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Regulation of Pesticides by the Environmental Protection Agency

by

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Regulation of Pesticides by the Environmental Protection Agency

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The basic governmental decision in the area of pesticide regulation—whether to allow a particular product to be sold on the market—currently is made within an organizational and statutory framework that has changed significantly in the past five years. The changes, made largely in response to the growing public concern about the environment in the 1960's and early 1970's,¹ were designed to ensure more thorough consideration of the ecological and human health risks associated with the use of pesticides.²

In late 1970, President Nixon transferred principal authority over pesticides from the Department of Agriculture to the newly created Environmental Protection Agency (EPA).³ Earlier that year, one commentator had criticized the Agriculture Department's activity in the area of pesticide safety as "scandalously derelict,"⁴ partly because "farm groups, food producers, and the manufacturers of agricultural chemicals [are] strongly represented in USDA"⁵ By contrast, the environmental groups that had been an important factor in EPA's creation

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1. See Roberts & Stewart, Book Review, 88 HARV. L. REV. 1644, 1656 (1975) ("environmental organizations had . . . convince[d] many elected officials by the late 1960's that they were a 'swing' constituency to be taken seriously").

2. See Message of the President Accompanying Reorganization Plan No. 3 of 1970, 84 Stat. 2086, reprinted in Appendix to 5 U.S.C. at 611 (1970) (statement of reasons for creation of Environmental Protection Agency) ("[intensified] concern with the condition of our physical environment"); S. REP. NO. 92-838, 92d Cong., 2d Sess. 8-9 (1972) (reasons for new pesticide law) ("increasing public concern [in 1960s] regarding the longer run public health and ecological effects of some of the chemical pesticides . . ."; continuing wide public discussion of adequacy of pesticide regulatory procedures).

3. Reorganization Plan No. 3 of 1970, *supra* note 2.

4. Rodgers, *The Persistent Problem of the Persistent Pesticides: A Lesson in Environmental Law*, 70 COLUM. L. REV. 567, 571 (1970).

5. *Id.* at 570.

could be expected to have substantial influence on the new agency's actions. With its presidential mandate to "ensure the protection . . . and enhancement of the total environment,"⁶ EPA was likely to be more concerned than was its predecessor about the long-term risks associated with pesticide use.

A second major change occurred in 1972, when Congress amended in its entirety the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁷ FIFRA had focused principally on product labeling requirements, which were designed to ensure that the farmer received a product of the effectiveness indicated on the label, with instructions for safe application.⁸ While retaining controls on labeling, the new law, called the Federal Environmental Pesticide Control Act (FEPCA),⁹ introduced, as its name suggests, an explicit environmental concern. Under FEPCA, the Administrator of EPA must consider the risks associated with use of a pesticide each time he makes a regulatory decision.¹⁰

EPA thus has had authority over pesticides for only a few years, and it is still in the process of implementing some of the provisions of FEPCA. Yet the intensity of its involvement during a period of increased environmental awareness, and the difficulty and importance of the policy issues it has faced, are significant enough to call for some evaluation of the way in which decisions have been made.

After summarizing the provisions of FEPCA that require decisions on environmental effects, this article describes the bureaucratic framework within which those decisions are made. It then presents a case history of one pesticide that EPA removed from the market, as an introduction to the types of problems that can arise in the pesticide regulation process. These problems next are analyzed in a more general context, the principal evaluation criteria being whether current procedures and recommended changes are likely to improve the usefulness of the information available to the decisionmaker, and to ensure that the decisionmaker, in considering all points of view, is ultimately responsive to broad public concerns in the complex process of balancing costs against benefits.¹¹ The specific policy recommendations that result from

6. Message of the President Accompanying Reorganization Plan No. 3 of 1970, *supra* note 2.

7. 7 U.S.C. §§ 135 *et seq.* (1970), *as amended*, 7 U.S.C. §§ 136 *et seq.* (Supp. III, 1973).

8. See Comment, *The Federal Environmental Pesticide Control Act of 1972: A Compromise Approach*, 3 *ECOLOGY L.Q.* 277, 278-81 (1973).

9. 7 U.S.C. §§ 136 *et seq.* (Supp. III, 1973), *amending* 7 U.S.C. §§ 135 *et seq.* (1970).

10. 7 U.S.C. §§ 136a(c)(5), 136a(d), 136d(b), 136d(c)(1) (Supp. III, 1973).

11. *Cf.* Roberts & Stewart, *supra* note 1, at 1648 ("Any general discussion of environmental policy . . . must ultimately be political in perspective—concerned with the design of processes through which . . . preferences can be solicited and expressed.").

this analysis do not eliminate the necessity of making difficult choices between food production and environmental protection. They may, however, help to focus attention on the regulatory procedures and organizational structures that so significantly affect these substantive value judgments.

I

THE DECISIONMAKING FRAMEWORK

A. *The Statute*

The comprehensive 1972 FEPCA established an important new standard¹² to be used by EPA in evaluating whether a pesticide should be allowed on the market. The standard, "unreasonable adverse effects on the environment," is defined in FEPCA to mean

any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.¹³

The balancing of risks and benefits required by this definition is of particular significance with regard to four major types of decisions that the EPA Administrator must make: registration, classification, cancellation, and suspension.

A pesticide cannot be sold in the United States unless it is registered with EPA.¹⁴ The applicant for registration must file any information requested by the Agency,¹⁵ and the Administrator is then directed

12. It has been suggested that the FEPCA standard is actually a codification of the test developed in earlier court decisions under FIFRA. *See Comment, supra* note 8, at 297, *citing* Environmental Defense Fund, Inc. v. Environmental Protection Agency, 465 F.2d 528 (D.C. Cir. 1972); Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1970).

13. This statutory standard is so vague as to amount to essentially no standard at all. At one time it might have been considered an unconstitutional delegation of legislative power, although it would probably be constitutional today. *Compare* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 529-42 (1935) (invalidating provision of National Industrial Recovery Act authorizing President to approve "codes of fair competition"), *with* United States v. Rock Royal Co-operative, Inc., 307 U.S. 533, 577 (1939) (upholding delegation to Secretary of Agriculture of power to fix "reasonable" milk prices). (The author is indebted to Professor Henry Monaghan of Boston University for suggesting this issue.)

As one response to the problem of broad delegation, courts have required agencies to limit their own discretion by adopting more precise rules. *See, e.g.,* Amalgamated Meat Cutters v. Connally, 337 F. Supp. 737, 758-59 (D.D.C. 1971) (three-judge court). *See generally* K. DAVIS, ADMINISTRATIVE LAW TREATISE § 2.00-5 (Supp. 1970). Apparently without explicit court prodding, EPA recently promulgated regulations that give somewhat more content to FEPCA's "unreasonable adverse effects" test. *See text accompanying notes 116-123 infra.*

14. 7 U.S.C. § 136a(a) (Supp. III, 1973).

15. *Id.* § 136a(c)(1) & (2).

to register the pesticide if he determines that it meets statutory requirements with regard to labeling and will not cause "unreasonable adverse effects on the environment."¹⁶ If he decides that registration is warranted, the Administrator must make an additional classification decision: a registered pesticide can be classified for restricted use—which allows the Administrator to impose the limitation that the product be applied by a certified applicator—if restrictions are necessary to prevent "unreasonable adverse effects."¹⁷ If the Administrator denies registration entirely, or if he wishes to change a product's classification, the applicant or other interested persons are entitled to a hearing.¹⁸

These registration and classification guidelines do not apply only to new pesticides. The Act requires that all products previously registered under FIFRA be re-registered and classified under the FEPCA standards between October 1974 and October 1976.¹⁹ As a result, EPA is currently in the process of formally applying the "unreasonable adverse effects" test to every pesticide sold in the United States.

Under the statute, registration of a pesticide does not end the inquiry concerning its environmental safety. The registrant is under a continuing statutory duty to submit any information it obtains concerning unreasonable adverse effects.²⁰ Other interested persons may provide EPA with relevant information,²¹ and the Agency's own scientists frequently review the available literature and conduct research on registered products and their chemical constituents.²² Hence there are several sources from which the Administrator may obtain new information that changes his previous assessment, made at the time of registration, that the benefits of a pesticide's use outweighed its risks. Moreover, a change in Administrators or in societal values may lead to a fresh evaluation of the seriousness that should be ascribed to predicted risks.

16. *Id.* § 136a(c)(5).

17. *Id.* § 136a(d)(1).

18. *Id.* §§ 136a(c)(6), 136a(d)(2), 136d(b). The statute does not provide for a hearing to protest an *initial* classification decision. A right to such a hearing might be implied from the statutory framework, but was not included in the recent EPA regulations on classification. *See* 40 C.F.R. § 162.11(d), at 40 Fed. Reg. 28284 (1975).

19. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 4(c)(2), 86 Stat. 97.

20. 7 U.S.C. § 136(d)(a)(2) (Supp. III, 1973).

21. Although the statute does not explicitly provide for EPA receipt of relevant information from interested persons other than the registrant, nothing in the statute forbids such receipt. Indeed, EPA may be under an implied statutory duty to receive offered information, since interested persons must be provided an opportunity to comment prior to registration, *id.* § 136a(c)(4), and must be allowed to participate in the formal public hearing that usually occurs when a current registration is questioned by the Administrator, *id.* § 136d(d).

22. *See* Criteria & Evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, Summary of Functions, Organization, and Responsibilities 1 (undated); Environmental Protection Agency, Strategy of the Environmental Protection Agency for Controlling the Adverse Effects of Pesticides 16-17 (May 1974).

To allow for these possibilities, FEPCA gives the Administrator authority to "cancel" a registration, the principal statutory test being "unreasonable adverse effects."²³ In addition, a registration is cancelled automatically after five years unless the registrant requests continuation of registration; through this provision, the risk/benefit balance for each registered pesticide is subject to periodic review.²⁴ Upon receiving notice of the Administrator's intention to cancel, the registrant may request a public hearing,²⁵ during which it may keep the questioned product on the market. At the close of the hearing, the Administrator issues a final decision on the cancellation question. If no hearing is requested, the cancellation notice becomes "final and effective" after thirty days.²⁶

Because hearings prior to cancellation may last several months,²⁷ FEPCA also contains a procedure for the immediate removal of a pesticide from the market. The Administrator may "suspend" a registration if necessary to prevent an "imminent hazard,"²⁸ a term defined by reference to the likelihood of "unreasonable adverse effects . . . during the time required for cancellation proceedings."²⁹ Suspension is a temporary measure, reserved for those situations in which immediate removal of the product seems required to avoid hazard. Suspension must always be accompanied or preceded by a notice of intention to cancel the registration,³⁰ since only cancellation can result in permanent removal of the product from the market. A registration can be suspended, at the Administrator's option, without any prior hearing³¹ or following an "expedited" hearing.³² In either case, a final decision to suspend does not affect the cancellation proceedings; a registration that has been suspended could later be reinstated, if the Administrator were to decide that his initial assessment of risks and benefits, in the context of the somewhat hasty suspension decision, was incorrect in light of the more fully developed evidentiary record presented at the cancellation hearing.

23. 7 U.S.C. § 136d(b) (Supp. III, 1973).

24. *Id.* § 136d(a)(1). The statute does not clearly indicate that review must occur when a registrant requests continuation of registration at the end of five years, but such a requirement should be implied. There otherwise would have been little reason for Congress to have included the five-year provision.

25. *Id.* § 136d(b).

26. *Id.*

27. The DDT cancellation hearing lasted approximately seven months. *See* Environmental Protection Agency, *Environmental Facts—DDT and the Environment* 4 (July 1974). The Aldrin-Dieldrin cancellation hearing had been in progress for a year and was incomplete when interrupted by suspension proceedings. *See* Environmental Protection Agency, *Environmental Facts—Aldrin and Dieldrin* 2-3 (January 1975).

28. 7 U.S.C. § 136d(c)(1) (Supp. III, 1973).

29. *Id.* § 136(1).

30. *Id.* § 136d(c)(1).

31. *Id.* § 136d(c)(3).

32. *Id.* § 136d(c)(2).

FEP-CA provides one final alternative for the Administrator, in situations in which the available evidence, although indicating some hazard, does not appear strong enough to justify issuance of a notice of intention to cancel. In these situations, the Administrator may simply call a hearing to assist him in deciding on the cancellation question.³³ Although this procedure still puts EPA in the position of casting some doubt on the product's safety, the adverse inference may be less strong than when EPA issues a notice of intention to cancel. Because this procedure has the same effect as the cancellation notice—both trigger full-scale, formal hearings—but avoids some of the stigma attached to the notice, it may be more widely used in the future.³⁴

As this summary of statutory provisions indicates, the “unreasonable adverse effects” standard is important at every stage in the pesticide regulation process. The Administrator is required to assess continuously the costs and benefits of a pesticide's use; beginning with the initial registration decision, he must make decisions on classification, cancellation, and suspension whenever he receives new evidence suggesting a change in the balance of factors. Beyond the broad definition in FEP-CA, however, the Administrator has no external guidelines to aid him in his frequent application of the “unreasonable adverse effects” test. Moreover, no workable internal Agency guidelines have yet emerged, in part because of the nature of the bureaucratic framework within which decisions are made on pesticide matters.

B. EPA Organization

In addition to the Administrator, who is nominally responsible for all pesticide decisions, two major groups within EPA play key roles in applying the unreasonable adverse effects test. The Office of Pesticide Programs (OPP) has primary regulatory responsibility over day-to-day pesticide matters, such as registration, evaluation, and monitoring. The OPP staff includes persons with administrative duties and many scientists and economists.

In contrast to OPP, the Office of General Counsel (OGC) has no day-to-day regulatory responsibilities. The lawyers in OGC must be consulted at crucial stages in the regulatory process, however, particularly when regulations are drafted and when the decision is being made on denial of registration or on initiation of cancellation or suspension action. Once an action is initiated and a hearing requested, the OGC attorneys act as proponents of the Agency's position, representing OPP, which is viewed as their client.³⁵ In preparation for a hearing, OGC

33. *Id.* § 136d(b)(2).

34. See Butler, *Federal Pesticide Law*, in *FEDERAL ENVIRONMENTAL LAW* 1254 (E. Dolgin & T. Guilbert eds. 1974).

35. Technically, OGC represents the person in charge of OPP, the Assistant

must develop evidence, which is derived principally from testimony by scientific witnesses. These witnesses need not be, and often are not, from OPP; many are from universities and other research institutions. At the hearing, in addition to presenting evidence, the OGC attorneys cross-examine opposing witnesses for the manufacturer, with technical advice sometimes provided by members of the OPP staff.

The overlapping responsibilities of OPP and OGC in drafting regulations and in litigating cases suggest that the personnel of the two groups must work closely together and that little could be accomplished without substantial cooperation between them. Decisionmaking authority on close questions, however, must ultimately rest with one group or the other, or with some higher level arbiter. Currently the most difficult decisions are made by an arbiter, the Administrator himself, but OPP has final authority over most questions leading to the final decision, including authority over the important staff recommendation to the Administrator on whether registration should be granted or continued.³⁶ On the other hand, the special expertise of OGC in legal matters means that OPP cannot act for long without OGC's concurrence, nor can OPP refuse to take action every time that OGC advocates it. In terms of Professor Allison's "governmental politics paradigm,"³⁷ OPP is situated on a formal "action-channel," but OGC has substantial bargaining advantages.³⁸ As the following discussion of the history of a single pesticide action makes clear, the policy that results from this bargaining cannot be viewed as an isolated decision by a "rational actor,"³⁹ but rather must be viewed as a product of "compromise, conflict, and confusion, . . . as something that emerges from intricate and subtle, simultaneous, overlapping games among players located in positions"⁴⁰ both inside and outside of EPA.

II

THE SUSPENSION OF ALDRIN AND DIELDRIN: A CASE HISTORY

Prior to their suspension in 1974, Aldrin and Dieldrin were two registered pesticides of a chemical group known as the chlorinated

Administrator for Water and Hazardous Materials. See Findings of Fact and Recommended Decision of the Administrative Law Judge on the Suspension of Aldrin-Dieldrin, 39 Fed. Reg. 37249 (1974) [hereinafter cited as Recommended Decision].

36. The staff recommendation is recognized officially as an important part of the decisionmaking process in EPA's recent regulations on pesticide registration. See 40 C.F.R. § 162.11(a)(5)(iii), at 40 Fed. Reg. 28282 (1975).

37. G. ALLISON, *ESSENCE OF DECISION* 162 (1971).

38. *Id.* at 168-69.

39. *Id.* at 4-6.

40. *Id.* at 162.

hydrocarbons, a group that includes DDT, which EPA cancelled in 1972.⁴¹ Although they were sold separately, Aldrin when applied broke down into Dieldrin, its metabolite;⁴² the two products could be considered one in terms of their impact on man and the environment. In recent years, the most important use of Aldrin and/or Dieldrin (hereinafter referred to as A/D) had been against soil insects that damage corn crops; other major uses included termite control and treatment of fruit tree foliage and vegetable seeds.⁴³ A/D was widely used in the United States in the early 1950s, but its use had declined gradually over the past two decades.⁴⁴ At the time of its suspension, A/D was used on only about eight to ten percent of the acreage devoted to corn in the United States,⁴⁵ and it was predicted that this use would have continued to decline in the future as soil insects developed more resistance to the compound.⁴⁶

The regulatory history of A/D between 1970 and 1975 provides a useful introduction to the way in which EPA has interacted with environmental groups, pesticide manufacturers, and the courts in implementing the cancellation and suspension procedures of FIFRA and FEPCA. On December 3, 1970, the day after EPA formally came into existence, and thus the day after authority over pesticides was transferred to EPA from the Department of Agriculture, the Environmental Defense Fund (EDF) petitioned the Agency to cancel and immediately to suspend all uses of A/D.⁴⁷ In March 1971, the EPA Administrator, then William Ruckelshaus, issued a notice of his intention to cancel most uses of A/D, but stated that the available evidence did not justify a finding of "imminent hazard," which was necessary for suspension.⁴⁸

Both manufacturers and environmentalists reacted to this decision. The manufacturers exercised their statutory rights to have a public hearing and to have a scientific advisory committee, selected by the National Academy of Sciences, evaluate the evidence.⁴⁹ Meanwhile,

41. See Environmental Facts—DDT and the Environment, *supra* note 27, at 1, 4.

42. See Environmental Facts—Aldrin and Dieldrin, *supra* note 27, at 1.

43. See Recommended Decision, *supra* note 35, at 37251.

44. *Id.* at 37250-51.

45. *Id.* at 37260.

46. *Id.* at 37251.

47. See Opinion of the Administrator, Environmental Protection Agency, on the Suspension of Aldrin-Dieldrin, 39 Fed. Reg. 37265, 37266 (1974) [hereinafter cited as Administrator's Opinion].

48. *Id.*

49. Recommended Decision, *supra* note 35, at 37249. Under the 1972 FEPCA, a registrant can no longer obtain scientific advisory committee consideration simply by requesting it. Instead, upon a party's request, the hearing examiner must decide whether referral of "relevant questions of scientific fact" to an advisory committee is either necessary or desirable. 7 U.S.C. § 136d(d) (Supp. III, 1973); see Butler, *supra* note 34, at 1259.

EDF appealed to the Court of Appeals for the District of Columbia Circuit for review of the Administrator's refusal to suspend A/D.

A year after the Administrator's initial decision, the scientific advisory committee and the court of appeals both issued written opinions. The committee agreed with the Administrator that suspension was not warranted and stated additionally that cancellation was not necessary for the major uses of A/D on corn soil, on seeds, and for termite control.⁵⁰ Two months later, the court of appeals acted, remanding the A/D case to the Administrator for a more detailed explication of costs and benefits,⁵¹ and indicating particular concern about the Administrator's "one-sentence discussion" of the carcinogenic risk.⁵²

The Administrator's response, in June 1972, was to reaffirm his intention to cancel A/D and to request further public comment on the suspension question.⁵³ In December 1972, the Administrator issued a supplemental opinion discussing the available evidence and concluding that suspension still could not be justified.⁵⁴ Finally, in August 1973, nearly two and one-half years after the Administrator's initial notice of intention to cancel, the hearing on the risks and benefits of A/D use began.⁵⁵

In August 1974, with the cancellation hearing in progress, a new EPA Administrator, Russell Train, issued notice of his intention to suspend A/D.⁵⁶ The manufacturer planned to begin production of ten million pounds of A/D in September, and the Administrator was concerned about the environmental risks involved in disposing of this quantity of chemicals if he decided in favor of cancellation when the hearing ended in an estimated four to five more months.⁵⁷ The timing of this notice may have been partly the result of an article, written by an environmentalist, critical of EPA for not suspending A/D; the article, which suggested congressional influence as a reason for EPA inaction, had appeared in the *Washington Post* just four days before the Administrator acted.⁵⁸ In addition to the manufacturing factor, the Administra-

50. Report of the Aldrin-Dieldrin Advisory Comm. to William D. Ruckelshaus, Administrator, Environmental Protection Agency, Mar. 28, 1972. The Committee recognized that its recommendations were based on incomplete data and recommended several additional studies on specific topics.

51. *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 465 F.2d 528 (D.C. Cir. 1972).

52. *Id.* at 537-38.

53. 37 Fed. Reg. 12904 (1972).

54. See Administrator's Opinion, *supra* note 47, at 37266.

55. See *id.*

56. Notice of Intention to Suspend and Findings as to an Imminent Hazard, 39 Fed. Reg. 37246 (1974) [hereinafter cited as Suspension Notice].

57. *Id.* at 37247.

58. Crane, *Politics and Pesticides: Dieldrin Gets a Reprieve*, *Washington Post*, July 28, 1974, § C, at 5.

tor's notice mentioned that the cancellation hearing had elicited new evidence on carcinogenicity, evidence that had not been available to former Administrator Ruckelshaus when he initially refused to suspend A/D.⁵⁹ In October 1974, two months after his notice of intention to suspend, following an expedited fifteen-day hearing and a recommendation of suspension by the administrative law judge presiding at the hearing,⁶⁰ the Administrator issued a final suspension order prohibiting further production and sale of A/D.⁶¹ This order was affirmed in 1975 by the Court of Appeals for the District of Columbia Circuit.⁶²

The length of the proceedings against A/D—from the first petition in 1970 to removal from the market nearly four years later—was caused in part by policy conflicts within EPA and in part by the difficult nature of the scientific issues presented by the case. As indicated by the conclusions of the A/D scientific advisory committee,⁶³ the predominant view within the scientific and technical community was that the need for substantial controls on A/D had not been established. The OPP technical staff, many of whom transferred from the Department of Agriculture and the Food and Drug Administration when EPA assumed responsibility for pesticide regulation,⁶⁴ largely shared this view. By contrast, the OGC attorneys for the most part favored the course of immediate action urged by EDF. The policy disagreements between the two groups were exacerbated by mutual suspicion: the OGC attorneys viewed OPP personnel as unnecessarily sympathetic to the pesticide industry's claims, while many in OPP perceived the younger OGC staff, which was less experienced in pesticide matters than the OPP staff, as overly concerned about environmental protection and eager to initiate legal action against beneficial pesticides.⁶⁵

Internal Agency division was thus an important factor underlying the length of the A/D regulatory proceedings. Equally significant, however, was the statute's approach to difficult scientific issues. The balancing of "economic, social, and environmental costs and benefits"

59. Suspension Notice, *supra* note 56, at 37247.

60. Recommended Decision, *supra* note 35, at 37265.

61. Administrator's Opinion, *supra* note 47, at 37272. The Administrator's order allowed continued sale and use of existing stocks of A/D manufactured prior to August 1974, because of the environmental risks involved in attempting to dispose of the product by other than normal use patterns. *See id.*; Suspension Notice, *supra* note 56, at 37248, 37249.

62. Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F.2d 1292 (D.C. Cir. 1975).

63. *See* text accompanying note 50 *supra*.

64. *See* Carter, *Controversy over New Pesticide Regulations*, 186 SCIENCE 904 (1974).

65. *See id.*; Testimony of William A. Butler, *Hearings on Pesticide Oversight Before the Subcomm. on Environment of the Senate Comm. on Commerce*, 93d Cong., 2d Sess., ser. 93-109, at 34 (1974).

required by the statute⁶⁶ forces the Administrator to evaluate evidence for which standards of evaluation may be lacking. With regard to the risks of continued A/D use, for example, the Administrator had two types of evidence available to him: evidence of cancerous tumors developing at virtually all dosage levels in laboratory animals,⁶⁷ and evidence that A/D is present in significant amounts in virtually all human adipose (fatty) tissue, with particularly high concentrations in fetuses and infants.⁶⁸ The problem facing the Administrator was whether and to what extent the laboratory data on cancer could be extrapolated to make predictions about the long-term effects on man.

The manufacturer argued that extrapolation could not occur without some knowledge of the mechanism by which the chemical induced tumors, some evidence of causation beyond statistical association. It additionally argued that conclusions on human carcinogenicity should not be drawn until there was at least one incident of cancer developing in man because of the chemical.⁶⁹ The administrator responded firmly to the latter suggestion, stating "[w]e reject the 'body count' approach to protection against cancer."⁷⁰ He also noted that in any event human data might be impossible to obtain, since the entire population has been exposed to A/D, meaning that there cannot be a valid control group.⁷¹ Responding to the argument that causation must be shown, the Administrator indicated that, in the context of his statutory mandate to protect the population from the "unreasonable adverse effects" of a pesticide, he would not be inhibited from acting by the inconclusive nature of current extrapolation techniques:

Our knowledge of cancer mechanisms is still imperfect, and it may take many years before we understand the mechanisms with certainty. . . . It is the carcinogenic effect of Aldrin-Dieldrin, not the mechanism that concerns us here.⁷²

The Administrator was presented with similarly inconclusive evidence in his evaluation of the benefits of A/D use. The principal issue was whether the unavailability of A/D would lead to crop yield reductions in corn. The estimates of crop reductions prepared by a private contractor for the manufacturer were ten to fifteen times as high as the

66. Federal Environmental Pesticide Control Act, 7 U.S.C. § 136(bb) (Supp. III, 1973), quoted in full at text accompanying note 13 *supra*.

67. See Administrator's Opinion, *supra* note 47, at 37267-69.

68. See *id.* at 37270.

69. See *id.* at 37269.

70. Suspension Notice, *supra* note 56, at 37248.

71. See *id.*; Administrator's Opinion, *supra* note 47, at 37270. See also *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 510 F.2d 1292, 1299 (D.C. Cir. 1975).

72. Administrator's Opinion, *supra* note 47, at 37269.

estimates of a government economist.⁷³ None of the estimates was based on actual monitoring data; moreover, they were rather based on predictions by local entomologists⁷⁴ and farmers,⁷⁵ making the reliability of all of the estimates open to question.⁷⁶ The Administrator nevertheless concluded "that the macroeconomic impact of the proposed suspension order would be almost negligible."⁷⁷ This conclusion apparently was based on the greater methodological validity of the government economist's study and on the tendency of both studies to underestimate the efficacy of available alternative pesticides and to ignore the extent to which farmers might have used A/D as a "prophylactic" measure when protection was not needed.⁷⁸

In comparing the risks and benefits, the Administrator was forced to make a decision on whether to remove A/D from the market without having fully satisfactory evidence available. This evidentiary inadequacy cannot be attributed to the fact that the Administrator was forced to make the decision on suspension after an expedited fifteen-day hearing. The transcripts and other evidence from the year-long cancellation proceedings were incorporated by reference into the suspension proceedings,⁷⁹ and the same administrative law judge presided at both hearings before recommending suspension to the Administrator.⁸⁰ Hence the substantive problems in the A/D case must be examined in a wider context, as representative of difficulties that may be inherent in current procedures for regulating pesticides or, more fundamentally, that may be inherent in any attempt to formulate legal answers to questions of great scientific complexity.

III

THE ADJUDICATORY APPROACH

As the history of the suspension of A/D indicates, final decisions with regard to "unreasonable adverse effects" usually occur only after a pesticide has undergone intensive scrutiny in formal adversary hearings.⁸¹ Within the legal system as a whole, the adversary model of

73. See *id.* at 37271.

74. See Recommended Decision, *supra* note 35, at 37260 (government economist's study).

75. See *id.*; Administrator's Opinion, *supra* note 47, at 37271 (private contractor's study). The questionable ability of farmers to make accurate, unbiased predictions was conceded by the manufacturer. *Id.*

76. See Recommended Decision, *supra* note 35, at 37260 ("We have been casting about in these proceedings for a reliable estimate of the reduction in yield . . .").

77. Administrator's Opinion, *supra* note 47, at 37271.

78. See *id.*

79. See Recommended Decision, *supra* note 35, at 37249.

80. See Administrator's Opinion, *supra* note 47, at 37265.

81. See *Pax Co. v. United States*, 454 F.2d 93, 96 (10th Cir. 1972) (FIFRA

factfinding generally is viewed as the best method of eliciting the "truth," or at least of approaching that goal. The Supreme Court has stressed the utility of "a clash of adversary argument"⁸² as a means of "exploring every aspect of a multifaceted situation embracing conflicting and demanding interests"⁸³ and of "illuminati[ng] difficult . . . questions."⁸⁴ In pesticide matters, however, the process of factfinding seems substantially different from both the jury trial process and the appellate court decisionmaking process, suggesting that there may be less value in an unmodified adversary approach to pesticide issues.⁸⁵

The most important differences between pesticide proceedings and traditional court proceedings concern the nature of the facts and of the ultimate decision. The paradigm court trial looks backward in time to consider events that already have occurred; the normal assumption is that all relevant facts can be discovered. A pesticide hearing, by contrast, looks forward in time to predict the future; the assertions of the parties with regard to the likely harm from, or the need for, a pesticide never can be fully proved. The truthfulness of witnesses with regard to past facts is rarely questioned in a pesticide proceeding; rather, the focus is on how various expert witnesses interpret the past facts—usually experimental laboratory data—and on what conclusions they draw from the past in predicting the future.⁸⁶

These differences in the nature of the facts are reflected in differences in the nature of the ultimate decision. The decisionmaker at a court trial commonly is called the "factfinder," and he is not supposed to rely on either his technical expertise or his personal beliefs on policy questions in arriving at a decision on the merits. In a pesticide matter, by contrast, the decisionmaker, the EPA Administrator, is expected to have technical competence in the area and, more importantly, is expected to make essentially political tradeoffs between ecological and human health considerations on one side and economic and food supply considerations on the other. As the Supreme Court has noted in a related context, the procedures developed in courtroom trials "are of limited utility" in making such "delicate judgment[s]."⁸⁷

procedures are "careful, deliberate and protracted, so that no product is cancelled unless there has been abundant and extensive due process").

82. *United States v. Fruehauf*, 365 U.S. 146, 157 (1961).

83. *Id.*

84. *Baker v. Carr*, 369 U.S. 186, 204 (1962).

85. An attorney for EDF has testified that "the heart of the [pesticide regulation] problem . . . is, simply stated, whether an adversary legal proceeding is the best way to regulate problem pesticides." Testimony of William A. Butler, *supra* note 65, at 36.

86. *See, e.g., Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 510 F.2d 1292, 1298-1300 (D.C. Cir. 1975) (disagreement between EPA and manufacturer as to interpretation of laboratory tests and extrapolation from tests to conclusions about danger to man in A/D case).

87. *United States v. Topco Associates, Inc.*, 405 U.S. 596, 609, 612 (1972)

Despite the differences between trials and pesticide hearings, it is plain that some adversary procedures are necessary in the pesticide context, since manufacturers, environmentalists, and Agency personnel may all wish to present data, hypotheses, and conclusions for the Administrator to consider. The differences indicate, however, that the customary adversary procedures of a trial should be modified to serve the particular purposes of a pesticide hearing. An examination of the A/D and other cases suggests two areas in which relatively minor procedural modifications could significantly improve the decisionmaking process.

A. *The Problem of Delay*

One major problem with the adversary approach is the time that it takes, a point strikingly illustrated by the four-year delay between the EDF petition and the removal of A/D from the market. Unless suspension action is taken, as finally occurred in the A/D case, a product can remain on the market throughout cancellation proceedings, even though the Administrator has indicated, by issuing notice of his intention to cancel, that he believes "unreasonable adverse effects" are likely to result from the product's continued use.⁸⁸ This statutory framework builds an incentive into the system for the manufacturer to prolong the hearings as long as possible.⁸⁹

The Agency, and environmental groups intervening in favor of cancellation, might seem at first to have counter-incentives in favor of shortening the hearing time, motivated by budget and manpower constraints as well as by concern about the adverse effects of continued use of the pesticide during the hearing. A concern with winning the case, however, may be of more immediate importance than general budgetary considerations to the lawyers litigating the cancellation action. They may be unwilling to accept a possibility of removing the pesticide from the market more quickly, if they win the case after a somewhat shortened hearing, in exchange for incurring what they may perceive as a greater risk of losing the case, and thus a greater risk of the pesticide remaining permanently on the market, if they introduce less than all of the supporting evidence in an effort to shorten the hearing. Therefore, the incen-

(antitrust). See also Boyer, *Alternatives to Administrative Trial-Type Hearings for Resolving Complex Scientific, Economic, and Social Issues*, 71 MICH. L. REV. 111, 119 (1972) ("trial-type procedures may well be inherently ill-suited to the job" of finding the optimal tradeoff between variables).

88. See Federal Environmental Pesticide Control Act, 7 U.S.C. § 136d(b) (Supp. III, 1973).

89. See Testimony of William A. Butler, *supra* note 65, at 36. The Administrator implied that such an attempt might have been a factor in the length of the A/D hearings. See Administrator's Opinion, *supra* note 47, at 37266 & n.4.

tives for those seeking cancellation may be the same as the incentives for those opposing it: to place in the record every available item supporting their positions.⁹⁰ An analogous incentive structure should operate when the Administrator gives notice of his intention to deny registration or to change a classification.

One solution to the problem of lengthy hearings would be to accord the administrative law judge wide discretion to exclude evidence he deems not to be helpful. This solution, however, might be ineffective in practice if the judge is reluctant to exercise his discretion. This reluctance may stem from the difficulty of knowing in advance what is and is not useful and the concomitant concern about reversal by an appellate court for excluding probative evidence.⁹¹ A similar concern may undermine the recent Agency effort to shorten the length of hearings by allowing the judge to take official notice of facts developed in earlier pesticide proceedings.⁹² The understandable risk aversion of the hearing officer may make any discretionary powers of little actual value in curtailing the length of the hearings.⁹³

A solution not subject to these problems of discretion would be establishment by the Administrator of a maximum time limit for the hearing in his notice of intention to cancel or deny a registration or to change a classification, the time to be divided equally between proponents and opponents. The Administrator sets such a time limit for the A/D suspension hearing,⁹⁴ and a similar action for other hearings does not seem barred by any provision of the statute. The order establishing the maximum time limit could allow for an extension to be granted by the Administrator in exceptional cases, with the question of an extension to be first argued before, and a recommendation made by, the administrative law judge.

A maximum limit would force the parties to budget their time carefully, to present only their best witnesses, and to discuss only the most important issues, thereby focusing the attention of the decision-maker on the strongest arguments for each side. With regard to A/D, for example, evidence was presented in the year-long cancellation pro-

90. The EPA lawyers' tendency to do this during the A/D cancellation hearing was termed the "kitchen sink approach" by attorneys for the manufacturer—presumably because "everything but the kitchen sink" was placed in the record by EPA. Interview with Herbert L. Perlman, Chief Administrative Law Judge, United States Environmental Protection Agency, Washington, D.C., Jan. 28, 1975.

91. See MCCORMICK'S HANDBOOK OF THE LAW OF EVIDENCE § 350, at 841 (2d ed. 1972) [hereinafter cited as MCCORMICK].

92. 40 C.F.R. § 164.81(e) (1975).

93. Cf. MCCORMICK, *supra* note 91, § 60, at 138 (trial judges hearing case without jury lean toward admission of evidence).

94. See Suspension Notice, *supra* note 56, at 37246.

ceeding on several different types of costs and benefits for the several different uses of the pesticide, but all parties seemed to agree that the crucial and ultimately decisive issues were "cancer and corn."⁹⁵ Thus, in addition to assuring a more rapid resolution of whether a product should be taken off the market, the maximum time limit, by structuring incentives for careful planning into the hearing process, might lead to a hearing record that is more useful to the Administrator than is the current, virtually unlimited record.

Limiting the duration of hearings would remove only one, albeit a significant one, of the impediments to quick resolution of "unreasonable adverse effects" questions. In the A/D case, there was more than a two year delay between the Administrator's notice of intention to cancel and the commencement of the hearing. Approximately one year of this time apparently was spent waiting for decisions by the court of appeals and the scientific advisory committee, another six months waiting for a final decision on the suspension question, and a final half-year preparing for the hearing.

Many of these delays, aggregating to years of extra time in which the fate of a pesticide is uncertain, do not seem necessary. As soon as a notice of intention to cancel or deny registration or to change a classification is issued and a hearing requested, preparations for that hearing should begin. The hearing could be held within a few weeks, since much of the Agency evidence is developed before the notice is issued. Except for the time the parties may need to file and respond to an interlocutory court appeal, such an appeal should not interfere with the basic Agency proceeding if that proceeding must reach a final resolution regardless of the appellate court outcome.⁹⁶ Similarly, the referral of some technical questions to a scientific advisory committee should not foreclose the concurrent consideration of these and other issues at the hearing. The scientists are required under the statute to report back within sixty days after the referral of questions to them,⁹⁷ a deadline that, if adhered to,⁹⁸ should help the hearing participants to meet a maximum time limit. Such a time limit, combined with a determined effort to avoid all unnecessary delay, could reduce significantly the period currently required to reach final regulatory decisions.

95. See Administrator's Opinion, *supra* note 47, at 37266.

96. For example, an appeal of a suspension decision should not affect a cancellation proceeding, since the cancellation outcome is not dependent on the appellate result with regard to suspension. See text accompanying note 32 *supra*.

97. Federal Environmental Pesticide Control Act, 7 U.S.C. § 136d(d) (Supp. III, 1973).

98. See Butler, *supra* note 34, at 1260 (extensions might have to be granted because of the difficulty of making a scientific report in 60 days).

B. *Expert Testimony and Cross-Examination*

In addition to presuming that the parties should have time to present all conceivably relevant evidence, the adversary system generally allows the parties to present any witnesses they desire. Since most of the exclusionary rules of evidence need not be followed in federal administrative proceedings,⁹⁹ including FEPCA proceedings,¹⁰⁰ there are essentially no limits imposed from outside the Agency on the types of evidence that parties to a pesticide hearing can introduce.

Expert testimony by scientists and economists is the most important type of evidence presented at pesticide hearings. These experts are usually in the best position to evaluate the overall risks and benefits of a pesticide. The individual farmer or consumer could base testimony only on first-hand observations, which on a small scale would be of little value to an Administrator charged with assessing societal effects. Expert testimony has inherent difficulties, however, which EPA has some latitude to mitigate within the relatively flexible framework of FEPCA.

The major problem with expert testimony in any adversary context is that each party naturally selects as its expert witnesses those persons most likely to support the party's case, rather than the most knowledgeable or best qualified persons.¹⁰¹ This problem becomes particularly significant in an area like cancer prediction, where competing hypotheses abound concerning how the disease is caused, the relationship between dosage and response,¹⁰² and extrapolation from laboratory results to man.¹⁰³ Rather than seeking to provide the factfinder with a scientific consensus on such issues, the parties may present sharply conflicting viewpoints in an understandable attempt to strengthen their opposing positions.

The most important safeguard against abuse of the right to present expert witnesses is the other party's right to cross-examine them. The administrative law judge who presided at the A/D hearings found cross-examination quite helpful to him in evaluating scientific evidence and deciding how much weight to give particular testimony in his final decision.¹⁰⁴ Reliance on cross-examination to elicit problems with an expert's testimony, however, may depend on the cross-examining lawyer himself becoming an expert. Although Agency or private lawyers specializing in an environmental area are likely to develop substantial

99. See McCORMICK, *supra* note 91, § 349.

100. 40 C.F.R. § 164.81(a) (1974).

101. See generally McCORMICK, *supra* note 91, § 17, at 38.

102. See Administrator's Opinion, *supra* note 47, at 37267 & n.35 (four basic models correlating dosage to response).

103. See *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 510 F.2d 1292, 1299 (D.C. Cir. 1975).

104. Interview with Herbert L. Perlman, *supra* note 90.

scientific competence, they nevertheless have been trained professionally, not in science, but in law.¹⁰⁵

Even expertise on the part of the cross-examiner, moreover, will not ameliorate a more basic defect of cross-examination. Confronted with hostile questions on the validity of his observations or conclusions, a witness will often follow the natural impulse of insisting more vigorously that he is correct, becoming more reluctant to acknowledge deficiencies that, he may believe, will unfairly undermine the weight given to his testimony by the decisionmaker. In the usual trial of issues of past fact, this tendency of cross-examination to emphasize conflicts in testimony is considered desirable; the factfinder can draw on his own experiences in similar situations, as well as on his observations of the witnesses' demeanor, in deciding which testimony to believe. The decisionmaker in a pesticide proceeding, by contrast, often lacks an independent basis for choosing between conflicting experts, and inferences drawn from scientific witnesses' demeanor may provide little guidance. Conflicting scientific witnesses may both be telling the "truth"; they may simply have different opinions, honestly derived, concerning future probabilities. With scientific testimony, it would be desirable to emphasize areas of agreement, rather than the areas of conflict that are emphasized by cross-examination.¹⁰⁶

Apparently in recognition of these problems with expert testimony in the adjudicatory setting, FEPCA provides for a scientific advisory committee to which the hearing judge can refer "relevant questions of scientific fact."¹⁰⁷ The committee must come from the National Academy of Sciences (NAS), and the EPA Administrator is required to make arrangements with NAS to assure that, in general, the panels selected will be "objective."¹⁰⁸ Under the statute, however, a panel can be convened only if a party requests it, suggesting that the request for a committee could become merely a tactical device in the adversary framework, with requests on specific issues coming from parties who think that the balance of scientific, or NAS, opinion favors their positions on those issues. A second statutory problem with scientific advisory committees is that they need only publish their final report, without detailing internal deliberations and thought processes.¹⁰⁹ The final report

105. For a discussion of some of the differences between the scientific and legal perspectives, see text accompanying notes 147-149 *infra*.

106. See McCORMICK, *supra* note 91, § 17, at 38. *But see* Boyer, *supra* note 87, at 128-29 (advantages of cross-examination in administrative hearings).

107. 7 U.S.C. § 136d(d) (Supp. III, 1973); *see* note 49 *supra*.

108. 7 U.S.C. § 136d(d) (Supp. III, 1973). One authority has criticized the way in which the Administrator has implemented this statutory duty, claiming that "[t]o date a preconceived ideological position has not been a disqualifying factor" for advisory committee membership. Butler, *supra* note 34, at 1259-60 & n.117.

109. Butler, *supra* note 34, at 1260.

may tend to be conclusory in nature, with the scientists seeking to support particular positions they have taken rather than striving to present a balanced picture of the evidence for the decisionmaker. The report of the panel in the A/D case, for example, took explicit stands on cancellation and suspension,¹¹⁰ stands that may have influenced their presentation of the data.

In the absence of statutory modifications aimed at eliminating these problems with scientific advisory committees, the Agency can act informally within the statute to mitigate some of the difficulties with expert testimony. The administrative law judge could call experts of his own to testify¹¹¹ under the provision of FEPCA that authorizes the Administrator to seek advice in connection with cancellation and suspension proceedings.¹¹² Although these experts might represent particular viewpoints, and should probably be subject to questioning by both sides, the fact that they were called by the neutral factfinder, with the goal of assisting him, may lead to a balanced presentation of the issues, free from the strictures of an advocate's perspective.¹¹³

Even if the hearing officer calls experts of his own, the parties can be expected to continue to present their witnesses as well. Another informal procedure, however, may reduce the extent to which this adversary presentation emphasizes conflicts between experts. After all sides present individual testimony on a particular issue, the administrative law judge could call together the scientists for each side, along with any judge-appointed experts, for a panel discussion of the issue. At such a discussion, the scientists could explore their areas of agreement and uncertainty, with the goal of focusing the hearing record on their areas of disagreement and the precise differences in hypotheses, methodology, or data interpretation that led to disagreement. A provision might be made for limited attorney questioning of the panel, largely to help focus the record on the most relevant questions, but attempts at individual cross-examination should be barred as inconsistent with the purpose underlying the convening of the panel. This procedure might save a substantial amount of hearing time that otherwise would be spent in cross-examination on points not actually at issue, thus making it more

110. See text accompanying note 50 *supra*.

111. Cf. McCORMICK, *supra* note 91, § 17, at 38-39 (same proposal in context of court trial).

112. 7 U.S.C. § 136s(b) (Supp. III, 1973).

113. Judge Leventhal of the United States Court of Appeals for the District of Columbia Circuit recently made a similar proposal for scientific experts, called by appellate courts, to aid them in establishing "the relative significance of petitioners' scientific contentions . . . [.] in understanding problems of scientific methodology and in assessing the reliability of tests . . . in light of specific criticisms." Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. PA. L. REV. 509, 550 (1974).

feasible to set maximum time limits on the hearing. More importantly, by isolating the genuine issues, it should present the decisionmaker with a clearer picture of the value choices he must ultimately make in weighing the costs and benefits.¹¹⁴

IV

THE RULEMAKING APPROACH

An alternative to making decisions concerning "unreasonable adverse effects" on the basis of an adversary presentation of evidence would be for the Agency to receive evidence or develop data itself and then to make decisions based upon guidelines specifying the action to be taken for various categories of data. This rulemaking model of decisionmaking might have significant advantages over the ad hoc, case-by-case approach that has characterized EPA's pesticide decisionmaking in the past.¹¹⁵ If adequate standards could be established in writing, they would give manufacturers and the public prior notice of the situations in which a pesticide would be considered unsafe. Such standards also would allow for more effective judicial review of Agency decisions and would minimize the long delays and the obfuscation of issues by conflicting experts that are problems with the adversary system. In addition, the existence of general rules provides a check on the Agency's discretion to discriminate or show favoritism in individual cases, thus tending to ensure that broad societal considerations dominate the decisionmaking process.¹¹⁶

These advantages were doubtless important factors behind EPA's recent decision to shift toward greater reliance on written rules in making determinations of unreasonable adverse effects. In July 1975, the Agency promulgated comprehensive regulations for the registration and classification of pesticides under FEPCA.¹¹⁷ In a section that is likely to be of major importance, the regulations establish criteria—a "screening mechanism," in the words of one Agency official¹¹⁸—that apply to cancellation decisions as well as to registration. The mechanism used is a rebuttable presumption against new or continued registration of a pesticide with high acute toxicity characteristics, immediate danger from inhalation, skin contact, or residues in human or animal food, or with any chronic toxicity characteristics, which primarily in-

114. See generally McCORMICK, *supra* note 91, § 17, at 39-40.

115. See Butler, *supra* note 34, at 1256.

116. See generally Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1698-1702 (1975).

117. 40 C.F.R. §§ 162.1-162.23, at 40 Fed. Reg. 28267-86 (1975).

118. Testimony of James L. Agee, EPA Assistant Administrator for Water and Hazardous Materials, before the House Agricultural Committee, May 1975, in 6 BNA ENVIR. REP. (Current Developments) 203 (1975).

volve long-term danger from cancerous tumor formation or genetic mutation.¹¹⁹

Once a presumption is raised, the proponent of registration has a rebuttal opportunity to show that the toxic effects are not significant.¹²⁰ If the Administrator is not persuaded that the proponent has met this "affirmative burden of proof,"¹²¹ he issues notice of his intention to deny or cancel registration or to hold a hearing on the registration question.¹²² For those pesticides that meet the initial standards for registration, or for which rebuttal of the presumption against registration is successful, the regulations establish separate toxicity standards for classification of products into general and restricted use categories.¹²³

The new regulations thus require three distinct decisions: on the raising of a presumption against registration; on the success of an attempt to rebut a presumption; and on classification. This sequential decisionmaking process could be used by EPA as the basis of a systematic approach to recurrent problems of pesticide regulation. Such an approach would be particularly useful in gathering information on which decisions are based and in allocating decisionmaking responsibility between personnel levels within the Agency.

A. Sources of Information

In the determination of whether to raise a presumption against a pesticide, the initial stage of review under the new regulations, the major issues faced by EPA are well-defined and can be objectively resolved: whether the pesticide's acute toxicity exceeds numerical standards and whether any chronic toxicity effects have been shown in laboratory experiments or in man.¹²⁴ At this stage, although some data from sources other than the manufacturer may be used by EPA,¹²⁵ the regulations contemplate primary reliance on information supplied by the manufacturer. The obvious interest of the manufacturer in a particular result suggests that the Agency should, in addition, conduct tests of its own, but budget constraints may prevent an adequate EPA research effort.¹²⁶ As an alternative to direct Agency research, the regulations

119. 40 C.F.R. § 162.11(a)(3)(i) & (ii), at 40 Fed. Reg. 28281-82 (1975).

120. 40 C.F.R. § 162.11(a)(4)(i) & (ii), at 40 Fed. Reg. 28282 (1975).

121. 40 C.F.R. § 162.11(a)(2), at 40 Fed. Reg. 28281 (1975).

122. 40 C.F.R. § 162.11(a)(5)(ii), at 40 Fed. Reg. 28282 (1975). For a discussion of procedures that follow issuance of a notice of intention to deny or cancel registration or to hold a hearing, see text accompanying notes 25-34 *supra*.

123. 40 C.F.R. § 162.11(c), at 40 Fed. Reg. 28283-84 (1975).

124. 40 C.F.R. § 162.11(a)(3)(i) & (ii), at 40 Fed. Reg. 28281-82 (1975).

125. See text accompanying notes 21-22 & note 21 *supra*.

126. FEPCA gives EPA explicit authority to undertake research. 7 U.S.C. § 136r(a) (Supp. III, 1973). It appears that the Agency's current research is directed toward the broad problems of developing models and methodologies for testing and

and accompanying proposed guidelines prescribe in detail the testing procedures that the manufacturer must follow and the types of information that must be supplied.¹²⁷ With these specifications, reliance on the manufacturer, although less than ideal, may be sufficient at the first stage of decisionmaking.

The adequacy of the information available to EPA must be judged by different standards, however, once the presumption of adverse effects is triggered. The manufacturer then has the burden of proving that the risk indicated by the raising of a presumption is not "likely" to be "significant."¹²⁸ As the quoted words indicate, the decision that EPA must make at this second stage is more a judgmental one, not readily resolved by reference to an objective standard. An interpretation of the data is required, and often, particularly in cancer matters, several conflicting conclusions or hypotheses legitimately may be drawn from the the same facts. As a consequence, the manufacturer can be expected to take an adversary position at the second stage, seeking to influence the decisionmaker's evaluation by presenting scientific testimony or other interpretive evidence on the minimal nature of the risks.

In light of the qualitatively different evidence that the manufacturer will present at the second, rebuttal, stage, EPA's ability to obtain opposing views becomes important. Without such views, the decisionmaker would receive a one-sided presentation of the ways in which the data can be interpreted. This need for opposing evidence suggests that no rulemaking approach to pesticide decisions can fully replace adjudication so long as EPA is dependent on the pesticide manufacturer for much of its data. Under the regulations, individual scientists or others within EPA or from outside the Agency who believe that registration should be denied will have no structured opportunity, comparable to the manufacturer's, to present their views, although in practice such views could be presented informally. Since one purpose of the regulations is to avoid the formal adversary process, informal channels of communication should be encouraged, and the person deciding whether a presumption has been rebutted should make every effort to ensure that he receives a balanced picture of the evidence. As long as the adversarial quality of the evidence is recognized and both sides are considered, the rebuttal procedure can provide a useful forum for initial exploration of a pesti-

understanding the effects of pesticides and developing alternatives to chemical pest control. The only individual pesticides studies are those for which litigation is pending and those that seem "suspect." See Strategy of the Environmental Protection Agency for Controlling the Adverse Effects of Pesticides, *supra* note 22, at 16-17, 32-34.

127. See regulation governing test data requirements, 40 C.F.R. § 162.8, at 40 Fed. Reg. 28275-77 (1975), and proposed guidelines, 40 C.F.R. §§ 162.40-162.96 & Appendix, at 40 Fed. Reg. 26804-928 (1975).

128. 40 C.F.R. § 162.11(a)(4)(i) & (ii) (Supp. 1975).

icide's hazards, a forum that avoids some of the more objectionable features of the adjudicatory approach.¹²⁹

B. Levels of Decisionmaking

Someone at EPA must decide if a presumption against registration should be raised and, once raised, if it has been successfully rebutted. Although the Administrator has formal statutory authority over registration matters,¹³⁰ and the regulations state that he will make the final decision on whether the presumption has been rebutted,¹³¹ he clearly cannot be expected to study personally the factors for and against registration for each pesticide that has a presumption raised against it. Even if the number of such pesticides is small, the evaluation of all of the technical evidence for each is a formidable and time-consuming task. Hence the Administrator is likely to rely on a recommendation from a subordinate individual or group within the Agency, just as he must rely on an administrative law judge to conduct formal hearings and make a recommendation in situations like the A/D suspension.

Basic registration decisions within EPA usually are made by lower level personnel at OPP. At the first stage of decisionmaking under the regulations, when the question is a relatively objective one,¹³² a decision at this lower level seems appropriate as a means of conserving the time of those at higher levels of authority. At the second stage, however, when the issues become more subjective,¹³³ a decision by civil service personnel with relatively limited perspectives¹³⁴ does not seem desirable.

The decision whether a presumption against registration has been successfully rebutted is a difficult one. By raising the presumption the Agency indicates its belief that there is a high probability of significant danger, whereas the manufacturer's attempted rebuttal is an indication of its belief that the hazard is less significant than the initial tests suggest. The decision is thus likely to require a complex evaluation based upon competing, and perhaps equally tenable, explanations of the data. Moreover, the policy implications of the decision often may extend beyond the individual case, since manufacturers and lower level personnel are likely to view past EPA decisions as setting informal precedents. A decision under these circumstances, as Professor Stewart has noted in

129. Cf. Boyer, *supra* note 87, at 113 (suggesting usefulness of "hybrid forms of procedure incorporating various elements of both adjudication and rule-making").

130. Federal Environmental Pesticide Control Act, 7 U.S.C. § 136a(c)(5) (Supp. III, 1973).

131. 40 C.F.R. § 162.11(a)(2), at 40 Fed. Reg. 28281 (1975).

132. See text accompanying note 124 *supra*.

133. See text accompanying note 128 *supra*.

134. Cf. G. ALLISON, *supra* note 37, at 81 ("parochial priorities and perceptions" of bureaucrats in interagency context).

a more general context, "is an inherently discretionary, ultimately political procedure . . . [, one that] clearly do[es] not turn on technical issues that can safely be left to the experts."¹³⁵

These factors suggest that whenever a presumption is raised and an attempt made at rebuttal, decisionmaking or recommendation authority within OPP should be given to persons able to place the significance of the risk presented by a particular pesticide within a broad policy context. In order to ensure that there is a conscious policy choice, the decision or recommendation should be made at a level at which the person responsible is directly accountable to the Administrator and to the political institutions that give the Agency its authority to regulate pesticides. Such a shift in authority would not be without costs, of course; lower level personnel might resent the change, which in turn could cause a decline in employee morale and make lower level positions appear less attractive. But the fact that the shift in authority would occur as the result of a written rule might help to minimize friction,¹³⁶ with the presumption in the regulations serving as an objective signal that a higher level of decisionmaking is warranted by the increased importance of the ultimate decision.

V

ORGANIZATIONAL CHANNELS AND SUBSTANTIVE GUIDELINES IN PESTICIDE DECISIONMAKING

The preceding discussion on allocation of decisionmaking responsibility under the regulations focused on differences between higher and lower levels of authority within the group that administers EPA's pesticide programs on a day-to-day basis. A broader issue is whether that group (OPP) or some other group (such as OGC) should have final authority with regard to the most important decisions concerning the use of pesticides. The Administrator has nominal authority over all questions of "unreasonable adverse effects,"¹³⁷ but, as indicated above, the time required for resolving these questions is such that a person with many responsibilities in addition to pesticides clearly could not make all

135. Stewart, *supra* note 116, at 1684.

136. In a somewhat analogous situation, the Food and Drug Administration recently promulgated a regulation specifying the circumstances under and the procedures by which a lower level employee's decision will be reviewed at a higher level. See 21 C.F.R. § 2.17, at Fed. Reg. 22995-96 (1975). This regulation appears aimed at ensuring orderly consideration of issues by higher level personnel while avoiding the friction engendered by discretionary review of only some lower level decisions. See 40 Fed. Reg. 22961 (1975) (FDA explanation of regulation).

137. Federal Environmental Pesticide Control Act, 7 U.S.C. §§ 136a(c)(5), 136a(d), 136d(b), 136d(c)(1) (Supp. III, 1973).

of the key decisions. Delegation of the Administrator's power is thus inevitable.

The way in which the Administrator has delegated authority, and alternatives to the present structure, can be analyzed from two related perspectives. First, delegation occurs through organizational channels, and the channels selected are likely to have an effect on the final outcome. Second, some explicit or implicit guidelines usually accompany any delegation of power; the way the person delegating responsibility thinks about problems is likely to affect his subordinates' approaches to similar problems, if effective ways of communicating those modes of thought can be developed.

A. *Scientists and Lawyers*

As indicated in the discussion of EPA's bureaucratic framework,¹³⁸ two groups share principal responsibility for pesticide policymaking: the Office of Pesticide Programs and the Office of General Counsel. OPP has much of the formal decisionmaking authority, with OGC nominally having the role of legal adviser. In fact, however, the most important decisions result from a process of bargaining and compromise between the two groups. Because such bargaining often can lead to results that appear inconsistent, an attempt to explain Agency decisions solely in terms of a unitary rational actor may prove unsatisfactory. As occurred in the A/D case, apparent inconsistencies in pesticide enforcement may leave all interested groups—manufacturers, farmers, environmentalists, EPA personnel—feeling that their concerns have not been fairly considered by the Agency.¹³⁹

One alternative to the way in which cancellation and suspension decisions are made currently is suggested by the prosecutorial model found in the criminal justice system. This model would view the lawyers in OGC as analogous to prosecutors, charged with initiating action whenever they perceive a violation of the law. Under FEPCA, action can be formally initiated only by the Administrator,¹⁴⁰ but he could give the lawyers a prosecutor-like role in the decisionmaking process. Rather than serving as advisers to a client who makes the actual recommendation to the Administrator, the lawyers themselves would make the recommendation; the scientists in OPP would provide advice on the technical issues, much as prosecutors have access to the services of police investigators and technicians.¹⁴¹ The analogy between pesticide

138. See text accompanying notes 35-40 *supra*.

139. See Testimony of William A. Butler, *supra* note 65, at 33-34.

140. Federal Environmental Pesticide Control Act, 7 U.S.C. § 136d(b) & (c)(1) (Supp. III, 1973).

141. See Boyer, *supra* note 87, at 124.

enforcement and the criminal justice system is not perfect, of course, but one important difference between the two suggests that the prosecutorial model may be even more appropriate in the pesticide than in the criminal context. A pesticide registrant, unlike a criminal defendant, bears the burden of proving compliance with the law.¹⁴²

In evaluating whether a change to the prosecutorial model would be likely to improve pesticide decisionmaking, it is important to examine what such a change might imply in terms of substantive outcomes. As mentioned in the A/D discussion,¹⁴³ the lawyers of OGC generally are considered more environmentally oriented and less sympathetic to the pesticide industry than are the scientists of OPP.¹⁴⁴ Because of OGC's environmental orientation, it is possible that, if a prosecutorial model were adopted, manufacturers might come to believe that they could not succeed in contesting pesticide actions, or that they could succeed only after an expensive and time-consuming legal battle. If manufacturers thought that they were likely to be unduly harassed when dealing with EPA,¹⁴⁵ they might have less incentive to develop new products, since the probability would increase that they would not be able to market the product after spending money on development.¹⁴⁶ On the other hand, the cumulative effect of more pesticide enforcement actions might alter incentives somewhat less sharply. Manufacturers with relatively safe products presumably would receive registration with few problems and their development efforts might be directed toward obtaining greater environmental safety in new and existing products, an incentive effect that seems clearly desirable in light of FEPCA's explicit environmental concern.¹⁴⁷

Apart from the current differences in the substantive orientation of the personnel at OPP and OGC, differences in the types of analytical skills possessed by scientists and lawyers may be relevant in assessing

142. See Administrator's Opinion, *supra* note 47, at 37267 n.27 and cases cited therein; Butler, *supra* note 34, at 1258.

143. See text accompanying notes 63-65 *supra*.

144. See Testimony of William A. Butler, *supra* note 65, at 33, 34 ("bias [of OGC lawyers] is toward enforcing pesticide law, . . . spotting violations and trying to eliminate them").

145. There are indications that pesticide manufacturers currently believe EPA is biased unfairly against them. In testimony before the House of Representatives' Agriculture Committee in May, 1975, the vice-president of the National Agricultural Chemicals Association (NACA) predicted that EPA "has started a trend that will turn our farms back to the insects, weeds, and fungi" and complained about EPA's "excess concern for absolute security from risks. . . ." 6 BNA ENVIR. REP. (Current Developments) 202 (1975). See also Carter, *supra* note 64 (concern of NACA regarding whether presumption in regulations would in reality be rebuttable).

146. In an analogous context, it has been contended that the Food and Drug Administration's rigorous scrutiny of drugs proposed for marketing has discouraged significantly the development of new drugs. See TIME, Sept. 29, 1975, at 53-54.

147. See text accompanying notes 9-10 & 13 *supra*.

the usefulness of the prosecutorial model. In general, scientists are trained to seek causal relationships and to avoid drawing conclusions from data until, if causation cannot be shown, there is at least a high statistical probability that the conclusion is correct. The lawyer, by contrast, is trained to determine whether the weight of the evidence is on his side. One recent study of environmental decisionmaking summarized the differences between scientific and legal approaches in similar terms:

Scientists must always be concerned with the limitations in predicting the future from the present. . . . Lawyers are not much concerned with what actually did happen or might occur but instead are interested in the circumstances in which it is legitimate to treat an event as having happened or likely to occur regardless of what did in fact happen or may occur.¹⁴⁸

It is true that both scientists and lawyers in government learn, by necessity, how to act in the face of uncertainty, but the training received by lawyers may give them a relative advantage in this regard. An action-oriented perspective in his decisionmaking subordinates might be valued by the Administrator for its own sake because action, by establishing definite deadlines, can stimulate research and force persons in and out of the Agency to take stands when they might otherwise prefer to postpone commitment.¹⁴⁹ As noted above, however, the types of incentives communicated by an action-oriented perspective are uncertain and probably cannot be predicted in advance. Therefore, rather than giving all of the final decisionmaking authority to one or the other group, the Administrator might prefer to take an intermediate position.¹⁵⁰ He could delegate some prosecutor-like authority to OGC, but require the attorneys to listen and accommodate their legal strategies to the views of the scientists in OPP. Such a split in authority, requiring bargaining between the two groups, would be similar in many ways to the present system, but a fundamental difference would be the new institutional role given to the environmental, action-oriented perspective of OGC in the formal decisionmaking process. Although some implications of this

148. Gelpel & Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371, 385-86 (1974). See generally *id.* at 374-88.

149. See G. ALLISON, *supra* note 37, at 168. See also *id.* at 178:

Because he faces an agenda fixed by hundreds of important deadlines, the reasonable player must make difficult policy choices in much less time and with much less agonizing than an analyst or observer would.

150. Even if he wanted to give principal decisionmaking authority to OGC, the Administrator might be precluded from doing so by political considerations. At a recent hearing before the House Agriculture Committee, a congressman asserted critically that lawyers were making the key EPA decisions. The Administrator replied defensively that "we're not just a bunch of lawyers," mentioning explicitly the important role of scientists in the decisionmaking process. See 6 BNA ENVIR. REP. (Current Developments) 557 (1975).

change for EPA policy and pesticide development can be identified, the desirability of the change ultimately can be evaluated only by the Administrator in light of his substantive policy concerns.

B. *Value Judgments and Decisionmaking Guidelines*

As the discussion of the A/D case and of problems with the current adjudicatory and rulemaking models indicates, the complexity of pesticide decisionmaking and science's current inability to quantify the risks and benefits of pesticide use force the Administrator or his subordinates to make what are essentially value judgments in deciding whether to ban a pesticide. In a more general context, Professor Tribe has written:

In the absence of reliable and reproducible information . . . , the process of technology assessment becomes a matter of reconciling highly imprecise professional hunches, and the final judgment becomes highly susceptible to the influence of extraneous subjective factors.¹⁵¹

This subjective influence is not necessarily either unpredictable or even undesirable. Value judgments are not made in a vacuum. Each decisionmaker is constrained by the personal background he brings to the choice as well as by the necessity for achieving some consensus within the Agency and political acceptability outside it. Moreover, the final judgment must be justified, usually in writing. This process of justification operates as an additional constraint, limiting the scope of personal prejudice, while also providing important predictive information about likely future outcomes.

The Administrator, a political appointee who must delegate his statutory responsibility, presumably would prefer that the value judgments made by his subordinates be somewhat similar to those that the Administrator would have made had he been able to evaluate fully the evidence in each case. The new regulations may achieve more uniformity in subordinate decisionmaking through the objective criteria for raising a presumption against registration, but they leave a broad scope for discretion in deciding whether the presumption has been rebutted successfully. The Administrator might best assure additional uniformity or predictability in decisionmaking by developing frameworks for decision. If they could provide a common approach to difficult pesticide problems, such frameworks would minimize and highlight the places where lower level value judgments must be made.

One possible framework for decisionmaking in pesticide cases involves a formal method often known as "decision analysis."¹⁵² De-

151. L. TRIBE, *CHANNELING TECHNOLOGY THROUGH LAW* 33 (1973).

152. See generally H. RAIFFA, *DECISION ANALYSIS* (1968).

signed partly to clarify the nature of the value judgments involved in complex choices made under uncertainty, decision analysis requires that the decisionmaker list the possible outcomes of various policy options, the likelihood that each outcome will occur, and the subjective value, or "utility," that he attaches to each outcome.¹⁵³ These requirements significantly limit the usefulness of decision analysis in pesticide matters,¹⁵⁴ since a finite list of outcomes and probabilities usually will be inaccessible or unavailable. With regard to hazard, for example, the outcomes to be considered might range from a few persons being ill tomorrow to many persons dying of cancer in forty years, with an infinite number of combinations of persons and symptoms for each intervening year. Even if discrete categories of outcomes could be approximated, the current state of scientific knowledge makes a reliable assignment of probabilities almost impossible. Under these conditions, an attempt to structure the decision problem in terms of objective magnitudes and probabilities is likely to prove frustrating and ultimately fruitless.

The decision analysis concepts of utility and probability need not be rejected entirely, however. They can serve as a conceptual foundation supporting the development of general principles to guide lower level decisionmaking.¹⁵⁵ Pesticide decisions might be structured, for example, in terms of a tradeoff between the risks of making two kinds of mistakes. One mistake occurs when the Administrator refuses to ban a pesticide and then finds out later, after much more of it has been ingested, that its danger to humans is so high that he would have acted at the earlier time if he had known the actual extent of the danger. The converse mistake occurs when the Administrator bans a pesticide and later finds out, after much food production has been lost, that the hazards are actually far less significant than he had thought. Every pesticide decision, to act or to refrain from acting, contains a risk of making one of these mistakes, and the final decision may hinge on which type of mistake the Administrator most wishes to avoid.¹⁵⁶

The Administrator's judgment about the most undesirable mistake will be dependent to a significant degree on the particular societal context within which the judgment is formulated. In the United States in the mid-1970's, the majority of citizens are not starving, nor even

153. See *id.* at ix-x. See also *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 595 (D.C.Cir. 1971) (pesticide decisionmakers "must consider both the magnitude of the anticipated harm and the likelihood that it will occur").

154. See Boyer, *supra* note 87, at 160.

155. The framework proposed here bears some resemblance to the "heuristic" approach used in systems analysis, which relies on general principles to guide action in particular situations. See *id.* at 161.

156. Cf. L. TRIBE, *supra* note 151, at 22 (decisionmaker must decide who should bear "the burden of uncertainty").

particularly hungry, but many have known someone who has had a form of cancer. This experience is reflected in such EPA pesticide statements as the new regulations, with the presumption against registration once there is any indication that the product causes cancer,¹⁵⁷ and the Administrator's A/D suspension opinion which, although it considered the food production problem, prefaced that discussion by noting:

Since Aldrin-Dieldrin has been found to be carcinogenic . . . , it is arguable that any use of Aldrin-Dieldrin, however significant or beneficial in social or economic terms, cannot be justified

[I]t is apparent that any . . . benefits attributable to Aldrin-Dieldrin must be of a high order to affect the findings on carcinogenicity.¹⁵⁸

This emphasis on cancer risks indicates an Agency responsiveness to present public concerns.¹⁵⁹ It suggests, however, that the emphasis could shift to a concern for food production if a possibility of imminent hunger ever were feared by a politically significant number of Americans.

The principal difference between a decisionmaking framework based on avoiding mistakes and formal decision analysis is a difference in emphasis. Although the mistake-avoidance framework necessarily requires estimates of the likelihood that a mistake will occur and of the probable magnitude of a mistake, those estimates can be in the nature of educated guesses, since no effort is made to identify by numerical calculations the clearly preferred decision. Similarly, the concept of the most undesirable mistake is comparable to the notion of utility in decision analysis, but again the judgment can be less precise. Although this imprecision allows more scope for value judgments than would a precisely quantified system, imprecision may be a significant advantage when science lacks the tools for accurate and comprehensive quantification. As Professor Tribe has persuasively demonstrated, attempts to be precise in such situations frequently lead to "dwarfing"—ignoring or understating—those "soft" variables that cannot be satisfactorily quantified, such as the value attached to plants and animals, and to an emphasis on final results at the expense of the interactive processes of decisionmaking that shape value consensus over time.¹⁶⁰ The mistake-

157. See text accompanying note 119 *supra*.

158. Administrator's Opinion, *supra* note 47, at 37270, citing *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 596 n.41 (D.C. Cir. 1971).

159. See *Environmental Defense Fund, Inc. v. EPA*, 465 F.2d 528, 538 (D.C. Cir. 1972) (cancer is a "sensitive and fright-laden" subject).

160. See Tribe, *Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality*, 46 S. CAL. L. REV. 617, 625-33 (1973); Tribe, *Policy Science: Analysis or Ideology?*, 2 PHIL. & PUB. AFFAIRS 66, 75-105 (1972); Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 84 HARV. L. REV. 1329,

avoidance framework or a similar one, by contrast, explicitly recognizes that hard choices based on soft, unquantifiable variables must be made. Moreover, satisfactory decisionmaking principles can only be developed through an evolutionary process involving constant interaction between affected groups inside and outside of the government.

VI

CONCLUSION

For those concerned about improving the quality of decisionmaking in pesticide matters, wider recognition that value judgments, rather than objective scientific facts, currently are the principal determinants of particular outcomes would be desirable for two major reasons. First, public and congressional awareness of this situation might lead to a larger commitment of resources to pesticide research, with the goal of narrowing the large area of uncertainty that presently makes discretionary value judgments unavoidable. Second, this recognition would focus attention on the process-oriented concerns analyzed in this article, with particular emphasis on the adjudicatory and rulemaking models and the allocation of decisionmaking responsibility within EPA. The recommendations presented here are tentative in nature and fall far short of entirely resolving the problems this article has raised concerning EPA's regulation of pesticides. But the suggestions here do represent initial steps toward ensuring that the statutory standard, "unreasonable adverse effects on the environment," has a meaning in practice consistent with current knowledge of risks and benefits and with broad public sentiments regarding the necessary tradeoffs between food production and environmental protection.

1361-65, 1368-76, 1381-83, 1389-93 (1971). See also Tribe, *Ways Not to Think About Plastic Trees: New Foundations for Environmental Law*, 83 YALE L.J. 1315 (1974).