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Pesticide Safety Regulation under the Federal Insecticide, Fungicide and Rodenticide Act: Debacle at the EPA

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NOTES

PESTICIDE SAFETY REGULATION UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT: DEBACLE AT THE EPA

INTRODUCTION

The chemical industry, environmental groups and Congress have all raised a chorus of criticism against the Environmental Protection Agency's (EPA) pesticide programs authorized under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[1]. In 1980 the General Accounting Office (GAO), published a report entitled *Delays and Unresolved Issues Plague New Pesticide Protection Programs*, which, referring to its 1975 report on the same subject, stated that:

> Our 1975 report to the Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. The Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report.[2]

In 1986 the GAO once again reported that the EPA's pesticide safety programs remained significantly flawed.[3]

This Note focuses primarily on those failures of federal pesticide regulation which affect public health and safety. This inquiry includes a general examination of FIFRA, the vehicle by which Congress intended pesticide safety to be assured. In particular, this Note will show that the public confronts a serious health risk due to the ineffective implementation of an administrative procedure, authorized under FIFRA, called "RPAR" or "Special Review."[4] Consideration thus centers upon Special

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1. 7 U.S.C. § 136 *et seq.*, 15 U.S.C. §§ 1261, 1471, 21 U.S.C. §§ 321, 346(a) (1982 & Supp. IV 1986). This Act was recently amended and signed into law by President Reagan on Oct. 25, 1988. *See infra* notes 109-112 and accompanying text.

2. UNITED STATES GENERAL ACCOUNTING OFFICE, DELAYS AND UNRESOLVED ISSUES PLAGUE NEW PESTICIDE PROTECTION PROGRAMS, 2 (1980).

3. *See* UNITED STATES GENERAL ACCOUNTING OFFICE, PESTICIDES: EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS, (1986) [hereinafter EPA'S FORMIDABLE TASK].

4. Special Review Procedures, 40 C.F.R. § 154 (1986). Special Review was formerly called Rebuttable Presumption Against Registration or RPAR. *See* 40 Fed. Reg. 28,268 (1975); 40 Fed. Reg. 32,329 (1975).

According to the EPA the purpose of Special Review is:

> [T]o help the Agency determine whether to initiate procedures to cancel . . . a pesticide product because uses of that product may cause unreasonable adverse effects on the environment in accordance with sections 3(c)(6) and 6 of [FIFRA]. The process is intended to ensure that the Agency assesses risks . . . and the benefits of use of those pesticides, in an open and responsive manner. The issuance of an Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that,

Review: what it was intended to do; what it has failed to do; and some remedies that have been proposed. There is a general consensus that the Special Review process must be accelerated. There continues to be debate concerning how this should be accomplished—whether through the imposition of strict procedural timetables or the integration of Special Review with due process administrative appeals.

I. FIFRA AND REGULATION OF THE PESTICIDE INDUSTRY

Prior to 1972, FIFRA was a loosely-administered statute, marginally designed to protect the public.[5] As pesticides increased in potency and power[6] the statute proved to be a watchdog without teeth.[7] The EPA,

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following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel . . . the registration of the product(s) in question unless it has been shown . . . that the Agency's initial determination was erroneous . . . or that the benefits of the pesticide's use outweigh the risks.

40 C.F.R. § 154.1(a) (1986).

Special Review may consist of up to four stages: 1) Pre-Special Review involves an examination of validated health effects studies, literature and exposure routes of a suspect pesticide. Benefits are not weighed at this point. The pesticide registrant is informed of the EPA's concern and allowed to comment. The Agency's preliminary findings (qua concerns) are published as "Position Document 1" (PD 1); 2) Phase Two follows, and involves the gathering of more risk information. The public is invited to participate. The pesticide registrant may attempt to rebut the Agency's presumption that the product does pose a health/environmental risk. If none of the Agency's risk criteria are met at this point the Special Review Process ends with the publication of "Position Document 2" (PD 2); 3) If Phase Two uncovers risks the Agency publishes "Position Document 2/3" (PD 2/3), wherein the benefits of the pesticide are examined and regulatory options short of cancellation are explored; 4) The EPA's final risk/benefit decision is published in "Position Document 4" (PD 4). The product will either remain on the market or be removed via revocation of its registration. *See* Special Reviews of Pesticides; Criteria and Procedures, 50 Fed. Reg. 12188, 12191 (1985).

5. FIFRA, as enacted in 1947, Federal Insecticide, Fungicide and Rodenticide Act, Pub. L. No. 80-104, ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. § 136 *et seq.*, 15 U.S.C. §§ 1261, 1471, 21 U.S.C. §§ 321, 346(a) (1982 & Supp. IV 1986)), did not directly prohibit the misuse of a registered pesticide. The Act largely regulated labeling and made it unlawful to sell a "misbranded" pesticide. *See* 7 U.S.C. § 136(q) "Misbranding" was defined, in part, as merchandising a product without a warning sufficient to prevent injury to humans who would use that pesticide, either as directed on the label or in accordance with commonly recognized practice. *Id.*

6. The earliest pesticides were organic compounds. Preparations from the plant sabadilla have been used as louse powders in South America for centuries. As early as 1763 ground tobacco was recommended in France to kill aphids. Petroleum, kerosene, creosote, and turpentine were introduced as insecticides in the 18th century. A major watershed occurred with the advent of World War II, when the use of synthetic compounds exploded. DDT, whose insecticidal properties were discovered in 1939, was pressed into service during the war and achieved startling success, halting a typhus epidemic in Italy in 1943 and 1944. Thereafter, some predicted that all major insect pests would be eradicated. When DDT resistent insects were discovered, major efforts were devoted to finding new pesticidal compounds without DDT's limitations. Little energy was spent considering long range biological consequences. U.S. Dep't of Health Educ. & Welfare, REPORT OF THE SECRETARY'S COMMISSION ON PESTICIDES & THEIR RELATIONSHIP TO ENVIRONMENTAL HEALTH 44-46 (1969). In all deference to those in Congress in 1947, there were probably few who accurately foresaw the full effects of modern pesticides. The

formed[8] during the national environmental fervor of the 1970s,[9] was given oversight of FIFRA[10] and was thereby thrust into the hotly contested pesticide debate.[11]

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amazing results achieved by the new compounds surely overshadowed any thought of adverse human effects.

7. The U.S. Department of Agriculture (USDA) was the first agency entrusted with implementing FIFRA, and did so from 1947 through the 1960s. In the 1960s, the USDA came under attack for being inefficient, failing to place adequate emphasis on pesticide safety, and ignoring recommendations of the Food and Drug Administration (FDA). *See* STAFF OF SUBCOMM. ON ADMINISTRATIVE PRACTICE AND PROCEDURE OF THE SENATE JUDICIARY COMM., THE ENVIRONMENTAL PROTECTION AGENCY AND THE REGULATION OF PESTICIDES, 94th Cong., 2d Sess. 4 (1976) [hereinafter SENATE JUDICIARY COMMITTEE]. This inefficiency stemmed in part from the USDA's antithetical missions of promoting agricultural production through pesticide use and with safeguarding the public health. UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESS; NEED TO IMPROVE REGULATORY ENFORCEMENT PROCEDURES INVOLVING PESTICIDES 4 (1968) [hereinafter NEED TO IMPROVE]. The USDA was less than diligent in its enforcement of FIFRA. In 1968 the GAO reported that:

> there have been no actions by [the USDA] to report violators of the FIFRA for prosecution in 13 years, even in instances where repeated major violations of the law were cited by the agency and when shippers did not take satisfactory action to correct violations or ignored [USDA] notification that prosecution was being contemplated.

Id. at 7.

In his February 8, 1971 environmental message, President Nixon stated that:

> . . . Federal controls over pesticides consist of the registration and labeling requirements of the Federal Insecticide, Fungicide and Rodenticide Act. The administrative processes contained in the law are inordinately cumbersome and time consuming, and there is no authority to deal with the actual use of pesticides. The labels approved under the Act specify the uses to which pesticides may be put, but there is no way to insure that the label will be read or obeyed. The comprehensive strengthening of our pesticide control laws is needed.

Address by President Richard M. Nixon (Feb. 8, 1971) *reprinted in* S. REP. No. 970, 92d Cong., 2d Sess. at 9 (1972), *and in* 1972 U.S. CODE CONG. & ADMIN. NEWS 4092, 4093-94.

8. *See* Reorg. Plan No. 3 of 1970, 3 C.F.R. § 1072 (1970), *reprinted in* 1970 U.S. CODE CONG. & ADMIN. NEWS 6322.

9. That ecological concerns heavily charged the political atmosphere in 1970 is plain, as even a cursory examination of New York Times articles during the period demonstrates:

President Nixon, in his State of the Union address committed the administration to an effort to "make our peace with nature" and urged more environmental research and new regulations to resist and reverse contamination, N.Y. Times, Jan. 23, 1970, at A22, col. 4;

Governors and legislative leaders in 12 states gave environmental issues top priority. N.Y. Times, Feb. 24, 1970, at A1, col. 5;

The first "Earth Day" observance was held on April 22, with millions in U.S. participating. N.Y. Times, Apr. 23, 1970, at A1, col. 4. Up to 100,000 persons filed through Union Square Park in New York City in celebration of Earth Day. Mayor Lindsay closed portions of 14th St. to automobile traffic. N.Y. Times, Apr. 23, 1970, at A1, col.3;

President Nixon called for a major reshuffle of Government agencies and a transfer of most pollution control activities to an independent "Environmental Protection Administration". N.Y. Times, July 10, 1970, at A1, col. 1.

10. Reorg. Plan No. 3 of 1970, § 2.(a)(8), 3 C.F.R. § 1072 (1970), *reprinted in* 1970 U.S. CODE CONG. & ADMIN. NEWS 6322-23.

11. The furor over DDT was perhaps the most noteworthy anti-pesticide event of the decade. A series of proceedings to ban DDT and DDD were spearheaded by the Envi-

Congress enacted major amendments to FIFRA[12] in 1972.[13] The amendments required that new pesticide products, in order to be registered,[14] were to perform their intended function without causing "unreasonable adverse effects on the environment."[15] Likewise, pesticides already on the market which caused "unreasonable adverse effects on the environment" were to have their registration revoked.[16] In order to determine which pesticides fell into this second category, the amendment specifically required that all previously registered pesticides be re-reviewed for adverse effects on health or the environment.[17]

"Unreasonable adverse effects on the environment," as used in the context of registering new pesticide products or cancelling the registration of old products, was defined as "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."[18] Within this broad

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ronmental Defense Fund (EDF), and were originally directed against the United States Department of Agriculture. *See* Environmental Defense Fund v. Ruckelshaus 439 F.2d 584 (D.C. Cir. 1971); and Environmental Defense Fund v. United States Environmental Protection Agency, 485 F.2d 780 (D.C. Cir. 1973).

Pro-pesticide sentiment was not lacking during this period. Nobel peace laureate and noted agronomist Dr. Norman Borlaug stated, "I'm horrified by what I read . . . about some of these theories of the purists—who are suddenly going to shut off the use of chemical products that we need to continue the improvements of our agricultural production, and I say it broadly—fertilizers and pesticides." Remarks at the 9th Federal Reserve District Farm Forum, Minneapolis, Minn. (Mar. 3, 1971), *reprinted in* H.R. REP. No. 511, 92d Cong., 1st Sess. 3 (1971).

12. *See* Federal Environmental Pesticide Control Act of 1972 (FEPCA), Pub L. No. 92-516, 86 Stat. 973 (1972).

13. The House Committee on Agriculture, recommending passage of the Federal Environmental Pesticide Control Act of 1972 (FEPCA) stated that "[t]his bill is in part a result of the growing awareness of possible undesirable effects of pesticides and a realization of the necessity of considering these disadvantages along with the beneficial effects realized through protection of public health and enhancement of agricultural productivity." HOUSE COMM. ON AGRIC., The Environmental Pesticide Control Act of 1971, H.R. REP. No. 511, 92d Cong., 1st Sess. 4 (1971). To effect the needed balance, the Committee found "the greatest need for revision of existing laws to be in the areas of strengthening regulatory controls on the use and users of pesticides, speeding-up procedures for barring pesticides found to be undesirable, streamlining procedures for making valuable new measures, procedures and materials broadly available . . . ." *Id.*

14. Registration was required if a person wished to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive a pesticide. FEPCA, Pub. L. No. 92-516 § 3(a), 86 Stat. 973, 979 (1972).

15. FEPCA, Pub. L. No. 92-516 § 3(c)(5)(C), 86 Stat. 973, 980 (1972). The amendment required that this determination be based upon widespread and commonly recognized practice. *Id.* § 3(c)(5)(D), 86 Stat. 973, 980 (1972).

16. FEPCA, Pub. L. No. 92-516 § 6(b), 86 Stat. 973, 984-85 (1972). The section gives the Administrator an option to cancel registration or to hold a hearing. *Id.* Surely the intent of Congress was to have the registration revoked if the hearing confirmed the original suspicions.

17. *See* SENATE JUDICIARY COMMITTEE, *supra* note 7, at 5.

18. FEPCA, Pub. L. No. 92-516 § 2(bb), 86 Stat. 973, 979 (1972). There was debate whether "substantial adverse effects" should be used instead of "unreasonable adverse effects". The Senate Commerce Committee considered the choice of phrase a pivotal criterion to the registration and removal actions of the new Act. By adopting the "unrea-

framework the EPA was required to publish guidelines specifying the information necessary to support the registration or cancellation of a pesticide.[19] It was through these guidelines that "unreasonable adverse effects on the environment" would be defined with greater precision.[20]

Congress plainly did not appreciate the scope of the task it had set before the EPA. It was expected that by October 21, 1976, 50,000 pesticides would be completely re-reviewed.[21] The enormity of this task was compounded in that the EPA had virtually no administrative framework in place.[22] It was not until December of 1975 that the Office of Special Pest Reviews (OSPR) was created and charged with the mission of removing from the market pesticides causing unreasonable adverse effects.[23] The OSPR developed an administrative procedure for effecting this removal of suspect chemical pesticides called the Rebuttable Presumption Against Registration (RPAR).[24]

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sonable" language it was the Committee's understanding that "the bill on its face would require that EPA make a full weighing of competing interests in making its determinations. Thus, it is intended that any adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide." S. REP. No. 970, 92d Cong., 2d Sess. at 10-11 (1972), *reprinted in* 1972 U.S. CODE CONG. & ADMIN. NEWS 3993, 4094-95. By so adopting, the Committee sought to avoid a later interpretation of the statute by the courts (and one must assume by the EPA) that "a 'substantial' level of adversity must be reached before the [EPA] invokes the necessary balancing of risk verses benefit . . . ." *Id.* The Committee did not wish the EPA to remain powerless if a pesticide was found to pose "significant" but not "substantial" adverse effects. *Id.*

19. *See* FEPCA, Pub. L. No. 92-516 § 3(c)(2), 86 Stat. 973, 980 (1972).

20. *See Id.*

21. *See* SENATE JUDICIARY COMMITTEE, *supra* note 7, at 5.

22. The EPA was to receive the data necessary to review and evaluate each pesticide from the registrant/manufacturer of each compound. There were relatively few instances of non-compliance by manufacturers in submitting data. A larger problem existed in that the data received—laboratory reports and the like—were not uniform. Also, the EPA simply did not have the resources to properly organize and evaluate this data. *Id.*

23. *See* SENATE JUDICIARY COMMITTEE, *supra* note 7, at 11; *see also* 40 C.F.R. § 162.11 (1975).

24. In essence, the presumption was that any product the Administrator placed into the RPAR process was unsafe, which presumption the manufacturer would be given opportunity to rebut. *See* 40 C.F.R. § 154.7 (1975). As explained by the EPA:

> The process (a) was intended to provide an administrative mechanism for identifying pesticide uses which might pose substantial questions of safety, (b) was expected to provide an exchange of information between the Agency and interested persons on the question of whether a substantial question of safety in fact existed, (c) attempted to provide a forum for broad public participation during those steps, and (d) required initiation of formal adjudicatory processing under FIFRA if the risk criteria were not rebutted.

EPA Special Reviews of Pesticides; Criteria and Procedures, 50 Fed. Reg. 12,188, 12,190 (1985). The cancellation process which RPAR replaced was a formal, adversarial hearing procedure which did not provide either the regulated industry or the public with an opportunity to provide relevant information to the Agency prior to commencement of hearings. *Id.*

A. *Availability Of Data Necessary To Properly Evaluate Suspect Pesticides*

The OSPR intended RPAR to be a two-step process. First, a pesticide would be evaluated by a series of health-risk standards or "triggers".[25] Pesticides which demonstrated some evidence of being unsafe[26] were then to be subjected to a priority investigation in which the risks of using the pesticide would be weighed against its economic benefits.[27]

The effectiveness of the first step of the RPAR process to screen dangerous pesticides was integrally linked to the quantity and quality of health information available regarding the pesticide. Yet, in 1972, it was widely recognized that information for virtually all 50,000 pesticides on the market was either non-existent or in a state of chaos.[28] Because a pesticide could not have its registration revoked until there was sufficient information to enter it into the RPAR process, the implication was that no pesticide could be removed from the market.

EPA administrators must have realized the hopelessness of this situation. With less than one year left to complete the Congressional mandate to re-review all 50,000 pesticides and without one re-review having been

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25. *See* EPA Special Reviews of Pesticides; Criteria and Procedures, 50 Fed. Reg. 12,188 (1985); *see also supra* note 4 (Special Review starts with a pure risk assessment and then weighs the economic benefits against the determined risks). Any benefits derived through use of a chemical pesticide were not to be considered in the decision to initiate a Special Review. *See* 40 C.F.R. § 154.23 (1986) (Criteria for initiation of Special Review). Note that § 162.11, "Criteria for determination of unreasonable adverse effects," was the predecessor to the current § 154 in the C.F.R.; *See also* EPA'S FORMIDABLE TASK, *supra* note 3, at 102.

26. Risk assessment has been defined as:

> [T]he characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and duration; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment includes characterization of the uncertainties inherent in the process of inferring risk.

NATIONAL RESEARCH COUNCIL, COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 18 (1983).

Risk assessment can be divided into four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. 50 Fed. Reg. 12,188, 12,193. "Of the four steps, hazard identification is the most easily recognized in the actions of regulatory agencies. It is defined here as the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (cancer, birth defects, etc.). It involves characterizing the nature and strength of the evidence of causation. Although the question of whether a substance causes cancer or other adverse health effects is theoretically a yes-no question, there are few chemicals on which the human data are definitive." *Id.*

27. 40 C.F.R. § 162.11(a)(5)(iii) (1975).

28. *See* SENATE JUDICIARY COMM., *supra* note 7, at 23.

initiated, the Agency quietly abandoned plans for a product-by-product analysis.[29] Instead, the Agency committed itself to the task of merely confirming that some data was available.[30] A subsequent Senate staff report found that "[t]he decision, in effect, was to validate the presence of data submitted over the last 25 years by pesticide manufacturers, and not the adequacy of the data."[31]

Today, over a decade later, the situation remains virtually unchanged. The National Research Council of the National Academy of Sciences has concluded that there is sufficient toxicity and exposure information available for a complete health-hazard assessment on only a small fraction of registered pesticides.[32] This estimate is largely corroborated by the small number of pesticide active ingredients which have been completely re-

29. *See id.* at 1. The EPA's decision to shortcut a total re-review was allegedly adopted at an unpublicized meeting held with industry representatives. *See* SENATE JUDICIARY COMM., *supra* note 7, at 12-14.

30. Even this seemingly simple task proved a formidable chore for the EPA. The Agency's pesticide data files in the early 1970's were seriously disorganized. It was not until mid-1974 that OPP made an effort to modernize its filing system. One effort to computerize, in the opinion of EPA personnel, may have caused more problems than it attempted to solve. EPA file reviewers complained that the computer printouts, which were supposed to identify the specific location of data, were inaccurate. Often, data have been found to be misfiled, or missing completely. Ms. Elsie Kelly, a reviewer on the registration task force, stated, "In one file folder I found recently, there was just a table of contents, and nothing else . . . . EPA doesn't give enough importance to the files . . . . The files are a mess."

SENATE JUDICIARY COMM., *supra* note 7 at 16.

31. SENATE JUDICIARY COMM., *supra* note 7, at 14-15 (emphasis in original).

32. *See* NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMY OF SCIENCE, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984) [hereinafter TOXICITY TESTING]. In September of 1980 the Natural Toxicology Program (NTP) contracted with the National Research Council and the National Academy of Sciences (NAS) for a study with two principle charges: (1) To characterize the toxicity-testing needs for substances . . . to which there is known or anticipated human exposure, so that federal agencies responsible for the protection of public health will have the appropriate information needed to assess the toxicity of such substances; (2) To develop and validate uniformly applicable and wide-ranging criteria by which to set priorities for research on substances with potentially adverse public-health impact. *Id.* at ix. From a "select universe" of 65,725 toxic substances, samples and sub-samples were drawn and analyzed and the results extrapolated to the select universe. *See id.* at 1.

The National Research Council found that proportionately more testing has been undertaken on pesticides and inert ingredients of pesticide formulations than other sample groups (such as food additives and commercial compounds). *See id.* at 119. Yet, while relatively more voluminous than information pertaining to other toxic substances, that information was still noticeably lacking. For only ten percent of the pesticide formulations was a complete health hazard assessment possible. For sixty-six percent of the pesticides in the select universe there existed minimal toxicity information or less, with no toxicity information available whatsoever for thirty-eight percent of the pesticides. *See id.* at 12.

The National Research Council qualified even these findings. "If requirements for testing were rigidly adhered to, it would be necessary to say that, in light of intended use, not one of the 100 substances in the subsample met the requirements according to the strictest standards set by the protocols chosen by the Committee on Toxicity Data Elements." *See id.* at 99.

viewed and re-registered by the EPA since 1972.[33] Of the approximately 600 pesticide active-ingredients subject to re-registration, the EPA has completed standards leading toward re-registration for about 127 products.[34] However, a registration standard does not equal re-registration. In fact, the EPA has issued standards for which there were no chronic health effects data whatsoever.[35]

B. *Accuracy Of The Data Available to Evaluate Pesticides*

Much of the data supporting the EPA's pesticide re-registration and inspection procedure has proved to be flawed.[36] For example, in 1976 an FDA scientist uncovered by chance what has proved to be one of the greatest scientific scandals in recent decades.[37] Industrial BioTest Laboratories (IBT), an independent lab used by numerous pesticide manufacturers to conduct health tests, systematically submitted large numbers of falsified research studies and fraudulent data. The EPA estimated IBT

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33. Around 1974, the EPA, in an effort to speed the re-registration procedure, dropped the goal of evaluating each of the 50,000 registered pesticides and decided to review similar "batches" of pesticides, i.e., those with same active ingredients. *See* SENATE JUDICIARY COMM., *supra* note 7, at 12.

It is noteworthy that "inert" ingredients, those components of a pesticide not directed towards the intended function of the product (i.e., killing the pest) are largely ignored under FIFRA. "Inerts" may comprise a significant proportion of a pesticide and yet, until recently, the EPA required no chronic data and exempted inerts entirely from tolerance requirements. Wood preservatives sold for home use often use Captan, *see* text accompanying note 74 *infra*, a fungicide, as the active ingredient. However, the inert ingredients in these products frequently comprise eighty-eight percent of the whole and include such suspect chemicals as vinyl chloride, benzene, ethylene dichloride and formaldehyde. *See FIFRA; Pesticide Import and Export Act of 1985: Hearings on H. 1910, H. 1416 and H. 2482 Before the Subcomm. on Department Operations, Research and Foreign Agriculture of the House Comm. on Agriculture*, 99th Cong., 1st Sess. 332 (1985) [hereinafter *DORFA Hearings on H.R. 2482*] (statement of Albert Meyerhoff, Senior Attorney, Natural Resources Defense Council).

34. *Amendments to the Federal Insecticide, Fungicide and Rodenticide Act: Hearings on S. 2215 and S. 2346 Before the Comm. on Agriculture, Nutrition and Forestry*, 99th Cong., 2d Sess. 4 (1986) [hereinafter *Hearings on S. 2215*] (statement of John A. Moore, Assistant Administrator, Pesticides and Toxic Substances, EPA).

35. As noted by Albert Meyerhoff,

> [T]he issuance of a registration standard is in no way equivalent to a re-registration of the pesticide. By the end of FY 1985, EPA had issued 117 Registration Standards. But for only eight of these did EPA have complete health and safety data submitted at the time the standards were issued. Indeed, for twenty-one pesticides, standards were issued with no chronic health effects data whatsoever. In short, issuance of a Registration Standard no longer means that a pesticide has been re-registered. EPA's current re-registration program is re-registration by sleight of hand.

Id. at 156, n.6 (statement of Albert Meyerhoff, Senior Attorney, Natural Resources Defense Council).

36. *See* SUBCOMM. ON ENVIRONMENT, ENERGY AND NATURAL RESOURCES OF THE HOUSE COMM. ON GOVERNMENT OPERATIONS, PROBLEMS PLAGUE THE ENVIRONMENTAL PROTECTION AGENCY'S PESTICIDE REGISTRATION ACTIVITIES, H.R. REP. NO. 1147, 98th Cong., 2d Sess. 28 (1984) [hereinafter PROBLEMS PLAGUE EPA].

37. *See Hearings on S. 2215*, *supra* note 34, at 161 (statement of Albert Meyerhoff).

to be responsible for thirty-five to forty percent of the toxicological tests in the entire country, including data used for the registration of over 200 pesticides. The EPA eventually deemed ninety percent of IBT's studies to have been invalid.[38]

As the EPA now interprets FIFRA, the Agency has the legal authority to cancel or suspend a registered pesticide but may not do so with data that is false, inaccurate or fabricated.[39] As noted by one commentator, "[i]n a Catch 22 analysis, [the] EPA says that such cancellation may occur only where there is evidence of adverse effect on the environment which cannot, by definition, be shown with invalid studies."[40]

C. *Length of the Special Review Process*

The extremely lengthy nature of Special Review has received great criticism.[41] It seems ludicrous that a process which is supposed to provide an expedited review of chemicals suspected of posing a danger to the public should take two to six years or longer to complete.

The case of Captan is typical. Captan, a chemical relative of thalidomide,[42] was placed in RPAR in August 1980.[43] Several other agencies had acted on Captan prior to the EPA's notice of RPAR. The Department of Health Education and Welfare had reviewed the significance of adverse effects data on a number of pesticides and recommended unanimously that human exposure to Captan be considered a potential health hazard.[44] The Department of Labor revoked all waivers permitting employment of ten and eleven-year-old minors in hand harvesting of Captan treated crops of strawberries because Captan was a suspected carcinogen.[45] The EPA Office of Water Planning and Standards designated Captan as a hazardous substance in February of 1979.[46]

Captan, at this writing, is still in Special Review and a final decision, originally expected in April of 1987, has still not been received.[47] One reason for this extraordinary delay is the difficulty in weighing Captan's

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38. *See id.*

39. *See id.*

40. *See id.*

41. An extensive list of critics is provided in REPORT OF HOUSE COMM. ON AGRICULTURE RECOMMENDING PASSAGE OF H.R. 2482, H.R. DOC. NO. 695, 99th Cong., 2d Sess. 17 (1986) [hereinafter H.R. REP. ON 2482].

42. DORFA HEARINGS ON H.R. 2482, *supra* note 33, at 330 (statement of Albert Meyerhoff).

43. *See* EPA Pesticide Programs; Rebuttable Presumption Against Registration (RPAR) and Continued Registration of Pesticide Products Containing Captan, 45 Fed. Reg. 54,938 (1980).

44. The Department found Captan to cause: 1) dermatitis in agricultural workers; 2) mutagenic effects in bacteria, human embryonic lung cells and cell lines derived from the kidney of the kangaroo rat; 3) teratogenic effects in developing chicken embryos; 4) increased tumor incidence in mice. *Id.* at 54,943.

45. 44 Fed. Reg. 22,059 (1979).

46. 44 Fed. Reg. 10,271, 10,280 (1979).

47. *Hearings on S. 2215*, *supra* note 34, at 166 (statement of Albert Meyerhoff).

risk factors against substantial benefit claims. The EPA has estimated that if Captan were not available, twenty-five percent of the oat and wheat crops would be lost each year.[48]

D. *Politicization of Administrative Processes Has Significantly Hampered Special Review And Re-registration*

President Reagan came into office committed to reversing the growth of federal programs and regulatory influence in the United States.[49] He did not propose to effect this program solely through legislative initiative. David Stockman, President Reagan's first Director of the Office of Management and Budget, (OMB) declared the executive's commitment to "an orchestrated series of unilateral administrative actions to deter, revise, or rescind existing and pending regulations where clear legal authority exists."[50]

President-elect Reagan's transition team included a group organized specifically for this administrative restructuring. At the time of Mr. Stockman's comment, the OMB had already produced a "hit list" of some 242 regulations for possible reconsideration.[51] Prominent among these "reconsiderations" were EPA regulations affecting the chemical industry.[52]

To effectuate these reconsiderations, President Reagan established a new regulatory analysis system.[53] This program not only set the criteria (weighted towards economic considerations) to be used by agencies in making and analyzing regulatory decisions,[54] but also required those decisions to be cleared through both the OMB[55] and a presidential task

48. *See* ECONOMIC ANALYSIS BRANCH, BENEFITS AND FIELD STUDIES, OFFICE OF PESTICIDE PROGRAMS, EPA, FUNGICIDES: AN OVERVIEW OF THEIR SIGNIFICANCE TO AGRICULTURE AND THEIR REGULATORY IMPLICATIONS (1974) (Concerning fungicides in general, the report concludes that from the economic standpoint, if chemical fungicides were not available, certain crop losses might be as high as one-hundred percent, as in the use on grapes, or seventy-five percent for peanuts).

49. One week after the election, Murray Weidenbaum, chief of President-elect Reagan's regulatory task force, called for a freeze on new government rules during the first year of the new administration. *See* Taylor & Schershel, *Ways Reagan Will Curb The Regulators*, U.S. NEWS & WORLD REPORT, Dec. 15, 1980 at 34; *See also* Fritz, *What Will Reagan Do As President*, U.S. NEWS & WORLD REPORT, Nov. 17, 1980 at 22.

50. Nat'l Journal, Jan. 3, 1981, at 28, *reprinted in* Andrews, *Deregulation: The Failure at EPA*, in Environmental Policy in the 1980's: Reagan's New Agenda 161, 163 (N. Vig & M. Kraft eds. 1984) [hereinafter *Deregulation Failure at EPA*].

51. *See id.* at 163.

52. *See id.*

53. *See* Executive Order No. 12,291, 46 Fed. Reg. 13,193 (1981).

54. The order required that agencies: (1) refrain from regulatory action unless potential benefits outweigh potential costs to society; (2) choose regulatory objectives that maximize net benefits to society; (3) select alternatives that will impose the least net cost to society while achieving regulatory objectives; and (4) set regulatory priorities to maximize aggregate benefits to society, taking into account factors such as the condition of the national economy and of particular industries. *See id.*

55. As one commentator noted,

The OMB director can review agencies' regulatory documents—proposed rules,

force on regulatory relief chaired by the Vice-President.[56]

While the Reagan program ostensibly operated within the risk/benefit parameters of FIFRA,[57] critics alleged that the process had become "tainted with an obvious deregulatory bias and a hidden agenda of OMB control."[58] This is perhaps most evident in the substantial budget and staff cuts at the EPA.[59] Overall federal agency reductions from 1980 to 1984 were on the order of twenty-nine percent for staff and forty-four percent for budget.[60] Most amazing however was the seventy-five percent reduction in the EPA staff responsible for administering the RPAR program.[61]

EPA inaction evidences implementation of the presidential de-regulation program.[62] By 1984 EPA had singled out sixty-eight potentially dangerous pesticides. This designation should have made these products prime candidates for the RPAR process. Yet, not one RPAR was initiated between April, 1981 and March, 1984.[63]

The failure to initiate an RPAR on these sixty-eight suspect pesticides may also be attributed to the EPA's alteration of the RPAR procedures such that proceedings would not be initiated immediately upon the discovery of an RPAR trigger, as required by FIFRA.[64] The EPA purposefully chose to ignore risk triggers until complete data was developed through the much slower registration standards procedure. The EPA's purpose, allegedly, was to provide time to uncover all potential hazards.[65] The effect, however, was to halt the entire safety process.

> preliminary regulatory impact analyses, final rules, and final regulatory impact analyses—prior to the publication of these documents in the Federal Register. . . . The agency, unless otherwise required . . . must then refrain from publishing until the review is concluded. The agency also must refrain from publishing its final rule and analysis until it has responded to the director's views and incorporated those views and its own response in the rulemaking record.

Liroff, COST-BENEFIT ANALYSIS IN FEDERAL ENVIRONMENTAL PROGRAMS, in Cost-Benefit Analysis and Environmental Regulations: Politics Ethics, & Methods 35, 39 (D. Swartzman, R. Liroff & K. Croke eds. 1982).

56. *See id.* at 36.

57. Authorization to make FIFRA a risk/benefit statute is found in FEPCA, Pub. L. No. 92-516 § 2(bb), 86 Stat. 973, 979 (1972).

58. *Deregulation Failure at EPA*, *supra* note 50, at 175.

59. *See* SENATE JUDICIARY COMMITTEE, *supra* note 7, at 12.

60. *See id.* at 165-66.

61. The staff went from between eighty-five and one hundred individuals down to twenty-two. PROBLEMS PLAGUE EPA, *supra* note 36, at 41.

62. *See* Executive Order 12,291, 46 Fed. Reg. 13,193 (1981).

63. EPA's record on RPAR proceedings prior to 1981 was not one of active pursuit either. Of the sixty-eight candidates identified for RPAR by 1984, the agency initiated actions (before 1981) on only thirty-six and failed to complete action on ten of those by June of 1984. *See* PROBLEMS PLAGUE EPA, *supra* note 36, at 41.

64. 40 C.F.R. § 162.11(a)(3) (1981) (A rebuttable presumption shall arise if a pesticide meets or exceeds such triggers).

65. Anne Burford (formerly Gorsuch), director of the EPA's Office of Pesticide Programs, set as a policy agenda for the EPA the requirement of a more detailed prepublication review of all internal and contractual studies by senior administrators and by the

Displacement of risk factors for cost factors in the initial evaluative process at the EPA (and thus the subversion of RPAR proceedings) is most potently demonstrated by the initiation of what have variously been termed "science courts"[66] or "decision conferences."[67] Essentially, these were closed door meetings between EPA administrators and industry executives, held in lieu of an RPAR proceeding, from 1981 to 1984.[68] The

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EPA's Science Advisory Board. The reviews raised staff complaints of increased administrative delays and bottlenecks. *See Deregulation Failure at EPA*, *supra* note 50, at 168.

Congressional dismay over this manipulation of FIFRA, when uncovered, is evident from this exchange between William Gray, professional staff member, House Subcommittee on Environment, Energy and Natural Resources, and Edwin Johnson, Director of OPP/EPA at a committee hearing:

Mr. Gray:

> You have regulations that set certain triggers that are to start an RPAR process—cancer, mutagenic effects, and so on. Now you seem to be saying that even when you have one of those triggers, you are going to go ahead and do the total review necessary for a registration standard for that product before you initiate the RPAR process. The question is: Doesn't that defeat the purpose of RPAR? As we have understood it and have discussed it, the RPAR is to provide for an expedited decision because of the seriousness of certain potential side effects. Are you telling us that you are not going to do that so that you can look at all other potential problems with that pesticide? Is that what you are saying?

Mr. Johnson:

> That is part of the answer . . . .

Mr. Gray:

> I guess the question is: How many triggers do you need? It only takes one to kill somebody; doesn't it? Why do you need more than one trigger? If you have a trigger, you have a trigger, it seems to me, and you have a potential problem. To say that we want to find out all the other potential problems seems to be kind of defeating the whole purpose of having an RPAR process.

Mr. Johnson:

> I think there are several ways of looking at it, and we were looking at it partly from an efficiency point of view. We had seen the inefficiencies with the old process . . . . In trying to improve the process, it seemed that one which improved it tremendously was to know more about the chemical and be able to deal with the issues better and that should speed up the process.

EPA's Pesticide Registration Activities: Hearings Before the Subcomm. on Environment, Energy and Natural Resources of the House Comm. on Government Operations (part two), 98th Cong., 1st Sess. 174-75 (1983) [hereinafter *Hearings: EPA Pesticide Activities*].

66. *See Deregulation Failure At EPA*, *supra* note 50, at 168.

67. *Hearings on S. 2215*, *supra* note 34, at 165 (statement of Albert Meyerhoff).

68. Daminozide, also known as Alar, is a plant growth regulator used to delay fruit maturity, extend storage life for apples and enhance redness. In the early 1970's a series of studies indicated that Alar was a potent animal carcinogen. The EPA did not act on this information until 1980 and then only to inform Alar's registrant, Uniroyal, of its risk concerns. Closed door hearings were held for four years, during which time no carcinogenicity tests were initiated by Uniroyal and the EPA delayed the RPAR process. Finally, in September 1985, the EPA issued a proposed decision on daminozide cancelling its food uses because of an unreasonable health risk. When the EPA's Science Advisory Panel (SAP) subsequently faulted the studies upon which the EPA had based its decision the agency reversed itself and ordered Uniroyal to do more testing. Interestingly, the flaws in the data involved a smaller-than-usual number of test animals and would therefore understate the carcinogenicity of daminozide. The product was still on the market in 1986. *See Hearings on S. 2215*, *supra* note 34, at 167 (statement of Albert Meyerhoff).

The case of "EDB" is similar. The EPA continued to accept additional information

practice left the consumer public completely uninformed.

II. PROPOSED REMEDIES

Congress has once again turned its attention to FIFRA and major reforms have been proposed.[69] The most significant areas of debate and criticism are: 1) the need to reform the Special Review (RPAR) risk criteria or triggers; 2) the inordinately lengthy time being taken to complete Special Review of suspect pesticides; 3) the duplicative nature of the administrative reviews which follow Special Review; and 4) the extent to which the public may participate in the Special Review process where industrial trade secrets are involved.

Budgetary constraints are likely to circumscribe any proposed reform. From 1980 to 1985 funding for the EPA's Special Review program went from $13.4 million to $5.8 million.[70] Given contemporary concern over the federal budget deficit any significant restoration of previous spending levels is improbable. This is likely even though the EPA anticipates a need for a fifty percent increase in the EPA staff handling pesticide programs if, as is estimated, forty percent of pesticide active ingredients are placed in Special Review.[71] Therefore, any reforms to FIFRA's Special Review program should mitigate repetitive procedures and minimize processes that draw heavily on personnel resources.

A. *Risk Triggers*

Senate Bill S. 2215 proposes to allow the EPA to use risk "triggers"[72] based on hazard and exposure.[73] While this bill allows exposure to be a

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and arguments from the registrant long after deadlines for submissions under FIFRA had passed. Much of the information received had no relation to whether EDB presented an unreasonable risk to man or the environment and was received in closed door negotiating sessions with no official record made of what transpired. *See Problems Plague EPA*, *supra* note 36, at 42-43.

69. *See H.R. 2482*, *supra* note 41; *Hearings on S. 2215*, *supra* note 34.

70. *See EPA's Formidable Task*, *supra* note 3, at 107.

71. *See id.* at 108-9.

72. *See supra* note 25 and accompanying text.

73. "Hazard", or "toxic effects", and "exposure" are facets of toxicity, the mechanism of drug/chemical action in living organisms. Toxicity is divided into three phases: exposure, toxokinetic, toxodynamic. As explained in one text on the subject:

> Given a chemical in the environment—a dose—the presence of that chemical does not always mean exposure in the toxicological sense. It is simply not enough to state that because a chemical is present and humans may also be present that some type of cause and effect relationship of beneficial or detrimental nature may occur. For exposure to have a significant biological action, a route of absorption must be supplied and available . . . . [I]t is important [to] . . . determine the chemical . . . the duration [of exposure], the concentration at which the chemical was present and . . . the route of exposure.

S. Wagner, CLINICAL TOXICOLOGY OF AGRICULTURAL CHEMICALS 40-41 (1983) [hereinafter *Wagner*].

There are three routes by which any chemical can enter the body: the dermal (skin); the gastrointestinal; or the respiratory. *See id.* at 39-41. During the toxokinetic phase

factor in the initial decision to conduct a Special Review, the bill prohibits the EPA from delaying a Special Review due to the unavailability of exposure data.[74] Several groups support this change.[75] Their basic concern is that without this prohibition the EPA will postpone initiation of Special Reviews, thereby repeating the unnecessary delays of the early 1980s.[76]

The EPA is opposed to triggers which rely solely on toxic effects, and recently adopted criteria that rely on toxicity and exposure.[77] The EPA's concern is that there will be instances when the Agency has clear knowl-

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(a.k.a. pharmacokenetic) the chemical leaves the external environment and the process of absorption, distribution, metabolism and excretion occur. *See id.* at 42. The toxodynamic phase is where actual toxic effects are exhibited in an organism (e.g., humans), and is the most critical factor in EPA's hazard analysis. A pesticide's toxic effects are the result of some mechanism such as the inactivation of enzymes, interference with certain types of protein or small molecule synthesis, interference with oxygen transport or hemoglobin formation, allergic reactions or interference with immune mechanisms. *See id.* at 55.

74. The bill renames Special Review "Interim Administrative Review". Section 3(c) paragraph 8(A)(iii) reads: "Criteria for initiating an interim administrative review shall be established on the basis of levels of risk, and may include consideration of currently available exposure data." Paragraph 8(A)(iv) requires that the "[a]bsence of exposure data shall not delay or preclude initiation of an interim administrative review." *Hearings on* S. 2215, *supra* note 34, at 364.

75. *See id.* at 32 (statement of Dr. Jack D. Early, President, NACA).

Senate bill S. 2215 is particularly unique in that a rather odd coalition has endorsed the bill: The National Agricultural Chemicals Association (NACA), with ninety-two members; and the Campaign for Pesticide Reform, with forty-one members from environmental, consumer and labor groups. *See id.*

76. *See* text accompanying note 65, *supra*.

77. The old criteria were at 40 C.F.R. § 162.11(a) & (b) (1981). The new criteria are at 40 C.F.R. § 154.7 (1986). The EPA determined to place greater emphasis on exposure criteria because:

> [t]he [pre-1986] risk criteria for initiation of a comprehensive risk/benefit review have proven to be impractical and inflexible. Because these criteria are often based on narrow toxicologic determinations and do not adequately address the likelihood that significant exposures will actually occur, the Agency has developed new criteria for initiation of a Special Review. These proposed criteria assure that the determination of risk will be based both on the toxic effects associated with a pesticide and considerations of exposure of humans and nontarget organisms to the pesticide. For example, factors such as the magnitude and duration of exposure and the size of the exposed population will be taken into account. The significance of the risk will be determined according to the weight of the evidence of the toxicological information and the magnitude and scope of exposure.

Proposed Rule: Special Reviews of Pesticides; Criteria and Procedures, 50 Fed. Reg. 12,188 (1985) (to be codified at 40 C.F.R. § 154).

There is independent evidence that exposure data should be considered in the decision whether to initiate a Special Review. The National Research Council (NRC), "[i]n examining traditional approaches [of toxicity testing] . . . found some common themes that can be considered conventional wisdom and with which it agrees: . . . [t]he two key elements for screening are estimated human exposure and suspicion of toxic activity." *Toxicity Testing*, *supra* note 32, at 14 (1984). As the NRC developed criteria by which to set priorities for research on substances with potentially adverse public health impact, "[s]everal design principles became evident and were used by [NRC] in developing an illustrative priority-setting system . . . . Both exposure and suspected toxicity considerations are useful in every stage of priority-setting." *Id.* at 16.

edge that a compound poses no "real-world" threat because exposure levels are minimal but, if forced to use toxicity criteria alone, would be compelled to initiate a Special Review.[78] Thus, the EPA reasons that the Agency would be forced to initiate an expensive process to uncover an answer which is already known.

Given its limited resources, it seems unreasonable to require the EPA to ignore available exposure data and conduct a Special Review if the Agency is convinced exposure is in fact minimal. However, where the toxic properties of a pesticide are significant, the EPA's former practice of delaying an RPAR until the registration standards[79] for the product are complete also appears unreasonable. The Agency should have the flexibility to postpone a Special Review if there is adequate information on exposure to determine that risk to the population is minimal.[80] Senate Bill S. 2215 strikes a balance in that while exposure may be considered, such consideration must not slow the initiation of Special Review if the quantity of that data is small.

B. *Shortening the Time Required For Special Review*

If FIFRA is reasonably to fulfill its mandate to protect the population from adverse pesticide compounds, it is logical to expect that harmful substances will be removed quickly. However, as discussed above, Special Review has proved to be anything but an expeditious process. Proposals to accelerate Special Review are perhaps the most crucial changes under consideration.

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78. *See Hearings on S. 2215, supra* note 34, at 134 (statement of J. Moore, EPA).

79. *See supra* note 65 and accompanying text.

80. According the EPA, the flexibility to postpone Special Review of a product based on a probability of low exposure poses major difficulties in those instances where there is evidence that suspect ingredient may be carcinogenic. Dr. Roy Albert, professor of environmental medicine at New York University and chairman of EPA's Carcinogen Assessment Group has expressed great concern over the fact that there has never been a Federal cancer policy that really works. Out of the "hodgepodge" of laws purporting to control carcinogens, regulators have little guidance on how to regulate. Not only is there a lack of consensus on how and to what extent carcinogens should be regulated, there is little guidance as to how to translate available evidence into sound regulatory judgment. Thus, postponing critical review of a substance suspected of being carcinogenic because population exposure is low is a questionable procedure when dealing with non-threshold toxicants, and carcinogens are generally considered to be non-threshold toxicants. Dr. Albert emphasized that a national program should be initiated to develop: 1) policies relating to risk assessment (based on detached scientific criteria); 2) policies relating to regulation; and most important, 3) a mechanism to separate scientific evaluation from the regulatory decision process. The alternative, according to Dr. Albert, "is that the whole enterprise will continue to be bogged down in endless polemics and legal warfare." *Regulation of Pesticides: Hearings Before the Subcomm. on Department Operations, Research and Foreign Agriculture of the House Agriculture Comm.*, 98 Cong., 1st Sess. 49-52 (1983) (statement of Roy Albert, Institute of Environmental Medicine, New York University Medical Center).

1. Integration of Special Review Procedures with the Re-registration Program

The EPA has attempted to make the Special Review program more efficient by integrating it with the registration standard program.[81] By waiting until a complete toxicological picture of a pesticide is available through the registration process, the Agency claims that it will be aware of all Special Review criteria that may have been exceeded. This, it is further claimed, will avoid the possibility of having already initiated a Special Review based on one risk trigger and later finding that another trigger has been met, requiring the pesticide to go through another Special Review.[82]

This reasoning alone seems specious. Once a risk trigger is met and a product is in Special Review, a thorough investigation should uncover the presence of other risk triggers. If, in fact, a Special Review can be conducted such that significant risks can be missed, one must question the effectiveness of the process altogether.

In any event, the instances when the EPA would ignore a significant risk trigger in order to complete a registration standard would probably be few. The Chief of the Special Review Branch of the EPA has stated that "if EPA has a risk concern about a pesticide during the development of the interim registration standard, it will ask the registrant to expedite the completion of the studies addressing this concern."[83] If after reviewing these studies, the EPA has substantial concern, it will immediately put the pesticide into special review without waiting to complete the registration standard.[84]

2. Integration of Special Review and Administrative Review into a Rulemaking Procedure

Perhaps the greatest flaw in the Special Review process is that it is essentially like an informal notice-and-comment rule-making, except that it has no binding effect if an adversely affected party objects to the Agency's Special Review decision. A party adversely affected in the Special Review proceeding may request an administrative hearing[85] where the same risk/benefit issues are re-examined.[86] During an administrative

81. *See Hearings: EPA Pesticide Activities*, *supra* note 65 at 168 (statement by Mr. Johnson, EPA).

82. Administrators at the EPA claim to have "initiated many RPAR's based on one study and after we got into the RPAR we found that we had done inadequate analysis of the rest of the data base, that we didn't have sufficient data to reach a conclusion . . . . We had enough data to start but not enough to finish and we had to wait for years to get the information to finish." *Id.* Thus, EPA decided to fill all chemical data gaps during the registration standards program before initiating an RPAR (Special Review), "rather", as Mr. Johnson put it, "than going through this serial thing that just drags on forever." *Id.*

83. *EPA's Formidable Task*, *supra* note 3, at 112.

84. *See id.*

85. 7 U.S.C. § 136d (1982).

86. *Hearings on S. 2215*, *supra* note 34, at 5 (statement of John A. Moore).

hearing, which may last two or more years[87] and is extremely resource-intensive,[88] products which may give every indication of posing a serious health threat are allowed to remain on the market.[89]

To end this unacceptable situation the EPA seeks to combine the most useful features of both processes to speed the entire review procedure and remove dangerous products as quickly as possible.[90] The EPA has pro-

87. *See EPA's Formidable Task*, *supra* note 3, at 114.

88. The administrative hearing for the pesticides 2,4,5-T and Silvex took one year. More than 100 witnesses appeared, over 1,500 exhibits were entered into the record and more than 23,000 pages of transcript were made. Of the fifteen EPA attorneys assigned to the pesticide division, it is typical to have eight to ten working on a hearing, with numerous staff members of the Special Review branch lending support. *See EPA's Formidable Task*, *supra* note 3, at 114.

89. Pentachlorophenol (PCP) is a prime example. Placed in special review in 1978, a final decision was issued in July, 1984. PCP is still in the process of administrative appeal. What is most remarkable about this process of review and hearings to determine PCP's safety is that data indicating it is extremely toxic has existed for decades. In 1956 there were nine cases of PCP "intoxication" at an industrial site, five of which ended in death. *See* Gordon, *How Dangerous is PCP*, 2 MED. J. AUST. 485 (1956). Technical grade PCP has been implicated in causing teratogenic effects. *See* Kimbrough, *Toxicity of Chlorinated Hydrocarbons and Related Compounds*, 25 ARCH. ENVTL. HLTH. 125, 129 (1972). In 1974 PCP was linked with birth defects. *See Hearings on S. 2215*, *supra* note 34, at 166 (statement by Albert Meyerhoff). In 1978 one commentator noted that "[i]n view of studies that suggest that [PCP] is mutagenic or at least a comutagen, it seems likely that current human exposure to PCP poses a significant health hazard." Dougherty, *Human Exposure To Pentachlorophenol*, PENTACHLOROPHENOL: CHEMISTRY, PHARMACOLOGY & ENVIRONMENTAL TOXICOLOGY 351, 359 (K. Rao ed. 1978).

Even if PCP were eventually found to have a low toxicity level, exposure to the product is extensive. PCP is "[o]ne of the most widely used pesticides in the country. It is used as an insecticide, fungicide, herbicide, algicide, disinfectant and as an ingredient in antifouling paint. It finds its applications in industries manufacturing leather, masonry, wood and wood products, cooling towers, rope and paper mills." Wagner, *supra* note 73, at 122. A pesticide with low toxicity may be harmless in low quantities and yet be hazardous if present in the environment in large quantities. *See supra* note 73.

The chemical PCP itself is not the sole danger. "When discussing the effects of PCP on the environment one should have in mind that PCP itself is just a part of the problem . . . . [C]hlorinated phenoxy-phenols, which can act as precursors of dioxins, are often present [in PCP] in one to five percent." Nilsson & Norstrom, *Impurities In Commercial Products Related To Pentachlorophenol*, PENTACHLOROPHENOL: CHEMISTRY, PHARMACOLOGY AND ENVIRONMENTAL TOXICOLOGY 313 (K. Rao ed. 1978). A concern is that burning of chlorinated phenoxy-phenols will yield chlorinated dioxins. Wagner, *supra* note 73, at 124. 2,3,7,8 Tetrachlorodibenzo-p-dioxin (TCDD), though one of the most toxic of dioxins, is chemically similar to dioxin contaminants found in PCP. Anemia, leukopenia, gastritis and ulceration, early abortions, abnormal births, alterations in the immune response and cancer may be an aftermath of chronic low level exposure to TCDD. Dougherty, *supra* at 357. While the manufacturers of PCP argue, at the administrative review level, that the dioxins found in PCP are not as toxic as TCDD, their product remains available on the market. This is due, in part, to the fact that toxicity and exposure information for any pesticide must be balanced against the benefit society derives from that product. This risk/benefit analysis therefore must consider that "[i]n the U.S., treatment of wood with PCP results in a 7.5 billion dollar savings by lengthening the useful life of wood. This also helps to conserve our timber resources by sparing an estimated 43 million dollars worth of additional timber." Conklin & Fox, *Environmental Impact of PCP and Its Products: Roundtable Discussion*, PENTACHLOROPHENOL: CHEMISTRY, PHARMACOLOGY & ENVIRONMENTAL TOXICOLOGY 389, 394 (K. Rao ed. 1978).

90. *See Hearings on S. 2215*, *supra* note 34, at 5 (statement of J. Moore, EPA).

posed a hybrid procedure that would combine the openness, efficiency, and speed of rule-making with the opportunity for cross-examination at a hearing. This would accelerate the whole process while still permitting detailed scrutiny of important issues.[91] At the heart of the Agency's proposal is a new rule-making procedure which would replace Special Review and the administrative hearing.[92] If a hearing were requested after the rule-making decision, its scope would be limited and the substantive risk/benefit issues decided by rule-making would not be reexamined.[93] The Assistant General Counsel for pesticide matters has estimated that under rule-making, a hearing following special review would probably take no more than six weeks.[94]

The EPA's rule-making proposal has not received much support. When H.R. 2482 emerged from the House Agriculture Committee, the rule-making provisions were gone, replaced with procedural processes relying largely on deadline provisions to make special review more expeditious.[95] Senate bills S. 2215 and 4513 have very limited rule-making provisions, relying primarily on deadlines to achieve their purpose of expediting Special Review and administrative appeal, both of which would remain features of FIFRA under those bills.[96]

3. Deadlines

A number of groups, environmental and industrial, strongly support

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91. *See id.*

92. EPA was apparently instrumental in writing bill H.R. 2482, which contained rule-making amendments. *DORFA Hearings on H.R. 2482, supra* note 33, at 275, 282. The Reagan administration refused EPA's request to submit the bill, but Congressmen Roberts and Bedel submitted the bill to the Subcommittee on Department Operations, Research and Foreign Agriculture for debate. *Id.* at 312 (statement by Rep. Synar); *see also EPA's Formidable Task, supra* note 3 at 114.

93. H.R. 2482 as originally submitted by EPA, contained § 5(a) - Rulemaking Proceedings To Determine Whether Products Cause Unreasonable Adverse Effects On The Environment. As the caption suggests, the Agency would have rulemaking powers at the Special Review stage of investigation. Any rule made at this level of investigation could be challenged but would not operate as a stay of the regulation, *i.e.*, the pesticide would remain off the market through any subsequent administrative or judicial appeals if found to pose a hazard. *See DORFA Hearings on H.R. 2482, supra* note 33, at 282, 289.

The pesticide industry is opposed to giving EPA rulemaking power. Jack D. Early, President of the National Agricultural Chemical Association has stated that: "[s]crapping the present cancellation procedures in favor of rulemaking would speed removal of products from the market, but at the cost of procedures that ensure due process, where literally millions of dollars of investment, crops, health, the livelihood of thousands of members of the public ride on the product's registration." *Id.* at 335; *See also EPA's Formidable Task, supra* note 3 at 114-15.

94. *EPA's Formidable Task, supra* note 3, at 115.

95. *See* H.R. REP. ON 2482, *supra* note 41, at 25, 208.

96. *See Hearings on S. 2215, supra* note 34, at 5. The only significant rulemaking authority given to EPA in S. 2215 would be to make label changes. Even this power is undercut by a qualification that the rulemaking power may not be used if such label change would have a major economic impact. EPA argues that almost all label changes could be asserted to have a substantial impact. *Id.*

imposing deadlines on the special review and administrative hearings.[97] House bill H.R. 2482 schedules each step in the Special Review process.[98]

The EPA contends that simply specifying short deadlines will not promote efficiency or provide any procedures necessary to meet the deadlines.[99] The EPA is concerned that, with its limited resources, deadlines will be missed, encouraging registrants to seek redress in federal court and thereby further taxing the Agency's resources.[100] It is logical that the EPA, constrained by deadlines and a diminished staff, would be forced to shorten or forego comprehensive evaluation of a suspect product. Deadlines might be met, but at the expense of accuracy and thoroughness, with a result that is of no greater value to the commonweal than the present procedures.

C. *Public Participation*

In 1984, the EPA's practice of holding closed door meetings with industry representatives was challenged in court by the Natural Resources Defense Council.[101] The Agency responded to the suit with regulatory reform measures[102] that significantly mitigate the likelihood that the "science court" debacles will be repeated.[103] The establishment of spe-

97. *See EPA's Formidable Task*, *supra* note 3, at 115.

98. The procedure is renamed "Public Interim Administrative Review Proceeding" (PIAM) under the bill. H.R. REP. No. 2482, *supra* note 41, at 208.

Section 3(c)(8) of H.R. 2482 sets a precise schedule to be followed by the EPA administrator:

1) upon receiving significant evidence that raises prudent concerns that a product causes unreasonable adverse risk to humans or the environment, the Administrator shall notify the pesticide registrant of that fact;

2) the Administrator may then receive more information but must determine whether to initiate a PIAM within 60 days;

3) the Administrator then has 18 months to decide what regulatory action to take, with a maximum extension of one year if necessary. *Id.*

The PIAM would have a maximum limit of 32 months. Section 3(c)(8)(G) permits any person to seek judicial review if the Administrator fails to act within the time prescribed. *Id.*

99. The EPA's contention is that the time required to complete a particular special review is influenced by factors that are unique for each pesticide. In addition the EPA has stated that deadlines would have the effect of forcing the Agency to delay initiation of a special review until sufficient data were available to complete the process. *See EPA's Formidable Task*, *supra* note 3, at 115.

100. *Hearings on S. 2215*, *supra* note 34, at 5 (statement of John A. Moore, EPA).

101. *Natural Resources Defense Council v. Environmental Protection Agency (Ruckelshaus)*, No. 83-1509 (D.D.C. settlement approved Oct. 14, 1984). The claim alleged that the Agency violated the Freedom of Information Act and Administrative Procedure Act by excluding the public from participating in pesticide rulings and adopting major decisions without notice under a system of "regulatory reform measures" instituted by Anne M. Burford and John A. Todhunter. Settlement included a pledge by EPA to open to the public future pesticide regulatory proceedings. 15 Env't Rep. (BNA) 844-5 (1984).

102. *See* 40 C.F.R. § 154 (1986).

103. *See supra* note 66-68 and accompanying text.

cific procedures for responding to public inquiries[104] and keeping records thereof will hopefully preclude some of the more blatant administrative errors of the past.[105]

As now amended, FIFRA does not afford the public access to health and safety data submitted by a manufacturer during the registration process. Only after a product is registered may the public review registration data. House Bill H.R. 2482[106] would amend FIFRA to provide the public with access to registration data before the Agency reaches a conclusion. The amendment strikes a balance between the interest of the public in gaining access to health data, and the need for adequate protections to prevent the disclosure of research data to commercial competitors.[107]

CONCLUSION

There can be no doubt that the American public derives enormous benefit from the use of pesticides. There are critical uses of pesticides, such as preservation of as much as twenty-five to thirty percent of certain food crops.[108] Benefits can also be as simple as extending the lifespan of a wooden porch on the back of one's home.

The number and toxicity of pesticide products has increased explo-

104. A docket for all Special Review proceedings is now required under 40 C.F.R. § 154.15(b)(7) (1986). Any meeting between Agency personnel and any other person outside the Agency must be documented in a memorandum based on notes taken at the meeting and must specify the date, time of meeting, participants and their affiliations, who requested the meeting, the subject matter of the meeting and the person who prepared the memorandum. There are further requirements where confidential business information forms the basis of the meeting. *Id.*

Section 154.27 (a) contains guidelines that must be followed "to assure openness and responsiveness" in the Special Review process. "No person or party outside the government will be afforded special or preferential access to Agency Special Review decision makers or the Agency Special Review Process." Any meeting must conform to § 154.15 procedures. *Id.*

105. The Subcommittee on Environment, Energy and Natural Resources of the House Committee on Government Operations has reported on many procedural failings at EPA. Some of these failures show either a lack of any basic filing skills by EPA staff or intent to subvert pesticide regulatory procedures. For example, the committee found that a recommended final decision document on EDB, which had been forwarded to the Assistant Administrator for Pesticides and Toxic Substances, John A. Todhunter, for his approval and signature, inexplicably disappeared, delaying the special review process for a considerable time. *See Problems Plague the EPA*, *supra* note 36, at 43.

106. H.R. REP. ON 2482, *supra* note 41, at 18-20 (committee comments).

107. Requests for data under the amendment must include an affirmation that the person requesting access is not affiliated with a person engaged in the pesticide business and a statement that the person will not intentionally or recklessly violate that provision. The data will be made available at designated EPA offices, making the data readily available to all interested public parties while assuring that unauthorized release of information is not made. In addition, data obtained under amended § 3(c) could not later be used in any proceeding of any court or agency of the U.S. or any State. The provision would not affect the use in such a proceeding of data otherwise obtained through discovery or obtained after registration had been granted. *See id.* at 19-20.

108. *Need To Improve*, *supra* note 7, at 3-4.

sively since the Second World War. Our understanding of the biological effects of chemical pesticides remains woefully inadequate. On October 25, 1988, just days before this note went to the printer, President Reagan signed S. 659, the "Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1988" into law.[109] The bill was passed as a compromise measure, as is evidenced by comments such as those of Senator Leahy that, "we all would have preferred to see more comprehensive legislation . . . [i]t is clear that this year, however, it is simply not possible to enact the kind of omnibus legislation many of us would like."[110] Senator Dole has noted that some prefer to refer to the new law as "FIFRA lite."[111] The appellation is not unfitting. While the 1988 amendments do address several important safety issues, it may have left the entire Special Review Process, as it now stands, intact.[112]

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109. Pub. L. No. 100-532.

110. 134 CONG. REC. S.13454 (daily ed. Sept. 28, 1988).

111. 134 CONG. REC. S.13456 (daily ed. Sept. 28, 1988).

112. S. 659 amends FIFRA in four basic ways. First, paybacks to manufacturers and users for pesticides whose registration is cancelled has been radically altered. In large measure, only end users will receive compensation for stores of pesticide products in their possession. Second, the storage, transportation and disposal of pesticides whose registration has been revoked is now regulated. Third, fees will now be assessed on manufacturers to pay a substantial part of the cost involved to reregister their products. Fourth, and most relevant to this Note, a new procedure for the compilation of data necessary to reregister the over 600 active ingredients in pesticides has been passed into law.

Section 102 of S. 659 is to be inserted after the current section 3 (7 U.S.C. § 136a), and designated "Section 3A - Reregistration of Registered Pesticides." Subsection (b) of the new section 3A summarizes the five phases by which registration will take place:

> (b) Reregistration Phases. - Reregistration of pesticides under this section shall be carried out in the following phases:
> "(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.
> "(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants of missing or inadequate data within the applicable time period.
> "(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).
> "(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, or requests for additional data.
> "(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator. . . .

Reregistration, as structured under section 102, is to take place within precise time frames. The EPA Administrator may assess penalties, including cancellation of a product's registration, at various "phases" of the process if the new procedures are not complied with.

It has been estimated that the reregistration process under the 1988 amendments will take eight to nine years. The bill's sponsors contrast this time frame with pre-amendment projections for reregistration of up to 36 years.

What remains to be seen is the actual administrative processes that develop from the 1988 amendments. It is unclear whether the EPA will incorporate the provisions of S.

Legislators have promised that further amendment of FIFRA is likely in the one hundred first Congress.[113] It is clear, however, that the debate on how best to regulate pesticides will continue while highly suspicious compounds remain on the market. The 1988 amendments to FIFRA are encouraging new reforms. However, it is well established that the EPA is not immune from political tampering. The new legislation and President George Bush's espoused environmental concern gives further room for hope. Yet, the time necessary to complete individual Special Reviews must be shortened. Administrative processes must be clear, efficient and removed from the political sphere. Duplicative administrative reviews must be streamlined and integrated with judicial review.

Most important, Congress and the President should realize that the nation, despite the new pesticide amendments, has no clear-cut approach towards compounds that have carcinogenic, teratogenic or mutagenic qualities. Our national policy in this area of health care is largely ad-hoc. We remain unsure how to structure an administrative process which balances the risk of pesticide use against its benefits. This is largely the reason Special Review may take up to eight years—we are unsure of how to weigh incommensurables.

Thus, the risk-benefit question remains, for example, how will we, on a national basis, weigh increased corn production against cancer deaths? Until Congress and the nation can clearly answer this type of question in relation to pesticides, it is likely that the pesticide Special Review program and its progeny will remain mired in lengthy debate and unsatisfactory solutions.

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659, section 102 and the data generated thereunder, with the older process of "special review" and create a new hybrid procedure. FIFRA's current section 3(c)(6) (7 U.S.C. § 136a) and section 6 (7 U.S.C. § 136d) upon which "special review", administrative review and judicial review of pesticides are based have neither been repealed nor significantly modified.

There is, therefore, need for consideration as to just what impact the new law will have. The bill's sponsors and advocates have noted that under the current law, there was a temptation on the EPA's part not to regulate. *See* 134 CONG. REC. S.13455 (daily ed. Sept. 28, 1988) (statement of Sen. Proxmire). This was due to the need to indemnify a manufacturer whose registration was revoked. Two or three revocations might use OPP's total budget for one year. Now, with the scope of indemnity payments severely restricted, it is believed EPA will more readily remove suspect products. However, if "special review" and administrative appeals remain as currently constituted, it seems likely that a manufacturer with no hope of indemnification should his product fail to be reregistered under the new processes, would have great incentive to exploit the delays available under the special review and appeal processes.

Thus, even though the new 1988 legislation has streamlined reregistration and the development of pesticide health data, it is by no means certain that suspect products will be expediently removed from the market if current special review procedures remain as they are.

113. 134 CONG. REC. S.13456 (daily ed. Sept. 28, 1988) (statement of Sen. Dole).