REGULATION OF AN INDUSTRIAL SECTOR:

A CASE STUDY OF THE TOXIC SUBSTANCES CONTROL ACT

By

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A DISSERTATION

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

DOCTOR OF PHILOSOPHY

Department of Resource Development

1984

ABSTRACT

REGULATION OF AN INDUSTRIAL SECTOR: A CASE STUDY

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The threat of toxic substances in the environment emerged as a significant controversy in the early 1970's. A lack of appropriate statutory controls prompted Congress to pass a new format of environmental law. Congress established the Toxic Substances Control Act (hereafter TSCA) as a prospective program similar to the Food, Drug and Cosmetic Act. TSCA blended this format of a long-range planning framework as well as the problem-solving structure of traditional environmental law. In theory, this framework mitigated immediate toxic problems plus this format prevented the future release of new toxics.

A case study of the initial rulemaking, under TSCA, focused on the Inventory section, the foundation of all the subsequent regulation under the Act. The Inventory established a list of existing chemicals in commerce. This review of the chemical industry was to be completed 315 days after the signing of TSCA. The Environmental Protection Agency (hereafter E.P.A.) took nearly three years to complete the Inventory process. Confusion, procedural delays, and the inherent difficulty of fusing scientific principles with legal processes deferred E.P.A.'s rulemaking.

In this study it was found that limited data hindered E.P.A.'s progress during the complicated rulemaking and created a dependency

on the more informed chemical industry. Information, within E.P.A., was ineffectively communicated among staff members due to a centralized structure and poor record keeping. The staff lacked the experience and interdisciplinary focus to conceptualize the long-range planning of a prospective statute.

The Inventory and TSCA itself, illustrate the problem of operationalizing practical regulations for complex problems within institutional constraints. Future research might consider these institutional and informational constraints as they impact on prospective statutes such as TSCA.

ACKNOWLEDGEMENTS

This research was supported by a grant from the National Oceanic and Atmospheric Administration, grant #NA80AA-D-0072,Project #R/TS/0 and by funds provided by the Michigan State University Experiment Station.

I would like to take this opportunity to express my appreciation for the advice, time and constructive criticism given me by the members of my guidance committee, Dr. Daniel A. Bronstein, Dr. Martin Benjamin, Dr. Warren J. Samuels, Dr. Lawrence Libby and Dr. Milton H. Steinmueller. Their high standards and professionalism encouraged me to undertake and complete this research. A special thanks is owed to Dr. Daniel A. Bronstein, my major professor. His support nurtured and challenged my growth and progress.

I would like to thank the professional staff of the Department of Resource Development. Ms. Cindy Erickson typed the first and final draft. She was assisted by Ms. Patsy Johnston and Ms. Barbara Visser. To these three individuals, I extend a grateful thank-you and praise for your professionalism.

Many friends and family must remain unnamed solely because of space limitations. My parents receive my thanks for their help and patience. Special thanks go to several of my colleagues (fellow graduate students) for their intellectual interactions. Valuable assistance and friendship were given by Michael R. Thomas, Kyle M. Kittleson, Scott G. Witter, James T. Parrish, Dan Engelberg and Richard J. Sjolander. I thank them and wish them their just deserts (a job or whatever) which matches their special skills. Personal friends of many years also deserve acknowledgment. I would like to thank Jennifer Woods and D. Darren

Meahl for their unflagging support and refreshing senses of humor. They and many of my colleagues kept me sane in the dark moments.

A special note of thanks and appreciation goes to Michael N. Beaulac. His encouragement and love smoothed out the rough path of graduate school. For this and all that we have shared, I express my gratitude and affection.

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INTRODUCTION

History of the Toxicity Problem

Toxic substances in the environment emerged as one of the most controversial environmental issues of the 1970's. Public concern about toxics was the result of growing awareness about environmental quality.[1] It came to be recognized that human actions, through a massive technological system, can have deleterious effects on the bioshpere. Growing knowledge of the interconnections among flora, fauna and the physical elements of the biosphere indicated that human health could be affected.[2] Pollution was revealed as a threat to health and a waste of resources.

Traditionally the environment had been used as a huge sink for all manner of wastes and residuals, but the realization of potential poisoning by these wastes prompted scientific concern.[3] Anxiety was expressed over previously accepted practices of development, release and disposal of various pollutants, especially toxic substances.[4] Chemicals in the environment are not inert, and reactions often have been poorly understood, particularly the effects on the dynamic biosphere.

Such evidence as fish kills or vegetative die-offs resulting from chemical exposure began to appear in the literature.[5] Environment assays showed pervasive levels of chemicals. Data were initially inconclusive but indicated that many chemical concentrations resulted from human intervention and not natural processes.[6] Vital items, such as drinking water and food, were found to be chemically contaminated.[7]

Controversy ensued as to the source and effect of human-introduced chemicals.

Scientific evidence did not dispel the confusion and ignorance. Monitoring equipment with sophisticated capabilities for testing the environment was developed. Increasingly sensitive data were produced and minute concentrations of chemicals were found throughout the natural system. Interpretations of the expanded data set lagged behind technological advances. The question of human health and its relationship to environmental factors was in its infancy.[8]

Beyond the question of the present effect of toxics in the environment was the disquieting intuition that future generations could also be affected by toxic exposure. One could link to toxics exposure birth defects and changes in the genetic make-up of exposed people. Scientific evidence was bandied about, but no clear consensus emerged. The effect of chronic exposure to low levels of toxics in the environment was especially in contention among experts. Long latency periods might be required before measurable changes were detected in the individual.[9] Attempts to apply animal or bacterial tests (generally at very high dosages) to low levels of human exposure only yielded more disagreements.[10] Most scientific predictions were based on limited data approximating the dynamic environment. The only point about which there was agreement was that toxics existed throughout the environment.

An expanding data base gave credence to the concern that unexpected synergestic reactions occured in the environment. Once loose in the biosphere, toxics created diverse conditions that encouraged further chemical reactions. These could produce compounds and residuals even more toxic than the original.[11] Chemical reactions also stimulate the

exchange and migration of a toxic through the physical system. Although a chemical may be inert, its toxics composition and effects may persist once in the environment. This potential has short- and long-term health implications. Questions were raised about the relationship between a persistent toxic and such diseases as cancer.

Mutagenic substances were found with disturbing regularity among the myriad of environmental contaminants.[12] It has been theorized that the mutation of healthy cells into those that grow unchecked is the beginning of cancer in an individual. One recent theory posits a two-step process: an initiator (perhaps a toxic chemical) damages the DNA and a promotion agent (again, possibly, a toxic chemical) transforms the localized damage into a cancerous tumor.[13] Cancer afflicts one out of every four Americans sometime in his/her lifetime, and about one out of every five of these die of the disease.[14] Recent studies suggest that 70-90 percent of all cancers are environmentally induced.[15] The environment is broadly defined as the "physical, chemical, nutritional, biological and psychological" factors affecting the individual.[16] Toxic hazards are among the external factors that can induce genetic damage and cancer.

Even more disquieting than cancer is the likelihood of the long-term health effects related to genetic damage. Findings have linked birth defects to fetal exposure from external agents.[17] The placenta, once considered an effective barrier to harmful inputs, has been shown to allow certain chemicals to pass freely from the mother's body into the fetus.[18] Changes in parental germ plasm could be passed on to succeeding generations. Release of a chemical now, even in

ignorance, can seriously affect a future individual's health or viability.

Evidence was sought about the interaction between people and their environment in order to assess the present and future risks from toxic exposure, but few definitive data materialized. Sound statistical predictions on the magnitude of risk are still impossible. Intuitively, scientists have the fact that toxics have an intergenerational effect but estimating the gravity of the situation has proved elusive. Even so, the possibility of debilitating or lethal results cannot be ignored.[19]

Potential threats from released toxics alarmed the public. Scientists offered few concrete results, dubious estimates of probability, and little reassurance. Media coverage expanded as the monitoring equipment found unsuspected levels and forms of chemical contamination. The public's curiosity changed to fear. Chemicals seemed to be an invisible threat to life, and cries for protection began to be heard. Technical experts had established that toxics were present in the environment, and it was clear that health effects could be expected. The public felt that toxic emissions had to be controlled and monitored.[20] It was assumed that economic constraints and the weak structure of incentives would not induce the chemical industry to control toxic releases voluntarily.[21] The federal government seemed the most likely agent for instituting a comprehensive plan to control toxic problems. Environmental protection <u>per se</u> originated at the federal level with the passage of the National Environmental Policy Act (NEPA) in 1970.[22]

Within the federal government, the Environmental Protection Agency (hereafter E.P.A. or the Agency) was the logical choice. E.P.A. had been created by President Richard Nixon's Executive Order to undertake federal responsibilities for environmental affairs.[23] Toxics were clearly in E.P.A.'s domain. As an administering agency, E.P.A. had the power to regulate behavior to promote environmental quality under various acts. A review of existing federal legislation found several laws within E.P.A.'s purview that expressly addressed toxics. The Clean Air Act (CAA) was amended to monitor the release of toxics into the air.[24] Similar jurisdiction in the Clean Water Act (FWPCA) covered toxic emissions into water resources.[25] Amendments to the Insecticide, Fungicide and Rodenticide Act (FEPCA, the subsequent amendments to FIFRA) strengthened E.P.A.'s authority over the use of pesticides.[26] The specific language of each Act and its regulations limited E.P.A.'s power to monitor and control toxics as a general problem. Coverage by these laws was disjointed and would not generate the comprehensive data base E.P.A. required. Without a straightforward mandate from Congress and the power to assemble relevant data, E.P.A's staff expressed doubts over effective toxic control.

Congressional concern about toxics culminated in the passage in 1976 of the Toxic Substances Control Act (hereafter TSCA), the product of five years of debate and compromise regarding the regulation of the chemical industry.[27] TSCA gave E.P.A. broad powers to collect, disseminate and use appropriate chemical data. The Act established more than a clearinghouse for information, E.P.A. staff members were to formulate policy for control of toxic emissions based on the more comprehensive data base. TSCA was the stop-gap measure to fill voids in

existing legislation. If a given situation was expressly covered in another statute, E.P.A. would acknowledge the supremacy of the statute over TSCA.[28]

TSCA expanded the previous responsiblities of the agency in two areas. First, E.P.A. was to regulate the entire chemical industry. Although other agencies such as the Interstate Commerce Commission, Civil Aeronautics Board, and Federal Reserve Board had instituted industry-wide controls, E.P.A. had never undertaken such a massive task. The scale of TSCA overwhelemed the Agency staff. Second, TSCA was the first attempt at a prospective environmental statue.[29] Previous environmental laws had been reactive. They were designed to attack a problem once an environmental hazard was discovered, with the focus on the detection and containment of released pollutants.

TSCA combined the old and the new approaches. It incorporated the accepted, reactive method of toxics control in its ban on PCBs.[30] E.P.A. was generally mandated to "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards."[31] Reaction to an "imminent hazard" was in keeping with the traditional powers in environmental law.

TSCA's prospective nature was patterned on the Food and Drug Administration's (hereafter F.D.A.) power to review a drug's safety and efficacy prior to marketing.[32] TSCA was the first of the "second generation" environmental laws, designed to anticipate hazards.[33] The effects on human health and environmental quality had to be researched before a new chemical could be manufactured and sold.[34] Efficacy, while

a viable issue in human drug use, was not included in TSCA. The Act represented a fundamental shift in legal scope for E.P.A. A prospective law was an outgrowth of earlier reactions to environmental problems. Understanding and control of pollution problems had become more sophisticated. The enhanced data base permitted a more comprehensive plan for controlling environmental degradation. Clean-up efforts of Love Canal in New York,[35] and along the James River, in Virginia,[36] had emphasized the massive resources required to purge the environment of a released chemical. Contemporary technology could not restore the environment to a pristine state. Containment of a toxic before it was emitted could save both money and protect environmental quality. TSCA's prospective controls were a logical step toward lessening the possibility of toxic release through ignorance or irresponsibility.

TSCA expressly outlined the importance of data and the responsibility of the chemical industry. It stated "adequate data should be developed with respect to the effect of chemical substances and their mixtures on health and the environment and...the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[37]

E.P.A. was given the extensive task of drafting intelligible regulations for TSCA. The slow, hesitant implementation of the basic Inventory section illustrated TSCA's uniqueness. E.P.A. was to regulate an industry which possessed the bulk of the available data. The Agency was to integrate the fragmented bits of information from industry and other sources.

Within accepted legal and economic constraints, the lack of data and of legal precedents hampered the Agency. The more basic problem for

TSCA was more than a change in routine; it was a fundamental shift in the process of environmental regulation and protection.

Nature of the Problem, Methodology and Organization

Environmental Law evolved into a distinct field relatively recently. Its evolution progressed through specific case law and the broad acts passed by Congress. Few legislators grasped the technical and scientific intricacies required for effective regulation of human activity in the environment. As in other areas of the law, a responsible agency was empowered to "flesh out" the environmental statute with specific, systematic regulations. Congress prescribed the general environmental goals for the protection of public health, safety, welfare, and morals. Detailed policy for meeting this goal followed, the result of an agency formulating regulations in the process of Administrative Law.

An agency's actions to establish regulations combine legal, economic, and social concepts within the scope of the empowering act. Regulations order much of the detail of governmental control over an individual's life. Administrative Law, with its regulations, has been and will continue to be a major factor affecting the social structure. The study of this process provides insights into the power and direction of regulatory agencies.

Environmental Law offers the opportunity to examine the legal system in a multidisciplinary fashion. Crucial economic, political, and scientific issues are addressed in complex regulations. TSCA, passed in 1976,is a logical choice for an in-depth study of rulemaking and regulation. The Act emerged as the first attempt by E.P.A. to regulate

the output of the entire chemical industry. Since that output averaged 12 percent of the total G.N.P. of the United States, the Act affected a sizeable segment of the American economy.[38] The task of regulating a major sector of the economy was a new responsibility for an agency established to monitor environmental hazards. TSCA was a new format for environmental protection in its control over an entire industrial sector and in its prospective approach.

Concentration of the study on TSCA's first major set of regulations illustrates the process of rulemaking by a federal agency. This first rulemaking under TSCA was the Inventory section, § 8b.[39] The Inventory developed under TSCA is an uneasy blend of legal principles and scientific considerations. Those regulations formed the basis for future E.P.A. action under TSCA.

In sum, the study of an enviromental statute as it becomes translated into regulation provides insight into the orientation and future direction of the agency in question. In this case, examination of the Inventory regulations clarifies E.P.A.'s procedures and illustrates the diverse disciplines involved. It also illuminates the more general process of Administrative Law. Serious questions emerge about the Agency's ability to function during the administrative process to regulate environmental issues adequately, especially toxics. The process of rulemaking places burdens on an agency to utilize the available information and to follow specific procedures. This study attempts to comprehend the actual regulation process under TSCA and its implications for the more general field of environmental law.

A case study has been chosen as the most appropriate method to trace the development of regulation under TSCA. The Inventory section

was selected because it formed the basis for all subsequent regulation and because the Act required its rapid implementation. Furthermore, it exemplifies the interaction of scientific, legal, and economic principles in regulation. Informal rulemaking for the Inventory was expected to follow the general procedures of Administrative Law. However, a simple legal analysis of the final regulations would provide little insight into Agency procedures. A review of E.P.A.'s performance requires an in-depth analysis of all relevant data, communications, and staff research into the Inventory regulations.

This analysis of the Agency's procedures and information also provides insight into how such complex decisions are made. A series of interviews was conducted over a three-year period with E.P.A. staff to better determine internal decision making and procedures of the Agency. Contacts were established in the nine regional offices and headquarters in Washington, D.C. The regulations resulted from a lengthy process of compromise between the staff and external interests. The public record of hearings, correspondence, and telephone conversations illustrates the relationship between the regulatory agency and the diverse groups influencing the rulemaking. Examination of Agency action memoranda and files helped establish the connection between internal staff work and the released regulations. Pivotal staff interviews were invaluable, often augmenting undated or undocumented materials in the file. Many gaps in the record could only be filled by personal recollections of staff members.

Key definitions for the Inventory and succeeding sections of the Act often had little factual base in the Agency files. Poor recordkeeping by the staff necessitated further interviews with the

special interest groups submitting information to E.P.A. These included environmental/public interest organizations, the chemical industry, trade organizations, labor unions, and state and federal agencies. Personal access to their files, comments, and data illustrated the conflicting information given E.P.A. Strategic submissions by such groups further strengthened the public record. Many items submitted were incorporated into draft and final regulations with no Agency comment.

The specifics of the Inventory have broad implications for the entire process of Administrative Law and its application to environmental law. In this study, research into the legal history and theory provides further insights into the limits of regulation. A review of the relevant legal, economic and philosophical literature connects the various disciplines involved in complex rulemaking, such as TSCA's Inventory. In summary, a thorough study of specific regulations under TSCA was compared to the traditional theory of Administrative Law.

The study will proceed as follows. Chapter II presents the control case study of the rulemaking under the Inventory. A legislative history prefaces the analysis to contrast Congressional intent with subsequent Agency action. E.P.A. procedures are described and analyzed in the context of appropriate files, interviews, and regulations. Problems within the process are delineated to illustrate TSCA's difference from traditional environmental statutes. In addition to the influence of § 8b on succeeding regulations under TSCA, more generalized conclusions about the process of Administrative Law in relation to environmental protection are presented.

The institution of Agency rulemaking is reviewed in Chapters III and IV. The evolution of Agency action, especially in informal rulemaking, is reviewed from a legal perspective in Chapter III. Procedural requirements are critiqued in light of court opinions and legal theory to address the adequacy of Administrative Law in terms of environmental regulations. Chapter IV discusses external interest groups within the administrative process. References to Chapter II will highlight the sensitivity of an agency to political pressure and selected information. Environmental questions, especially toxics, have severe information gaps, forcing the regulator to depend on those being regulated for data. Chapter III and IV, based on the factual account given in Chapter II, describe the general administrative process.

Chapter V discusses the basic philosophical concepts supporting the traditional structure of governmental action, of which, agency rulemaking is one example. The case study, presented in Chapter II, illustrates the difficulty of operationalizing the philosophical framework. This structure of values underlies the resistance to the alternative format of TSCA and the new generation of environmental laws. Alternative concepts are presented to indicate possible avenues for future research on complex environmental decision making.

A critique of the process's influence on TSCA and related environmental statutes is found in Chapter VI. This summarizes the events discussed in Chapter II and the relationship to the insitutional structure examined in Chapter III, and IV and V. Conclusions and suggestions for future research complete this study.

Objectives and Focus of this Study

The objective of this study is the review a piece of environmental legislation from its passage through the complex rulemaking process. During rulemaking, the integration of scientific, legal and economic data forms around the general mandate enacted by Congress. Environmental law has recently emerged as an attempt to formulate workable policy to protect the environment. Toxic substance law illustrates the process of specific rulemaking within legal, scientific and economic restraints. A study of toxic substance legislation investigates the diverse disciplines inherent in such rulemaking and attempts by a federal agency to formulate workable environmental policy.

This study focuses on the process of rulemaking under the Inventory section of TSCA. Congress passed TSCA to regulate toxic hazards in the environment. The Act mandated E.P.A. as the regulatory agency, with responsibility for monitoring of the chemical industry in commerce. The enormity of this task was magnified by E.P.A.'s inexperience with such forms of prospective regulation. A case study of the Inventory section illustrates the Agency's attempt to regulate a complex environmental law with potentially large economic effects. Such economic effects could impact in many ways upon the American economy. TSCA represents both a potentially powerful force on an important American industrial sector and a shift in the structure of environmental law. It deserves an in-depth study of the regulatory processes employed by E.P.A. TSCA also illustrated a more general situation within environmental law. The study of internal decision making within E.P.A. illustrated the process of weighing and drafting regulations with a controversial and limited

information base. Congressional intent in TSCA emphasized a prospective long-range plan for toxics control. The question emerged as to whether the Agency could formulate this new format of Environmental Law given the established process of Administrative Law and the amount of available information. Three specific topic areas have been chosen for study:

1. What was the state of scientific evidence for evaluating the effects of toxics in the environment?

2. What procedural (including statutory) requirements faced E.P.A. when regulating toxics?

3. What steps did the E.P.A. take to translate the prospective intent of TSCA into workable regulations?

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24. 42 U.S.C. 7401 et. seq.

25. 33 U.S.C. 1251 et. seq.

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28. Completely excluded from coverage under the Toxic Substances Control Act are the following: Firearms and ammunition subject to taxes under Section 4181 of the Internal Revenue Code, 26 U.S.C. 4181; Food, food additives, drugs, cosmetics, or devices regulated by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.; Meat and meat products regulated by the Federal Meat Inspection Act, 21 U.S.C. 601, et seq.; Eggs and egg products regulated by the Egg Products Inspection Act, 21 U.S.C. 1031, et seq.; Poultry and poultry products regulated by the Poultry Products Inspection Act, 21 U.S.C. 451, et seq.; Any pesticide regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136, et seq.; Tobacco or any tobacco product; Any source material, special nuclear material, or byproduct material regulated by the Atomic Energy Act, 42 U.S.C. 2201, et seq.

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Chapter II

A CASE STUDY OF THE TOXIC SUBSTANCES CONTROL ACT

Introduction

In this chapter TSCA will be discussed in more detail. Agency actions during official rulemaking will be emphasized. TSCA'S unique prospective approach to environmental protection generated much confusion among the E.P.A. staff. A dearth of available information also made the Agency dependent on outside actors for policy input and review. The scale of the regulations required E.P.A. to combine technical, economic, legal and scientific disciplines into a coherent rule structure. E.P.A. was to oversee the entire chemical industry but it was expected that its

> authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerces in such chemical substances and mixtures do not present as unreasonable risk of injury to health or the environment.[1]

A fine balance between human health and environmental quality had to be struck within the economic viability of the industry. This general section set the tone for the later controversies among the interest groups and Agency staff. Congressional intent may appear obvious, but drafting this idea into a practicable regulation required E.P.A. to define the Act across very diverse disciplines.

TSCA provided a study into innovative regulation. This research was the culmination of three years of observation of the Agency wrestling with the Inventory.[2] It was an opportunity to follow a

selected regulation through the administrative process. The Inventory has importance to the rest of TSCA under E.P.A. and the more generalized system of Administrative Law. A brief legislative history is included to show the record of Congressional intent which guided the Agency through its rulemaking.

Legislative History

In 1971, the Council of Environmental Quality submitted a report which outlined the toxic substance problem.[3] Public concern and the report created the impetus for the first attempts at toxics legislation. The Nixon administration drafted a bill and E.P.A. submitted the draft bill to Congress in February 1971. E.P.A. would be designated as the responsible agency, restricting the use or distribution of a toxic chemical. Both the House and Senate passed versions of the bill but, Congress adjourned prior to a conference on the separate versions. No toxics legislation was passed in the 92nd Congress.[4]

Senators Philip Hart (D-Mich.), Warren G. Magnuson (D-Wash.), and John V. Tunney (D-Calif.) reintroduced the bill in the 93rd Congress. The prospective status of toxics legislation emerged as debate centered on the power E.P.A. would exercise over premarket testing. The Agency, under premarket testing, could control the sale and distribution of a chemical.[5] Industry would be required to submit evidence that an individual chemical was not toxic prior to its marketing. This concept was based on F.D.A.'s experience controlling drugs. Controversies such as the chlorofluorocarbon releases to the environment were not adequately controlled by other statutes. The regulatory mechanism chosen by Congress was to control a toxic substance in commerce.[6] This

mechanism would mitigate present threats and plan a long-range program to control future emissions.

The 93rd Congress appeared to have ample time to achieve a settlement between the two Houses. The House and Senate passed dissimilar toxics bills but conferees had over a year's time to reach a compromise prior to adjournment. Little action was taken and no compromise was reached. Again, the toxics legislation was deferred to the next session of Congress.[7]

The 94th Congress passed the Toxic Substance Control Act, ending nearly six years of debate and compromise. Senator John V. Tunney submitted S-776 on February 20, 1975.[8] Individuals who had been active throughout the five years of legislative action acknowledged a sense of urgency. Tunney and other legislators said the 94th Congress was the last time they would sponsor toxics legislation.[9] Individual House and Senate bills were considered, and compromise continued with the House version substituted as S-776 and passed by the Senate.

The conferees met in September 1, 1976, intending to compromise further until an acceptable bill was finalized. Procedures for controlling a chemical pending completion of testing presented a point of contention but the conferees compromised to complete the process on September 14. Both Houses favorably voted on the conference report with the Senate vote 73-6 in favor, and the House 360-35.[10] The bill was then sent to President Ford.

The bill, received by President Ford, was the result of many compromises effected by special interest group activities. The chemical industry (with the exception of a major corporation, Dow Chemical Company) accepted some form of regulatory control as inevitable.[11] They

presented the most extensive data base on the subject of toxics and pressed for limited controls. Environmentalists and labor unions claimed a more vigorous control of chemicals via the chemical industry would better protect the general public. Labor union support was a critical factor just prior to final action by the House and Senate.[12] Other federal agencies voiced concern that E.P.A. was delegated such broad powers and discretion over an entire industry.

> E.P.A. Administrator Russell E. Train and Council of Environmental Quality Chairman Russell W. Peterson had consistently stated the need for the legislation and supported its enactment, the Office of Management and Budget (hereafter OMB) had opposed it. OMB had written a letter of support for the McCollister bill, but when the House Commerce Committee reported H.R. 14032, OMB opposed its premarket notification requirements as unnecessarily broad.[13]

The resulting bill sent to the President was based on the less strict regulation found in the House version.

Again, the adjournment of the Congressional session had the potential to delay toxics legislation another year. The support of the bill in Congress implied an adequate margin was possible to override a Presidential veto, but the session was over on October 2, 1976, and the President had not signed or rejected the bill. President Ford had the power to "pocket veto" by simply holding the bill without signing; thus Congress would be unable to take any action on a toxics bill until the 95th Congress.[14]

The delay indicated a "pocket veto" was to be expected, but instead President Ford signed the bill into law on October 11, 1976. He praised TSCA saying: "I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress".[15] Ford's signature on TSCA surprised members of the E.P.A. staff and the various interest groups.[16]

The focus of the Act was its Inventory section § 8b, which required E.P.A. to draw up a list of all chemicals which were produced or distributed in commerce during the three years prior to the passage of the Act. These chemicals were to be "grandfathered" in, forming the basis of the information system required for E.P.A. to regulate the chemical industry. A chemical not so "grandfathered" in was defined as a "new" chemical and was subject to E.P.A. review of the available data prior to its manufacture and release. Congress intended the Inventory to be the base for all subsequent regulation under TSCA. Section 8b stated:

> 1) The administrator shall compile, keep current and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 (Manufacturing and Processing Notices) or subsection (a) (Reports) of this section, is manufactured in the United States. Such a list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules. In the case of a chemical substance for which a notice is submitted in accordance with section 5, such a chemical substance shall be included in such a list as of the earliest data (as determined by the Administrator) on which such a substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such a list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for the purposes of scientific experimentation or analysis or chemical research on, analysis of, such substance or another substance including such research or analysis for the development of a product.
> 2) the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.[17]

The language of the Act granted broad discretion to the Administrator of E.P.A. An Inventory was needed to set the foundation for future regulation, but the scope of the information needed to compose a list of chemicals was not clearly defined.

The Administrative Process

The intent of TSCA was debated among the E.P.A. staff.[18] Congress defined only a general framework of action; E.P.A. was to draft a range of specific regulations. Some members of Congress voiced doubts that the scientific, legal and economic disciplines required by the Act would blend together; several expressed fears that TSCA would not be implemented.[19]

The five year debate in Congress resulted in a massive skeleton of general goals. The Congressional framework required strengthening by the responsible agency with regulations. Congress established some of the more restrictive definitions but was unprepared to wrestle with most technical issues. E.P.A. undertook informal rulemaking procedures to generate applicable regulations. This would include notice of hearings published in the Federal Register, hearings, solicitation of comments, proposal of draft rules, more public comment and the publication of final regulations. Publication of the Agency's rules and external comments in the Federal Register made the process public. A citizen could review a comprehensive file of the public record at agency headquarters in Washington, D.C. Ideally, the informal rule-making process encouraged the flow of appropriate information into and from the regulating agency. Chapter III will discuss this process and the Administrative Law process will be discussed in more detail in chapter III.

Any regulation under TSCA required an interdisciplinary blend of economic, scientific and legal judgment. The Inventory was not an exception as it contained crucial definitional questions and

responsibilities. As the first regulation processed under TSCA, the Inventory forced many of these interdisciplinary problems into the open. Major administrative hurdles for E.P.A. included assembling a competent staff and directing the staff through the regulatory process. Some definitions, compelling staff action on parts of the Inventory and subsequent regulation, appeared in the Act. Accepted scientific or industrial terminology was often defined differently by Congress; this created administrative difficulties for E.P.A. Other key definitions, left to E.P.A. discretion, demanded staff attention. Attempts at formulating interdisciplinary regulation required various types of expertise from the E.P.A. staff. TSCA was a unique environmental statute through its prospective status and its technical-administrative format; the Act required an extremely diverse staff with extensive experience.

One technical aspect of the Inventory impacted on the entire regulatory process. The Act mandated the completion of the Inventory within 315 days of passage.[20] Even cursory reviews of § 8b prompted all involved to express doubts that the goal could be met.[21] This initial Inventory list was closed on May 19, 1980; after that date substances could no longer be included on the list without undergoing premanufacture reviews.[22] TSCA was signed on October 11, 1976, so the regulations missed the deadline by years.

E.P.A. addressed its administrative problems and prescribed much of the subsequent action undertaken on technical issues such as the time frame. The Staff's administrative problems will be discussed first.

Administrative Issues

The Presidential election in November of 1976 changed Administrations, and thus created a "lame duck" situation for legislators and the agencies. Established programs and agencies including E.P.A. took a cautious "wait and see" posture until the new Administration took control. Congress passed TSCA in October of 1976; it had neither functioning staff nor budget present in E.P.A. The "lame duck" mentality stalled most immediate staff action on TSCA. Most of the limited attention TSCA received was from upper level administrators or non-functioning staff members. These upper level civil servants initiated the regulatory process of the Inventory without direction from the political levels or help from the technical groups within the Agency.[23]

The technical issue of the 315 day timetable prompted those on the staff to immediately begin drafting regulations for the Inventory. Regulations were compiled in December of 1976 and January of 1977. A minimal amount of information was required.[24] E.P.A. feared any expansion beyond a simple list would delay the Inventory past its statutory schedule.

The Pesticides Office provided TSCA with additional staff and subsequent technical expertise. Staff from the Pesticides Office in E.P.A. were used to provide technical and, especially, chemical knowledge. E.P.A., in the "lame duck" situation, felt these individuals had the most appropriate expertise in the Agency to regulate toxics. However, TSCA's unique prospective nature was contrary to any previous environmental policy from the Pesticides Office. Though the staff had applicable technical knowledge to comprehend toxics problems, it lacked administrative experience with a prospective law.

Draft regulations for the Inventory were completed by this most skeleton staff. Review by the Agency, at large, awaited the arrival and briefing of the new Administrator's staff. E.P.A.'s political and policy individuals reviewed the Draft, presumably to change any confusing or conflicting language. Little public record is available to review what events happened at this time. Only minor modifications were imposed and the regulations became public when published on March 9, 1977, in the Federal Register.[25]

The timetable forced the staff to draft regulations requiring only a list of chemicals in commerce. Issuance of the March 9, 1977, draft regulations prompted the entry of interest groups into the administrative process. Environmental/public interest (hereafter environmental) groups used the public comment period to go on record against the limited Inventory concept. They demanded expansion of the reporting under the Inventory to generate more data and inform the public. E.P.A. had just acquired Douglas Costle as the new Administrator to end the "lame duck" confusion. Costle was informed of the concerns voiced by the environmental groups which apparently had some effect. The Administrator announced that the Inventory should require more than the minimum cited in the draft regulations. His announcement of this policy shift came during a television interview on "Face the Nation" on May 27, 1977.[26] He had not conveyed his decision to members of the TSCA staff prior to the interview; staff members were shocked and confused by the unexpected expansion of the Inventory without clear guidelines as to how to proceed.[27]

In addition to the confusion surrounding the expansion of the Inventory, E.P.A. faced the administrative problem of directing a

growing staff under a new statute. The Carter Administration decided early on, to centralize TSCA's regulatory process in Washington, D.C.28 . This centralization of the rulemaking activity was assumed to be the logical means to handle a large-sale federal action. New staff were needed to form the expanded Office of Toxic Substances (hereafter OTS) in E.P.A. headquarters. OTS was to be responsible for the rulemaking under TSCA and all new staff were concentrated in Washington. With the expansion, previously low level staff were suddenly promoted to be responsible for entire sections of the Act because they were the only individuals with any experience with TSCA.29

Centralization of OTS concentrated the power and scope of rule making in the headquarter's staff. None of the administrative duties were allocated to the regional offices of E.P.A. No comment on the proposed regulation from the regions can be found in the public record. Communication was often initiated by the regional staff, unaware of the progress or direction of the regulations. The regions were briefed through a headquarter's "road show"; information was given to the regions at the same time as the general public. Further erosion of the regional staff's input into TSCA came with the establishment of the "Office of Industry Assistance" (hereafter OIA) in Washington. Traditionally, the regions had served as intermediaries between the industry and E.P.A. headquarters: centralization in the OIA removed the regions from an active position on the Inventory (and subsequent) regulations. The regional staff felt ignored by headquarters and OTS; this resulted in disinterest, confusion and alienation in the regional offices.30

The centralization of OTS prompted severance of established ties with the regions and allowed rapid promotion of relatively low-level staff at headquarters. A very technical orientation emerged in the OTS staff which lacked regulatory and policy experience. Promoted individuals concentrated on the technical issues within their expertise. After Costle's announcement of an expanded Inventory, no one in OTS below the level of Acting Assistant Administrator had a broad overview of TSCA's goals or policy. The staff was segregated into small committees in OTS to work on specific technical issues.[31] Communication within the levels of E.P.A. ignored the regional staff and did little to encourage the long-range planning approach of a prospective law. The emphasis of the OTS became increasingly fragmented.

The expansion of the OTS staff further fragmented the Inventory regulations. E.P.A. hired many individuals directly from out of undergraduate and graduate programs at universities. E.P.A. encouraged continual transfers of individual staff from one environmental program to another. For example, TSCA "borrowed" staff from the Pesticides Office during the beginning of the Inventory process.[32] With the influx of new staff, OTS acquired many people with little experience either outside or inside the Agency. Most of the OTS staff joined the Inventory effort after the initial proposal. Incomplete files and public record of previous Agency action hampered attempts to educate neophyte staffers. It was not surprising that staff members complained of confusion and the lack of available information.[33] The lack of continuity and comprehensive policy review allowed for the repetition of mistakes as the administrative process progressed. Outside actors became a necessary source of imput and information.

When reviewing E.P.A.'s administrative procedures during the Inventory rulemaking, three groups of external actors must be given close attention. These were other involved governmental agencies (both state and federal), environmental groups and chemical industry groups, all of whom attempted to influence OTS during the Inventory rulemaking. Governmental agencies acted generally as ineffective change agents. State governmental officials were frustrated by the same centralized bureaucracy which ignored its own regional staff. The tradition of E.P.A.'s use of regional offices to link Washington with the states was neglected.[34] Even individuals within E.P.A. designated to serve as "state liasons" were based at the regional level and not utilized. With no communication established, the states submitted written comments just like an individual citizen. The states offered little information to OTS, and they only requested clarification of policy during the formal comment period.[35]

Federal agencies utilized correspondence, written comments and information more often than the regional offices of E.P.A. Generally the issues centered on questions of jurisdiction. These were areas of jurisdiction which expressly pre-empted TSCA's application. TSCA had specific prohibitions to exempt chemicals already controlled by the F.D.A., the Treasury, and Agriculture Departments. Each of these agencies reminded OTS of their power to monitor toxics in specific sectors of the human environment.[36] Attempts were made to lessen the possibility of conflict and agency infighting. The Occupational Safety and Health Administration (hereafter OSHA) was more supportive of TSCA and offered information and shared its experience of regulating toxics in the work place. OSHA even lent staff members with appropriate past

experience to OTS.[37] Confusion at E.P.A. during the drafting of the Inventory was found to a greater degree in the Consumer Products Safety Commision (hereafter CPSC). Internal problems consumed the CPSC's time; hence it had little input into the Inventory.[38] Other federal agencies submitted comments on individual parts of the Inventory, but as a rule, offered little concrete data or input.[39]

Special interest groups, such as the environmental groups, took a far more active stance, exerting concerted pressure during the administrative process. Their use of informal interaction and formal comments influenced specific sections of the rulemaking. The Environmental Defense Fund (hereafter E.D.F.) emerged as the leader among environmental groups. E.D.F. had a Washington office and an experienced staff to consider the complex issues surrounding toxics in the environment. In fact, it was the publication of comments made by E.D.F.'s Jacqueline Warren in the Washington Post which led to Costle's public announcement expanding the scope of the Inventory.[40] E.P.A. staff members felt Ms. Warren was of great importance in determining the future functions of OTS; she appeared a crucial factor in the early months of Costle's administration.[41]

Other environmental groups were active in the administrative process. Citizens for a Better Environment (hereafter C.B.E.) had a technical staff working on toxics regulation, especially the Inventory. Its impact was expected to be considerable due to its expertise and high visibility. The Chicago-based C.B.E., however, was often shut out of the daily routine by a centralized OTS. This situation mirrored the lack of feedback available to E.P.A.'s regional staff and the state governments. C.B.E. even considered moving its TSCA staff to a new

Washington office to better influence the Inventory regulations.[42] The Natural Resources Defense Council (hereafter NRDC) and the Sierra Club provided only formal comments on the Draft Regulations. This deviated from the active role these groups had played earlier in the actual passage of TSCA.[43] Overall, the environmental groups complained that their input and information had been ignored by the agency. E.D.F. had been the most influential of all the groups but not as successful as the environmentalists desired.[44]

A concentrated industrial reaction also emerged in the rulemaking process; the effort was basically coordinated by the Manufacturing Chemists Association (which has since changed its name to the Chemical Manufacturers Association or CMA). Influence came from CMA members during the comment period and through the use of CMA staff in Washington. CMA's Washington staff addressed the problem of the centralized OTS. CMA solicited select pressure from specific trade associations or firms when such input could influence or inform the OTS staff.

Such select pressure affected the TSCA staff as the Act provided E.P.A.'s first opportunity to regulate the entire chemical industry. The Agency knew comparatively little about the industry's organization and structure. The lack of information forced E.P.A. to ask for pertinent information from the most obvious source, CMA, or undertake its own investigation. The Inventory's timetable made the second option impossible. Environmental groups argued that this data would present a less than accurate picture of the industry and even staff members of E.P.A. expressed doubts that a regulated industry would be objective when presenting such information to a regulating agency. There is no

evidence to show, however, that the CMA data had not been assembled in good faith.[45]

CMA, serving as the chosen representative for the diverse chemical industry, provided information for E.P.A. Its soliticitation and coordination of its members' formal comments also cast CMA as an organized, potent advocate. Members of CMA received letters urging a response to E.P.A. in the formal comment period. Industry directed most of the comments towards crucial sections of the regulations and definitions considered the most damaging. Response by members generated considerable comments in the public record; excessive costs to the industry or TSCA's effect on research and innovation formed the bulk of the comments.[46]

To summarize, several key administrative factors influenced the rule making process for TSCA's Inventory section and its subsequent regulations.

1. Once OTS was centralized in Washington, it selected against input by its regional offices and the states governments.
2. The centralization magnified the importance of Washington-based environmental and industrial groups while it lessened the impact possible from non-Washington groups.
3. Little policy direction from the upper levels of E.P.A forced an inexperienced technical staff to make policy decisions.
4. As OTS expanded in size, low-to-middle rank staffers were rapidly promoted to policy level positions without the benefit of additional training or guidance.

5. The OTS staff did not grasp the broad conceptual picture of TSCA's regulation, instead it directed attention to discrete, unrelated technical questions.

The Technical Issues

The technical issues can be separated into three main categories: legal-scientific, legal-economic and legal-administrative. Problems with definitions in the Act and Inventory regulations originated in the first two categories; legal scientific issues included definitions of "mixture", "intermediate", "inpurity" and "byproduct"; legal-economic concerns included definition of "small manufacturer 'and' small quantities for research." The remaining category was the legal-administrative problems involving the creation of procedures to meet E.P.A.'s legal obligations: the examples considered are the reporting of amount and site of manufacture, and the preservation of industry confidentiality without restricting entry of new producers. These categories may appear somewhat arbitrary and relative due to the interconnections among the separate problems. They are used as the most coherent formula for analysis.

Legal-Scientific Definitions

"Mixture" was a term defined in the Act itself as "a combination of two or more chemical substances if the combination does not occur in nature and is not in whole or in part, the result of a chemical reaction."[47] "Mixtures" were not to be reported for the Inventory; the components (the two or more chemical substances) were to be reported individually. Technical staff at E.P.A. stated "The term mixture under

TSCA has a meaning which is different from its usual meaning. Many compositions commonly considered to be mixtures are "chemical substances."[48] The accepted definition of "mixture" to the chemist was "two or more substances which are mixed, but not chemically combined. Mixtures are non-homogeneous and may be separated by mechanical means."[49] However, the staff drafted the initial regulations of March 9, 1977, with the Act's definition intact. The statutory definition was expanded with specific combinations such as solutions, hydrations, stabilizers, coloring agents, anti-oxidants, etc. which were being excluded from the Inventory.[50]

This regulatory definition prompted much formal comment, all of which requested revision of the term "mixture".[51] Therefore, the re-issuance of Draft Regulations on August 2, 1977, redefined "mixture" to include only the statutory language and hydrates.[52] New categories contained definitions to expressly exempt the other listed exceptions. The staff defined the exemptions as "chemical substances excluded from the Inventory" and not a "mixture".[53] No further changes in the definition of "mixture" emerged in the Final Regulations of December 23, 1977.[54]

Few memos explicated the internal staff's deliberation of "mixtures." The principal chemical consultant on the Inventory staff argued for a definition similar to what eventually appeared in the final form because it would lessen industry confusion and administrative problems for E.P.A.[55] Technical staff at E.P.A. received their desired changes in policy only after outside comments during rule making demanded this re-definition.

Similar problems blending technical terminology with the statute faced the staff on the issues of "intermediate," "impurity" and "byproduct." The following description of these terms is included to better illustrate the definitional questions. Picture the following manufacturing process:

Chemicals A and B are put in a vessel to produce chemicals C and D

(i) A + B —> C + D.

Chemical D is then withdrawn from the vessel and chemicals E and F are added resulting in chemicals F and G

(ii) C + E + F —> F + G.

Chemical G is then withdrawn from the vessel and piped to another vessel where it is stored for one month before it is added to chemical H to produce the desired product, chemical I. A small but inseparable amount of chemical J which is not desired but is unavoidable is also produced

(iii) G + H —> I + J

while chemical F is reclaimed and stored until the next batch is ready for processing. To the chemist or chemical engineer the characterization of these chemicals is quite clear

Feedstocks (raw materials)	A, B, E, H
Product	I
Byproduct	D
Intermediates	C, G
Calatyst	F
Impurity	J

The accepted technical definitions are added here to explain the industry and E.P.A. staff's difficulty with combining chemical terms with applicable legal thought. An intermediate bore these general definitions "usually a derivative of the "crudes" or raw materials"[56] or the industrial definition of, "an organic chemical produced because it is the necessary intermediate stage in the manufacture of one or more ultimate end products such as dyes, drugs, etc."[57] An impurity was a chemical produced in a chemical reaction as a trace residual when the reactants transformed into the resultants. Generally it resulted from less than pure chemical reactants being used.[58] A byproduct was defined as "A material obtained in addition to the principal or primary material in a manufacturing process."[59] The term calatyst also appeared in the Inventory regulations. It had been previously defined by the technical literature as

> A substance whose presence changes the rate of chemical reaction without itself undergoing permanent change in its composition. Catalysts may be accelerators or retarders. Most inorganic catalysts are powdered metals and metal oxides, chiefly used in the petroleum and heavy chemical industries. Vitamins and enzymes are organic catalysts of the chemical process in the (human) body.[60]

The first Draft Regulations in March 1977 defined an intermediate as

> any chemical substance 1) deliberately present in a reaction sequence...whose presence is known or reasonably as certainable, and...could be isolated and identified...in the environment or 2) is a—catalyst.[61]

The definition expanded to include the "reasonably ascertainable" and" identified in the environment" to address problems presented by specific industrial practices. Such industries as the pulp and paper manufacturers knew that in their vats there were chemicals that had never been isolated or identified but which were transient; i.e., which never left the vessel.[62] The regulations defined intermediates as

"chemical substances" required by the Act to be included in the Inventory. E.P.A. never explicitly stated this inclusion in the rules.

The definition re-proposed in August, 1977, removed catalysts.[63] Other changes were minor from the March draft. Both intermediates and calatysts were still included in the definition of "chemical substance" used for a "commercial purpose".[64] TSCA's language required this reporting for the Inventory. E.P.A. never defined the term "calatyst" during the regulation process.[65] The staff also proposed that chemicals used only on one site be so designated. They informed Administrator Costle of the low regulatory priority as such chemicals were unlikely to present environmental hazards.

Public comments on the listing of intermediates and calatysts were predominately from technical associations and the chemical industry. These comments opposed the new listings because of the possible cost increases forced upon the regulated industries.[66] This position of resistance by the chemical industry appeared surprising. Anything listed in the Inventory was "grandfathered" in and required E.P.A. to prove it dangerous. Should a substance not be in the Inventory, the responsibility for proving the chemical to not be a hazard rested on the producer.[67] An expanded Inventory removed more of the later testing burden imposed on the industry. Little data, except from the industry, was presented, so one was left to assume the industry's objections regarding cost were accurate and in good faith.

In the Final Regulations of December 1977, E.P.A. redefined the term to accommodate some of the industry objections. The OTS staff defined an intermediate as,

> a chemical substance...removed from the equipment in which it was manufactured and...either is consumed in chemical reactions...for the intentional manufacture of other chemical substance(s) or mixture(s) or is intentionally present for the purpose of altering the rate of such chemical reactions.[68]

An explanatory footnote explained that

> equipment in which it was manufactured includes the reaction vessel [and ancilliary equipment]...and other equipment through which [it]...may flow...but does not include tanks or other vessels in which the chemical substance is stored.[69]

The "chemical substances which are not intentionally removed from the equipment in which they are manufactured" were excluded from the Inventory, yet the intermediate was considered a "chemical substance" and had to be reported.[70] As the internal action memorandum explained, this separation "should significantly reduce the costs of reporting and at least some of the potential claims of confidentiality".[71] E.P.A. attempted to streamline its procedures after vocal opposition in the comments emerged from selected industries such as pulp and paper manufacturers.

The administrative process also evolved the definitions of "byproduct" and "impurity" until the Final Regulations were established. In March, a by-product was "a secondary chemical substance produced during the manufacture, processing, storage or end use of another chemical substance...(if it) does not appear only as an impurity."[72] At the same time an impurity was "a chemical substance which is unintentionally present in another chemical substance".[73] The March regulations further provided that, "any chemical substance which is (i.) only an impurity or (ii) only a by-product not used for any commercial purpose, is excluded from the initial inventory."[74] The timetable constraints were assumed to be a factor. The only explanation was that "E.P.A...considered but decided to postpone gathering information on

by-products and impurities".[75] Both the cost and delays inherent in further research could have caused E.P.A.'s decision.

Public comments from industry predictably endorsed the exclusion of byproducts and impurities from the Inventory. The phrase "not used for commercial purposes" prompted requests for clarification from the Agency staff. Some by-products from chemical processes are burned as fuel, used as fertilizer, etc., which gave them commercial value. Industry representatives questioned the staff with inquires about whether or not such by-products were included in the Inventory.[76] By contrast, little environmentalists activity focused on the exclusion of by-products and impurities. A few groups responded but their comments were relatively muted in tone.[77]

E.P.A. modified the definition of by-product to accommodate industry concerns. The August reproposal defined by-product to be "a chemical substance produced without separate commercial intent". No change in the definition of impurity was proposed.[78] These categories of chemicals were still exempted from the Inventory. An answer to previous comments from the various industries in a note stating that if a by-product "has commercial value...as a fuel...for enriching soil or...[as a source of] component chemical substances...it may be included in the Inventory."[79] This statement did little to answer industry concerns because of its ambiguous language.

The explanation presented by E.P.A. for its exclusion of impurities and byproducts appeared in the introduction of the August re-proposal.

> Certain chemical substances which are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the mixture or article of which they may be a part are excluded.[80]

This statement did little to answer industry questions or environmentalist objections. Staff members relied on the language of TSCA to limit the Inventory to only "chemical substances manufactured or processed for commercial purposes."[81] E.P.A.'s strict interpretation of the Act here may be contrasted to its simultaneous attempts to broaden its data collection capabilities. Site and volume data on chemical production desired by the staff were admittedly beyond E.P.A.'s authority under § 8b; however, the Agency decided to collect such data for the Inventory. The public record gave no evidence why by-product and impurity information could or could not also be collected by the Agency.[82]

The Final Regulations adopted the August proposals.[83] E.P.A. published a new explanation for the exclusion, assuming to answer the various comments. A staff statement settled the issues around by-products that "as a matter of policy, the Agency has decided that by-products which have no commercial purpose shall not be reported for the Inventory."[84] Staff members also dismissed questions over impurities by saying that "as a matter of policy, this first Inventory should not distinguish among chemical substances which are identical except with respect to their impurities."[85]

This stance was a policy decision made within E.P.A. It was possibly directly from Administrator Costle's desk, or it was chosen from the basic recommendations of alternatives proposed by the TSCA staff. As a matter of fact, there are no documents in the public files reflecting any consideration or discussion of this matter at any level. Costle's predecessors had discussed this topic; it is possible the policy decision was formed then.[86] E.P.A. staff still under the Ford

Administration had discussions in January 1977 with several representatives of the environmental groups and CMA. No records documented this interaction.[87] The lack of a comprehensible public record and filing system was evident throughout research on the Inventory. The Agency would have been better protected by an extensive record of the options considered during the administrative process. A complete and documented record offered a strong answer to possible charges brought by interest groups charging the Agency acted in an "arbitrary and capricious" fashion when writing a regulation.[88] Though the OTS staff expressed fear over possible litigation, it kept little record of its internal procedures and review of technical decisions. Several staff members complained that most of the basic reasoning behind policy decisions could only be found through the questioning of responsible staff.[89]

A review of the final regulations in light of the public comments, indicated E.P.A. attempted to conceptualize the legal-scientific issues raised by the industry. Statutory language and the difficulty of phrasing an accepted scientific concept into an operable regulation made the resulting regulations a composite of traditional chemical and legal ideas. The chemical industry did not receive all of the concessions it demanded during the administrative process. Exactly what E.P.A. achieved in the regulation of the Inventory is presented below. The chart illustrates the chemist or chemical engineer's classification and E.P.A.'s own classification of substances for the Inventory. Also the Chart includes E.P.A.'s final requirements for reporting under the Inventory. (See Chart I)

Recall the reactions (i) A + B-->C + D, (ii) C + E + F-->F + G, and (iii) G + H-->I + J:

CHART I

Substance	Chemist	E.P.A.
A, B, E, H	feedstock (chemical substance)	chemical substance (reported)
C	intermediate	substance not intentionally removed from equipment (not reported)
D	byproduct	Byproduct (not reported unless has commercial value
F	catalyst	intermediate (reported)
G	intermediate	intermediate (reported)
I	product (chemical substance)	chemical substance (reported)
J	impurity	impurity (not reported)

Legal-Economic Definitions

The chemical industry expressed concern that the regulation by the federal government would dampen research and innovation of new chemicals and technology. Fear centered on the control of new product development or technical grade chemicals used for laboratory purposes. Debate in Congress during TSCA's passage noted this fear. An exemption for such chemicals was mandated, but the specific definitions were left for E.P.A. to complete.[90]

"Small quantities for research" was the notation E.P.A. drafted into the March 9, 1977, regulations. The staff added three general criteria: a chemical could be produced in "quantities no greater than necessary," "used solely for such purposes," and are used "or directly

supervised by a technically qualified individual."[91] E.P.A. drafted explicit language in the preamble that the definition "is intended to include quality control testing."[92] A "technically qualified individual" was chosen to supervise because of his/her awareness and training. These individuals would be aware of risks and lessen the likelihood of toxic release to the environment. Knowledgeable control by such an individual would monitor uses and exposure.

OSHA and the labor unions sensitized E.P.A. to the threat of toxics in work places. The subsequent definition was not "intended to remove any responsibilities to inform workers of hazards to which they had been exposed." The staff had explored two other options to define "small quantities for research." One suggestion proposed a numerical base amount for all chemicals but was judged to be too broad and indiscriminate. The second alternative was a more individual numerical base set for specific classes of chemicals. Staff discussion of the administrative costs and delays forced the rejection of this option. [93]

EPA modified the definition in the August 2, 1977, reproposal with the removal of "are...used solely for such purposes."[94] No explanation could be found in the Federal Register or any section of the Agency's record. Several staff members assumed the action was to remove redundant language because the "quantities no greater than necessary" remained in the draft Regulations.[95]

When the final regulations were completed, the August 2 definition remained intact. An additional section was added: "NOTE--any chemical--[produced] in quantities of less than 1,000 pounds annually shall be presumed to be--for research and development puposes." A substance was not to be included on the Inventory unless "certif[ied]

research and development".[96] The 1,000 pound exemption emerged into the public record but exemplified the poor record-keeping by the Agency staff. No published materials, inter-office communication or public files document the origin of this concept. Comments by various industries requested an established numerical base for a consistent policy, but none described a limit of 1,000 pounds.[97] This addition to the Final Regulations ran counter to the initial March preamble which eliminated a one set numerical base as an option. Exactly how or why the 1,000 pound limit was adopted was not documented by the staff. The "small quantities for research" concept generated much interaction between the industry and OTS but the incomplete record sheds no light on this sudden shift.[98]

The technical issue of the Inventory timetable limited the initial regulations of March 1977 to the minimum amount of information required in §8(b). The Inventory required no exemption for groups defined as "small manufacturers."[99] Administrator Costle's decision to expand the Inventory included information reportable under §8(a)(3)(b).[100]

E.P.A. had made progress defining "small manufacturer" prior to the expanded Inventory requirements. The initial TSCA staff in December 1976 established the criteria judging the level of industrial activity. The Standard Industrial Classification (SIC)28, "Chemicals and Allied Products" provided aggregate industrial census data. This information could be categorized by gross sale percentages (i.e. 90% of firms had gross rates of $X; 80% had gross sales of $Y, etc.).[101] The staff would then choose a category which provided the needed information. An expanded Inventory fueled a more critical staff review of this method.

E.P.A. lacked experience in regulating the chemical industry, but Congress had presented the Agency with a clear mandate to utilize the expertise found in the Small Business Administration (hereafter S.B.A.) on the issue. The two agencies began discussion on the definition of "small manufacturer." S.B.A. utilized a broad concept of small business to award loans and contracts. E.P.A. calculated that this general definition weakened the regulations and allowed the exclusion of up to ninety percent of the firms which produced more than forty percent of all chemicals. Both agencies agreed that the S.B.A. definition was inappropriate for E.P.A. regulatory purposes.[102]

E.P.A. went in two directions to obtain a workable definition. First, an external consulting firm, Arthur D. Little (hereafter Little), was contracted to study the cost to the aggregate group called small manufacturers. Since no agency had previously regulated the entire chemical industry and E.P.A. was a novice in this form of regulation, more data was needed. Little coalesced the fragemented data on costs etc. from industry, especially the trade associations. Use of an outside contractor to collect and process data was and still is a common practice within E.P.A.[103] This is most common when economic analysis of a large data base is required in the process of regulating an industry. TSCA possessed a technical staff primarily of chemists, or of policy analysts, so it was not surprising that economic consultants were hired.

The lack of information initiated E.P.A.'s second action. A "Straw-Man Definition" became a strictly internal agency concept; it had no basis in current economic or industrial practices. Use of a stringent "Straw-Man Definition" was discussed within E.P.A. to force

the industry to counter with their own data and ideas. This idea illustrates the discretion within the administrative process to bargain during the early regulatory drafting. It was an option solely to gain more information for internal policy decision making within the Agency.[104]

Though the August 2, 1977 reproposal presented a very restrictive definition, it was not as rigorous as the "Straw-Man" concept originally discussed within E.P.A. The staff considered several conditions prior to exempting a manufacturer due to size. A manufacturer could have "only a single manufacturing site and either--total annual sales of less than $100,000--or--items [less than] 2000 pounds annual production--of each--chemical."[105] The Agency proposed under this definition to exempt up to twenty percent of the companies in the Industry which accounted for less than one percent of total sales. Staff members needed more information and data, so a less forceful option than the "Straw-Man Definition" emerged. E.P.A. requested information when it solicited "comments on this proposal definition--including any quantitive data on the estimating costs of compliance the number sizes and types of firms--(and) other information."[106] The OTS staff received information in industry comments and the draft report from Little. OTS consulted E.P.A.'s own Economic Analysis Division who further recommended modifications to the definition proposed. Suggestions included 1.) that the "single plant" requirement be removed from the definition; and 2.) that the sales figure of at least one million dollars and the production figure be 100,000 pounds to establish a clear cut-off point for "small manufacturers".[107]

EPA assembled three alternatives from the available data and circulated them in the internal action memorandum for the December Final Regulations. Two charts (here condensed into one, see Chart II), listed the options as one million dollars and 100,000 pounds; five million dollars and 100,000 pounds; and ten million dollars and 100,000 pounds. These different categories represented the levels below which any manufacturer could fall and be exempted from the Inventory.[108]

The E.P.A. staff discussed the Final Regulations with the SBA prior to publication. The Agency reasoned that the definition should be set at five million dollars due. This level of production was judged to generate a workable data base to monitor smaller producers without an undue burden being placed on the smallest producers. E.P.A. decided the cost difference would not be as important as the loss of information and chose the five million dollar limit. The SBA accepted this reasoning and the five million dollar limit to define "small manufacturer."[109] EPA's own staff acknowledged a lack of depth in the internal analysis. In an Action Memorandum, the following note was circulated:

> NOTE: If there had been more time, a more complete analysis--could have been prepared. The Economic Analysis Division advises that the Agency may be critized for the failure to prepare a more thorough analysis although the Office of General Counsel believes that the Little analysis satisfies the requirements under TSCA to consider the costs to industry.[110]

Costs to industry had to be considered when balancing the impacts of toxics on the environment.[111] The final regulations established the five million dollar level to define which manufacturers could be exempted from the Inventory due to small size.

CHART II

DEFINITION ($ Annual Sales)	Number of Firms (%)	Number of Facilities (%)	Number of Multiple sites exempted	% of total sales	% of total employment	Costs of Reporting (As % of profit) § 8(b) only	Costs of Reporting (As % of profit) § 8(b) plus other data	Total Cost (million $)
All Manufacturers Required to Report	6400	8400	0	100%	100%	-	-	14.4
$1 Million	2400 (44%)	2400 (28%)	0*	0.8%	1.4%	1.5%	2.7%	13.7
$5 Million	4200 (78%)	4600 (55%)	430	4.1%	5.5%	0.55%	1.2%	12.2
$10 Million	4600 (85%)	5200 (62%)	600	6.3%	7.6%	0.37%	0.8%	11.6

*because no company with this small a sales volume has more than one site.

Consolidation of charts A & B following p. 15 of Dec. 12, 1977 memorandum entitled "Promulgation of Inventory Reporting Regs." from S. Jellinek to Administrator.

Legal-Administrative Problems

This section reviews the basic problems found in TSCA which were not technical definitions. One of the major thrusts of the Act revolved around the creation of a comprehensive data base for future policy decisions. Congress mandated that E.P.A. was to become a repository of pertinent data from the diverse chemical industry. The staff defined the scope of the Inventory and the amount of information required by the expanded §8(b). E.P.A. was responsible for the regulations and a structure to process the submitted information. TSCA mandated E.P.A. to consolidate the fragmented data base and to create an appropriate information system for future reference. E.P.A. had no experience with this form of a comprehensive information system.

The "lame duck" situation discussed earlier affected the Agency's attempt to establish an information system in the March 9, 1977, proposal.[112] TSCA's timetable for the Inventory forced the core staff to propose a very limited information requirement. A combination of the cautious "lame duck" status and desire to comply with the Act pressured the staff to ask only for the reporting of chemicals produced by company headquarters. A similiarly restrictive option was considered to rely only on existing lists of chemicals. Other alternatives for the collection of data included production volume, use, by-products, etc.[113] The staff abandoned any expansion of the Inventory with these alternatives because of the imposed 315 day schedule. Future regulation would require at least the identities of the manufacturer, so the staff rejected the use of only existing chemical lists.[114]

Environmental groups actively opposed this limited information Inventory. The March 9, 1977 proposal prompted an immediate

reaction and a meeting was scheduled between the staff and the representatives of six groups within one week after publication.[115] The Acting Assistant Administrator (AAA) attended and summarized the environmentalist position to be, "that E.P.A.'s proposal was timid, contrary to legislative intent and inadequate to enable E.P.A. to properly assess chemical risks".[116] The AAA informed his superior, the Administrator, of this interaction. The AAA stated; "It is my preliminary opinion that the final reporting rules...should be expanded to produce basic production and use information."[117]

E.P.A. staff voiced opinions for expanding the Inventory concept. The Departments of Labor and Health, Education, and Welfare (hereafter HEW) submitted similiar objections. Both agencies communicated their concerns to E.P.A. through the formal comment period. Their objections stated that a mere listing of chemicals had little potential information value.[118] Predictably, formal comments by industry lent support to the limited Inventory regulations, but specific forms and agency procedures generated confusion among them. E.P.A. received requests from many actors for clarification of E.P.A. of the reporting procedures.[119]

As mentioned earlier, the memorandum from the AAA to the Administrator pressed for an expanded Inventory early in the administrative process.[120] Lower level staff at E.P.A. admitted surprise and confusion at the Administration's announcement to broaden the information gathered.[121] The extent of communication between the upper-levels and the functioning TSCA staff appeared scant. Memoranda within the Agency's files discussed the expansion of the Inventory. Poor record-keeping by the staff left these memoranda undated. The exact progression in the evolution of the regulation cannot be determined.

The first memorandum bore no indication of origin and was titled "Scope of Inventory Reporting Requirements." It was stamped "DRAFT" with internal evidence dating the report between April 1 and May 9, 1977.[122] The four policy options under consideration are listed and paraphrased below:

1) A simplification of industrial reporting could be instituted by not forcing duplicate reporting among firms or trade associations.

2) Regulation under the proposed March 9, 1977 rules.

3) Expansion of the March 9, 1977, rules to include reporting of site "and/or—whether—the chemical is utilized only as a chemical intermediate within a closed system."

4) Use of alternatives 2) and 3) could be enlarged to require a report of "current use of each chemical and current and projected production levels.[123]

A small work group had been formed among the OTS staff targeting issues related to the Inventory. They received a briefing of several comments pertinent to the March 9, 1977, regulations in the second memorandum, also undated. Two federal agencies, the Office of Management and Budget and the Department of Labor, formally commented that E.P.A. should "consider asking for reporting by plant site". Internal pressure from the E.P.A. regional staff also petitioned for this expansion. The OTS staff was then informed "that we should consider expansion of the proposed Inventory reporting requirements to include plant site and production information."[124] The third memorandum was an internal policy statement discussing the unexpected expansion of the Inventory required by Costle's announcement. It spoke to the staff

confusion and the proper direction for the new policy. Staff members were encouraged to

> accept the slippage [of the time limits in TSCA]. Plan, if necessary, to publish an incomplete list initially. An incomplete list will not meet the requirements of section 8(b)(1) of TSCA and we are likely to be sued.[125]

No announcement of the Administrator's decision to expand the Inventory had been forwarded to the functioning work group in OTS. When the Administrator made his decision is not clear but can be assumed to have been made shortly before the interview on May 29, 1977.[126] The shocked staff either heard the policy shift on live television or waited for the confirmation from the Administrator's office.[127] Desire to meet the statutory timetable was evident. Confusion over the best route to achieve an expanded Inventory within the time constraints troubled many staff members. The memorandum which urged the issuance of an "incomplete list" was an attempt to release something to satisfy the Act.[128] With the expanded Inventory the staff had to assess and propose the scope of information required and the Agency's system to utilize the data.[129]

The August 2 re-proposal resulted from the two options presented in an action memorandum from the AAA to the Administrator. If the Agency maintained the March 9 regulations, without change, a duplication of reporting could occur. The March 9 rules required every manufacturer of a chemical to report. Discussion by the AAA cited the generation of identical data by the non-chemical companies as examples:

> In the pulp and paper industry, pulp mills manufacture sodium hydroxide--as part of their recovery processes--[under this approach] there would be more than 400 establishments reporting they manufacture sodium hydroxide [in the pulp and paper industry]."[130]

Such a duplication of data created more administrative responsibility for E.P.A. but produced no new information.

A more practical option emerged when the AAA structured the reporting to be only from firms in SIC Group 28[131] and Group 2911, Petroleum Refining.[132] The AAA recommended usage of these established categories. Using SIC groups reduced the number of firms involved from 225,000 to a more manageable 20,000. These categories were more easily administered but still listed over ninety-five percent of all chemical production in the United States.

The Administrator's announcement of an expanded Inventory was incorporated into the August 2 re-proposal. The regulations included site and quantity information in the Inventory. Uses of chemicals were not required by the rules, as the Agency feared this data would be difficult to collect and process. The staff judged the concern over the statutory timetable to be paramount, so the use data was not proposed.[133]

Industry met these regulations with an organized comment campaign. The inclusion of site quantity data in the Inventory initiated the bulk of the comments. Allegations by the various industries attacked these rules alleging undue economic burdens and illegal Agency discretion.[134] Federal intervention further countered E.P.A.'s progress drafting the regulations. The Census Bureau refused E.P.A.'s request for the names of firms in SIC Groups 28 and 2911. TSCA's work group was informed "(w)hile we might learn these SIC designations from the manufacturers directly, OMB has formally objected to E.P.A.'s relying on Census designations for enforcement purposes."[135] The lack of information transfer within federal agencies continued; however, O.T.S. did continue

to pursue the expanded site and quantity data. A desire to ease the administrative burden caused the staff to suggest three different combinations of site and quantity data. They were:

1) The name of chemical by site, quantity by corporate headquarters
2) selected chemicals by site and quantity, the remainder by corporate headquarters
3) reporting by corporate headquarters with a list of plant sites by zip code, number of employees and/or quantity in terms of pre-set ranges of quantities.[136]

These alternatives produced the possibility of an explicit proposal which minimized the economic burden on industry while generating usable data for the Agency. OTS responded in part, to the comment period pressure from the industry.

The Inventory staff re-worked the alternative proposals for the next three months. It combined the various options into a final product which both the staff and the Assistant Administrator found workable. An action memorandum discussed the final rules:

> Defining—in terms of those manufacturers in SIC groups 28 and 2911 posed unanticipated legal and administrative problems--the Census Bureau has serious reservations concerning E.P.A.'s use of the actual SIC designation that the Bureau assigns to each manufacturer.[137]

A change in the regulatory language overcame the resistance of the Census Bureau. E.P.A. no longer needed the Bureau's actual manufacturer identification; it required data on any site where thirty percent by weight of its products were "of the types described under (SIC) group 28 or 2911."[138] OTS assumed a more strenuous standard was necessary as the proposed option might "not include [some] large volume manufacturers

whose production--accounts for less than one-third the weight of the total products they distribute."[139]

The expanded proposal contained two new criteria. One, the earlier use of the SIC 28 and 2911 categories remained in the new language. Two, if a company produced a total of one million pounds of all chemicals on site or at least 100,000 pounds of one chemical per site, all chemicals had to be reported in the Inventory.[140] These criteria answered internal concerns by the staff to offset possible exemptions for the larger firms.

Industrial comment had emphasized that the economic burden inherent in an expanded Inventory exceeded the Agency's authority. OTS read these comments but found little concrete information to substantiate the industry claims. The Agency acknowledged potential costs and adopted a series of "ranges" for reporting. The ranges were set up for production data in multiples of ten, except at very high levels of production, here each range was split in two. These were published in the Federal Register as: less than 10^3 pounds, 10^3-10^4 pounds, 10^4-10^5 pounds, 10^5-10^6 pounds, 10^6-10^7 pounds, 10^7-5 x 10^7 pounds, 5 x 10^7-10^8 pounds, 10^8-5 x 10^9 pounds and over 10^9 pounds.[141] "Ranges constituted general categories for the specific amount of production retained by the manufacturer. A manufacturer needed to offer E.P.A. only the general category when it reported for the Inventory. E.P.A. still compiled the necessary data within ranges while expressly addressing the industry comments to lower the costs.

Comments challenged the legality of the expanded Inventory prompting another change in regulatory language. Industry contended

that the site and the production volume E.P.A. requested was beyond the scope or intent of §8(b). An explicit statement by E.P.A. avoided this controversy, explaining that

> [p]roduction volume information is not being required to publish the inventory under section 8(b). This information is being required under the general authority or section 8(a) of the Act, to require submission of information necessary for the administration of TSCA.[141]

Once the Administrator re-directed the staff to expand the Inventory, formal comments from industry emerged and influenced the regulation. Controversy over this rulemaking was multi-faceted; including such factors as, economic definitions, feasibility, methodology and utility of alternative information systems. These factors produced a weighting of alternatives by the E.P.A. staff. Environmental groups originally requested an expanded Inventory but confined their efforts during the regulatory process to countering industry claims of confidentiality for all forms of submitted data. Confidentiality of the requested data was the most difficult legal-administrative problem facing E.P.A. in the Inventory.

The economic considerations in the expansion of E.P.A.'s data base through §8(b) revolved around the cost of compiling the data and then processing it into useful form. Industrial costs resulted from the compiling, organizing, and submitting data according to prescribed procedures and forms. The Agency's cost originated in the formulation of a workable policy to process the incoming data and to establish a viable information base. Confidentiality as a concept necessitated more than the relatively simple calculation of a cost outlay to generate a data set. The central issue in the confidential data was the protection of trade secrets vis-a-vis the public's "right to know." A trade secret

represents a tangible, but often not quantifiable, economic advantage to the parent manufacturer. E.P.A. accepted this concept but had no system to protect the holder of a trade secret. Confidentiality is an example of the interdisciplinary problems inherent to the Inventory and TSCA as a whole. The economic value of trade secrets had to be evaluated by the staff and defined in a legal manner for the regulation. It raised questions as to how the information system could be administered to protect trade secrets. Environmentalists commented on the ethical question of the public's right to protection and knowledge. Without an open data base, they feared, no member of the general public could evaluate the Agency's regulation of the chemical industry.

TSCA itself provided little direction for the staff as the legislation was poorly written. This judgment is apparent in the obvious conflict found with two other sections of the Act, relevant to the confidentiality question in the Inventory. Trade secrets are protected by §14[143] while §8(b)[144] requires all substances to be in the Inventory and §5[145] says premanufacture notice (hereafter PMN) and review is not needed for the substances already in use; for they are listed on the Inventory. The Inventory was intended to list all chemicals presently in commerce. The one-time Inventory established the present data base on chemicals in use.[146] The provision allowed PMN any chemical listed on the Inventory to be "grandfathered in" to the law and therefore exempted from testing prior to manufacture.[147] PMN was on-going data collection, monitoring and screening for all new chemical substances. E.P.A. built on the initial Inventory to define new chemicals. However, the three sections were interpreted by the various actors to give conflicting responsibilities to E.P.A.

E.P.A. admitted that these conflicts existed when the initial March 9, 1977, proposals were drafted. Special regulations such as the consideration of confidentiality concurred with the minimalist stance and scope of the Inventory. E.P.A. proposed to use existing Agency rules governing confidential information.[148] The regulations required only the following special provisions to substantiate a claim of confidentiality; the real name, a proposed name "only as generic as necessary to protect the confidential identity," the elements composing and molecular weight of the substance, and a bibliography of literature concerning the substance and its effects.[149]

Formal comments on the March 9 rules underlined the confusion and resistance found in all the interest groups commenting. Industry cited the bibliography concept as contrary to the protection of trade secrets. If the substance was found in the literature, its confidentiality would be lost.[150] However, state governments in their comments, complained that they were unable to obtain confidential information to better protect their citizens. They felt ignored, treated no differently than a private sector competitor.[151] Interest group comments resisted the language of the March 9 rules. Policy on confidentiality prompted further debate and comments, urging subsequent Agency clarification.[152]

Before the August 2 re-proposal, the staff re-drafted the policy on these issues raised during the first comment period. Industry applied the most concerted resistance, and the E.P.A. staff acknowledged the pressure on this issue. Technical members of the staff without industrial experience lacked the skills to manage controversy.[153]

Compromise on this issue appeared unlikely hence E.P.A. was unsure how to proceed. The Inventory staff broke the confidentiality issue

into three main sub-issues and some smaller ones and proposed alternative solutions to each. The August 2 re-proposal presented these alternatives to stimulate further comment. E.P.A. needed more feedback, especially from the industry as to what procedures would be the least onerous. The Agency listed its questions in the preamble to the August reproposal as:

1. What substances may be confidential?
   (a) any and all,
   (b) those limited to one site,
   (c) none;
2. How should confidential substances be handled on the published inventory?
   (a) no indications that any exist,
   (b) generic names for confidential substances,
   (c) random code numbers for confidential substances,
   (d) publish non-confidential list and indicate other do exist;
3. How to handle PMN's for confidential substances from new manufacturers?
   (a) tell if substance already reported,
   (b) refuse to tell whether already reported,
   (c) require current manufacturer to give a PMN and to stop production for 90 days at reporting time and new manufacturer to submit PMN and wait 90 days,
   (d) require current manufacturer to submit PMN but not stop production and new manufacturer to submit PMN and wait 90 days. E.P.A. requested further comments.[154]

E.P.A. attempted to draft regulations for trade secrets governing the entire chemical industry, a task in which the staff had little understanding or expertise. The staff scaled down the demand for information in the March 9 regulations in the August 2 re-proposal. A claim of confidentiality required only the real name and proposed generic name "only as generic as necessary."[155] Industry's pressure sensitized an unaware E.P.A. staff on this issue. An Action Memorandum from the AAA underscored this awareness by anticipating industrial responses. "Industry will focus on the problem of handling claims of confidentiality. . ."[156]

The August 2 re-proposal generated renewed comment. These comments formed the fundamental considerations used by the staff to draft a final rule. The action memorandum accompanying the final rules in December specified the options and their strengths and weaknesses as follows:

A. No specific chemical Indentity is Confidential for Purposes of the Inventory...This approach would be based upon the conclusions that sections 8 (b) and 5 (a) override the general mandate of section 14 for confidentiality because sections 8 (b) and 5 (a) would not be enforceable if some confidential identities are not included on the inventory.

Advantages:
1. This is a clean approach. Litigation will result immediately, and the issue should be resolved soon.
2. Future administrative problems...may be eliminated.

Disadvantages:
1. This approach would be viewed by industry as indicative of E.P.A.'s lack of respect for trade secrecy.
2. It will create political problems and might result in pressure in Congress to amend TSCA.

B. Any Specific Chemical Identity May be Confidential.. and EPA Will Not Disclose the Identity Except as Authorized Under Section 14...EPA would publish an inventory of only nonconfidential substances. All Freedom of Information requests and inquiries from new manufacturers would be denied.

Advantages:
1. ...(W)ould be most popular with industry.
2. It gives full effect to section 14 and shows EPA will respect confidentiality.
3. Industry will not sue...

Disadvantages:
1. The public will have no knowledge...
2. New manufacturers... will not know whether their "new" substance is in fact new and subject to premanufacture notification...The effect of this approach would be anticompetitive.
3. New manufacturers and public interest groups would sue EPA.

C. Any specific Chemical Identity May Be Confidential...; EPA Will Respond to Inquiries From Persons With A Bona Fide Intent to Manufacture a Chemical Substance...EPA would publish an inventory including all nonconfidential chemical substances and a list of generic names, a manufacturer could ask EPA whether the specific substance had been reported... EPA would deny Freedom of Information Act requests on the specific identities of these chemical substances.

Advantages:
1. ...(G)ives effect to both section 14 and sections 8 (b) and 5 (a). It represents a balance...
2. (P)ublic's knowledge is greater than Alternative B.
3. New manufacturers have a means of avoiding premanufacturer notification...,
4. Trade secrets are protected...

Disadvantages:
1. There will be future administrative problems... It will call for findings in connection with future rulemaking whether identities can be confidential under the future rules.
2. Some parts of industry will disagree;...litigation may result.
3. The test for finding a bona fide intent...may be challenged by industry.
4. Finding bona fide intent will require...resources in OTS to make the determinations.
5. Large numbers of individual confidentiality determinations will have to be made...
6. This approach does not provide disclosure to persons concerned with health or environmental hazards...

Recommendation:
Alternative C, because it represents the best compromise... EPA will not appear unreasonable."[157]

The final regulations in December, 1977, permitted a claim of confidentiality for a reported chemical substance. These rules finalized the proposed guidelines of the August rules claiming confidentiality of the actual identity and a proposed generic name no more general than necessary to be required.[158] In addition, the manufacturer had to provide a written substantiation[159] of the confidentiality claim, and "agree that E.P.A. may disclose to a person with a bona fide intent to manufacture the substance...the fact that [the]...substance is included in the Inventory."[160] and a manufacturer had to agree to furnish to E.P.A. upon request...an x-ray diffraction pattern...or a mass spectrum...,a sample of the substance in its purest form, the elemental analysis [and]...other data that may be required...[to establish] the identity of the substance.[161] If a manufacturer did not meet the data requirements or the procedures, it lost the option of confidentiality. This waiver forced the substance to be published in the Inventory.[162]

One issue raised in the comment period connected the possibility of duplication of data with the emergence of a "new producer" of a chemical. E.P.A. answered this question with the requirement that such a new producer had to establish a bona fide intent with an elemental analysis, an x-ray diffraction pattern or mass spectrum, a report of all R & D progress on the substance to date, and a signed statement of intent to manufacture. E.P.A. requested a sample or any other relevant information to analyze the chemical.[163] The Agency avoided duplication of reporting, for E.P.A. would review the data originally submitted by the initial producer to decide if the chemical was included in the

Inventory. The rules provided that new producer would be informed if it chemical had been previously reported; if not, s/he was required to report it to the Agency.[164]

Formal comments played a major role in the evolution of the confidentiality regulations. E.P.A. used the comments to remove conflicts; the bibliography requirement, for example, was not in the final regulations.[165] Industry organized the most successful campaign to influence the administrative process. States and, by implication, public interest groups (including the environmentalists) lost the opportunity for access to confidential information without meeting specific, rigorous criteria.[166] In effect, E.P.A. denied the information to these groups. E.P.A. explicitly stated it would deny all inquiries for confidential information, ignoring all issues raised during the comment period for all data to be under the Freedom of Information Act.[167]

General Conclusions

Specific actions by the TSCA staff during the Administrative Process formed the Final Regulations for the Inventory. Administrative difficulties for the Agency emerged as the problem of combining scientific or economic thought into a legal structure plus the unique prospective status of TSCA. The study of the Inventory rulemaking produced the following general conclusions.

The prospective or long-range planning emerged as a source of confusion for the entire staff. It found no precedents in the environmental policy arena. Without an established procedural base, all levels of the agency lacked the tools to implement the Act. Even upper

level Agency staff admitted uncertainty over the correct means to accomplish the prospective intent mandated by Congress. The confusion fragmented the staff's efforts to produce a comprehensive, operable set of regulations when faced with vacillating goals and methods.[168]

The change in administrations (and the resulting policy) further fragmented and disorganized the staff during the initial work on TSCA. Direction from upper level staff was inconsistent; this forced the OTS staff to coalesce into small "work groups" to attack problems. This "work group" approach to TSCA isolated the various staff members from other interrelated components of the Inventory and other sections of the Act. For example, the fragmentation of the staff came during the controversy over confidentiality. Conflict between the Inventory and PMN procedures came from the statutory language. However, the staff attempt to bridge the two sections was accomplished with great difficulty. Similar problems also appeared in the rule-making on the definitions of "impurity", "by-product" and "intermediate".

The confusion generated by TSCA's prospective nature remained past the change of administrations. Individuals with little Agency experience were rapidly promoted to policy positions in OTS. Their inexperience with the Administrative Process in general and especially with long-range planning offered little insight. Lack of procedures and the Agency's inexperience as an industrial regulator resulted in a general fear of litigation among the staff. Many within OTS were from technical disciplines and they lacked legal training. The external groups often threatened litigation during the rulemaking for the Inventory. The staff's confusion and inexperience caused them to retreat from controversy. This further fragmented OTS's approach to the

Inventory. The staff's confusion and inexperience caused them to retreat from controversy. This further fragmented OTS's approach to the Inventory. The appointment of a permanent Assistant Administrator is OTS removed the responsibility of litigation from the inexperienced OTS staff. Litigation became less of an issue during subsequent rulemaking.[169]

Regulation of the chemical industry required the Agency to mass appropriate information. Centralization of the rulemaking efforts in Washington cut the feedback loop between Headquarters, the E.P.A. regional offices, and the States. OTS released information to these groups at the same time and in the same fashion as the general public. Little or no information was routed to Headquarters. E.P.A. had little experience or information but ignored two obvious sources of data and expertise. It was only in late April, almost six months after the start of work, for example, that the Washington staff learned that the Regions would like to have volume and use information included in the Inventory. Such a constricted process was inappropriate especially in light of the inexperience present in the OTS.

As a matter of established procedure, O.T.S. learned little from the previous criticisms directed to other divisions in E.P.A.[170] Record-keeping was a requirement of the informal rulemaking process, however, OTS compiled a less than definitive public record. Many crucial internal decisions were undocumented in the Agency files.[171] Litigation was and remains a possibility. It is doubtful that the Agency held sufficent documentation to convince a court that"...an act of reasoned judgement occured, an assumption which further contemplates the existence of a body of material...[including] statements in various

Industry used the comment period effectively during the Administrative Process. No other interest group succeeded in their attempts to influence regulatory language and scope. Environmental groups had definite success only in the expansion of the Inventory to include volume and site data. E.P.A. did not further expand the regulations to include use data, requested by the environmentalists. This does not imply undue or illegal influence by the industry. Industry, especially through trade associations such as CMA, provided the bulk of the necessary information. E.P.A. relied heavily on this data; this represents a tradition among regulatory agencies attempting to control any major industrial or commercial activity.[173] Environmentalists found that this cooperative sharing became a problem. When industry ceased to assist the Agency, E.P.A. continued to compromise on specific regulations.[174]

These compromises centered on the interaction between a regulatory agency and the various "publics" affected by the issuance of rulemaking. An understanding of the complex procedures inherent in any regulation of an environmental issue by administrative law would better explain the position of an agency relative to external interest groups. The next chapter will explain the administrative process in light of its general procedures and their specific impact upon the Inventory regulations under TSCA.

REFERENCES

1. 15 U.S.C. 2601

2. The research for this study included numerous interviews with members of the E.P.A. staff, as well as review of all the available documents. As requested by those E.P.A. staff members, they are not indentified by name in these footnotes, but the author is convinced that the information furnished by them accurately reflects their perceptions of the process. Hereafter, these shall be cited as E.P.A. staff interviews.

3. Council of Environmental Quality, Report, Toxic Substances, Washington D.C., U.S. Government Printing Office, 1971.

4. Druley, Ray M. and Girard L. Irdway, The Toxic Substances Control Act, The Bureau of National Affairs, Inc., Washington D.C., U.S. Government Printing Office, 1977, pg. 11.

5. Ibid. pg. 11.

6. Ibid. pg. 10.

7. Ibid. pg. 12.

8. Ibid. pg. 12.

9. Supra n. 2, Chapter II: A CASE STUDY OF TSCA.

10. Druley and Ordway, op. cit, "The Toxic Substances..." pg. 12.

11. E.P.A. staff interviews, supra n. 2.

12. Interview with Linda Billings, formerly of Sierra Club.

13. Druley and Ordway, op. cit. "The Toxic Substances..." pg. 27.

14. Ibid., pg. 27.

15. Statement by the President, Gerald R. Ford, October 12, 1976.

16. Supra n. 2.

17. 15 USC 2607.

18. Supra n. 2.

19. Druley and Ordway op. cit., "The Toxic Substances...", pg. 10-26.

20. 15 USC 2607 (b).

21. E.P.A. staff interviews supra n. 2a, and interviews with E. Choffnes, Citizens for a Better Environment; J. Warren,

Environmental Defense Fund; S. Gusman, Conservation Foundation; L. T. Banks, Natural Resources Defense Council; L. Billings, formerly of The Sierra Club; E. Blair, Dow Chemical, U.S.A.; G. Socha, Dow Chemical, U.S.A.; written communications from B. Davidoff, Allied Chemical Corp. See also, Bronstein, "The New Toxic Substances Control Act," 13 Forum 371 (1978); Bruley op. cit. pg. 13-27.

22. "Inventory Reporting: Statement of Policy," 45 Fed. Reg. 2652 (4/18/80).

23. E.P.A. staff interviews, supra n. 2, indicate the original work group formulated key positions early in the implementation process. Normal sharing of personnel was not extensively used as TSCA's unique approach did not allow ready use of on-line officials from the program areas.

24. E.P.A. staff interviews, supra n. 2, Warren interview, Socha interview, Supra n. 21.

25. 42 Fed. Reg. 13130 (3/9/77).

26. Administrator Costle announced this decision while being interviewed on "Face the Nation", May 29, 1977; See 1 Chem Reg. Rptr. 431 (6/3/77).

27. The effect on the staff came from E.P.A. staff interviews, supra n. 2 and Warren interview, supra n. 21.

28. Correspondence and interviews finds little information flow between head-quarters in Washington, D.C. and the regional offices of E.P.A. When asked for information a regional official could only search the Federal Register. When S. Jellineck, Assistant Administrator for Toxic Substances was asked about this at a public meeting he replied that TSCA was to be considered a Federal program based in Washington as toxics could not be controlled at the regional level. Personal recollection of the author; present at ABA Section of Natural Resources Law Toxic Substances Conference, Washington, D.C., Nov. 29, 1978.

29. Attachment to memorandum from K. Johnson, Asst. Adm., to the Administrator, entitled "Request for Approval of Development Plan", undated; E.P.A. Staff Interviews, supra n. 2.

30. E.P.A. staff interviews, supra n. 2; E.P.A. interviews, supra n. 28.

31. Id.

32. E.P.A. staff interviews, supra n. 2.

33. Id.

34. Correspondence and E.P.A. interviews, supra n. 28.

35. New York state used the public comment period after the 9 March 1977 Regulations (40 CFR 13/30) to address the issue of toxics as a state responsibility. See also S. Jellineck's response to questions regarding the inputs of states and regions into the implementation process, supra n. 28.

36. §3 (2) (B) (iii)-(vi), 15 USC 2602 (2) (B) (iii)-(vi). See, e.g., letter from Department of Interior to K. Johnson, 6/6/77, regarding minerals.

37. See, e.g., report of Testimony of G. Wrenn of OSHA in support of E.P.A., 1 (Chem Reg. Rptr. 819 (8/26/77); "Interagency Agreement on the Regulation of Toxic and Hazardous Substances," 42 Fed. Reg. 54856 (10/11/77).

38. Despite CPSC's adherance to the "Interagency Agreement", supra n. 37, E.P.A. staff interviews, supra n 2, indicate that CPSC had no contribution to make.

39. Public comments by the Department of the Interior (081001/C.203 and C.21) and Department of Defense (081001/C.86) again re-iterated agency policy.

40. The article was Scott, "Toxic Chemicals--E.P.A. Enforcement Undercuts New Law," Washington Post, May 29, 1977, Sect. B, P. 5. E.P.A. staff interviews, supra n. 2, gave the information on the effect of the announcement on the staff.

41. Although Ms. Warren expressed frustration with her effectiveness, E.P.A. staff saw her as a powerful force on the Agency. (Warren interview, supra n. 21, E.P.A. staf interviews, supra n. 2).

42. Choffnes interview, supra n. 21.

43. Public comments by NRDC and Sierra Club reflected earlier activity before the Act was passed. See also, Druley & Ordway, op. cit. pg. 10-11.

44. The representatives of environmental groups felt that they had been "beating against brick walls" and that E.P.A. totally ignored them. Warren interview, Choffnes interview, supra n. 21.

45. E.P.A. staff interviews, supra n. 2, Choffnes interview, Blair interview supra n. 21.

46. The primary technique used by CMA was to send copies of all formal CMA comments to the members and include such phrases as "we expect that other interested parties will comment." Letter from CMA to Ms. P. Tucker, CEQ, 8/22/77.

47. §3 (8), 16 U.S.C. 2602 (8).

48. Response to comment 36, 42 Fed. Reg. 64585 (12/23/77).

49. Hackk's Chemical Dictionary Third Edition Grant, Julius, ed., McGraw-Hill Book Co., New York, New York, 1944 pg. 542.

50. § 700.2 (s), 42 Fed. Reg. 13135 (3/9/77).

51. See, e.q., comments of National Steel Corp., Am. Fertilizer Inst., Portland Cement Assoc., Dow Chemical Corp., etc. collected in Sect. 5 of E.P.A., "Summary of Comments Received on Proposed Inventory Regulations, Revised May 23, 1977" in E.P.A. public files (hereinafter, "Summary of Comments").

52. § 710.2, 42 Fed. Reg. 39131 (8/2/77).

53. § 710.2, 42 Fed. Reg. 39191 (8/2/77).

54. § 710.(q), 42 Fed. Reg. 64576 (12/23/77).

55. Memorandum from S. Gusman to C. Kelly 5/1/77.

56. Grant, op. cit. Hackh's... pg. 443.

57. The Condensed Chemical Dictionary,, Fifth Edition, Richhold Publishing Cr., New York New Yor, 1956, pg. 593.

58. Id.

59. Grant, op. cit. Hackh's..., pg. 152.

60. op. cit. The Condensed Chemical... pg. 235.

61. § 700.2 (p), 43 Fed. Reg. 13135 (3/9/77).

62. 42 Fed. Reg. 13133 (3/9/77).

63. § 710.2, 42 Fed. Reg. 39191 (8/2/77).

64. Id.

65. Id.

66. Supra n. 46.

67. Druley and Ordway, op. cit. pg. 36-37.

68. § 710.2 (n), 42 Fed. Reg. 64576 (12/23/77).

69. Id.

70. § 710.4 (d)(8), 42 Fed. Reg. 64578.

71. "ACTION MEMORANDUM--Promulgation of Inventory Reporting Regulations" from S. Jellinek, Assistant Administrator for Toxic Substances to the Administrator, undated (hereinafter, December Action Mem.) p. 12.

72. § 710.2 (c), 42 Fed. Reg. 13135.

73. § 700.2 (o) id.

74. § 710.5 (a) (2), 42 Fed. Reg. 13137.

75. 42 Fed. Reg. 13130.

76. Summary of Comments, supra n. 51, Section 12.

77. Comments of Natural Resources Defense Council, id.

78. § 710.2, 42 Fed. Reg. 39190, 191 (8/2/77).

79. § 710.4 (d) (1), (2), 42 Fed. Reg. 39192 (8/2/77).

80. 42 Fed. Reg. 39186 (8/2/77).

81. § 8 (i), 15 U.S.C. 2607 (f).

82. E.P.A. staff interview, supra n. 2.

83. § 710.2 (g) (m), 422 Fed. Reg. 64575, 710.4 (d) (1) (2), 42 Fed. Reg. 64577 (12/23/77).

84. Response to Comment 52, 42 Fed. Reg. 64587 (12/23/77).

85. Response to Comment 61, 42 Fed. Reg. 64588 (12/23/77).

86. Personal communications from members of the Inventory staff.

87. The author had been told a memorandum exists documenting this decision, but no copy of it has ever been located.

88. Home Box Office vs. F.C.C., 567 F. 2d 9 (D.C. Cir. 1977) see chapter III, n. 49, supra.

89. E.P.A. staff interviews, supra n. 2.

90. "The Administrator shall not include in such list any chemical substance which is manufactured or processed only is small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product." 8 (b) (1), 15 U.S.C. 2607 (b) (1).

91. § 700.2 (aa), 42 Fed. Reg. 13136 (3/9/77).

92. 42 Fed. Reg. 13132 (3/9/77).

93. Id.

94. § 710.2, 42 Fed. Reg. 13132 (8/2/77).

95. Again, no documentation exists, but this is the information received from some members of the Inventory staff.

96. § 710.2 (y), 42 Fed. Reg. 64576 (12/23/77).

97. See Summary of Comments, supra, n. 51 Section 9.

98. The author was repeatedly assured that documentation on this point existed but, as it has never been produced, one is forced to believe this is not so.

99. 15 USC 2607 (b).

100. "The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors." 8 (a) (3) (b), 15 U.S.C. 2607 (a) (3) (b).

101. Memorandum from S. Ng to C. Kelly, 12/30/76.

102. Memorandum from Olsen to G. Schweitzer, 5/23/77.

103. E.P.A. staff interviews, supra n. 2.

104. Supra n. 102.

105. §710.2, 42 Fed. Reg. 39191 (8/2/77). The proposed "straw-man" defintion had been "10 or more employees or annual sales of $250,000", Olson memorandum supra n. 102.

106. 42 Fed. Reg. 39184 (8/2/77).

107. Memorandum from S. Weil to C. Kelly, 10/21/77.

108. Memorandum entitled "Promulgation of Inventory Reporting Regulations" from Steven Jellneck to the Administrator, pg. 15, 12/2/77.

109. December Action Memorandum supra n. 71.

110. Id. at pg. 9.

111. Supra n. 1.

112. See text accompanying n. 23 and 24, supra.

113. Memorandum from I. Gruntfest to C. Kelly; "ACTION MEMORANDUM--Proposed Inventory Reporting Regulations" from K. Johnson, Acting Assistant Administrator for Toxic Substances to J. Quarles, Acting Administrator, rubber stamp dated 15 Feb. 1977, pp. 2-3.

114. Id.

115. Sierra Club, Natural Resources Defense Council, Environmental Action, Environmental Defense Fund, Conservation Foundation, Center for Science in the Public Interest.

116. Memorandum from K. Johnson, Acting Assistant Administrator for Toxic Substances to The Administrator, undated, rubber stamped "DRAFT" entitled "Comments of Environmental Group Representatives," p.1.

117. Id.

118. Comments of National Institutes of Health attached to memo from D. Fredrickson, Director NIH to OTS, 5/9/77, p. 2; Letter from E. Bingham, Asst. Sect., OSHA, to D. Costle, 5/9/77, p. 2; and, most particularly, letter from E. Bingham to D. Costle, 6/7/77, p. 3-5.

119. Summary of Comments, supra n. 51 Section 1.

120. See text accompanying n. 25-27, supra.

121. Supra n. 27.

122. Despite numerous inquiries, nobody has been able to identify this memorandum more accurately. Hereafter it shall be refered to as "Unidentified Scope of Inventory Memorandum."

123. "Unidentified Scope of Inventory Memorandum" pp. 2-3.

124. Undated one page memorandum "from C. Kelly to Work Group Members, Subject: Inventory Reporting Requirements."

125. Undated Memorandum from L. Regelson, Senior Policy Advisor, to W. Drayton, Special Ass't. to the Administrator, entitled "Issues with Respect to the Initial Inventory," rubber stamped DRAFT.

126. See text accompanying n. 25-27, supra.

127. No copy of this confirmation has been found.

128. Supra n. 125.

129. Id.

130. "ACTION MEMORANDUM -- Reproposed Inventory Reporting Regulations" from K. Johnson, Acting Assistant Administrator for Toxic Substances to The Administrator, rubbed stamp dated 12 July 1977 (hereinafter, July Action Mem.) p. 2.

131. Chemicals and Allied Products, see text accompanying n. 1010, supra.

132. Id.

133. 42 Fed. Reg. 39183 (8/2/77).

134. See "response to comments 1-12", 42 Fed. Reg. 64580-1; information from the Inventory staff.

135. Memorandum from C. Kelly to Work Group members dated 8/31/77, p.1..

136. Id. p. 3.

137. December Action Memorandum, supra, n. 71, pg. 2.

138. § 710.3(a)(1)(i)(A), 42 Fed. Reg. 64577 (12/23/77).

139. December Action Memorandum, supra n. 71, pg. 3.

140. § 710.3(a)(1)(i)(B), 42 Fed. Reg. 64577 (12/23/77).

141. 42 Fed. Reg. 64578 (12/23/77).

142. Response to Comment 4, 42 Fed. Reg. 64580 (12/23/77).

143. 15 U.S.C. 2613.

144. 15 U.S.C. 2607 (b).

145. 15 U.S.C. 2604 (a).

146. Supra n. 145.

147. Supra n. 67.

148. "These types of claims must be asserted in accordance with the Agency's business confidentiality rules contained in Part 2, Subpart B of Title 40 ... [CFR], and will be disposed of in accordance with the rules in that part." 42 ed. Reg. 13134 (3/9/77).

149. § 710.6 (d), 42 Fed. Reg. 13137 (3/9/77).

150. Both industry and environmental groups attacked the proposal on this basis. See comments of CMA and CBE in Sect. 15, Summary of Comments, n. 51, supra.

151. See e.g. comments of States of New Jersey and Virginia, ibid.

152. Ibid.

153. Supra n. 2.

154. 42 Fed. Reg. 39188 (8/2/77).

155. §710.7 (e), 42 Fed. Reg. 39193 (8/2/77).

156. July Action Memorandum, supra n. 130, pg. 6.

157. December Action Memorandum, supra n. 71, pg. 9-12.

158. §710.7 (e)(2)(ii), 42 Fed. Reg. 64579 (12/23/77).

159. §710.7 (e)(2)(iii), id.

160. §710.7 (e)(2)(iv), id.

161. §710.7 (e)(2)(v), id.

162. Ibid.

163. §710.7 (f)(2), id.

164. §710 (f)(4), (5), (6), id.

165. See text accompanying n. 144, 145, supra.

166. Response to comment 103, 42 Fed. Reg. 64543 (12/23/77).

167. Response to comment 101, 42 Fed. Reg. 64592 (12/23/77).

168. E.P.A. Staff Interviews, supra n. 2.

169. Private communication from members of TSCA staff. See also, Severa "E.P.A. Slow to Act on 3 Year Old Law," N.Y. Times May 6, 1980, Section C, pg. 1.

170. "It may well be that the public reference procedures of this...agency can be improved." Ethyl Corp. v. E.P.A., 541 F. 2d 1 at 49, n. 102 (D.C. Cir. 1976); See also the dissent, 541 F. 2d 1 at 79 (n. 34), 82, 90-91.

171. Home Box Office v. FCC, op. cit., pg. 54.

172. See, e.g., Metcalf & Reinemer, Overcharge (1967); Lamel, "The Property Insurer's Data Group," 9 Brief No. 3, p. 13 (May 1980).

173. Druley and Ordway, op. cit., "The Toxic Substances...," Chapter 2.

174. Warren, Choffnes, interview, supra n. 21.

CHAPTER III

THE ADMINISTRATIVE LAW PROCESS

Introduction

This chapter reviews the evolution of the Administrative Law process, emphasizing the regulatory agencies as the instruments. Procedures and responsibilities evolved gradually into the "fourth branch of government".[1] Its traditions incorporated judicial, legislative, and executive functions into a structure to administer specific laws. This broad power developed in response to a perceived need for a faster, less expensive alternative to the established executive, legislative, and judicial branches of government.[2]

Agencies evolved this independent authority, and the court system and the legislatures allocated power over time. Broad mandates required distinct technical skills not found in judges or legislators. Congress, for example, passed TSCA as a directive for action by the most appropriate agency, E.P.A. Chapter II catalogued the process E.P.A. followed during the Inventory rulemaking. Chapter III explains the basic administrative process; determining any form of complex environmental regulation of which TSCA is an example.

The Defintion of Administrative Law

Administrative Law is defined as "...The law concerning the powers and procedures of administrative agencies, including especially the law governing judicial review of an administrative agency."[3] A governmental authority with the power of rulemaking or adjudication is defined as an administrative agency. Adjudication is defined as "To settle in the exercise of judicial authority. To determine finally."[4]

Individuals such as the President or groups (i.e., municipal commissions or federal agencies) are delegated the powers of rule making or adjudication by legislative mandate. Both the judicial and legislative branches of government are excluded from this option to "borrow" powers held by other branches.[5] Courts are to interpret constitutional or statutory questions. Their opinions are not intended to formulate policy, though opinions may actually redefine the statutory or regulatory intent.[6] Legislators retain broad vested power to write legal mandates, determining the substantive direction of policy through legislation. Administrative agents evolved the responsibility for the creation of subsidiary policy based on the general mandates.

Though regulatory agencies are a small component of Administrative Law, they receive most of the attention and visibility. Legal theorists and the general public perceive the agency role as a regulator, even in daily activities. Regulatory agencies are delegated both general and specific powers to control human activities. They are created "...Only by statute, by executive order authorized by statute or by state constitutional provisions...the principal powers and functions of agencies are normally defined by the instruments which create them..."[7]

Administrative Law progressed to its present state often through judge-made law or dicta defining acceptable procedures. Much of that dicta was and still is found incorporated into the process.[8] This dicta developed in response to constitutional or statutory controversies. The body of common law expanded, as other individual cases required court action with or without obvious links to an Act or the Constitution. The Constitution restrained the courts from imposing judgment in non-justiciable matters. Court opinions only responded when the

presence of a case and controversy existed.[9] A case bore the definition of the invocation of judicial power only as a last resort. This came from the prohibition of advisory opinions by a court. Judgments, subject to revision elsewhere, could be defined as merely advisory, while court opinions were intended to be final. A case required an existing legal authority (i.e. a statute or the Constitution), an adversary situation and affected parties needing a decision.[10] A controversy rested on the premise that the courts made no pronouncements at large. Abstract opinions had no value; a controversy required aggrieved parties in an adversary situation to be present. No political questions were to be considered by the courts, only the actual individual rights recognized by statute or common law.[11] The injunction primarily confined the sphere of judicial influence in the Administrative Law process as it reacted with statutory or Constitutional intent.

The growth of the regulatory agency as a unit in the administrative process originated in a series of incremental changes. Complex or tedious legislation required the regulating by another group other than Congress, which lacked procedures to detail applicable rules. The judicial branch had its powers derived from a history of centuries of English common law. Federal agencies began less than two hundred years ago, being relatively recent phenomena. Theoretical concepts defined the United States government by the separation of powers. Administrative Law evolved as a practical option to fill imperfections resulting from the fragmentation of powers to solve problems. Certain agencies (e.g., E.P.A.) were clearly delegated a blend of the powers inherent in the separate judicial, legislative and executive branches.

The administrative process expanded by degrees as a set of procedures to better superintend specific legal problems.

The Evolution of Administrative Law

Congress began the delegation of the rulemaking powers to agencies in 1789. A statute instituted the regulation of military pensions but gave control to the President's office.[12] This initiated the practice of delegating responsibility through a specific directive or law.[13] The need for an alternative such as Administrative Law emerged an extension to the traditional division of duties among the legislative, executive and judicial branches. Constraints on individuals in the judicial and legislative branches included lack of time and expertise in which to formulate detailed regulations. Legal mandates required an increasing amount of specific technical competence. The structure of the legislature and the courts evolved a cumbersome bureaucracy to specify the necessary controls. Regulation without the delegation of power implied that the general mandates from Congress could only be applied on a case-by-case basis through the court system.[14]

The concept of Administrative Law began unobtrusively with the first delegation of power in 1789. Congress intended to create a corps of clerks to manage the military pension program.[15] These clerks spared the legislators the tedious task of regulation in order to devote more of their time to more general societal concerns. The delegation of power also excused judges from the costly and repetitious tasks of a case-by-case approach to decision making. Military pensions or patents needed programs which could be managed cheaply and rapidly by lower-paid clerks. Thus the delegation of power within Administrative Law began as an aggregation of clerks processing paperwork and individual claims.

The practice of delegating responsibilities proved to be a useful alternative. Agencies resulted from a considered use of the administrative process to regulate human activities under general statutory guidelines. It developed over time as an extension of legislative authority to regulate the public. Congress has developed this option since its orgin in 1789 as, "...about one-third of federal peace-time agencies were created before 1900, and another third before 1930."[16] Federal regulatory agencies emerged as an identifiable unit with the establishment of the Interstate Commerce Commission (hereafter ICC) in 1887.[17] The ICC initiated the example of the delegation of the power embodied in an agency. Public outcry motivated the formation of the ICC to regulate the railroad industry. Railroads had abused various segments of the population through their monopolistic control. Procedures given the ICC included the right to adjudicate, to draft regulations, to enforce the resultant regulations and to prosecute offenders.[18] Congress mandated the ICC to regulate the monopoly structure of the railroads to protect the public from injury. The ICC represented the first delegation of major power to a regulatory agency. Thus, Administrative Law underwent a fundamental transition as an institution. Functional difficulties rendered the legislative or judicial branches of government incapable of the complex regulation of an entire industry. The ICC represented the first of the empowered regulatory agencies, a practical alternative to judicial or legislative control.

Administrative Law continued to develop new programs to control other institutions such as utilities. One such program established the Federal Trade Commission in 1913, another example of the developing

regulatory agency approach using the ICC model.[19] Congress enacted specific programs and agencies once a problem brought pressure to bear on the legislators. The administrative process evolved gradually, with agencies developing as "chameleonic" to meet the individual needs of the enabling statute.[20] Agencies answered the perceived need for a flexible alternative with the practicality and applicability of these groups promoting wider use of the independent agency.

Although administrative process had begun early in the history of the United States, legal theorists ignored the expanding process for nearly one hundred years. The legal profession said nothing of this process until 1893 when Frank J. Goodnow published the first of his two books categorizing the process. The first, entitled Comparative Administrative Law, was a review of English and American administrative process; American legal structure was further identified in the second volume, the Principles of the Administrative Law in the United States, published in 1903.[21]

This resistance of the legal profession, expressed in the lack of publications, did not stifle the enlargement of responsibilities delegated to regulatory agencies. New Deal legislation in the 1930's marked an increased use of regulatory agencies to monitor human activity under Congressional mandates to promote public welfare. The bulk of the statutes were responses to political pressure for protection from the impacts of the Great Depression.[22] The National Labor Relations Board[23] (NRLB, 1936) and the Federal Deposit Insurance Company[24] (FDIC, 1933) are examples of the expanded role played by the federal government and its agencies.

During this time, President Roosevelt pressed for the involvement of the regulatory agencies to mitigate conditions he felt were not to be in the public interest. The flurry of activity of New Deal legislation focused the controversy over the separation of governmental powers which existed until the 1940's.[25] Legal scholars promoted the theoretical division among the branches, each group serving to oversee the other two branches. Government implied a separation of powers as

> ...essential to the system that the persons entrusted with the power in any one of these branches shall not be permitted to encroach upon the power confided onto others but that each shall by law of its creation be limited to the exercise of the powers appropriate to its department and no other...[26]

The dispute emerged clearly in the 1930's. Congress continued its delegation of power to new or established agencies. Overall, increased governmental intervention in human activity generated an expansion of regulation by distinct agencies. It also expanded the role of an agency through the power of rulemaking. Congress delegated to an agency the necessary power to detail regulations implementing the goals of a specific statute. These rules had the force of law including the power to enforce and to adjudicate the detailed regulations.[27] The abstract theory of law relied on the separation of powers while in reality, the Administrative Law expanded its scope fusing these separate jurisdictions.

The Supreme Court upheld the traditional theory as late as 1932, saying "that the legislative power of Congress cannot be delegated is, of course, clear".[28] The delegation of power did continue. An expanding administrative bureaucracy had developed throughout American government. Legislators ignored legal theory and embraced the

practicality of the administrative process and its instruments, the regulatory agencies. Resistance to the "fourth branch of government" emphasized the illegal delegation to and combination of powers in a regulatory agency. Real problems pressed for rapid and explicit answers. Agencies offered a workable alternative to legislative and judicial procedures alone; complex problems required a volume and minutiae of regulation.[29] Existing institutions lacked the flexibility and expertise found in a regulatory agency.[30] Agencies responded as a national alternative to an incomplete structure. The judicial and legislative branches institutionalized such agencies through enabling acts and court cases. Though beyond the scope of traditional law, agencies blended the legislative and judicial functions of separate groups. Davis summarized the evolution of Administrative Law as follows:

> This system facilitated not merely the promulgation of law through rules and regulation but the correlation of rulemaking with such necessary activities as adjudication, investigating, prosecuting and supervising.[31]

Maturing judicial and legislative acceptance of the process resulted in an expansion of a regulatory agency's independence. The autonomy of agencies was, in part, a function of its acquired judicial powers. Theoretically, members of the judiciary required a structure not politically controlled or allied to exercise their duties fairly. Agencies held these responsibilities therefore they must be also sovereign.[32] The independent status of agencies was given further institutional support by the unaminous opinion of the Supreme Court which held "The authority of Congress in creating quasi-legislative or quasi-judicial agencies, to require them to act in discharge of their duties independent of executive control cannot be doubted."[33]

The essential services provided by the consolidated legislative and adjudicatory powers in agency rulemaking won out over traditional legal theory. The Supreme Court mirrored its acceptance of this modification through various rulings on the process of regulation. Opinions christened the agencies as adjuncts to the three branches of government in the ruling for the FTC which stated:

> To the extent that it exercises any executive power in the constitutional sense--it does so in the discharge and effectuation of the quasi-legislative or quasi-judicial powers, or as an agency of the legislative or judicial departments of government.[34]

The Supreme Court also defined the range of powers vested in the agencies to include judicial procedures. These powers fell within the scope of statutory law conferring specific powers of review in an agency.[35]

Justice Jackson spoke to the reality behind the institutional growth and legitimization of regulatory agencies as instruments of the larger branch of Administrative Law. He wrote,

> They [administrative bodies] have become a veritable fourth branch of government, which deranged our three branch legal theories much as the concept of a fourth dimension unsettles our three-dimensional thinking. Courts have differed in assigning a plan to these seemingly necessary bodies in our constitutional system. Administrative agencies have been called quasi-legislative, quasi-executive or quasi-judicial, as the occassion required, in order to validate their functions within the separation of powers scheme of the Constitution.[36]

Judge Jackson's words came after the controversy between the separation of power and the actual utilization of the alternative, Administrative Law, had been settled. Congress continued to mandate new agencies since the delegation of power to the ICC; a total of sixty three independent agencies had been established.[37]

Controls Imposed on the Administrative Process

The judicial and legislative branches integrated the agencies, as "necessary bodies", into an established framework. Delegation of such power to an alternative institution necessitated the introduction of the same "checks and balances" controls found in the separation of power. Autonomy for the agencies required avenues for external review by the legislative, judicial and executive branches of government. Review of agency action began in response to concern during the 1930's that agencies were expanding in power and number. President Roosevelt requested each agency to compile a monograph on its administrative procedures.[38] The independence of agency action demanded explicit listing of responsibilities to allay fears that agencies were out of control. Congress received the separate monographs as a complete report. A clear procedure of checks and balances was required to explicate the interconnections of Administrative Law with the three older branches of government. Congress reviewed the monographs to determine the need for legislation to further institutionalize the checks and balances over agencies. The resulting statute emerged as the Administrative Procedures Act (hereafter APA).[39]

APA provided a standardization of procedures for an agency's performance. The Act set criteria by which the courts could hold an agency accountable for its actions. APA incorporated agency procedures into a framework of action through the institutional set of checks and balances. The APA building on the earlier court cases further legitimized the regulatory agency. The Act illustrated the acceptance of the practical nature of administrative process.

APA defined the role of a regulatory agency within the larger Administrative Law framework as:

> (a) This chapter applies to the provisions thereof, except to the extent that-
> (1) statutes preclude judicial review
> (2) agency action is committed to agency discretion by law.
> (b) For the purposes of this chapter-
> (1) "agency" means each authority of the government of the United States or subject to review by another agency, but does not include-
> (A) the Congress
> (B) the courts of the United States...[40]

The Courts and Congress possessed the ability to review agency action, retaining the oversight responsibilities practiced on other units of government. The specific procedures required during the regulation process were also codified. Standards of conduct required an agency to follow this standard or risk a court action brought by an aggrieved party. APA set up a consistent framework to minimize unaccountable agency actions. Congress spelled out the specific procedures inherent in the informal rulemaking:

> (b) General notice of proposed rulemaking shall be published in the Federal Register unless persons subject here to are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include--
> (1) a statement of the time, place and nature of public rulemaking proceedings.
> (2) reference to the legal authority under which the rule is proposed :and
> (3) either the terms or substance of the proposed rule or a description of the subject and isues involved. Except when notice or hearing is required by statute, this subsection does not apply-
> (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest.

> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rulemaking through the submission of written data views, or arguments with or without for oral presentation. After consideration of the relevant material presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.
>
> (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except (1) a substantive rule which grants or recognizes an exemption or relieves a restriction. (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.
>
> (e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.[41]

The courts used the APA to measure agency performance. An aggrieved party or "interested person" petitioned the court system to review the agency's mandated responsibilities.[42] APA defined a court's scope of review as:

> To the extent necessary to decision and when presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning of applicability of the terms of an agency action. The reviewing court shall-
>
> (1) compel agency action unlawfully withheld or unreasonably delayed: and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be-
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law:
>
> (B) contrary to constitutional right, power, privilege, or immunity:
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right:
>
> (D) without observance of procedure required by law:
>
> (E) unsupported by substantial evidence in a case subject to section 556 and 557 of this title or otherwise reviewed on this record of an agency hearing provided by statute: or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations, the court

> shall review the whole record or those parts of it cited by a party...[43]

General terms such as "arbitrary, capricious, or an abuse of discretion" were intended to preserve the flexibility of the administrative process but grant court review. Litigation under APA represented another evolution in Administrative Law; sovereign immunity no longer protected federal agents acting beyond the scope of their authority. Sovereign immunity, as a concept, traced its origins to traditonal English common law.[44]

Prior to the APA, an aggrievied party could only sue an agent of the federal government with the expressed consent of the agency (or Sovereign). The APA institutionalized standard procedures for agency activities and made the agency (or Sovereign) responsible in a court of law.[45] Overall, the APA answered the legal questions stemming from the lack of checks and balances from the traditional three branches of government. It accepted the institution of Administrative Law to have autonomy, but alleged abuses of power faced court review. The APA further widened the accountability of federal agencies by removing barriers to legal action. Courts exercised the power to oversee agency performance and consistency.

The dynamic needs for flexible regulation produced the administrative process and its appropriate legal controls in the APA. Subsequent amendments to the APA[46] and the passage of the Freedom of Information Act[47] built additional structure and controls into the administrative process. Broad Congressional mandates required complex technical interpretation to produce workable regulations. Controversy

over the agency's data and interpretation prompted increasing involvement of the courts. Since a bulk of the administrative process used by agencies is defined as informal, the courts were employed to determine the appropriateness of an agency rulemaking.[48]

A recent court decision resulted in the clarification of informal procedures permissible for an agency action. Home Box Office vs. the Federal Communications Commission (hereafter FCC)[49] centered around the use of ex parte (off the public record) communication during the FCC's regulation of the cable TV company. Home Box Office vs. the Federal Communication Commission (hereafter Home Box Office) generated a court opinion clarifying the process of agency rulemaking under the APA. The Washington, D.C. Circuit Court prescribed the acceptable components of informal rulemaking as "...an agency must comply with the procedures set out in section 4 of the APA."[50] Home Box Office defined the informal rulemaking process under section 4 and the legal precedence of previous areas. The Court stated that:

> From this survey of the case law emerge two dominant principles. First, an agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible. Second, the concise and general statement that must accompany the rules finally promulgated must be accommodated to the realities of judicial scrutiny, which do not contemplate that the court itself will, by a laborious examination of the record, formulate in the first instance the significant issues faced by the agency and articulate the rationale of their resolution...[The record must] enable us to see what major issue of policy were ventilated by the informal proceedings and why the agency reacted to them as it did.[51]

Agency evaluation of policy alternatives was to promote a documented record of all information and subsequent decisions. Unrecorded comments or information gathered by the agency lessened the Court's ability to review an agency's regulatory activities.[52] Ex

parte communication was an example of improper procedures in the open forum of Administrative Law. The Court ruled the use of ex parte communications to be inappropriate in an agency's rulemaking for it

> ...would not have the benefit of an adversarial discussion among the parties. The importance of such discussion to the proper functioning of the agency decision making and judicial review processes is evident in our cases. We have insisted, for example, that information in agency files or consultants' reports which the agency has identified as relevant to the proceeding be disclosed to the parties for adversarial comment. Similarly, we have required agencies to set out their thinking in notices of proposed rulemaking. This requirement not only allows adversarial critique of the agency but is perhaps one of the few ways that the public may be apprised of what the agency thinks it know in its capacity as a repository of expert opinion.[53]

Off-the-record communication between the regulating agency and some segment of the regulated public prevented a basic premise of judicial review to function. Without "a full administrative record"[54] courts had incomplete evidence to review the discretion used by an agency during rulemaking.[55] Ex parte comments were more than a circumventor of judicial processes; such interactions also violated fundamental precepts of fairness implicit in due process.[56] An administrative record required agencies to faithfully record all communication with an external interest during the regulatory process, lessening the lack of accountability found in incomplete documentation.[57] The court discussed the impact of ex parte communications or other deviations from accepted procedures to violate the premises established in Administrative Law. It held that:

> Even the possibility that there is here one administrative record for the public and this court and another for the Commission and those "in the know" is intolerable. Whatever the law may have been in the past, there can now be no doubt that implicit in the decision to treat the promulgation of rules as a "final" event in an ongoing process of administration is an assumption that an act of reasoned

> judgment has occurred, an assumption which further contemplates the existence of a body of material--documents, comments, transcripts, and statements in various forms declaring agency expertise or policy--with reference to which such judgment was exercised. Against this material, "the full administrative record" that was before [an agency official] at the time he made his decision.[58]

"The court explained the role of the judiciary as it is the obligation of this court to test the actions of the Commission for arbitrariness or inconsistency with delegated authority."[59] Home Box Office served as the legal precedent by which courts reviewed the role an agency during informal rulemaking. It further delineated how a court would judge agency action via the public record.

Home Box Office judged ex parte communication to be inconsistent with the due process concept of fairness. Off-the-record statements also eroded the ideal of "reasoned decision-making which undergirds all of our Administrative Law."[60] The Court also cited the expansion of the APA by the passage of the Sunshine Act. Congress mandated the Act to be, "...the policy of the United States that the public is entitled to the fullest practicable information regarding the decision making processes of the Federal Government."[61] Home Box Office formed the legal precedent and standard for future informal rulemaking procedures utilized by agencies. It forbade the solitication or acceptance of ex parte communication. Simple record-keeping presented a basic legal issue but there were implications beyond the documentation of external contacts. Congress intended the APA and the more recent Sunshine Act to structure informal rulemaking and to require agency accountability. Such standards responded to earlier concerns that agencies were not reviewable or controlled. The case of Home Box Office strengthened the standards of the APA and designated the present purpose of

Administrative Law. Home Box Office impacted on any regulatory agency's procedures and structure. Home Box Office represented the evolutionary status of Administrative Law as an institution within the federal government. The Court addressed the questions about the legality and utility of the process. Formal controls developed to review the instrumental agency's actions, an extension of the checks and balances previously confined to the three branches of government. The court accepted the informal rulemaking process by an agency to be the most logical avenue to form and enforce complex policy.

Administrative Law originally began as an inexpensive alternative to a structured legislative or judicial approach to policy formulation. Congress employed the concept of delegating power to a technical agency with increasing regularity. Regulatory agencies grew in number and power as legislators accepted the administrative process as a practical and proper means to achieve detailed regulations. Agencies acted only through a specific power explicitly conferred by a legislative body. Legal thought asserted this concept throughout the early to middle twentieth century. Any power or activities resting in the agency required a clear mandate. Constitutional prohibition and legal tradition constrained the courts inferring powers not found in a statute. The present judicial attitude is a response to a perceived need for more flexible limits of litigation. Some legal scholars note a shift toward measuring the extent of administrative power in terms of the needs of a legislative policy, not in terms of the specific wording of the statute.[62] The Courts responded with a similiar evolution found in the legislative branch. Legal theory resisted the unsupervised growth of the regulatory agency; the theory preferred to draw on the

precedents of cases and the foundations of governmental structure. The practicality of the administrative process and its regulatory agencies forced the evolution of case law and legal theory. The assumption rested on the idea that regulatory agencies offered the least expensive and most experienced review. These agencies were practical alternatives for the drafting and enforcement of specific regulations.

Congress continued to allocate responsibility to agencies under broad mandates. The Courts monitored the expanding agency role through the APA and the Sunshine Acts. The applicability of the expanded agency role to detail effective regulations was debated, especially in the complex, uncertain arena of environmental protection. This controversy was defined:

> In the United States we are experiencing a transitional period that reflects general trends of social evolution: regulatory agencies, which in accord with centuries old traditions have been allowed to wield quasi-autonomous normative powers, find themselves increasingly at odds with expanding demands for due process in the resolution of uncertain perceptions and conflicting values.[63]

Rule-Making Under TSCA

Normative values generally rely on the determination of standards, beginning with empirical evidence and then incorporating newly acquired information.[64] Lack of unambiguous scientific proof fueled the passage of TSCA, mandating the creation of a data base under E.P.A.'s guidance,[65] yet the Agency was required to formulate rulemaking prior to the completion of its data collection. Uncertainty affected the TSCA staff which acknowledged its limited information base.[66] TSCA demanded the framing of acceptable normative values into a policy to regulate toxics in the environment. The evolution of the administrative process structured the blending of a technically complex problem with an

assumedly appropriate administrative bureacracy. Environmental issues were one such complex problem necessitating agency action. TSCA and other environmental statutes have inherent scientific, economic and philosophical controversies. Congress gave E.P.A. the responsibility for environmental protection in the administrative process but the Agency was forced to regulate with uncertain data. The difficulty faced by the regulator, in this case E.P.A., to effectively regulate with limited information, deserves scrutiny.

Any regulatory action by E.P.A. to mitigate environmental problems has inherent uncertainties and controversies. Environmental statutes, are responses with general language and frameworks relevant to the perceived problem that are passed by Congress as political compromises. Congress retains the power to pass critical disputes on to the regulatory agency involved. Environmental issues present E.P.A. with responsibilities and limited information, staff, budget and expertise. This area of Administrative Law is difficult because

> The decisions made by E.P.A. under its statutory authority are seldom simple resolutions of factual disputes; instead, they involve complex technical issues and controversial value judgements that can effect significant numbers of persons and activities.[67]

Administrative Law has sparked renewed debate because it has been perceived as becoming dilatory, expensive and generally unresponsive to societal needs.[68] Environmental protection became primarily a responsibility at the federal level of government. Public concern over environmental deterioration prompted this concentration of responsibility as a societal need.[69] The focus of this segment on Administrative Law centers on the present Administrative Law process and its applicability to an area of great scientific and economic

uncertainty, environmental regulation. TSCA, as the first prospective environmental statute, underscores the resistance to institutional change and the lack of flexibility found in the administrative process. Study of the Inventory rulemaking provides more generalizable insights into the process of regulation and its possible future orientation.

Traditionally, Administrative Law achieved powers expressly conferred by Congress. Legislators reacted to a definable problem focussing public concern. Statutes summed up the Congressional reaction to perceived political situations and needs. Congress mandated agencies to investigate problems within a general framework. The ICC began this trend when Congress enacted its regulatory framework to correct abuses by the railroads. Both regulatory agencies and the judiciary held the power to act only upon legislative mandates; neither drafted policy without a statutory framework. Administrative Law incorporated the reactive formula of problem solving into its structure and procedures.

TSCA was the first attempt at expanding environmental regulation into both a reactive and a long-range prospective plan. This prospective framework was a fundamental shift of outlook for the Agency. Staff members of E.P.A. admitted that their confusion stemmed from this unique approach. The staff acknowledged that potential problems necessitated monitoring in order to protect the public from the release of chemicals to the environment. Prevention of the release of toxics, through long-range planning, offered a more reasonable, inexpensive approach to toxics control. Prospective planning appeared a rational concept, but few staff members saw a practical means of implementation. Confusion over this idea prompted staff complaints that TSCA could not be implemented, as it stood.[70]

Lack of precedent found in the administrative process, and in previous environmental regulation, magnified the E.P.A. staff's resistance to change. Regulation previously emphasized the mitigation of immediate environmental problems. The reactive nature of the administrative process, used previously by E.P.A., was in opposition to TSCA's new format. A conflict going beyond simple resistance to change emerged. The Agency drafted regulations in a climate of uncertainity and inexperience. The flexibility of early Administrative Law had been encumbered with traditions.[71] E.P.A. staff found little support for TSCA's unique prospective focus. The fragmentation of the staff into small work groups accelerated the loss of TSCA's overriding goal. Confusion among the upper level administrators further stifled the development of TSCA as a prospective law.[72]

Most of the activity centered on completing an Inventory regulation, but no one evaluated the unfolding of the entire Act. This emphasis on the statutory deadline was crucial. The Inventory formed the basis for all subsequent regulation, however, no one at any level of E.P.A. left any record of policy considerations tying the Inventory to TSCA's larger purpose. Ignorance of possible options and resistance to institutional change re-defined TSCA's prospective status during the administrative rulemaking process on the Inventory.[73] A more reactive regulation emerged in the Inventory; the questions of implementing an alternative concept remained unaddressed and unanswered. Staff members expressed confusion over this issue but appeared unconcerned; the staff felt that the administrative process gave them little chance to explore and develop the prospective, comprehensive nature of the Act.[74]

E.P.A. was delegated the regulatory authority to monitor the chemical industry. Under the authority, the Agency assumed the stance of informal rulemaking defined by section 4 of the APA.[75] The APA outlined the procedures expected within Administrative Law by an agency such as E.P.A. Tradition within Administrative Law had evolved the assigning of specialized regulations to a appropriate agency. Personnel in E.P.A. represented the most acceptable range of technical skills of any federal agency to regulate toxics in the environment. The discussion in Chapter I explained the problems facing E.P.A.; the inherent scientific debates offered little concrete theory to decision makers.[76] Toxics in the environment fueled a statutory response, but the technical disciplines lacked evidence to draft or enforce regulations. Congress mandated E.P.A. to act with only a tenuous data base available. Previously, administrative process evolved the means to confer broad powers on regulatory agencies. The mandates to regulatory agencies required action and regulation often through expressed timetables. Complex regulation, in turn, necessitated the availability and applicability of reliable and extensive data. Insufficient data to support conclusions exposed the regulatory agency to the increased likelihood of litigation. The lack of a clear scientific link between a chemical in the environment and environmental deterioration, especially when balancing the environment against the economic impacts of regulation, raised legal questions of "arbitrary and capricious" rulemaking.[77]

The E.P.A. staff acknowledged charges of "arbitrary and capricious" policy in the Inventory regulations; the Agency formulated regulations

under the threat of litigation by aggrieved parties. Although the courts are only allowed to judge an individual case at the bar and not make abstract opinions, an interpretation of statutory or regulatory language has the potential of setting policy. Administrative Law originated as an alternative to the costly and slow case-by-case approach of the courts; litigation evolved to establish a check on an agency's accountability. The same delays considered in rulemaking by the court system were instituted in the administrative process. TSCA's regulation of the Inventory illustrated a fundamental weakness of regulating environmental problems through Administrative Law. An agency's ability to regulate rested on the data base available; information was the support for any rational policy decision. Possible delays, uncertainty and confusion lessened E.P.A.'s flexibility in formulating the Inventory. Incomplete information utilized by the Agency sparked disputes with the various external interests.[78] Lack of information and concerted external pressure forced E.P.A. to compromise on key technical issues such as the definition of "by-product" and "intermediate" rather than risk lengthy litigation.[79] External groups included industrial associations and environmental groups, who pressed for desired changes in the regulation.

Information emerged as a critical factor in the Inventory rulemaking as E.P.A. lacked any previous experience as an industrial regulator. Economic issues found in the definitions of "small manufacturer" and "small quantities for research" went beyond the Agency's initial expertise. The Act required rulemaking to proceed simultaneously with information collection. This locked E.P.A. into the drafting of regulations without a grasp of the in economic concerns

TSCA was mandated to consider. Both the technical and economic issues in the rulemaking suffered from a dearth of unambiguous data and precedent.[80] This information gap left the Agency vulnerable to court intervention in the decision making. Judicial review forced possible inherent delays which the staff was attempting to avoid, so compromises were struck.[81] Congress delegated responsibilities to E.P.A. to draft rules, but the confusion in its staff stalled the progress of the Inventory regulations nearly two and one-half years beyond its deadline.

The need for information expressed by the E.P.A. staff indicated another weakness faced by regulators of environmental problems in Administrative Law. Regulation required the acceptance of an external group's information and data, but E.P.A. lacked the time and available expertise to completely understand the diverse chemical industry.[82] Collection of such data had clear guidelines developed in the APA and expanded in Home Box Office. The issue of ex parte communication rested on the potential impact of unfair influencing the rulemaking. Judicial review of such regulations would not receive the "full administrative record" nor be able to adequately judge the exercise of an agency's discretion. Analysis of the procedures employed by the TSCA illustrated the paucity of the public record.[83] E.P.A.'s rulemaking on the Inventory conflicted with prescribed procedures in which "...the notice required by the APA, or information subsequently supplied to the public, must disclose in detail the thinking that has animated the form of the proposed rule and data upon which the rule is based."[84] A more in-depth analysis of the relationship of external interest groups and the administrative process will be discussed in the next Chapter. The lack

of information and precedent left E.P.A. vulnerable to the political pressure assembled by groups with more data. The evidence indicated E.P.A.'s record-keeping was minimal and that ex parte communication may have been a determining factor.

Overall, the administrative process modified TSCA's prospective nature and forced the Agency to act with unproven concepts. The very structures it evolved to become the "fourth branch of government" proved cumbersome, costly, and inflexible when regulating toxics in the environment.

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CHAPTER IV

INTEREST GROUPS IN THE ADMINISTRATIVE LAW PROCESS

Introduction

The Administrative Law process evolved into an institutional structure, to meet the demands for another branch of government to regulate human behavior. Congress and the courts intended this "fourth branch of government" to promote active information exchange between a regulatory agency and the various "publics." The Courts upheld and strengthened the framework of interaction between an agency and interested citizen groups. Clarification of the accepted procedures came in the recent Home Box Office case stating

> these procedural requirements are intended to assist judicial review as well as to provide fair treatment for persons affected by a rule...[1] To this end there must be an exchange of views, information, and criticism between interested parties and the agencies."[2]

Rulemaking offered a forum for public involvement and agency scrutiny.[3] Congress incorporated this concept into the APA, structuring the participation of individuals or groups during the drafting of a regulation.[4] Interested parties offered information and relevant experiences pertaining to an issue being regulated. The institutional structure of Administrative Law rested on the American ideal of "government by the people, for the people".

The concept emerged, in practice, to define the "people" or "publics" as special interest groups. Political scientists described these special interest groups as respresenting a pluralism. Pluralism was the countervailing balance between interest groups assessing policy options in terms of perceived group benefits or costs.[5] In theory, these

groups were assumed to represent all the diverse groups within a society. However, in practice, special interest groups produced a partial pluralism where

> not all citizens are represented in this process and some citizens have representation-influence and power-substantially in excess of others. Although this is oversimiplifying, the citizens who gain effective representation in a partially pluralistic system are those able to form effective political and lobbying organizations with other like minded individuals.[6]

These individuals organized around given specific issues appearing within the regulatory process.

The effect of an organized group on the administrative process resulted from a combination of many factors during a rulemaking. The ban on ex parte communication in Home Box Office indicated the potential effects of such "off-the-record" contacts on decision makers. The lack of a record further prevented consistent court review of agency actions. Administrative Law evolved controls to mitigate an advantage held by an organized or vocal minority. Court review, using legislation such as the APA and previous court decisions, served as a check on agency action. These judicial and legislative controls constrained the organized interest groups through this codification of procedures; but these groups were and still are often a concerted force in rulemaking.[7] A study of a specific regulation in the Administrative Law process should consider the impact of such external groups on a regulating agency. The interaction of E.P.A. with external groups during the Inventory rulemaking is discussed in this Chapter. The dialogue between the Agency and the interest groups represents an example of the response to rulemaking among diverse groups and interests. One author characterized this interplay (albeit dramatically) as:

> Government is omnipresent--regulating, subsidizing, allocating--and it is highly susceptible to manipulation by well-organized groups (which are not necessarily big-business groups). It is in the nature of democratic (and perhaps of any) government that a numerous, durable, articulate, and focused interest group, able to organize financial and field support of political campaigners, to propagandize, to draft and shepherd bills through legislatures, to maintain continuous contact with regulatory officials, and to mobilize voters, will wrest privileges and benefits from government and thwart efforts to control its behavior. Consumers, citizens, taxpayers constitute too diffuse and amorphous a group to compete in this league...The very democratic structure that we so highly - and rightly - prize facilitates the plundering of taxpayers and consumers by interest groups able to use the powers of government for their own ends.[8]

Institutional Considerations

A study of any policy issue must take into consideration the institutions involved; Administrative Law is no exception.[9] The legal framework developed by legislative and judicial action evolved, in turn, with additional inputs from the regulated industries. Regulatory agencies received expanded power based the precedent of the ICC's mandate to regulate the railroad industry.[10] The ICC was the first of many regulatory agencies controlling industrial actions. Congress diverted the control of whole or partial components of different industries to specific regulatory agencies. Regulation constitutes a major factor in the present market structure accepted in the United States.

Administrative Law was an example of a societal institution intended to coerce individual behavior.[11] The ultimate scarcity of a finite world limits the range of choices available to individuals seeking resources. Resources were and still are restricted by their physical supply and the range of opportunities available for their use

which are held by individuals.[12] Scarcity of resources promotes human interdependence. Therefore, institutions evolve as: "sets of ordered relationships among people that define their rights, exposure to rights of others, privileges, and responsibilities."[13] Society promotes the growth of institutions as social mechanisms to allocate scarce resources among individuals or groups. Institutions form the framework to guide individual action in relation to other people and the limited resources available. Institutions, in turn, structure property rights as: "...the instrumentality by which any society controls and orders human interdependence and resolves the question of who gets what."[14]

Whenever scarcity exists, the issue of allocation (who gets what) arises. An institution assigns property rights to provide continuity and lessen conflict.[15] Property rights define the range of opportunities available to the individual within a limited and interconnected system. Possession of a given property right gives an individual the power to impose certain costs on other people in the interdependent situation. The costs are more than the cost of simple exclusion; such a right defines the potential actions delegated to those involved.[16] The physical limits in the individual or his/her environment plus the institutional structure of available property rights modifies the opportunity set available.[17] Thus property rights and their supporting institutions acknowledge both scarcity and human interdependence. Mutual coercion channels social institutions as an individual attempts to use his/her property rights to the exclusion of another's opportunity for that right.[18] Coercion does not imply physical attack, rather it is manifested through interaction in the various institutions assigning property rights. As institutions evolve,

property rights change to reflect accepted social standards and practices. Society's interdependencies establish a system of mutual coercion found in the allocation of property rights.

Institutions develop a mutable set of property rights. Individuals receive a modified opportunity set after each market transaction occurs.[19] Changes in either the institutional structure or its allocation of property rights also transform the available opportunity sets. The scarcity of resources and the human interdependence precipitate both the institution and its evolution over time.

Individuals do not possess the perfect knowledge to calculate the constant, minute changes in their opportunity set. The power held by individuals to coerce others depends on the range of property rights designating sets.[20] Institutional structure may require an outlay of individual effort to effect changes in property rights and their subsequent power to coerce. The cost to an individual may accrue in the attempt of influencing institutional changes. These costs may have to be weighed against perceived individual benefits.[21] An attempt to influence the allocation of property rights involves risks and uncertainty for the individual actor. The interdependencies of human behavior spawns contractual costs on individual bargaining for a change in the institutional structure.[22] If an individual decides these contractural costs required to compromise are too high then the status quo may be maintained.[23] The evolution of property rights over time may require the assumption of costs by the individual desiring the change.

Uncertainty forces the individual to accept risk. Uncertainty also presents information costs to the individual who lacks perfect knowledge on his/her optimal actions.[24] An individual may have to bear the costs

of contracting through an institutional structure to attain change. He/she is also responsible for the collection, simulation and presentation of information to support the claim for alternative institutional structure. The property rights structure determines which individual may bear the costs of producing the necessary information and the uncertainty of the final outcome.[25] Property rights establishes a basic status quo, which may force the costs of change upon those desiring a more advantageous position.

Contractual costs, uncertainty costs, and information responsibilities placed on individuals created the body of transactional costs inherent in an attempt to modify an institutional structure.[26] These costs are balanced against the possible gain in favorable institutional (and therefore property rights) changes. An internal calculus of the possible costs and benefits rely on the realization that:

> An individual's impact on the process will depend upon, among other things, the resources and information channels he controls, his influence on others and on how much he tries to influence each particular outcome.[27]

The size of the personal investment required to influence an established institution implies high transaction costs on the individual. Individual desire for a re-allocation of property rights consolidates diverse individuals among complementary interests. Group action concentrates the pressure of selected information and diffused costs among the individual members. A group or social movement is defined as: "a primarily power oriented movement; a deliberate, voluntary effort to organize individuals to act in concert to achieve group influence to make or block changes."[28] A defined interest group

addresses the questions moderating an individual's attempts to act for institutional change or maintain the desired status quo. Individual costs and uncertainty are still considered among group members but weighed against the alternative of a more powerful voice. Acceptance of the transaction costs inherent in organizing group activity indicates that individual perceives an overall benefit from interest group activities. This approach to institutional change achieves varying amounts of individual support especially when: "...coordinated group actions are thought to be the necessary means to obtaining some elements in a larger social context the changes desired by participants."[29]

Costs attributed to the participation in a power movement may be high when compared to immediate outcomes. Transaction costs diverted individual time, energy, and resources into a group activity, but the group activity offers no guarantees that the desired benefits will be captured by the members.[30] Structural solutions bear no guarantees, as:

> For the organization as a whole, the consequences of its actions will turn in depend on the responses of various external actors (competitors, buyers and regulators) and on the nature of the organization relationship to them.[31]

This expanded interaction exacts many of the same transaction costs of contractural change facing individuals. Yet interest group activity emerges as a voice modifying institutional structure.

Attempts to explain the emergence of interest groups expanded in the literature. One concept relied on the occurrence of

> ...relative deprivation explicitly or implicity as a central variable in the explanation of social movements, and thus to explain the processes of social change that are engendered by social movements. The basic notion is that feelings of deprivation, of discontent over one's situation, depend on what one wants to have; that is, deprivation occurs in relation to desired points of reference, often reference groups" rather than in relation to how little one has.[32]

Goals motivate an individual action because the individual assumed s/he deserves this goal due to perceived personal investments. Such expectations are blocked by an institutional structure and the coercion of property rights. This blockage of expectations continues, forcing the individual to join a similar reference group pushing for a desired institutional change.[33] An individual judges his/her own relative deprivation and determines group pressure the most likely means to influence institution change. An interest group provides a logical route, bearing the diverse costs while providing an aggregate of selected information and political pressure. The costs of uncertainty inhibits individual action, so groups disperse this transaction cost over its members. A group's combined resources cushion the risk of uncertainty to the involved individual. An interest group evolves over time, responding to the changing institutional structure and available information. It defines a goal of action when: "...satisfactory solutions are sought to a series of "problems" as these are generated by changing external circumstances."[34] The response of special interests to perceived changes in circumstances may provide crucial input into the institutional allocation of property rights over time.

The Importance of Interest Groups in the Administrative Process

In response to the pressures of external interest groups, Administrative Law evolved into an established institution, exercising extensive power over property rights held by affected individuals. Regulatory agencies served as the enforcement arm of the institution. The passage of any new statute constituted a potential institutional and property rights shift from the status quo. Subsequent rulemaking and

enforcement by the responsible agency defined the term "in the public interest." There were and remain many "publics" desiring an expanded set of property rights.[35]

Various interest groups calculated their specific information costs and other administrative burdens prior to organization and action. A regulating agency and other governmental units also calculated their own costs inherent with a change in policy.[36] A change in any institution was not an isolated event, this change could not ignore the procedures and powers held by the other governmental units. Vested interests included the impacted "publics," organized interest groups, the overall institutional structure and the regulating agency.

Congress delegated the power to change individual opportunity sets through property rights to a regulatory agency. The regulatory agency also incurs the transactional costs affecting any interest group with a stake in institutional change. The most crucial factor contributing to an agency's uncertainty is the information costs imposed during rulemaking. An agency faces high information costs as:

> The fact is, of course, that in a highly industrialized society, the basic problem is precisely to obtain information initially available only outside the decision making unit itself, and that this is the background for the complicated problems of coordination with the "outside world, i.e. with other decision making units.[37]

Often industry is the main source of the external information required by a regulating agency. The control over industrial activities by an agency has become a major responsibility since the original foundation of the ICC.[38] An industry attempting rational business practices often possesses a stable information base. Information generally comes from the organized industrial sector; agencies receive far less relevant data from other groups; for example:

> It has been claimed that, because of limited resources, citizen groups often have an incentive to participate in cases that they feel reasonably certain they can win, or that will generate significant publicity, rather than in those that may have major environmental or social impact.[39]

The transaction costs imposed by the interaction of involved actors affects groups both internal and external to the Administrative Law structure. All act to minimize uncertainty and information costs while establishing a property rights base.

The Effect of Interest Groups on TSCA

E.P.A. presented an example of the dynamic interaction between various interest groups and the institution of Administrative Law. The Agency formulated its Inventory rules often with little data, facing concerted external group pressure and internal uncertainty.[40] Environmental policy substantially modified the property rights structure held prior to the passage of a statute. Subsequent industrial or general public controls represented a substantial shift of the coercion found in property rights. Interest groups negotiated to acquire or maintain the institutional status quo. The most controversial drew the most pressure as:

> The decisions made by E.P.A. under its statutory authority are seldom simple resolutions of factual disputes; instead they involve complex technical issues and controversial value judgements that can affect significant numbers of persons and activities.[41]

The "value judgments" were a result of the incomplete data base possessed by the Agency. These contractural costs on EPA operated in favor of the group providing data and expertise to the staff. Overall

> ...participation by the general public and organized citizen groups, though substantial, has been far less extensive than that of industry in part because public participants have smaller resources.[42]

Resources included the lack of highly trained technical staff, money and access to a fragmented data base.

The reliance on industry-generated information was the general pattern for E.P.A. Industry data represented the least expensive means to acquire large banks of data for regulation. The Agency judged the saving of staff time and expertise so that "...it is inevitable and essential that E.P.A. continue to rely on industry for important scientific and technical information."[43] The cost of acquiring information combined with the perceived administrative problems convinced E.P.A. to accept industry data. Industry possessed the most complete and available data set. The Agency felt the industrial data to be most practical and inexpensive option. Evaluation of such data, however, was not possible as: "...there are no simple protocols or uniform measures of technical feasibility with which to generate and evaluate industry information."[44] E.P.A. accepted most of the industrial data to be accurate, unless obvious errors appeared in the submissions.

TSCA followed this pattern by abandoning an adversarial position against the chemical industry.[45] Staff members voiced concern over the general validity of such selected information. There was no public record from the staff indicating the discovery of false data or mis-information.[46] No conclusion on this issue emerged, due to the little evidence to support allegations that the industry was dishonest or not acting in good faith.[47]

The public record shows that the industry offered the bulk of the usable data, including the economic feasibility studies of the proposed

Inventory regulations. E.P.A. kept little documentation of the internal deliberation and information used during the decision making. Poor record-keeping provided limited insight on the alternatives weighed by the staff. The power of information elevated the position of industry into a cooperational stance (through the sharing of information) with the regulating agency.[48] An incomplete record prompted questions of the possibility of ex parte communication and influence. No evidence indicated E.P.A. had a restricted public forum or acted beyond the scope of the law.[49] The inexperienced staff and lack of an available data base fostered such a fraternal relationship between the Agency and the regulated industry.

Environmental groups, on the other hand, lacked the information desired by the Agency. These groups exerted the most influence through media campaigns and threats of litigation. The influence manifested itself in the Agency's attempts to adhere to informal rulemaking procedures and deadlines. Rulemaking on the Inventory typified an Agency pattern when:

> In general, the statutory imposition by E.P.A., combined with the enforcement of such deadlines through litigation by citizen groups, has been beneficial in allowing and forcing E.P.A. to implement its program responsibilities.[50]

The environmental groups used established institutional procedures to force E.P.A. to act; however, it could not compete with the substantial information advantage held by the industry.

TSCA was an example of the interconnections and difficulties intrinsic to policy formation in the administrative process. The amount of influence exerted specific interest groups was extensive but poorly documented. E.P.A. plodded through "...an almost overwhelming

complexity that arises from an implementation effort involving many actors at different levels of government."[51] Administrative Law encouraged such input and thereby allowed political pressure on a regulating agency. The philosophical structure which shapes such political institutions will be further defined in Chapter V. It raises doubts that current Administrative Law can process such complex environmental laws as TSCA.

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CHAPTER V

A CONSIDERATION OF THE PHILOSOPHICAL FRAMEWORK

Introduction

Toxics in the human environment present philosophical as well as scientific and political dilemmas. Earlier chapters in this study focused on the scientific and political problems faced by the regulating agency, E.P.A. This chapter will attempt to link the process described in Chapters II, III, and IV with an area of philosophy deserving future study.

Scientific evidence, discussed in Chapter I, indicated that toxics persist and threaten human health over the span of generations.[1] The philosophical dilemma arises from the question of what, if any, obligations are owed to future generations when regulating toxics in the environment. The fact that data indicate long-range negative effects from such toxics suggest a present responsibility to mitigate the toxics threat to humans and to the environment. The power to change human behavior (e.g., through governmental regulation) allows a society to meet this responsibility. There is an obligation to protect human health once a toxic threat becomes known. Thus, the scientific evidence and institutional concerns for future generations raise the issue of obligations over time.

TSCA acknowledges these temporal concerns as the first prospective environmental legislation, in the United States.[2] That legislation like most, exemplified the Utilitarian nature of American government.[3] The philosophy of Utilitarianism recently has come under fire for several reasons, including its limitations in addressing obligations to

future generations.[4] This chapter will review the ideas of several leading theorists in order better to define Utilitarianism and offer two alternatives to the Utilitarian position on the responsibility to future generations. The Utilitarian philosopher selected is J.J.C. Smart.[5] Chosen to reflect the non-Utilitarian side are Joel Feinberg[6] and Ernest Partridge.[7] This comparison will identify the underlying social philosophy of American government and suggest possible alternatives. The specific example of toxics control will illustrate the philosophical dilemma of extending obligations beyond the present generations under the prevailing utilitarian social philosophy.

Philosopher John Rawls has judged the Utilitarian framework inadequate for a number of complex social issues including obligations to future generations.[8] Utilitarianism claims that the right thing to do in any situation is whatever will maximize the greatest general good or welfare.[9] Rawls questioned the adequacy of utilitarianism in dealing with questions of social justice, both within and between generations.[10]

J.J.C. Smart has defended Utilitarianism from the criticism raised by Rawls. Smart's sophisticated, comprehensive definition of it is presented below. The earlier chapters on the implementations of the Inventory exemplify the efforts to put Smart's Utilitarian framework into practice.

Utilitarianism in Theory

It has been said that social policy and legislation in of the United States rests on a Utilitarian framework.[11] How functional is this framework in practice?

Utilitarianism, as a framework, originally evolved as a reform of an existing governmental structure. Jeremy Bentham and John Stuart Mill were instrumental in developing this moral theory as a basis for social reform. Indeed, Bentham's framework of Utilitarianism "was developed largely in order to provide a justificatory framework for legislation.[12] Mill claimed that the Utilitarian framework provided a moral theory for both individual and institutional action.[13] The heritage of these two philosophers "has been a profoundly influential one, and the liberal tradition in Anglo-American law has reflected ever since the basic view that the maximization of social welfare is the proper object of legislative activity."[14] There has been, however, as seen in the case study of TSCA, a gap between theory and application.

Smart describes the theory of Utilitarianism as the "view that the rightness or wrongness of an action is to be judged by the consequences, good or bad, of the action itself."[15] An action is assessed in terms of "the total goodness or badness of its consequences, i.e., on the effect of the action on the welfare of all human beings or perhaps all sentient beings."[16] Individual choices combine in Utilitarism to promote a general aggregate welfare for a society. Each action by an individual affects the general welfare. Economists define this interaction in terms of the interdependencies of individuals.[17] Any action by an individual affects the scarcity of a desired resource, therefore modifying the options held by other individuals in their opportunity sets.[18] Utilitarianism accepts these human, societal interdependencies, and the philosophy attempts consider these individual actions to promote a general welfare and rational system of ethics.[19]

Smart builds his theory of Utilitarianism on Bentham's concept of the maximization of individual or aggregate happiness. Smart assumes that this maximization should form the basis for identifying commendable actions in a Utilitarian society.[20] Smart defines aggregate social welfare as encompassing the concept of average social welfare.[21] Overall, good actions out weigh the bad actions throughout a Utilitarian Society.

Whether a society based on Utilitarianism values the maximization of pleasure or the minimization of suffering, a way to evaluate actions exists. Certain actions are commended and others condemned as they either contribute to or detract from the overall social good. Utilitarianism, through the various assessments of good and bad, imposes an imperative on all individuals to choose actions maximizing the perceived overall benefit to society.[22]

Smart supports this concept of individual evaluation with the assumption of generalized benevolence and disinterested impartiality among individuals.[23] Generalized benevolence is defined as "the disposition to seek happiness, or at any rate, in some sense or another, good consequences for all mankind or perhaps all sentient beings."[24] Individuals, on the average, desire that their actions benefit not only themselves but others. Smart adds that because most individuals "...have a favorable attitude to the general happiness, surely they will have a tendency to submit to an ultimate moral issue which does no more than express this attitude."[25]

Therefore, Utilitarianism is the social philosophy of rational choice. Individuals promote their own happiness and add to the aggregate happiness.[26] The agent or individual deliberates among the

available alternatives, then chooses the option providing the greatest overall "satisfaction of desires" or utility.[27] The term "rational" is a commendation for any individual action that is likely, based on the available information, to produce the best results for both the individual and society.[28]

Smart and other Utilitarians have few doubts that Utilitarianism can apply to large social problems as well as the problems involving a few identifiable individuals. Any differences, they would contend, are simply matters of degree and complexity.[29]

However, as suggested in the Inventory example discussed in Chapter II, the actual result of using Utilitarian theory to calculate social welfare may not follow ideal lines. A gap between the sophisticated theory and a constrained, real-world example, such as the legislation regarding toxic threats, illustrates the problem of implementing Utilitarian theory in the framework of complex procedures of governmental regulation.

The Gap Between Utilitarian in Principle and in Practice

A gap exists between ideal Utilitarian theory and actual attempts by decision makers to use the theory in government. Individuals may diverge from the ideal structure of the theory when applying it in the context of corporate-governmental constraints. A review of Chapter II offers an example of the problems that resulted from E.P.A.'s attempts to draft regulation based on the conceptual framework mandated by Congress.[30] TSCA serves as an example of the well-intentioned Utilitarian ideal (in the form of the Act) and the way in which the actual development of realistic regulation diverged from that ideal.

Utilitarianism aims at maximizing overall welfare or the satisfaction of desires. Rawls characterized this concept in the following manner: "...one reaches the principle of utility in a natural way; a society is properly arranged when its institutions maximize the net balance of satisfaction. The principle of choice for an association of men is interpreted as an extension of the principle of choice for one man."[31] This aggregation of individual choice rests on the singular principle of utility. It was this combination of individual desires into a collective good that stimulated Congress to pass TSCA.[32] Congress intended TSCA to address the comprehensive problem of toxics in the environment. TSCA was to be a vehicle to promote social utility.

Utilitarian theory does not exclude the unborn from the calculation of aggregate social welfare.[33] This concept lent support to the passage of prospective laws that explicitly plan for the distant future. TSCA, for example, gave E.P.A. a mandate to exercise long-range planning power in order to better protect present and future individuals from toxics exposure.[34] Pressure from an alarmed scientific community and general public had sprung from increased information about a persistent toxics threat. This pressure had prompted Congress to pass an enabling act for regulatory action by E.P.A. The Agency received a mandate in TSCA to regulate toxics with the first prospective environmental law. Congress considered the present and future generations through the intent of TSCA.[35] This intent represented the sophisticated ideal of Utilitarianism advanced by philosophers, such as Smart. Both present and future individuals were to be considered in the process of regulating toxics.

In contrast, during the Inventory regulation, the attempts to operationalize Utilitarian goals met various obstacles. These constraints in the actual situation limited the regulatory action taken by the Agency staff. The problem was that complex issues (such as the regulation of toxics in commerce) were beyond the evaluation capability of even the most sophisticated Utilitarian. Evaluation of the alternatives within a complex problem and the choice of an action relied on available information. The lack of information on which to base individual choices was a crucial problem.[36] Information proved to be a constraint for the Agency, especially in attempts to meet statutorial and judicial standards for rulemaking.[37]

In the case of TSCA, an enormous burden was placed on E.P.A. to collect and weigh information. The Utilitarian principle requires each individual to maximize his/her utility. However, the knowledge needed to make these individual decisions was, in the case of TSCA, not available.[38] Even should this information be obtainable by the individual, how does s/he "validly calculate" the happiness that would result from a given isolated action?[39] This problem of an enormous information burden prompted earlier criticism of Bentham's ideal Utilitarianism. Philosopher Adam Sedgewick found this information requirement to be a barrier to practical application of Utilitarianism. He explained that "man has not foreknowledge to trace the consequences of a single action of his own: and hence...utility...is, as a test of right or wrong, unfitted to his understanding, and therefore worthless in its application."[40]

TSCA was an example of an application of the Utilitarian theory to a complex, uncertain problem. The available information was limited and

often held only by the regulated industry.[41] Much of the information necessary for a Utilitarian decision was simply not available to the decision makers.

Another problem facing E.P.A. was the cost of obtaining information. In principle, philosophers may have theorized the costs of such information should be paid to better facilitate decisions for the aggregate social welfare. Decision-making costs were expected to be borne by the decision maker and considered with the available options for action. Yet this requires the consideration of information that imposes high costs on an individual agent attempting to decide a course of action. In practice, the cost of necessary information may be horrendously high. Should an individual decide that the overall process is too costly, a less than ideal Utilitarian choice may result. Without the information, a decision maker can not impartially choose among a comprehensive list of alternatives. The decision may produce the best Utilitarian decision because all Utilitarian calculations, in theory, consider decision-making costs as well as the overall benefits. However, the results may be that the lack of information about distant future generations removes the unborn from the calculations.

The lack of information confused the Inventory staff when it attempted to choose specific definitions and procedures during rulemaking.[42] The constraint of limited information narrowed the range of options to be considered. If the information about alternatives was sufficently constrained, then decision makers had little impetus to alter the status quo. Again, the Inventory case study illustrated this situation when E.P.A. attempted to establish the first prospective

environmental law without the support of precedents within the Agency.[43]

Further complicating the role of information in practical decision making was the requirement of the APA to mitigate the possibility of an "arbitrary or capricious" Agency action.[44] Specific procedures were established, requiring that the agency keep a complete record of all information considered during rulemaking. The agency was required to document how and why specific decisons were made. A court review of the agency's record was used to determine the information used by an agency. A lack of information resulted in an incomplete record, with the agency acting without a firm base of fact. This lack of information forced the agency to act within a constrained view of present and future consequences. This constrained view offered an example of the difficulty a decision maker faces when attempting to act in established political institutions.

Moreover, the decision maker in any actual instance is not the sophisticated philosopher. The decision makers in the U.S. government were given mandates presupposing the Utilitarian social theory but were constrained from acting. The burden of information and its costs, inherent in the Utilitarian philosophy, restricted the scope of the actions of the corporate and government bureaucrats.

Some areas, such as environmental protection, expanded the responsibilities of decision makers to provide for future generations. This broadened obligation further complicated the collection of information by a decision maker implementing the Utilitarian concepts into practice. Detailed knowledge of the distant future, necessary for the impartial observer of Utilitarian theory, simply might not be

available. Even if such information could be obtained, the high cost would deter the decision maker. A Utilitarian theorist, with a strong committment to the interests of distant future generations, might opt to pay these transaction costs. However, in the bureaucratic structure of government, individual decision makers do not make such costly choices.[45] The decision maker faces a collection of information and decision costs that necessitate the assigning of priorities during rulemaking. These priorities provide a practical limited review of a less than comprehensive set of alternatives. Such limiting of options, based on a fragmented data base, were found throughout E.P.A. process of drafting the Inventory.[46] The constraints of costs, time, and available information determine the manner in which future generations will be considered by governmental decision makers under Utilitariansim.

Regulatory agencies operate in a constrained world of short-run pressures, scarce resources, and limited time. An agency is mandated by Congress to act within given boundaries of a specific law. The agency cannot exceed its legislative authority without risking intervention by the courts.[47] Congress sets the format for agency actions. TSCA illustrates the power of an enabling act to structure subsequent agency action through the inclusion of timetables.[48] The Act defined crucial terminology although Congress did leave some definition to E.P.A. discretion. Information for the Inventory was further constrained by a statutory deadline imposed by Congress. The time frame forced the Agency to limit information gathering and concentrate on information from the regulated industry.[49] Limited information, limited staff time, and budgetary constraints forced the staff to function as less than the

impartial, benevolent observer weighing adequate information for the consideration of both present and future generations.[50]

Because E.P.A. faced numerous constraints, primarily of information and time, it was vulnerable to the added political pressure of external interest groups.[51] The chemical industry used the value of the information to form a cooperative relationship with its regulatory agency.[52] Environmental groups, lacking the valuable information held by the industry, used procedural and legal coercion to pressure the Agency.[53] These pressures further constrained the decision makers attempts to define a"satisfaction of desires" of the public in the present and in the future. Aggregate social welfare, in theory, considers both present and future generations, however, in practice, such welfare was defined in terms of the most effective pressure supplied by an interest group.

Future generations, of course, were not represented by any interest group. E.P.A. faced vocal and concerted political pressure and selected information from various interest groups. The fact that future generations were not represented explained the staff's hesistancy about considering the prospective nature of an environmental law. Since consideration of future generations would have imposed increased costs on decision makers, and since the unborn offered no vocal opposition, E.P.A. ignored this consideration. The Agency acted to lessen the practical constraints of the political pressure and the information gap by emphasizing specific statutory timetables and the compromises possible between the interest groups.[54]

In summary, the theory of Utilitarianism offered sophisticated answers to complex problems such as the control over toxics that is

found in TSCA. In practice, the theory presented E.P.A. with an inadequate framework in the face of political pressure and limited information. The Inventory rulemaking illustrates the gap between theory and practice.[55]

While the theory of Utilitarianism addresses the consideration of future generations, even Smart admitted the inability of a practitioner to see far into the future. "The future..is dim, largely because of the potentialities of technological advance are unknown to us."[56] However dim the future, intuitions remain that certain issues are not adequately addressed in the Utilitarian framework. Among these issues is the question of what obligations, if any, the present decision maker has to the future individual. One must look for non-Utilitarian grounds for the support of these intuitions. Utilitarianism, by itself, lacks the information about future generation to put the theory into practice with regard to distant future generations. The theory relies on one principle, that of utility. Any philosophical theory considers utility a rational consideration; however, utility's supremacy of position in Utilitarianism, if it is the support our intuitions about future generations, places an enormous burden on the availability of cheap, accessible information.[57] This information is crucial for the determination of the best choice among options to satisfy desires. In the case of TSCA, the information simply was not available to the decision makers. A constrained political system limited the consideration of the aggregate social welfare to those individuals present, vocal and in possession of information. Consideration of future generations would have added information burdens to an already constrained situation.

Hence the future generations issue in the prospective view of TSCA was ignored by the E.P.A. staff.

Given current institutional constraints, does the example of TSCA indicate that the intuitions related to consideration of future generations must be forgotten?[58] Sophisticated philosophers have begun to offer alternatives to Utilitarianism, by addressing these intuitions about future generations. Two summaries of these non-Utilitarians will follow. These summaries will suggest the expansion of a philosophical framework to consider more than just utility and just present generations.

Alternative Considerations of Future Generations

Joel Feinberg develops an application of the "interest principle" in "The Rights of Animals and Unborn Generations."[59] This "interest principle" allocates rights to those who have (or can have) an interest in the outcome of an action. A right holder must have interests to be represented and must be able to benefit individually from these interest.[60] Feinberg develops his example of the quality of the environment as a short-run gift for one's immediate descendants and as a fundamental right for individuals far into the future. The future individuals are assumed by Feinburg to be essentially human beings of the same nature as present individuals.[61] Therefore, earlier philosophic works that exclude these individuals are in error; the future individual meets the qualifications of being a right holder and therefore must be considered.[62] Feinberg defines rights as follows: "To have a right is to have a claim to something and against someone, the recognition of which is called for by legal rules, in the case of

moral rights, by the principles of enlightened conscience."[63] Conservation of the environment is needed because present individuals have the power to modify the environment that will be left for the unborn. Future individuals can not presently claim their right to a livable environment; however, custodians or agents can be appointed to protect their rights through legal means.[64] Feinberg states that should the assumption that future individuals will be human just as present individuals are defined as human, then present individuals have the knowledge and power to act.[65] He considers the lack of such consideration explainable in the following manner: "The real difficulty is not that we doubt whether our descendants will ever be actual, but rather that we don't know who they will be. It is not their temporal remoteness that troubles us so much as their indeterminancy--their present facelessness and namelessness.[66] The indeterminacy does not remove the underlying assumption that such individuals will be human and therefore hold rights. Feinberg argues that the problems of environmental protection will affect the daily lives of individuals (similar to present people) far into the future.[67] The future generations do possess rights and present individuals can impinge on these rights by present action. Feinberg builds his argument on non-Utilitarian grounds. He intends that the argument stimulate discussion of the rights implied for future generations but heretofore ignored on the grounds of their indeterminacy.

Ernest Partridge discusses the rights of future generations as a response to the Utilitarian argument that "human beings are generally incapable of caring for the remote future and thus are absolved of a moral obligation to do so."[68] Partridge argues for the future

individual's rights in "Why Care About the Future."[69] He cites the example of parks, foundations, and other means by which present individuals explicitly act upon the future.[70] Such things enrich both present and future society. Partridge argues that an isolated individual or society, without explicit links to the future, is bankrupt and alienated.[71]

An alienated individual lacks "self-transcendence," the concept that one's ideas, projects and community continue beyond his/her isolated lifetime. The concept of self-transcendence is introduced as a bold claim that human nature requires social interaction in the present and the future in ways the individual finds meaningful. This expression of self-transcendence is "a consequence of the universal condition and circumstances of individuals human development. A sense and expression of self-transcendence is thus necessary for mental health."[72] Partridge proposes the process of identification with others as a justification of his premise that "we owe it to ourselves to be duty-bound to posterity, in a manner that genuinely focuses on future needs rather than out own. By fulfilling our just duties to posterity, we may now earn and enjoy, in our self-fulfillment, the favors of posterity."[73] Self-fulfillment is enhanced by links to the future. An individual has the antithesis to alienation in his/her investment and expansion of self into a surviving institution.[74] The institution links the individual to the lives of both present and future generations of the society. This individual involvement in significant events connects the individual to the flow of events. An isolated individual is a finite individual.[75] Caring for the future lessens the finiteness and isolation of the individual; these conditions that are receiving more and more attention in modern

societies.[76] Partridge calls for a more open consideration of the future to ease the present individual's alienation and to protect the unborn from a short-sighted society with no value extending beyond an individual's death. This use of self-transcendence is a simple thing.

> When men act for the sake of a future they will not live to see, it is for the most part out of love for persons, places and forms of activity, a cherishing of them, nothing more grandiose...To love is, amongst other things, to care about the future of what we love...This is obvious when we love our wife, our children, our grandchildren but it is also true in the case of our more impersonal love of our institutions, places and other forms of activity.[77]

Therefore, the consideration of future generations is no novelty, nor is it the valuing of faceless, unknown beings. Partridge argues that present day individuals and their societies need this involvement with the future to add meaning to their lives through the perpetuation of institutions and descendants.[78] Present generations lose their isolated status when linked to future individuals with similar institutions and communities. He also assumes that future individuals have rights in the present situation. The benefit of considering the future may be felt, not in hundreds of years, but in the immediate society.[79] Thus Partridge builds on Feinberg's discussion of rights to link the present individual with a not-so-indeterminant group of people living in the future. Feinberg also attempts to posit future generations rights on the premise that such individuals are human in the same fashion as are present individuals.

Possible Future Research

These alternatives offered by Feinberg and Partridge illustrate the beginning of non-Utilitarian thought in the consideration of complex

issues. The issue of future generations raises in tentative questions about total reliance on the concept of utility. If one relies solely on the Utilitarian framework, then one must have access to enormous amounts of information and a concrete means of evaluating complex problems. Since the future provides little information and great uncertainty, Utilitarianism, in practice, has ignored future generations. Perhaps if augumented with non-Utilitarian grounds for taking the interests of distant future generations into account, Utilitarian principles may better answer the intuitions considering the rights of the unborn.

Possible research into this area may concentrate on the development of non-Utilitarian alternatives for action. Such research must include philosophers and actual decision makers (i.e. government bureaucrats). One of the problems with Utilitarian theory is the difficulty of putting the principles into practice. The debate and confusion over basic definitions of chemicals under TSCA offers one example.[80] Such a detailed, complex problem has rarely received the interdisciplinary attention of actual decision makers and philosophers. Philosophical theories are valuable frameworks; however, actual constraints may require attention from various disciplines.

Beyond the gap between the principle and practice of Utilitarianism, future research may open discussion into the intuitive questions resulting from consideration (or lack of consideration) of future generations. Actions in the area of environmental pollution (e.g. toxics) pose threats to both present and future individuals. If the moral theory of Utilitarianism cannot, in practice, consider this evidence, then what becomes of the intuition that demands consideration of future generations? It is possible that, if the present Utilitarian

framework continues, such intuition may be discarded as superstition. Future research may study what this loss of intuition means to a society. It also may further the discussion of alternatives for a non-Utilitarian framework. Both paths deserve more intensive research before one is chosen over the other.

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12. Id.

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46. See text accompanying n. 47-167 supra, Chapter II: A CASE STUDY OF TSCA.

47. See text accompanying n. 15-19 supra, Chapter III: THE ADMINISTRATIVE LAW PROCESS.

48. 15 U.S.C. 2607 (b)

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59. Supra n. 6.

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Chapter VI

SUMMARY, CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

Summary

This study reviewed the administrative process during a specific rulemaking. The Inventory regulations of Toxic Substances Control Act were studied for their importance to the Act and for more generalizable observations on their relationship to the established environmental law. TSCA provided an example of the new generation of environmental laws, integrating a prospective, long-range plan with a reactive, problem-solving framework within E.P.A. The prospective nature of TSCA was a fundamental shift from the established tradition of environmental regulation. TSCA's new concept was evident throughout the administrative process; however, implementation of this new format complicated the Inventory rulemaking. The policy implementing the Inventory was finalized three years after its mandated deadline. Such a delay indicated problems, proceeding from the governing institution. These problems were beyond the the scope of the actual regulations. At the present time, E.P.A. has completed only two rulemaking processes, on the Inventory section and TSCA's specific ban on polychlorinated biphenyls.

The Administrative Law evolved to satisfy the need for a bureaucracy to administer regulations over specific human behavior. Agencies bore specific responsibility for the systemization of broad

policy directives. E.P.A. emerged as the primary federal agency responsible over environmental issues. TSCA delegated broad responsibilities to E.P.A. for the drafting of specific regulations and subsequent enforcement. One basic responsibility for E.P.A. was the collection and analysis of the available data. This data formed the information base for subsequent regulations. In the case of toxics, the necessary information was very limited in scope and subject to controversy among experts and the general population. Interest groups augmented the flow of information during the administrative process of the Inventory rulemaking. Over time, the institutional framework of rulemaking has expanded to encourage such varied inputs by individuals and groups affected. Ideally, this open forum facillitated information exchange and discussion. Access into the institution of Administrative Law, through the regulator agencies, imposed contractural and information costs on all involved. Transaction costs encouraged collective or group action; such groups attempted to influence the process with select information and political pressure. TSCA illustrated the methods by which interest groups influenced decision makers during the administrative rulemaking on the Inventory.

Administrative Law evolved in a political and economic structure emphasizing the reaction to immediate stimuli. Utilitarianism emerged as a fundamental philosophy shaping American policy. A social calculus became institutionalized into the present day balancing of perceived benefits and costs. The principles of Utilitarianism, the consideration of present and future utility, were embodied in such laws as TSCA. The Act expanded E.P.A.'s authority beyond the traditional philosophy of environmental policymaking. Long-range prospective planning was added,

reflecting new evidence that a toxic threat reached beyond its immediate release far into the future. Intuitions, from the experts and general public, supported this as a more explicit attempt to consider both present and future generations. E.P.A.'s attempts to operationlize these principles did not, in reality, implement a long-range plan. Short-run constraints and political pressure shifted E.P.A.'s attention away from the long-range plan to more immediate realities in the face of a statutory deadline.

Conclusions

E.P.A.'s decisionmaking is not an example of the efficient alternative theorized by Administrative Law for such complex problems as environmental law. Difficulties result from the prospective nature of the statute, which implies a fundamental shift in the philosophy of E.P.A. The process of the Inventory rulemaking demonstrates the procedures within E.P.A. which are often cumbersome and hesitant.

Such cumbersome and hesitant procedures were evident in E.P.A.'s consideration of the Inventory. The regulations were finalized after many delays, changes and attempts to answer pressure from selected interest groups. Evaluation of E.P.A.'s record on its first attempt at regulating the chemical industry is judged as piecemeal and timid. Will such conclusions apply in the future to subsequent TSCA regulations based on the Inventory? This confused and dilatory response raises larger questions about the appropriateness of current Administrative Law to regulate prospective environmental statutes in the face of limited and controversial information.

The lack of necessary information crucial to the process of rulemaking, raises doubts that a complex prospective environmental statute could be administered with the present organizational structure within E.P.A. Uncertainty and the lack of an information base stymies Agency action. Criticism of Administrative Law as an alternative institution, regulating environmental concerns can be summarized as:

> Instead of a flexible and highly informed body of problem solvers which can swiftly identify and authoritatively dispose of all the frictions and disputes arising out of a highly urbanized and industrial society (much as Equity allegedly softened the hard "bite" of strict "Common Law") administrative process has proved slow, expensive and generally unresponsive to societal needs, or as it is more frequently put, to the public interest.[1]

TSCA exhibits the weakness of the administrative process in the face of uncertainty information costs, pressure from interest groups and the need for long-range planning. The unique prospective format and highly integrative, technical orientation of the statute represents a new development in the traditional approach to environmental problems. In conclusion, TSCA was (through its implementation by E.P.A.):

1. Lacking precedents for administrative action due to its prospective format.
2. Slow in emerging from the administrative process because institutional structure hampered E.P.A. action and confused the responsible staff.
3. Subject to procedural delays and fears of costly, slow judicidal proceedings.
4. Sensitive to concentrated political pressure through the exchange of selected information.

5. Acting to control a perceived threat with a incomplete data base, making the entire regulation more vulnerable to judicial review.
6. A promising approach to environmental control but lost most of this promise when forced through a constrained, bureaucratic system facing high information costs.

The process of Administrative Law proceeds in direct correlation with the data base and expertise found in the responsible regulating agency.

Limitations

This study of TSCA centered on the rulemaking under section 8(b), the Inventory. These regulations will define future rulemaking under TSCA through established definitions and procedures. Predictions on the future development of TSCA, however, are based on a limited review of one crucial rulemaking. Although this study offers general insights into the institutional structure of administrative procedures within E.P.A., it is not the final review of TSCA or E.P.A. Subsequent regulation under the Act will require attention and study. The single case study of the Inventory, as the only completed major rulemaking under TSCA, acknowledges the slow progress of E.P.A. to fully implement TSCA's other regulations. As a detailed analysis of an actual procedure of compiling the Inventory, this study acknowledges the limited scope of a review of only one (albeit basic) section of TSCA.

Review of any law, regulation or court decision is a snapshot in time. Succeeding litigation, statutes, or Agency re-organizations could result in modifications of the regulation or statute. Such events may

also change the institutional structure of the administrative process within E.P.A. itself. The entire system is on an evolutionary path. It is beyond the scope of this research to foretell the outcomes of future court cases and similar actions within Environmental Law. This study is an attempt to explain the existent system of administrative processes and its impacts on a fundamental shift in the environmental law.

Recommendations

Follow-up studies on subsequent regulation under TSCA are needed. The Act is a major effort to consolidate an information base while regulating the entire chemical industry. Research into the scientific controversies inherent in regulating toxics are a little explored area. Other controversies deserving in-depth study include an overview of the range of legal options to control toxics and alternative institutional structures that might be feasible to regulate environmental concerns. These alternative considerations included the philosophical dilemma of the obligations, if any to future generations.

TSCA is the first prospective environmental law. Congress has also passed the Resources Conservation and Recovery Act[2] (hereafter RCRA) to create a "cradle to grave" program for the managing of hazardous wastes. E.P.A. is also responsible for RCRA which lags behind TSCA in the amount of completed rulemaking. TSCA received first priority over RCRA in E.P.A.; RCRA staff expected to learn from the lessons and experience of TSCA.[3] These experiences of TSCA will be informative to the decision makers as the regulations for RCRA are drafted. Environmental law may

be evolving a prospective framework in its administrative procedures based on such progressive statutes as TSCA and RCRA. Future research on both statutes will more fully define the current administrative process within E.P.A. and the subsequent institutional effects of prospective environmental laws.

A more immediate and practical concern rests in the insufficent record kept by the TSCA staff. The lack of documented and dated entries leaves many gaps in the open process of Administrative Law. E.P.A. should strengthen staff recordkeeping to lessen the likelyhood of the disruptive effects of litigation and court opinions. Such record keeping is required by law and court opinion to promote accountable agency action. It has been recommended previously that,

> E.P.A. should ensure that on orderly system for access is established to facilitate review...E.P.A. should establish a systematic procedure for compiling documentary records and should issue decision papers to explain fully its actions and the rationale for its actions.[4]

E.P.A. needs to revamp its own record keeping and internal information system. This will minimize the likelihood of disruptive judicial intervention.

A final recommendation centers on the research into alternative structures to regulate environmental issues in the midst of scientific controversy. Agencies are especially vulnerable to pressure from interest groups when in the process of rulemaking and regulating in the absence of an underlying data base to support policy. An earlier discussion explained the use of court-held power to review agency actions based on available information.[5] The issue here goes beyond the strict legal question on an individual rulemaking. Decision makers are now forced by statutory timetables to regulate inputs to the

environment, with or without the necessary information. The information costs to the agency may be extremely high due to the state of the science and the difficulty of the consideration of effects over time. TSCA represents a basic ethical problem through its balancing the possible short and long-run harm to the environment (including human health) against possible economic or societal disruption in the short run. The gap between the principle and the practice deserves more thought and research. This gap illustrates a moral problem underlying the institution of Administrative Law and regulatory agencies. Without adequate information or institutional structure, an agency often makes sweeping decisions about the lives of present and future individuals in near total ignorance, based on intuitions and implicit value judgements. This is a crucial area for interdisciplinary study given the expansion of the federal government's role in such a complex and controversial area as environmental protection.

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