Pesticide regulation: Why Not Preventive Legislation?
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Abstract

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Technological advancements are, by and large, inspired by economic considerations. They are spurred by motives to reduce labor and production costs, and to increase profits. In the twentieth century, man has implemented many such technological improvements, which have usually brought about their expected benefits. In his haste to advance and improve technology, however, man has created new problems, more complex and dangerous than those he originally sought to solve. It seems that pollution, ominous and difficult to control, lies invariably in the wake of technological innovation.

This discussion deals with one type of pollution—that of our food supply by the chemical residue of pesticides. It will show that the traditional means of regulation used to eliminate the hazards posed by pesticide residue are inappropriate and ineffective. If protection of human health is the rationale for environmental control and regulation, then adequate means of achieving this worthy goal should be adopted. It is suggested that the traditional political process of regulation should yield to a more scientific process of regulation. Regulation, preventive in nature and based on scientific data, would achieve more efficiently the purpose of environmental control by giving greater consideration to preventing potential harm, rather than merely attempting to rectify past harm, as the political process has done.

1. THE DILEMMA

The question boils down to whether to proceed with regulation given an imperfect and ambiguous scientific base or wait until further data has been collected . . . waiting for a body count before regulating is an approach which is hardly the mark of a civilized society.¹

This critique on the federal regulation of environmental contaminants expresses the growing concern over human exposure to hazardous

substances. However, the solution to this problem can be achieved only within specified guidelines and boundaries, which also mark a civilized society.

Laws which embody these guidelines reflect a balancing of adverse interests. Specifically in pesticide regulation, legislatures and courts are confronted with the task of balancing the chemical producers' demands for a free and unfettered market, with the environmentalists' pleas for strict constraints to avert the frightening proposition of an indiscriminately polluted environment. The difficulty of this balancing process increases when a present benefit is counterbalanced by a potential future harm. Within the legal framework of assessing the propensity and gravity of a future uncertainty, the ability of present circumstances to indicate reliably the occurrence of a future event is determinative. The understanding of present circumstances, however, is limited by existing technological knowledge and scientific expertise. Predicting future events from them is extremely difficult, especially in the field of environmental health, where dealing with the unknown and unpredictable is not uncommon. Invariably, under the legal process, such a balancing standard has resulted in the scales of regulation being favorably tilted to the chemical producer's demands.

The legal approach to resolving problems has failed to protect the American people and their environment from exposure to pesticide pollution. Its major flaw is that it does not adequately compensate for the lack of conclusive scientific evidence of potential harm. Those entrusted to make environmental decisions, particularly legislators, should adopt a standard that would emphasize the potential health hazards posed by the heavy use of pesticide chemicals. Such an approach which allots greater concern to future consequences would better protect the environment for future generations.

The scientific approach to decision-making, by comparison, is oriented much more toward the future. The scientific method discourages

2. Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown. This language was used by the Court in Ethyl Corp. v. Environmental Protection Agency, 1976 8 Envir. Rep. (BNA) 1785, 1801. (Not officially reported. For further discussion of case, see note 120 infra.)

For discussion on the amount of scientific knowledge available for regulatory decisions, see E. Burger, Regulation and Health: How Solid Is Our Foundation, 5 Envir. L. Rep. 50, 179 (1975).
hasty action, especially if the consequences of that action cannot be predicted. Rather, if uncertainty exists, the major concern of the scientific method is to refrain from action until such time as scientific knowledge allows a reasonable prediction of future events.

The differences between the legal and the scientific approaches may be best distinguished in their different interpretations of such terms as "cause" and "proof." For example, to prove a hypothesis successfully, a scientist must use certified evidence, in which the probability of error by standard statistical measurements must generally be less than 5%. Likewise, to show cause, a scientist must prove his hypothesis by rigid laboratory experiments. In the judicial or administrative process, however, testimony by a scientist, given in his professional capacity, can be deemed competent proof and can establish that the likelihood of occurrence of a certain event is simply more probable than not.

The legal requirements of cause and proof have burdened the efforts of those attempting to regulate suspected harmful substances. Regulation through the legal framework has been proven inadequate in other areas of society, with the resulting problems being resolved only by stricter legislation. The regulation of environmental contaminants, e.g., pesticide chemicals, has apparently run that same frustrating gamut. Legalities have hampered not only the regulators' enforcement procedures, but their administrative and perfunctory duties as well. Implementation of stricter legislation, employing scientific concepts, would remove the burden of having to show that a harm is more likely than not to occur. Conversely, pesticide manufacturers would clearly have to establish that their products are safe. This type of legislation would include standards mandating the complete testing of all substances before they could be mass-produced. If their full effects were not ascertainable, their production would not be permitted. Such legislation would foster the application of a scientific approach, because it would force the support of research which hopefully would remove the limitations of existing scientific predictive knowledge. At present, those to


4. Id. In most civil proceedings, a preponderance of the evidence test is used, which demands only a certainty of 51%.

whom is allotted the task of regulating pesticide residues found in foods are confronted by the dilemma of which approach to use, scientific or legal. Agricultural codes and federal regulations, entangled among legal and technical considerations, essentially ignore the serious ecological shortcomings inherent in the use of modern pesticides. It has become clear that legislation which merely regulates the labeling and application of pesticides is not sufficient to protect the American people and their environment. A regulatory pattern must be implemented that also limits the extent of pesticide residue to which man is exposed. Up to the present, the effectiveness of residue limitations has been greatly curtailed, due to the "legally insufficient" certainty of detrimental results.

Hopefully, hindsight will no longer continue to be our guide, and reparation of the damage afterward our burden. The thought underlying future legislation should be that we must stop treating the population as guinea pigs and the environment as a laboratory. Regulation of environmental contaminants offers a tangible and achievable opportunity to practice preventive medicine through preventive legislation.

2. EXTENT OF PESTICIDE USE

In the mid-1940's, as one war had come to an end, another was being initiated. The new war was not against man, at least not intentionally so. It was against insects, pathogens, and weed pests. Its principal weapons were not artillery or armies, but chemicals. Since then, this chemical warfare has intensified. Today in the United States alone, over 1.2 billion pounds of synthetic pesticides are used annually for the

8. Under traditional principles, the party bringing the suit against the producer of a particular substance must produce factual evidence to show that the substance is responsible for bringing about a specific harmful condition. See, e.g., Casenote, 25 Cath. U. L. Rev. 178, 180 (1975) (emphasis added); W. Prosser, The Law of Torts § 41 (4th ed. 1971); Comment, 1975 Utah L. Rev. 581, 584 (comment on Scientific Uncertainty and Environmental Threats to Human Health).
9. For an excellent essay assessing the role science plays in the regulation of environmental contaminants, see E. Burger, supra note 2.
10. After World War II, the world experienced the widespread growth of the use of pesticide chemicals. For a general discussion, see Rogers, supra note 7, at 835.
11. For information concerning the extent of pesticide use, its successes and
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prevention of crop loss and the eradication of pestiferous organisms. That amounts to six pounds of pesticides applied annually for every man, woman, and child in this country. In an address to Congress in 1971, it was calculated that there would be a 13% annual increase in the use of pesticides, and that by 1985 there would be a sixfold increase. Recent estimates show there are over 1,400 active chemical ingredients present in pesticides. Combined in various amounts and arrangements, there are over 40,000 different pesticide products, each of which must supposedly be individually tested for safety in order to be registered.

Alarmingly, once applied, the chemicals do not simply achieve their purpose and then degrade or decompose. The pesticides retain their chemical identity and continue to function for an extended period of time. This trait of pesticides has given rise to the use of the common failures, alternative methods of pest control, and the infeasibility of pesticide use in light of the food and energy crisis, see Pimentel, World Food Crisis: Energy and Pests, 22 BULLETIN OF THE ENTOMOLOGICAL SOCIETY OF AMERICA, 20-26 (1976), and Pimentel, Bioenvironmental Control of Pests: A Research Assessment (July 9, 1974) (unpublished work prepared for Dept. of Entomology and Section of Ecology and Systematics, Cornell University, Ithaca, N.Y.).


13. These estimates were based on the amount of pesticides then employed in pest control, 833 million pounds. Hearings on Proposed Amendments to Federal Insecticide Fungicide and Rodenticide Act (FIFRA), before the House Committee on Agriculture, 92d Cong., 1st Sess. (1971).


15. Before a pesticide can be registered, the manufacturer must submit with the application the results of various safety studies. However, the EPA can, at its discretion, register a pesticide with chemicals similar to those of a pesticide already registered, without requiring additional safety tests. Conditional registrations can also be granted, pending the outcome of safety tests. These two procedures, by which a manufacturer can legitimately avoid showing a particular pesticide's safety, seem to have reduced greatly the effectiveness of the registration process.

A senate subcommittee staff recommended that safety-testing data on pesticides should be done for each compound prior to registration. Theoretically, this is an ideal proposition. The task may, however, under existing registration procedures, prove insurmountable. The estimates of the General Accounting Office in 1975 predicted that over 46,000 pesticides were to be registered. For a further breakdown of the workload, see note 71 infra. See also U.S. GENERAL ACCOUNTING OFFICE, Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards? (Dec. 4, 1975) [hereinafter cited as GAO Report]; [1977] 8 ENVIR. REP. (BNA) 350 on subcommittee recommendations. See generally ROGERS, supra note 7, at 850, 856, 872; W. BUTLER, Federal Pesticide Law, FEDERAL ENVIRONMENTAL LAW, 1240 (ELI 1974), discussing conditional permits and experimental use.

16. See generally U.S. DEPT. OF HEALTH, EDUCATION AND WELFARE, REPORT

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descriptive term "persistent pesticide." Two other common descriptive terms used for pesticides are "subacute" and "general." Subacute means that the toxicity of the pesticide causes adverse effects in an organism only upon repeated exposure. The pesticide is considered general when its composition is such that it does not specifically attack one pest.

The persistent attribute provides an economic advantage to the farmer or other applicator because the pesticide retains its toxic effect for a long time. Thus, once a sufficiently lethal dosage is applied to eradicate the intended pest, continual application is unnecessary. The subacute characteristic of a pesticide is beneficial because it is safer for those who handle the pesticides in transportation or application. The chemicals, not being as acute, are not as potentially lethal to one who accidentally comes in contact with the substance. Most pesticides also have a general characteristic because it is financially favorable to the manufacturer. A general pesticide can attack various pests, thus making the development of innumerable different pesticides unnecessary. This can be a substantial saving, considering that the cost of development may be anywhere from $2.1 million to $4 million.

Of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health (1969) [hereinafter cited as Mrak Commission Report].


19. Comment, supra note 17.

20. "Acute" is that property of a substance or a mixture of substances which causes adverse effects in an organism through a single exposure. GAO Report, supra note 15, at glossary.

There is no reliable system capable of reporting, collecting, collating, and disseminating accurate information on the status of pesticide poisonings today in the United States. A recent EPA study, however, was conducted nationwide. From 1971 to 1973, the study estimated, there were 8,248 hospital-admitted pesticide poisonings. Of that figure only 28% (2,295) were occupationally related poisonings. Farmers and agricultural workers accounted only for 36% (817) of that group. United States Environmental Protection Agency, National Study of Hospital Admitted Pesticide Poisonings at 4, 168, 169 (April 1976).


Today the cost of producing a pesticide can run as high as $12 million and is heading upward. One contributing factor is that the time between discovery of a new pesticide and the time it gets to market can be more than eight years. Business Week, September 27, 1976, at 56.
3. EFFECT OF RESIDUES

The beneficial aspects\(^{22}\) of pesticides are subverted to the extent that they remain active and potentially poisonous to man. This dangerous situation arises, as previously indicated, because the chemicals utilized in pesticides do not rapidly decompose. For instance, DDT, one of the first and most commonly applied, takes two to five years to break down.\(^{23}\)

Man unwittingly ingests these pesticide residues. He consumes them daily with his food, which has been sprayed in the field or in storage.\(^{24}\) Man can also absorb residues from the meats and dairy products that he eats.\(^{25}\) Processed foods may be another source of residue intake, since they are generally packed or stored in containers which are treated to prevent loss to rodents and contamination.\(^{26}\)

Man is subjected to an arguably low amount of pesticide residue per food product.\(^{27}\) Nevertheless, United States Department of Agricul-

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22. Just how beneficial pesticides have been is debatable. Some say that many of the diseases seemingly eradicated by the synthetic chemicals would have been eliminated by natural causes, e.g., better nutrition, improved health care, and good hygiene. See R. Carson, Silent Spring (1970). Also, the overall percentage of crop losses to pests has been increasing. Post-harvest losses (13%) plus pre-harvest losses (35%) indicate that pest populations are consuming and/or destroying nearly half the world's food supply. Pimentel, World Food Crisis: Energy and Pests, supra note 11.

For an opposite view praising DDT and other pesticides, see War on Pesticides, DDT was Number One on the Casualty List, Barron's, November 10, 1975, at 3.


24. Crops are in contact with pesticides or their residues all along their route from seedlings in the field to products in a store. The soil that grows them and the water that nurtures them contain chemical residues. The foodstuffs are sprayed in the fields, after harvest in storage, and in the boxcars on their way to market, to prevent loss to rodents, micro-organisms, and insects. Pimentel, World Food Crisis: Energy and Pests, supra note 11.

25. For example, the two pesticides Heptachlor and Chlordane are found in 73% of all dairy products and 77% of all meats, fish, and poultry samples. 5 Envir. L. Rep. 10,163 (1975).

26. See, e.g., Natick Paperboard Corp. v. Weinberger, 525 F.2d 1103 (1st Cir. 1975), holding that paper packaging material containing polychlorinated biphenyls (PCB) in excess of tolerance levels will in many instances be an "unsafe food additive" within the meaning of the Federal Food, Drug, and Cosmetic Act; see also Pimentel, World Food Crisis: Energy and Pests, supra note 11.

27. EPA determines the acceptable daily intake for residues of each pesticide which may be present in or on agricultural commodities. Acceptable daily intake for man is usually one per cent of the pesticide concentration which was found to have no toxic effect in the most sensitive animal species tested. Total possible exposure to
ture (USDA) figures show that the average American consumes 1,435 pounds of food annually. Although the food is readily broken down, the pesticide chemicals contained therein are not. Virtually every person in the United States has residues of pesticides in his body tissue. The potential harm posed to man from such continued exposure to low levels of pesticides is presently being debated. Exposure at these levels, however, has been proven to be toxic to other species. In laboratory tests it has been shown that 0.1 parts per billion in seawater of the pesticide Mirex, which is used to control the fire ant in the southeastern United States, had a lethal effect on crabs, and killed 11% of the shrimp population in ten days and 50% after three weeks of exposure. The potentially poisonous effect may be more startling and ominous in human consumption of pesticide residues.

pesticide residue is computed in the average diet of a 132-pound man. However, as will be shown below, the safety tests upon which the tolerances are set are of dubious validity and the FDA, whose duty it is to monitor the foodstuffs for pesticide residue, only test for the presence of about 90 of the 230 residues in food for which tolerances have been set. GAO Report, supra note 15, at 38-44.

30. "Scientists are concerned that so little is known about the ecological effects of pesticides on the plants and animals (200,000 species) making up man's life system. Information on the effect of pesticides is available for less than 1% of these species, and at best most of this information is incomplete." Pimentel, Bioenvironmental Control of Pests: A Research Assessment, supra note 11, at 14.

Since so little is known, most debates center on the question of whether "the facts must come first, and social judgments later," or whether to allow the marketing of a pesticide, whose effects are unknown, based upon the possibility and seriousness of the threatened harm. The latter argument seems to have support because of the underlying premise that man can resolve (eventually) any problem he has created.

Such illusions are antiquated. Recently, we have realized that our resources are finite and that they must be conserved and utilized rationally. As David Pimentel indicated, large quantities of fossil fuel energy is used in controlling pests. Most pesticides are formulated with a petroleum base and their development and application expend great quantities of fuel. Also, many other activities necessary to our system of food production consume enormous amounts of fuel. If the present world population ate a diet derived from a food production system equivalent to that of the United States, petroleum reserves would be exhausted in thirteen years.

See also Comment, 21 S.D. L. REV. 425, 427-28 (1976). (Debate between Prof. Green and Dr. Handler on which approach is better: to restrict production until facts are known, or to allow production so that facts can be gathered which will form the basis of subsequent social judgments.)
31. Duvall, supra note 21, at 82.
Man is at the top of the food chain, at each step of which the pesticide residue is stored and the chemical concentration increases. This process, known as biomagnification, continues until it reaches man at the top. In addition, the effects of pesticides are sometimes magnified by interaction with other chemicals or drugs, resulting at times in synergistic effects. This occurs when the co-operative action of separate substances produces a total effect much greater than the sum of the effects of the two compounds acting independently. The opportunity for synergistic interaction is apparently greater today, with the ever-increasing amount of chemicals that the American public consumes, either in the form of food additives or by means of "medical drug intoxication."

4. HISTORY OF REGULATION

The Food and Drug Act of 1906 was the forerunner of statutory regulation.

Originally, FIFRA was designed to provide for safety and product quality through labeling and registration. It called for the registration of all pesticides with the United States Department of Agriculture (USDA). The FDCA, administered by the Department of Health, Education and Welfare (HEW), complemented FIFRA in protecting the public from food contamination by pesticides. Its civil and criminal sanctions, however, were operative only if an "adulterated" food was introduced into interstate commerce bearing a level of pesticide residue exceeding HEW's established tolerance.

In the 1960's, as national concern grew about the effects of pollution and the extent of "uninvited additives" present in food, environmental groups attempted to use FIFRA to prevent the indiscriminate application of pesticides. Their efforts in a series of court cases were

40. The 1954 Amendment gave the administrator of the Food and Drug Administration the power to establish tolerance limits for pesticide residues on raw agricultural commodities and processed foods. H. A. TOULMAN, A TREATISE ON THE LAW OF FOODS, DRUGS AND COSMETICS § 19.6 at 396 (1963). The 1959 amendment brought defoliants and other newly developed pesticides under the regimes of FIFRA. Id. § 19.7 at 397. The 1964 amendment laid the foundation for today's registration process, by trying to restrict marketability prior to registration. 100 CONG. REC. 2948 (1964). See generally Comment, supra note 17.
41. See Bennett, supra note 23, for an explanation of how the administrator of the FDA set the tolerances while the registration of the pesticide was under the control of the USDA. Both departments split the monitoring of foods for excess residues duties.
42. 21 U.S.C. § 331 (1970 & Supp. 1975). The term "adulterated" applies to a food or pesticide containing chemicals or substances inconsistent with the tolerance levels prescribed by law. The definition can be found under the FEPCA, 7 U.S.C. § 136 (C) (1976).
43. For a description of pesticide residues existing in our food supply, see Rogers, The Persistent Problem of Persistent Pesticides: A Lesson in Environmental Law, 70 COLUM. L. REV. 567, 595 (1970).
The inadequacy of FIFRA's narrow scope was exemplified by those decisions. The Act was impotent because (1) it failed to meet its original product safety purposes, i.e., the setting of tolerances; (2) it could not enforce its provisions; and (3) it did not provide for monitoring of food residues.

Overlap of agency control also caused the Act's failure to meet its original product safety purposes. HEW was to base its decision, whether to grant a tolerance of a pesticide, upon safety. However, USDA had the initial determination of whether to register a pesticide, and based its decision on other considerations. Thus, if HEW found the residue of a certain pesticide to be unsafe, it could not effectively prohibit its use if the USDA continued to allow its registration. Such an occurrence

44. Stearns Electric Paste Co. v. Environmental Protection Agency, 461 F.2d 293 (7th Cir. 1972). The court rejected the Environmental Protection Agency's attempt to cancel the manufacturer's registration of a rodenticide. The court held that the agency had overstepped its authority in attempting to apply the "intricate balancing test" in this instance. FIFRA is basically a labeling act, the court continued, and a registration can be cancelled only if the product is misbranded. It is inappropriate, however, to determine that a product is misbranded when it is being used in accordance with commonly recognized practices.

Continental Chemist Corp. v. Ruckelshaus, 461 F.2d 331 (7th Cir. 1972). The court said the basic purpose of FIFRA is to regulate the labeling of poisons. The fact that the use of the poison in compliance with the directions on its label would cause certain food to become "adulterated" within the meaning of the Food, Drug and Cosmetic Act does not mean that the poison was necessarily misbranded, within the meaning of FIFRA. Thus, the manufacturer's registration, the court held, could not properly be cancelled. See also Wellford v. Ruckelshaus, 439 F.2d 598 (D.C. Cir. 1971) (administrative process must be concluded to properly suspend registration of a herbicide).

Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971). The EDF petitioned for review of an order of the Secretary of Agriculture which failed to suspend federal registration of a pesticide or to commence formal administrative procedures that could terminate that registration. The court favorably remanded the case for further proceedings. The court held that it would require the administrators to articulate the factors on which they based their decisions, but noted that on matters of substance the courts regularly would uphold agency decisions.

45. See W. BUTLER, supra note 15, where the author discusses the problems created by agency overlap and designates these areas as critical.

46. Safety was based upon the consideration of three factors: "the nation's need for food; effects of the pesticide on the consumer; and the USDA's opinion concerning the pesticide's usefulness." Bennett, supra note 23, at 359.

47. The determination was to be based upon agricultural usefulness and probable residue levels involved in the establishment of tolerances. SEN. REP. NO. 1635, 83d CONG., 2d SESS. (June 25, 1954), reprinted in [1954] U.S. CODE CONG. & AD. NEWS 2626, 2629.
was not uncommon. 48

Also, the USDA failed to enforce adequately the provisions of FIFRA. Such inadequacy was noted in a report to Congress in 1971. "[T]he Department not only failed to initiate a single criminal prosecution for 13 years despite evidence of repeated violations, but . . . it did not even have any procedure for determining the basis for action." 49

Finally, its powers to monitor were also virtually ineffective. The Department of Agriculture relied heavily on inadequate and incomplete data to determine if the pesticide should initially be registered. 50 Also, a great deal of information regarding the toxicity or other characteristics of a pesticide was supplied by manufacturers, who had a substantial investment in the pesticide 51 and a vested interest in securing a speedy registration. 52 A monitoring plan utilizing only such biased information would assuredly not lead to the cancellation or suspension of a pesticide.

If the USDA administrator determined that the weight of evidence supported the cancellation or seizure of a hazardous pesticide, his action would be reviewable by the courts. However, this system of court review before a pesticide could be taken off the market was a sham, because the procedural process could delay any affirmative action up to 390 days. 53 Apparently, the agencies were still at the mercy of the manufacturers and had to rely largely on voluntary recalls. 54

To patch these gaping holes in FIFRA, Congress responded in 1970 by approving the President's Reorganization Plan, which expanded the government's environmental concerns and consolidated fifteen federal organizations under the Federal Environmental Protection Agency (EPA). 55 This consolidation of power would have been fruitless had it

48. Rogers, supra note 43, at 570. See also 117 CONG. REC. 2009-10 (introduction of the National Pesticide Control and Protection Act).
49. Id. at 2010.
50. Id.
53. 117 CONG. REC., supra note 48.
not been accompanied by significant improvement of the law. The con-
gressional response to criticism of FIFRA by courts, legal commenta-
tors, and environmental groups was the Federal Environmental Pesti-
cide Control Act (FEPCA), which completely overhauled the federal
environmental authority. An in-depth study of the Act is not within
the scope of this report. Some of its more important aspects, however,
deserve mentioning.

Under the FEPCA, regulation of pesticides will no longer be re-
stricted to those involved in interstate shipment, but will include all
aspects of transfer, solicitation, and sales even if totally intrastate. The
FEPCA also expands the previous registration procedure. By employing
a system of use control, it cures one of the major deficiencies of FIFRA.
The use, either "general" or "restricted," is determined by demonstrat-
ing whether the pesticide, when applied according to its labeling instruc-
tions, will cause an unreasonable effect on man or the environment. If
affirmatively determined that the pesticide will cause substantial ad-
verse effects on the environment, it will be classified for restrictive use.
As of October 1977, 23 pesticides had been classified for restrictive use
and 38 more were being considered. Such categorization of a pesticide
requires that it be applied only by those competent to handle such
materials and restricted by other limitations as determined by the ad-
ministrator of the EPA.

The major advancement in the pesticide registration process
brought about by FEPCA is the provision stating that any pesticide

56. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516,
58. 7 U.S.C. § 136a(a) (1976), states in pertinent part: "[N]o person in any State
may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive
and (having so received) deliver or offer to deliver, to any person any pesticide which is
not registered with the Administrator.”
59. 7 U.S.C. § 136a(d)(1)(B) (1976) states:
If the Administrator determines that the pesticide, when applied in accordance
with its directions for use, warnings and cautions and for the uses for which it is
registered, or for one or more of such uses, or in accordance with a widespread
and commonly recognized practice, will not generally cause unreasonable adverse
effects on the environment, he will classify the pesticide, or the particular use or
uses of the pesticide to which the determination applies, for general use.
The FEPCA defines unreasonable adverse effects as “any unreasonable risk to man or
the environment, taking into account the economic, social and environmental costs and
which fails to meet certain criteria will be subject to a "rebuttable presumption" against registration.\textsuperscript{61} This provision also applies to pesticides that are already on the market, since the Act requires that all pesticides registered with the EPA before the 1972 amendment be reregistered before October 21, 1976.\textsuperscript{62} After that date, all pesticides must be reregistered every five years.

The reregistration procedure may tactically be used as an alternative to cancellation or suspension, as a means of removing a pesticide from the market. Instead of becoming entangled with the expensive and unchanged lengthy cancellation process, the EPA will allow the pesticide to be used up until the time reregistration is required. Then the application for reregistration will be denied, based upon the rebuttable presumption that the pesticide will cause adverse effects on the environment. This "phase out" of a pesticide is currently being used against Mirex.\textsuperscript{63} It succeeds not only in saving money and time, but also shifts

\textsuperscript{61} 6 ENVIR. L. REP. 10,087 (1976). A notice of intent to deny registration or cancel an existing registration will be issued by the EPA if the applicant fails to prove the safety of his product. The presumption of unacceptability is based upon risk. However, even if the chemical's use gives rise to a presumption of risk, this presumption can be rebutted by showing the pesticide's economic, social, and environmental benefits. 40 CFR § 162.11 (1977).

Note that, although this is a patently strong provision, it is doubtful if its application can be effective in eliminating from the market a pesticide with hazardous effects. Manufacturers can avoid the ramifications of this provision and refute contentions of a pesticide's possible safety risks by producing evidence of attainable economic costs and benefits.

This provision still does not rectify the problem that has plagued EPA's analysis of information submitted in support of registration of a pesticide. Adequate review of safety tests data continues to be difficult because (1) EPA lacks its own scientific research and evaluating knowledge and (2) private environmentally interested groups are of no assistance, since the data supporting the registration are not published in the Federal Register until 30 days after the product is registered. Compounding this flaw is the fact that a good portion of the data is not published. Trade secret protection is allotted to that test data which the originator of the product claims. Under this provision, health and safety data are often excluded from the published information. See Rogers, supra note 7, at 861, 862; [1977] 8 ENVIR. REP. (BNA) 280; E. Burger, supra note 2.

\textsuperscript{62} 7 U.S.C. § 136(a) (1976). All FEPCA provisions were to be effective by October 21, 1976. This meant that all pesticides were to be registered according to its provisions, including presently active pesticides. As will be shown later, this task proved to be impossible. 41 FED. REG. 7218 (1976).

\textsuperscript{63} See [1976] 7 ENVIR. REP. (BNA) 849.
the burden on the pesticide manufacturer to prove the safety of his product.64

5. CONTINUING PROBLEMS

Theoretically, under the FEPCA, the residues from pesticides in our foods will be restricted to limited and safe levels. The registration process requires the manufacturer to provide the EPA with safety studies on the active ingredients in each type of pesticide. The EPA then reviews the studies to ensure the pesticide's safety and effectiveness. Based upon the studies submitted, the EPA establishes tolerances for the maximum pesticide residue concentration allowed in a food product. The monitoring of the residues in food for violations of the tolerances is done via the food inspection functions of the Food and Drug Administration (FDA), and by the meat and poultry inspection and chemical monitoring services of the USDA.65 If a violation of a tolerance level is detected, then appropriate regulatory66 action will be initiated. If the administrator of the EPA determines it necessary, he may notify the registrant of his intentions to cancel or suspend the registration of the pesticide or change its classification.67

The above system, however, does not operate as successfully, routinely, or effectively in practice as it hypothetically was proposed. The FEPCA has apparently filled the gaping holes of previous legislation. Unfortunately, crevices still exist which permit persistent pesticides to continue to seep into our environment and food supply. The EPA realized its deficiencies in the review of tolerance regulations and procedures in 1975, but said that it would devote its attention to reassessing the existing tolerances and making a comprehensive evaluation of the whole scientific basis for tolerance setting.68 Good intentions, however, do not make good regulations. A Senate subcommittee staff report released

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64. Id. For a discussion of the effects of Mirex, see H. WELLFORD, supra note 32, at 296, 297.
65. Id. at 354.
66. The EPA can initiate cancellation or suspension hearings of the pesticide or, if necessary to prevent further contamination, it can issue a “stop sale, use or removal order” to any person who owns, controls, or has custody of such pesticide. 7 U.S.C. § 136k (1976). The Food and Drug Administration can remove the adulterated foodstuff from the market under the authority of the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331 et seq. (Supp. V 1975).
67. 7 U.S.C. §§ 136d(b) & (c) (1970) [before 1972 amendments].
68. GAO Report, supra note 15, at 49.
two years later in 1977 came to the "unfortunate conclusion that pesticide regulation in the U.S. is still fundamentally deficient." 69

The foundation of such criticism lies in the basis of pesticide regulation—the registration process. The FEPCA, enacted in 1972, required the EPA to register all pesticides during the two-year period ending October 1976. 70 That called for, in addition to the normal workload, 71 the registering of 46,000 pesticides. To magnify the enormity of the project, EPA failed to have the proposed guidelines for registering and classifying pesticides ready for public viewing until June 25, 1975. 72 Since registrants needed such information to know what was necessary to support their registration, and the FEPCA registration program could not start without such regulations, "the EPA lost about nine months of the 2-year period provided by the Act." 73 The problem still exists. An EPA official told a Senate subcommittee in March 1977 that "the registration of pesticides could take as long as 15 years." 74

This excessive workload has given rise to other problems. The comprehensive evaluation of the scientific basis for tolerance-setting may once again be shoved to the rear of the workload. Time and resources are limited, so the EPA must make a policy decision of whether to proceed with the registration process as quickly as possible, and accordingly sacrifice the integrity of the data submitted by a manufac-

69. Senate Judiciary Subcommittee on Administrative Practice and Procedure prepared a report on the EPA, a summary of which can be found in [77] 7 ENVIR. REP. (BNA) 1284-86.

70. See text accompanying note 62, supra.

71. GAO Report, supra note 15, at 67. The report also stated: "In addition to the 46,000 FEPCA registrations, EPA's projected workload during the 2 year period included 13,000 . . . new pesticide registration applications and 14,000 [applications for amended registrations as to product formulation, uses labeling, etc.]. Id. The 46,000 figure represented 29,000 currently registered pesticides that [had to be] reregistered and 17,000 intrastate pesticides . . . not previously required to be registered. . . ." Id.

72. Id. at 68 (40 FED. REG. 26,801-928. The final proposals were not published until July 3, 1975 (40 FED. REG. 28,241-86 and did not become effective until August 4, 1975.

73. Id. at 69. The two-year period specified by the FEPCA was from October 22, 1974 to October 21, 1976. The lapse between the passage of the Act in 1972 and the time the registration period was to begin allowed ample time for the EPA to devise some standards of safety and risk benefit, to which the registrants could conform. They did not, however, do so.

74. Assistant Administrator for Water and Hazardous Materials Andrew W. Briendenback noted: "In no case could the process take less than five years." [77] 7 ENVIR. REP. (BNA) 1742.
turer in support of registration. Such sacrifice is questionable in light of past experiences by the EPA with the safety data submitted by registrants. A General Accounting Office study in 1975 showed that many manufacturers failed even to submit safety studies on active pesticide ingredients. The reliability of many of those submitted was questionable. EPA Deputy Administrator John R. Quarles noted "that in virtually every instance, independent pathologists diagnosed many more cancerous and pre-cancerous tumors in test animals than did the original laboratory pathologists." Reliance by the EPA on the safety data for registration qualification and tolerance-setting by those who have a "vested interest" in having the pesticide registered is without substantial foundation. Concealment of certain hazardous attributes have been made without prosecution for violation of the Federal Environmental Pesticide Control Act.

75. [1977] 7 ENVIR. REP. (BNA) 1286. Note that the former EPA Administrator cancelled the reregistration program in August of 1976 pending resolution of the data validity issue.

A year later, the problem of laboratory test deficiencies still exists. However, the agency recently has requested 31 pesticide manufacturers and two federal agencies (FDA and USDA) to review and certify the accuracy of tests conducted by a suspect independent laboratory. If review uncovers "serious human health or environmental hazards," then evidence of faulty testing will be handed over to the Department of Justice for appropriate action. This could lead to the first civil or criminal penalties assessed against a testing laboratory under FIFRA. [77] 8 ENVIR. REP. (BNA) 585. See also [77] 8 ENVIR. REP. (BNA) 644.

76. GAO Report, supra note 15, at 7-11. The requirements of safety data have been becoming more and more stringent on the active ingredients. The GAO report, however, shows that compliance has not been on a reciprocal increase. The two most recent testing requirements for teratogenicity, 1970 (to determine if exposure to the chemical will cause birth defects), and mutagenicity, 1972 (to determine if exposure will cause permanent genetic change), have been generally ignored. Safety data were missing for the 36 active chemicals present in the 100 sample pesticides chosen for the GAO study, in 14 instances (39%) for teratogenicity and 23 instances (64%) for mutagenicity.

77. A pathologist is someone in the branch of medicine who studies the nature of the structural and functional changes caused by disease, and the conditions and processes that result in disease. See J. SCHMIDT, ATTORNEYS' DICTIONARY OF MEDICINE at 38 (1975).

78. A comment made when seeking a criminal investigation of the Veliscol Chemical Corporation of Chicago. The firm was suspected of withholding data of possible cancer-causing properties of the pesticides, Heptachlor and Chlordane. PREVENTION—THE MAGAZINE FOR BETTER HEALTH, May 1976, at 202 [hereinafter referred to as PREVENTION].

79. W. BUTLER, supra note 45, at 1267-68.

Experience has shown that because of the paucity of EPA enforcement personnel
In light of the Act, the motive for such an incomplete presentation by the manufacturer is obvious. Under the FEPCA, the biggest burden on the pesticide manufacturer is getting his product registered. Once that is accomplished, the pesticide is permitted to be used. It then is relatively safe from being removed from the market. The cancellation procedure is still a seemingly endless and almost non-existent process.\(^{80}\) The possibility of suspension is also slight, since the EPA must resort to "courtroom" proof that the pesticide presents a risk to man or the environment.\(^{81}\) Moreover, even if a cancellation or suspension enforce-

and the low priority which the Justice Department gives to even criminal violations of the pesticide laws, violations, when uncovered, provoke nothing more than a slap on the wrist, a warning to go and sin no more, and a minor fine. \(^{Id.}\) There are also legal ways to conceal. The agency requires animal tests in the safety studies for registration. The registrant is given the choice of which two species to use in the experiments. The law's requirement for animal testing may be fulfilled if the manufacturer, as is frequently done, chooses the species which has been found to be the most resistant to the substance at issue. The validity of the chemical's "safe" characteristic is only a partial truth. \(^{Id.}\) at 1277. EPA's reporting requirements are less stringent for inert ingredients than they are for active ingredients, and non-existent for synergistic effects, \(i.e.,\) toxic effects caused by chemicals in combination which are greater than the effects of the individual chemicals acting independently. GAO Report, \(^{supra}\) note 15, at 6, 12. In addition, the present system allows the granting of conditional registrations, which "permit exposure of the public to occur and user reliance to develop before the safety of the product has been established." Extension of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., 1st Sess. 223 (1977) (statement of Maureen Hinkle, pesticides monitor, Environmental Defense Fund), \(reprinted\) in \([1977]\) \(8\) ENVIR. REP. (BNA) 281.

80. In the CBS broadcast, "The Politics of Cancer," reporter Lesley Stahl interviewed three senior EPA lawyers who resigned in February 1976. Their resignation was to protest the EPA's inaction under its existing authority to control toxic chemicals. For quite some time, the EPA had a list of over 100 suspected carcinogenic pesticides and no action was taken. Even if action were taken, the process is "very long."

Frank Sizemore, one of the three attorneys who resigned, said: "The conservative estimate is that if a chemical goes into that procedure [referring not to the process to take the pesticide off the market, but merely the procedure before the administrator is allowed to decide whether he wants to do something] it won't come out until 12 or 18 months later, and then we start a big hearing." CBS REPORTS, "The Politics of Cancer," as broadcast over the CBS Television Network, pp. 2, 13 of transcript (June 22, 1976).

81. Environmental Defense Fund v. Environmental Protection Agency, 489 F.2d 1247, 1250 (D.C. Cir. 1973), stating: "[T]he order of the Administrator cancelling registrations must be based on substantial evidence of record developed at a hearing if a public hearing is held, and the order must set forth detailed findings of fact." \(See\) \([1977]\) \(8\) ENVIR. REP. 586, where an EPA Office of General Counsel attorney noted that
ment procedure is undertaken, some comfort is still provided for the powerful pesticide manufacturer. A conciliatory and undermining "indemnity provision" was included in the final version of the FEPCA to facilitate its acceptance. It provides that if a pesticide is not found to be unsafe upon registration, but is subsequently discovered to have hazardous effects, then the manufacturer is to be reimbursed. Ironically, the reimbursement is to come from the public, whom the manufacturer has endangered.

There are other flaws in the FEPCA regulatory scheme. For example, no provision exists for environmentalists or consumers to bring suit to challenge the refusal, granting, or cancellation of a pesticide's registration, although provisions were present in earlier drafts of the Act. In the recent past, citizen participation has been encouraged by the EPA. Such a vital element as an interested party should not be included or excluded from a registration hearing at the whim of the administrator.

Administrative agency overlap, which impedes the implementation of action, still exists. When the EPA was formed in 1970, only a partial transfer of the pesticide regulation function was effectuated. The entire registration process was assumed from the USDA, but portions of the

"EPA would have to meet a stringent imminent hazard standard to suspend registration."

82. 7 U.S.C. § 136 m (1976). The provision allows not only the manufacturer, but anyone who owns a portion of the pesticide at the time it is suspended or cancelled to be reimbursed for its costs by the EPA. One author notes that the indemnity provision does not apply where it can be shown that those claimants caught with quantities of the pesticide had prior knowledge of its hazards or had some reasonable way of attaining such knowledge. Even then, the exclusion depends upon whether the EPA bears its burden of proving the manufacturer's knowledge. W. Butler, supra note 15, at 1260, 1261.

83. Comment, supra note 52, at 308-9.
85. Id. "EPA has encouraged citizen participation in the implementation of FEPCA, as provided by § 21(b) of the Act, especially by inviting comment upon implementing regulation." Id.
86. Surely citizens concerned with leading a healthy and safe existence have an interest in proceedings (administrative as well as judicial) whose outcome will determine if a pesticide, with potential detrimental environmental effects, will be permitted to be produced and applied. See Casenote, 52 J. Urb. L. 609 (1974) (discussing Pinkney v. Ohio Environmental Protection Agency, 375 F. Supp. 305 (N.D. Ohio 1974) (no fundamental right to a healthful environment)).
responsibility for setting tolerances of residues in food were left with the FDA.\textsuperscript{88} Also, the entire program for the monitoring of residues of pesticides was scattered among several different agencies,\textsuperscript{88} with the FDA and USDA primarily handling the monitoring function for foods.

This division of authority created co-ordination problems. The FDA and EPA have attempted to alleviate some of them by reaching an inter-agency agreement to exchange all information and investigative reports.\textsuperscript{90} Similar co-operation with the USDA has not blossomed. To the contrary, the USDA has been at times more a hindrance than a help.\textsuperscript{91} Perhaps such lack of co-operation emanates from the loss of pesticide regulation to the EPA, or, as many have commented, from the fact that USDA’s principal obligation is the protection of agricultural business.\textsuperscript{92}

6. A NEW APPROACH

A current crisis exists in pesticide regulation. The inadequate evaluation of safety testing data for registration results practically in the invalidation of the tolerance-setting program. The consequence of falsely-based tolerances is the inundation of the market with pesticides that are dangerous to health and the environment. Congress blames the EPA for poor planning and management.\textsuperscript{93} The EPA seeks exoneration by citing the lack of resources, time constraints, and the enormity of the task.\textsuperscript{94} Regardless of how this political problem of regulation is resolved,
the burden of inadequate protection from pesticide hazards ultimately falls on the public and the environment.

It is apparent that regulation is not keeping pace with scientific development and thus is not achieving the goals intended for environmental legislation.\(^95\) The greatest impediment to successful regulation appears to be the regulations themselves! The EPA is strangling in its own red tape. It needs help in the form of stronger legislation which abandons the traditional legalistic approach. Regulations based upon legal concepts of cause and proof in the context of environmental protection are inappropriate and inefficient. A "substantial adverse effect on man or the environment"\(^96\) must be shown "likely to occur"\(^97\) before strict enforcement practices can be implemented to prevent further contamination by the hazardous substance. Pressure has already been applied to modify the standards of proof and methods of review applied by the courts in public health hazard litigation.\(^98\) It seems anomalous,

95. The purpose of environmental legislation is:
(1) [to] fulfill the responsibilities of each generation as trustee of the environment for succeeding generations;
(2) [to] assure for all Americans safe, healthful, productive and aesthetically and culturally pleasing surroundings;
(3) [to] attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences. . . .


97. In the case of Reserve Mining Co. v. Environmental Protection Agency, 514 F.2d 492, 500 (8th Cir. 1975), an action was brought seeking a permanent injunction. This action was brought against Reserve to abate the industrial discharge of asbestos fibers into the waters of Lake Superior and the emission of the fibers into the ambient air.

At issue were the long-term effects of low level exposure to asbestos fibers. The effects of such exposure, like the harm of pesticide residue consumption, have not been conclusively established by scientific proof. The court concluded that it could not be said that "the probability of harm is more likely than not." Reserve was granted a "reasonable time" for abatement despite claims by the EPA that any delay could endanger the surrounding community. Thus, as other commentators have noted, the burden on the environmental litigant remains a proof that the risk of harm is "more likely than not" to occur. See generally Comment, supra note 30; Comment, UTAH L. REV. 58 (1975); Casenote, 25 CATH. U. L. REV. 178 (1975).

98. For discussion of proposed legislation after the Reserve Mining decision, see Note, 59 MINN. L. REV. 893, 923 n. 138 (1975) discussing S. 841, 94th Cong., 1st Sess. § 3 (1975), a bill to make the risk-benefit approach applicable to all environmental suits. Especially instigating the legislative response was the court's decision to resolve "all uncertainties . . . in favor of health safety." This was a "legislative policy judgment
though, to wait until the litigation stage to enjoin the use of a pesticide. Legislation requiring the manufacturer to prove that his substance will not have a detrimental effect on man and the environment could prevent a dangerous pesticide from ever being used. At the present time, prevention of the use of hazardous pesticides cannot be successful, owing to (1) the limited tests now required of a pesticide’s safety and (2) the rigid standard of proof required by courts in reviewing agency decisions on the safety of a product.

These problems can be resolved by drafting legislation which (1) includes requirements of extensive testing, as recommended by the General Accounting Office and (2) concomitantly provides for the adoption of the scientific concept of proof to determine the pesticide’s safety. The former provision would require tests on every individual pesticide product, not merely on the product’s active ingredients. Also, information would have to be supplied on the product’s inert ingredients and mutagenic effects. The latter provision calling for the use of a scientific approach in restricting environmental contaminants would allow the EPA, in reviewing a pesticide application for registration, to require nearly “scientific proof” that the manufacturer’s product is safe. This approach, which would limit the exposure of the environment to substances the effects of which were unascertainable by present technology, could be characterized as an “absolutist stance against uncertainty.” This stance would prevent a pesticide from being produced or applied if its safety test results did not meet “the conditions for valid scientific predictive inferences” that the product’s use would be safe.

100. An active ingredient in a pesticide is one which will:
(1) prevent, destroy, repel, attract or mitigate any pest,
(2) regulate the growth of a plant,
(3) cause foliage to fall from the plant (defoliant),
(4) artificially accelerate the drying of plant tissue (dessicant).

Id. at glossary.
101. See Comment, supra note 3.
102. Such terminology is used to describe the level of criteria that would substan-
The use of such a stringent standard as scientific certainty would also be beneficial when the agency's decision to cancel, suspend, or deny registration of a pesticide is subjected to court review. Fewer decisions would undergo unresolvable scientific debate in the courtroom because the agency's decisions would be based on more definite data. With judicial review limited to a determination of whether the manufacturer proved the safety of his product by more than a mere preponderance of the evidence, it seems likely that fewer agency decisions would be overturned.

In banning a pesticide, strong scientifically-based legislative action will prove more effective than the risk-benefit analysis presently used by the courts in reviewing whether a chemical substance poses an adverse effect to man and his environment. Professor Owen Olpin summed up the reasons why the risk-benefit test is less than acceptable:

First, available knowledge is often inadequate to permit a meaningful balancing of benefits and costs, since the costs are often unknown and incapable of measurement. Second, the balancing often requires the comparison of incomparables, and raises serious ethical questions, such as those arising from weighing the value of production of certain items for human convenience and monetary gain against serious risks of human death and injury.

Indeed, the choices available with a balancing test are not rational ones. First, although the expenses of research, development, and lost profits can be evaluated, what value should be assignable to a healthy human existence? In a recent hijacking of a Japanese airplane, the Japanese government paid $6 million for release of the hostages. Life should not be of any less value to Americans. Chemicals on the market should not be cloaked in the same presumption of innocence as people; they should not be presumed innocent until proven guilty.

Second, a court that uses the risk-benefit test while weighing the value of a suspect chemical is not as qualified as an administrative

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103. For discussion of the development and use of the risk-benefit analysis, see Comment, 1975 Utah L. Rev., supra note 97; see also Casenote, supra note 97.
106. CBS, supra note 80, at 3. See also Casenote, supra note 97, at 180.
agency to consider the risks posed or the available alternatives that are equally, if not more, effective. In this area, a Washington newspaper report indicated that human death and injury are present risks, which the now utilized legalistic methodology of enforcement has failed to curb.

Ominous recent reports of a sharp increase in the cancer rate in 1975 tend to support those who say that we are now seeing the start of a cancer epidemic caused in part by massive use of synthetic chemical pesticides since World War II.108

Dr. Samuel S. Epstein, an environmental toxicologist, has criticized the introduction of potent chemical agents which are largely untested for adverse public health effects. He remarked: "[C]ancer rates have gone up one percent a year since 1933 . . . and by 3.8 percent in 1975. There is no question that cancer is a major epidemic, and the environment and what man has done to it is indeed a major source for this great killer."109

The Council of Environmental Quality concurred with this view in its sixth annual report.110 It noted that of approximately two million known chemicals, only 6,000 have been tested in the laboratory for carcinogenic properties. Furthermore, the report continued, a thousand people every day are killed by cancer; one out of four is likely to con-
tract it, and sixty to ninety per cent of all cancer is attributed to environmental causes.\textsuperscript{111}

7. RECENT DEVELOPMENTS

Congress is cognizant of the controversy surrounding the regulation of chemical pollution. Its awareness was evidenced by the passage of the Toxic Substance Control Act of 1976 (TSCA).\textsuperscript{112} The relative strength of this legislation reflects the intent of Congress to provide for the regulation of toxic substances, a health priority.

The Act requires that a manufacturer submit to the EPA administrator a "notice of intent" to market a new chemical, or one having a significant new use.\textsuperscript{113} The notice should contain, among other information, "all known data on health and environmental effects."\textsuperscript{114} This significant provision places an affirmative duty on the manufacturer to submit all information and test results, even if they are damaging to the chances for marketability of the chemical. Hopefully, such explicit and encompassing requirements will eliminate the concealment of safety data that has plagued pesticide regulation and control. The manufacturer also has a continuing duty to inform the administrator of "information which reasonably supports the conclusion that "[the] substance . . . presents a substantial risk of injury to health or the environment."\textsuperscript{115} The incentive for filing the required information is considerable, with a maximum $25,000 fine for each violation,\textsuperscript{116} and treatment of each day of continued violation as a separate offense.\textsuperscript{117}

The Toxic Substance Control Act takes a significant step in achieving the aspired goals of pesticide regulation, by giving broad authority to the administrator to act during the notification period. The administrator may limit, delay, or prohibit the manufacturing of a suspect

\begin{itemize}
  \item \textsuperscript{111} Id.
  \item \textsuperscript{113} 15 U.S.C. § 2604 (a) (1976).
  \item \textsuperscript{114} 15 U.S.C. §§ 2604(a), (b), (d), 2607(b) (1976).
  \item \textsuperscript{115} This provision, like the registration process in pesticide regulation, may prove to have all the impact of a Hollywood set—all great facade and no substance. As Rogers, supra note 7, at 906-907 points out, "this reporting obligation can succumb to the rationalizations that the risk isn't all that 'substantial' or the threat of it not 'reasonably' justified."
  \item \textsuperscript{116} 15 U.S.C. § 2615(a) 1 (1976).
  \item \textsuperscript{117} Id.
\end{itemize}
chemical, and his basis for doing so will not be scrutinized by stringent requirements of proof. If the administrator, having evaluated the data supplied (1) deems it insufficient or (2) considers that the substance's use presents an unreasonable risk, then he may limit or prohibit the manufacturer's marketing of the chemical. The administrator may be compelled to go to court to justify (1) the injunction pending further information or (2) the prohibition against manufacturing because anticipated uses present an unreasonable risk of injury to health or the environment.

Under the TSCA, the courts will not be able to place an excessive burden of proof on the administrator to show that the chemical will adversely affect the environment. In taking steps toward a new approach to pollutant regulation, Congress lessened the burden of justification imposed on the administrator for his actions. He will be able to justify his limiting or prohibiting decisions on the same basis that has been evolving in the courts, that is, whether an adverse result is "more likely than not" to result from an action. The administrator will not be required to offer impossible proofs. He can make his decision in the balancing of risks and benefits, which disregards the traditional concepts of causal connection, and resolve "the uncertainties in favor of concern for possible harm to the environment and public health, and not for immediate economic advantage."

120. Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d 1292 (D.C. Cir. 1975). The court ignored the traditional concepts of proof in this action to suspend the registration of the pesticides Aldrin and Dieldrin. The EPA administrator, as the party alleging the harm, was not required to bear the burden of demonstrating a direct link between the particular substance and the specific damage. He would not, as determined by the court, be required to prove facts that scientists have been unable to prove. Id. at 1298. Where the risk involved is so great as to create a strong possibility that the substance causes a harm, the registrant has a duty of proving the safety of his product. See also Ethyl Corp. v. Environmental Protection Agency, 176 U.S. App. D.C. 373, 541 F.2d 1, cert. denied, 96 S. Ct. 2263 (1976).
121. This language, first used in Reserve Mining, does reflect a "legislative policy..."
Congress also extended broad authority to the administrator and established the grounds necessary to substantiate his decisions. Such measures were necessary to assure fulfillment of the Act’s purpose, namely, that all suspect chemicals be tested adequately before the commencement of the manufacturing process. In order to prevent exposure to suspect chemicals, action must be taken “before commercial production begins.” If an injunction were not possible at that stage, not only would the purpose of the Act be frustrated, but the cost of removing the chemical from the market would be substantially greater. The standards which restrict a manufacturer’s production of a chemical reflect an intent by Congress to supplant, at least in the instance of chemical regulation, the traditional elements of proof required to be shown before a court will exercise its equitable jurisdiction to grant an injunction.

The impetus for the Toxic Substance Control Act was, as Professor William H. Rogers had observed, “the technological revolution in the chemical industry that had outflanked thoroughly the traditional legal judgment not a judicial one.” Reserve Mining Co. v. Environmental Protection Agency, 514 F.2d at 500. However, even in the immediate aftermath of Reserve Mining, the legislature still seemed hesitant to make just such a determination. The courts, in interpreting the environmental statutes (see Ethyl Corporation (Clean Air Act), Environmental Defense Fund v. Environmental Protection Agency (FIFRA)), continued to prod for a legislative policy decision by noting their restrictions. “We are a court of law, governed by rules of proof, and unknowns may not be substituted for proof of demonstrable hazard to the public health.” Reserve Mining v. Environmental Protection Agency, 498 F.2d at 1084 (from a preliminary injunction hearing which was denied because the activity of Reserve was not found to be an imminent hazard to health).


123. Id.
124. The Act expresses an intent to avoid a “body count” approach to determine the health and safety hazards posed by a substance whose effects are dubious. Id. at 4550.
125. The purpose of the Act is to “assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment. . . .” 15 U.S.C. § 2601(b)(1) (1976).
126. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. [1976] U.S. Code Cong. & Ad. News, supra note 122, at 4550.
regimes such as the pesticide laws." Congress, with this legislation, clearly intended to put the burden on the manufacturer to develop toxic substance information, to emphasize the manufacturer's responsibility for the chemical's possible detrimental effects, and to assess them and to take corrective measures to alleviate their hazards. For the first time, the government is able to gather extensive information necessary to make a valid determination of a substance's potentially hazardous tendencies. The Act also contains a citizen-suit provision that will have substantial impact, since the participating party may be provided with compensation for attorney's fees, expert witness fees, and other costs. Thus, concerned environmental groups will be able to compete economically with the rich agribusiness and chemical corporations.

Ostensibly, the "political science of regulation" is losing ground to a much needed "science of regulation." The Toxic Substance Control Act, by requiring the administrator to collect and record all information on the attributes of the toxic chemicals, indicates a growing support by Congress for government acquisition of scientific knowledge. Although the information is still for the most part supplied by concerned

128. ROGERS, supra note 7, at 899.
130. The administrator under section 8 of the Act (15 U.S.C. § 2607 (1976)) has broad power to gather information, keep records, and report health and safety studies. This power under the TSCA is all encompassing. Unlike § 10 of FIFRA, health and safety test data will not escape scrutiny and recording because the manufacturer makes the claim that it is a "trade secret." Douglas Costle, the administrator of the EPA, is presently pushing to have the pesticide regulations amended to be consistent with the Toxic Substance Control Act. Again the deficiency of FIFRA is noted. In this instance, the law is too general and does not expressly state what data may qualify as trade secrets. Also exhibited is the court's comforting but not curative assistance. The "narrower view" of what are trade secrets, Costle predicted, would be upheld by courts, but only after a lengthy legal process. [1977] 8 ENVIR. REP. (BNA) 280.
133. Burger, supra note 2. The political science of regulation is the term used to categorize the conflict among various interest groups to have legislation and regulations passed which are favorable to their respective causes. They are more concerned with regulation for regulation's sake than in the quality and quantity of information available upon which to render a regulatory decision. Burger contends that "he who controls the information controls the regulatory activity." The government which has few independent sources of its own must make speculative and inconclusive decisions based upon information supplied by those to be regulated. This has resulted in a prominent lack of scientific information for regulatory decisions.
interests (manufacturers), the administrator now has the authority to conduct research, development, and monitoring in pursuit of the objectives of the Act. Realizing that "he who controls the information for regulation controls the regulatory activity," Congress acted to retrieve control from the industry by authorizing the EPA to develop its own sources of gathering data.

The political clout of the chemical manufacturers and their constituents has not disappeared from the spectra of regulations. The scope of TSCA is incredibly limited. The act specifically excludes the regulation of a number of substances, particularly pesticides, which is covered by another law whose ineffectiveness has been manifested. President Carter may have erred in his environmental address when he noted that, with the TSCA, no further comprehensive federal legislation should be necessary. Only time will reveal if the Act can be efficaciously en-

136. Burger, supra note 2, at 50,184.

Since information control is so important, it is advantageous for the parties concerned with the character of the regulation to supply the information. Id. Both environmentalists and businesses have an interest in health and environmental regulation. The environmentalists favor strict legislation fostering economic complacency, while the businesses encourage a laissez-faire approach, which would promulgate unrestricted progress, and profit. Therefore, to serve best their own interests, they would neither encourage the government to collect nor develop its own resources for scientific data.

137. 15 U.S.C. 2602(B) (1976). The term chemical substance does not include:
   (I) any mixture.
   (II) any pesticide [as defined by 7 U.S.C. § 136(u) (1976)].
   (III) tobacco or tobacco product.
   (IV) nuclear material or by-product.
   (V) article subject to tax under § 4184 of IRC of 1954 (as amended through December 31, 1976).

138. [1977] 8 ENVIR. REP. (BNA) 132 at 133. In his environmental address to Congress, President Carter noted the necessity of a co-ordinated federal effort to exclude these chemicals from our environment. Idealistically, interagency co-ordination would offer a better guarantee that hazardous materials would not be allowed to be mass-produced into our environment. Environmental Protection Agency Administrator Douglas Costle even proposed a transfer of that agency’s administration of pesticide programs to the Office of Toxic Substances.

The integration, however, may only prove to be beneficial for clerical convenience. In the area of enforcement, the Federal Insecticide, Fungicide and Rodenticide Act will continue to provide the guidelines for registration, record keeping, and cancellation or suspension of pesticide registration. See note 137 supra. Any attempt by the Administration to apply wider discretion allowed under the TSCA, or use of any of its other strong
forced to achieve successfully the purposes sought by Congress. Also the Act's authoritative parameters are subject to speculation. If merely applicable to the straggler substances that have eluded other regulatory controls, the gap-filling legislation is an enormous gesture with no impact.

While the operative capabilities of the Toxic Substance Control Act are being determined, the Federal Insecticide, Rodenticide, and Fungicide Act remains the governing legislation over pesticides. Its inadequacies will continue to allow many pesticides to be registered without knowledge of their full effects, and tolerances for human consumption to be based on limited questionable information.

8. CONCLUSION

Pesticide regulation has undergone heated debate and radical reconstruction in recent years. Whether the result has achieved a successful goal of protecting the health and environment of the American people is dubious at best. Conflicting interests between environmentalists and chemical industrialists have produced only conciliatory legislation.

The pattern is classic. The concerned public relieves its fears by pressuring for a dramatic gesture from the government, while representatives of the affected industry quietly prepare devices to absorb the pressures. Typically they take the form of enforcement procedures, where exasperating technicalities and labyrinthine delay mask Federal inaction in a camouflage of tedium—until the public tumult subsides.

Such a pattern undermines the regulation of pesticide residue allowed in foodstuffs. The "indemnity provision" was not the only at-
tempt to undermine insidiously the power of the EPA. Other instances include: the establishment of a Pesticide Policy Advisory Committee,\textsuperscript{142} which has pesticide industrialists as members; an attempt to give the secretary of the USDA veto power over any pesticide classification decision;\textsuperscript{143} the creation of a Scientific Advisory Commission;\textsuperscript{144} the requirement of a sixty-day notification before any action can be taken by the EPA;\textsuperscript{145} and, most recently, the inclusion of a provision on the FIFRA Extension Bill\textsuperscript{146} which would provide for congressional review and possible disapproval of EPA regulations. The "legislative wisdom" purporting to establish an efficacious regulatory scheme has created a severe conflict of interest by allowing the proponents of chemicals to test their own product for defects that may keep them off the market.\textsuperscript{147} Hopefully, these compromising practices will not continue until the pesticide industry exclusively controls the entire spectra of regulation.

The courts offer little redress. In the area of environmental contaminants, prevention—not subsequent reparation of the damage—is the logical method of control and enforcement. Most law suits, however, focus exclusively on past events.\textsuperscript{148} Courts, sympathetic to environmen-

\textsuperscript{142}Prevention, December 1975 at 202-3.
\textsuperscript{144}Id. at 1371; 7 U.S.C. § 136 (d) (1976).
\textsuperscript{145}Id. All of these provisions deal with administrative review. The details of the intricacies involved in notification of the Secretary of the U.S.D.A., publication of notice of intent to cancel registration, and consultation with the Scientific Advisory Committee are prime examples of "the exasperating technicalities and labyrinthine delay" that hinder prompt action to remove a pesticide from the market.
\textsuperscript{146}H. R. 12944 vetoed, H. Doc. No. 585, 94th Cong. 2d Sess. (1976) to extend FIFRA was vetoed by President Ford, because it contained the provision requiring an executive agency to submit its regulations to Congress for review and possible veto. See [1976] Envir. Rep. (BNA) 627.
\textsuperscript{147}It is doubtful whether the chemical industry, one of the largest and most powerful in the United States, will, in its economic self-interest, foster restrictions on productivity, while they expend substantial capital to market a product. See 6 Envir. L. Rep. 10,138, 10,042 (1976).
\textsuperscript{148}Id. Courts in suits for injunction have had difficulty in assessing a risk-
tal concerns, palliate the deficiencies of pesticide regulation, but cannot cure the flaws that allow people to be exposed to the pesticides and their residues.

Even when successful in removing a pesticide currently on the market, the court battles are a time-consuming and expensive method of regulation for the EPA. The cancellation process of a pesticide registration is lengthy and the suspension process difficult, since courts are restricted in their decision-making to the burden of proof required to establish the likelihood of an event's occurrence.

Pesticide proponents understandably prefer to use the courts as the means to enforce regulations. They know that the court's assessment of the potential gravity of a situation is entangled in legalities. Consequently, when the judicial process is circumvented, as was done in the Mirex "phase-out" used by the EPA, pesticide proponents vociferously condemn the termination of cancellation hearings. In the Mirex situation, they criticized the EPA's use of the registration process as a means to phase out Mirex from the market. The Mirex manufacturers, however, did not confront the propensity of the harmful effects caused by the pesticide. They complained, instead, that the EPA's approach was a wholly inadequate substitute for adjudicatory findings—not legally justifiable and not based on facts. 149

Facts are history—an established actuality; the state of things as they are. A stringent standard requiring an absolute factual determination should not be the basis of proof required before restricting the use of a potent killer. To remove a pesticide from use, it should not be necessary to establish, merely to satisfy a legal technicality, that the residue in food consumed by man is a carcinogenic, mutagenic, or teratogenic substance.

At present, the responsibility of enforcement of FEPCA is lodged with the administrator of the EPA. In justifying his decisions, he is not


Environmental law marks a domain where knowledge is hard to obtain and appraise, even in the administrative context; in the courtrooms, difficulties of understanding are multiplied. See Environmental Defense Fund v. Environmental Protection Agency, 465 F.2d 528 (D.C. Cir. 1972). See also Note, Imminent Irreparable Injury: A Need for Reform, 45 S. CALIF. L. REV. 1025, 1026-28 (1972).

For courts limiting review to procedural basis, see Latham v. Brinegar, 506 F.2d. 677 (9th Cir. 1974), National Helium Corp. v. Morton, 486 F.2d 995 (10th Cir. 1973).
confined to legal standards of proof. Scientific expertise, familiarity with specific issues, and insight into the development of an environmentally sensitive situation assist him in the risk assessment, which focuses toward future consequences. However, his decisions are subject to review by the courts, which lack his insight. Also, whether to take action against a pesticide is almost exclusively at the discretion of the administrator. This "tremendous discretion" has resulted in selective enforcement, which has been greatly criticized by some. Clearly, what is needed is stricter and more concrete legislation. Regulations that include a provision for citizens' suits would add another dimension to the enforcement of FIFRA. Environmentalists and other interested persons could then compel the administrator to take action against a suspect pesticide.

If strictly legal concepts continue to be employed in pesticide regulation, then the outlook for the acceptance of legislation that will prevent future ill health is bleak. If, in the future, scientific discovery exhibits with certainty that an extensive and continuous exposure to a low level of pesticide residues is carcinogenic, the banning of their use

150. Id. See also 6 ENVIR. L. REP. 10,138, 10,042, and Ethyl Corp. v. Environmental Protection Agency, 176 U.S. App. D.C. 373, 541 F.2d 1, cert. denied, 96 S. Ct. 2263 (1976). In discussing the administrator's ability and authority to assess risks, the court stated that he is not confined by reliance on facts. Those entrusted with enforcement of the laws protecting against "gross environmental modification" are not endowed with "a prescience," which removes speculation from the decision-making. Yet, there must be regulations and decisions. Consequently, it must be based upon theoretical and even conflicting data. Such a delicate balancing, the court held, should be left to the administrator, whose familiarity better qualifies him to make the risk assessment. Although his decisions may not be based on intuition, most courts will limit their review to procedural questions, or to whether his decision was arbitrary or capricious. Environmental Defense Fund v. Environmental Protection Agency, 465 F.2d 528, 539 (D.C. Cir. 1972).

For examples of courts favoring substantive review of agency action, see Environmental Defense Fund v. Corps of Engineers, 470 F.2d 289 (8th Cir. 1972); Environmental Defense Fund v. Froehlke, 473 F.2d 346 (8th Cir. 1972); Conservation Council of North Carolina v. Froehlke, 473 F.2d 664 (4th Cir. 1973).

151. 7 U.S.C. § 136 (1976). Agency regulation has its advantages over judicial implementation of pesticides statutes. However, the administrator has great discretion whether to take action and has resisted attempts to undermine that power. See Environmental Defense Fund v. Corps of Engineers, 470 F.2d at 289; Environmental Defense Fund v. Froehlke, 473 F.2d at 346.

152. A citizen suit would allow individual citizens to bring suits against persons, companies, and governmental agencies, for violations of the Act or for failure to enforce its provisions. See Comment, supra note 52, at 303. See also note 13 supra, at 2010, remarks by Senator Nelson; Comment, 68 MICH. L. REV. 1254, 1259-62 (1970).
will be a futile exercise, as the harm will already have occurred. The effects of exposure to such carcinogens are insidious, irreversible, and cumulative. 153

It may be possible to avoid this disastrous effect if a scientific approach to legislation is adopted whereby the future health, safety, and general welfare of the population are considered. An approach such as this, if adopted, would ban a chemical whose repercussions were not presently ascertainable. Furthermore, the quest of overcoming the technological limitations of prognostication of pesticide and chemical absorption would be propelled. Regulation prior to production and marketing would logically compel manufacturers to discover and rectify defects or develop alternatives in order to remain economically competitive.

Immediate consideration should be given to the incorporation of a novel scientific concept in the regulation of environmental contamination by pesticides and their residues. Then and only then would EPA enforcement no longer be evaluated critically as "too little, too late and unpredictable." 154

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153. For a discussion of different mortality studies of cancer, see A. LILIENTIELFELD, M. LEVIN & I. KESSLER, CANCER IN THE UNITED STATES (1972); for an easy non-scientific reading on cancer, see R. GLASSER, THE GREATEST BATTLE (1976). See also U.S. GOVERNMENT PRINTING OFFICE NATIONAL PANEL OF CONSULTANTS ON THE CONQUEST OF CANCER, NATIONAL PROGRAM FOR THE CONQUEST OF CANCER (1971).
154. [1976] 7 ENVIR. REP. (BNA) 42.