A THEORY OF THE CHOICE OF REGULATORY FORM

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Abstract

Various pieces of federal legislation attempt to regulate hazards associated with chemicals, food additives, drugs, consumer products, pesticides, airborne and waterborne pollutants. This legislation spans many decades and varies in the kinds of regulatory mechanisms created and in the degree of discretionary authority granted to regulatory officials. The stated goals of this legislation are to identify and prevent significant health and environmental hazards before they become widely dispersed throughout our society and economy. Despite their seemingly broad and straightforward congressional mandates, however, implementation of these programs has been slow.

In this paper we will present a model of governmental regulatory choice. The model is based upon the behavior of institutional actors in the decision process—legislators, bureaucrats, and interest groups. The model will relate the institutional motivations of these actors and the influence of environmental factors, such as decision uncertainty and group conflict of interest, to the choice of regulation. It will be deduced that increased uncertainty over the impact of proposed regulations will induce the legislature not only to delegate the choice of regulation to an administrative agency but also to provide the agency with increased substantive discretionary authority and increased procedural decision making requirements. Conflicting interest group preferences, for a given level of uncertainty, will reinforce these tendencies. The model and these results will be employed to develop a systematic explanation for the performance of environmental, health and safety regulation. A few illustrations are presented to explore the validity of this explanation.
A THEORY OF THE CHOICE OF REGULATORY FORM

Introduction

This paper presents a theory of the form of regulatory intervention. The theory relates two key factors — decision uncertainty and group conflict of interest — to the institutional motivations of legislators, bureaucrats and interest groups and thence to the choice of regulatory form. In that the model predicts (conditioned on these two factors) the form of the regulatory intervention to be chosen by Congress, the model has further implications for the performance of regulatory agencies created to administer differing regulations.

The paper departs from previous work on the theory of regulation in three ways. First, existing theories of regulation have focused largely on questions of origin: How does regulation arise and who was behind it (Abrams and Settle, 1978; Jordan, 1972; MacAvoy, 1965; Moore, 1961; Plott, 1965; Posner, 1971-1974; Rainey, Backoff, Levine, 1976; and Stigler, 1971)? In contrast, we focus on the form of regulation. The legislative choice of regulation can be seen as a multidimensional choice in which the legislature chooses not only the policy objectives of the regulation, but also the form of the regulatory intervention; i.e. the policy mandate, the substantive discretionary authority of the administering agency, the regulatory instruments employed to implement the regulation, and the procedures whereby the administrative decisions will be made.

Second, existing theories have tended to be either bureaucratic or legislative in focus, centering upon the behavior of regulatory agencies and their relationship with regulated groups (DeAlessi, 1974; Eckert, 1973; Hilton, 1972; Moll, 1971a,b,c; and Russell and Shelton, 1974) or upon the electoral process and the influence and incentives of the legislative institutions (Fiorina, 1981, 1982; McClellan, 1970; Niskamen, 1975; Peltzman, 1976; Shepsle and Weingast, 1980; Weingast, 1978a,b). Critical reviews of the literature on regulatory choice can be found in Joskow and Moll (1978) and McCubbins (1982a). In contrast, our model focuses on interactions among the three institutional actors: the legislature, the administrative agency, and interest groups.

Third, existing models have tended to be descriptive, while ours is predictive in nature. The possibility of prediction arises because we identify two determining factors (degree of uncertainty and level of conflict). In particular our model can be used to predict the structural and operative features of an administrative agency, in terms of these two factors.

We argue that increased uncertainty and conflict of interest will induce the legislature not only to delegate the choice of regulation to an administrative agency but also to provide the agency with increased substantive discretionary authority and increased procedural decision making requirements. Endowed with broad substantive authority and faced with rigorous procedural requirements, the regulatory agency will respond by expending large amounts of effort in promulgating a relatively small number of well defended regulations.

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The Model.

Our model is one of interaction among three institutional actors: the legislature, regulatory agencies, and interest groups. Clearly, these are not monoliths. They are not individuals maximizing a single objective function by "rational choice." Each is made up of large numbers of individuals, and there are many complicated interactions within each of them. However, for this paper we are most concerned with interactions between institutions, and we attempt to emphasize less the interactions within each of the institutions. (For discussion of some of the interactions within, and how the interactions within relate to the interactions between, see McCubbins 1982a,b.)

McCubbins (1982b) presents a simple model of regulation in which the choice of regulatory policy and the form of regulatory intervention are the result of interactions between these three institutional actors. We extend that model here.1

*FIGURE 1 HERE*

Figure 1 shows the principal means of action for the three actors. In the model the principal motivation for Congressmen is to seek continued electoral support. A principal means of gaining support, and thence votes, is through enacting legislation to ameliorate problems within their districts. Interest groups, who have preferences over regulatory outcomes, are assumed to seek their own net benefit from regulation by supplying campaign contributions to legislators, by lobbying, by supplying expert information, direct publicity, or by court action. Administrative agencies, responding to the incentives created by the institutional structure of government and as supplied by the legislature, act as agents for the legislature. As in other principal-agent relationships, however, the agency may not necessarily act wholly in the interests of the legislature. The means of action for an agency include command and control regulation, provision of information or other public goods, and establishment of decentralized incentives such as effluent taxes or liability rules. The agency, naturally enough, follows its own interests (to discover and fulfill its congressional mandate; to preserve or increase its level of funding of authorization) and the objective of the legislature in this relation is to use its powers (as largely related to appropriations, authorization, and oversight) to create incentives for the agency so as to align the agency's interests with its own.

The Form of Regulation

There are several aspects which characterize the form of a regulatory intervention; the policy mandate of the act, the substantive authority, the regulatory instruments, and the administrative procedures. In choosing the form of regulation, Congress makes choices which define these aspects.

(1) Policy mandate. The policy mandate is found in the preamble or the findings at the beginning of the act. In the Toxic Substances Control Act (TSCA) the policy mandate is to protect health and environment from toxic chemicals but not "unduly" to interfere with innovation. Typically, the policy mandate is stated in noble language, designed to appeal to as many groups as possible. Whatever differences
there may be in the form of regulation, they do not appear to show up in the policy mandate. In vagueness and desirability ("platitudeous wish lists" Fiorina, 1982) preambles appear remarkably the same across otherwise differing forms of regulation.

(2) Substantive authority. In the body of an Act, specific responsibilities and powers are spelled out. Often substantive authority is specified in statements beginning "The Administrator shall...". In TSCA, for example, the administrator has specific authority and duty to provide information on the toxicity and exposure of chemicals in commerce (Section 8); to require testing of chemicals that "may present an unreasonable risk (Sections 4 and 5); to establish a prematerial notification program for new chemicals (Section 5); and to regulate chemicals which present an unreasonable risk or an imminent hazard (Sections 6 and 7).

(3) Instruments. A regulatory act also spells out the legal tools or instruments that the administrator can use to implement the act. Generally stated the instruments are of the following types: command and control, provision of information, direct provision of some public good, and decentralized economic incentives. For example, in TSCA the administrator, by requiring manufacturers of chemicals to file reports, can provide information on exposure and toxicity. The administrator can also promulgate rules to require chemical manufacturers to test chemicals. Specific regulatory instruments are spelled out, as well, in Section 6 of the Act, most of which are of the command and control variety.

(4) Procedures. To use a particular regulatory instrument, the agency must satisfy certain legal requirements, which are also spelled out in the Act (sometimes in reference to the Administrative Procedures Act). The Act specifies the process of hearings, the standards and burdens of evidence in decisionmaking, the points of access for outside parties, the opportunities of judicial review, and the standards of review.

Conflicting Interests

In the model, the nature of conflict among interest groups and decision uncertainty are the principal determinants of form of regulatory intervention. For example, TSCA was enacted only after five years of legislative struggle. There were different goals among the interest groups. Environmental groups and the public at large wanted protection against the latent hazards of toxic chemicals; chemical manufacturers wanted to protect innovation and the benefits of chemical products. A great degree of group conflict of interest ensures a lengthy and inharmonious legislative consideration. When there is a long legislative battle, fine print accumulates at the various high water marks and turning points much as material and other debris mark the advances and retreats of a protracted military campaign. The longer the legislative battle the more procedures, safeguards, and conditions that get built into the act. At the same time, to broaden support for the bill, and to decrease the expressed hostility of particularly wounded interest groups, the policy mandate becomes broader and more diffuse.
With a high level of conflict among affected interest groups, the proposed legislation becomes a hot potato. If the legislature makes substantive decisions in the legislation, it will almost certainly offend some already aroused interest group. In this situation in the model substantive decisions are delegated to the agency, by means of greater discretionary authority on substantive matters. For example, in TSCA the key term "unreasonable risk" is used some forty times, but its definition is left to the administrator. When the agency then acts under its substantive authority, the Congressman can bring the administrator to the Hill before an oversight committee to explain why the agency imposed such heavy costs on industry. Alternatively, when the agency does not act, the administrator can be criticized for not acting in spite of the strong and broad substantive authority in the act.

However, not only is the amount of conflict important, so is its composition. A common pattern of conflict helps explain the procedural complexity and lack of discretion in strongly contested acts, such as TSCA or the Federal Food, Drug and Cosmetic Act of 1938 (cf. McCubbins, 1982a). Some interest groups, like chemical manufacturers, are concentrated, relatively wealthy, and can more easily bear the costs of organization, lobbying, and campaign contributions. Initially the industry used its resources to oppose TSCA altogether. However, it also sought procedural "safeguards" against "over-regulation". The safeguards would incidentally increase the cost of regulation to the agency and subsequently decrease the number of regulations. In contrast, environmental groups, having smaller financial resources, relied more on access to the media and the courts as they attempted to affect the legislation and its implementation. It was also in the interest of environmental groups to load a bill with procedures which would become "action forcing" points of judicial access. For different reasons both the industry and the environmentalists wanted fine print. Indeed, they wanted different fine print, and each attempted to eliminate or tone down the other's fine print, but often the compromise was to add fine print to fine print and condition on condition.

In sum, then, under circumstances of high conflict of interest the Congressman will prefer to pass the hot potato to the administering agency by delegating to the agency a great deal of substantive discretion over the policies to be pursued and the regulatory instruments to be employed. On the other hand, conflicting interest group preferences will lead to a greater level of administrative requirements for decisionmaking (i.e., less procedural discretion).

Uncertainty

The amount of uncertainty is a second determinant of the form of regulation. The uncertainty may have to do with the nature of the problem regulation is supposed to redress (it is not known which chemicals are toxic or how toxic). Alternatively, the uncertainty may have to do with the potential costs of controlling the hazard (at the time of regulation it was not known if the cost of reducing vinyl chloride emissions would be in the billions, as industry claimed, or much less, as it eventually turned out). Or, the congressman may be uncertain as to the true preferences or powers of the interest groups.
When there is uncertainty the pattern established for conflict of interest is reinforced. Greater uncertainty implies a greater likelihood of unintended but harmful effects to occur, some cost of control to be miscalculated, or some harmful chemical to be overlooked. With greater uncertainty comes greater political risk and a greater incentive to pass on the hot potato to someone else. But even with greater uncertainty there is no need to relinquish control totally. More complicated procedural requirements can be written in to cover unexpected contingencies. A hot potato may be passed on but there is no need to send over a loose cannon.

Moreover, with greater uncertainty a Congressman will not know beforehand what his interests will ultimately be. He would like the interest groups to reveal their preferences and powers before being pinned down to particular substantive solutions of particular problems. He would like to delegate specific problem solving responsibility to the agency and sit back in an oversight role, awaiting clarification of the issue (cf. McCubbins and Schwartz, 1982). Delegating broad substantive discretion with narrow procedural discretion provides a solution to the legislator's problem of decisionmaking under uncertainty.

The pattern of uncertainty, therefore, defines the legislator's subjective probabilities over the net benefits (and, therefore, his electoral reward) to be associated with his possible courses of action. When there is a great deal of conflict between interest groups and the legislator's subjective uncertainty is great, the legislator is likely to act in ways that appear risk averse, even if he is an expected value maximizer. He may reject actions with potentially high costs, he may seek "security" points, he may delegate.

In general, then, the greater the decisionmaking uncertainty the greater the substantive discretion and the set of regulatory instruments delegated to the administering agency. Further, the greater the decisionmaking uncertainty the smaller the procedural discretion granted the administering agency.

Implication for Regulatory Performance

The form of the regulatory intervention has important implications for the performance of regulation. First if an agency has stringent procedural requirements which allow little discretion, regulatory actions are likely to be few and far between. If an agency has broad discretion in its substantive authority as in addition to narrow procedural discretion, there may be more attempted actions (again with few results) and, therewith, more frustrations inside the agency as well.

There are several ways to evaluate the performance of a regulatory agency. It can be evaluated in terms of the economic efficiency of its regulations, or its addition to social welfare. Alternatively, the agency can be evaluated from its own perspective — did it accomplish its goals, did it generate a large number of significant regulations? Performance can be measured from the point of view of the legislature as well. Though we shall discuss a few of these views the model is predictive in nature and does not depend on any particular definition of performance.
Economists have argued for over a decade that regulation has generally failed by relying too heavily on command and control instruments, and not heavily enough on decentralized economic incentives. Kneese and Schultz (1975) suggest a reason for this "overemphasis" on command and control instruments—discipline bias; most Congressmen are lawyers and their education, therefore, makes them familiar and comfortable with regulation by legal order. While education is likely to be a factor in the choice of regulatory instrument, we may ask, if it were in the interest of legislators to choose decentralized economic incentives would not they become familiar and comfortable with them?

The model provides another explanation (beyond discipline bias) for Congressional preferences for command and control over decentralized economic incentives in regulation. When there is more conflict and greater uncertainty, Congressmen have greater concern with procedural safeguards. The very flexibility of economic incentives (the source of their strength to economists) is interpreted by the Congressman as uncontrolled uncertainty. A more favorable political climate for decentralized economic incentives is where there is little conflict and uncertainty. For example, in establishing the CAB, where there was relatively little conflict and uncertainty, a decentralized instrument, price setting, was in fact delegated to the agency. (But note that some of the uncertainty associated with price setting was controlled by also delegating power to restrict industry entry.)

In the agency, performance is evaluated not in terms of a global concept of economic efficiency, but in terms of its own structure of incentives. In order for the agency to grow and prosper it is important for the agency to show some visible signs of accomplishment toward its policy mandate and its specific goals as spelled out in its substantive authority.

To communicate with Congress and to have its accomplishments believed, it is useful for them to be concrete. To say "we improved the public health" is too vague without considerable evidence, especially of a quantitative nature. To say "we banned dioxin" carries more weight as the achievement is easily verifiable. When there is greater conflict and more uncertainty there is greater peril for the agency and incidentally a greater need to justify its actions before Congress. To maintain the support of its Congressional sponsors, without whom the agency could not survive, the agency must report, very concretely, its achievements (because the sponsors are particularly sensitive to criticisms that the agency is "doing nothing"). The agency's activities are described in terms of its "planned program achievements," or p.p.a.'s or "beams." Beans have the advantage of being countable and verifiable. Banning dioxin is a bean. On the other hand, instituting an effluent tax is less of a bean.

Thus the agency will respond to the form of the regulatory intervention mandated by Congress, and the environmental factors of conflict and uncertainty by pursuing only the most concrete and highly visible regulations. Such regulations have disadvantages, however, as they become targets for Congressional critics who represent interest groups hurt by the planned program accomplishments. The agency, realizing this vulnerability, has added incentive to make its
accomplishments defendable. Increasing the defendability of the concrete, and visible, regulations in turn adds to the already high fixed cost per regulation. The result is the 1000 page regulation, infrequent but well fortified. And to justify its large (fixed) cost of promulgation, often large in scale.

The strategy of a few big beans has led at times to a sense of frustration within the agency. Some regulatory attempts become too cumbersome to make it through the agency—for example, after 48 tries, the attempt to regulate asbestos was abandoned, having never gone beyond EPA's Office of Pesticides and Toxic Substances. It would have been a billion dollar regulation. Other billion dollar regulations such as on benzene are remanded by the courts. And though a few big regulations survive, only a minute fraction of the problems are being addressed.

A final characteristic of such regulatory process follows from the reliance on command and control. Having chosen, partly in response to congressional wishes, regulation by legal order, the agency often finds itself dictating specific technologic solutions. To survive court tests and political pressures for defendability this means that the agency must understand, or claim to understand, specific technological processes as well as the experts in the affected industry. Having maneuvered itself into a position where it needs this type of specific information, the agency puts itself at a particular disadvantage relative to the regulated firms, which specialize in this information in the course of their business.

Within Congress, performance of an agency is often evaluated in terms of whether the agency has on balance benefited the constituencies of individual congressmen. When the answer is negative, the agency is likely to find out during oversight hearings, by hostile queries, by legislative veto, or by reduced authorization or reduced budget.

In sum, then, conditions of high conflict of interest and great uncertainty will lead to a great deal of substantive discretion and little procedural discretion for the administering agency. Under such conditions, and with such a regulatory form, relatively few regulations will be developed. And those regulations which are developed are likely to be quite complicated and costly. Increased conflict and increased uncertainty are, therefore, the ingredients of regulatory delay and inaction.

Conditions of lower conflict of interest and less uncertainty, on the other hand, will lead to greater procedural discretion over a smaller range of substantive choices. Under such conditions, and with such a regulatory form, regulatory interventions will tend to be more flexible and less controversial from the standpoint of both Congress and the agency.

**Illustrations**

It has been suggested elsewhere that environmental, health and safety regulation entails a relatively greater degree of decision making uncertainty than does economic regulation (Joskow and Moll, 1978; McCubbins 1982b). Further, McCubbins (1982a, 1982b) has argued
that environmental, health and safety issues often present a relatively greater level of group conflict than do economic regulatory issues.6

If indeed there is more uncertainty and more conflict in environmental, health and safety regulation than in economic regulation, then the model predicts a difference in the form of regulation, for these two areas. Specifically, the model predicts:

(1) A broader scope of substantive (and discretionary) authority delegated to the Administrator under environmental, health and safety compared with economic regulation.

(2) Along with the broader scope in substantive authority, a larger number of regulatory instruments, and a wider variety of them, delegated to the agency under environmental, health and safety regulation, compared with economic regulation.

(3) More procedural requirements for decisionmaking in environmental, health and safety regulation, compared with economic regulation. The model predicts more public hearings and comment, more points of access to agency decisionmaking by outside parties, more access to judicial review and more strenuous standards and burdens of evidence of environmental, health and safety regulation. We consider these comparisons in this section, for a few specific illustrations.

The Toxic Substances Control Act

The policy mandate of Congress in legislating authority to EPA under the Toxic Substances Control Act (PL 94-469, Oct. 1976; referenced as TSCA) is described, in quite noble language, in section 2(a)(2) of the act,
Section 6(a) (emphasis ours)

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—(A) prohibiting the manufacture, processing or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in rule imposing the requirement, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal, or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make or retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6) (A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, (B) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such a substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

As suggested by this excerpt from subsection 6(a), Congress was very generous with regard to the regulatory instruments EPA could employ to implement policies under TSCA. EPA can implement regulations pertaining to the production activities (manufacture, processing and distribution) of chemical manufacturers through command and control mechanisms (prohibitions and limitations), as specified in subsections 6(a)(1), 6(a)(2), 6(a)(5), and 6(a)(6). Congress also clearly mandated informational mechanisms for the regulation of other activities as detailed in subsections 6(a)(3) and 6(a)(7) (warnings and instructions and public notice).

This generosity with regard to regulatory instruments was an attempt by Congress to require EPA to take substantial action on toxic hazards. It was felt that by specifically mandating such a broad range of instruments EPA could approach a wide range of problems using methods which would not only lead to swift resolution but would also pass tests of validity in court. In any case the pattern of instruments specified fits precisely with the predictions of the model.

Along with these varied mechanisms, extensive procedural and due process requirements were detailed (in sections 4, 5, 6, 9, 19, 20 and 21) for the exercise of the broad regulatory authority granted EPA under the act. Sections 4, 5, 6 and 9 of the statute, though defining who has what rights before EPA, are primarily concerned with defining EPA regulatory decisionmaking procedures. Figure 2 details the lengthy procedures specified in the act that EPA is required to follow for the promulgation of a regulation under sections 4, 5 or 6.

FIGURE 2 HERE
Under the regulatory procedure defined in sections 4, 5, and 6, a manufacturer must submit notice of intent to manufacture a new chemical substance 90 days prior to manufacture; upon such notice, and within the time frame specified in the act, EPA can take one of four courses of action: take no action (the usual decision); obtain a court order to require more testing pursuant to a test rule developed in section 4 (notice that the procedures necessary to develop a test rule, outlined in parts 4 and 5 of Figure 2, are extensive in their own right); propose a regulation for the chemical which, if challenged, is subject to a court review necessitating the fulfillment of the numerous due process requirements of section 6 (part 6 figure 1); or finally, if the chemical presents an imminent risk of serious and widespread injury, EPA can obtain a court order to seize the chemical and then begin its rule-making activity.

This lengthy procedure, outlined in Figure 2, guarantees that all interested parties will have numerous points of access and influence in EPA decisionmaking under TSCA. Such access points are boxed in Figure 2. However, few rules have been written, less than a dozen actions have been completed under the rule making procedures specified in the act. The vast majority of the 70,000 chemicals in commerce have not been affected by TSCA.

EPA, under Section 4, must promulgate test rules for those chemicals which it requires to be tested. Such tests are used to generate information about the health and environmental effects of the new chemical. Each test rule is in itself voluminous and requires many months, even years, to develop. In the case of chloromethane the cost of promulgating the test rule (about $300,000) was several times more than the cost of the tests to be required. So far only a small fraction of the 70,000 chemicals in commerce have been tested and only a few test rules have been written in TSCA's six year existence.

Almost all decisions by EPA under TSCA are subject to hearings and court appeals. Further access is provided by sections 20 and 21 which enfranchise all citizens, through the use of citizen petitions or civil suits, to require enforcement of TSCA by EPA (or reversal of action). Section 19 further specifies that all actions by EPA under TSCA are subject to judicial review in a federal district court. Though it is quite possible that all actions taken by EPA under TSCA would be subject to court review without section 19 it is noteworthy here that Congress specifically enfranchised all interest parties (not just those adversely affected by a ruling) to have a right of bringing a court review. Further, unlike many other regulatory acts, court review of EPA decisionmaking is possible at many junctures before a final ruling is made.

EPA is further required to coordinate closely its activities with other federal health and safety programs. As each of these programs has its own legislative mandate, decisionmaking structure, congressional oversight committees and clientele groups, each interaction required of EPA magnifies the decisionmaking procedures and the number of interested parties involved in any rule making under TSCA.

In subsection 4(e) EPA is required to develop a priority list of chemicals for the promulgation of test rules under section 4. However,
The membership of the committee to develop this list is not EPA's sole domain; only one member of the eight member committee is appointed by EPA.

Together the procedural specifications, due process guarantees, and inter-agency cooperation provisions serve to extend the decision-making process in the Office of Toxic Substances and to enlarge the set of interest groups enfranchised to have a voice in agency decision-making. This ultimately inhibits EPA from exercising the broad regulatory authority granted under TSCA.

EPA was granted broad substantive discretionary authority to promulgate regulations controlling toxic chemicals in TSCA. This substantive authority was defined, largely in section 6, through a broad range of regulatory instruments. This wide ranging substantive authority nicely fits the model and supports the argument advanced herein. The complex and labyrinthine regulatory procedures defined in the act similarly support the propositions and generalizations of the model. The performance of toxics regulation, then, is not a result of ill-designed legislation nor of sinister legislators nor of interest groups pursuing their own self-interests in smoke-filled backrooms, but can be seen as a natural consequence of the political process and of the uncertainties and controversies surrounding environmental, health and safety regulatory issues.

The Federal Food, Drug and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended, provides the Food and Drug Administration and the Secretary of Health, Education and Welfare with broad discretionary authority over the regulation of foods, food additives, pesticide residues, drugs, devices, animal drugs and cosmetics. This broad substantive authority conforms to the predictions derived in the model. The authority of the FDA, beyond its authority to prohibit the adulteration and misbranding of foods, drugs and cosmetics is outlined in Table 1.

Table 1 Here

As Table 1 indicates, FDA can establish standards of quality and fill of container for food products, and can establish regulations limiting the quantity of poisonous or deleterious substances in food. Thus the FDA can establish "filth levels" for hot dogs, "rodent excrement levels" for flour, and "mercury levels" for swordfish. FDA can similarly regulate the levels of pesticides in raw agricultural commodities, and the quantity of food additives, such as cyclamates, in foods.

New drugs must be certified as safe and efficacious for use prior to manufacture, as must new animal drugs. FDA further has the mandated authority to regulate color additives, such as red dye number 2.

With the exception of section 407, the authority of the FDA over foods, drugs and cosmetics is limited to the regulation of the production activities of firms producing such commodities, having had its authority over marketing transferred to the FTC prior to the 1938
act. The broad discretionary authority the FDA has under the statute to regulate the production of foods, drugs, and cosmetics is also outlined in Table 1.

However, this broad discretionary authority over the production of foods, drugs and cosmetics, as in the case of the Toxic Substances Control Act, is coupled with a great amount of procedural and due process specificity. The complex and convoluted procedures specified for the regulation of pesticide residues, food additives, and new drugs are readily evident in figures 3, 4 and 5, and need little elaboration. That the FDA is indeed encumbered by these regulatory procedures and due process requirements should, by now, come as no surprise.

Figures 3, 4 and 5 Here

However, the reluctance to regulate in the case of the Federal Food, Drug and Cosmetic Act has had different consequences than similar difficulties under the Toxic Substances Control Act. In the case of TSCA the labyrinthine regulatory procedures serve to restrict EPA’s regulatory activities; as a result few chemicals of the hundreds of thousands developed each year are subject to regulation. On the other hand, a similar set of regulatory instruments and procedures for the regulation of new drugs under the FFDCA, though similarly restricting the FDA’s regulatory activities, have a much different market outcome. Without the test rule requirements and explicit time limits for action as specified for EPA decisionmaking in TSCA, the FDA can "sit on" new drug applications indefinitely without taking action, and thus few new drugs are certified for production and use.

Society thus foregoes the potential benefits associated with many of these new drugs because they cannot find their way out of the legislated FDA procedural maze. Similarly, the catacombs of EPA’s legislated regulatory procedures ensure that few of the potentially dangerous chemicals developed each year are subject to EPA regulation. Neither situation is an optimum as each presents an extreme "solution" to the introduction of new products.

The similarities in scope, form, and substance of health and safety acts such as TSCA and the FFDCA, passed nearly 40 years apart, offer compelling evidence for the model and propositions developed earlier. The broad substantive and narrow procedural authority granted in the FFDCA implies that the implementation of the food and drug act will suffer from maladies similar to those evidenced for EPA in TSCA. The form of the regulatory intervention chosen by Congress, as a result of the institutional structure of legislative decisionmaking and environmental influences (uncertainty and conflict of interest), prevents the FDA from swiftly promulgating significant regulations.

The Federal Aviation Act

The Civil Aeronautics Act of 1938 and the Federal Aviation Act of 1958 established an economic regulatory agency, the Civil Aeronautics Board (originally the Civil Aeronautics Authority). The form of the regulatory intervention established is much different than those witnessed for the health and safety acts examined.

The Federal Aviation Act (PL 85-726, August 1958) continued the existence and the economic regulatory functions of the Civil
Aeronautics Board. In the act the Civil Aeronautics Board (CAB) was granted authority to issue certificates of public convenience and necessity (i.e. to restrict entry), to issue permits to foreign air carriers, to approve tariffs (i.e. to set prices), to fix minimum mail loads, to establish rates of return for the transportation of mail, and to approve airline mergers.

Thus, unlike the authority granted the health and safety agencies, wherein each agency has broad regulatory authority over a wide range of activities for a great many industries and segments of society, the CAB was granted a fairly narrow authority to regulate the economic activities of a specific industry—the airlines. The authority of the CAB to carry out its functions is granted largely in Title IV through a variety of command and control mechanisms. Section 401 specifies the CAB’s authority over entry,

Section 401. (a) No air carrier shall engage in any air transportation unless there is in force a certificate issued by the Board authorizing such air carrier to engage in such transportation.

Section 403 defines the CAB’s price-setting powers (emphasis ours),

Section 403. (a) Every air carrier and every foreign air carrier shall file with the Board...tariffs showing all rates, fares, and charges for air transportation between points served by it,...and showing to the extent required by regulations of the Board, all classifications, rules, regulations, practices, and services in connection with such air transportation. Tariffs shall be filed, posted, and published in such form and manner, and shall contain such information, as the Board shall by regulation prescribe...

And, Section 406 describes the CAB’s power to set prices for the transportation of mail,

Section 406. (a) The Board is empowered and directed, upon its own initiative or upon petition of the Postmaster General or an air carrier, (1) to fix and determine from time to time, after notice and hearing, the fair and reasonable rates of compensation for the transportation of mail by aircraft,...

The authority granted to CAB is very similar in scope and in language to the authority granted the Interstate Commerce Commission in the Transportation Act of 1920 and the Motor Carriers Act of 1935. Such economic regulatory acts, born in similar interest group environments, share a similarity of purpose and statute. The specific authority vested in such acts enables Congress, to deliver particularized benefits to specific industries.

Unlike TSCA or the FFDCA, however, the Federal Aviation Act and the Civil Aeronautics Act specified few procedural guidelines for the exercise of the CAB’s rule making authority. This flexibility of procedure enabled the CAB to respond quickly and easily to applications filed by air carriers and to approve thousands of such applications each year. The striking difference in the level of procedural discretion granted the CAB under the act, in relation to the health and safety acts as outlined in figures 2 through 5, is evidenced in the following subsections and in figure 6; for the application for a certificate of public convenience,

Section 401. (b) Application for a certificate shall be made in writing to the Board and shall be so verified, shall be in such form and contain such information, as the Board shall by regulation require, (emphasis ours)

and for an application for a permit,
Section 402. (c) Application for a permit shall be made in writing to the Board, shall be so verified, shall be in such form and contain such information, and shall be accompanied by such proof of service upon such interested persons, as the Board shall by regulation require. (emphasis ours).

The simplicity of the regulatory procedures specified in the act for the establishment of airline tariffs is quite apparent in the above passage and in figure 6. The procedural requirements of the act largely specify that the application must be filed 30 days prior to enforcement and that the document must meet the technical requirements as determined by the Board.

Figure 6 Here

The Civil Aeronautics Act and the Federal Aviation Act present examples of regulatory legislation which do not mandate rigid and extensive regulatory procedures for rule making. The history and form of these economic regulatory acts, though vastly different from the two environmental, health and safety acts examined previously, are quite consistent with the model and propositions outlined earlier. In circumstances where the effects of regulation are known and where the regulation is not controversial the legislature can prescribe a form of regulatory intervention conducive to the swift resolution of regulatory matters and the promulgation of significant regulations. Thus, due to the influence of environmental factors (i.e. uncertainty and little conflict of interest) economic regulation, unlike environmental, health and safety regulation, is implementable in an American democracy.

Discussion

We have suggested that increased conflict and uncertainty are prime ingredients of regulatory inaction. Moreover, the way in which these two factors affect the form of regulation. It has also been suggested that to some extent the difficulties of is rooted in the American Constitutional system itself. The electoral and legislative institutions established by the Constitution provide the motivation for the choice of regulatory form.

However, we are not suggesting that environmental, health and safety regulation has failed altogether or that its limitations are completely due to our particular system of democracy. A very large factor is the large amount of uncertainty associated with potential environmental risks. This uncertainty arises from our limited understanding of cancer mechanisms, ozone depletion and the other environmental problems. The uncertainty is part of the nature of the problem. It is augmented in many cases by long latency periods (twenty to forty years for carcinogens).

Nor are we suggesting that attempts to improve regulatory performance depend upon changing the basic features of American democracy. It appears that there are possible, less fundamental, changes which might improve the prospects of environmental regulation. First, decentralized instruments are not going to increase in usage merely because of economists' exhortations. When it becomes in the interest of legislators and regulators to use them their usage will increase. To promote their use, they need to be designed to decrease group conflict and uncertainty. For example, marketable quotas decrease uncertainty as to the resulting levels of air or water
quality. Sharing quota revenues within the polluting industry may reduce group conflict. Other compensation systems may be tied to decentralized instruments promoting efficiency. Liability rules may be tied to conditions of behavior which limit liability. In many ways both uncertainty and group conflict can be diminished within the design of decentralized instruments.

Second, uncertainty can be reduced directly by research on environmental and health effects. Third, legislative and bureaucratic politics change with changed perceptions of hazards, as in the case of thalidomide, PBB's, or Three Mile Island. Fourth, the interaction between legislators, agency and interest groups changes with changes in campaign financing.

Conclusion

We have constructed a model in which the form of the regulatory intervention is determined by uncertainty and group conflict of interest. Environmental, health and safety regulation present issues which involve a great degree of uncertainty and involve a large amount of conflict of interest. As a result legislators choose to delegate broad substantive discretion and narrow procedural discretion to the administering agency which limits the agency's ability to pursue its legislative mission.

The analysis in the foregoing pages demonstrated that a relatively simple model of regulatory choice can provide relatively general statements about various puzzles, patterns and regularities in the politics of regulation. Extensions to the model to include other influences, such as the structure of the regulated industry (McCubbins, 1982a), and other institutional actors, such as the President and the courts, might fruitfully extend the analysis presented here.
## Summary of the Regulatory Mandate of the Federal Food, Drug and Cosmetic Act (52-Stat. 1040)

<table>
<thead>
<tr>
<th>No.</th>
<th>Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Sec. 401</td>
<td>Establish common name for food products.</td>
</tr>
<tr>
<td>2.</td>
<td>Sec. 401</td>
<td>Establish a standard of identity for food products.</td>
</tr>
<tr>
<td>3.</td>
<td>Sec. 401</td>
<td>Establish standards of quality for foods.</td>
</tr>
<tr>
<td>4.</td>
<td>Sec. 401</td>
<td>Establish standards of fill of container.</td>
</tr>
<tr>
<td>5.</td>
<td>Sec. 406</td>
<td>Establish regulations limiting the quantity of poisonous or deleterious substances in food.</td>
</tr>
<tr>
<td>6.</td>
<td>Sec. 408</td>
<td>Establish tolerance levels for pesticides in or on raw agricultural commodities.</td>
</tr>
<tr>
<td>7.</td>
<td>Sec. 409</td>
<td>Establish regulations limiting the quantity of food additives in foods.</td>
</tr>
<tr>
<td>8.</td>
<td>Sec. 409</td>
<td>Establish regulations limiting the varieties of foods in which a food additive may be used.</td>
</tr>
<tr>
<td>9.</td>
<td>Sec. 409</td>
<td>Set the manner in which a food additive may be added to or used in or on foods.</td>
</tr>
<tr>
<td>10.</td>
<td>Sec. 409</td>
<td>Establish directions or other labeling or packaging requirements for food additives.</td>
</tr>
<tr>
<td>11.</td>
<td>Sec. 505</td>
<td>Certify new drugs as safe for use.</td>
</tr>
<tr>
<td>12.</td>
<td>Sec. 506</td>
<td>Certify batches of drugs containing insulin as safe for use.</td>
</tr>
<tr>
<td>13.</td>
<td>Sec. 507</td>
<td>Certify batches of drugs containing antibiotics as safe for use.</td>
</tr>
<tr>
<td>14.</td>
<td>Sec. 508</td>
<td>Designate an official name for any drug.</td>
</tr>
<tr>
<td>15.</td>
<td>Sec. 512</td>
<td>Certify new animal drugs as safe for use.</td>
</tr>
<tr>
<td>16.</td>
<td>Sec. 706</td>
<td>Establish tolerance limitations for color additives in foods, drugs or cosmetics.</td>
</tr>
<tr>
<td>17.</td>
<td>Sec. 706</td>
<td>Establish specifications as to the manner in which a color additive may be added.</td>
</tr>
<tr>
<td>18.</td>
<td>Sec. 706</td>
<td>Establish directions or other labeling or packaging requirements for a color additive.</td>
</tr>
</tbody>
</table>
Figure 1

Legislative authorization in acts
Budget
Oversight

Agency

Command and control regulations
Direct provision of public goods
Information
Decentralized economic incentives

Information

Facilitation

Legislature

Campaign contributions
Votes
Provision of information and testing

Interest Groups

Court suits
Testimony
Petitions
Figure 2
Procedures for the Toxic Substances Control Act
(90 Stat 2005)

PREMANUFACTURING NOTIFICATION

Manufacturer decides to manufacture a "new chemical substance" or an existing chemical substance for a "significant new use".

Has the administrator issued a rule under Section 4 requiring testing of the substance?

NO

Is the substance on the Suspect Chemical Substances List compiled under Section 5(b)?

YES

Has manufacturer performed testing pursuant to a rule under Section 4?

NO

If no test rule has been issued, manufacturer develops own test data which he believes shows that the substance will not present an unreasonable risk to health or the environment.

Manufacturer submits notice of intent to manufacture and relevant test data to the administrator 90 days prior to manufacture.

Administrator may extend 90 day notification period for an additional 90 days for good cause shown.

Does the administrator propose a rule or order prohibiting or limiting the manufacture of the substance on the basis of insufficiency of information or a finding of an unreasonable risk

NO

Manufacturing may proceed after expiration of the notification period.

YES

Section 5 Activities

Section 5 Activities
Manufacturer submits notice of intent to manufacture

EPA publishes notice of premarket notification

Section 5 Activities

- EPA publishes reasons for not requiring additional testing of selected products, or does nothing on those not requiring notice. (Section 5(g))
- Market product or use

If Administrator finds there may be an unreasonable risk from use requires benefits test

Section 5(a) EPA issues proposed rule, 45 days prior to expiration of premarket notification period, regulating the substance pending development of additional data pursuant to a section 4 test rule

If necessary get section 5(e)(2)(ii)(B) district court injunction

Section 4 Testing Activities

- Publish rule in Federal Register

If rule challenged judicial review required

Expedite as specified in Section 6(d)(2)(B)

Section 6 Activities

- Go to Federal District court. Can seize, require repurchase, replacement, notification or recall

Start section 6(a) rulemaking

Section 6 Activities

To Section 6 activities

Section 7 If chemical or mixture presents an imminent and unreasonable risk of serious and widespread injury

Issue proposed rule limiting chemical before end of notification period

If rule prohibits manufacture or use get injunction in district court

Section 6 Activities
TESTING ACTIVITIES

Information from
- Notification process §5
- Priority list §4e
- Outside §4f

If administrator finds
the chemical or mixture
(a) may present an
unreasonable risk
or
(b) produced in
significant
quantities
and insufficient data

Propose
Rule
Requiring
Tests

Manufacturer or
processor may file
for exemption 4(c)(2)
if tests duplicative

Final Rule
Public Comment
Hearings

Judicial Review

Administrator promulgates
rules on fair and
equitable reimbursement
for testing costs

Judicial
Review

Public Comment
Hearings

firms conduct
required tests,
results published
in Federal Register
From Section 5, Rule may be declared to be immediately effective if "likely" to result in unreasonable risk of serious injury before final rule.

If prohibited manufacture or use need court order.

From Section 4, Publish regulation in FEDERAL REGISTER.

Section 6(b) FPA can require quality control changes.

Proposal Rule

Notice and Hearings, Delay for comments (Section 6(c))

Final Rule

Judicial Review

Section 9 if Administrator decides other Federal law applies.

Send report to agency with jurisdiction.

Administrator has already started a Section 6 or 7 regulation.

Other agency consults.

No section 6 or 7 rule applicable if other agency finds no unreasonable risk or starts own proceedings.
Procedures for Federal Food, Drug and Cosmetic Act for Establishing Tolerance Limits for Pesticides

Test data and information filed

Notice published

Certification of usefulness by Secretary of Agriculture under FIFRA

Advisory committee reviews application

Request to refer petition to advisory committee

Secretary establishes regulation

Adversely affected parties may file objections

Copy of objections serve to petitioner

Petitioner replies to objections

Public Hearings

Secretary acts on objections

Publishes notice

Adversely affected parties may file for Judicial Review
Figure 4
Procedures for Federal Food, Drug and Cosmetic Act,
Regulation of Food Additives

Manufacturer conducts tests

Petition to Secretary proposing the issuance of a regulation prescribing the conditions under which a food additive may be safely used.

Petitioner files relevant information concerning additive as specified in Section 409 (b)(2)

If requested manufacturing data must be submitted (Section 409 (b)(3)) and samples (Section 409 (b)(4)).

30 days
Notice published
90 days (90 day extension)
Secretary shall issue a REGULATION (Section 409 (c))

30 days
Publish in FEDERAL REGISTER

Objections by adversely affected parties (Section 409 (f))

Public Hearings
RULE with respect to objection

Those adversely affected by regulation or rule may petition in U.S. District Court for Judicial review.

Secretary may propose a regulation of a food additive on his own initiative (Section 409 (e))

30 days
Adjudication, Abandoning or Issued

Hearings (Section 305)

Court Order

Seize Product
Figure 5

FTDCA Procedures for Regulation of New Drugs

Manufacturer conducts tests

(Section 505 (a)) Application for new drug field

(Section 505 (b)) Reports on safety, composition, use, quality control, samples are submitted

Exemption by rule (Section 505 (i))

In light of new evidence Secretary may proceed to withdraw approval

Public Hearings

Determination

Testing not adequate for determination

Information not adequate for determination of safety

Information not adequate for determination of efficacy

Testing shows drugs unsafe

Quality control is not adequate

Proposed labeling is false or misleading

Disapprove application

Application approved

Judicial Review
Figure 6
CAB Tariff Procedure

<table>
<thead>
<tr>
<th>AIRLINE DOCUMENT MEETS TECHNICAL REQUIREMENTS</th>
<th>CAB</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO AS SPECIFIED IN 14 CFR 211</td>
<td>WAIVER</td>
</tr>
<tr>
<td>TARIFF</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEW TARIFF WITHIN BOUNDS ESTABLISHED UNDER SECTION 10026(6) (4) OF THE FEDERAL AVIATION ACT OF 1958 AND SPECIFIED UNDER 14 CFR 399</th>
<th>14 CFR 399</th>
<th>EXEMPTION SPECIAL REJECT</th>
</tr>
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<tbody>
<tr>
<td></td>
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<tr>
<th>ACCEPT TARIFF</th>
<th>ACCEPT TARIFF</th>
</tr>
</thead>
</table>

Footnotes

1. This model is developed formally in McCubbins (1982a). On the model of legislative behavior see Mayhew (1974), Fenno (1973), Fiorina (1977), Schwartz (1982), Shepsle and Weingast (1980) and Weingast (1978). A good source of references for the literature on interest group behavior can be found in Harmon (1978) and Ornstein and Elder (1978). In this paper the view of interest groups is similar to that developed by Stigler, 1971. This version of administrative agency behavior is discussed by Joskow (1974), Ferejohn (1981) and McCubbins (1982a).

2. Briefly, instruments in this framework may be categorized into four general categories for analysis: a) command and control instruments – individualized instruments which regulate behavior through constraints on the choice sets of actors (for example; price limits, route setting, quotas and effluent emission levels), b) informational instruments – instruments which regulate behavior through a recharacterization of the good or service in transaction (examples are warning labels, formula disclosures, advertising controls and ingredients disclosures), c) incentive-based instruments – universal instruments which regulate behavior through an alteration of incentives for action (examples are taxes, subsidies, marketable permits, marketable ration coupons), d) public provision – instruments which regulate behavior through competition from non-market provision of goods and/or services (an example is the regulation, through competition, of electrical power pricing by the TVA).

3. Congress must prescribe explicit statutory limitations on administrative discretion for the delegation of legislative authority to fit within the framework established by the courts in Panama Refining Co. v. Ryan, 1935 (243 v.s. 388), A.L.A. Schechter Poultry Corp. v. United States, 1935 (245 v.s. 495), and Carter v. Carter Coal Co., 1936 (298 v.s. 238). Broad delegations of authority by the legislature must be accompanied with procedural protections or an opportunity for judicial review (see also Yakus v. United States, 1944 (321 v.s. 414)). However, there will still be a great difference between the procedures prescribed for various acts which fit within the framework of the delegation doctrine.

4. According to Jacquelyn Warren, who worked for the Environmental Defense Fund during the drafting of TSCA, much of the complexity of the act is due to the lengthy legislative struggle. "There are layers of conditions which arose from the composition of the subcommittee and its staff that day. Some of the legal requirements are stronger or weaker depending on who was absent and who was tired day by day. Inconsistencies got in during the ebb and flow of the battle and not all of them were taken out."

5. For a discussion of definitions of regulatory performance see Cutler and Johnson, 1975.
6. A notable difference is that the Teamsters and the Airlines have opposed economic deregulation (price and entry); whereas the chemical industry supports deregulation of potentially toxic chemicals.

References


