Technological Forecasting & Social Change 77 (2010) 951–959

Contents lists available at ScienceDirect

Technological Forecasting & Social Change

Planned adaptation in risk regulation: An initial survey of US environmental, health, and safety regulation

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ARTICLE INFO

Article history:
Received 1 May 2009
Received in revised form 23 November 2009
Accepted 25 November 2009

Keywords:
Regulation
Decision-making
Adaptation
Learning
Environment
Health
Safety
Government
Knowledge
Planned adaptation
Self-correction
Air pollution
Pharmaceuticals
Regulatory reform
Policy
Evaluation

ABSTRACT

In principle, we want regulatory programs to be based on current realities, as reflected for example in the best knowledge of relevant experts. That would imply that old rules now on the books should be consistent with today's knowledge base, not just what was known when a rule or standard was originally set. This paper reports on a survey of US programs, examining how often existing rules are actually updated in light of better knowledge, and identifies five programs that attempt to make policy routinely adaptive. These programs exhibit what we term Planned Adaptation: they both revise rules when relevant new knowledge appears, and take steps to produce such improved knowledge. While Planned Adaptation is rare, it is used in several nationally prominent programs, including air pollution, airplane safety, and drug safety. Planned Adaptation is a policy tool that deserves more attention.

1. Introduction

This paper asks how real organizations have coped with advances in knowledge that may affect the soundness of their past policy decisions. A few examples are found that use an interesting policy approach that we term Planned Adaptation as a strategy for making policy under conditions of persistent scientific and other uncertainties.

Much energy has been expended in discussing how to align new government decisions with the best available scientific knowledge. This is because regulatory decisions often involve many scientific and other substantive uncertainties. Analysts and policy officials must in such cases formulate plausible working assumptions about the benefits and risks that a new policy will bring to the public. The reasonableness of those assumptions is often at the heart of public debates over policies, and, as a general matter, unreasonable assumptions should be identified and amended before a final decision is made. In the United States, elaborate legal and administrative safeguards have been put in place to promote the substantive accuracy of such assumptions. In Europe, too, institutional arrangements have been made to promote thorough assessment of relevant science; examples are found in the Impact Assessments required for new regulations considered by the European Union.

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0040-1625/$ – see front matter © 2009 Published by Elsevier Inc.
doi:10.1016/j.techfore.2009.12.001

But if the overall public objective is to link policy with factual knowledge, this is only a fleeting victory. Over time, things change. Science evolves, technology advances, and implementation costs migrate, so assumptions that were once reasonable can become much less supportable. When this occurs, the delivered benefits of a policy decision and its actual social costs may fall substantially out of the intended balance. Over time, a policy may come to embody benefits that are unreasonably low or costs that are too high, as reflected in updated knowledge.

Thus, the larger question is whether practical means can be devised to *keep* policy yoked to an evolving knowledge base, once decisions are put on the books.

2. Approach

To address this question, we used an inductive approach, one that focuses on US regulation and that seeks to find practical lessons of the past in delivering policy that can adapt to new realities. Is adaptive policy a realistic possibility?

While such writers as Charles Lindblom, Aaron Wildavsky, and Karl Deutsch have written of policy as an inherently dynamic process, none has focused on the everyday aspects of coupling old policy to new knowledge [1]. More recent treatments have begun to refine conceptual notions of adaptive policy processes [2]. Respecting the reality that reform ideas must be both conceptually sound and administratively practical, our survey asks what actual American programs have evolved with induced-learning features, and what lessons we can learn from those cases.

As detailed below, this exploratory survey turned up a handful of such heuristic cases. We employ the term "Planned Adaptation" to describe their shared features. Our use of the term is reserved for cases where [a] there is a prior commitment to subject an existing policy to *de novo* re-evaluation and [b] systematic effort is made to mobilize new factual information for use when the re-evaluation takes place. Our search field is primarily US Federal regulation with respect to the environment, health, and safety.

In any society, rules are constantly subject to change. Such change often comes as a result of a "reality bites back" failure. A rule fails to prevent some highly visible calamity, or its political opponents undermine its legitimacy, and thus its revision is forced by events. Our interest is in fostering policy adjustment without the ruckus: Can governments bring new knowledge to old policies in a more thoughtful way, and one in which the underlying uncertainties are successively reduced – or at least better characterized – over time?

Our survey of US regulatory experience proceeded in two phases:

- Phase One: Identification of plausible examples.
- Phase Two: Evaluation of candidate cases for relevance.

3. Phase One: Case identification

Our survey began as an investigation into how common it is for regulatory agencies to re-open their books of existing regulations to see if they needed to be adjusted. As we proceeded, however, we found that some programs were using similar methods to ensure agency learning over time – methods using Planned Adaptation. We then sought additional candidate examples of Planned Adaptation across US regulatory programs – mostly in the fields of public health and safety and the environment.

The general idea that Federal agencies should not ignore evolving evidence on the actual effects of their existing rules is one that has actually had surprisingly lively history in the US. As early as 1946, the Administrative Procedures Act laid out an explicit provision allowing interested and affected groups to ask for the amendment of an existing rule, and prohibiting the authorizing Federal agency from declining to consider such requests without explaining why [3]. In 1978, President Carter's Executive Order on regulation required that "agencies shall periodically review their existing regulations," especially when "technology, economic conditions or other factors have changed" [4]. Immediately upon taking office in 1981, President Reagan issued his own order on regulatory reform; it called for agencies to "initiate reviews of currently effective rules" and also gave the Office of Management and Budget the power to designate specific rules for review [5]. Eleven years later, when President George H. W. Bush issued a moratorium on all new Federal regulations, he gave all US agencies 90 days to examine all their existing rules to "weed out unnecessary and burdensome government regulations" [6]. The Clinton Administration too set up a program under which each agency "will periodically review its existing regulations to determine whether any such regulations should be modified" [7]. And later, responding to a Congressional mandate, the Office of Management and Budget issued a public appeal for help in identifying specific rules that needed adjustment. OMB reported in 2002 that the public had named 71 such rules, and that 23 of these were deemed "category 1" suggestions, meaning that the agency that had issued the rule was next required to defend it in writing [8].

The ultimate impact on policy of this decades-long flirtation with the re-assessment of existing regulations is, at best, unremarkable. With one exception, neither Congress nor the four Administrations involved (two of them Republican, two Democratic) even made public an account of the actual results of these ambitious screening plans. It is tempting to conclude that the idea of routine policy adjustment is one that is sweet in the abstract but decidedly unappealing in the application.

That lone exception is the 1992 George H. W. Bush initiative. This is an exception because it left a visible trail. It was not a clear policy success. In fact, economist Murray Weidenbaum, a senior Republican advisor to both Reagan and Bush's regulatory reform efforts, later wrote that "it is difficult to pinpoint specific changes that resulted" from President Bush's ambitious government-wide 90-day canvassing [9]. However, it did lead to a tangible listing of agency actions across the Federal landscape. Each agency

Table 1
Reported US initiatives involving programmed rule revision. (The five cases selected for this paper are in bold type.)

Case	Unit	Description
		A. Reported agency-based review initiatives—EHS
1	EPA	NAS review of radiation effects standards
2	DOT/NHTSA	Post-hoc evaluation program highway safety rules
3	**EPA**	**5-year reviews of National Ambient Air Quality Standards**
4	EPA	Reviews under the Toxic Substances Control Act
5	DOT	Review/elimination of 66 DOT-wide regulations
6	**DOT/FAA**	**Review of aircraft safety certifications**
7	**FDA**	**Drug safety under post-marketing surveillance and review**
8	OTA	Review of the costs of occupational safety rules
9	EPA	Review of drinking water standards
10	EPA	Section 312 Review—"The Cost of Clean Air"
11	DOT/FAA	Solicitation of nominations for the "Worst Three" FAA rules
12	**FDA**	**NAS review of Recommended Daily Allowances for human nutrients**
13	**USDA**	**NAS review of nutrition requirements for animals**
14	USDA	Cyclical 5-year review of the Farm Act
15	USDA	Review of Food Safety and Inspection Service rules
16	EPA + OSHA	Evaluation of Cost Estimates (Under Contract with RFF)
17	EPA	Accountability project at the Health Effects Institute
18	DOI	5-year review cycle of the Department of Interior programs
19	CPSC	Pilot Program—review of selected consumer product rules
		B. Reported agency-based review cycles (non-EHS)
20	DOD	2-year review cycle of Defense Programs
21	FTC	Review of costs of Federal Trade Commission rules
22	NCUA	3-year review cycle of all credit union rules
23	FDIC	5-year review cycle of deposit insurance rule
		C. Reported government-wide initiatives
24	Congress	APA Section 553—Petitions to revise rules
25	OMB	Executive Order 12044—Improving Regulations
26	SBA	Reviews under the Regulatory Flexibility Act
27	OMB	Executive Order 12291—Review of benefits/costs
28	OMB	One-time review—all federal rules
29	OMB	Executive Order 12866 – Review and adjustment of rules
30	OMB	Government Performance and Results Act (GPRA)
31	OMB	"Costs of Regulation" report to Congress
32	Congress/OMB	Public's nomination of rules needing reconsideration

was required to file a report on its reconsideration of existing rules. This provides a useful point of departure for the survey conducted for this paper.

The Bush Administration's agency reports were summarized in a 1996 report to the Administrative Law and Regulatory Practice Section of the American Bar Association (ABA) as compiled by Eisner and Kaleta, two Department of Transportation attorneys [10]. The summary is admirably complete in its discussion of the legal basis for executing *de novo* reviews, but we found it much less specific in its reports of actual agency progress in reassessing their existing rules. Nearly 40 regulatory agencies were covered, but we could identify only eleven items to include in our sample of candidates as adaptive policy experiences.

For this paper, we made persistent but informal efforts to identify other relevant agency practices, with emphasis on initiatives that occurred in the years after the ABA report. We asked administrative lawyers, agency representatives, and others to suggest cases to add to our list. Twelve more agency efforts surfaced in this effort. Adding other government-wide reform initiatives including those described above, we thus assembled a set of 32 Federal initiatives to evaluate.[1] Table 1 lists these cases, which comprise 19 agency-based environment, health, and safety (EHS) cases, 4 agency-based cases in security and economic programs, and 9 government-wide measures that apply to EHS and other agencies.[2]

4. Phase Two: Evaluation

Next, we worked to authenticate the 32 cases and assess their relevance to the subject of this paper. Our *authenticity* criterion specifies that both [a] the reported initiative was actually implemented, and that [b] it involved substantive changes to existing regulations, rather than, say, minor reporting or procedural requirements.

[1] Summary descriptions of the 32 cases, and further details on how we reached conclusions from analyzing them, are in a technical document at http://web.mit.edu/cis/petp_wp.html; click on the link "Planned Adaptation in Federal Regulation," by Lawrence McCray.

[2] Thus, 28 of the cases pertain to the activities of agencies with EHS responsibilities, including the Environment Protection Agency (EPA), the Food and Drug Administration (FDA), and units within the Department of Transportation that address aviation and automobile safety.

Applying these criteria eliminated over half of the sample from further consideration. Six of the excluded cases were past policy statements promising review cycles every 2, 3, or 5 years for examining an agency's existing rule. We were unable to confirm that any had been implemented in practice. Unconfirmed, too, was the Federal Aviation Administration's (FAA) interesting plan to regularly elicit from the public nominations for the "worst three" FAA rules most needing change [11]. Similarly, the FDA was reported in 1993 to be ready to invite public comment on which of its rules needed fresh review [12], but we were unable to find later confirmation of this program. And by 2004, the Office of Management and Budget (OMB) had evidently abandoned its new Congressional mandate to promote reconsideration of rules that had been deemed outmoded by private parties [13].

Our criteria for *relevance* reflect our definition of "Planned Adaptation" above. This definition most closely reflects the common usage of the term "feedback." To count as Planned Adaptation, a case must show both a prior commitment to a *de novo* policy review and a means of assembling updated scientific and factual information for use in that review. That is, both policy reconsideration and new evidence need to be involved.

A few cases were eliminated because they exhibited *changing without learning;* that is, rules were changed or eliminated, but without a concerted attempt to develop fresh information on the actual impact of the rule on public benefits or costs.

Several more cases were eliminated because they seemed to amount to *learning without changing*. These include a number of programs intended to ascertain the actual costs or benefits of past regulatory decisions, for which there was no evident attempt to adjust the rule to enhance public benefits and/or reduce public costs. An example was the National Highway Traffic Safety Administration's (NHTSA) lively post-hoc Review Program, which has assessed the effects of past highway safety rules. A series of reports was produced, but agency personnel were unaware, when interviewed, of the use of such studies to re-adjust the existing rules themselves.

5. Results

Our screening process leaves us with the five cases (3, 6, 7, 12, and 13) highlighted in Table 1 as US programs that can be typified as Planned Adaptation. Further investigation may well reveal others. This yield is not impressive in number, but it does demonstrate that Planned Adaptation is administratively – and politically – feasible. Furthermore, the national significance and high visibility of the first three of these examples is impressive, suggesting that sometimes when the stakes are highest, government has already turned to Planned Adaptation to make sure that its policy assumptions remain valid.

We review these five cases below.

5.1. Case #3—Human health standards for air pollutants, especially for US ambient standards for particulate matter

The EPA program for ambient air standards is likely the most fully-developed existing program of Planned Adaptation. Congress mandated regular reviews of existing health standards beginning in 1980. In this program, new knowledge assessments of the health effects of selected pollutants are performed periodically, and each is then linked to a fresh policy assessment to determine whether and how the old standard should be changed. If one believes that regulatory policy ought to be cybernetic in nature, the program is something of a model of what is possible.

US air quality is regulated by EPA under the Clean Air Act. For six air pollutants (e.g., particulate matter, nitrogen oxides, carbon monoxide), EPA sets National Ambient Air Quality Standards (NAAQS) in order to prevent pollution-caused health effects. The agency then undertakes to limit – and to ensure that individual American states limit – pollutant emissions so as to achieve those ambient standards. EPA also monitors air quality to detect areas of the country that are "in nonattainment" with current ambient standards.

The Act, as amended, specifies that each of these standards be subjected to fresh scientific reviews every five years. Congress added the continuous updating as a last-minute detail in reconciling the House and Senate versions of the Clean Air Act Amendments of 1977.

The administrative mechanism that has evolved to perform the reviews is complex. A cycle starts when EPA staff in its research office drafts an extensive "criteria document" on a pollutant, one that summarizes all available scientific information on the effects of human exposure to the pollutant. A group of outside specialists then assesses the document for currency. This review is managed by the Clean Air Scientific Advisory Committee (CASAC), which is administered under EPA's Science Advisory Board. The scientific vetting thus operates at some organizational distance from the EPA air office, which actually manages EPA's air pollution control program. CASAC's primary function – one that it guards zealously – is to ensure the scientific integrity of the updated knowledge assessment. Once it completes that task, policy officials at EPA consider whether there is reason to recommend an adjusted standard to the EPA Administrator. This reticulated process is clearly an attempt to isolate the interpretation of the knowledge base from the policy pressures that impinge on the weighing of the public benefits to be achieved in the standard-setting process.

Is this EPA program effective in keeping policy and knowledge in synch over time? Measured against apparent Congressional expectations, it shows obvious imperfection. In the ensuing decades, EPA has fallen short of the Congressional five-year time schedule, and several reviews were only begun in response to unfriendly lawsuits that led to court orders to proceed. However, reviews have been completed for six criteria pollutants after 1977 (the PM standard itself has been adjusted three times since 1980). Many standards have changed as a result, some of them to tighten the existing standard, and some of them to relax the standard. While some are critical of EPA's inability to adhere to a strict 5-year cycle, the pace of science and the deliberateness of the policy review may suggest that a longer period would be adequate for policy purposes.

The most noteworthy segment of the NAAQS program is the use of Planned Adaptation for the regulation of particulate matter (PM). Anyone who thinks of particulate matter as just another pollutant is missing a key point: PM dominates the calculations of the overall benefits of all US regulation, which comprises dozens of programs. When OMB took on the tough task of reporting the aggregate national costs and benefits of regulation, it found that some three-quarters of the benefits were attributable to the Clean Air Act (CAA) regulations [14], and one observer has calculated that the prevention of premature death and of sickness by controlling PM accounts for 90% of those CAA benefits [15]. This implies that, while the range of uncertainty in such calculations remains very large, PM regulation may well have provided a lion's share of the total worth produced of all US regulatory programs in recent times.

But what is most interesting about the PM emissions standard is the aggressive effort to advance the relevant science, and not just to settle for dealing with advances that happen to turn up. Congress added significantly to the sums EPA requested for PM research, and, with guidance from the autonomous NAS/NRC, a 10-year research attack on uncertainty about the effects on humans of exposure to PM emerged. That research was specifically aimed at the coming planned reviews of the PM standard. EPA asked for further help from the NAS/NRC in determining how that enlarged EPA research budget was apportioned and then spent, thus keeping a constant eye on the major remaining gaps in policy-relevant knowledge. The PM case stands as the most fully articulated Planned Adaptation example we have: it is a program that both systematically creates, and adapts to, new knowledge pertinent to airborne particulates.

Partly because of the linkage between policy and the evolving knowledge base, the American strategy to reduce the health effects of PM has evolved significantly over the years. The result was not just an incremental adjustment of the PM standard, but a rethinking of how to attack the PM health problem. Early policy concern had been directed at visible black smoke, measured as Total Suspended Particulates. When studies later showed that it is the smaller particles that are most strongly associated with adverse health effects, the standard was changed to focus on particles under 10 μm in size; later yet, the standard was further modified to limit ambient levels of 2.5 μm.[3] One can ask whether this sequential problem redefinition would have happened as readily, or as rapidly, in the absence of the mandated sequence of PM reviews.

5.2. Case #6—Air transportation safety

Planned Adaptation is seen in a different form in the US program to regulate safety in commercial air transportation and other modes of civil transportation. For civil aviation safety, substantive knowledge about safe design is brought to bear when certificates of aircraft airworthiness are granted by the Federal Aviation Administration (FAA).

If transportation safety were a typical regulatory program, this simple means of licensing might be deemed sufficient to meet national needs. But for air safety we find an additional layer of ongoing safety protection in the independent work of the highly visible National Transportation Safety Board (NTSB). The NTSB′s role is to investigate accidents in order to ensure that previously undetected causes of safety failures are discovered and addressed. The “planning” in this form of Planned Adaptation is not a general knowledge assessment tied to a scheduled review cycle. Instead, it is the provision, in advance, of ample investigatory capacity (seen in the NTSB “go-teams” that are quickly mobilized to examine every civil aviation accident) to enable diagnosis of problems when they arise.

This special investigatory function is not vested with the DOT/FAA itself. In fact, NSTB was been housed within the Department of Transportation (DOT) until 1975. In 1974, the cargo doors on some DC-10 aircraft had failed in flight, and the resulting public controversy raised charges that the plane's manufacturer, the FAA, and the White House had resisted implementing the Board's recommendations for eliminating that problem. Congress then passed a 1975 law that ended NSTB's dependence on the FAA. While FAA personnel do participate in some NTSB investigations, they are pointedly excluded from NTSB deliberations to determine the “probable cause” of civil aviation accidents. NTSB takes obvious pride in its reputation for technical competence and independence. A report of the Congressional Research Service pointed out that the Board has issued well over 10,000 safety recommendations covering all forms of transportation, and that the relevant authorities have implemented over 80% of them. [17]

Over time, the mission of NTSB has evolved to expand beyond mere disaster response. It is also proactive. It has built, and it maintains, a data base on non-military air accidents, useful in identifying patterns that would otherwise go undiscovered in the review of individual crashes. It examines “near miss” events to identify underlying risks. It also publishes a list of “Most Wanted” safety improvements across a broad range of air and surface transportation modes, which has had the effect of focusing public attention on those areas where technical or policy innovation is needed. Examples include recommendations relating to the risk to children of automobile airbags, nominally a subject for the DOT's National Highway Safety Traffic Administration. NTSB is constantly working to convert new knowledge to new policy improvement.

5.3. Case #7—Pharmaceutical regulation

The US Food and Drug Administration (FDA) regulates pharmaceuticals. It has long used a weak form of Planned Adaptation in dealing with new drugs. Once the requisite clinical trials for a candidate new drug have been accepted, and a new drug application approved, FDA's longstanding Post-Marketing Surveillance Program was intended to help detect any adverse reactions that arose as the general population began using it. One can see why such a program makes sense; a clinical trial tracks the reactions of a

[3] There are still uncertainties concerning the health relevance of these size-based indicators [16]. Attacking such scientific uncertainties may lead to a future policy focus on the nature or structure of particles instead of size.

comparatively homogeneous and relatively small group of fairly healthy adults, and some might construe the *real* trial as starting after that, when far larger numbers of more physiologically diverse Americans are exposed to the approved drug.

The relative weakness of the old program is seen partly in the lack of strong incentives to detect or report adverse reactions to newly-introduced medications. To suspect an adverse drug reaction, for example, a busy physician would have to first infer (from narrow evidence) that the drug itself was causing a health problem, to entertain-self doubt about the therapy he or she had chosen, and to take the trouble to submit a report. The program was incapable of adding much knowledge on how effective a marketed drug actually was, in practice, or whether it was either more or less effective in particular subpopulations. In addition, many physicians prescribe some drugs for "off-label" uses, and the program has, to now, been unable to shed systematic light on either their efficacy or their risks in such circumstances.

More recently, after highly visible headlines about the serious side effects of the pain medication Vioxx and other marketed drugs had appeared, the public spotlight fell on the FDA's role in post-marketing decision making. Lapses were decried, and reform was called for.

Among those suggested remedies was a set of 25 ideas advanced in *The Future of Drug Safety*, a 2006 report of the Institute of Medicine, which is a component of the National Academies complex. Those proposals embody and extend the concept of Planned Adaptation.

The heart of the IOM plan was a mandated review of all available knowledge – and not just data on adverse events – about each new medical entity after it has been on the market for 5 years. (The European Union had previously committed to periodic reviews of newly-marketed drugs.) That review would no longer be led solely by the FDA's Office of New Drugs, which clears drugs for marketing; a considerably strengthened Office of Safety and Epidemiology would share authority for the post-marketing decisions. Just setting a target date for a review would provide encouragement for developing empirical data on a marketed drug's performance. The IOM recommends taking a critical extra step and setting up a new public–private partnership organization charged to find ways to actually fund the studies needed in the reviews. Thus, manufacturers themselves might be drawn into supporting a full range of data on the actual implications of drugs on the market. This feature is not seen in other cases of Planned Adaptation: it would mean that the burden of reducing uncertainties after regulation would rest, in some part, with the regulated sector.

5.4. Cases #12 and #13—Nutrition standards

Two programs, both operated by the NAS/NRC, relate to the systematic adjustment of nutrition guidelines in light of new scientific knowledge.

5.4.1. Human nutrition

Established in the 1940s, the Food and Nutrition Board (FNB; since 1988 a part of the Institute of Medicine of the National Academies) is a panel of scientists from leading universities that has periodically updated Recommended Daily Allowances (RDAs) and other standards for many human nutrients and vitamins. In each case, a special review group is formed to consider all available scientific information and change recommended levels as needed.

Government agencies fund the work. However, these are independent assessments, and they follow the rules of the National Academies, under which sponsors can neither choose panel members nor clear draft reports for public release. Recommended Daily Allowances, the best known of the nutritional standards, represent the daily intake needed by nearly all healthy people, and comprise separate levels set for females and males and for several age groups. After the FNB issues revised levels, they are reportedly then reflected in mandated food labels and in public sector guidance to nutritionists, and, as needed, they are accommodated in the USDA's Food Pyramid guidance.

While in earlier decades these standards were routinely reviewed about every five years, more recent Federal agency support has permitted only an *ad hoc* approach. Until 1995, core funding for the program had been provided by the National Institutes of Health. Now, multiple sponsors are assembled on a case-by-case basis. The 2008 review of Vitamin D and calcium, for instance, was supported by 9 government agencies (including two in Canada) [18].

5.4.2. Animal nutrition

Similarly, the National Academy's Board on Agriculture and Natural Resources has produced a long series of reports on the nutrient requirements of animals, covering some 30 species of farm animals, pets, and laboratory animals. These "species reports" date back 65 years, and have been iterative; for instance, nutrition standards for horses have been reassessed twice since 1980, and those for dogs have been reviewed three times since 1970. State governments apply the minimum nutrients rules in animal feed, using the evolving NAS reports, which have the tricky task of keeping up with the effects of rapid selective and artificial breeding in commercially important animals; these are no longer just the traditional chickens and cows that were found on yesterday′s family farms. In the last ten years, funding from key sponsors – USDA and FDA – has declined, and reviews are now done only when a funding consortium can been assembled among public and private organizations.

6. Discussion

Finding so few examples of Planned Adaptation – especially in view of the repeated government-wide support for the reconsideration of existing rules – is a spur to contemplation.

Planned Adaptation has attracted, to this point, an exceedingly peculiar constituency. As a general proposition, it has considerable appeal. Surely there is no harm in asking whether the assumptions made in predicting the benefits and costs of past decisions have proved accurate in fact, and an undertaking as complex as regulation is surely best approached as a matter of trial-and-error learning. However, it has never developed a sustained or strong backing from any specific group. We might infer that the demand for self-corrective mechanisms in American regulation is persistent as a general nonpartisan "good government" principle, but is as yet unpopular in application. An Administration's leaders might lean toward it, but its agencies, mostly, do not. It is worth briefly exploring some simple conjectures about what practical impediments are making Planned Adaptation an exception, and not a commonplace, on the American landscape.

The simplest explanation for the scarcity of adaptive mechanisms is that the regulators themselves just do not like them. There is, obviously, some merit in this observation. It is fair to say, at this point in our investigation, that no agency has enthusiastically promoted the idea of installing substantive self-correction measures, even for isolated policy areas.

And what is seen as the basis for such reluctance? A superficial but not uncommon view is that public bureaucracies always prefer the status quo to new ways – that they are bound by red tape – whether because of habitual laziness or some inborn fear of the unknown. But we need to look beyond such caricature. There are, in fact, creditable reasons to value stability in policy. One strong influence is the need to render regulations enforceable and credible to those who must comply with them. Is it fair to force someone to comply with a rule that might soon be softened or removed?

Beyond enforcement, an agency's public reputation may be threatened. In policy, as in politics, "flip-flopping" is an unappealing trait. It may imply weakness or, worse, unprincipled malleability in the face of political pressure. Some agency officials we talked to raised another issue: their slim budget for analyzing and writing expensive new rules is already stretched, and re-examining past rules is an unaffordable luxury.

Whatever the power of such *internal* arguments, we encounter a seemingly larger mystery in the expressed preferences of *external* groups. Agency programs are regularly criticized by both those who want tougher regulation and those that want milder regulation. One might expect regulated interests and their usual opponents (consumer, environmental, and other public-interest advocates) to form a natural constituency favoring the re-visiting of existing rules. It is common, for example, for some subset of 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 that this is true. One might expect that such aggrieved interests groups would 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 them to be a flawed decision? Partisan groups on all sides typically spend heavily to convince regulatory agencies to decide in their favor when new rules are written, and often enough spend more to appeal them in the courts; would one not expect them to devote similar effort to correct mistakes in the existing rules?[4]

Given this array of colorable arguments against Planned Adaptation, one could be tempted to conclude that this policy idea is, overall, plainly infeasible; it should never occur in nature. But it *does* occur in nature.

This paper presents a preliminary survey. To better understand the actual forces that favor and impede self-correction in policymaking, broader inquiry is needed. For example, it may be useful to look beyond the terrain represented by US regulatory policy. Dealing with uncertainty, and an actively changing knowledge base, is found in several other policy domains, and there may be lessons to learn there. For example, the Federal Open Market Committee conspicuously and regularly reviews the "Federal funds" interest rate, which drives the prime rate for bank loans. Institutional arrangements for accomplishing those frequent reviews may prove instructive. Nutrition guidelines for the public are subject to ever-changing ideas about what is healthy (the area of dietary fats has been an ongoing adventure in recent times) and may be an instructive case to examine. Military practices likely demonstrate attempts at self-correction, because the stakes are so high. In fact, the US military has employed a "lessons learned" practice for US troops in Iraq. There also may be lessons to be learned from such areas as programs for reducing the risks of household fires, a matter that is addressed by private code-writing groups and coverage decisions made by insurance firms, and the further reduction of medical errors in hospitals.

Non-US experience can also be examined. One place to start might be to conduct a survey similar to ours for other regions, such as the European Union or Japan. Comparative study of how different nations organize themselves to handle decision making in areas where knowledge is volatile may prove useful. Do European programs for air pollutant health standards and for improving civil air safety employ Planned Adaptation? Why, or why not? Is the Netherlands' vigilant program for dealing with the risk of inundations approximated in some other coastal nations?

Also, international regimes merit study. Under international law, the general precept that treaties must be respected (*pacta sunt servanda*) is qualified by the understanding that they may be rendered inapplicable by changing conditions (*rebus sic stantibus*). We find specific provisions for Planned Adaptation in response to new information in a variety of international regimes, including the Montreal Protocol on Ozone Depleting Substances, in the International Whaling Convention, and even in UN Security Council Resolution 1441 on weapons of mass destruction in Iraq. The incidence and effects of such experiences merit further analysis.

Corporate practices may also have procedural implications for policymakers. Self-correction may be somewhat easier for business firms than for government bodies, in that ready indicators of success and failure are found in such measures as product sales and market share. A new product introduction is, in a sense, a new policy for the firm, and if sales of the product do not thrive,

[4] One can speculate that regulated firms desire sound rules, but more than that they desire stability; better a poorly conceived rule than a changing rule that defeats the companies' business plans. And one can speculate that public-interests groups fear that they would be at a relative disadvantage vis à vis such firms in re-contesting existing rules again and again.

the firm needs to know that right away, and to take corrective action. When the "new Coke" flopped in 1985, the Coca-Cola Company acted with alacrity in recognizing the public displeasure, in admitting error, and in committing to deliver the newly branded "classic Coke" onto store shelves within a period of three months.

7. Conclusions

Planned Adaptation is feasible as a decision strategy, even in tough policy areas. The examples summarized above demonstrate the feasibility of Planned Adaptation as a formal decision strategy. In fact, varying versions of the approach are being used in policy areas – i.e., the major air pollutants, public safety in air travel, safe drugs – that involve high stakes, public visibility, and new science – factors that regulatory administrators often find most challenging. It is as if when regulation is most sensitive, the forces of inertia are overcome, and a system of Planned Adaptation is demanded.

Still, instances of Planned Adaptation are relatively rare. Judging from the sparse results of our survey, Planned Adaptation is plainly not common in US rule-making.

Where Planned Adaptation is found, it is notable that it has been imposed from outside the executive agencies themselves. It was the Congress, and not the EPA, that designed the system of *de novo* reviews into the air quality standards program. The move to fortify the management of pharmaceuticals after market approval came neither from within the FDA nor from its interested publics. It was not the FAA that moved to strengthen NTSB by making it an independent force in identifying and remedying problems in civil air safety.

This general pattern suggests that Planned Adaptation may be regarded as a destabilizing influence by those closest to the rule-making process, including the agencies and nongovernmental advocacy groups on both sides.

In the preceding section we have enumerated some of the plausible reasons that such entities may oppose adaptive strategies. Whatever the particular objections might be, we need to recognize that Planned Adaptation generally entails a new way of thinking about public policy: it requires a public acknowledgement that policymaking is *open-ended*. We seem to have been most comfortable, in the past, with the idea that strong public programs are those that feature *definitive, permanent solutions*. In contrast, Planned Adaptation implies a more fluid working environment. In such an environment, new knowledge that is inconsistent with the assumptions embodied in past decisions is seen as a destabilizing factor, a factor that may reopen old debates and undo past consensus-building.

If the risk of destabilization is a reason that self-adjustment is now rare in regulation, it needs to be taken seriously. It needs to be weighed, case by case, against the need to keep regulation consistent with the best knowledge about the actual benefits and costs. In areas where new knowledge is not pervasive, adaptive policies may be found to be unhelpful. Perhaps Planned Adaptation should be used selectively, when major factual uncertainties are present, or when very large public benefits and costs are at stake. But as a general premise, does it make sense to unthinkingly continue to uphold and enforce rules now that are based on assumptions that still incorporate the knowledge base of the 1970s or 1980s, in areas where new knowledge is plentiful?

Deliberate organizational separation is a common feature of current Planned Adaptation efforts. All five examples of Planned Adaptation feature the deliberate segregation of organizational roles. The "learning" function (reassessing the relevant evidence) is carefully isolated from the "changing" function (deciding whether and how to re-craft the rule). Thus, the National Transportation Safety Board assesses crash evidence, but works at some distance from the licensing process at the Federal Aviation Administration, and for air pollution standards the science assessment is conducted in a unit that operates at some organizational distance from EPA's air pollution policy office. And four of the five cases of Planned Adaptation involve interaction between a government regulator and the National Academy of Sciences/National Research Council, a non-governmental body that jealously guards its independence from the undue influence of the governmental (and other) sponsors of its study projects.

A key advantage of Planned Adaptation is that it creates incentives for creating new policy-relevant knowledge. One of central tensions in many of today's most interesting regulatory arenas is the intense ambivalence about dealing with uncertainty. For a public health issue involving chronic disease, for example, typical uncertainties in the benefits of reduced exposure (i.e., the human health risks) can span orders of magnitude [19], uncertainties in the costs of controls can easily span a factor of two or more, and the uncertainties in rates of compliance might also be significant.

In such a setting, the selection of the best regulatory option necessarily represents – to use colloquial language – a "best scientific guess" as to how to set a reasonable rule. When uncertainty is huge, one cannot really expect any more than that. However, after a decision is made, long tradition holds that it be presented as both definitive and durable. At this point in the process, of course, everyday authority passes from rulemakers to enforcement officers, and the underlying uncertainties naturally receive considerably less attention. The demand for better knowledge dims.

The plain fact is that if a decision is construed to be permanent, there is scant incentive to pursue relevant new knowledge. Why try to further characterize and/or reduce the uncertainties in the assumptions made in past decisions if there is no plan to reconsider them? Within the agencies, research programs are strongly encouraged to devote their resources to future decisions, rather than for the closed cases for which decisions are already on the books. The same incentives are presented to researchers and their funders outside the government; why invest in knowledge about issues that have already been definitively decided? And because the needed fact-finding is of an applied nature, scientific curiosity cannot normally be expected to fill in the needed data, as it might for basic research questions: directed funding is the key to most regulatory learning.

As is manifest in our actual cases of Planned Adaptation, such disincentives are minimized when it is clear to all that the books are still open on a given policy issue. Whether the next review is firmly scheduled, as is found with the EPA particulate standards and the NAS/NRC nutritional reassessments, or whether it depends on future anomalies, like the NTSB accident evaluations, it is

obvious that there will be a time when better knowledge will be in high demand, and research funders are not immune to the lure of upcoming opportunities to improve public policy. Only if we institute better incentives for generating new policy-relevant knowledge can we, over time, arrive at evolved policies that remove the effects of any unsupportable assumptions that are embedded in the corpus of existing rules.

We believe that this paper demonstrates that Planned Adaptation is a particularly interesting species of decision making, and one that is at least minimally effective in improving policy where it has been tried. It is a species that arose as a result of natural evolution in regulatory programs, and it seems appropriate to ask if it should be emulated across US regulatory programs, and perhaps beyond.

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