Goldstein, Kenneth Abbott, and Robert Keohane and on norm dynamics consider how old structures are revised in light of new knowledge. In their work on ideation and international affairs, Robert Keohane and Judith Goldstein analyzed the construction and cumulation of knowledge in international relations, anticipating though not embracing the rise of interpretive approaches to the study of politics. Their work links the evolving nature of beliefs and the changing design of international regulatory regimes.[15] Robert Jervis's studies on complexity and misperception feature explicit attention to the psychological elements of updating beliefs and to the organizational and political elements of updating international arms control agreements.

International reformers have succeeded in building elements of "planned adaptation" into some international regimes. Although explicit requirements for review with well-developed models and widely accepted methodologies are as rare in international affairs as in

[9] ACUS was an independent agency dedicated to improving administrative practice. Congress eliminated the 30-year old Conference in the 1990's to eliminate unnecessary costs. ACUS' annual budget had been about $2 million.

[10] Further interest may have been stimulated by the Roth Bill, S.291, which would require agencies to formally review all of their existing regulations in ten years. Another bill, S.243 [the Grassley/Hatch Amendments], aimed to spur petitions from private parties for the review of existing rules.

[11] Shapiro, Sidney, "Agency Review of Existing Regulations," April 1995.

[12] ACUS Recommendation 95-3, 60FR43108, August 8, 1995, introduction

[13] ACUS Recommendation 95-3, 60FR43108, August 8, 1995, section V.B

[14] ACUS Recommendation 95-3, 60FR43108, August 8, 1995, introduction.

[15] Martha Finnemore and Kathryn Sikkink, "International Norm Dynamics and Political Change," *International Organization*, Autumn 1998. International Organization Special Issue on Legalization, Judith Goldstein et al "Introduction" and Kenneth Abbott et al, "Concept of Legalization," Summer 2000.

domestic regulatory life, planned adaptation through institutionalized mechanisms for reappraising scientific and technical knowledge are features of some regimes.

The European Union set forth explicit procedures for review and updating of BSE policies, including testing, feedbans, and treatment of specialized risk materials. The resulting EU TSE Roadmap was the product of a carefully structured multinational process that included a systematic appraisal of initial assumptions in light of experience.

The UN Framework Convention on Climate Change, the Kyoto Protocol, and the Conference of the Parties include explicit provisions for appraising unfolding scientific information and assimilating information within the regime. In a chapter entitled "Adaptation," Farhana Yamin and Joanna Depledge offer an exceptionally insightful study on learning and self correction within this major environmental international regime.[16]

International economic regimes, including the WTO, provide for updating in the interpretation of regulations through the panel process, with explicit assessment of the regulatory policies of member states in light of the adequacy of risk assessments and other mechanisms for incorporating late scientific and technical information into policymaking.[17]

Adaptive mechanisms appear to be less common in security affairs than in environmental, health, and trade affairs, Fiona Simpson is among the many who find that adaptation of security regimes is commonly a product of international political renegotiations; she notes that provisions for adaptation were not included in the nuclear non-proliferation regime itself. A significant exception to this generalization on limited reliance on adaptation within security agreements and regimes may be found in UNSC 1441, the Security Council resolution that set up UNMOVIC and IAEA inspections to attack key sources of uncertainty on the issue of Iraq and Weapons of Mass Destruction. That case will be discussed in this paper.

ANTICIPATION IS INTRINSICALLY DIFFICULT AND PREDICTIONS ARE HARD TO SELL
- "Model based anticipation" – methods, structure and parameter values
- "Canary based anticipation" – leading indicators and early warning signs

BUT credibility of models and early warnings subject to intensive scrutiny
- Significant intrinsic uncertainty associated with models and early warnings
- Knowledge appraisal in advance of policy ⇔"deconstruction of knowledge claims"

ADAPTATION OF POLICY TO INFORMATION REVEALED AFTER INITIAL POLICY IS KEY
- Side effects and interaction effect are revealed after initial lines of policy are set
- Policies will elicit technological change and generate mass public reactions

BUT public policies and private strategies tend to lock in – "Dead Hand"
- Incentives for harvesting revealed information are limited
- Revealed information after the fact ⇔ hardened "reconstructed rationales" for policy
- Bureaucratic interests and business interests limit self correction

SELECTION FOR SELF-CORRECTING AND AGAINST MALADAPTIVE ORGANIZATIONS
- What happens in the absence of adaptation and self correction?
- On what issues and organizations on what time scales will selection for self correcting organizations, firms, governments, and countries be strong? Be weak?

To recap, anticipation will be difficult and predictions will be hard to sell. As a consequence, adaptation of policy to information revealed through policy experience becomes a critical design feature of domestic and international regulatory systems. The prospect of selection against actors that cannot anticipate or self correct provides a spur for identifying examples of adaptation in domestic and international realms.

[16] *International Climate Change Regime: A Guide to Rules, Institutions and Procedures* (Cambridge UP 2004)

[17] Monika Butler and Heinz Hauser, "WTO Dispute Settlement System: A First Assessment from an Economic Perspective," Journal of Law, Economics and Organization, October 2000; Peter Rosendorff, 'Stabilized Rigidity: Politics and Design of WTO Dispute Settlement Procedures," American Political Science Review, volume 99 number 5, August 2005, 389-400.

III. ADAPTATION IN US REGULATIONS AND INTERNATIONAL REGIMES

To understand how and whether planned adaptation works and why people might endorse or oppose it as a technique, this paper starts by looking for specific examples. As will become evident, there are few attested examples of planned adaptation in federal practice. Once this emerged as our likely outcome, we expanded our collection criterion in two directions.

First, "planned adaptation" involves a commitment by the decision-maker to revisit the decision at a later time in order to make any needed modifications. In this paper, we relaxed the condition that the reconsideration in domestic US cases be "planned." Whether the review was planned or adventitious, we reasoned, the dynamics of the review were likely to be informative. The domestic cases presented here in brief should be viewed as a prelude to the detailed comparative case studies on adaptation and anticipation in US and European sulfur and particulates policies prepared by Katherine Martin, Arthur Petersen, Jeroen van der Sluijs, Willemijn Tuinstra, and Hans Visser (scheduled for TAUC Workshop Session Tuesday 10 October 3:15-3:55 PM); and to powerpoint mini-cases on Pharmaceuticals Aftermarket Surveillance (scheduled for TAUC Workshop Session Wednesday 11 October 9:45-10:25 AM).

Second, the limited number of attested examples of "planned adaptation" in domestic US practice spurred our search for examples of planned adaptation in international regimes. In this paper, we consider adaptation and learning by the European Union on the recent TSE roadmap; in UNSC 1441 as an example of an explicit though perhaps insincere agreement to harvest information, update priors and revise policies on WMD in Iraq; and in a prospective application to GMO crops within the context of the recent WTO dispute. The cases presented here in brief will be supplemented by detailed powerpoint mini-cases, including adaptation in BSE regulations in the US and Japan as well as EU (scheduled for TAUC Workship Session Wednesday 9:45-10:25 TAUC Session).

A. PLANNED ADAPTATION IN US REGULATION

Those who perceive the federal government as resistant to change and resistant to new ideas might well assume that if planned adaptation is rare, it is because our national bureaucracy has stifled it. But is that true? Has the systematic review of existing rules never been encouraged? Are there imposing formal barriers – erected within the agencies or by contending interests -- to regulatory adaptation? The answer may surprise. There has, in fact, been a long and steady history of ***general*** guidance requiring federal regulators to give fresh reconsideration of existing rules. In fact, nine government-wide initiatives [cases **F1 – F9**, detailed below], extending from 1947 to 1996, provided formal mechanisms to do that, and every President from Jimmy Carter to Bill Clinton put his Administration behind the notion.

We identified 32 U.S. candidate cases [see Tables 1, 2 and 3 below] for exploration. About half of these cases were drawn from writings on "look-backs," chiefly from the paper by Eisner and Kaleta[18] and by Shapiro.[19] The others came from personal knowledge and

[18] Eisner, Neil, and Judith Kaleta, "Federal Agency Reviews of Existing Regulations," Administrative Law Review , volume 48, Winter 1996.
[19] Shapiro, Sidney, "Agency Review of Existing Regulations," April 1995.

searching conversations with colleagues and other well-positioned informants; there appears to be no more systematic way to proceed – but the reader should keep in mind the ad hoc nature of our search for cases. Another investigator might well have identified a different set. Not all of these cases could be verified – some, for example, appear to have been bravely announced but only incompletely implemented. Appendix A lays out what is now known about each case.

1 What types of initiatives did we find in the 32 cases?
Eighteen of the cases [Table 1] are found in health-and-safety agency programs, and of these, seven involve the Environmental Protection Agency EPA]. Three are associated with the Food and Drug Administration, three more within the Department of Transportation, and the other six are found spread among five other agencies.

Table 1 – US Health and Safety Agencies

Case No.	Unit	Description	Year	Status	Project Folder
1	FDA	RDA Reviews (by NAS)		Ongoing	31
2	FDA	Animal Nutrient Req'ts (by NAS)		Ongoing	32
3	EPA	NAS Review of Radiation Effects for EPA	1970ff	Ongoing	4
4	NHTSA	Post hoc Eval. Program	Ca '75ff	Ongoing	6
5	EPA	5-year Review of Air Quality Standards	1980ff	Ongoing	1
6	EPA	TOSCA Reviews		Ongoing	19
7	DOT	Elim. of 66 Regs	1992	Completed	16
8	DOT	Review of FAA Aircraft Cert. Regs	1994	Completed	24
9	FDA	Rule Review Solicitations	1994	Unconfirmed	14
10	OTA	Review of Costs of OSHA Regs	1995	Completed	9
11	EPA	Drinking Water Stds Review Cycle	1996	Ongoing	5
12	EPA	Sect. 812 Review of Costs of Clean Air	1997	Completed	2
13	DOT/FAA	"Worst Three Rules" Nominations	1997	Unconfirmed	15
14	USDA	5-year Reviews, Farm Act		Unconfirmed	12
15	USDA	FSIS Rule Review Office		Unconfirmed	25
16	EPA and OSHA	Review of Cost Estimates (by RFF)	1999	Completed	3
17	HEI/EPA	HEI's "Accountability Project"	2002	Ongoing	29
18	CPSC	Pilot Plan to Review Regs	2004	Ongoing	27

Nine cases [Table 2] are government-wide initiatives, most of them administered by the Office of Management and Budget on behalf of the Executive Branch.

Table 2 – Federal Government Wide Initiatives On Health/Safety Agency Programs

Case Number	Unit	Description	Year	Status	Project Folder
F1	Cong.	APA section 553 Petitions to Revise Rules	1946	Ongoing	8
F2	OMB	Ex. Order 12044	1978	Rescinded	20
F3	SBA	Reg. Flex Act reviews	1980ff	Ongoing	17
F4	OMB	Ex. Order 12291	1981	Gone	22
F5	OMB	One-time reg review	1992	Completed	18
F6	OMB	Ex. Order 12866	1993	Ended	21
F7	OMB	Govt Perf and Results Act [GPRA]	1993	Ongoing	23
F8	OMB	Costs of Regulation Report	1997ff	Ongoing	7
F9	Cong.	Rule Identification	1997ff	Abandoned	10

The remaining five cases [Table 3] are found at five federal agencies that are not health-and-safety programs.

Table 3 – Initiatives in US Agencies Not Health/Safety

Case Number	Unit	Description	Year	Status	Folder
X1	DOD	2-year review cycle	1988	Unconfirmed	13
X2	FTC	Reg. cost review	1992	Unconfirmed	11
X3	DOI	5-year review cycle		Ongoing	28
X4	NCUA	Three-year review cycle for all rules		Ongoing	26
X5	FDIC	5-year review cycle		Ongoing	30

All the cases were inaugurated between 1946 and 2004, but most are of recent vintage; the median year of origination is 1992, and nearly one-half were started in the 1990's.

Nine of the cases involve a single, *ad hoc* retrospective review. [While we may learn some practical lessons from these experiences, these cases are not technically examples of *planned* reviews, in that a decision to revisit the existing regulation or standard was not part of a prior plan.]

Most, but not all, of the cases reportedly involve a general process for reviewing some set of existing rules. The programs reported as ongoing efforts, about one-half undertake to re-examine the full range of existing rules – a typical example [**Case 11**] is

EPA's statutory requirement to review *all* of its drinking water standards every five years – and the other half undertake, as part of a regular process, to single out particular rules or standards to treat, as the CPSC reports is doing in a new rule review pilot project [**Case 18**].

About one-third of the candidate cases are *de novo* reconsiderations of existing standards or rules, sometimes thought of as "sunset" programs. These efforts are governed by the calendar; after a specified period, the government conducts a mandatory fresh look that the rule and its effects. Five of these twelve reported efforts were set in motion in a statute, four were reportedly instigated by individual agencies, and three were set forth by Presidents in Executive Orders.

For eight of the cases, the focus is on involving nongovernmental entities in identifying rules that need to be given a new look. A striking recent example [**Case F9**] is OMB's national call for nominations from regulated firms and other commenter of existing rules that are in need of a fresh re-evaluation.

Five of the case examples address the costs but not the benefits of regulations. It is interesting to note that half of the cases seem, as far as can be determined, to have been set in motion by the Congress [ten cases] or the administration in power [six cases], and the other half appear to be initiated by particular regulatory agencies.

2. How many cases were verifiable as true "planned adaptation?"

On closer inspection, a large proportion of the 32 candidate cases fall short of being routine programs of planned adaptation. They remain interesting to students of government because they illustrate policy innovations that seem not to have worked as originally designed, or they stand as one-shot experiments that help inform us about how practical ongoing programs might be structured. Fifteen cases[20] were never implemented. They were announced as intentions, and in some cases appeared as formal policy [e.g., in Executive Orders, public laws, and rulemakings] but we could not confirm that the announced action ever took place. Another nine cases[21] involved one-time retrospective reviews, ending without a commitment to continue the re-assessment into the future. That leaves eight cases of what appear to be routinely planned adaptation:

[1]EPA's "National Ambient Air Quality Standards" [NAAQS] Program – case 5 below. Under this program, each of six air pollutants are review periodically to determine whether the national standard needs to be adjusted based on new knowledge.

[2]OMB's "Costs of Regulation" Program – case F8 below. OMB has annually produced a report on the costs to the economy of federal rules that are on the books.

[3]NHTSA's Rule Evaluation Program – case 4 below. The National Highway Traffic Safety Administration, a part of the Department of Transportation, has a program of routinely evaluating specific existing NHTSA rules.

[4]The FDA asks the National Academy of Sciences/National Research Council to periodically review the Recommended Dietary Allowances [RDAs] for vitamin intake in humans – case 1 below.

[5]The FDA asks the National Academy of Sciences/National Research Council to periodically review minimal Animal Nutrient Requirements for assorted pet and livestock animals – case 2 below.

[20] Including cases 6, 9, 13, 14, 15, F1, F2, F3, F4, F6, X1, X2, X3, X4, and X5, below.
[21] Including cases 3, 7, 8, 10, 12, 16, F5, F7, and F9, below.

[6] EPA's drinking water safety program plans to review each of its drinking water standards every five years. [This is a new requirement that cannot be assessed yet.] See case 11 below.
[7] The EPA and industry support the Health Effects Institute's "Accountability Project," which will attempt to objectively assess the tangible progress made in improving air pollution in the US. [This is a new program that cannot be assessed yet.] See case 17 below.
[8] The Consumer Product Safety Commission [CPSC]'s program to select one existing rule each year for a retrospective evaluation. [This is a new commitment that cannot be assessed yet.] See case 18 below.

Of these eight instances of planned adaptation, it seems manifest that the EPA NAAQS program was by a large margin the most robust and instructive. The last three cases listed above are too new to evaluate. Two are small and technical in nature. And, as we will see, two others are limited in the difference they make in improving regulatory performance.

3. Did the selected cases result in adaptive public policy?

We have been focusing on input considerations -- on how the subject cases have been planned and executed. We also need to consider their outcomes, and whether the results amount to adaptive governmental behavior. To do this, it is useful to draw on the basic theory of feedback. The two necessary components of true feedback include *sensing* and *controlling* a process. [A common example of feedback is a room thermostat, which both senses current room temperature and controls the on/off switch for the room's air heating source depending on whether the room is above or at or below its target temperature.] For our application, the two essential functions are [a] post-hoc *assessment* – finding out what rule's actual effects are -- and [b] a decision whether, as a consequence, to *change* the rule. There should be, that is, both a *learning* and a *changing* function. Among our 32 candidate cases, we can identify 14 for which results can be accounted for.[22] Do they show both learning and significant changes as a result? Each of the 14 cases can be thought of as falling into one of three classes.

Category One –"Changing Policies without Really Learning First"

Three[23] of the 14 cases involve reported attempts to adjust past regulatory decisions, but without a serious effort to collect systematic data on such matters as whether the original estimates of benefits and costs are being realized in practice. The Department of Transportation, for example, reported[24] that it had shelved 70 regulations (never particularly claiming that any had been the cause of significant burdens or safety benefit). However, there is no indication that such changes were preceded by substantive evidence-gathering on actual impacts.

Category Two – "Learning Without Really Changing Policies"

Seven[25] of the 14 cases entail attempts to understand the actual effects (positive and/or negative) of past regulatory decisions, but without using that knowledge to improve things. The most visible of these efforts, perhaps has been OMB's series of national reports on the Costs and Benefits of Regulation.[26] These reports mandated by Congress, lay out the aggregate benefits [estimated at $3500 billion] and costs [about $200 billion] of regulation on

[22] Including the five cases of true planned adaptation were results have occurred, and the nine cases of non-systematic [one-shot] reviews of existing policy.
[23] Cases 7, 8, and F5, as described below.
[24] DOT – 70-regs cite
[25] Cases 4, 10, 12, 16, F7, F8, F9, as described below.
[26] Costs of Regulation

the US economy. These reports have, undoubtedly, many merits [its detractors, however, fear that its ultimate purpose is to demonstrate the workability of a regulatory budget[27]], but at this stage the systematic scrutiny and correction of faulty past cost analyses is not one of them. Similarly, the Office of Management and Budget's requested nominations from the public of federal rules in need of change, and received nominees, but did not proceed to re-assess the merits and costs of the nominated rules.[28]

One form of government learning is demonstrated by the interactions between EPA and the National Research Council relating to the health effects of ionizing radiation. EPA funds fresh studies of the extent of exposure to ionizing radiation, and of how exposure relates to health response. However, the results of this stocktaking has not led to regulatory changes. Among the more interesting cases of *post hoc* review is one that, while not expansive in scope, is pertinent here. . . the Post Hoc Review Program of the National Highway Traffic Safety Administration[29] This relatively modest program addresses the actual safety impact [but not normally the costs] of selected NHTSA rules. For example, this program has conducted a *post hoc* assessment of the NHTSA rule requiring a third ["high, centered"] tail light for passenger vehicles. The assessment examined 200,000 crashes and determined that the rule has had a positive effect. Personnel in the program – mostly engineers – do not see rule *modification* as a primary goal of their work, and did not report instances in which a review led to rule change. [Still, it would be helpful to be able to explain why this agency, rather than agencies with higher profiles, seems to show such a keen interest in knowing what its actual impacts are.]

Category Three –"Learning and Consequently Changing Policies"

Four[30] of the 14 cases appear to meet a full definition of regulatory feedback: the Air Quality Standards program of EPA, the periodic review of radiation effects, the review of RDAs, and the review of animal nutritional requirements. It is noteworthy that all four of these involve standard-setting, not rulemaking; that is, each of them results in the critical review of scientific and other knowledge to determine whether a standard – e.g., the concentration of an air pollutant deemed to be substandard – is still valid. But none of them deal with changing the means of regulating private actions to achieve those standards. All four cases also involve the National Academy of Sciences/National Research Council.

4. EPA's NAAQS Program: A Possible Model of Planned Adaptation?

It is the EPA NAAQS program that is by far the most interesting of the four cases of actual planned adaptation. In this program, knowledge assessments are performed periodically, and they are routinely linked to policy adjustment in the US air quality program. If one believes that US regulatory policy ought to be cybernetic in nature, the program is worth a good look for lessons learned.

Air quality is regulated by EPA under the Clean Air Act. For each of six named air pollutants [e.g., particulates, NOx, carbon monoxide] EPA sets National Ambient Air Quality Standards – NAAQS – and then issues rules on sources of emissions o reach those health-based ambient levels. The Act requires that each of these six standards be subjected to fresh scientific reviews every five years to ensure that they reflect the latest scientific

[27] This proposal could lead to the setting of a cap on the overall costs of US regulation, under which new rules would be permitting only if compensating relaxation were made in existing rules.

[28] OMB

[29] NHTSA evaluation office

[30] Cases 1, 2, 3, and 5, described below.

understanding. To do this, EPA staff prepares a new "criteria document" on a pollutant and then a group of outside specialists reviews the document. This review is managed by the Clean Air Scientific Advisory Committee [CASAC], which is housed in EPA's Science Advisory Board – at some organizational distance from the agency's air office, which regulates air emissions.

Is the NAAQS program effective in keeping policy and knowledge in synch? Measured against apparent Congressional expectations, it shows obvious imperfection. After 25 years of experience, for example, only 12 reviews were tackled by EPA (6 of them forced by the courts following lawsuits) when strict adherence to the 5-year deadlines for six pollutants should have produced 30 such reviews. However, that is 12 more reviews than most other regulatory programs have accomplished. Furthermore, 6 of the 12 completed reviews resulted in some adjustment of the associated health standard . . . some of them tightening the standard and some of them loosening the standard.

Furthermore, the NAAQS review program has evolved so as to provide, over time, new scientific findings that assessors have deemed important in order to fill gaps in knowledge. This has happened in two ways. First, CASAC is required under the Clean Air Act's section 109(d)(1)(2)(c) to "advise the [EPA] Administrator of areas in which additional knowledge is needed."[31] Second, in the case of airborne particulates – arguably the most important single pollutant, whether measured in regulatory costs or in health benefits provided – EPA has asked the National Research Council to regularly review EPA's own substantial research efforts in light of existing knowledge gaps.[32]

Thus, the key elements of a formal feedback system are in place: key research gaps are routinely identified, new research is commissioned, and new findings are examined as a routine part of de novo reviews of regulatory standards. It is interesting to see that this mechanism gives discrete roles to outside scientific groups – the NRC and EPA's CASAC. The reader should keep in mind that the governmental sector covered in this paper, and in these cases, is that of environmental health and safety regulation. It may be that other sectors show quite different patterns.[33]

[31] CAA 109c cite

[32] NRC air reports [add cites]

[33] In fact, it would appear that the general area of accident prevention for transportation is more adaptive. One can only be impressed by the vigor with which the Federal Aviation Administration and the National Transportation Safety Board hunt down the causes of accidents and amend their policies to prevent recurrences. The regulation of pharmaceuticals is also an interesting sector to think about. FDA oversees a post-marketing surveillance program to identify hazards that were not anticipated when it approved new drugs; however, recent headlines concerning Vioxx and other drugs raise doubts about the effectiveness of that attempt at planned adaptation.

B. US DOMESTIC POLITICS OF ADAPTATION

1. Past Government-Wide Attempts to Foster Adaptaton, 1946-2004

The first traces of apparent interest in adaptation go back six decades. Most regulatory actions are governed by the terms of Administrative Procedure Act [APA] of 1946, as amended, that appear in the U.S. Code [See **Case F1**.**]**. The APA makes it clear that affected parties have "the right to petition for issuance, amendment, or repeal of a rule," [34] and imposes upon the agencies an obligation to either conduct the requested review or to promptly explain why the petition is to be denied.[35] Thus, the APA makes clear that, if an argument for adapting an existing rule can be made, the relevant agency must take it seriously.

This route to relief, however, has apparently been used only rarely. It is generally believed that petitions for reconsideration of existing rules [or, in fact, consideration of new rules] are futile, because petitioners bear a heavy burden of showing cause[36], and agencies will routinely deny them. [There was, however, a 1987 appeals court ruling that required such a review in one interesting case,[37] however, it does not appear that that case has led to a discernable increase in such petitions.].

President Carter issued Executive Order 12044 in March 1978. [See **Case F2**.] The order is now perhaps best remembered among regulation-watchers for requiring a "Regulatory Analysis" for all major regulations in development. However, its Section 4, titled "Review of Existing Regulations," required that "agencies shall periodically review their existing regulations," selecting some for a fresh look [a review that was to use the general procedures in place for issuing new rules], depending among other things on the length of time the rule has been on the books and the extent to which knowledge and other factors have changed since then. There is no indication that agencies complied with Section 4, or that the Carter Administration insisted on compliance.

Shortly after the inauguration of Ronald Reagan as President, the new Administration issued Executive Order 12291, which solidified OMB's role in the formal Executive Branch reviews of new rules before they are issued by agencies. [See **Case F4**.] While the new order revoked the Carter order, its section 3(i) directed agencies to:

> "initiate reviews of currently effective rules . . . and conduct Regulatory Impact Analyses of currently effective rules. The Director, subject to the direction of the [Vice President's regulatory] Task Force, may designate currently effective rules for review . . . and establish schedules for reviews.[38]"

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[34] 5 USC, 553(e). In the 104th Congress [1995], Senator Dole introduced S. 343, [later amended by Senators Hatch and Grassley] which sought to reinforce the post hoc petition process, especially for major rules, and provide deadlines within which agencies should examine the costs and benefits of the targeted rule. Citizens also, of course, have a First Amendment right to petition the government.

[35] 5 USC, 555(e).

[36] In 1979, the DC Circuit had held [*Geller v. FCC*, 610 F.2d 973 [DC Circuit, 1979]] that "an agency may be forced by a reviewing court to institute rulemaking proceedings if a significant factual predicate (emphasis in original) of a prior decision . . . has been removed." In 1985, the Supreme Court seemed to say that while court reversals of agencies' decisions to deny petitions should occur "only in the rarest and most compelling of circumstances," but specifically excluded rulemaking petitions from its ruling. See Heckler v. Chaney, 470 US 821 (1985).

[37] See American Horse Protection Association, Inc. v. Lyng, 812 F. 2d 1 [D. C. Circuit, 1987], as discussed in Jeffrey S. Lubbers, Unpublished Presentation on Petitions for rulemaking, Animal Law "Conference, American University (April 17, 2004), copy on file with the author at American University. In this case the USDA declined to revise an existing rule on the humane treatment of horses, despite the results of a study sponsored by USDA itself that concluded that the rule ignored a type of device that causes lesions and bleeding. On appeal, the D. C. circuit found that USDA's denial of the petition was arbitrary and capricious, and directed USDA to undertake new rulemaking on the matter.

[38] Executive Order 12291, February 17, 1981; 46 FR 13193.

There is no indication that this provision was enforced.

In January 1992, President George H. W. Bush issued a Presidential memorandum that imposed a 90-day moratorium on the promulgation of new rules. [See **Case F5**.] Bush also directed each agency to use that 90 day period to evaluate existing regulations with an eye toward eliminating unnecessary burdens.[39] It was this action that seemed to stimulate the American Bar Association and the Administrative Conference of the U.S. to commission work on "look-back" provisions for existing rules.

Less than two years later, President Clinton issued Executive Order 12866, Regulatory Planning and Review. [See **Case F6**.] Its section 5, called "Existing Regulations," requires each agency to submit a plan to OMB:

> "under which the agency will periodically its existing significant regulations to determine whether any such regulations should be modified or eliminated."[40]

In March 1995, President Clinton added to the reform tasks in Executive Order 12866, directing agency heads to [among other things] "conduct a page by page review of all of your agencies now in force and eliminate or revise those that are outdated . . . [41]" He thus virtually repeated the Bush requirement of 1992, giving agencies about 90 days to conduct a dragnet of all their existing rules.[42]

More recently, the Republican Congress has added its voice. Public Law 104-208, a 1996 appropriations act that covered general government accounts, was primarily intended to require the Office of Management and Budget [OMB] to assemble a comprehensive report on the costs and benefits of U.S. regulation. [See **Case F8** and **Case F9**.] However, it also contained as its section 4 a directive for:

> "recommendations from the [OMB] Director and a description of significant public comments to reform or eliminate any Federal regulatory program or program element that is inefficient, ineffective, or is not sound use of the Nation's resources."[43] OMB duly requested and received suggestions from the public on such program elements.

Congress has, on occasion, dictated a review of particular rules in particular agencies. In 1994, for example, it passed the Community Development and Regulatory Improvement Act, which required the Fed, FDIC, and two other financial regulators to "conduct a systematic review of their regulations and written policies to improve efficiency, reduce unnecessary costs, and eliminate inconsistencies and outmoded and duplicative requirements."[44] A year

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[39] January 28, 1992: from http://bushlibrary.tamu.edu/papers/1992/92012805.html. Some agencies later told an ABA committee that the lack of time to conduct this sweeping review greatly undercut its value.

[40] Executive Order 12866, September 30, 1993.

[41] "Regulatory Reinvention Initiative," a memorandum to heads of departments and agencies, March 4, 1995.

[42] President Clinton later reported that 16,000 pages of outdated rules were to be eliminated after regulators had reviewed 86,000 pages of their rules, and the Administration also announced that agencies planned to "reinvent about 40% of their rules to conform to a new regulatory spirit of trust and cooperation." [National Partnership for Reinventing Government, Reinvention Express, volume 1 number 11 (July 5, 1995).] I have as yet been unable to locate the specifics details of final outcomes of these plans.

[43] Public Law 104-208, section 645(a)(4), 1996. Later, a bill co-sponsored by Senators Thompson [R-Tenn] and Levin [D-Mich], the Regulatory Improvement Act of 1997 [S.981], included a requirement that each agency establish an advisory committee every five years to oversee the review of existing rules. The committees were to identify a list of rules that might be revised to substantially increase net benefits. Each committee was to comprise a "balanced cross-section" of public and private interests affected by the agency program.

[44] 103 PL 325, 108 Stat 2160 (September 1994), codified at 12 USC sec 4803(a). The four agencies issued reports on their implementation efforts in September 1996 and August 1999, the latter under the title Joint Report: Update on Review of Regulations and Paperwork Reductions (August 5, 1999.

later the Senate passed S. 333, the Risk Management Act of 1995,[45] which proposed to require the President to issue a directive mandating that each agency set up an external advisory committee to oversee "both the review and revision of existing risk assessments," and to receive petitions from the public on rules that need attention.

Most recently, it appears that a new initiative, OMB's Program Assessment Rating Tool [PART] program[46] may lead to some regulatory reviews. The current Bush Administration began to make annual PART reviews of each agency. [See **Case F7** and **Case 18**.] In response, the Consumer Product Safety Commission has inaugurated a pilot study that will lead it to review one rule in each of its enabling statutes.[47].

Whatever else one might think about the actual *impact* this series of inducements,[48] one has to admire the constancy of the emerging common theme -- that it certainly would be good if regulators would pay attention to the viability of rules that are already on the books. These broad exhortations cover five decades, both major parties, and the entire succession of four Presidents – two Democrats, two Republicans -- from Carter to Clinton. It is also noteworthy that all of the four Presidential actions are exceedingly ambitious; they require, roughly, a complete scan of the many thousands of pages of regulations, and in case of the 1992 Bush order, expected this *tour d'horizon* to be completed in about 65 working days.

At least two states have targeted their existing rules for fresh review. California's Office of Administrative Law is tasked under California's Code section 11349 to conduct reviews of existing rules upon request by the Legislature. The provision's requirements include a short deadline for each review and for formal agency appeal when their rules are marked for review.[49] In 1998, the Commonwealth of Virginia's Governor James Gilmore, observing that "regulations should not be perpetual," required that new Virginia regulations unfailingly a specific review date and a set of goals that can later be evaluated.[50]

The General Accountability Office [GAO] has been one source of continued interest in *post hoc* assessments. An example was its 1999 review, "Assessing the Impacts of EPA's Regulations through Retrospective Studies."[51] GAO reported that EPA rarely looked back at costs: "According to EPA, the agency issued 101 economically significant regulations from 1981 through 1998, and only five of these have been the subject of retrospective studies. Of the more than 2600 environmental regulations issued during this period that were not economically significant[52], but 23 were the subject of retrospective studies.[53]" Noting that EPA had found it appropriate to spend $43 million on *prospective* estimates of regulatory

[45] See Senate Report 104-087 -- Department of Energy Risk Management Act of 1995. The Congressional Budget Office estimated that compliance with the review requirements of S. 333 for all affected agencies "would probably range from $20 million to $40 million annually"

[46] PART, it is claimed, is meant to build upon the long and complicated history of work under the Government Performance and Results Act on 1993 [PL 103-62], a bipartisan effort to focus attention on policy outcomes across the entire federal landscape.

[47] CPSC 2004 Budget and Performance Plan, March 2004, page 94. It is not known at this point if OMB's PART effort has recommended similar initiatives in other regulatory agencies.

[48] The preceding list of initiatives omits the Regulatory Flexibility Act of 1980 [5USCode section 601 ff], which calls for: "the review of all such agency rules existing on the effective date of this chapter within ten years . . . and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule." [5 USC, 610(a)]. This requirement is a narrower one, and is restricted to the rule's impact on small business, and does not call for a review of the rule's overall effectiveness.

[49] California Code 11349.7.

[50] Virginia Executive Order 25 (1998).

[51] Report GAO/RCED 99-250, September 1999.

[52] That is, they fell below the federal cost threshold for the rules with highest impact– LM

[53] Ibid, page 3.

results for its significant rules, GAO apparently pressed the agency as to why *retrospective* studies of actual results were so rare. "Program officials told us that they had limited discretionary funds and resources and needed to use them in developing new regulations."[54]

2. How Effective Were these Government-Wide Measures?

What have been the *results* of these attempts to focus on regulatory outcomes? Unfortunately, a definitive answer is not readily found. Writing of the most visible reform in this area, regulatory economist [and Bush Administration official] Murray Weidenbaum was later to observe that "it is difficult to pinpoint specific changes that resulted,"[55] from this whirlwind Bush Administration review of 1992. The general view appears to be that not much of importance has come out of any of the efforts – not least because of a lack of follow-up on the part of the series of promulgating authorities. In fact, the best evidence for that proposition may be that the same basic idea has been raised again and again over the years, with each reform proceeding in the apparent belief that the preceding initiatives fell far short. Of the cases of planned adaptation that are surveyed in this paper, none appears to have stemmed from this series of Presidential initiatives.

Planned adaptation, then, has attracted an exceedingly peculiar constituency. As a general proposition, is has considerable appeal, and it is a concept whose potential benefits are, evidently, easily understood. However, it has never developed a sustained or strong backing from any specific group. In general, we can infer that the demand for self-corrective mechanisms in American regulation is peculiar: it seems popular as a general principle, but is as yet unpopular in application. Thus, an Administration's leaders might lean toward it, but its agencies, mostly, do not. It is worth briefly exploring some simple conjectures about why that is.

The broad appeal of the concept seems to be political in nature. Proposing the broad concept – e.g., the Bush 90-day review, the Clinton Executive Order – shows voters that an Administration is supporting a common-sense means to curtail regulatory excess . . . and an acknowledgement that potential excess is to be found as readily in the large mass of existing rules as it is in the thin edge of new regulations under development. Furthermore, a broad review mandate is a measure that can be readily explained as neither pro-industry nor pro-regulation – it's just good government. On the other hand, active follow-through and enforcement appears to be much less attractive, politically, because specific interests feel threatened.

3. Apparent Obstacles to Planned Adaptation

a. Regulatory Opposition: Perhaps the dominant simple explanation – what would pass as today's conventional wisdom on the subject among those who follow regulatory policy -- for the scarcity of adaptive mechanisms is that the regulators themselves just don't like them. There is, obviously, some merit in this claim; and it is fair to say, at this point in our project, that no agency has enthusiastically promoted the idea of installing substantive self-correction measures, even for isolated policy areas.[56] Congress, OMB, courts, regulated interests, and non-government activist groups have often induced policy changes in agencies for which agencies themselves have had little enthusiasm.

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[54] Ibid, page 11.

[55] Weidenbaum, "Regulatory Process Reform from Ford to Clinton," Regulation, vol. 20, no. 1.

[56] As detailed below, two current programs that come closest to serving as counterexamples are the NHTSA evaluation program and the air standards program of EPA.

And what is seen as the basis for agency opposition? A common view, perhaps, is that public bureaucracies always prefer the status quo to new ways -- that they are bound by red tape -- whether because of simple laziness or a pusillanimous fear of the unknown. While it would be difficult to disprove this suggestion, many close observers of regulation would dismiss it as simplistic. There are, in fact, creditable reasons to value stability in policy. One major influence is the need to render regulations enforceable. If an agency regards a rule as effectively permanent, some potential enforcement disputes can be avoided. (Consider what might happen, for example, if highway signs read "SPEED LIMIT 55 MPH, PENDING REVIEW IN JUNE." Would drivers continue to see a legitimate basis for the speed limit? Would those who are cited in May for traveling at 63 MPH feel abused if the review later relaxed the limit to 65 MPH?) A public acknowledgement that rules are based on incomplete or actively-evolving findings can obviously undermine its credibility and compliance.

An argument that the agencies themselves have raised as a reason not to question existing rules seems less persuasive: that such a program of review would divert analytic and other administration resources away from the writing of new rules. Whether an agency's effort should be devoted to setting new targets or to re-setting old ones is, it seems obvious, a matter of case-by-case decision. An argument against adaptation lacks logic. To conclude that the public benefits more from establishing every new rule than from adjusting any existing rule is dubious – especially if one feels that the agencies have, in the past, reliably tackled the rules that bring the largest benefits [and which thus allow large costs]. It is hoped that later phases of this project, by examining a set of actual cases, can shed additional some light on actual agency motivations.

b. Grass Roots Indifference? But a larger mystery, perhaps, is found in the attitudes of interested and affected parties[57] toward the adjustment of existing rules. Here again, the broad record is plain: with minor exception, we find below no outside support for introducing adaptation routinely into regulatory decision making. Why is this? One might expect regulated interests and their usual opponents (public-interest advocates) to form a natural constituency favoring the re-visiting of existing rules. It must be common, for example, for contending parties to feel that a regulatory agency has reached the wrong conclusion in writing a new rule – the prevalence of court appeals of new rules being a good indicator. Shouldn't, therefore, such aggrieved interest groups favor both the systematic gathering of new evidence on the actual costs and benefits of the rule and the subsequent reopening of what seems to be a flawed decision? Partisan groups on all sides typically spend heavily to convince regulatory agencies to decide in their favor; why don't they devote effort to correct old rules that they think are not working right? Perhaps they should, but they don't. And why don't they?

Here again, we look to further analysis of our cases we examine will elucidate this question. A possible answer (at least for corporate bodies) is that policy stability is so highly valued: "better a stable bad rule than a better one that is constantly changing." One primary function of the business organization to is to control, to the extent possible, perturbations in their operating environment. Does this imperative outweigh the pain of existing regulations that they see as unfair or arbitrary? Should it? But the silence of other partisans is a different matter. Environmental and consumer groups do not have profit-and-loss statements that may be affected by constant regulatory change. One can speculate about why they do not press

[57] These groups are called "stakeholders" in some circles.

for the modification of existing rules. Perhaps they feel that they receive more support from their constituents – membership dues and donations need to be maintained – for joining new battles than revisiting old ones.

Interest Group Process?

One more hypothesis can be advanced to account for the apparent paradox that groups seem to express their self-interest more acutely for prospective rules than for existing one. It relates to the logic of participative government – the inherent rules of the game. The dominant mode of policymaking in the regulatory sphere is notice-and-comment rulemaking, as laid out in the Administrative Procedure Act. The APA specifies that under this process, an agency can make a regulatory decision only after a period structured public discussion. An agency thus publishes a proposed rule, invite comments on it, and then consider those comments before reaching a decision. In essence, then, an agency is expected to manage a formal consultative process that collects and considers arguments from the whole range of interested and affected groups. Unless it handles this process carefully, it could invite later court reversal of their eventual decision as measured against the "arbitrary and capricious" standard used in for judicial reviews.

While it is clear that these sometimes quite elaborate, lengthy, and expensive preliminaries involve a consultative process, and not a consensus process, in reality they take on some aspects of negotiation. And that, of course, means that implicit "deals" are necessarily made. The phrase that comes up in such policy consultations is, commonly, "can you live with this?" So agency staff might approach an important trade association that has scorned some draft proposal A in order to suggest a compromise proposal B, one that might already have been vetted with other vocal groups. The real point is to determine whether the association's members "can live with" the compromise.

Now the question for us is what might be implied in a "yes" - either given explicitly or by the absence of a vociferous "no" - at this point.[58] Does it mean that, while the association isn't very happy with proposal B, it will go along with it – and forgo carping, forgo appealing the outcome to the Congress and/or higher authorities in the Administration -- if the agency promulgates it as a formal rule? And if so, does it imply that the association will *never* work to undermine the rule, in perpetuity? Is this why the publics that surround the agencies, and that spend so much effort trying to get favorable new rules issued so rarely seek redress unfavorable old ones?

C. INTERNATIONAL AGREEMENTS WITH PROVISIONS FOR UPDATING

Elements of "planned adaptation" are features of some international regimes. This section of the paper will consider two past examples and one prospective example of institutionalized mechanisms for reappraising scientific knowledge and updating policies. First, the European Union "TSE Roadmap" case represents a clear instance of planned adaptation, with a scheduled review of evidence leading to changes in policies. Second, UN Security Council Resolution 1441 was an explicit agreement to acquire information on the status of chemical,

[58] One might surmise that at this stage in a consultation, the answer might take the form "well, we don't really like Proposal B, but we think we could live with it *if you commit to taking a hard look later to seeing if it's really hurting us, and we can be part of that later review."* It seems manifest that such offers are either never made or never accepted. One would like to fully understand why.

biological, and nuclear weapons in Iraq and to revise and update policy accordingly. Third, a short prospective case on the WTO and GM crops raises the possibility of negotiating international agreements to gather information on risks and benefits where no convergence on priors exists. These three cases represent no more than plausibility probes on planned adaptation in international regimes, and should eventually be supplanted by a more systematic survey of cases.

1. Planned Adaptation as a Means of Managing Fights over Precaution

Substantial uncertainty over environmental and health risks precludes easy judgments on the legitimacy of regulatory differences. Governments will differ in their priors on environmental, health and security risks and in their inclination or disinclination to invoke precaution. David Gee of the EU Environment Agency notes that "… the absence of proof of harm is not proof of absence of harm" to argue for invocation of precautionary principle with respect to health effects of estrogenic compounds and GMO foods. Donald Rumsfeld of the US Department of Defense observed that "the absence of proof is not proof of absence" as he argued for war against Iraq to eliminate possible chemical and biological stockpiles and nuclear weapons programs. To expect agreement up front on the legitimacy of precaution in such cases is unrealistic. Our focus should not just be on how to incorporate information on science and technology into initial decisions, but also on how initial decisions might be revised in the face of new scientific and technical information elicited by regulatory experiments.

The case for precaution is defended most systematically in the European Environment Agency report on *Late Lessons from Early Warnings: The Precautionary Principle 1896 to 2000.* This report offers twelve well documented cases where early but inconclusive warnings on environmental and health risks were ignored until after enduring harms were done. Studies on benzene, lead, PCBs, CFCs, MTBE, and other hazards focus on a combination of industrial resistance to regulation and scientific review processes weighted to filter false claims on causal links on risks. This creates a bias for generation of false negatives within the regulatory process, a bias that results in fatal delays in action. *Late Lessons from Early Warnings* suggests that the precautionary principle offers an offset against these biases. Regulators should act before conclusive proof exists but after there is reasonable evidence on the existence of harms because harms are often irreversible. The case for proof before action has been made by analysts ranging from John Graham to Harvey Sapolsky. They cite cases where costly regulations addressed exaggerated or nonexistent risks. Their studies on alar, breast implants, saccharine, and food irradiation suggest that regulatory bureaucracies, the tort system, the media, and mass psychology of risk perception are weighted heavily to amplify fears of environmental and health risks. This creates a bias for generation of false positives within the regulatory process, a bias that often results in acceptance of costly regulations that lock into place. Insistence on proof before action offers an offset against these biases. Regulators should not act until after there is conclusive proof of harms, because regulatory actions are often irreversible.

The fight over precaution is intense because both sides of this debate are correct in their basic claims. The problems they identify coexist, but do not offset each other to produce evaluative neutrality, efficiency, or fairness.

First, up front uncertainty ensures that many regulatory choices with enduring consequences will be in error. The choice between precaution and proof before action is a choice between minimizing either Type I or Type II errors.

Second, up front uncertainty ensures that it will be difficult to appraise the sincerity of those that invoke precaution and those that insist on proof before action. Because one cannot differentiate between sincere and insincere adversarial statements of priors on serious and irreversible risk, defense of precaution or insistence on proof before action.

Third, back end irreversibility fuels up front fights. The prospect of irreversible harms and irreversible costly policies leads to exceptionally intense fights over policies up front. Near term battles over application of precaution are effectively battles with enduring consequences.

The combination of inevitable error, suspicion of motives, and enduring consequence of error does not portend well for disputes over precaution.

The fight over precaution is also fueled by the misconception that the EU favors precaution while the US favors proof before action. Although this is true for many current controversies, from EU acceptance of precaution on climate change policy, antibiotic use in animal feeds, estrogenic compounds, foods with GMO content, and cultivation of GM crops, on other issues the US accepts precaution while EU members insist on proof before action. Relative to the EU, the US federal government has favored precaution on cancer causing substances under the Delaney clause and on regulation of nitrogen oxides, while US states and locales have been leaders on the issue of second hand smoke. As the papers on EU and US particulates regulations by Arthur Petersen and Katherine Martin suggest, US standards on particulates are in practice more stringent than those of the US. On security issues, including export controls on technologies and war against states of concern with possible chemical, biological or nuclear capabilities, the US explicitly invokes precaution. The fight between the US and the EU is not over the precautionary principle per se. The fight is over applications of the principle in cases with differences in priors on risks and costs.

How can international conflicts over the invocation of precaution be mitigated, if not resolved? As argued above, initial regulatory choices may be constructively viewed as experiments that elicit information on risks, monitoring, mitigation options and side effects associated with regulation. One constant theme of this paper is that, under conditions of uncertainty, initial regulatory choices will typically be wrong and that initial policies will generate useful information on risks, costs, and public responses. The issue is how to use information from policies as experiments. Philosopher of science Carl Cranor has called for explicit attention to gathering "Precautionary Information," while ecologist Anne Myhr has recommended "Precautionary Motivated Science." In the literatures on integrated assessment, Lawrence McCray and James Foster of MIT, Warren Walker of Delft University of Technology, and Adnan Rahman, Jonathan Caves, Paul Davis, David Gompert and Richard Kugler of RAND urge greater attention to problems of adaptation. The spirit of this proposal is in line with their recommendations. A Bayesian analytic frame may used to attack information problems that make conflict over precaution intense:

* uncertainty over the probability and magnitude of substantive risks of harms; and
* uncertainty over the sincerity of the motives of those invoking precaution

The emphasis in most of the environmental policy literature is on integrated assessment up front, and it is manifestly appropriate to make systematic use of the best available information on risks and mitigation methods to improve the quality of decision making. Conventional approaches reduce uncertainty to estimates of probabilities of contingencies and estimates of values associated with contingencies, then postulate methods for identifying optimal initial policies given point estimates. By contrast, the sequential approaches stressed here cope with uncertainty by identifying strategies for eliciting information on underlying substantive phenomenon, by devising strategies to elicit information on the sincerity of statements by other actors, and by identifying and attacking impediments to the more effective utilization of information.

Past Case: European Union TSE Roadmap[59]

The European Union's evolving recommendations on BSE are an example of planned adaptation by an international organization. Member state policies and European Commission guidelines on BSE were established on the basis of scientific knowledge as it stood before 1995, with explicit invocation of the precautionary principle in the face of significant uncertainty. With limited information on the effectiveness of actions taken to limit spread of BSE among animals and humans, the Commission adopted stringent standards on testing, required removal of all Specialized Risk Material from beef for human consumption, implemented a ban on the feeding of mammalian meat and bone meal to cattle, sheep and goats (1994), adopted an even more stringent total EU wide suspension on use of processed animal protein in feed for any animals farmed for food production, and banned consumption of UK beef from cattle over thirty months old (OTM rule).

The Commission set up a systematic reappraisal of these policies, analyzing data derived from an extensive program of testing and reporting on BSE. In July of 2005, the European Commission issued a document entitled "The TSE Roadmap." Analysts had observed a decline in the number of cases of BSE in the EU from 2129 in 2002 to 850 in 2004 (Figure 1), a rise in the year of birth of positive BSE cases detected since 2001 (Figure 2), and a rise in the mean age of positive cases in healthy slaughtered animals (Figure 3). In addition, the Commission found that implementation of BSE requirements in Member States was improving. In effect, the Commission learned that the policies it had adopted earlier were working well, and that some relaxation in those policies was possible. The European Commission's package of near term recommendations for 2005-2009 included allowing use of central nervous system tissue from younger animals, possible use of some specialized risk materials including tallow, collagen, and gelatine, and reductions in numbers of animals tested. The Commission is now considering lifting the requirement banning consumption of beef from UK cattle aged over 30 months at slaughter and beef from the UK with bone in.

[59] European Commission, "The TSE Roadmap," Brussels, 15 July 2005, COM (2005) 322 Final; and interviews with Elizabeth Saunier (AFSSA France), Jean-Philip Delys (CEA France), Danny Matthews (Weybridge Veterinary Laboratory, England), Connie Lasmézas (Scripps) 2004 and 2005.

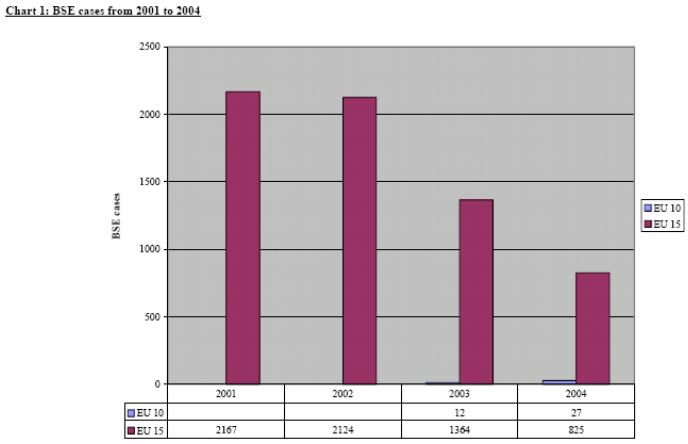


Chart 1: BSE Cases 2001-2004

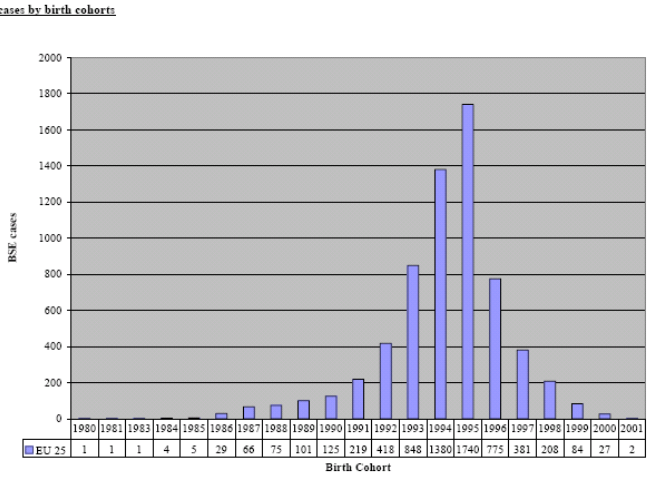


Chart 2: BSE Cases by Birth Cohert

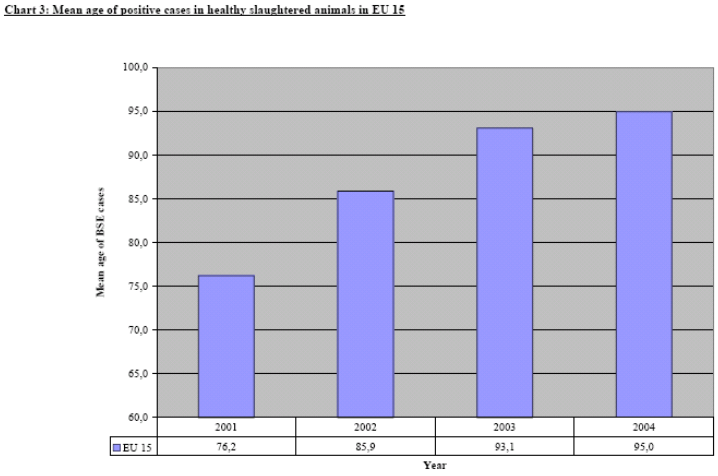


Chart 3: Mean Age of Positive Cases in Healthy Slaughtered Animals

In the words of the European Commission in the TSE Roadmap:

> Different factors indicate a favourable trend in the BSE epidemic and a clear improvement of the situation over the past years due to the risk reducing measures in place. The goal for the coming years for the TSE Regulation is to ensure a relaxation of the measures while assuring the high level of food safety introduced through the TSE controls over the past 10 years. The relaxation of the measures should be risk based and reflect advances in technology as well as evolving scientific knowledge and would also have a positive impact on the competitiveness of the industries and farmers involved within the Community.

This case represents a riposte to predictions of "lock in" following invocation of precaution. The combination of data from systematic observations on the changing incidence and age distribution of the disease and panels of national experts organized under the aegis of the commission permitted significant reversals in policy.

3. Past Case: UN 1441 and Iraq Weapons of Mass Destruction

The year 2003 was marked by disagreement over the Bush administration's call for preventive war against Iraq, with Britain and the United States in conflict with France, Germany, China and Russia. The combination of Iraq's history of production and use of chemical and biological weapons and the absence of international inspections in the period 1998-2002 created genuine uncertainty over the status of Iraqi unconventional weapons programs. This uncertainty was consistent with a wide range of plausible projections, from a worst case on possession of chemical and biological weapons and active efforts to develop nuclear weapons to a best case of inactive programs and with no stockpiles. The security risks posed by possible Iraqi possession of weapons of mass destruction were not the only area of uncertainty. The sincerity of US invocation of the precautionary principle as a justification for war, and the sincerity of French and German requests for proof before possible military action were also matters of controversy. These mutual suspicions were amplified by pstatements of the parties, particularly Bush administration declarations of intent to engage in war against Iraq and with French and German criticisms of such war.

UN Resolution 1441 may be viewed as an information harvesting strategy that yielded information on these two key areas of uncertainty: (a) the status of Iraq chemical, biological, and nuclear programs; and (b) on the sincerity of statements of motive by the governments of the US, France and Germany as well as Iraq. In essence, the parties were unable to agree on the nature and magnitude of the threat from Iraq, but were able to agree on an UNMOVIC and IAEA inspections strategy that reduced zones of uncertainty over the substance of WMD threats and the sincerity of American and European commitments to the UN process. Ironically, one reason why the parties were able to agree on UN 1441 was because of differences in their priors. At the time that agreement on UN 1441 was reached, President Bush honestly believed that UN inspections would yield active programs and weapons stockpiles while President Chirac may well have viewed the resolution as preferable to the alternative of immediate war.

Based on analysis of Iraqi declarations, the results of inspections, captured documents, and analysis of manifests, IAEA Director El Baraidi reached the conclusion that there was no active nuclear program. UNMOVIC Director Blix gradually altered his priors on the presence of weapons programs and stockpiles. His inspectors found no evidence of an active biological weapons program and no evidence of an active chemical weapons program. With respect to possible stockpiles of old mustard gas, sarin and other chemical weapons produced before 1991,

Blix and his team were working to reconcile inconsistencies between the Iraqi Declaration of weapons produced, weapons expended during the Iraq-Iran war, weapons destroyed and weapons unaccounted for. Blix and his inspectors acted on numerous US intelligence tips on the ostensible location of known active chemical and biological weapons sites, but found that none of the US tips checked out. As the inspections continued and Saddam shifted from obstruction to cooperation, Blix concluded that Iraqi capabilities were at most limited and called for continuation of monitoring and verification to address remaining areas of uncertainty. In effect, UNSC 1441 was a vehicle for planned adaptation, with a commitment by all parties to gather information and to use that information as a basis for planning next steps. And the monitoring and verification conducted under UN 1441 auspices gradually eroded presumptions on the existence of nuclear, chemical and biological programs and weapons in Iraq.

UN 1441 also generated information on the sincerity of statements by the US, Germany and France as well as Saddam. Had inspections revealed active chemical, biological or nuclear programs, or concealed stockpiles of chemical and biological weapons, or had Saddam continued to obstruct the inspectors, then UN 1441 would have tested French, German and Russian statements of willingness to act on proof. In fact, with Iraq cooperating and with inspections suggesting strongly that the pre-inspection worst case was wrong, UN 1441 tested the sincerity of Bush administration statements expressing support for the provisions of UN 1441. As UN monitoring and verification eroded the WMD case for war, the Bush administration moved to terminate the UN inspections. When President Bush issued a 48 hour ultimatum calling on Saddam and his sons to leave Iraq, he also warned international journalists and UN inspectors to leave Iraq before the war began. The Bush administration's termination of inspections before UNMOVIC could further erode the case for war suggest that his invocation of precaution as a justification for war was insincere.

4. Prospective GMO Case: Precaution and Adaptation Beyond the WTO Panel Decision

The recent WTO Panel decision on EU denials and delays in approval of GM foods and crops does not resolve rather fundamental differences between the US and EU over the characterization of present states of knowledge over risks and over what actions should be taken to reduce uncertainty. Disagreements over the relationship between proscribed actions and environmental, health and safety risks sit at the core of difficult to resolve trade disputes. The WTO dispute settlement procedures sometimes take the form of knowledge appraisal mechanisms that pass judgment on the plausibility of claims that underpin regulations, with updating based on available evidence.

(a) Uncertainty reduces the effectiveness of formal dispute resolution approaches that are predicated on the ability to differentiate between bona fide and illegitimate regulations. Appeals to scientific risk assessment as the sine qua non of dispute settlement do not work well in settling conflicts on issues where the precautionary principle is invoked and supported in a systematic manner.

(b) In instances where conflicts over invocation of the precautionary principle in the presence of uncertainty intense, this section suggests that a combination of updating strategies with commitments to modify regulations as information comes in may ameliorate conflicts over precaution.

The WTO GMO panel decision should be viewed in context. Conventional wisdom in environmental circles holds that the WTO has been all too willing to sacrifice domestic environmental regulations to defend an open global economic order. An initial examination of WTO panel findings would appear to support that conclusion. WTO panels ruled against provisions of the US Clean Air Act and US rules protecting sea turtles, struck down EU, Australian, and Japanese environmental regulations on Bovine Growth Hormone, salmon importation, fumigants and GMO foods. With the single exception of the asbestos case, the outcomes in these cases did not favor domestic environmental regulations. Under conditions of limited uncertainty in the BGH, salmon, fumigant cases and more substantial uncertainty in the GMO case, WTO panels leaned against invocation of the precautionary principle. The reasoning used by the WTO panels in all but the GMO decision appear to us to be unproblematic.(See Appendix 2: WTO Panel and Appellate Rulings in Environmental Cases). The merits of the WTO panel decision striking down EU policies on GMO crops remain controversial within Europe and North America.

Could planned adaptation strategies offer a potential route beyond the impasse? Consider the conflict between the US and the EU over GM foods from an information harvesting perspective. We suggest that information yielded by divergent regulatory experiments in the US and EU should be used systematically to update US and EU priors on this issue.

The EU is running a program of monitoring without much experimentation. The EU set up a model program for identifying and analyzing the environmental effects of GM crops and the health effects of GM foods. The elements include careful validation and testing of detection methods, a model Preliminary Standard Action Protocol, a requirement for submission of samples to develop and validate tests, strict labeling requirements to warn of health concerns, and documentation requirements that will allow traceability of inputs and outputs in the event that problems develop. But with only 10,000 hectares of GM crops under cultivation and very limited GM approvals in the past five years (BT-11 in May 2004), the extensive EU program of monitoring cannot yield much useful information.

The US is running a program of experimentation without monitoring. With over 40,000,000 hectares of GM crops under cultivation and over 56 products approved, the US is conducting an experiment on a grand scale. Yet the US has a weak program for monitoring effects, with limited validation of detection methods, no labels of content for health concerns, limited documentation with negligible tracing potential, and extremely limited means of monitoring compliance with what can only be described as lax regulations. With such limited monitoring, the likelihood of US early detection and analysis of health or environmental problems if they develop is small.

The mismatch here is obvious. The EU is acting on a prior of substantial risk to environment and health, with highly restrictive limits on crops and with careful monitoring. The US is acting on a prior of negligible risk to environment and health, with lax limits and minimal monitoring. Starting from these priors, the US and EU cannot agree on what policies on certification make sense. But can the US and EU agree on a planned adaptation strategy that may yield useful information on substantive environmental and health effects and on the sincerity of statements of belief? Specifically, could the EU and US agree to a program of transplanting EU

monitoring methods within the US, and to modify EU and US policies on approval of products in light of information harvested by monitoring? An agreement on monitoring and contingent agreement on how to act on information produced may be more feasible than any up front agreement on substance.

Europe and the United States could proceed with sensitivity to the manifest need for regulatory experimentation and flexibility, by fostering the development of domestic regulations to make effective use of new information in a manner compatible with WTO standards. The central challenge in the period ahead is to manage the tension between improving the capacity of domestic regulators to make the best possible use of information gleaned by regulatory experiments and strengthening international mechanisms for minimizing trade distortions associated with differences in domestic regulations. An international agreement such as proposed above could represent a step in that direction.

D. INTERNATIONAL POLITICS OF ADAPTATION

In practice, securing access to information associated with regulatory experience and making use of that information to update international regimes may be impeded by a set of interlocking problems.

1. Institutional Arrangements and Incentives to Reveal and Conceal

The design of domestic regulatory institutions and international regimes should take account of incentives to reveal or conceal information. Unfortunately, domestic regulatory systems and international regimes often create strong incentives to conceal rather than reveal the very information needed to improve causal beliefs. One problem was treated in the literature review. Sheila Jasanoff's observation on the deconstruction of knowledge claims during rulemaking, and their reconstruction and defense when a policy comes into place fits many of our international regimes and domestic regulatory cases perfectly. The Bush administration's unwillingness to reveal information that cut against strongly their public rationales for war with Iraq is an exceptionally clear example. In domestic affairs, the reconstruction of plausible scientific rationales for proposed actions to legitimate final decisions is strong, and resistance to evidence revealed after decisions are made that should produce revisions of causal beliefs is strong. For example, the Department of Defense staunchly defended the scientific rationale on effectiveness of ballistic missile defense systems against evidence of failure of the Patriot I during the first Gulf War and of failure in tests of advanced BDM components during the Clinton and George W. Bush administrations. Other plausible instances may include the US Department of Agriculture mishandling of testing on the second US BSE case. In each of these cases, evidence that would be useful in updating understandings of complex problems was hidden from view to marshall legitimacy for a fixed line of policy.

This hardening of causal beliefs against the consideration of evidence that emerges after initial decisions are made appears to be less pronounced for international regimes than for domestic regulatory and procurement systems However, Jasanoff's finding on domestic regulatory systems are also evident with respect to someinternational regimes. The effects

of rulemaking in international settings on the character of knowledge claims can be seen clearly in the area of food policy. Compare CODEX deliberations over the quality of evidence on food safety issues before and after the WTO SPS agreement. When CODEX discussions were pursuant to voluntary standards and guidelines, knowledge claims were challenged and debated within working groups and standards eventually emerged. After CODEX standards were set up as a baseline against which WTO panels would assess the legality of domestic food safety regulations, CODEX has been stalemated in a process of what Jasanoff would call deconstruction of knowledge claims or what Europeans refer to as post normal science.

More mundane considerations shape incentives for surfacing or suppressing information. In US domestic cases, the prospect of litigation serves as a strong impediment to free flows of information needed to update and correct regulations in the areas of consumer product safety, drug efficacy and safety, and medical practices. When a case does make it to the courts and is settled, typically the terms of the settlement and the data that generated a plausible basis for claims are held closely. In cases as diverse as tobacco litigation, the Ford-Firestone case, and the Boston priest abuse scandals, information that was badly needed to improve public policies was not revealed under the terms of legal settlements.

2. Choice of Performance Indicators, Causal Structures and Lock In

The problems addressed above center on the availability of information needed to engage in adaptation. This section considers problems that may preclude adaptation even if adequate information is available. The indicators of performance embodied in a domestic regulation or an international agreement matter – the choice of indicator may facilitate adaptation or promote lock in on preexisting lines of policy.

David Reiner of Cambridge University has differentiated among indicators suitable for legitimating lines of policy, measuring progress on intervening states, and assigning responsibility for actions. To set up discussion of these bidirectional connections between causal beliefs and regime indicators, consider definitions of three classes of indicators, with illustrations from domestic and international arenas.

A. CONCRETE ACTIONS -- DEFINE GOALS IN TERMS OF BEHAVIORAL INDICATORS
B. INTERVENING STATES OR LINKS -- DEFINE GOALS IN TERMS OF OBSERVABLES ON CAUSAL PATH
C. ULTIMATE OBJECTIVES -- DEFINE GOALS IN TERMS OF PROXIES FOR CONSUMMATORY VALUES

	BEHAVIORAL INDICATORS	INTERVENING INDICATORS	CONSUMMATORY INDICATORS
STRENGTH	ASSIGNING RESPONSIBILITY	NOMINAL MEASURABILITY AND OSTENSIBLE OBJECTIVITY	LEGITIMATING POLICY
WEAKNESS	LEGITIMATING POLICY	RELEVANCE TO LEGITIMACY AND RESPONSIBILITY	ASSIGNING RESPONSIBILITY

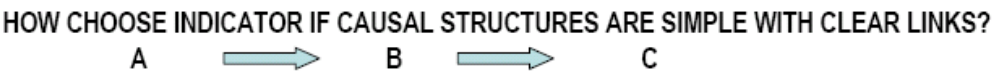
1. **Proximate or behavioral indicators** focus on concrete actions under direct control of parties governed by regimes, agreements, or regulations. Domestic examples include air

regulations that set standards for ultra low sulfur fuels or for cars with advanced three way catalysts, food regulations that specify use of HAACP in meat processing, and agricultural regulations that bar the production or use of animal feed containing mammalian brain or spinal tissue. International examples include arms agreements that prohibit testing of missiles at ranges over 100 kilometers, environmental agreements that set caps on carbon emissions from specific countries, capital adequacy standards that specify what limits banking authorities shall impose on lending relative to capitalization, WHO guidelines on polio vaccinations administered, and EMS fiscal balance targets. Proximate behavioral indicators are useful in assigning responsibility for actions to specific parties, but the actions measured may or may not link to useful ultimate outcomes.

2. **Intervening indicators** focus on variables that appear to sit on causal paths that link behavior to ultimate outcomes. Domestic examples include air regulations that set ambient levels of nitrogen oxides and particulates, food regulations that set acceptable levels of bacteria counts in meats. International examples include environmental agreements that establish target levels of ozone or carbon dioxide in the atmosphere, trade regimes that focus on tariff equivalents, financial arrangements that focus on numbers of bank failures, monetary agreements that focus on exchange rate stability, or WHO counts of SARS and polio cases. Intervening indicators are usually, though not always, observable and quantifiable, and their use creates an appearance of objectivity, precision, and neutrality. Too commonly, intervening indicators of regime performance morph into ultimate goals, even when intervening indicators are not closely linked to ultimate values.

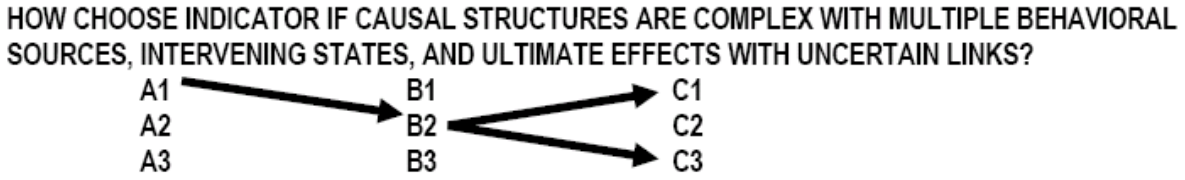
3. **Ultimate indicators** focus on what could be termed consummatory values and objectives. Reductions in pulmonary disease, cuts in salmonella cases, and WHO measures of infant mortality and life expectancy are near proxies for longevity and health, while growth in gross domestic product per capita and measures of species diversity are imperfect proxies for quality of human and nonhuman life. By their very nature, ultimate indicators are not of direct value in assigning responsibility. However, by emphasizing what is ultimately valued, these indicators of performance are useful in spurring reappraisals of proximate and intervening indicators that are producing perverse side effects and in legitimating regimes and regulatory systems.

The relationship between the structure of causal beliefs and indicator selection is straightforward in situations where causal beliefs are simple and linear and where uncertainty over causal beliefs is limited. If one takes a simple causal structure where action A causes intervening state B causes ultimate effect C, then it does not much matter whether one chooses proximate behavioral indicators, intervening indicators, or ultimate indicators of regime performance.



Where one cause produces one intervening effect that in turn shapes one variable of ultimate interest, then classes of indicators may be used interchangeably. For example, the WHO uses numbers of vaccinations (proximate) and number of polio cases (intervening) and life expectancy and disability figures (ultimate) as indicators of its polio programs. Though not synonymous, all of these variables are reasonable indicators of regime performance given the

relatively simple causal structure linking vaccinations to polio cases to life expectancy and disability. The problem, of course, is that these simple causal conditions are rarely found.



If one considers complex and interactive causal structures, with multiple actions linked to multiple intervening states with interaction effects, and with conflicting effects on desired ends, then the issue of selecting indicators of regime performance is crucial.[60]

	BEHAVIORAL INDICATORS	INTERVENING INDICATORS	CONSUMMATORY INDICATORS
AIR QUALITY	FUEL FORMULA ENGINE SYS OBD CATALYST	LDV NOX EMISSIONS AMBIENT NOX LEVEL OZONE LEVELS	MORTALITY HEALTH
ANTITRUST	COLLUSION	PRICE CORRELATIONS	WELFARE/INNOVATION
FOOD SAFETY	TEMPERATURE HANDLING HACCP PROCESS	E.COLI COUNTS FOOD POISONING INCIDENCE	MORTALITY HEALTH QUALITY OF LIFE
EDUCATION	CLASS HOURS CURRICULUM TEACHER/PUPIL SPENDING/PUPIL TEACHER PAY	ACCEPTANCE&YIELD RATE AVERAGE SAT (SOME TAKE) AVERAGE MCAS (ALL TAKE) DROP OUT PERCENT COLLEGE BOUND PERCENT	WORKFORCE PROD INTELLECT QUALITY POL DELIBERATION

[60] The Montreal Protocol is an example of a case where changes in causal beliefs on the links between CFC manufacture and use and depletion of stratospheric ozone resulted in the creation of an effective international regime. The effects of Molina and Rowland's studies taken together with observations on the ozone hole reshaped causal beliefs of a wide range of actors and these changes were clearly critical in mobilizing support for a phase out of CFC use. The simplicity of the A => B => C causal structure linking CFC production and use to ozone depletion also simplified the task of identifying indicators of regime performance. By contrast, consider the causal structures associated with a less studied aspect of the Montreal Protocol case. Methyl bromide is another ozone depleting substance covered by the Montreal Protocol whose scheduled phase out had been delayed repeatedly with a tentative agreement reached only in 2004. Manufactured and natural sources of methyl bromide exist, and intervening links between these sources of methyl bromide and ozone depletion are complicated by the existence of sinks and natural mechanisms for breakdown. Furthermore, methyl bromide is used as a nonpersistent fumigant, and potential substitutes are chlorinated compounds that are persistent and biocumulative; this creates a tradeoff across environmental gains and environmental costs from a phase out. Each link above is wrapped in a bit of scientific and technical uncertainty and each link is the object of some controversy. Enter a small group of strawberry and tomato growers in relatively warm areas who relied on methyl bromide to sterilize soils and kill nemotodes. Without a substitute, these growers had a clear economic interest in resisting a phase out. By contrast, countervailing groups that would gain from a phase out – particularly growers in colder climes that could shift production patterns to fill gaps after a phase out – could not self identify, much less mobilize or organize. Although traditional means of influence mattered, the tomato and strawberry growers principal strategy for delaying a phase out centered on mustering evidence to amplify the complexity and uncertainty of causal structures. They stressed natural sources and sinks to diffuse the link from human production to ozone depletion and they drew attention to ultimate indicators of environmental performance rather than the proximate indicator of tons of methyl bromide produced and used to draw attention to what they argued were environmental benefits associated with methyl bromide use. In the far more important case of the Kyoto Agreement, a similar pattern has emerged, as narrow economic interests with far more power than the small group of growers have grossly amplified areas of uncertainty over underlying causal mechanisms. The principal indicator of regime performance in Kyoto – green house gas emissions – sits at a critical juncture in causal maps, with an extraordinary number of proximate actions linking to the indicator and with many complex and lagged consequences following from the indicator. As a consequence, moving left toward more proximate indicators or moving right toward ultimate indicators may be impractical. However, the use of an intervening indicator of GHG emissions presents problems in partitioning responsibility and in legitimating the regime.

When domestic regulations or international regimes are defined with respect to indicators of consummatory significance, updating and revising is facilitated. Conversely, when domestic regulations or international regimes are defined with respect to behavior indicators like "use of three way catalyst," then the capacity of a regulatory system to adapt to emerging information on causal structures and interaction effects is likely to be limited. However, recognizing this tendency toward fixity with behavioral indicators and flexibility with ultimate indicators does not translate into easily accepted policy advice. As noted above, each of these indicators has strengths and weaknesses, and moving up the line toward consummatory indicators may not be practicable.

IV CONCLUSIONS AND IMPLICATIONS

A. FINDINGS: DO WE SEE ADAPTATION IN US AND INTERNATIONAL POLICY?

In particular instances, provisions for adaptation or updating in international agreements and domestic regulations can follow directly from the divergent expectations of parties with a stake in outcomes. If parties hold genuinely divergent expectations on what the data will ultimately show, then there is the potential for agreement to gather data on the point of disagreement. The auto industry and utilities and EPA were able to agree to the HEI reappraisal of the HSPH Six Cities study because the auto industry and utilities believed their own studies claiming that the Harvard results were marred by fatal methodological flaws. Had their realized that a reappraisal would reaffirm most of the results of the Harvard study, it seems unlikely that they would have funded the reappraisal. Similarly, Presidents Bush and Chirac were able to agree to UN 1441 because most President Bush genuinely expected inspections to either confirm the existence of WMD or demonstrate Saddam's intransigence. Had President Bush realized that his priors would not be supported by UN monitoring and verification, it is doubtful that he would have supported UN 1441.

But our main interest is less in isolated cases of adventitious reassessment than in the possibility of making adaptation *routine* – cases of planned adaptation in which a decision includes the seeds of its own later knowledge-enriched improvement.

In conditions of great uncertainty and change, most individuals and most organizations adopt some form of trial-and-error operating philosophy. The US regulatory system, however, does not act this way; most often, regulators adapt their rules when the rules come under outright attack. The usual operating premise is that new standards and rules are to be regarded as valid in perpetuity.

Thus, US regulation cannot be generally said to show long-term learning. In recent decades, it is true, extensive knowledge is mobilized when a new rule is written, but once it is promulgated, knowledge-generation usually stops. This means, inevitably, that rules based on past assumptions about costs, benefits, compliance rates, and social preferences become less and less linked to a sound knowledge base.

It is true that Presidents and Congresses have not infrequently made token efforts to induce regulators to review existing regulations. We found initiatives from 1978, 1981, 1992, 1993, 1995 and 1996 that promised systematic attention to the soundness of rules already on the books. However, the idea has gained neither currency nor noticeable support among regulators, outside parties to rulemaking, or among other regulation-watchers. It seems alluring to those at the top, but not at the working level.

The reasons for the obvious aversion to planned adaptation are not adequately understood. Groups whose interests should impel them to insist on revision of existing rules to accommodate current knowledge hardly ever do so. Agencies that work hard to understand in some detail the potential costs and benefits of prospective policies show little inclination to apply the same energy to seeing a removing obsolescence in existing rules.

Our study made an effort to find cases that stand as exceptions. Our hope was to discover how often federal practice exhibits planned adaptation, and whether such cases are succeeding in providing adaptive programs – programs that both re-evaluate past decisions and fix them as needed. We examined 32 reported instances, and found a few that show both features.

Finding 1. Thus, in a handful of known cases, planned adaptation *does occur*. The most instructive of those cases is EPA's NAAQS program for setting air quality standards for particulate matter [PM] in light of health effects information. EPA has now conducted several iterations of such standard-setting, each time systematically reviewing the latest expert knowledge – which is now routinely abetted by a major EPA-funding PM research effort --needed to improve air quality standards and incorporating that knowledge new standards. This process has, over time, seen the redefinition of PM pollution from "total suspended solids" to one of special concern for very fine particles.
A second prominent example is that of the post-marketing surveillance effort by the Food and Drug Administration. The point of this program was to understand and correct decisions about adverse health effects of new drugs after based on knowledge that came to light after the drugs are approved. Weaknesses in this program have become clear, and it is noteworthy that the remedies now being discussed would make the program similar to EPA's NAAQS program. These exceptional cases demonstrate that there is no formidable legal or political barrier to planned adaptation. The cases appear to be stable, and to be systematically accommodating new scientific and other knowledge into regularly-evolving decisions. They represent self-corrective behavior.

Finding 2. It is notable that, for most of the eight federal cases that currently amount to planned adaptation, the reanalysis is done by an entity [e.g., independent bodies like NAS and HEI, and/or semi-independent advisory entities like CASAC] that is *has meaningful autonomy from* the regulatory body that wrote the original rule. This technique may be important in overcoming the informal barriers to self-evaluation and self-correction in regulation.

B. POLICY IMPLICATIONS: THREE GENERAL & THREE SPECIFIC SUGGESTIONS

Much remains to be done in gauging the experience to date with planned adaptation in US regulation and in international actions. Successive drafts of this paper may provide some of that. Still, we can lay out some plausible policy implications that can be kept in mind at this early stage in our inquiry.

Some general areas for exploration by policy officials and researchers include:

1. Incentives to Reveal, Conceal Existing Knowledge and to Find New Knowledge

Organizational processes, bureaucratic interests, simple embarrassment, reconstruction of authoritative bases for policy, and fear of vulnerability to liability create incentives for actors to hide rather surface information needed for adaptation.

Suggested Remedy: Systematic attention to elimination of at least some of these disincentives; and funding information acquisition are advised.

2. Lock in by organized and concentrated interest groups

Constituencies for stasis are often stronger than constituencies for change.

Suggested Approach: Tacit or explicit compensation of those adversely affected by adaptation may be necessary. The SOx updating case is an unusually interesting example, with those holding stocks of emissions permits benefiting from the price increases created by more restrictive quotas.

3. Better Indicators of Performance? It is now commonplace to observe that compartmentalized and specialized regulations may not be readily revised as learning takes place. For example, quotas for sulfur dioxide emissions could not be revised quickly, even when the substantial health benefits associated with PM reductions were identified.

Suggested Approach: Defining operational goals in terms of ultimate indicators of performance, such as human health, facilitates adaptation to information on interaction effects, tradeoffs, and complements. However, moving up towards ultimate indicators may come at the expense of assigning responsibility or partitioning uncertainty.

Some specific ideas that policy official come implement are:

[1] Replicate the NAAQS Process Elsewhere in Government

The NAAQS program appears to uniquely integrate policy updates with relevant new knowledge – and for one of the 6 NAAQS pollutants, PM, a significant public research effort is subjected to systematic reference to the largest and most significant gaps in understanding. Should this approach not be tried in other programs and regulatory agencies? (An obvious question – but perhaps not the largest one – is whether The NASQS 5-year review cycle is

long enough. EPA's deliberate and thorough process for writing and revising NAAQS criteria documents alone takes upwards of three years. For major scientific questions, a review cycle of 8 to 10 years may prove to be more practical than one of 5 years.)

Suggested Approach: The President or Congress should identify three regulatory programs in which legislated reviews should become mandatory. Criteria for identifying these programs should include:

- economic and environmental/health importance of the sector
- salience of current uncertainties that need to be addressed by new research
- comments by interested and affected parties

[2] More Practical Incentives to Conduct Selective *De Novo* Reviews

If anything is clear from a review of past federal experience, it is that broad, government-wide initiatives are ineffective. Instead, agencies should be encouraged to tackle, at least initially, *manageable* review objectives.

Suggested Approach: The President or Congress should require that each major regulatory agency annually select one past decision that the agency, or its assorted publics, consider ripe for review. In light of the original expectations – as expressed in pre-promulgation statements and analyses – an assessment of actual costs and benefits should be undertaken, and regulatory options that maximize benefits and reduce costs raised and considered. Agencies should ask interested and affected parties for nominations of past decisions where the original assumptions seem obsolete, and where adaptation may lead to significantly improved rules.

[3] Better Benchmarking

It is now commonplace for significant rules to be accompanied by extensive analyses of the projected costs and/or benefits of alternative policy decisions. Nonetheless, final rules are too rarely clear enough about the costs and benefits to the public – or even the *range* of costs and benefits -- that the agency expects to see. This means that there is too often no clear benchmarking against which to actual experience under the rule.

Suggested Approach: The President or Congress should ask the National Research Council or a functionally similar organization to suggest administrative mechanisms to improve public benchmarks for new significant regulation. One such mechanism might be an expanded version of the current-required "statement of basis and purpose" for new rules. A clear yardstick against which to judge a rule would give the agency, interested and affected groups, and the general public a way to gauge whether regulatory impacts are as expected and thus whether adjustments are in order.

APPENDIX I: US CASE SUMMARIES

INITIATIVES IN HEALTH-AND-SAFETY AGENCIES

Case 1: Regular Updates of "Recommended Daily Allowances" in Food

The National Academy of Sciences has a long history of reviewing scientific information relating to maximum recommended daily intakes of chemicals in food.

Case 2: Animal Nutrition Standards

The National Academy of Sciences has a long history of reviewing and adjusting the recommended nutritional needs of domestic animals, including pets.

Case 3: Successive Reviews of Radiation Effects by the NAS

Since 1970, the Environmental Protection Agency has commissioned seven studies at the National Research Council – National Academy of Sciences on the effects of exposure to radiation. These reports have provided the scientific basis for EPA regulations aimed at protecting workers and the general public. The series is known as the "BEIR" [Biological Effects of Ionizing Radiation] reports. BEIR I [1972], BEIR III [1980], BEIR V [1990], and BEIR VII [forthcoming, 2005] have examined the effects of "low linear energy transfer" radiation, i.e., x-rays. BEIR IV [1988] and BEIR VI [1999] examined the health effects of exposure to radon gas.

The successive studies were undertaken to incorporate new scientific information as it evolved over the decades. For example, BEIR III incorporation inferences from the long-term study of Japanese survivors of the two World War Two nuclear bombs, and also made adjustments to reflect updates in what was known about the radiation doses actually received by those victims. BEIR VI incorporated new information on radon effects, especially that relating to residential exposures.

It is worth noting that these sequences of studies were undertaken even though there were reportedly no startling changes in the basic understanding of cause and effect from human exposure to radon. According to NRC staff:

> "While in general overall risk estimates for radiation-induced health effects such as cancer induction and genetic damage have not changed dramatically over the last 35 years, BEIR rep orts have contributed new advice regarding issues such as the reduced effects of dose protraction, the effects of age at time of exposure, the shape of the risk model at low doses, . . . and the potential role of new biological phenomena of radiation risk models.[61]

Case 4: Regulatory Evaluation Program at the National Highway Traffic Safety Administration [NHTSA]

NHTSA reports a long tradition of retrospectively reviewing its rules and program decisions. Currently the agency observes that:

> "Most of NHTSA's crashworthiness and several crash avoidance standards have been evaluated at least once since 1975. NHTSA has also evaluated a number of consumer-oriented regulations, such as bumpers, theft protection, fuel economy and the New

[61] Douple, Evan, "Biological Effects of Ionizing Radiation: The BEIR Studies and Reports," received August 2004.

Car Assessment Program (NCAP), as well as some promising safety technologies that were not mandatory under Federal regulations, such as antilock brake systems.[62]"

The agency appears to take some pride in its evaluation effort. It notes that since 1981 various government-wide orders [all of them discussed in the text of this paper] encourage retrospective assessments, but states that "even before 1981, however, NHTSA was a leader among Federal agencies in evaluating the effectiveness of existing regulations and technologies.[63]"

According to its current Four Year Plan for evaluation, NHTSA has fifteen studies under way,[64] and reports that 44 studies have been published since 1979.[65] Program personnel indicate that a typical study is conducted by contractors and costs on the order of $500,000, and takes one to two years to complete. The Program employs a handful of full-time workers and has an annual budget in the general vicinity of $80 million.[66]

Judging from the descriptions of completed studies, it appears that a majority of retrospective studies address the effectiveness [e.g., crashes avoided] of a NHTSA requirement, and that cost estimates are much rarer. It is evidently uncommon for these studies to include recommendations about the suitability of the relevant NHTSA rule and/or the need to adjust it. Program personnel did not suggest examples of regulatory adjustments that were made as a direct result of NHTSA evaluations, and did not indicate that there is regular interaction between the agency's evaluators and its regulation-writers.[67]

Case 5: Mandated Periodic Review in the Clean Air Program; National Ambient Air Quality Standards [NAAQS]

Congress has mandated that the standards for the concentrations in the air of the handful of "categorical" air pollutants be revisited de novo every 5 years.[68] By my count[69], EPA had completed 10 such reviews between 1985 and 1997 [XXXXX needs update] for a total of 7 pollutants, and the standards for each two most prominent of them, ozone and particulates, have been taken through two review cycles. It should be noted that the NAAQS are standards, not regulations. Air emissions are largely regulated for mobile sources by EPA and for stationary sources by the individual states by means of State Implementation Plans. However, a change in these standards can have substantial regulation effects, and can thus influence the benefits and the costs of cleaner air.

There is now a fairly standard process for EPA's NAAQS reviews, and one that gives defined roles to several actors. It is the staff of EPA's Office of Research and Development, for example, that drafts the "Criteria Document" that summarizes, anew, existing knowledge on the health and ecological effects of the pollutant under review. It is EPA's air office – its developer of actual air pollution rules – that drafts the "Staff Paper" that suggests what the

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[62] http://www.nhtsa.dot.gov/cars/rules/regrev/evaluate/index.html, accessed August 27, 2004.
[63] http://www.nhtsa.dot.gov/cars/rules/regrev/evaluate/809699.html, accessed August 27, 2004.
[64] NHTSA report DOT HS 809 699, Evaluation Program Plan 2004 - 2007, January 2004, page iii.
[65] Ibid., page 37.
[66] Interview with C Kahane, 12/9/99.
[67] Ibid.
[68] XXXXX Clean Air Act Amendments of 1977 [XXXXX cite]. The 5-year cycles were required to be instituted in December 1980. These amendments also specified the establishment and important role of the Clean Air Scientific Advisory Committee [CASAC], which operates under the Federal Advisory Committee Act as advisory to EPA in setting the standards.
[69] I am now beginning a paper on the workings of the NAAQS process, with focus on particulate matter regulation, that will investigate the sources of the most significant new knowledge and how and why it was developed.

new standard should be, or recommends retention of the existing standard -- and justifies that choice. It is the independent-minded Clean Air Scientific Advisory Committee [CASAC] that much review and issue a "closure statement" on the accuracy and adequacy of each Criteria Document and Staff Paper prior to EPA's final decision.

In the case of the standard for particulate matter [PM], an interesting additional process has arisen to supplement the review cycle. EPA's has a substantial research significant research program for PM, one that over 10 years will fund about a $500 million in new scientific studies. EPA now routinely has that program reviewed by an expert committee of the National Research Council [NRC], and the NRC helps EPA tighten the linkage of research to the key remaining uncertainties found in the standards development process. If one adds to this picture the new "Accountability" work that EPA and industry are supporting at the independent Health Effects Institute [see **Case 8**, below], a relatively fully articulated policy planned adaptation process is in place, one that both creates and adapts to new knowledge on air pollution.

Case 6: Annual Reviews Under the Toxic Substances Control Act

The Toxic Substances Control Act [TOSCA] specifies that EPA review the merits of testing requirements within a year.

Case 7: Elimination of 66 Rules at DOT

In its 1992 "Moratorium" review of existing rules that had been ordered by President G. H. W. Bush, the Department Transportation reviewed "all its existing regulations"[70]

The Department had identified about 70 rules that it found to be obsolete, redundant, or could be re-issued as non-regulatory guidance. These rules had been on the books of five DOT agencies and the Secretary's Office. DOT had announced that it would eliminate these rules earlier, and had received 19 comments from outside groups. In December, it eliminated 66 such rules.[71]

The Department did not claim that these rules had been imposing real costs to regulated or other outside entities, and the sparse volume of comments confirms the impression that few burdens were being lifted. Still, however, DOT argued that "by removing these unnecessary regulations, the Department substantially reduces the size of its portion of the Code of Federal Regulations, and thus reduces the administrative burdens on the public."[72]

Case 8: Review of FAA Aircraft Certification Rules[73]

The Department of Transportation's Federal Aviation Administration reviewed all of its aircraft certification rules over a period of eight years. Having received nearly 2000 suggestions for changes, the FAA adopted about 500 changes in nine rules comprising about 200 pages in the Federal Register.[74]

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[70] Federal Register, Volume 57, Number 246 (December 22, 1992), page 60725.
[71] Ibid., pages 60725-60728.
[72] Ibid., page 60726.
[73] Federal Agency Reviews of Existing Regulations, American Bar Association Section of Administrative Law and Regulatory Practice, 1994, page 17.
[74] Federal Agency Reviews of Existing Regulations, American Bar Association Section of Administrative Law and Regulatory Practice, 1994, page 16. The ABA description does not give a citation for this program.

Case 9: FDA Advisory Committee Evaluation of Rule Review Needs

According to the ABA report,[75]

> "Agencies could also use advisory committees to make periodic recommendations on rules that need to be reviewed. The Food and Drug Administration invited public comment of what should be reviewed and then used an advisory committee to narrow down the list. The agency said this worked very well."

As far as can as yet be determined, the FDA's 2004 Regulatory Procedures Manual[76] contains no routine process for identifying rules that need change, and the duties of the major FDA advisory committees do not specify a role in setting agency priorities.[77]

Case 10: Review of OSHA's regulatory cost estimates by the Office of Technology Assessment

In response to requests in 1992 from the Senate Committee on Education and Labor and Human Resources and the House Committee on Education and Labor, the Office of Technology Assessment [OTA] in 1995 issued *Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytic Approach.*[78] The report had been prepared with the help of an outside advisory group that included economists, company and union representatives, and academic health researchers.

Among the target questions of the review was, "How reliable are the agency's rulemaking estimates of actual outcomes? What are the apparent major sources of disparities?[79]" For eight of OSHA's existing standards, OTA examined actual outcomes and compared them with OSHA's estimates made during rulemaking. Among OTA's conclusions are:

- In a good number of the cases that OTA examined, the actual compliance response that was observed included advanced or innovative control measures that had not been emphasized in the rulemaking analyses, and the actual cost burden proved to be considerably less than what OSHA had estimated.[80]
- The agency devotes relatively little attention to examining the potential of advanced technologies or the prospect of regulation-induced innovation. . . .this is a substantive deficit.[81]
- It is surprising . . . how little systematic knowledge exists about the actual effects of the agency's standards. . . . OSHA would, no doubt, significantly benefit from a more routine effort to collect and interpret information pertaining to actual regulatory outcomes and impacts.[82] OSHA could make a more regular effort to conduct retrospective case studies.[83]

OTA also compared OSHA's approach to that of seven other US agencies, finding OSHA "generally comparable to the best practices of other health and safety agencies."[84]

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[75] American Bar Association, Section of Administrative Law and Regulatory Practice, Federal Agency Reviews of Existing Regulations, 1994, page 30 [no citation provided].
[76] http://www.fda.gov/ora/compliance_ref/rpm/, accessed July 23, 2004.
[77] http://www.fda.gov/oc/advisory/charter.html, accessed July 23, 2004.
[78] Report OTA-ENV-635, September 1995 [GPO Stock # 052-003-01445-9].
[79] Ibid, page 9.
[80] Ibid, page 10.
[81] Ibid, page 11.
[82] Ibid, page 11.
[83] Ibid, page 72
[84] Ibid., page 13.

Case 11: Six-Year Reviews by EPA Under the Safe Drinking Water Act

Under the Safe Drinking Water Act, as amended in 1996;

> "The [EPA] Administrator shall, not less often than every six years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title."[85]

EPA later articulated the general idea of the reviews:

> "The intended purpose of the review is to identify those [rules] for which current health risk assessments, changes in technology, and/or other factors, provide a health or technical basis to support a regulatory revision."[86]

Subsequently EPA, working with the National Drinking Water Advisory Council, established a procedure for conducting these reviews, one that entails review by the EPA Science Advisory Board [SAB] Drinking Water Committee.[87] In the year 2002, when the six-year clock was running out, EPA announced the tentative results of its sweep of existing rules, saying that it had reviewed 69 such regulations and "the Agency preliminarily believes that the 68 chemical [rules] remain appropriate at this time, and that the TCR [the 69th rule, relating to Total Coliform standards] should be revised.[88]

[Remaining questions: why did Congress do this, and with what precedent in mind? What has been the ultimate disposition of the 2002 proposal? What process lessons has EPA learned from the first cycle of reviews?

Case 12: Review of the Actual Costs/Benefits of Air Pollution Cleanup

Section 812 of the Clean Air Amendments of 1990 called for a retrospective review of the total costs and benefits of cleaner air. EPA undertook a six-year project to design and do the review, process that involved peer review along the way.

The model runs for the study were completed in 1994[89] The report itself, Benefits and Costs of the Clean Air Act 1970 – 1990 was issued in 1997, after further peer review. [90] It concluded that, as compared to the "no control" case, 205,000 Americans would have dies, and millions would have suffered illness associated with exposure to polluted air. The range of the value of these benefits was estimated at from about $6 trillion to $50 trillion, while the costs were about 0.5 trillion. The study itself was reported to have cost $4 million to produce.[91]

Case 13: FAA Solicitation of "Worst Three" Rules as Part of Its Systematic Three-Year Reviews

According to the 1994 ABA Report,

> "When resources are limited or when agencies prefer to respond first to the most important problems, agencies could take additional steps to help the public focus their

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[85] Safe Drinking Water Act, section 1412(b)(9).
[86] National Primary Drinking Water Standards, Federal Register Volume 67, number 74, April 17, 2002, page 19030.
[87] Ibid., page 19032.
[88] Ibid, page 19030. Four other contaminants, arsenic, radionuclides, disinfectants, and disinfectant by-products, had already been treated on a shorter schedule.
[89] "1990 Clean Air Act Amendments Section 812 Prospective Study," EPA, http://www.epa.gov/asmdnerl/cleanair.htm, accessed 11/10/98.
[90] http://www.epa.gov/air/sect812/copy.html, accessed 7/30/04
[91] Assessing the Impacts of EPA's Regulations Through Retrospective Studies, General Accounting Office report GAO/RCED-99-250, 1999, page 12.

attention on those areas most in need of attention. For example, as the Federal Aviation Administration recently did, they could ask the public to identify the top three rules that they believe need review (rather than asking them to list everything without priority) and then compile a master list of the most frequently identified rules."[92]

In fact, this process was set forth as official FAA policy in September 1996 in the FAA's Docket 28311:

> FAA Plan for Periodic Regulatory Reviews: Beginning January 1997, and every 3 years thereafter, the FAA will conduct comprehensive regulatory reviews. The review will be initiated with a published announcement in the Federal Register inviting the public to identify those regulations, issues, or subject areas that should be reviewed by the FAA. In order to focus on those areas of greatest interest and to effectively manage agency resources, commentors will be expected to limit their input to the 3 issues they consider most urgent. In addition, the public will be specifically requested to identify rules having a significant impact on small entities that appear to be no longer necessary or that are overlapping, duplicative, or conflicting with other Federal regulations. The FAA will review these rules in accordance with Section 610 of the Regulatory Flexibility Act unless they have already been so reviewed. The FAA will review and analyze the issues addressed by the commentors against its regulatory agenda and rulemaking program efforts, and adjust its regulatory priorities consistent with its statutory authority and responsibilities. Each review will conclude with a published summary and general disposition of the comments and, where appropriate, indicate how regulatory priorities will be adjusted.[93]

This docket reports interesting information on the positions of outside parties with respect to the advisability of a periodic review program. Eight groups, including the air carriers, several airport interests, and the pilots association, supported a systematic review program. Three groups, including the aircraft manufacturers [AIA and GAMA, the general-aviation builders], opposed it according to the FAA account.[94]

Case 14: Five-Year Reviews under the Farm Act

In 1999, former Presidential Science Advisor Jack Gibbons told an audience at MIT that the Farm Act contains a provision that all rules be reviewed *de novo* every five years. We have as yet been unable to confirm the existence or the workings of such a provision.

Case 15: USDA Program Has Special Office to Conduct Reviews

The Food Safety and Inspection Service of the U. S. Department of Agriculture set up a separate office to conduct reviews of existing regulations.

The FSIS Program Evaluation and Improvement Staff "formulates evaluation plans and conducts evaluations of existing and proposed programs, program components, inspection methods, and Agency policies, directives and regulations."[95]

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[92] American Bar Association, Section of Administrative Law and Regulatory Practice, Federal Agency Reviews of Existing Regulations, page 30. The ABA report does not contain a citation for the FAA request to the public.

[93] Department of Transportation, Federal Aviation Administration, 14 CFR Chapter 1 (Docket 28311), "Review of Existing Rules," September 27, 1996.

[94] Ibid.

[95] http://www.fsis.usda.gov/about/Program_Evaluation_&_Improvement/index.asp, accessed 7/30/04.

The number of existing rules that have been examined, and the process for conducting those reviews, is not indicated on the program's website, and needs to be determined. The list of projects completed by this office includes no reports after the year 2002.

Case 16: Regulatory Cost Estimates as Reviewed by Resources For the Future [RFF]

In 1999, the non-profit organization Resources For the Future [RFF] reported on its study, "On the Accuracy of Regulatory Cost Estimates.[96]

This study examined the direct costs of specific health-and-safety regulations, and compared expected costs to actual costs as later assessed. The study examined 25 cases – 10 for EPA actions, 8 for OSHA actions, 4 for California air pollution actions, and 3 foreign environmental actions.[97]

Of the 19 cases for which costs could be compared, almost two-thirds [12 cases] showed a significant overestimate of total costs at the time of decision, a quarter [5 cases] proved accurate to within plus-or-minus 25% of estimated costs, and about one-tenth [2 cases] showed significant underestimates of actual total costs.[98] There was no strong difference among how different regulators scored in comparing estimates with actual cost outcomes.

One major influence on the tendency toward overestimation of costs is new technologies are not fully appreciated by cost estimators. "The case studies support the usual explanation for regulatory cost estimates unanticipated technological innovation."[99] Another factor was that the rule was adjusted after the estimate was conducted, so that as implemented it incurred fewer costs than estimators expected. Commentators have criticized the study in two ways.

First, the study's "no control" case assumes that technologies remain static, while some believe that local and state programs, and voluntary moves to new ways of reducing emissions, would have occurred even without federal legislation.

Second, the report was not done in a way that would inform potential mid-course adjustments where, on the margin, costs seemed to be heavily outweighing benefits. Here's one such comment:

> "The Section 812 studies are presented in too gross a level to be relevant to most policy decisions (such as whether to continue to to expand existing programs or whether to initiate new ones). So far the EPA has not fully embraced the recommendations made by its own Clean Air Science Advisory Committee and others regarding the need for less aggregated analysis."[100]

[96] Harrington, Winston, Richard Morgenstern, and Peter Nelson, "On the Accuracy of Regulatory Cost Estimates," Discussion Paper 99-18 [RFF, January 1999].
[97] Ibid., Appendix B –Description of Cases, pp. 29-36.
[98] Ibid., page 14.
[99] Ibid., page 23.
[100] "Assessing Health Impacts of Air Quality Regulations: Concepts and Methods for Accountability Research," Health Effects Institute, September 2003, page 20.

Case 17: The "Accountability Project" of the Health Effects Institute [funded by industry and EPA]

The Health Effects Institute[101] [HEI] is a unique organization designed to bring the EPA and the automobile industry together in improving the knowledge base for air pollution regulations.

HEI's funding has come in roughly equal shares from EPA and industry. In the past, most of its resources have been devoted to the funding of new research by academic investigators. In its 2000-2005 Strategic Plan, HEI indicated its intention to begin work in the assessment of the actual health effects of regulations, and a new "Accountability" element of its research portfolio has since evolved. HEI explains that it adopted this as a priority research topic because "evidence is lacking on the extent to which control measures have improved health, prompting officials to attempt to assess and collect such evidence. Providing evidence that air quality regulations improve public health is part of this broader effort to assess the performance of environmental regulatory policy, an effort that has been termed *accountability*.[102]

HEI's selected two studies for initial funding in 2002[103]. Both were directed to foreign cases: one was to examine the health effects of the ban on coal use in 11 Irish cities; the other was to assess the impact on health of reduced air pollution in what had been East Germany.

Near the beginning of 2004, HEI indicated that up to $3.5 million was to be made available under its new accountability RFP.[104] HEI makes clear that it welcomes proposals on major US policy actions such as the new standards for particulate matter emissions and California's efforts to reduce diesel emissions.

Case 18: Product Safety Commission Pilot Study – Review of Existing Rules

According to the 2004 operating plan of the U.S. Consumer Product Safety Commission, the agency is now completing a plan to "systematically review its current regulations."[105]

According to the CPSC Plan, this initiative arose out in a recommendation by OMB at its PART recommendation #3 in the annual budget cycle. The agency formed a task force and "decided to conduct a pilot study beginning in FY 2004 to review one rule from each statute. The pilot study would begin in October 2004.[106]

FEDERAL GOVERNMENT-WIDE INITIATIVES

Case F1: Handling Petitions to Review of Existing Rules Under Administrative Procedure Act Petition Clause

Federal agencies' regulatory programs are governed by the terms of Administrative Procedure Act [APA] of 1946, as amended, that appear in the U.S. Code. The APA makes it clear that affected parties have "the right to petition for issuance, amendment, or repeal of a

[101] http://www.healtheffects.org/
[102] http://www.healtheffects.org/accountability.htm, accessed June 7, 2004.
[103] HEI Annual Report for 2002-2003, page 4.
[104] HEI Update, Winter 2004, p.2.
[105] "2004 Budget and Performance Plan (Operating Plan)," Consumer Product Safety Commission, March 2004, page 94. Http://www.cpsc.gov/library/foia/foia04/brief/Operate.pdf, accessed 7/30/04.
[106] Ibid.

rule," [107] and imposes upon the agencies an obligation to either conduct the requested review or to promptly explain why the petition is to be denied.[108]

This route to relief from the effects of existing rules has been used successfully,[109] but evidently only rarely. It is generally believed that petitions for reconsideration of existing rules [or, in fact, consideration of new rules] are almost futile, because petitioners bear a heavy burden of showing cause.[110] One reason for the courts' apparent deference to agencies in the case of existing rules may be that challenges are likely to rest on substantive rather than procedural grounds, and they have exhibited discomfort in substituting their expertise for an agency's expertise.

Case F2: President Carter's 1978 Executive Order #12044.

In March 1978, President Carter issued Executive Order 12044, "Improving Government Regulations."[111] Although Jimmy Carter had said during his Presidential campaign that he would "out-Nader Nader" if elected, in fact he felt pressures to do something about regulatory burdens, and this action was a result.

The main thrust of the Order was to establish more visibility and accountability in federal regulation. The Order, for example, saw the creation of the government-wide agenda of regulations,[112] set routine requirements for what were defined as "significant" regulations,[113] and laid out special analytic and procedural requirements for those rules.[114]

Section [4] of the Order was titled "Review of Existing Regulations." It specified that:

> Agencies shall periodically review their existing regulations to determine whether they are achieving the policy goals of this Order. The review shall follow the same procedural steps outlined for the development of new regulations.

Section 4 laid out 6 criteria for selecting rules for special review, including "the burdens imposed on those directly or indirectly affected"[115] and "the degree to which technology, economic conditions or other factors have changed."[116]

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[107] 5 USC, 553(e). In the 104th Congress [1995], Senator Dole introduced S. 343, [later amended by Senators Hatch and Grassley] which sought to reinforce the post hoc petition process, especially for major rules, and to provide deadlines within which agencies should examine the costs and benefits of the targeted rule. Citizens also, of course, have a First Amendment right to petition the government, but there appear to be no cases in which rules have been changed this way.

[108] 5 USC, 555(e).

[109] See American Horse Protection Association, Inc.v. Lyng, 812 F. 2d 1 [D. C. Circuit, 1987], as discussed in Jeffrey S. Lubbers, Unpublished Presentation on Petitions for rulemaking, Animal Law "Conference, American University (April 17, 2004), copy on file with the author at American University. In this case the USDA declined to revise an existing rule on the humane treatment of horses, despite the results of a study sponsored by USDA itself that concluded that the rule ignored a type of device that causes lesions and bleeding. On appeal, the D. C. circuit found that USDA's denial of the petition was arbitrary and capricious, and directed USDA to undertake new rulemaking on the matter.

[110] In 1979, the DC Circuit had held [*Geller v. FCC,* 610 F.2d 973 [DC Circuit, 1979]] that "an agency may be forced by a reviewing court to institute rulemaking proceedings if a significant factual predicate (emphasis in original) of a prior decision . . . has been removed." In 1985, the Supreme Court seemed to say that while court reversals of agencies' decisions to deny petitions should occur "only in the rarest and most compelling of circumstances," but specifically excluded rulemaking petitions from its ruling. See Heckler v. Chaney, 470 US 821 (1985).

[111] Federal Register, March 24, 1978], pp 12661-12665.

[112] Executive Order 12044, section [2][a].

[113] Executive Order 12044, section [2][d-e].

[114] Executive Order 12044, section [3].

[115] Executive Order 12044, section [4][c].

[116] Executive Order 12044, section [4][f].

The Carter Administration later proposed the Regulatory Reform Act which was intended to make the Order's changes permanent, to apply them to the "independent" agencies like the FCC and ICC. This bill added a bit of specificity to the Order's open-ended review requirement: "Each agency will establish a schedule to review its major rules and smaller rules which may be outmoded or ineffective. The reviews, to be conducted over a 10-year period, will ensure that rules are kept up-to-date or eliminated."[117]

Neither the agencies nor the Office of Management and Budget viewed the review feature as a major part of the Administration's regulatory program.[118] Executive Order 12044 was annulled in the initial days of the succeeding Reagan Administration, which issued its own regulatory program.

Case F3: The Regulatory Flexibility Act

Section 610(c) for the Regulatory Flexibility Act of 1980 mandates that federal agencies periodically review all existing rules that have "significant economic impact on a significant number of small entities." Rules that met that threshold were to be reviewed by 1990 or within 10 years or their promulgation, whichever was later. The reviews themselves were to consider the continued need for the rule, complaints received, overlaps with other rules, and whether and how relevant changes in "technological, economic, or other factors" bear on the case.

There is thus no specific requirement to assess the rule's actual costs or benefits, nor how such might relate to the costs and benefits that were expected when the rule was written.

Twenty four years later, when many federal rules should have been reviewed twice or more, the impact of the Act is unclear at best, and may be nil. The apparent reason for this is that the law has yet to find someone to enforce it.

It's not that compliance with the Act has gone unmonitored. In fact, the General Accounting Office [GAO] has examined how the Act was being implemented in 1991, 1994, 1997, 1998, 1999, 2001, and 2001.[119] In each of these reviews, GAO finds that agencies' interpretations of the Act vary in a bewildering way, and that there have only been a handful of cases in which an agency has fully complied with the plain language of the law. In 1992, for example, GAO contacted 83 federal agencies and found that only 13 had undertaken to prepare a review play – this being 12 years after the law was passed.[120] In 1998 GAO analyzed the 4560 entries in the semiannual compilation of federal agency agendas. It found that only 30 were noted as section 610 reviews, and that 53 agencies listed no section 610 reviews at all.[121]

Over this period, GAO repeatedly advised Congress that compliance with term of section 610 depended on the empowerment of some entity – perhaps the Small Business Administration [SBA], perhaps OMB – to enforce it. Congress has not done that, and neither SBA nor OMB has shown any appetite for the task. It is difficult to see what this law is contributing.

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[117] Tozzi, Jim, Towards a Regulatory Budget: A Working Paper on the Cost of Federal Regulation [1979], posted at http://www.thecre.com/ombpapers/regbudget.html.

[118] As the head of EPA's Regulatory Reform Unit, and later as Associate Director of the US Regulatory Council in the Executive Office of the President, I was aware of the range of such initiatives.

[119] Most of these reviews are touched on in GAO, Federal Rulemaking: Procedural and Analytical Requirements at OSHA and Other Agencies [GAO-01-852T], June 14, 2001, pages 6 and 7..

[120] GAO, Regulatory Flexibility Act: Status of Agencies' Compliance [GAO/GGD-94-105], April 1994, pages 13-15.

[121] GAO, Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary [GAO/GGD-99-55], April 1999, pages 10-11.

Case F4: President Ronald Reagan's Executive Order 12291

In February of 1981 President Reagan signed Executive Order 12291 – "Federal Regulations.[122]" its section 3(i) directed agencies to:

> initiate reviews of currently effective rules . . . and conduct Regulatory Impact Analyses of currently effective rules. The [OMB] Director, subject to the direction of the [Vice President's Regulatory] Task Force, may designate currently effective rules for review . . . and establish schedules for reviews.[123]

There is no indication that this provision was implemented. In fact, had it been implemented, President Bush's 1992 Moratorium would have referenced it, and would likely have been unnecessary.

Case F5: President George H. W. Bush's "Moratorium" Order

In January 1992, President George H. W. Bush contacted agency heads on the subject of "reducing the burden of government regulation."[124] Noting that excessive regulatory burdens amount to "a hidden tax on the average American household, the memorandum called for change: "a major part of this undertaking must be to weed out unnecessary and burdensome government regulations."[125] This weeding process was to take 90 days, during which agencies were directed to observe a moratorium on issuing new rules, and during which "agency resources should, to the maximum extent possible, be devoted to these [weeding] efforts."[126]

The memorandum contained a fairly elaborate process for conducting agency reviews, including explicit criteria for identifying problem rules, the appointment of an agency official to oversee the review, and the writing of a report on the results of the review directly to the President.[127]

We are attempting to determine what these agency reports said, and to learn details of their final impact. The indirect evidence is that the results were evanescent. Economist Murray Weidenbaum, himself a senior promoter of regulatory reform under a Republican president, later judged that Republican regulatory economist Murray Weidenbaum was later to observe that "it is difficult to pinpoint specific changes that resulted" from the massive and whirlwind review.[128]

Case F6: President Clinton's Executive Order 12866

In September 1993 President Clinton issued Executive Order 12866, "Regulatory Planning and Review." Its section 5 reads:

> Section 5. Existing Regulations. . . . . each agency shall submit to OIRA [in OMB] a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing regulations to determine whether any such regulations should be modified or eliminated."[129]

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[122] Executive Order 12291, 46 FR 13193 and 3 CFR, 1981 Compilation, page 127.
[123] Ibid., section 3[i].
[124] "Memorandum on Reducing the Burden of Government Regulation," January 28, 1992. Http://bushlibrary.tamu.edu/papers/1992/92012805.html, as accessed 12/12/03.
[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] Weidenbaum, Murray, "Regulatory Process Reform from Ford to Clinton," Regulation, 20, 1.
[129] Executive Order 12866, http:///reginfo.gov/eo12866.htm, accessed 11/10/99.

An October 1993 memorandum to agency heads from the OIRA Administrator, noting that earlier administrations' review efforts had been "so broad in scope that necessary analytic force has been disused, or needed follow-up has not occurred," OIRA noted that the new effort would focus on significant regulations, and underscored the desire for a substantive effort, not a cosmetic one. She wrote:

> "It is important to emphasize what the lookback effort is not. It is not directed at a simple elimination or expunging of specific regulations from the *Code of Federal Regulations.* Nor does it envision tinkering with regulatory provisions to consolidate or update provisions . . . . Rather, the lookback provided for in the Executive Order speaks to a fundamental reengineering of entire regulatory systems."[130]

However, the agencies appear not to have responded with enthusiasm, and in March 1995 President Clinton directed that all agencies again review all rules within 90 days. In June, it is reported, 28 agencies reported back, and in that month the President placed himself less distant from the "tinkering" aversion by committing his Administration to reform goals that were once again expressed in numbers of Federal Register pages eliminated or revised.[131] GAO would later conclude that only about 20% of the page removals had resulted in actual reductions in regulatory burden.[132]

As far as can be determined, OIRA did not issue a follow-up report relating to the Order's Section 5 hopes, and the 1995 agency reports were not made pubic.

Case F7: The Government Performance and Results Act – GPRA

In 1993, the Congress passed the Government Performance and Results Act, which called for all agencies to develop strategic plans and a results-oriented management outlook. The Results Act was uncommonly broad; it applied to a vast array of program types, and featured a seven-year implementation horizon.

The George W. Bush Administration introduced its own performance plan, known as the Performance Assessment Rating Tool [PART], and OMB has begun using PART at some agencies in developing the Administration's budgets.

Has all this attention to results led to adaptation? We have found no evidence that it has. The emphasis has appeared to have been on more detailed target-setting rather than on an assessment of the improvement of proven performance. The one known exception is shown in **Case 15** above.

Case F8: Mandated review of the costs and benefits of regulation by OMB

In September 1996 Congress passes a law[133] that, later extended, required a series of "regulatory accounting" reports from OMB. Its primary requirements were:

> [1] estimates of the total annual costs and benefits of federal regulatory programs, including quantitative and non-quantitative measures of regulatory costs and benefits
>
> [2] estimates of costs and benefits of each rule that is likely to have a gross annual effect on the economy of $100 million or more in increased costs.[134]

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[130] As quoted in GAO, Regulatory Reform GAO/T-GGD-96-185, page 15.
[131] Ibid.
[132] Ibid., page 22.
[133] The Treasury, Postal Service and General Government Appropriations Act for fiscal year 1997.
[134] Ibid., section 645(a). *Note*: this act also required OMB to recommend existing regulations that should be reformed or eliminated. This requirement is treated here as Case F3.

The OMB findings in its second report[135], issued in 1998, reflect the range of uncertainty in regulatory accounting; OMB estimated that total annual *net benefits* from regulation were between $30 billion and $3.5 trillion[136], a range of two orders of magnitude. Costs were more manageable than benefits, as OMB estimated that they fell within a range of $170 billion to $230 billion. Environmental regulations were both more substantial and more uncertain than transportation, labor, and "other" sectors. The annual cost of environment rules was estimated to be in a range of $120 billion to $170 billion, and benefits were estimated to fall in a breath-taking range of $93 billion to $3.3 trillion. OMB was careful to say that its estimates were not being used to prune back regulatory programs.[137]The OMB reports included several recommendations for improving regulatory accounting within the Executive Branch, including development of "best practices" guides. In 1997 OMB also recommended:

> "that an interagency group subject a selected number of agency regulatory analyses to *ex post* disinterested peer review in order to identify areas that need improvement and stimulate the development of better estimation techniques more useful for assessing existing regulations.[138]

However, by the following year this suggestion had evidently been dropped, and OMB reported instead an intramural process noticeably short on detail: "We reviewed examples of *ex post* analyses, including those of NHTSA, OSHA, and EPA regulations. This review has helped contribute to an investigation of the methodological problems associated with regulatory analysis."[139]

Originally, skeptics feared that the new regulatory accounting report was not what it seemed to be, and wondered if it was a Trojan Horse dragged in by anti-regulation forces. The real objective, they suggested, was not better *accounting*, but more *control* by means of an overall cap on regulations in the long-discussed "regulatory budget" concept. The Executive Director of OMB Watch explained:

> "the idea of regulatory accounting actually originated during the Reagan Administration as part of a proposal to create a regulatory budget, which later resurfaced again in the Contract with America. Under the Contract with America proposal, federal agencies would have to cap regulatory costs at a certain percentage of our GDP; if costs exceed that cap, agency rules would have to be eliminated and no new regulations could be issued. . . . . But to institute such an approach . . . ., you must first have a system that aggregates regulatory expenditures on an ongoing basis, [which] would put proponents of regulatory budgeting halfway to their final goal.[140]"

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[135] Report to Congress On the Costs and Benefits of Federal Regulations, Office of Management and Budget, 1998.
[136] Ibid., page 17.
[137] OMB wrote that it did not believe "that the existing evidence on aggregate costs and benefits rises to the level that would support a recommendation to eliminate any regulatory program. Virtually all the evidence discussed above is based either on dated studies of existing regulations or on estimates for proposed regulations. These data are not appropriate for determining whether existing regulations should be repealed or significantly modified because of the sunk cost and rising baseline problems raised above. Before supportable recommendations are made to eliminate existing regulatory programs or elements of programs, empirical evidence based on analytic techniques designed to solve the methodological problems discussed about must be developed." Http://www.whitehouse.gov/WH/EOP/OMB/html/chap4.htm, accessed 11/11/1998. One might ask whether OMB's standard of proof for changing existing regulations is not higher that the standard it uses for critiquing new ones, as it routinely does.
[138] Ibid., page 89.
[139] Ibid., page 90.
[140] Statement of Gary D. Bass, Executive Director, OMB Watch, before the Senate Committee on Governmental Affairs, April 22, 1999

OMB has submitted six annual reports to Congress, and a draft for its seventh, *Informing Government Regulation*[141] has been released.

Case F9: OMB's National Call for Rules Needing to be Revisited

In 1996 Congress required the Director of the Office of Management and Budget to prepare and publish:

> "a description of significant public comments to reform or eliminate any Federal regulatory program or program element that is inefficient, ineffective, or is not a sound use of the Nation's resources.[142]

In July 1997 OMB asked for public input on this matter.[143] In its first report to Congress, OMB did not discuss the results of its call for comments. An appendix to the report summarized public input:

> "Many of the recommendations we received were for reforms of the regulatory process. There were surprisingly few specific regulatory programs or program elements that were identified for us. The fact that we received so few proposals for reforming specific programs or regulations, especially accompanied by supporting studies, reinforces our conclusion that it is premature to make specific recommendations about reforming specific regulatory programs."[144]

The appendix named 6 commentors who had nominated 8 regulations for change. The commentors included the Business Roundtable, the U.S. Chamber of Commerce, three sector-specific trade groups, and Professor Thomas Hopkins of the Rochester Institute of Technology, who had formerly led the OMB office that prepared the report. Five of the commentors named EPA programs as needing reform, including the regulation of ozone, airborne particulates, automobile emissions standards, lead-based paint, and drinking water.[145]

OMB did little to encourage outside organizations to continue to nominate federal areas needing reform. It did not indicate that it would further examine the nominated rules, and did not ask for the kinds of supporting evidence that it said was missing. Its final note on the usefulness of the commentary: "In summary, we received many helpful comments from a diverse set of interests. We have much food for thought and much work to do."[146]

Congress renewed its report requirement the following year, and a similar pattern was followed. Again the law[147] called on OMB for a description of programs and rules needing to be changed. Again OMB sought comment on this topic, this time eliciting input on programs "on which there is objective and verifiable information" supporting change.[148]"

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[141] Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities. See http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

[142] The Treasury, Postal Service and General Government Appropriations Act for fiscal year 1997, PL 104-208, sec 645 (a)(4).

[143] Federal Register, July 22, 1997. [XXXXX page ref]

[144] Http://www.whitehouse.gov/WH/EOP/OMB/html/appendix.htm, accessed 11/11/1998.

[145] Ibid.

[146] Ibid.

[147] Treasury and General Government Appropriations Act of 1998, PL 105-61, section 625(1)(4).

[148] Federal Register, August 17, 1998.

The OMB report for 1988 reflects only one rule being named as needing review: the American Petroleum Institute "stated that EPA's estimates of benefits of its particulate matter rule is questionable and provided an alternative estimate."[149]

However, OMB had received a handful of comments urging it to push harder to find candidate rules for reform, including three letters from six Republican chairmen in the House and Senate. OMB wove a subtle reply:

> "In response to these comments, we reviewed that additional studies cited and regulatory initiatives recently published by the agencies in the Regulatory Plan and Unified Agenda of Federal Regulatory and Deregulatory Actions. As a result of this review, we added to the report discussions of ten additional regulations or regulatory programs that would benefit from reform."[150]

In its March 2002 draft annual report, OMB reported on a new approach; noting that it had received from the public suggestions for changing 71 regulations in response to its 2001 draft, it reported that it had classified 23 of these as Category 1 suggestions, which entailed specific follow-up with the relevant federal agency. It briefly summarized the status of each inquiry. For two of the 23 cases, agency revisions had been formulated [the wording does not indicate that the change was due to the OMB prompt], for two the agency had decided not to make a change, and the remaining 19 were unresolved. The short summaries do not distinguish substantive modifications from administrative ones.[151]

In its latest [2004] draft report, OMB's solicitation of public comments has been broadened, asking commenters to "suggest specific reforms to regulations, guidance documents, or paperwork requirements."[152] No tracing of the results of earlier public suggestion is including, indicating that OMB may have abandoned its earlier tracking program.

It is clear that OMB had no taste for a role in identifying candidate rules for revision. In later years, this requirement was dropped from the appropriations language that calls for OMB reports on the costs and benefits of regulation.

SIMILAR INITIATIVES REPORTED OUTSIDE HEALTH-&SAFETY AGENCIES

Case X1: Two-Year Reviews of All DOD "Issuances"

According to the 1996 Eisner and Kaleta article, "every DOD regulation is reviewed every two years."[153] They give the source as the DOD Directives Systems Manual (1988), Directive 5025.1.

The current [last update: February 2004] version of the Directive Systems Manual, labeled as 5025.1-M, is dated March 5, 2003. Its provision C.1.5.1 specifies that "DOD

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[149] Report to Congress On the Costs and Benefits of Federal Regulations, Office of Management and Budget, 1998, page 100.

[150] Report to Congress On the Costs and Benefits of Federal Regulations, Office of Management and Budget, 1998, page 93. In the report itself [page 84], OMB says plainly that the listed reform initiatives had already occurred does not claim that its own review was the reason the agencies had surfaced these ideas. "These efforts are important to the Administration. In particular, OMB endorses the following initiatives . . . "

[151] OMB, "Draft Report to Congress on the Costs and Benefits of Federal Regulations," Federal Register, March 28, 2002, Appendix B, pages 15036-7.

[152] OMB, Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, draft report, http://www.whitehouse.gov/omb/inforeg/draft_2004_cbreport.pdf, accessed 9/3/04.

[153] Eisner, Neil, and Judith Kaleta, "Federal Agency Reviews of Existing Regulations," Administrative Law Review , volume 48 [Winter 1996], page 143.

Issuances" shall be reviewed every 5 years by the Office of the Secretary of Defense to "ensure that the issuances are necessary, currently applicable, and consistent with DOD policy. Provision C.1.5.3 requires the reviewing body to certify in writing the disposition of the review.

It would appear that the reported 2-year review cycle was replaced with a 5-year cycle some time between 1988 and July 2000, when the Manual was recodified. See http://www.fas.org/irp/doddir/dod/d5025_01.htm.

Case X2: FTC Calls for Comment on Economic Impact

According to the ABA report on the reviews of existing regulations, [154] "the Federal Trade Commission, for example, as part of a regular cycle of review, asks for public comment on a series of questions about a rule's economic impact." It is reported that:

> "In 1992, the Commission implemented a program to review its rules and guides regularly. The Commission's review program is patterned after provisions in the Regulatory Flexibility Act, 5 USC 601 *et seq.* [See **Case F10** above]. Under the Commission's program, however, rules have been reviewed on a ten-year schedule as resources permit, not just once as usually required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, in that it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a "significant economic impact upon a substantial number of small entities." The program's goal is to ensure that all of the Commission's rules and guides remain beneficial and in the public interest.
>
> "As part of the ten-year plan, the Commission examines the effect of rules and guides on small businesses and on the marketplace in general. These reviews often lead to the revision or rescission of rules and guides to ensure that the Commission's consumer protection and competition goals are achieved efficiently and at the least cost to business."[155]

In early 1998, the FTC reported these results:

> "When the Commission adopted its expanded regulatory review program in 1992, 41 rules -- 16 of them required by statute -- were in effect. As a result of its regulatory reform program, the Commission has repealed 13 rules to date (more than 30% percent of those in effect in 1992). This number includes almost 50% of its discretionary trade regulation rules. In 1992, the Commission also had 40 industry guides in effect. Fifteen of these have been repealed as obsolete or otherwise no longer needed, and others have been revised or consolidated. Altogether, one-third of the Commission's rules and guides in the 1992 Code of Federal Regulations have been revoked and another 25% revised. The Commission is now just over half-way through the first 10-year cycle of its more comprehensive rule review program. By

[154] American Bar Association, Section of Administrative Law and Regulatory Practice, Federal Agency Reviews of Existing Regulations, 1994, page 30 [no citation provided].

[155] http://ciir.cs.umass.edu/ua/October2001/priorities/FEDERAL_TRADE_COMMISSION_(FTC).html[undated], accessed 7/29/04.

> the end of this fiscal year, however, the Commission anticipates that it will have accomplished more than 80% of the reviews of rules and guides existing in 1992."[156]

The current status of this program, and lessons learned, remains to be ascertained.

Case X3: Five-Year Reviews of All Department of Interior Rules

According to Eisner and Kaleta, the Department of Interior, "in its *Departmental Manual* [along with two other agencies] have established five-year review cycles for their regulations.[157]

The current Department Manual describes the requirement in section 318, chapter 8: "Review of Rules." See http://elips.doi.gov/elips/release/3212.htm. The requirement is clear: "You must review each CFR part at least every five years,"[158] and specifies that "You must complete each review within one year of its inception."[159] The third of eight review criteria is: "What are the benefits of the regulation, and do these outweigh its costs? Did you develop a cost/benefit analysis when you published the rule and, if so, is the analysis still valid?"[160] A written report on each review is required, and it must address all of the listed criteria.[161]

I have been unable to ascertain how and whether this rule is implemented at the Department.

Case X4 – Three-Year Reviews at the Federal Credit Union Administration

According to its current website:[162]

> The NCUA reviews all its existing regulations every three years. The NCUA Office of General Counsel maintains a rolling review schedule that identifies one third of NCUA's existing regulations for review each year and provides notice to the public of those regulations under review so the public may have an opportunity to comment.

NCUA indicated that 16 of its rule sections were to be reviewed in 2004. Comments on these sections were elicited from the public.

Case X5: Five-Year Reviews at the FDIC

Eisner and Kaleta[163] indicate that "the Federal Deposit Insurance Corporation, in its Statement of Policy,[164] ha[s] established five-year review cycles. The current policy[165] is as follows:

> "Regulations and statements of policy should be reviewed periodically. To ensure that the FDIC's regulations and written statements of policy are current, effective, efficient

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[156] Valentine, Debra, General Counsel of the FTC, testimony before the House Committee on Small Business, February 12, 1988, at http://www.ftc.gov/os/1998/02/regflex.htm, accessed 7/27/04.

[157] Eisner, Neil, and Judith Kaleta, "Federal Agency Reviews of Existing Regulations," Administrative Law Review , volume 48 [Winter 1996], page 143. They cite "Department of Interior, Department Manual, section 9.2B (1985)"

[158] DOI Department Manual, 318 (8.2A).

[159] Ibid., 318 (8.3).

[160] Ibid., 318 (8.4C).

[161] Ibid., 318 (8.5).

[162] http://www.ncua.gov/RegulationsOpinionsLaws/rules_and_regs/2004NCUARegulatoryReview.pdf as accessed July 22 2004.

[163] Eisner, Neil, and Judith Kaleta, "Federal Agency Reviews of Existing Regulations," Administrative Law Review , volume 48 [Winter 1996], page 143.

[164] Cites as FDIC, "Development and Review of FDIC Rules and Regulations, in FDIC Statements of Policy, 5057, 5059 (1984).

[165] http://www.fdic.gov/regulations/laws/rules/5000-400.html#5000developmentar, accessed 7/8/04. These terms were adopted in April 1998.

> and continue to meet the principles set forth in this Policy, the FDIC will periodically undertake a review of each regulation and statement of policy. The Executive Secretary of the FDIC will, consistent with applicable laws and in coordination with other financial institutions regulators, establish a schedule and procedures for the reviews. Factors to be considered in determining whether a regulation or written policy should be revised or eliminated include: the continued need for the regulation or policy; opportunities to simplify or clarify the regulation or policy; the need to eliminate duplicative and inconsistent regulations and policies; and the extent to which technology, economic conditions, and other factors have changed in the area affected by the regulation or policy. The result of this review will be a specific decision for each regulation and statement of policy to either revise rescind or retain the issuance in its then-current form. The principles of regulation and statement of policy development, as articulated at the beginning of this Policy, will apply to the periodic reviews as well."

Thus, it would appear that the FDIC no longer requires that its reviews follow a five year cycle, but that the general idea of regular review is, at least in principle, observed.

APPENDIX II: WTO PANEL FINDINGS

Regulation	Defendant	Outcome
Growth Hormone	EU	Struck down
Salmon Heat Treatment	Australia	Struck down
Fumigant Certification	Japan	Struck down
Shrimp-Sea Turtle Exclusion	US	Struck down
Gasoline Formulation	US	Struck down
Asbestos	France and US	Upheld
GMO	EU	Struck down

Growth Hormone: A WTO panel ruled against the EU ban on meat produced using synthetic growth hormones because the European measures: (1) did not conform to CODEX Commission standards; (2) were not based on risk assessment that exhibits "...a rational relationship between the measure and the risk assessment"; and (3) were arbitrarily higher than measures governing other potential risks, such as antimicrobial feed additives, hence were intended as a discriminatory barrier to trade. The WTO Appellate Body upheld the Panel ruling against the EU for failing to conduct a risk assessment to justify its standards. However, the Appellate Body overturned the Panel on the other two issues, offering more flexibility in the relationship between national and international standards; and holding that complainant had not provided sufficient evidence that the restrictions in this case had functioned as a discriminatory restriction on trade.

Salmon: A WTO panel ruled against Australian bans on fresh and frozen salmon imports to prevent the spread of fish borne diseases because the ban: (1) was not based on a risk assessment including identification of vectors, entry methods, and consequences; (2) were arbitrarily higher than measures governing other potential risks including bait fish and live ornamental fish without trade implications; (3) were not minimally trade restrictive, since beheading and eviscerating fresh and frozen fish would have been as effective as heat treatment. The WTO Appellate Body upheld the Panel ruling against Australia noting that the ban was not based on an assessment of risks and that the ban was a disguised restriction on trade.

Fumigant Certification: A WTO panel ruled against Japanese requirements for full testing of the effectiveness of methyl bromide as a fumigant against moth eggs and larva on every new variety of fruits and nuts, finding that the testing requirement for every new variety: (1) was not based on risk assessment; (2) was more trade restrictive than necessary since testing standards could set on basis of sorption level rather than full retesting; and (3) were not transparent since the requirements were not published. The Appellate Body upheld the Panel ruling against Japan, noting that the retesting requirements were not based on risk assessment and were not transparent, while overturning the Panel finding that the retesting requirement was needlessly trade restrictive because the finding was based on evidence provided by the Panel and not parties to the case.

Fuel Formulation: A WTO panel ruled against the US for imposing penalties on Venezuelan gasoline that did not meet oxygenation standards under American law. The panel found

that the US had established higher standards for gasoline of foreign than domestic origin, noting that the legislative history explicitly mentioned congressional intent to provide a modest favor for domestic producers. The WTO panel found that the penalty imposed by the US on Venezuela in this case was negligible, but that the differential standards were discriminatory. The WTO panel offered the US two methods of coming into compliance, by raising the domestic standard to meet the international standard or by lowering the international standard to meet the domestic standard.

Shrimp-Turtle: A WTO panel ruled against the US for banning some imports of shrimp harvested without benefit of sea turtle restriction devices. The WTO panel did not unconditionally strike down US reliance on import restrictions to address differences in how nations regulate fishing practices. The WTO panel did find that the US had set two different schedules for phasing in import bans linked to shrimping techniques, and in so doing had engaged in discrimination against countries faced with the tighter schedule for compliance and in favor of countries faced with the more relaxed schedule for compliance.

Asbestos: WTO panel considered a complaint by Canada against France and the United States challenging domestic regulations barring use of ceiling tiles and other products that use asbestos. The Canadian challenge on behalf of asbestos producers in Quebec contended that French and US regulations are not based on adequate scientific risk assessment. The core of the Canadian case rests on the claim that some varieties of asbestos are safe when used in ceiling tiles and other building materials, and that regulations that do not differentiate among varieties of asbestos are both arbitrary and needlessly trade restrictive. The WTO panel upheld French regulations.