Report for Recommendation 93-5

Regulating Pesticides: FIFRA Registration, Reregistration, Suspension, & Cancellation

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Executive Summary

The federal Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without significant change and improvement in the Agency's regulatory procedures. For over twenty years, EPA has been charged under the Federal Insecticide, Fungicide & Rodenticide Act ("FIFRA") to prevent "unreasonable risks" to public health or the environment from pesticide use. Yet scientists within and without the government repeatedly are finding that some pesticides may continue to pose unreasonable risks. There is growing evidence that EPA's lack of success in assessing, managing, and/or preventing such risks is related to glaringly ineffective administrative procedures.

Without significant improvements in regulatory procedure, moreover, the ambitious substantive changes to FIFRA and related provisions of the Federal Food Drug and Cosmetic Act ("FFDCA") now under consideration will be as incapable of successful implementation as the current statutory program. Among other things, policymakers in the 103rd Congress and the Clinton Administration are now debating the merits of replacing the current zero-risk standard for carcinogenic pesticide residues (in the so-called "Delaney Clause" of the FFDCA) with a more nuanced "negligible risk" standard. There is also debate about expanding the types of risks under FIFRA on which EPA's risk assessments focus (for example, by assessing the risks pesticides pose both to the general population and to infants and children in particular). In addition, there is interest in requiring EPA to expedite the registration and use of a new generation of "safer" pest management products and practices. Yet, the modern history of pesticide regulation makes crystal clear that FIFRA's substantive commands are only as real as the effectiveness of regulatory procedures provided for agency implementation.

This Report urges the need for, and recommends the adoption of, a coordinated and strategic procedural framework for FIFRA in which the Agency's multiple processes for pesticide regulation interrelate rather than interfere with each other, and reinforce rather than distract from the Agency's central regulatory mission. The legislative history of FIFRA reveals the steady accretion of procedural devices that may each, at the time of adoption, have seemed helpful to the particular concerns on which policymakers were focused. But viewed as a whole, FIFRA has become so overly proceduralized as to prevent EPA from doing its job. FIFRA now incorporates unnecessarily rigid procedures for each of the three major tasks assigned to EPA's Office of Pesticide Programs: the reregistration of existing pesticides; the cancellation and suspension of existing pesticides; and the registration of new pesticides. As importantly, EPA has not been given other, more flexible and incremental tools that could help the

Agency make defensible decisions in the face of disturbing but uncertain databases.

Even without any further change in its statutory responsibilities, EPA needs more streamlined procedures and the ability to use procedure more creatively to carry out its work. Above all else, EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants; for timely and accurate decisionmaking by EPA; and for effective public participation.

This Report recommends a package of procedural reforms that create overlapping incentives for the timely submission of adequate data from pesticide registrants during reregistration; for a more open but still flexible method of crafting interim risk reduction measures while final reregistration is pending; for ensuring that interim measures translate into real risk reduction in the field; for expediting the registration of safer pesticides; and for the increased, cost-effective use of safer pesticides through the "phase-down" of relatively risky existing pesticides that the Agency reasonably believes to be replaceable by safer pest management practices and products. Additionally, this Report recommends removing disincentives to cancellation and other agency actions by replacing the current opportunity for formal adjudicatory hearings with a more streamlined form of informal decisionmaking and by "de-coupling" the Agency's suspension and cancellation decisions.

The specific conclusions of this Report are as follows:

REREGISTRATION AND CANCELLATION: These central components of FIFRA now depend unfortunately on the lengthiest administrative processes among all government programs across the federal government. Registrants can now demand formal adjudicatory hearings, which have in the past averaged over 1000 days to complete, for cancellations of a pesticide's use as well as for changes in a pesticide's classification from "general use" to "restricted use" (even if no cancellation is involved), and even for denials of initial registration. Partially to address the problem, EPA designed a "Special Review" process to expedite regulatory attention on especially problematic pesticides, only to have Special Review itself come to take years—sometimes over a decade—to complete. The reregistration of all pesticides, which Congress originally wanted finished by 1976, was so mired in delay that Congress in 1988 adopted amendments to FIFRA specifically aimed at forcing reregistration to be completed by 1997. Yet the General Accounting Office has found, and EPA itself has admitted, that reregistration may not be completed until the year 2002, 2004, or beyond. The intractability of delay in reregistration and cancellation not only undermines the central premise of FIFRA—that pesticide registrants bear the burden of proof to

keep their products on the market—but is especially inexcusable because it occurs at a time when EPA's Science Advisory Board is finding that pesticide exposure is among the top risk-based priorities facing EPA and when the National Academy of Sciences is finding that pesticides not only may pose significant dietary risks but also that alternative products and practices exist to reduce these risks without losing pest management benefits. This Report recommends that FIFRA be amended to provide for the automatic suspension of higher priority pesticides, those classified as "List A" pesticides under the 1988 FIFRA Amendments, for which there remain, by a date determined by Congress, outstanding significant data gaps within the registrants' control. Nothing could better serve as a rough priority-setting device for Agency action or could better reverse the pervasive incentives for delay that permeate the reregistration process. Nor could any other single device better effectuate the underlying procedural premise of FIFRA that registrants truly bear the burden of not being able to demonstrate the reasonableness of their pesticides in the face of uncertainty.

It is also important that FIFRA be amended to remove unnecessary procedural disincentives to EPA from pursuing cancellation actions against those pesticides that the Agency already believes to pose unreasonable risks. To this end, FIFRA should provide more flexible and streamlined procedures than the formal adjudicatory hearings now provided under FIFRA Section 6(d). Especially as to formal hearings for cancellation, more streamlined decisionmaking can preserve constitutionally required process for registrants while offering direct benefits in efficient agency decisionmaking. Streamlined cancellation procedures, moreover, reduce the pressure on EPA to compromise with registrants on matters of substance during pre-hearing negotiations simply to avoid the resource drain on EPA personnel that formal cancellation hearings require. For this shift in process to be meaningful, however, it is imperative that new procedures not unduly deprive registrants of participatory rights (and thereby risk being set aside by the courts on constitutional grounds) but still be sufficiently streamlined to better protect public health and the environment. For this reason, this Report urges the need for a hybridized process generally patterned on notice-and-comment rulemaking but retaining several limited features usually associated with adjudication. The process urged here, however, is much simpler than the overly proceduralized form of "informal rulemaking" now advocated in the leading congressional FIFRA reform bill, the Lehman/Bliley bill.

As an equally important device for quickly achieving meaningful risk reduction in the short term, it also makes sense to provide EPA with more flexible procedural tools with which to regulate pesticides than the "all-or-nothing" alternatives of complete cancellation or cumbersome Special Review on the one hand and fully completed reregistration on the other. To this end, this Report

endorses the concept of tiered regulatory procedures. In particular, this Report urges that EPA develop an internal strategy for the selective use of Special Review, but also use a more informal process for negotiating label changes with registrants that might achieve risk-reduction gains more quickly than either Special Review or cancellation procedures. (To complement these regulatory tools, this Report includes in its recommendations on safer pesticides that EPA be given informal rulemaking authority to order the "phase down" of those pesticides awaiting reregistration when interim data on risk and the prospects of safer alternatives make continued levels of usage unreasonable).

As to label negotiations between EPA and registrants, it is important to anticipate predictable questions of public participation that may arise—indeed, questions that have already arisen due to EPA's current reliance on informal negotiations. The central problem arises from a dilemma. On the one hand, to open label negotiations to full public participation might well cut off the possibility that EPA can obtain quick, voluntary risk-reduction measures from registrants. On the other hand, EPA's programs under FIFRA have in the past been seriously distracted by charges of secret negotiations with pesticide registrants—a problem with a possibility of recurrence that would be foolish to ignore. This Report concludes that the tension between efficiency and wide participation in label negotiations should be managed by (1) allowing EPA to negotiate label changes privately with registrants, but only so long as (2) the Agency discloses in the Federal Register at the outset that negotiations have begun and opens a publicly available negotiation docket into which interested persons may submit information, (3) the Agency, promptly at the time negotiations are concluded, documents the date and time of meetings and the substance of negotiations in the public negotiation docket, (4) the Agency publishes the proposed label change in the Federal Register and provides a 30-day public comment period before it decides whether to publish the label change as final, and (5) the Agency, after the label change goes into effect, keeps open the public negotiation docket into which it and the affected registrant are REQUIRED promptly to submit any information they obtain regarding the efficacy of label changes in achieving (or not achieving) risk reduction.

SUSPENSION AND DATA MANAGEMENT: Although Congress has on several occasions recognized the wisdom of giving EPA authority to suspend as well as permanently cancel a pesticide's registration, improved regulatory design could make suspension a far more effective tool. Suspension is theoretically available in two general situations. First, to clear markets of pesticides whose registrants fail to fulfill their data obligations under the reregistration program. Second, to clear markets during the pendency of cancellation proceedings of pesticides that pose an "imminent hazard" to public health or the environment.

In both cases, the value of the Agency's suspension authority is unduly hobbled by existing constraints.

First, the use of suspensions to police data obligations must be made a more credible regulatory tool. FIFRA now puts two limitations on EPA's ability to issue Notices of Intent to Suspend ("NOIS") to registrants that fail to meet their data obligations: (1) registrants can request formal evidentiary hearings on the NOIS, and (2) all suspended registrations "shall be reinstated" whenever registrants fully comply with the data requirements at issue. Although EPA has found it increasingly necessary to issue NOIS due to the failure of registrants to meet deadlines for data submission, the prophylactic effect from such measures is undermined by the assurance of complete reinstatement of registration without further penalty upon the ultimate, untimely submission. This Report urges that EPA's authority to suspend registrations be streamlined to require a NOIS and a thirty-day opportunity to comment on the reasons given by the Agency in the NOIS. Registrants should be able to seek prompt judicial review of the Agency's action. To the extent registrants submit untimely data prior to suspension, EPA should be authorized to impose administrative penalties. To improve data adequacy, EPA should improve its procedures for promulgating clear data standards and for further elaborating on the Agency's data expectations proactively and informally with registrants. Having done its job, however, EPA should be authorized to impose administrative penalties on inadequate data (regardless of timeliness).

Second, as to those pesticides that pose "imminent hazards," EPA needs a more streamlined process on which to base suspensions. Except in certain emergency situations, EPA may currently suspend an imminent-hazard pesticide only after first affording registrants the opportunity to request a formal evidentiary hearing; although this hearing is expedited in the limited sense that it must begin relatively quickly and reach closure soon after the parties have presented their evidence, the normal rules governing the development of evidence in formal cancellation hearings generally apply. Moreover, EPA may not now suspend an imminent-hazard pesticide unless it simultaneously issues a notice of intent to cancel the pesticide's registration, forcing the Agency to contemplate the resource constraint of parallel, full-fledged cancellation hearings even if it seeks to act temporarily on new information of a pesticide's risks. EPA should retain its ability to act summarily in the face of true emergency situations, but should be able to suspend "imminent hazard" pesticides in non-emergency situations pursuant to a notice-and-comment process that can be promptly reviewed in the courts of appeals.

REGISTRATION OF SAFER PESTICIDES: To the extent that policymakers decide to encourage the registration of safer pesticides (a substantive decision involving a complicated, but not necessarily intractable, debate over the meaning of "safer"), it is important that there be a procedural framework which offers real, rather than symbolic, prospects for implementation. Perhaps more than any other regulatory innovation, the registration of safer pesticides can improve EPA's willingness to regulate existing pesticides because the Agency will have less concern that regulation must necessarily incur negative trade-offs in crop protection. Effective procedures for registering safer pesticides may go a long way to reducing "global" incentives for delay in EPA's innumerable reregistration, cancellation, and suspension decisions. A procedural strategy to encourage safer pesticides is not so much a subsidy for an arbitrarily selected class of new products as it is an equalizing mechanism that eliminates the regulatory asymmetry that now exists between new products that deserve to be tried despite some amount of uncertainty and older products that maintain their registrations and marketability in the face of data uncertainty.

To take advantage of comparative risk analysis and market-like regulatory incentives, EPA should also be authorized to conduct an informal rulemaking to "phase-down" the use of existing pesticides whenever the combination of risk data on the existing pesticides and the availability of safer pest management products or practices leads EPA to believe that current risk levels are unreasonable. "Phase-down" rulemakings would link in a strategic, reinforcing manner EPA's databases on existing pesticides with its registration of safer pesticides. Not only would such rulemakings provide an action-oriented mechanism by which the Agency could bring to bear comparative risk analysis (a form of analysis supported in principle by EPA's current and past political management, career staff, and Science Advisory Board), but the phased-in nature of the Agency's decisions would allow time for real-world feedback and further policy adjustment if necessary. In addition, phased-in use reductions—as opposed to outright product cancellations—would employ market mechanisms by which users who can most easily and cost-effectively shift to safer forms of pest management will do so while still leaving other users with access to existing pesticides at a higher (but still cost-effective) price.

Formal Proposed Recommendations reflecting these, and several other, suggestions for reform appear at the conclusion of this Report.

I. Introduction

Reform of federal pesticide regulation under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[1] and the Federal Food Drug and Cosmetic Act ("FFDCA")[2] has become one of the first environmental issues to come before the 103rd Congress and the Clinton Administration. Even prior to a flurry of activity regarding pesticide policy in the Summer and early Fall of 1993, political interest in regulatory reform had been awakened by reactivation of the so-called "Delaney Clause" in FFDCA Section 409 ("Delaney"). In February 1993, the Supreme Court denied certiorari in *Les v. Reilly,*[3] a Ninth Circuit Court of Appeals decision requiring the federal Environmental Protection Agency ("EPA") to interpret literally Delaney's prohibition in processed foods of residue from any pesticide "found to induce cancer in man or animal." EPA has indicated that the Court of Appeals' mandate will require it to cancel under FIFRA the registrations, and to prevent under FIFRA the reregistrations, of some widely used pesticides. Although concern over these prospects by growers, pesticide producers, and members of the food industry explained until recently much of the substantive focus of the current political debate, it never did explain the full scope of the debate. Once reopened, the debate over regulatory reform has grown to include longstanding concerns—many of them explicitly procedural in nature—with FIFRA's basic design and with the statute's implementation by EPA's Office of Pesticide Programs ("OPP"). The release in June 1993 of a much-anticipated National Academy of Sciences report on pesticide residues and children's health focused on the adequacy of underlying risk assessments.[4] In the wake of the NAS recommendations, the Clinton Administration has urged the streamlining of mechanisms under FIFRA for replacing unreasonably dangerous pesticides with relatively safer pest control products and practices.[5]

Historically, the underlying problem of pesticide policy has been to implement a defensible standard of "reasonable risk" that effectively placed the burden of proof on pesticide registrants to show that their products' risks are

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[1]7 USC §136-136y (1991).

[2]21 USC §301-394 (1990).

[3]968 F.2d 985 (9th Cir. 1992), cert. denied 61 U.S.L.W. 3584 (U.S. Feb. 19, 1993).

[4]*See* National Research Council, Pesticides in the Diets of Infants and Children 8 (National Academy Press 1993) ("Although tolerances establish enforceable legal limits for pesticide residues in food, they are not based primarily on health considerations, and they do not provide a good basis for inference about actual exposures of infants and children to pesticide residues in or on foods").

[5]*See* Joint Press Release R-141, June 25, 1993, Environmental Protection Agency, Food & Drug Administration, United States Department of Agriculture ("The Clinton Administration today announces its commitment to reducing the use of pesticides and to promote sustainable agriculture"); *see also* Executive Summary of Administration Proposed Reforms for Pesticides/Food Safety, 17 Chem. Reg. Rep. (BNA), No. 26, 1147 (Sept. 24, 1993).

acceptable under FIFRA's cost-benefit framework. Although FIFRA has been amended repeatedly to emphasize that registrants must bear this burden, the regulatory delay involved in making the reasonable risk determination effectively has allowed some (and perhaps many) pesticides to remain on the market despite real uncertainty that they reflect a reasonable accommodation of risks and benefits. For almost 20 years, the General Accounting Office has criticized OPP's efforts to reregister older pesticides and to remove from the marketplace or otherwise restrict pesticides with unacceptable risks.[6] Although OPP must surely share some accountability for regulatory failure, this Report suggests that poor statutory design has also played a significant role. FIFRA forces EPA to wander on an analytical treadmill that makes forward progress strenuous if not impossible.

The problem of regulatory delay dominates analysis of procedural reform under FIFRA. Among its most conspicuous failings, FIFRA in Section 6 allows EPA to cancel a pesticide's registration only after affording registrants the opportunity to demand a formal evidentiary hearing. The distortions created by formal adjudication go beyond the direct burdens on EPA of adequately staffing such proceedings—proceedings which are resource intensive affairs often taking years to complete.[7] Because both EPA and registrants realize the administrative burdens imposed by formal hearings, EPA is forced to make most of its actual cancellation decisions in the shadow of Section 6 through an extra-statutory process known as "Special Review," and through even more informal "pre-Special-Review" negotiations, in which OPP collects further data from, and negotiates with, registrants of suspect pesticides. The scale of bureaucratic delay in the combined Special Review/Cancellation process is notorious: among the

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[6]*See, e.g.*, U.S. General Accounting Office, Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts 2 (Nov. 1992) ("EPA's information management problems are traceable to inadequate systems planning and poor data management"); U.S. General Accounting Office, Pesticides: 30 Years Since Silent Spring—Many Long-Standing Concerns Remain 1 (July 1992) ("Since our first report on pesticides some 24 years ago, we have issued over a hundred reports and testimonies dealing with pesticide regulation"); U.S. General Accounting Office, Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks 4-5 (1986) ("EPA's Special Review process for dealing with pesticides where new evidence raises a concern about a significant health or environmental risk, has generally taken 2 to 6 years—contrary to EPA's goal of quickly making decisions on potentially hazardous pesticides"); U.S. General Accounting Office, Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately From Pesticide Hazards? i (1975) ("The American consumer has not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws....").

[7]*See* Study on Federal Regulations: Vol. IV, Delay in the Regulatory Process, S. Doc. No. 72, 95th Cong., 1st Sess. 33 (1977) (average of over 1,000 days from referral for hearing to termination), cited in Thomas O. McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 GEO. L. J. 729, 730 n. 11 (1979) ("Pesticide cancellation hearings on the average probably consume more total time for all decisions than any other administrative proceeding").

most lengthy administrative processes in the entire federal government have been OPP's Special Reviews of the fungicide Captan (nine years),[8] of fungicides containing cadmium (ten years)[9], and of a group of fungicides known as the ethylene bisdithiocarbamates or EBDCs (over 12 years).[10] President Bush's EPA Administrator, William Reilly, concluded in 1989: "The current pesticide cancellation process is complicated, duplicative, and inefficient. This country cancels trading in bad stock faster than it gets rid of a bad pesticide."[11]

The other major source of regulatory delay is found in FIFRA's registration and reregistration programs. When FIFRA was amended in 1972, it required EPA to base its regulatory decisions on an "unreasonable risk" standard which—in all contexts other than carcinogenic residues in processed foods governed by the zero-risk standard of the Delaney Clause—balanced the health and environmental risks against the agricultural benefits of pesticides. Not only was EPA required to use this standard in deciding whether to grant new registrations, but it was required to reregister all previously registered pesticides by applying the unreasonable risk standard to updated data on "old" pesticides. Although there is concern that the stringency of the Agency's initial registration procedures unduly hampers approval of newer, safer pesticides, it is in OPP's reregistration efforts that delay has been most notable. Despite a congressional requirement in 1972 that EPA reregister all pesticides by 1976, Congress was forced in 1978 to abandon its deadline after concluding that OPP's reregistration efforts had come to a "virtual halt."[12] Ten years later, OPP had reregistered only five active ingredients (out of the eight hundred active ingredients then registered),[13] prompting Congress in 1988 to adopt an altogether new set of strict timetables for reregistration in FIFRA Section 4. Although the new requirements call for the completion of reregistration by 1997, OPP has already indicated that this target date may not be met until the year 2006.[14] As of January 1993, only seven

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[8]*See* 45 Fed. Reg. 54938 (1980) (initiating Special Review of Captan) and 54 Fed. Reg. 8116 (1989) (Notice of intent to cancel most registrations; Conclusion of Special Review).

[9]*See* 42 Fed. Reg. 56574 (1977)(initiating Special Review) and 52 Fed.Reg. 31076 (1987) (conclusion of Special Review; intent to cancel registrations of pesticides containing cadmium).

[10]*See* 42 Fed. Reg. 63134 (1977) (initiating first Special Review), 52 Fed. Reg. 27172 (1987) (initiating second Special Review), and 54 Fed. Reg. 52158 (1989) (preliminary determination to cancel certain registrations of EBDCs).

[11]William K. Reilly, Press Conference on the Administration's Food Proposal, October 26, 1989 (quoted in Hearings on the Pesticide Safety Improvement Act of 1991, House Subcomm. on Department Operations, Research, and Foreign Agriculture, Comm. on Agriculture, 102nd Cong., 2d Cong. at 285 (March 18, 1992) (testimony of Erik Olson)).

[12]H.R. Rep. No. 663, 95th. Cong., 1st Sess. 18, reprinted in 1978 U.S. Code Cong. & Admin. News 1988, 1991.

[13]H.R. Rep. No. 939, 100th Cong., 2d Sess. 28, reprinted in 1988 U.S. Code Cong. & Admin. News 3474, 3477.

[14]U.S. General Accounting Office, Pesticide Reregistration May Not Be Completed Until 2006 7 (May 1993) ("According to program projections EPA made in March 1993, the agency...has estimated it

percent of older pesticides had been reregistered,[15] and as of May 1993 OPP had reassessed the data on and issued Reregistration Eligibility Documents for only ten out of 150 of the Agency's highest priority ("List A") pesticides.[16] EPA's task may become even more daunting if Congress demands that OPP elicit and evaluate more data on health risks to children,[17] and on the synergistic and cumulative effects of total pesticide exposure among the general population.

This Report focuses on procedural reform of FIFRA. Separating the procedural from the substantive can, as a general matter, present difficulties, especially in a statute such as FIFRA, which has inspired an academic literature analyzing the political and policy dimensions of several procedural provisions.[18] Nonetheless, it is often possible to draw practical distinctions between substance and procedure in the current debate over pesticide reform. For example, in February 1993 Senator Edward Kennedy and Representative Henry Waxman introduced into their respective chambers identical bills that would replace Delaney's zero-risk standard with a highly detailed set of statutory criteria defining the circumstances under which EPA may find a pesticide's risks to be "negligible;" speaking generally, these criteria would allow EPA to grant "tolerances" under FFDCA, and to grant registration or reregistration under FIFRA, to those pesticides that present less than a 1-in-1-million excess risk of cancer or other adverse human health effects. In contrast, Representatives Richard Lehman and Thomas Bliley introduced into the House in April 1993 a bill that would replace Delaney with a more open-ended principle of "negligible risk" depending to a much greater extent on EPA's discretion and professional

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would complete the reassessment of all 642 [active ingredients] only in 2001 or 2004 and complete product reregistration in 2003 or 2006, depending on whether projected funding limitations are addressed").

[15]U.S. E.P.A., Pesticide Reregistration Progress Report, EPA 738-R-93-001, at 1 (Jan. 1993). Through fiscal year 1992, EPA had reregistered only 31 pesticide products out of some 20,000 products requiring reregistration, although it had completed the reassessment of data and issued Reregistration Eligibility Documents for some 2,300 more products. *See* U.S. General Accounting Office, *supra* note 14, at 4.

[16]*See* U.S. General Accounting Office, *supra* note 14, at 14.

[17]*See*, e.g., National Research Council, *supra* note 4, at 8-12 (recommending that EPA needs to acquire more, and better, data on such risks).

[18]The most comprehensive study of FIFRA sounding this theme is Christopher J. Bosso, Pesticides and Politics (1987). For other examples in the political science literature, *see* Anthony J. Nownes, Interest Groups and the Regulation of Pesticides: Congress, Coalitions, and Closure, 24 Pol. Sciences 1 (1991); Angus MacIntyre, Administrative Initiative and Theories of Implementation: Federal Pesticide Policy, 1970-1976, 1985 PUB. POL'Y AND THE NAT. ENVT. 205. In the legal literature, I have elsewhere discussed FIFRA's legislative history in the context of modern positive political theory. *See* Donald T. Hornstein, Lessons From Federal Pesticide Regulation On the Paradigms and Politics of Environmental Law Reform, 10 YALE J. ON REG. 369 (1993).

judgment. As a rule, this Report views choices between policy options such as these as largely substantive and expresses no opinion.[19]

In contrast, some of the issues raised in pesticide reform proposals seem procedural in nature as an intuitive matter. The Lehman-Bliley bill, for example, proposes to allow EPA to "cancel" registrations under FIFRA by informal rulemakings rather than the formal adjudications that FIFRA now requires. The bill requires, however, a plethora of informal procedures, including requirements that any proposed rulemakings be preceded by an Advance Notice of Proposed Rulemaking and that the ANPR be itself preceded by consultation between EPA and a specially constituted "scientific peer review committee" (not to be confused with a separate "Scientific Advisory Panel" which is required to review all proposed rulemakings). This Report treats proposals such as these as fundamentally procedural—and fully within the scope of analysis.

Finally, there are some issues in which matters of administrative procedure and internal agency management cannot be separated easily from substantive policy matters. For example, there is currently a policy debate about the merits of promoting "safer" pesticides, yet this substantive policy decision is interwoven with the possibilities of adopting streamlined, "fast track" procedures for registering such pesticides. Similarly, the broader problem with delay in OPP's reregistration program may require consideration of substantive provisions for administrative penalties by which OPP can better police the timeliness and quality of registrants' data. To the extent this Report urges reform of provisions that might be said to intermix substance and procedure, it attempts to focus analysis on procedural measures and leave untouched as much as possible the related substantive matters of policy.

Before analyzing specific reform measures that might be made to FIFRA's cancellation, reregistration, suspension, and registration procedures, Part II of this Report seeks to explain the regulatory task with which EPA has been charged in FIFRA and the procedural framework with which EPA approaches this task. The Report takes up in Part III the regulation of existing pesticides and questions of streamlined reregistration, suspension, data management, and cancellation procedures. In Part IV, the Report takes up regulation of new pesticides and analyzes procedures that can accommodate a commitment to register and encourage safer pesticides. The Report has been written to allow readers sufficiently versed in the history and design of FIFRA to consult Parts III and IV.

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[19]The Report does mention in passing, however, how an open-ended or statutorily-specified definition of "negligible risk" might affect the constitutional due process analysis of streamlined cancellation procedures. *See* text *infra* at note 170.

II. Pesticide Regulation Under FIFRA[20]

At the core of federal pesticide regulation is a tale of two statutes, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and, secondarily, the Federal Food Drug and Cosmetic Act ("FFDCA"). Under FIFRA, no one may distribute or sell for a specific use a "pesticide"—defined broadly to include any insecticide, herbicide or other substance for the control of a "pest"[21]—unless the pesticide has been "registered" with EPA for that specific use.[22] EPA will register new pesticides and "reregister" older ones[23] so long as the pesticides are designed to accomplish their intended effects without causing "unreasonable adverse effects on the environment,"[24] a standard defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of [the pesticide's] use."[25]

If a pesticide's use is expected to cause residues to remain in or on food, EPA will not register that use under FIFRA unless it has also granted a residue "tolerance" under FFDCA.[26] Tolerance-setting is governed by FFDCA Sections 408 and 409. Section 408 governs tolerances for "raw" agricultural commodities such as milk and fresh produce.[27] Like a pesticide's registration under FIFRA, a Section 408 tolerance is granted on the basis of a risk-benefit calculus;[28] accordingly, EPA may, and has, granted tolerances for residues of oncogenic pesticides (those pesticides which can cause tumors in laboratory test animals under certain conditions) when the Agency believes that the health risks to

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[20]Much of the historical material in this Part of the Report is taken from Hornstein, *supra* note 18.

[21]*See* 7 USC §136(u) (the term "pesticide" means "any substance...intended for preventing, destroying, repelling, or mitigating any pest" and "any substance...intended for use as a plant regulator, defoliant, or desiccant"). *See also id.* 136(t) (the term "pest" means "any insect, rodent, nematode, fungus, weed...or any other form of terrestrial or aquatic plant or animal life or virus, bacteria or other micro-organisms [except those on living humans or animals]").

[22]*Id.* 136a(a).

[23]In 1972, FIFRA was amended to require the "reregistration" of previously registered pesticides under contemporary standards of "unreasonable risk." *See* Pub. L. No. 92-516, as amended by Pub. L. No. 94-140, Section 4.

[24]7 USC §136a(c)(5)(C),(D) (1988).

[25]*Id.* Section 136bb.

[26]*See* 21 USC §346a, 348 (1988); 40 CFR §152.112(g)(1991). EPA expresses tolerances as parts per million of pesticide residue in or on the food being evaluated.

[27]*See* 21 USC §346a(a).

[28]*See id.* (Administrator shall establish tolerances "to the extent necessary to protect human health" after giving "appropriate consideration" to the need for the production of an adequate, wholesome and economical food supply); Food Safety Amendments of 1989: Hearings on H.R. 1725 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 101st Cong., 1st Sess. 133-38 (1989) (testimony of EPA Acting Deputy Director John A. Moore) (EPA uses a subjective risk-benefit analysis for each case).

human beings are nevertheless relatively small.[29] Section 409 governs tolerances for "processed" foods such as applesauce.[30] In contrast to the risk-benefit standard for raw commodity tolerances, Section 409 is governed by the special decisional rule of the so-called "Delaney Clause" which prohibits any pesticide residues in processed foods "found to induce cancer in humans or animals."[31]

At the core of modern pesticide regulation under both statutes is the FIFRA reregistration program. Most of the 50,000 pesticide products now on the market derive from some 640 active ingredients that were registered under FIFRA on the basis of data sets that do not now meet contemporary risk assessment standards. The National Academy of Sciences estimated in 1987 that many of these older pesticides account for the lion's share of the contemporary risks from pesticides, under worst-case assumptions accounting for as many as 20,000 annual cases of pesticide-induced dietary cancer among consumers.[32] Other data indicate that these older pesticides may cause additionally between 80,000 and 300,000 occupational injuries (and as many as 1,000 deaths) annually among farmworkers.[33] Reregistration seeks to reevaluate these older pesticides under contemporary risk assessment standards.

In 1988, Congress adopted amendments to FIFRA designed specifically to expedite and regularize the reregistration process. Under the revamped statutory program, EPA is to complete in five "phases" by 1997 the complete reregistration

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[29]*See* National Academy of Sciences, Regulating Pesticides in Food: The Delaney Paradox (1987).

[30]*See* 21 USC §348 (1988). EPA, however, does not require a Section 409 tolerance for processed foods containing pesticide residues at or below the Section 408 tolerance level.

[31]The Clause is named after Representative James Delaney of New York who chaired extensive hearings on the safety of pesticides over a two-year period between 1950 and 1952. *See* Hearings Before the House Select Comm. To Investigate the Use of Chemicals in Foods and Cosmetics, 81st Cong., 2d Sess. and 82nd Cong., 1st & 2d Sess. (1950-1952) (popularly known as the "Delaney Committee" hearings). There are actually three "Delaney Clauses" in different sections of the FFDCA. *See* 21 USC §348(c), 367(b)(5)(B), 360b(d)(1)(H). Although the Clause seems unequivocally to allow no room for consideration of a carcinogen's dose, *see* Richard A. Merrill, Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act, 77 MICH. L. REV. 171, 181 (1978), EPA had, between 1988 and the Ninth Circuit's decision in Les v. Reilly, adopted a de minimis standard that allowed the agency to avoid the zero-risk impact of the Delaney Clause where the Agency believed the human dietary risk from a pesticide residue is "at most negligible," *see* Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41104 (1988).

[32]*See* National Academy of Sciences, *supra* note 29, at 74 (if worst case assumptions are valid, there would be an increased risk of 5,800 cancers per million people over a 70-year lifetime, translating into 1.4 million additional cases for the current population or 20,000 additional cases yearly). *See also* Meta-Analysis of Studies Indicates Higher Risks of Certain Cancers in Farmers, 16 Chem. Reg. Rep. (BNA), No. 26, at 1153 (Sept. 25, 1992) (National Cancer Institute's new meta-analysis of epidemiological studies suggests that the "rising rates for some tumors" among the general population may in fact be due to consumer exposure to agricultural pesticides).

[33]*See* OSHA Field Sanitation: Final Rule, 52 Fed. Reg. 16,050 (1987) (citing Bureau of Labor Statistics data); R. Wassertom & R. Wiles, Field Duty: U.S. Farmworkers and Pesticide Safety 3 (1985).

of all active ingredients that were first registered prior to November 1, 1984.[34] Phase 1 serves as a rough priority-setting device through the publication of four "lists" of pesticides—Lists A, B, C, & D— with pesticides in List A involving those products for which EPA had already developed interim registration standards and tending to involve those pesticides most commonly used on food. In Phase 2, registrants had to advise EPA whether they intended to seek reregistration and to identify any missing or inadequate data. In Phase 3, registrants had to reformat and summarize previously submitted data and to develop data necessary to fill existing data gaps. In Phase 4, EPA reviews all Phase 3 submissions and issues "data call-ins" for missing or inadequate data. In Phase 5, EPA is required within one year after all data have been submitted to determine whether an active ingredient is "eligible" for reregistration. EPA may require further data for specific products made from this active ingredient but, promptly upon the submission of such data, the Agency must determine whether a pesticide should be reregistered.

If, in the course of reregistration or otherwise, new information leads EPA to suspect that a registration can no longer be supported, it may begin proceedings to "cancel" the pesticide's registration, either in whole or as to specific applications.[35] EPA may also "suspend" a pesticide's registration during the pendency of cancellation proceedings if necessary to prevent an imminent hazard to the public.[36] Additionally, EPA may suspend a pesticide when registrants fail to fulfill their data obligations imposed in the reregistration process. Any registration suspended for data problems, however, must be fully reinstated upon the data's (untimely) submission. Registrants to whom EPA issues a Notice of Intent to Cancel or registrants of pesticides that EPA seeks to suspend because of "imminent hazards" are allowed to demand formal evidentiary hearings.

To understand fully the basic structure of pesticide regulation, it is important to appreciate the historical and practical link between reregistration and cancellation. In 1972, FIFRA was reconceived as an environmental protection statute under the direction of EPA. Soon after the 1972 FIFRA amendments, EPA's Office of General Counsel ("OGC") successfully adjudicated a series of resource-intensive cancellation proceedings against such highly visible organochlorine pesticides as DDT, Aldrin/Dieldrin, Heptachlor/Chlordane, and Mirex.[37] To simplify their evidentiary tasks in these proceedings, OGC attorneys shifted from an open-ended inquiry into all of a pesticide's risks and benefits into

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[34]*See* 54 Fed. Reg. 18,076 (1989).

[35]*Id.* 136d(b) (1988). *See* Environmental Defense Fund v. EPA, 564 F.2d 528, 532 (D.C. Cir. 1972).

[36]7 USC §136d(c).

[37]*See* MacIntyre, *supra* note 18, at 205.

a more focused "formula" that highlighted three factors: animal data showing the pesticide's carcinogenicity, evidence of widespread human exposure, and evidence of increasing pest resistance to the pesticide (from which OGC attorneys could downplay the pesticide's benefits).[38] OGC's success in these proceedings, however, only framed the immensity of EPA's larger regulatory task: the enormous effort required by the handful of cancellation proceedings hardly made a dent in the Agency's statutory duty to reregister the entire inventory of 50,000 existing products, containing hundreds of active ingredients.[39]

To simplify their task in reregistration, scientists at EPA's Office of Pesticide Programs borrowed the streamlined analytical approach pioneered by OGC attorneys in the early cancellation hearings and crafted an innovative regulatory device, the "rebuttable presumption against registration" ("RPAR") for use in EPA's reregistration program. If a pesticide ingredient was found to be oncogenic in test animals, it automatically triggered a RPAR process under which the burden of proof formally shifted to manufacturers to submit data rebutting the presumption to avoid Agency issuance of a Notice of Intent to Cancel.[40] If a pesticide's data did not trigger RPAR, and all necessary data were available and adequate, the pesticide became eligible for reregistration. The RPAR was viewed as a promising regulatory initiative that "proffered a substantial reduction of [the reregistration] caseload by providing a screening device that would rapidly isolate, and focus available evaluation capacity on, the worst chemicals while the safer ones underwent pro forma reregistration."[41]

In 1978, FIFRA was amended to allow for "Special Reviews" (a new term given to RPARs) when EPA could base such review on a "validated test or other significant evidence of unreasonable adverse risk."[42] The 1978 Amendments also allowed EPA to shift its reregistration focus from the 50,000 end products to the more manageable number of active ingredients,[43] and gave EPA "data call-in" authority by which the Agency could require registrants to provide data in support

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[38]*Id.* at 216.

[39]*See* Staff Report to the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, The Environmental Protection Agency and the Regulation of Pesticides, 94th Cong., 2d Sess. 11 (1976) (35,000 pesticide products had been registered under federal law and 15,000 more under various state laws).

[40]*See* 40 CFR §162.43(f)(1)(i)(A)(3) (1976).

[41]*See* MacIntyre, *supra* note 18, at 215-216.

[42]*See* 92 Stat. 826. This requirement, known as the "Grassley-Allen Amendment," was enacted out of concern for the "indictment-like characteristics" of the RPAR process, a concern which also led to the shift in terminology from "rebuttable presumption against registration" to "special review." *See* John D. Conner, Jr., et al., Pesticide Regulation Handbook 171 n.14 (3d ed. 1991).

[43]*See* 92 Stat. 819. There were in 1978 some 800 active ingredients, a number that has since been reduced to about 650 in 1993.

of a pesticide's reregistration.[44] During the late 1970's, EPA issued approximately 35 RPARS, many of which dragged on interminably.[45] In 1985, EPA revised its risk criteria for initiating Special Reviews to replace the original RPAR "triggers,"[46] a revision designed to "afford the Agency greater flexibility in evaluating potential risks" and initiating Special Review.[47]

By the mid-1980's, the Special Review process was preceded by private notification from OPP to registrants (in a document known as a "Grassley-Allen" notice) when OPP suspected a problem with a pesticide under EPA's revised risk criteria. If registrants could provide evidence to disabuse OPP of its suspicions, the Agency would publish in the Federal Register its reasons for not initiating Special Review.[48] If the Agency's concerns remained, OPP would publish in the Federal Register a Notice of Special Review, called "Position Document 1" ("PD 1") describing the risk criteria involved, the assumptions and data used in the Agency's analysis, and the strength of the Agency's conclusions.[49] EPA would also invite public comment and additional information on the pesticide. Following release of its PD 1, OPP would receive public comment, sometimes meet with interested parties, and occasionally hold informal public informational meetings.[50] Thereafter, the Agency would typically issue a "Position Document 2/3" (PD 2/3") announcing measures short of cancellation that address the risks of concern, often involving such measures as additional label warnings, use precautions, and protective clothing requirements.[51] EPA would solicit public comments on its PD 2/3 determination and also refer its tentative decision to the Secretary of Agriculture and to the FIFRA Scientific Advisory Panel for comment.[52] Following further input, OPP would announce its final determination in a "Position Document 4" ("PD 4").[53] Sometimes the PD 4 determination was accompanied by a Notice of Intent to Cancel, either because the risk reduction measures were inadequate to prevent "unreasonable risk" or because the Agency sought to use the cancellation process to make these risk reduction measures legally enforceable. EPA's regulations specifically allow EPA to collapse the

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[44]*See* FIFRA Section 3(c)(2)(B); *see also* Robert Perlis, The Push for Data on Existing Pesticides, 4 NAT. RES. & ENVT. 6, 7 (1990).

[45]*See* Pesticide Regulation Handbook, *supra* note 42, at 171.

[46]50 Fed. Reg. 49,003 (1985).

[47]*Id.* at 49,005; *see* Pesticide Regulation Handbook, *supra* note 42, at 172.

[48]*See* 40 CFR §154.23. This notice also afforded interested persons a thirty-day comment period prior to an announcement by EPA of its final decision not to initiate Special Review.

[49]*See* 40 CFR §154.25(c).

[50]*See* 40 CFR §154.26 (public comment), 154.27 (meetings with interested parties), 154.29 (informational public meetings).

[51]*See* Pesticide Regulation Handbook, *supra* note 42, at 176.

[52]*See* 40 CFR §154.31(b).

[53]*See* 40 CFR §154.33.

Special Review process to expedite decisionmaking,[54] and make it clear that cancellation proceedings may be initiated by EPA even in the absence of Special Review.[55]

Because Special Review itself had become so bureaucratic and time consuming,[56] however, EPA has since the late 1980's avoided the Special Review process entirely. Although several pesticides remain in the process,[57] the Agency has not initiated Special Review for any pesticide since 1988.[58] Instead, OPP has turned to informal negotiations with registrants to obtain risk reduction measures.[59] A recently completed but unreleased audit of the Special Review process by EPA's Inspector General has reportedly called this shift away from Special Review a "significant change in the regulations."[60] OPP's Acting Deputy Director has stated that informal label negotiations speed up the process of interim risk reduction "but the downside is that it is not as open as I'd like to see it."[61]

III. Regulating Existing Pesticides: Reforming Reregistration, Suspension, Data Management, and Cancellation Procedures

A. The Substantive Tensions Underlying Pesticide Regulation

However critical one might be of FIFRA's statutory design or EPA's record in implementation, it is intellectually dangerous to approach procedural reform without an appreciation of the genuine substantive difficulties of pesticide regulation. Underlying everything is the fact that pesticides, whatever their risks, can also have benefits. Even those who believe these benefits to be overstated, generally concede that a residuum (and often a quite significant residuum) of

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[54]*See* 40 CFR §154.34 (allowing for the Notice of Special Review and PD 2/3 to be combined).

[55]*See* 40 CFR §154.34(a).

[56]*See* notes 8-10 *supra* (Special Reviews of fungicide Captan took nine years, of fungicides containing cadmium ten years, and of the fungicides EBDCs, over 12 years).

[57]As of March 1992, eight pesticides remained in Special Review. *See* U.S. Envtl. Protection Agency, Status of Pesticides in Reregistration and Special Review, 9-50 (Mar. 1992).

[58]*See* EPA Actions in Special Review of Amitrole May Have Implications for Risk Assessments, 15 Chem. Reg. Rep. (BNA), No. 36, at 1359 (Dec. 6, 1991) (the last pesticide put in Special Review was dichlorvos in 1988).

[59]*See* Special Analysis: Special Review Process for Potentially Harmful Pesticides Sidetracked While EPA Negotiates Side Deals With Registrants, 17 Chem. Reg. Rep. (BNA) 1005 (August 27, 1993).

[60]*Id.* at 5.

[61]Acting OPP Deputy Director Dan Barolo, quoted in Special Analysis, *supra* note 59, at 3.

benefits from pesticides cannot be ignored.[62] Policy analysis can quickly become complicated when one realizes that these benefits may not only be measured in productivity gains, lower food prices, and increased grower profits—which one might plausibly argue should be trumped by concern for public health and environmental gains— but may also be measured in terms of public health benefits (from increased fruit and vegetable consumption due to lower prices) and environmental gains (more land may be available for wildlife habitat when agricultural land is farmed intensively)—depriving the analyst of easy resort to a blanket preference for public health and environmental values.

It is not, of course, impossible to simplify the complications that can arise from attempting to calculate and weigh all risks against all benefits. The Clinton Administration, for example, has proposed minimizing benefits analysis in setting FFDCA tolerances: tolerances instead would be set to assure no more than "negligible risks" from pesticides (defined to mean a "reasonable certainty of no harm" which, in turn, the Clinton Administration would further define for carcinogenicity as no more than a conservatively calculated one-in-one-million lifetime risk of cancer) and benefits could be considered to relax this target temporarily only when cancellation of a pesticide due to its lack of an FFDCA tolerance would "threaten to disrupt the food supply."[63] This Report takes no position on the desirability of truncating benefits analysis, viewing that decision more as a substantive policy judgment than a procedural device.

But even with a truncated analysis focused mainly on the "risk" side of the equation, the underlying difficulties in policy analysis remain evident. For example, there remains the question of which risk "end-points" to measure: neurotoxicity as well as carcinogenicity; risks to especially susceptible subgroups such as infants and children as well as risks to the general population; occupational risks to farmworkers as well as dietary risks to consumers; risks to wildlife and habitats as well as risks to people. Currently, EPA focuses on 15 different endpoints.[64] Then, there are the difficulties of making incommensurable

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[62]*Compare* David Pimentel et al., Environmental and Economic Impacts of Reducing U.S. Agricultural Pesticide Use, in Handbook of Pest Management in Agriculture (1991) (finding that if 50 percent of pesticides now used in American agriculture were replaced by nonchemical control techniques, crop yields would not decline and food prices would rise less than one percent) with David Pimentel et al., Benefits and Costs of Pesticide Use in U.S. Food Production, 28 BIOSCIENCE 772, 781 (1978) (for many crops, pesticides increase yields and reduce labor costs, with aggregate estimates of productivity gains indicating a 400% rate of return on the pesticide dollar).

[63]*See* Benefits Tossed Out of Risk Analysis, Delaney Repeal Sought in Reform Package, 17 Chem. Reg. Rep. (BNA), No. 26, at 1115 (Sept. 24, 1993).

[64]*See* Special Analysis *supra* note 59, at 2 (quoting OPP Acting Deputy Director Dan Barolo) (OPP focuses on 15 different endpoints, with the list of endpoints "still growing...[to include] risks involving ground water, acute dietary effects, cancer, avian risks related to granular pesticides...[and the] risks of destroying a critical habitat of any threatened or endangered species.... EPA concerns can be

trade-offs among these risks. EPA's decision to cancel many uses of the nematicide ethylene dibromide ("EDB"), for example, has been criticized as preventing a relatively small dietary risk to consumers at the expense of forcing the use of substitute pesticides creating a more significant occupational health risk to applicators.[65]

Compounding these difficulties is the scientific complexity of the underlying risk assessments. A review of the reregistration program by the General Accounting Office in May 1993 noted that "over 100 studies may be required to provide the information EPA needs to assess a food-use pesticide."[66] Moreover, the meaning of each of these studies may be open to legitimate interpretation. The National Academy of Sciences in 1983 identified almost 50 decisional points in risk assessments that may each present assessors with "inference options" requiring a choice among several plausible scientific judgments about uncertain data or theoretical connections.[67] Even though growing experience with risk analysis might be expected to make the science of risk assessment less soft as to some endpoints, the regulators' inevitable concern with new endpoints will continually raise serious interpretational difficulties. OPP's Acting Deputy Director noted in August 1993 that the National Academy of Sciences' June 1993 report on dietary risks to infants and children will make studies on neurotoxicity and immunotoxicity relevant to and more prevalent in pesticide reregistration, yet "no two scientists in the free world agree on how to deal with these endpoints."[68]

And compounding the scientific difficulties of risk assessment are structural concerns about the integrity of the raw data on which these assessments are based. OPP depends on health, safety, and environmental data developed by registrants themselves (or, more commonly, by the laboratories with which registrants contract). Yet because these data become public upon their

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triggered not only by agency studies, but also by studies of independent groups such as the National Toxicology Program or by the National Cancer Institute").

[65]*See* William B. Havender, EDB and the Marigold Option, Jan.-Feb. 1984 REGULATION 13.

[66]U.S. General Accounting Office, *supra* note 14, at 8.

[67]*See* National Research Council, National Academy of Sciences, Risk Assessment in the Federal Government: Managing the Process 29-31 (1983). Professor Mary Lyndon gives three examples of such inference options:

(1) What relative weights should be given to studies with different results? For example, should positive results outweigh negative results if the studies that yield them are comparable?....

(2) Should evidence on different types of responses be weighted or combined (e.g., data on different tumor sites and data on benign versus malignant tumors)?....

(3) How should physiologic characteristics be...factored into the dose-response relation? For example, is there something about the study group that distinguishes its response from that of the general population?

Mary Lyndon, Risk Assessment, Risk Communication and Legitimacy: An Introduction to the Symposium, 14 COLUM. J. ENVTL. L. 289, 291 (1989).

[68]Special Analysis *supra* note 59, at 4.

submission to EPA and cannot really be capitalized upon by registrants,[69] there is no real market incentive for registrants to produce especially good data and some obvious market incentives not to produce especially damning data.[70] This is not to suggest that all registrants will falsify data, although it is worth noting that OPP has been rocked more than once by falsification scandals,[71] but it is to argue that registrants have every incentive to put the best spin on their data within the broad scope of plausible scientific disagreement over the design and interpretation of risk assessment studies.

The predictable effect of this structural problem is that the adequacy of raw data becomes a constant and compounding difficulty for the entire risk assessment enterprise. An internal EPA audit in the mid-1970's on the data underlying 23 randomly selected pesticides found that "all but one of the tests reviewed were unreliable and inadequate to demonstrate safety."[72] In congressional hearings on EPA's suspension of heptachlor/chlordane in 1976, there were uncovered "innumerable examples of sloppy and inaccurate data in addition to abundant evidence that much of the pathology data as submitted by industry was based upon the diagnostic opinion of pathologists...whose views

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[69]A caveat to this statement is that registrants can, under FIFRA, seek payment from the producers of generic or "me-too" producers who rely on the registrants' original data, after all applicable patents on the original product have expired, for the purpose of registering copycat products. *See* FIFRA Section 3(c)(1)(D)(ii); Thomas v. Union Carbide, 473 U.S. 568 (1985) (upholding constitutionality of data compensation procedures).

[70]*See* Paul Portney, Toxic Substance Policy and the Protection of Public Health, in Resources for the Future, CURRENT ISSUES IN U.S. ENVIRONMENTAL POLICY 138 (Paul R. Portney ed., 1978) (Because there is no active market for good information, government regulators are peculiarly dependent on the regulated firms themselves for data generation. This creates numerous incentives for firms to choose testing procedures most likely to shed favorable light on the substances they wish to market); Kenneth Arrow, Economic Welfare and the Allocation of Resources for Invention, in National Bureau of Econ. Research, The Rate and Direction of Inventive Activity 609, 615 (1962) (the market for good information is further reduced because purchasers do not know its value until it has been produced, thereby reducing incentives for investment in information-producing entities).

[71]Most recently, in May 1993 EPA issued a data call-in to 13 registrants to replace over 290 studies that had been done by Austin, Texas-based Craven Laboratories, Inc., after testimony from twelve former employees of the company admitting wrongdoing caused the onset of a federal investigation for alleged falsification of data. *See* EPA Seeks Data on 20 Chemicals to Replace Studies Done by Craven Labs, 17 Chem. Reg. Rep. (BNA), No. 7, at 286 (May 14, 1993). An even more major scandal involved Industrial Biotest ("IBT"), the nation's largest chemical testing firm, which in 1976 caused OPP to halt all registration action after IBT was found to have falsified outright registration data for over 200 pesticides. *See* Staff of Senate Comm. on the Judiciary, 94th Cong., 2d Sess., Report on the Environmental Protection Agency and the Regulation of Pesticides 4 (Comm. Print 1976) ("[S]everal years of regulatory effort will have to be completely reexamined, substantially redone, and fundamentally redirected if the Congress and the public are to have a reasonable basis to conclude that today's pesticides do not pose a significant risk to human health and the environment").

[72]William E. Reukauf, Regulation of Agricultural Pesticides, 62 IOWA L. REV. 909, 917 (1977), citing Joint Hearings on Safety Testing of Pesticides in Nongovernment Labs Before the Subcomm. on Health of the Senate Labor and Public Welfare Comm. and the Senate Judiciary Comm., 94th Cong., 2d Sess. 619-20, 646, 649 (1976) (testimony of Melvin D. Reuber, M.D.).

were at best extremely conservative."[73] In 1990, the General Accounting Office expressed concern that as much as 60 percent of the disinfectants data on antimicrobial pesticides in one system may be inaccurate or incomplete.[74] In 1991, a report from EPA's Inspector General reported problems with data accuracy and completeness in another of the databases at the National Computing Center used by EPA to make pesticide reregistration decisions.[75] In 1992, internal agency reports by EPA's Special Review and Reregistration Division indicated that high rejection rates for data inadequacy across the reregistration program had become one of the most significant reasons for program delay.[76]

It is no answer to argue simply that EPA should suspend or cancel all pesticides whose registrants submit inadequate data. Because then, as the data are not known, there is the chance that the Agency's action could do more harm than good in terms of either creating more public health and environmental risks in the absence of the pesticide (due to user shifts to even worse substitute products) or foregoing benefits whose value outweighs whatever risks might be prevented.

We come, therefore, full circle to the underlying difficulties of policy choices on risks and benefits in regulating pesticides. EPA's job, however, is to square the circle as best it can. In the following section, this Report uses several regulatory case histories to illustrate how EPA goes about its job and how inadequate procedures can unnecessarily complicate an already demanding regulatory task.

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[73]EPA's Implementation of the Pesticides Control Act: Hearings Before a Subcomm. of the House Comm. on Government Operations, 94th Cong., 2d Sess. 34-35 (1976) (letter from Jeffrey H. Howard et al. to Hon. William S. Moorhead).

[74]U.S. General Accounting Office, Disinfectants: Concerns Over the Integrity of EPA's Data Base (Sept. 21, 1990).

[75]*See* Office of the Inspector General, EPA, Audit Report No. E1EFF1-05-0117-1100378, Inert Ingredients in Pesticides (Sept. 27, 1991).

[76]*See* Lowered Data Rejection Rate Needs to Meet 2002 Reregistration Target, Chem. Reg. Daily (BNA) (Aug. 4, 1992), available in LEXIS, BNA Library, BNACRD file (EPA openly worrying that its data rejection rate is "too high" and can compromise reregistration target dates of 1997 established in the 1988 FIFRA Amendments or even the Agency's own extended target date of 2002); *see also* U.S. E.P.A., Pesticides and Toxic Substances Report No. H-7508W, Pesticide Reregistration Progress Report 5 (April 1992) ("rejected studies pose the most significant potential for delays in the production of Registration Eligibility Documents").

B. Procedural Case Histories

1. Reregistration and Negotiated Label Changes on Atrazine[77]

Atrazine, an herbicide used to control weeds of such crops as corn, sugarcane, and wheat, is among the two or three most heavily used pesticides in the country. First registered for use in 1959, EPA had by 1983 completed its first comprehensive reassessment of atrazine under the Agency's pre-FIFRA '88 reregistration program. Under that program, EPA prepared a document called a "reregistration standard" that summarized available data, required submission of additional data, and outlined other conditions registrants had to meet for reregistration. In its 1983 standard, EPA concluded that the existing data (129 studies) were insufficient to evaluate the pesticide's long-term health and environmental effects, and requested the registrants to fill 48 data gaps, with the last study to be due November 1987. Especially concerned about data indicating atrazine's potential to contaminate groundwater, EPA also required in its 1983 standard that labels on products containing atrazine warn of potential groundwater contamination and advise that atrazine not be used on certain soils. EPA informed registrants at the time that it was unsure whether this label requirement would resolve the Agency's concerns about groundwater.

Studies generated after the 1983 standard, along with other data, indicated not only that atrazine could contaminate groundwater but also that it could cause cancer and heart disorders. As a result, in 1988, EPA informed registrants that the Agency was considering the initiation of Special Review and requested additional data. In response, one registrant contested the Agency's characterization of the magnitude of the risks and proposed several voluntary measures to reduce exposure (restricting use to certified workers, limiting use on certain crops, and requiring workers to wear protective clothing). Although EPA welcomed these measures, it issued a data call-in in November 1988 requiring the submission of 35 additional studies. In September 1989, atrazine's primary registrant asked to meet with EPA to discuss in more detail EPA's concerns about heart disorders detected in an earlier dog study. At some point thereafter, EPA decided not to initiate Special Review because it had been persuaded that a better interpretation of the dog study made risks of possible cardiac problems among atrazine users less than it first appeared because EPA used too low an exposure threshold.

In September 1989, EPA completed its second comprehensive reassessment of atrazine under its registration standards program. The Agency's second

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[77]Much of the information in this case study is drawn from U.S. General Accounting Office, *supra* note 14, Appendix II ("Case Study: Reassessment of Atrazine").

standard concluded that the existing data (143 studies) were insufficient to evaluate the pesticide and identified an additional 51 studies that registrants needed to conduct. EPA never implemented its second standard, however, because its reregistration program had been sufficiently changed by the FIFRA '88 amendments.

In September 1990, under the accelerated reregistration program of FIFRA '88, EPA issued a data call-in requiring most of the studies that had been identified in 1989. The last study was to be due in August 1994. As of November 1992, however, there were still 45 studies outstanding. As of May 1993, EPA was reconsidering placing atrazine in Special Review within the year, although it recognized that reregistration could not be completed for any uses that were the subject of an ongoing Special Review until that Review was completed.

2. Reregistration of Chlorothalonil[78]

Chlorothalonil is a fungicide used on crops such as peanuts, tomatoes, and potatoes. Originally registered in 1966, EPA completed its first registration standard for chlorothalonil in 1984, at which time it identified the fungicide as a possible cause of cancer and as a pesticide that leaches into groundwater. The standard also concluded that the existing data (135 studies) were insufficient to evaluate the pesticide's long-term effects and identified studies needed to fill 71 data gaps, with the last study to be due by December 1985. In the interim, EPA decided to minimize additional public exposure by restricting the registration of any new uses of chlorothalonil.

EPA completed its second registration standard for chlorothalonil in September 1988, at which time it confirmed the fungicide as a probable human carcinogen and determined that groundwater monitoring studies were needed. The carcinogenicity classification had been reached in 1987 after considering advice from EPA's Scientific Advisory Panel ("SAP") that recommended that the agency defer classification until the latest data had been fully evaluated. That evaluation was completed by May 1988 and an EPA peer review committee affirmed the carcinogenicity classification. EPA identified new studies that were needed to fill 62 data gaps and continued refusing any registrations for new uses of chlorothalonil until the new data were developed and evaluated.

In October 1988, EPA notified the public of its second draft registration standard and received voluminous comments from three affected registrants. EPA responded to each of the points raised by these commenters, even those to which it had previously responded in informal discussions, a time-consuming effort that delayed drafting of the final standard to March 1990. Although EPA

[78]Much of the information in this case study is taken from U.S. General Accounting Office, *supra* note 14, Appendix I ("Case Study: Reassessment of Chlorothalonil").

planned to issue data call-ins ("DCIs") as part of the second standard, actual issuance of the DCIs was delayed by eight months due to review of the draft DCI by the Office of Management and Budget ("OMB"). According to EPA officials, the requirement that OMB review and clear every proposed data request was time-consuming not only because of delay on OMB's part but also because the process imposed additional work on EPA. The DCIs were issued in July and September 1991, with the last study to be due by August 1995.

In March 1992, a registrant requested waivers for at least ten studies, a request that the Agency had not been able to fully evaluate as of February 1993. To the extent EPA denies the requests, it will probably grant the registrant requests for time extensions for an additional two years to complete the studies.

3. Label Negotiations on an Unanticipated Problem: Mercury in Paint

Although household paints do not require registration as a pesticide, to the extent that paint formulators add an ingredient such as mercury to prevent mildew, mercury producers must obtain a registration for that use from EPA and follow any label requirements imposed by EPA's pesticide office. In September 1989, a four-year-old boy living with his family in Michigan was hospitalized with acrodynia, a rare form of mercury poisoning. All members of the boy's family were also found to have unusually high mercury levels after their home had been painted, and the most likely cause was the use of mercury as an ingredient in the paint that had been used. At the time, approximately 1,800 paint companies "from Sherwin-Williams to your local paint company" used mercury-containing compounds when formulating their products.[79] The incident received national media attention and sparked nationwide concern about potential mercury poisoning from paint.

Spurred on by pressure from OMB and the White House to get a handle on the problem, EPA sent a survey letter in March 1990 to 1500 paint and coating formulators, began to identify data gaps in toxicology and risk exposure in the registration file for mercury, began to consider issuing an emergency suspension of mercury for use in indoor paints, and began to "prepare for cancellation hearings."[80] At the time EPA began this flurry of activity, mercury's FIFRA registration allowed approximately 330 parts-per-million of mercury to be added to paint as a pesticide; the paint used on the family house in Michigan was tested

[79]*See* EPA Investigating Mercury in Paint, 13 Chem. Reg. Rep. (BNA), No. 46, at 1499 (Feb. 23, 1990).

[80]*See* Mercury in Paint Action Expected by Labor Day, 14 Chem. Reg. Rep. (BNA), No. 6, at 236 (May 11, 1990).

to have over 900 ppm of mercury.[81] In April 1990, the federal Centers for Disease Control recommended a ban on mercury biocides in paint.

By June 1990, following informal negotiations with EPA, virtually all paint manufacturers agreed to eliminate the use of mercury biocides in interior paint and coatings. New label language submitted by some producers restricted mercury biocides to adhesives, drywall compounds, and acoustical plasters; reduced the maximum concentration of mercury to 120 ppm; limited use to products labeled with cautionary statements; and stated when the sale, distribution, and use of the products would be unlawful.[82]

In October 1990, Edwin Tinsworth, former Director of the Special Review and Reregistration Division in OPP, cited the example of the "voluntary fixes" achieved in the mercury-in-paint situation as an example of getting voluntary action in months rather than the years that would have been necessary for regulatory action.[83]

4. Reregistration, Special Review, Science Policy Disputes, and Negotiated Label Changes on Amitrole

Amitrole is an herbicide now used predominantly to clear weeds on non-crop sites such as rights-of-way. In 1984, on the basis of a registration standard which identified amitrole's carcinogenicity, EPA issued a PD 1 document and placed the pesticide in Special Review. Soon thereafter, both aquatic uses and forestry uses were voluntarily canceled. EPA, at the time Special Review was initiated, identified data gaps and issued DCIs to have the gaps filled. After fielding requests for data waivers and time extensions, EPA issued a PD 2/3 on September 30, 1985. The basis for the Agency's concern was evidence showing thyroid and liver cancers in mice.[84]

Between 1985 and 1989, however, OPP's regulation of amitrole became caught up in a science policy question on modeling carcinogenic effects. As a general matter, EPA followed a conservative model that assumed that there were no safe thresholds for exposure to a pesticide that caused carcinogenic responses in test animals. In 1986, however, some risk assessors became attracted to models that assumed that there were such safe thresholds (and which therefore would predict less risk from exposure). The data on thyroid cancers were

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[81] *See* EPA Investigating Mercury in Paint; Substance May Pose Unreasonable Risk, 13 Chem. Reg. Rep. (BNA), No. 46, at 1499 (Feb. 23, 1990).

[82] *See* Registration for Mercury in Indoor Paint, Plaster Canceled at Request of Manufacturer, 14 Chem. Reg. Rep. (BNA), No. 24, at 956 (Sept. 14, 1990).

[83] *See* OPP Director Edwin Tinsworth Leaves After 22 Years in Federal Government, 14 Chem. Reg. Rep. (BNA), No. 30, at 1106 (Oct. 26, 1990).

[84] *See* EPA Actions in Special Review of Amitrole May Have Implications for Risk Assessments, 15 Chem. Reg. Rep. (BNA), No. 36, at 1359 (1991).

particularly consistent with this model, which made amitrole a test case over which the risk assessment debate swirled. The question was complicated, however, by the fact that amitrole also induced liver cancers in mice, a form of carcinogenic response that did not comport well with the threshold model. In the end, EPA refused to apply its threshold model in its Special Review of amitrole, in part because the registrant simply could not provide EPA with enough "mechanistic data" to give the Agency confidence that a threshold model would better represent amitrole's risk than the Agency's default no-threshold model. The problem, said one of the advocates for the threshold model, is that "EPA has not determined with any one chemical that enough is enough."[85]

Dislodged from the science policy debate, EPA issued in 1990 a DCI requesting new worker studies to determine better the possibility of occupational exposure to the herbicide. Although Rhone-Poulenc, amitrole's primary registrant, contended that the worker studies were unnecessary, EPA maintained its request for data for most forms of amitrole applications, but did allow Rhone-Poulenc to substitute existing studies on bromoxynil for others.

In February 1991, however, at an EPA management retreat, OPP officials were said to have come away with a "new philosophy" that informal negotiations with registrants over voluntary risk reduction measures were preferable to Special Review.[86] OPP officials acknowledged that one of the benefits of Special Review was an "open and responsive" procedure based on public participation rules adopted by the Agency in 1985, and determined to think of a way to open up the negotiation process to more widespread public involvement. Allan Abramson, former Acting Director of the Special Review and Reregistration Division, stated that "Special Review is not an end in and of itself, it is a tool among others to achieve appropriate risk reduction...[but] I am proposing for management consideration that as a matter of policy on major chemicals of public interest, if we go into negotiations, results of the negotiations would be subject to public notice and comment and possibly change."[87]

In October 1992, EPA proposed to terminate Amitrole's Special Review after Rhone-Poulenc agreed to take voluntary actions to reduce worker exposure. These measures included the deletion of high exposure application methods such as knapsack sprayers; adoption of a "no-glug" container designed for liquid formulations to reduce splashing while pouring; addition of a protective clothing requirement to labels; and the packaging of a wettable powder formulation in water soluble packets (to prevent the need for the pouring of loose powder into mixing containers). EPA concluded that, in light of these measures, it had

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[85] *Id.*
[86] *Id.*
[87] *Id.*

completed its risk/benefit analysis of amitrole and had determined that "the benefits of amitrole outweigh the risks."[88]

C. Reforming Reregistration, Suspension, and Data Management Procedures

The reregistration of existing pesticides is the analytical centerpiece of FIFRA yet it lacks strategic mechanisms for success. Given the inherent indefiniteness of the Agency's underlying risk assessment project, and the incentives for both registrants and regulators to prefer further study to uncertain policy choices, the result is predictable: reregistration becomes an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, the submission of data that do not always meet EPA's adequacy standards, followed by yet another wave of data call-ins that restart the sequence. The most important procedural reforms are to create countervailing incentives to submit adequate data in a timely manner; to obtain real risk reduction in as efficient a manner as possible; and to provide adequate participatory rights to registrants and the various publics that have a stake in pesticide policy.

1. Create global, reinforcing incentives for the submission of timely, adequate data on EPA's higher-priority pesticides

By providing for the automatic suspension of all "List A" pesticides for which there remain, by a date certain, significant data gaps within the registrants' control, Congress would create a statute of repose that would drive both registrants and regulators to complete rather than perpetuate the data gathering enterprise. The 1988 FIFRA Amendments categorized pesticides into four categories that reflected roughly their potential for human exposure and risk. List A pesticides were those used on food, a group of pesticides to which Congress, ten years earlier in the 1978 FIFRA Amendments, had directed EPA to give regulatory priority.[89] It was for these pesticides that EPA had generally issued registration standards in its pre-1988 reregistration program[90] and it is therefore these pesticides that not only contain the greatest potential for risk but also represent those pesticides that EPA has been evaluating for the longest period of time. Unlike List B, C, or D pesticides, List A pesticides were not subject to the

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[88]Amitrole: Preliminary Determination to Terminate Special Review, 57 Fed. Reg. 46,448 (Oct. 8, 1992).

[89]*See* General Accounting Office, *supra* note 77, at 3-4.

[90]Indeed, List A pesticides under the 1988 Amendments were published on February 22, 1989 and contained 194 active ingredients for which EPA had already issued registration standards. *See* 54 Fed. Reg. 7740.

interim statutory deadlines established in the 1988 FIFRA Amendments for Phases 2, 3, and 4. Rather, Congress in 1988 expected these pesticides to move directly to Phase 5, in which EPA determines within one year of the submission of all data whether an active ingredient is eligible for reregistration, with favorable determinations commemorated by EPA's issuance of Reregistration Eligibility Documents ("REDs").[91] EPA issues REDs for pesticide "cases," with cases including either a single pesticide or a group of related pesticides. EPA has grouped the 642 active ingredients in the reregistration program into 407 cases to expedite reregistration.

EPA has made some progress in issuing REDs, but needs a strategic incentive to do much more, especially with REDs for List A cases. Through fiscal year 1992, EPA had issued REDs affecting only 2,200 of the 17,000 products containing List A pesticides, with REDs affecting only another 460 products containing these pesticides viewed as likely candidates for REDs in fiscal year 1993.[92] As of January 1993, EPA had not yet reviewed 3,900 of 10,800 studies (36%) that it had received in response to pre-1988 data requests to List A registrants,[93] nor had it yet reviewed another 800 of 2,000 studies (40%) that it had received from data requests issued between 1990 and 1992.[94] An additional 2,300 more List A studies are expected in response to outstanding data requests. And there are almost certain prospects for further data requests to follow due to relatively high rejection rates of List A studies deemed "unacceptable" (25%) or "upgradable" or "supplementary" (another 25%).[95] For all of these reasons, EPA is behind schedule in its reregistration of List A pesticides. Although EPA estimated in March 1990 that it would issue REDs for 11 List A cases by October 1990, no REDs were issued until January 1991 and by October 1991, only ten REDs for List A pesticides had been issued. In June 1992, EPA found that REDs for 62 List A pesticides had been delayed by an average of 18 months. As of March 1993, most of the REDs for List A pesticides were scheduled to be issued over a four-year period beginning in fiscal year 1994.[96]

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[91] Issuing a RED means that EPA "has evaluated the information submitted on the pesticide and determined that the pesticide poses no unreasonable risk to humans and the environment when used under the terms and conditions EPA has established." U.S. General Accounting Office, *supra* note 14, at 3.

[92] *Id.* at 5. In comparison, EPA had issued REDs affecting 210 products containing List B, C, and D pesticides through 1992, with another 1,113 related products awaiting REDs in fiscal year 1993.

[93] *Id.* at 7.

[94] *Id.*

[95] *Id.* at 12. In fairness to registrants, these high rejection rates may not be attributable even for the most part to the type of structural bias I identified earlier, *supra* notes 69-70. In June 1992, EPA issued the first chapter of a study of these high rejection rates that concluded that part of the problem was misinterpretation and poor guidance from OPP's case review managers to the registrants on what was expected. U.S. General. Accounting Office, *supra* note 14, at 12.

[96] *Id.*

Adding the suspension provision advocated here need not be altogether inflexible, but provisions for flexibility should not detract from the regulatory benefits of imposing real consequences to an unacceptable state of continual delay. It would be possible, for example, to afford automatically suspended registrants a relatively streamlined notice-and-comment procedure in which to make a case for reinstatement—after the fact.[97] But the benefits and fairness of automatic suspension are evident and relate directly to improved processes for reregistration. A meaningful List A deadline will provide a rough risk-based screening device, without elaborate ex ante exercises in prioritizing. Although this Report recommends that the date for automatic suspension be left to Congress, it is worth noting that Congress could choose September 1998—the last date for issuing REDs under the existing statutory timetable—and maintain both fairness and feasibility. Such a date would be fair because it compensates for some of EPA's "learning curve" missteps in implementing FIFRA 1988 in the early years, while still preserving the core integrity of the priorities and deadlines established by two separate Congresses in 1978 and 1988.[98] It is feasible because it comports with EPA's current "educated" estimate that, even after accounting for its own learning-curve mistakes, the issuance of REDs for List A pesticides can be accomplished by 1998.[99] Above all, this fair and feasible device would create a global incentive for registrants to ensure that they understand what EPA expects in data adequacy and to ensure that they do not unduly petition the

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[97]For example, it is plausible that the registrant had submitted all necessary data and was only awaiting at the deadline EPA review and issuance of the RED. To the extent that the registrant had not evidenced in reregistration a pattern of unjustified delay or unjustifiably inadequate submissions, it is conceivable that EPA might articulate in such a case a form of summary reinstatement pending the completion of its data reassessment. But of course the burden would be on the registrant to demonstrate its own lack of accountability for delay (and the time taken for this demonstration, however brief, would also be at the registrant's rather than the public's expense). Although it is also theoretically possible that more extreme cases might arise in which even temporary automatic suspension could arguably disrupt some supplies of food, it is overwhelmingly likely that any such scenarios would have been identified by both registrants, regulators, and affected publics (and presumably also by their representatives in government) as situations where EPA should put its highest regulatory efforts well before the statutory deadline. The incentives, in other words, would work in favor of regulatory prioritizing and against regulatory delay.

[98]Although FIFRA 1988 had evidently desired List A pesticides to be reregistered earlier than the protracted deadlines set for List B, C, and D pesticides, and therefore did not establish a timetable for these pesticides, EPA has interpreted the statute to support its commitment to reassess List A pesticides and reregister products containing them no later than the deadlines imposed for List D, the lowest prioritized pesticides, in September 1998. *See* General Accounting Office, *supra* note 77, at 4. The deadline imposed by automatic suspension relaxes this somewhat by requiring only that REDs be issued by September 1998. FIFRA now envisions roughly a one-year period after the issuance of REDs before EPA can evaluate specific product data and make final reregistration decisions as to particular registrations. *See* Pesticide Regulation Handbook, *supra* note 42, at 139. This one-year grace period roughly corresponds to evidence that EPA had itself delayed quick implementation of FIFRA 1988 by taking longer than expected to identify data gaps, *see* General Accounting Office *supra* note 14, at 13, or by otherwise unclear explanations to some registrants about data requirements, *see* note 95 *supra*.

[99]*See* note 96 *supra*.

Agency for either data waivers or time extensions—in short, to avoid rather than tolerate delay. Registrants (and other affected user groups), moreover, could be expected to pressure the Agency for timely decisions. To the extent the Agency is simply understaffed, the registrants' new stake in regulatory efficiency might lead them to consider political support for additional reregistration fees that would allow OPP to add staff and improve regulatory timeliness.

2. Create additional tactical incentives for adequate and timely data submissions

OPP's experience with chlorothalonil and amitrole indicate that requests for data waivers and time extensions, as well as OMB review of data call-ins, can all contribute to regulatory delay. In May 1991, EPA and OMB reached an agreement that eliminated the need for OMB to preapprove routine data requests under FIFRA.[100] Certainly this agreement should be continued; OMB delay in processing DCIs regarding chlorothalonil set reregistration back as many as eight months.

The problem of requests for data waivers and time extensions is a more difficult issue. In general, and as to the specific cases of chlorothalonil and amitrole, OPP has repeatedly noted how time-consuming these requests can be. This is so despite the fact that OPP has established criteria by which it evaluates requests for time extensions. Both types of requests impose regulatory costs on OPP personnel. The problem is that these requests are not nearly so costly to the requesters. In EPA's experience with chlorothalonil, for example, it granted time extensions to registrants simply to compensate for the time taken in denying the registrants' requests for data waivers.[101] When registrants miss regulatory deadlines for data submission, moreover, FIFRA provides that EPA "may" suspend a registration only after affording tardy registrants thirty days notice, the opportunity to require a limited hearing (which must be held within the next seventy-five days), and the right of having their registrations reinstated immediately upon the tardy submission of the data.[102] The results are predictable. Between August 1991 and February 1992, EPA found it necessary to issue 70 Notices of Intent to Suspend ("NOIS") for nonsubmittal of data.[103] In the majority of these cases (53), the registrant simply submitted data prior to exhausting any of its procedural rights and was no worse off for having missed the deadline.[104] For most registrants, tardiness was costless.

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[100]U.S. General Accounting Office, *supra* note 14, Appendix IV, at 34-35.

[101]*See* text *supra* at 29.

[102]*See* FIFRA Section 3(c)(2)(iv).

[103]*See* EPA, Pesticide Reregistration Progress Report 4-5 (April 1992).

[104]*Id.*

This situation could be improved by providing EPA with two procedural tools. First, EPA should be able to suspend registrants who fail to submit data after providing them simply with a NOIS and a thirty-day comment period (with the opportunity thereafter to seek prompt judicial review of the suspension). FIFRA should be amended to eliminate the registrant's right to an additional hearing. Such a hearing adds little to accurate decisionmaking yet adds to the Agency's administrative burden and can triple the time needed for OPP to impose sanctions for missing data. Second, to prevent the NOIS process from being converted into an automatic time extension within which registrants may freely submit tardy data, submitters of late data should be required to pay a financial penalty.

The problem of inadequate data also compounds regulatory delay: not only does it absorb extra agency processing time, but it can provide the registrant additional time within which to meet its data requirements. To some extent, of course, the added cost of redoing studies provides an incentive to registrants not to submit inadequate data. But the extraordinarily high rates at which EPA has been rejecting data suggest the need to improve incentives for data adequacy. Certainly EPA should provide registrants with competent guidance on the nature and design of studies. But to the extent EPA believes its guidance to have been adequate and the data requirements sufficiently clear, it should be provided authority to impose administrative penalties on those who submit inadequate data that the Agency reasonably determines to be "avoidable."

3. Confirm, regularize, and strengthen EPA's ability to seek interim risk reduction measures through informal negotiations with registrants

As all four of the case histories suggest, EPA has shifted its strategy away from the cumbersome Special Review process and toward informal negotiations with registrants over label requirements and other voluntary risk-reduction measures. Although EPA reserves its options to use the Special Review process to the extent the Agency believes justified, the increasing use of informal negotiations raises two issues. First, the statutory ability to regulate label changes outside of the cancellation process. Second, the openness and effectiveness of label negotiations as a regulatory tool.

(a) FIFRA should not be changed, as some FIFRA reform measures would, to undermine EPA's ability to use the misbranding provisions in FIFRA Section 12 to induce serious negotiations over inadequate labelling

For EPA to be able to achieve relatively quick risk-reduction measures through successful label negotiations with registrants, there must be something for both sides to gain. From the government's perspective, the advantages of negotiation are apparent. Assuming a government that is primarily interested in reducing unreasonable risks from pesticides—label changes can implement risk reduction measures on the basis of existing data, without waiting for the ultimate reassessment of a pesticide's full risks and benefits in reregistration, and can do so much more quickly than existing, time-consuming processes for Special Review and cancellation. From the registrant's perspective, however, the advantages of negotiated label changes are not quite so apparent. Assuming a registrant that is primarily interested in the continued unrestricted sale of its products, forcing the government to postpone restrictions pending the completion of reregistration or a prolonged Special Review/cancellation process has its advantages. A rational registrant will not make prematurely painful concessions during label negotiations unless there is something concrete to gain. The critical leverage to successful label negotiations is FIFRA Section 12 which makes it unlawful now for anyone to sell "misbranded" pesticides,[105] a term defined in FIFRA to include pesticides with labels that do not omit "directions for use which...if complied with...are adequate to protect health and the environment."[106] To the extent registrants fear enforcement of this labeling requirement now, they will rationally believe that there is more to gain from successful label negotiations with EPA.

Whether EPA can in fact bring enforcement actions against inadequately labeled pesticides was presented in *Ciba-Geigy v. EPA*,[107] a decision involving the herbicide Simazine. Registered since 1957, and widely used to control weeds and algae, EPA became concerned during its protracted reregistration of the pesticide with Simazine's potential to contaminate groundwater. Accordingly, in its 1984 registration standard, EPA decided to downgrade Simazine's registration from general use to restricted use, to urge a change in the product's label to indicate the new use restriction, and to include on Simazine's label a warning against use in areas "with specified soil and groundwater conditions."[108] EPA notified Simazine registrants of the Agency's intent to institute cancellation

[105]FIFRA Section 12(a)(1)(E).
[106]FIFRA Section 2(q)(1)(F) (definition of misbranded).
[107]801 F.2d 430 (D.C. Cir. 1986).
[108]*Id.* at 432.

proceedings against any Simazine products not containing the use restrictions and to consider products without new labels in the near future to have become "misbranded" and therefore subject to seizure under FIFRA.[109] In light of EPA's action, most Simazine registrants either complied with the new labeling restrictions or voluntarily cancelled their registrations.[110] Ciba-Geigy, on the other hand, believed that it was entitled to a formal hearing on the new requirements under FIFRA Section 6(b) as a prerequisite to Agency enforcement against it of the new registration standard. Ciba-Geigy sought declaratory and injunctive relief in federal district court (which has jurisdiction over claims that EPA failed to initiate a cancellation hearing).[111] The district court's dismissal for lack of ripeness was reversed and remanded on appeal, and the case settled before the district court could determine on remand the precise statutory question argued by Ciba-Geigy.

The issues left unresolved are whether EPA can now use, or should be more explicitly authorized by Congress to use, the Agency's authority over misbranded products to enforce changes in labels that current risk assessment data convinces the Agency are necessary to provide adequate protection of public health and the environment. As a matter of interpretation of the existing statutory text, such a result is consistent with the general deference that the agency's reading of the statute deserves under *Chevron v. NRDC*[112] for statutory questions that are not precisely addressed by existing statutory language.[113] And it is also consistent

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[109] *Id.* at 432-433.

[110] *Id.* at 433.

[111] 607 F. Supp. 1467 (D.D.C. 1985).

[112] 467 U.S. 837 (1984).

[113] EPA's position in Ciba-Geigy is supported by an analogous decision, arising under the Resource Conservation and Recovery Act ("RCRA"), decided by the D.C. Circuit in Chemical Waste Management v. EPA ("CWM"). At issue in CWM was EPA's issuance of a "corrective action" order to a licensed RCRA facility, which burdened the licensee in the sense that it created specific clean-up obligations. Although RCRA required such "orders" to be made after a "public hearing," the Court of Appeals upheld EPA's interpretation that an informal hearing would be better suited to factual issues that "relate almost entirely to technical (or policy) matters that create little need to establish witness veracity or credibility"...and can be more efficiently evaluated in an informal setting. Finding EPA's interpretation sufficiently reasonable to withstand Chevron Step 2 analysis, the court allowed EPA to use informal proceedings in lieu of formal adjudications.

In the analogous situation under FIFRA, it is equally reasonable to defer to EPA's resolution of the ambiguity between, on the one hand, formal hearings for cancellations and reclassifications and, on the other, enforcement actions against misbranded pesticides. Whichever avenue EPA pursues, the central issues ultimately boil down to whether the risk data supports EPA's view that a pesticide's label must be changed to assure that it adequately protects public health and the environment. This is precisely the same sort of technical or policy matter that the CWM Court concluded to be best resolved outside of formal hearings.

with a trend toward according deference especially to an agency's choice of procedures.[114]

The pending Lehman-Bliley bill, however, may actually reduce both the incentives for registrants to negotiate seriously over label changes and the procedural flexibility that EPA now enjoys. The Lehman bill provides that EPA "may, by use of informal rulemaking under this subsection, prescribe requirements regarding the composition, packaging, and labeling of a pesticide ...."[115] But "informal rulemaking under this subsection" in the Lehman-Bliley bill involves a multi-stage, nine-step process—complete with advanced notices of proposed rulemakings and referrals to the Scientific Advisory Panel—that is far more formal and time-consuming than the informal negotiations EPA now uses. By overproceduralizing EPA's regulation of inadequate labels, the proposed bill reduces the leverage EPA now has to induce registrants into serious label negotiations. As improvidently, the proposed bill would reduce the steadfastness with which EPA could insist on label restrictions. Knowing that the only procedural alternative to negotiation is a cumbersome nine-step rulemaking process, EPA would take what it could get. Knowing this, registrants would not offer much more.

FIFRA should be amended to clarify that EPA may continue to force label changes through an informal process of negotiations with registrants, and may police inadequate labels through enforcement of the Act's misbranding provisions. This comports not only with EPA's practice over the past few years, but is also consistent with proposals by the Clinton Administration to provide for informal "label call-ins" outside of cancellation and suspension procedures.

(b) Make informal label negotiations more open and effective

Creating incentives for registrants to negotiate seriously frames the importance of two additional features of interim risk-reduction procedures—their openness and effectiveness. The importance of publicly open procedures has long been recognized as a concern for EPA's newfound emphasis on label negotiations. As OPP's Acting Deputy Director acknowledged in August 1993, "it is not as open as I'd like to see it."[116] OPP's former Acting Director of the Special Review and Reregistration Division expressed similar concerns when he proposed that "as a matter of policy on major chemicals of public interest, if we

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[114]*See* generally PBGC v. LTV Corp., 110 S.Ct. 2668 (1990) (formal proceedings, not compelled by statute, are not required simply because the Agency is deciding an issue of large monetary significance to a person); Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519 (1978) (courts cannot compel agencies to use procedures more demanding than those required by statute or the Constitution).

[115]H.R. 1627, *supra* note 190, at Section 6(b)(1).

[116]*See* note 61 *supra*.

go into negotiations, results of the negotiations would be subject to public notice and comment and possibly change."[117]

The Agency's concern for openness is well-founded. Apart from the benefits to accurate decisionmaking and public acceptability that come with avenues for wider participation, the danger of overreliance on closed-door meetings with registrants should be burned into the Agency's institutional memory. In 1982, then-Representative Albert Gore excoriated the Agency for closed-door meetings with the regulated community under both its FIFRA and Superfund programs, despite Agency protests that its meetings were part of a strategy of voluntary compliance and negotiated settlements.[118] In 1983, the Agency was sued by the Natural Resources Defense Council for making decisions on initiating RPAR reviews in closed-door "decision conferences" with registrants.[119] In 1984, EPA settled the NRDC suit by agreeing to reopen its risk assessment decisions on 13 major pesticides, and by agreeing to promulgate regulations so that "no person or party outside of government will be afforded special or preferential access to agency decisionmakers or to the agency's decisional process."[120] In 1985, EPA promulgated regulations establishing that any private discussions with registrants over Grassley-Allen letters, when the Agency was in its "pre-Special Review" mode, would be summarized and placed in a public docket.[121] The regulations also provided that a decision not to initiate Special Review, along with the Agency's reasons, would also be placed in the public docket and made the subject of a 30-day public comment period, with a final Agency decision on Special Review not reached until after EPA reviewed all public comments.[122]

In evaluating EPA's present practice of private labeling negotiations, it is not enough simply to look at the Agency's pre-Special Review regulations and the regulatory history that spawned them. Technically, there appears to be nothing "illegal" about non-docketed negotiations that take place outside the context of Grassley-Allen letters. But functionally, there has certainly occurred a significant shift in opportunities for public participation. In 1985, Special Review and pre-Special Review were procedural devices at the center of OPP's regulatory program. The purpose of the 1985 regulations was to ensure public access to and

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[117] *See* note 87 *supra*.

[118] *See* Panel Calls EPA Enforcement "Disaster," Reprimands EPA Aide for Improper Conduct, 12 Env. Rep. (BNA), No. 50, at 1604 (April 9, 1982).

[119] *See* NRDC v. Ruckelshaus, No. 83-1509 (D.D.C. 1983); Registration, RPAR Decisions Reached in Closed EPA/Industry Sessions, Suit Charges, 7 Chem. Reg. Rep. (BNA), No. 10, at 387 (June 3, 1983).

[120] Closed Door Pesticide Suit Settled; EPA to Reopen 13 Chemical Risk Probes, 8 Chem.Reg. Rep. (BNA), No. 25, at 619 (Sept. 21, 1984).

[121] *See* 50 Fed.Reg. 49016 (Nov. 27, 1985).

[122] *Id.* at 49,017.

participation in these central activities. Currently, EPA has made a conscious policy decision to clear its Special Review docket, either because accelerated reregistration was sapping OPP's resources, because the Agency anticipated the need to "save" Special Review for those pesticides identified as problematic in REDs, or for some other reason.[123] But whatever the reason, OPP's central regulatory device is now label negotiation, and the public has far less access now to OPP's central avenue for regulation than it did in 1985.

This does not mean, however, that private negotiations between EPA and registrants are improper or should be opened to all. To the contrary, it is difficult to imagine how these negotiations might succeed were they to include a potentially unlimited number of participants. More importantly, it is difficult to imagine how publicly conducted negotiations could avoid the often-vast differences of orientation toward the risks and benefits of pesticides that so frequently mark public disputes on the subject. Although "extreme" positions can often turn out in fact to be quite correct, there is unlikely to be a less successful forum for showcasing such positions than negotiations—where the prime commodity is mutual agreement. Especially if one holds modest expectations for risk-reduction measures that might be agreed-upon in private meetings between registrants and the government, the least likely solution would be to open the negotiations at all times to the public—the prospects for polarization, public posturing, and lack of candor seem too strong. On the other hand, this hardly means that there cannot be creative procedural mechanisms that seek the best which both worlds—private negotiation and wide public involvement—can offer.

To seek the best of both worlds, this Report urges that EPA continue to use negotiations to identify real risk-reduction gains that can be achieved quickly through label changes and other measures. This endorsement is with the understanding, of course, that OPP will continue aggressively its obligations under the reregistration and safer pesticides programs to ferret out uses of pesticides that are unreasonable. The interim measures taken in label negotiations should not be allowed to become by default the government's maximum response. Interim label changes outside of OPP's larger programs are better viewed as tentative, even experimental, efforts. They should themselves be subject to change in the face of new data, and under no circumstances should they be viewed as insulating pesticides from the larger scrutiny of OPP's reregistration, Special Review, safer pesticides, and cancellation programs. Moreover, this Report's endorsement of label negotiations is based on the assumptions that registrants will bargain seriously because EPA has an effective alternative in FIFRA's misbranding provisions and, as the Report develops

[123] *See* text at notes 57-58 *supra* (EPA has since the late 1980's avoided the Special Review process entirely, having failed to initiate Special Review on any pesticide since 1988).

further in Section 4 below, OPP can bargain without fear that its only alternative recourse is an overly cumbersome and resource-intensive cancellation hearing.

Even with these caveats, this Report concludes that EPA's private negotiations with registrants needs to take place in a much larger, and more accessible, public context. This could occur, without losing the benefits of negotiations, by adapting for EPA's labeling decisions many of the procedural devices the Agency itself promulgated in 1985 to foster opportunities for public involvement in Special Review and pre-Special-Review decisionmaking. Specifically, EPA should inform interested persons and otherwise notice in the Federal Register that it has begun negotiations with registrants over interim risk-reduction measures. Simultaneously, EPA should open a public "negotiation docket" into which interested persons may submit any information on either the pesticide's risks and benefits or possible risk-reduction measures they believe might be useful.[124] Although EPA is not obligated to place into this public docket contemporaneous information on the status of its negotiations with registrants, Agency personnel must develop their own internal, contemporaneous notes and summaries of all meetings and communications with anyone outside of the Agency about the negotiations.[125] Promptly at the time negotiations are concluded to the extent the Agency wishes to propose label changes, it must place into the public negotiation docket the dates and times of all relevant meetings and communications with non-Agency personnel about label changes and a summary of all non-privileged information that was developed during the negotiations.[126] Before deciding finally whether to approve label changes developed during private negotiations, EPA must publish the proposed changes in the Federal Register and afford interested persons 30 days in which to submit comments.[127]

Striking a better balance between efficient negotiations and broader public participation is only part of the improvement that should be made to EPA's current efforts to negotiate label changes. As importantly, EPA should establish

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[124]The negotiation docket is analogous to, although not identical with, the publicly available "docket for Special Review" the Agency established in its regulations in 1985. *See* 50 Fed. Reg. 49016 (Nov. 27, 1985) (promulgating rules governing "docket for Special Review" now codified at 40 CFR §154.15).

[125]As with the case of communications made to the Agency concerning Special Review and pre-Special Review, submitters may have opportunities to assert their claims to confidentiality for certain business information. *See*, e.g., 40 CFR §154.15(c) (assertion of confidential business information claims).

[126]The analogous provision in the 1985 regulations is found at 40 CFR §154.15(b)(7) (EPA to develop memoranda for the public docket "describing each meeting between Agency personnel and any person or party outside of government which concerns a pending pre-Special Review...which shall describe fully and accurately all significant positions taken, arguments made, and facts presented by each participant in the meeting....").

[127]*Cf.* 40 CFR §154.25 ("If the Administrator [after private discussions with a registrant] decides not to initiate a Special Review...he shall issue a proposed decision for publication in the Federal Register...and provide a period generally not less than 30 days for submission of comments").

better procedures to ensure that label changes actually correlate with real risk reduction in the field. OPP has perennially had difficulty with follow-up procedures to ensure that the changes it makes on paper have real meaning in practice. In 1986, the General Accounting Office surmised, "[w]hile most registrants may be complying with the labeling requirements, several are not."[128] Generally, compliance with OPP requirements has been mixed. The EPA's fledgling Call-in Action Tracking System in 1986 found that almost half of the requirements imposed by 74 interim registration standards were not being met.[129] Similarly, in 1986, EPA "appear[ed] not to have routinely monitored the conditions imposed [in OPP's conditional registration program] and enforced registrants' compliance with these conditions."[130]

Especially with label changes, which are utterly ineffective in reducing risk unless they are actually implemented, it is imperative that there be numerous, reinforcing processes for monitoring and enforcement. At a minimum, EPA's newly reorganized Office of Enforcement and Compliance Assurance should recognize how central label compliance is to OPP's program and take steps to supplement the follow-up efforts that can be expected from an already overburdened program staff. But, precisely because most compliance information comes from the field, OPP itself should ensure that the public negotiation docket remains continually open to information from the field on non-compliance with risk reduction measures, and that OPP reopen its negotiations on label changes whenever it appears that earlier negotiations had achieved only paper victories.[131]

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[128]Pesticides: EPA's Formidable Task, *supra* note 6, at 43.

[129]*Id.* at 40.

[130]*Id.* at 96.

[131]Although outside the scope of this Report, it may be that FIFRA's apparent preemption of some common law actions is overbroad and out of sync with the regulatory realities of OPP's labeling decisions. The caselaw on preemption is often predicated on the comprehensiveness of the regulatory scheme and the thoroughness with which EPA approaches pesticide regulation in general and the contents of labels in particular. *See*, e.g., Papas v. Upjohn Co., 985 F.2d 516 (11th. Cir. 1993), cert. denied, No. 92-1938, 1993 WL 205212 (11th Cir. Oct. 12, 1993)(finding common law actions preempted); Arkansas-Platte & Gulf v. Van Waters & Rogers, 981 F.2d 1177, 1179 (10th Cir. 1993), cert. denied, No. 92-1784, 1993 WL 165024 (U.S., Oct. 4, 1993)(same). Although this rationale may well fit label decisions reached at the conclusion of the reregistration process, when EPA has compiled all of the relevant databases and reaches decisions based on a comprehensive assessment, it hardly seems to fit labeling decisions EPA itself characterizes as "interim" in nature and reaches on concededly incomplete databases in an extra-statutory, extra-regulatory practice of private negotiations with registrants. From a policy perspective, it may well be that FIFRA should be redrafted to preempt only those common law actions seeking to go beyond labels comprehensively and openly approved by EPA at the completion of reregistration. Such a policy would reinforce in fact the regulatory comprehensiveness valued so highly in preemption doctrine; indeed, restricted in this way, common law actions would help bring about comprehensive regulatory decisions by creating an incentive (protection from common law actions) for registrants to having the reregistration process completed rather than delayed.

4. Eliminate the ability of registrants to demand formal adjudicatory hearings[132]

The ability of registrants now to demand formal adjudicatory hearings can create procedural nightmares for EPA. FIFRA Section 6(b) now allows registrants to demand formal hearings whenever EPA proposes to cancel a registration, change the regulatory classification of a pesticide from "general use" to "restricted use," or suspend a pesticide because it poses an "imminent hazard" to public health and the environment.[133] In each of these situations, formal adjudicatory hearings add a largely repetitive layer of bureaucratic delay to EPA's central, substantive determination that a pesticide poses unreasonable risk. The prospect of formal hearings also weakens the Agency's substantive bargaining position in the innumerable, but inevitable, interpretive questions that arise—well before the initiation of cancellation proceedings—about the data on a pesticide's risks and benefits.[134] Almost fifteen years ago, Professor Thomas McGarity spoke candidly about his experience in EPA's Office of General Counsel when representing OPP:

> [A]s an attorney for the Office of General Counsel of EPA I often felt significant pressure from my clients in the Office of Pesticide Programs to take a conciliatory posture toward the industry position in order to conserve agency resources. Similarly, my superiors in the Office of General Counsel, operating under severe personnel restraints, constantly stressed accommodation, even if it meant sacrificing broader agency goals to the sad, but unavoidable fact that seven attorneys

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[132]FIFRA Section 3(c)(6) provides that any "applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6." Section 6, in turn, provides for formal evidentiary hearings. To the extent applicants for registration or their allies can now demand formal evidentiary hearings when EPA denies applications for registration, the analysis in this Section of the Report should also be read to explain why this formal process should be replaced by a far more streamlined one.

[133]As discussed *supra* at pages 5-6, there are modest provisions for expediting formal hearings regarding the proposed suspension of "imminent hazard" pesticides.

[134]The relationship between formal procedures and the ability of agencies forcefully to implement their substantive missions has been generally recognized. *See* Hamilton, Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, 60 CALIF. L. REV. 1276, 1312 (1972) (burdensome procedures lead to noncontroversial regulations by process of negotiation and compromise); Williams, "Hybrid Rulemaking" Under the Administrative Procedure Act: A Legal and Empirical Analysis, 42 U. CHI. L. REV. 401, 443 (1975) (right to cross-examination complicates and lengthens procedures thereby exerting pressure on agency to take "milder stand"), cited in McGarity, *supra* note 7 at 754 n. 115.

> cannot possibly manage more than two or at most three full-time adjudicatory hearings at a single time.[135]

In my interviews at EPA in 1992, I received similar messages from other staff.

In 1993, there is somewhat surprising evidence that streamlining cancellation proceedings—from formal adjudications to informal rulemakings—is viewed as a relatively noncontroversial idea whose time, politically, has come. The Lehman-Bliley bill pending in the 103rd Congress endorses the shift. Related bills introduced in the 102nd Congress that also urged the shift to informal rulemaking were supported in varying degrees by representatives of the National Agricultural Chemicals Association,[136] the National Agrichemical Retailers Association,[137] the National Food Processors Association,[138] as well as by representatives of the Natural Resources Defense Council[139] and the National Audubon Society.[140] Although there can never be unanimity on such matters,[141] there is remarkable breadth of political support for cancellation by less formal proceedings than FIFRA now allows.

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[135]McGarity, *supra* note 7, at 754 n. 115.

[136]Testimony of Jay Vroom, President, National Agricultural Chemicals Assn, Hearings on the Pesticide Safety Improvement Act of 1991 before the Subcomm. on Dept. Operations, Research, and Foreign Agriculture, House Comm. on Agriculture, 102nd Cong., 2d Sess. 201 (Mar. 18, 1992) ("Our message today...is that cancellation takes too long.... [but] if we must abandon the formal proceedings in current law, the public must retain the right to question participants, on the record, in the [informal] hearings provided in your bill").

[137]Testimony of Dooie Leach, Nat'l Agrichemical Retailers Assn, in Hearings on the Pesticide Safety Improvement Act of 1991, *supra* note 166, at 235 ("Although NARA supports a shortened pesticide cancellation process, we do not support regulatory actions based on unsubstantiated and unscientific speculation").

[138]Statement of Dr. Lester Crawford, Executive Vice President, Scientific Affairs, National Food Processors Assn, in Hearings on the Pesticide Safety Improvement Act of 1991, *supra* note 166, at 259-260 ([providing that consultation requirements are added] "eliminating the current adjudicatory hearing requirement and substituting notice and comment rulemaking...will better enable EPA promptly to cancel pesticides that pose an unreasonable risk and will assist in promoting consumer confidence in the food supply").

[139]Testimony of Erik Olson, Senior Attorney, NRDC, in Hearings on the Pesticide Safety Improvement Act of 1991, *supra* note 166, at 285-286 ([providing that initiation of cancellation proceedings is not delayed and informal processes stay within specified time limits] "the Rose bill would streamline EPA's cancellation and suspension processes, in an effort to reduce the procedural problems identified by Administrator Reilly").

[140]Statement of Maureen Kuwano Hinkle, Director, Agricultural Program, National Audubon Society, in Hearings on the Pesticide Safety Improvement Act of 1991, *supra* note 166, at 422 ([provided that consultation requirements do not delay matters or preclude participation by nonregistrants,] the process is "obviously in need of streamlining").

[141]*See* Statement of William J. Baldwin, American Wood Preservers Institute, in Hearings on the Pesticide Safety Improvement Act of 1991, *supra* note 166, at 575 ("The bill would establish an informal hearing procedure that EPA could conduct at its discretion. This is not an adequate substitute for an adjudicatory hearing at which pesticide registrants have the right to cross-examine Agency scientists and regulators about the adequacy of the basis for their proposal").

The popular groundswell for streamlining the cancellation process, however, cloaks considerable tension between two underlying questions: how formal a procedure is required by the procedural due process clause of the Constitution, and how streamlined a procedure is desirable as a matter of policy. After describing the unnecessarily complex hearing procedures that FIFRA now provides, this Report takes up these two questions in turn.

(a) FIFRA's formal cancellation process is a historical anachronism

President Bush's EPA Administrator did not overstate the case when he observed in 1989, "[t]he current pesticide cancellation process is complicated, duplicative, and inefficient. This country cancels trading in bad stock faster than it gets rid of a bad pesticide."[142] Even though the decision to initiate cancellation proceedings may have been painstakingly reached after years of EPA's Special Review process, and even further years spent evaluating the pesticide for the purposes of developing Registration Standards and/or Reregistration Eligibility Documents, EPA must still further precede initiation of cancellation proceedings by submitting for scientific peer review the scientific studies on which EPA would rely[143] and also for comment a proposed Notice of Intent to Cancel to the U.S. Department of Agriculture ("USDA") and to EPA's Scientific Advisory Panel ("SAP").[144] After affording USDA and SAP 60 days to comment, EPA may at last notify the registrant of the government's intent to cancel. Registrants may then request a formal adjudicatory hearing under FIFRA Section 6. If a hearing is demanded, an administrative law judge ("ALJ") is assigned and the parties enter into prehearing procedures and discovery not unlike the judicial process followed in federal court (complete with opportunities for pre-hearing conferences, in camera inspection of material alleged to be confidential, exchanges of witness lists, summaries of expected testimony, and lists of documents and exhibits).[145] Any party may also request the ALJ to refer "questions of scientific fact" to the National Academy of Sciences for resolution (although referral is discretionary with the ALJ).[146] Thereafter, the actual hearing is held in accordance with the formal procedures established in Sections 556 and 557 of the Federal Administrative Procedure Act. The ALJ must admit "all relevant, competent and material evidence, except evidence that is unduly repetitious."[147] With permission of the ALJ, interlocutory appeals may be filed with the EPA Administrator to resolve "important questions of law or policy

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[142]Supra note 11.
[143]*See* FIFRA Section 25(e).
[144]FIFRA Sections 6(b), 25(d).
[145]*See* Pesticide Regulation Handbook, *supra* note 42, at 188.
[146]*See* 40 CFR §164.50(e).
[147]40 CFR §164.81(a).

about which there is substantial ground for difference of opinion."[148] After testimony is completed, the parties propose orders, findings of fact and conclusions of law to the ALJ, who then prepares an initial decision.[149] Appeals may be made to the Administrator who is required to "consider restricting a pesticide's use or uses as an alternative to cancellation."[150] The Agency's final decision is appealable within 60 days to the courts of appeals which review the decision for "substantial evidence."[151]

Pesticide cancellation hearings have in the past averaged 1,000 days,[152] making them among the most time-consuming adjudicatory proceedings in the federal government.[153] What is rarely appreciated, however, is that this extraordinary commitment of decisional resources does not reflect—and has never reflected—a political consensus that formal procedures are necessary for good decisionmaking. Rather, there is ample evidence to support the thesis that Congress has steadily stitched together an amalgam of procedures designed to serve political rather than analytic goals. The historical argument is complex and, for those interested, is recounted at length in Appendix I to this Report. But for present purposes, suffice it to note that the opportunity for a formal hearing itself was added in the 1964 FIFRA Amendments as a political trade-off for eliminating what was then known as "protest registrations" (the ability of registrants to register their products over the government's objection).[154] The requirement for pre-cancellation notice to USDA was added in the 1975 FIFRA Amendments as political retaliation against EPA's aggressive cancellation hearings in the early 1970's.[155] And referrals to either the National Academy of Sciences or the SAP were added, deleted, and readded to FIFRA in response to congressional approval or disapproval of EPA's aggressiveness in regulating pesticides.[156]

(b) More streamlined procedures can surely pass constitutional muster

Although it has been argued that a cancellation proceeding involves polycentric issues and numerous stakeholders in the decision—and thereby is

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[148]40 CFR §164.100.

[149]40 CFR §164.100.

[150]FIFRA Section 6(b).

[151]FIFRA Section 16(b).

[152]*See* note 7 *supra*.

[153]*Id.*

[154]*See* Hornstein, *supra* note 18, at 427-429; *see also* Appendix I *infra*.

[155]*See* Angus MacIntyre, *supra* note 18, at 219-225; House Comm. on Agriculture, Business Meetings on FIFRA Extension, June-November 1975, 94th Cong., 1st Sess. (1975); Donald Hornstein, *supra* note 18, at 434.

[156]*See*, e.g., Donald Hornstein, *supra* note 18, at 429-434.

functionally more like a rulemaking than an adjudication[157]—even proponents of this position concede that "[t]his claim...is not very convincing, and it requires a considerable stretching of the rulemaking-adjudication categories."[158] The more intuitive proposition is that registration under FIFRA creates a statutorily-based property right within the threshold meaning of *Board of Regents v. Roth*.[159] This, of course, is enough at least to trigger constitutional concern over the procedures used by government in terminating the right.

The critical question becomes: what process is due? And the touchstone for this question is the Supreme Court's decision in *Mathews v. Eldridge*.[160] There the Court noted that "due process [is] not a technical conception with a fixed content unrelated to time, place and circumstances,"[161] but generally speaking is tailored to the private interest at stake, the government's interest (including the administrative burdens of additional procedure), and the risk of erroneous deprivation under existing procedures and the correlative value of additional procedures.

Although in the case of a pesticide's termination the first two *Mathews* factors cannot be precisely measured with a common denominator, the marginal balance would probably favor the government's interest in informality. The registrant's financial interest in continuing unimpeded all registrations can certainly be high, reflecting investment-backed expectations that have already been made in developing the data necessary for registration and in building a pesticide's clientele and market share. Indeed, investments in a pesticide's registration may have been made in part because cancellation was procedurally difficult.[162] On the other hand, registrants have chosen to make these investments in one of the most dynamic legislative regimes ever enacted (since its modernizing amendments in 1972, FIFRA has been amended in 1975, 1978, 1980, 1988 and 1990) in which the statutory standards and processes have evolved. Balanced against these interests is the government's interest (and perhaps even the industry's interest) in having a process for removing "bad" pesticides expeditiously. Evidence that formal cancellation procedures have

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[157]*See* McGarity, *supra* note 7, at 772 (arguing for the adoption of summary judgment practice in cancellation hearings because "a pesticide cancellation proceeding is really polycentric; it is general in form, and its resolution affects many parties in different ways").

[158]*Id.*

[159]408 U.S. 564 (1972)

[160]424 U.S. 319 (1976).

[161]*Id.*

[162]*Cf.* Ruckelshaus v. Monsanto, 467 U.S. 986, 1006-1007 (1984) (the lack of reasonable investment-backed expectations in a health, safety and environmental data submitted to support a pesticide registration is influenced by the fact that EPA never promised to keep that data confidential).

undermined OPP's ability to perform its substantive mission cannot be lightly ignored.[163]

The critical constitutional factor, however, will be the risk of erroneous deprivation. For the reasons that follow, this Report concludes that *Mathews'* concern for accuracy supports the constitutionality of a modified form of notice-and-comment rulemaking which allows a limited opportunity for cross-examination as well as several other procedural protections. To begin the analysis, it is useful to recognize several potential sources of error that could attend the use of "bare" notice-and-comment rulemaking to govern pesticide cancellations. First, the registrant would lose the protection of an insulated decisionmaker, at least as to initial decisions. This concern, however, hardly makes an administrative law judge a constitutional necessity. Although it is true that a "rulemaking" official will not be as insulated as would be an ALJ in a formal adjudication, the Supreme Court has held ever since *Withrow v. Larkin*[164] that even the combination of investigative and adjudicative functions in a single administrative decisionmaker "does not, without more, constitute a due process violation."[165] At the most, it would be enough to require the initial decisionmaker not to have been involved in any prosecuting or investigating functions in the cancellation proceeding at hand, and perhaps to provide a "show cause" mechanism by which registrants might offer proof of a real "risk of actual bias or prejudgment."[166]

A second source of error might be the heightened possibility of political or other outside influence—either from the White House, Congress, or other sources of ex parte contacts—that exists in an informal rulemaking as opposed to a formal adjudication.[167] Given the fact that there are some elements of an individualized adjudication inherent in a cancellation proceeding, it is important to recall the D.C. Circuit's decision in *Sangamon Valley Television Corp. v. United States*,[168] that the resolution of "private claims to a valuable privilege [requires in the name of] basic fairness [that] such proceedings be carried on in the open."[169] Here again, however, the concern could be easily addressed by requiring the disclosure of any ex parte contacts. Such a disclosure would operate

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[163]*See*, e.g., notes 7-11, 170 & 171 *supra*.

[164]421 U.S. 35 (1975).

[165]*Id.* at 58.

[166]CWM, 873 F.2d at 1484 (citing Withrow v. Larkin, 421 U.S. at 47).

[167]*Compare* Professional Air Traffic Controllers Organization ("PATCO") v. FLRA, 685 F.2d 547 (D.C. Cir. 1982) (taking seriously even the possibility of White House pressure on an agency in a formal adjudication) with Sierra Club v. Costle, 657 F.2d 298 (D.C. Cir. 1981) ("But where agency action involves informal rulemaking of a policymaking sort, the concept of ex parte contacts is of more questionable utility").

[168]269 F.2d 225 (D.C. Cir. 1959)

[169]*Id.* at 225.

prophylactically to dissuade at least some outsiders from attempting to interject nonstatutory factors into the Agency's decisionmaking. And, to the extent any ex parte contacts are disclosed in the rulemaking docket, the disclosure itself would alert reviewing courts to assure themselves that the Agency reasonably made its decision according only to legally relevant factors.[170]

Perhaps the most important procedural guarantee is an adequate opportunity to know the evidence in favor of cancellation and a meaningful opportunity to meet it. Yet this could be accommodated relatively efficiently by very detailed notice of the Agency's reasons for seeking cancellation (including the identification of and access to the data on which the government relies) and, at the outermost, perhaps a limited opportunity to introduce oral testimony and/or pursue cross examination. Generally speaking, orality rights, including the right to cross-examination, are not likely to be fruitful in the factual and trans-scientific disputes likely to predominate in a cancellation proceeding. Although cross-examination might be useful in identifying the costs and benefits of developing additional data,[171] it cannot elucidate the basic policy question of where to draw the balance between risk and benefit in determining unreasonable risk.[172] It is true that cross-examination can be "of great value in probing inferences" that recur in risk analyses,[173] but it "usually reveals only the depth of the disagreement among the experts; it rarely reveals any basis for choosing one expert's interpretation of the data over another's."[174] Given the types of "facts" likely to be at issue in cancellation proceedings, participants should have the burden of showing cause why orality and cross-examination rights would likely improve the accuracy of agency decisionmaking. It is difficult to see why the Constitution would demand more.

(c) Effective regulation requires streamlined procedures

The leading FIFRA reform bill now pending in Congress, the Lehman-Bliley bill (H.R. 1627), nominally calls for a shift from formal adjudication to

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[170]The extent to which standards for cancellation are well specified and relatively transparent to registrants can also enhance the procedural legitimacy of informal cancellation proceedings. Although it cannot be said that only a fully specified congressional standard for determining what constitutes "unreasonable" risk is constitutionally required, the more that EPA develops internal guidance documents and regulations on unreasonable risk, the more clearly adequate are fairly basic notice-and-comment cancellation proceedings. *See, e.g.*, Chemical Waste Management v. EPA, 873 F.2d at 1484 (upholding EPA's informal corrective action rulemakings despite lack of fully developed administrative standards for corrective action in light of other sources of agency guidance—for both EPA and affected permittees—on what constitutes corrective action.).

[171]*See* McGarity, *supra* note 7, at 777.

[172]*Id.*

[173]*Id.*

[174]*Id. See* McGarity, *supra* note 7, at n. 242 (problems encountered in FDA hearings partly due to wide-ranging and unproductive cross-examination of expert witnesses).

informal rulemaking—but actually offers hardly any real procedural reform at all. The Lehman-Bliley bill requires nine distinct procedural steps for cancellation, many of them carried over from the overproceduralized statute with which EPA now struggles. Under H.R. 1627, for example, EPA may not initiate an "informal cancellation rulemaking" unless it first receives comments from a "scientific peer review committee" (consisting of expert EPA employees or consultants) on a "validated test" or "other significant evidence" on which EPA wishes to base its rulemaking.[175] There are no time constraints within which the peer review committee must submit its comments to EPA. Second, EPA must then provide affected registrants "prenotice" of the evidence on which it proposes to base its rulemaking and allow them 30 days to "respond." Third, EPA must provide similar "prenotice" to USDA and the Department of Health and Human Services. USDA is required to provide a benefits analysis of the pesticide to EPA, and EPA cannot proceed until it obtains comments from USDA, but no time limitation is imposed on USDA's analysis.[176] Fourth, EPA must issue an Advanced Notice of Proposed Rulemaking ("ANPR") in the Federal Register in which it summarizes the factual data on which the notice is based, the major scientific assumptions involved, the "prenotice" given the registrant, and any significant comments received, and provides for a 60-day comment period.[177] Fifth, 60 days after the ANPR, EPA may issue a notice of proposed rulemaking in which it discloses factual data, major "scientific assumptions, legal interpretations, and policy considerations," a summary of available risk-benefit information, and EPA's tentative conclusions regarding the balancing of risks and benefits.[178] EPA must provide a 90-day comment period. Sixth, simultaneously with its general notice of proposed rulemaking, EPA must provide USDA and HHS with a copy of the proposed rule and allow them 90 days to comment.[179] Seventh, any person who comments may, within 15 days after the close of the comment period, demand an "informal hearing," not to exceed 20 days duration, to begin within 60 days of the close of the comment period; the informal hearing is to be conducted by a presiding officer "in a manner that encourages discussion and debate on questions of fact."[180] Eighth, simultaneously with its notice of proposed rulemaking, EPA shall provide the SAP with notice of the proposed rule and allow SAP to file a report no later than 30 days after the close of the comment period, unless the SAP chooses to hold a "public hearing to discuss the proposed rule," in which case the

[175]H.R. 1627, Section 6(b)(2).
[176]*Id.*, Section 6(b)(3)(B), (4)(A).
[177]*Id.*, Section 6(b)(4).
[178]*Id.*, Section 6(b)(6).
[179]*Id.*, Section 6(b)(6)(B).
[180]*Id.*, Section 6(b)(7).

SAP must report within 30 days after the close of its hearing.[181] Ninth, EPA may issue its final rule (but "may not prohibit the use of a pesticide if alternative requirements will assure that the pesticide...will not generally cause unreasonable adverse effects") that "shall" be accompanied by a statement explaining the Agency's reasons; responding to any comments made by USDA, HHS and SAP; and responding to "each significant comment" in the general rulemaking docket.[182]

In contrast to Lehman-Bliley, all that is constitutionally required and all that is needed for a full, fair, and efficient ventilation of the issues would be (1) detailed notice of the Agency's reasons for seeking cancellation, including the identification of and access to all data on which the Agency depends, (2) the disclosure of any discussions between agency personnel and all persons outside of the Agency regarding the proposed cancellation, (3) an opportunity to argue actual bias by the Agency's rulemaking officer, (4) a reasonable period of time in which to file written comments and submit data, and (5) an opportunity to show cause why further process is reasonably likely to improve the accuracy of agency decisionmaking.

IV. The Regulation of Safer Pesticides

The regulation of new pesticides is integrally related to EPA's success in regulating older pesticides. To the extent that newer, safer pesticides are available, EPA will be more aggressive in policing and evaluating the data for existing products, and more willing to find risks to be unreasonable, because the aggressive regulation of risk will not necessarily lead to lost benefits. In short, a successful safer pesticides program can catch the Agency up to the scientific warnings being sounded repeatedly about pesticide exposure. Rather than viewing a safer pesticides initiative as simply another burden to an already overburdened program, safer pesticides should be viewed as a key both to EPA's success in reregistration and to its ability to transform FIFRA into a prototype of progressive environmental legislation that combines incentive-based regulation, comparative risk analysis, and pollution prevention.

Without taking a position on the substance of the Agency's first steps toward a safer policy initiative taken in July 1992 when EPA first solicited public comments on possible ways in which the Agency might encourage safer pesticides[183] or further steps taken in January 1993 when EPA announced that the

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[181] *Id.*, Section 6(b)(8).

[182] *Id.*, Section 9.

[183] *See* Incentives for Development and Registration of Reduced Risk Pesticides, 57 Fed. Reg. 32140 (July 20, 1992) (request for comments).

Agency was still struggling with but excited by the idea of encouraging a safer pest management regime,[184] this Report urges that Congress consider an expressly procedural option with which EPA can implement whatever substantive decisions it reaches on safer pesticides.

EPA should seek from Congress informal rulemaking authority to "phase-down" the use of existing pesticides whenever the combination of risk data on existing products and the availability of safer pest management products or practices leads EPA to believe that current risk levels may be unreasonable. Such a mechanism, rather than being merely another "tool" for an overworked agency to contemplate, can offer widespread and reinforcing incentives for effective regulation throughout EPA's pesticide programs.

First, phase-down rulemaking would provide an expeditious vehicle for moving beyond interim label changes when the data suggest continued concern about an existing pesticide but are just inconclusive enough to dissuade the Agency from full cancellation.

Second, phase-down rulemaking would provide a vehicle for EPA to offer concrete market entry to entrepreneurs willing to invest their resources in products that will advance the risk-benefit frontier closer toward a truly sustainable agriculture in which effective pest management and environmental protection can better coexist. It is hardly incongruous for EPA to offer such market advantages; its current program under FIFRA provides market protection to existing pesticides by preventing the entry of competing products.

Third, phase-down rulemaking provides for an incremental style of decisionmaking in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides (where the data are incomplete) and safer pesticides (where the data are incomplete)—it provides a built-in method for making progress while at the same time hedging one's bets.

Fourth, phase-down rulemaking provides a flexible form of rulemaking that can be used to reinforce other programs EPA administers. For example, to the extent EPA's water office identified pesticide run-off as a significant problem for Chesapeake Bay, EPA could choose to phase-down in that one region alone the pesticides of concern and phase-in a more promising alternative.

Fifth and perhaps best, phase-down rulemaking provides a way to implement efficient markets for safer pest management practices. Because growers face innumerable local differences that affect their pest problems, it is impossible for any centralized command-and-control system to know where farmers can efficiently use safer pest management practices and where they

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[184] *See* Incentives for Development and Registration of Reduced-Risk Pesticides Program, 58 Fed. Reg. 5854 (Jan. 22, 1993).

cannot. By restricting a pesticide's use, however, phase-down rulemaking will cause the price of the pesticide to rise. This creates an efficient market for pest control alternatives. Those farmers for whom the safer products work will switch to the extent the price is cost-effective (producers of safer products will price accordingly). Those farmers for whom the safer products may not work will still be able to purchase pest protection at a higher but still cost-effective price (existing producers will also price accordingly). If data indicate that the pesticide that at first appeared safer actually is ineffective, regulators can always reopen the rulemaking and phase-up the older products. If data indicate that the safer pesticide is even better than expected, regulators can decide whether this makes the older products' risks unreasonable.[185]

V. Conclusions and Proposed Recommendations

Pesticide regulation should be reformed to create incentives for reduced risk, regulatory compliance, program flexibility, and wider public participation. To these ends, the following recommendations are made to Congress and the Environmental Protection Agency.

1. Because good data are central to the integrity of EPA's substantive decisions, and because the submission of such data is critical to the timeliness of agency action, EPA should promulgate, whenever possible, clear, written standards on the adequacy of data and communicate those standards to registrants.

2. Congress should provide EPA with the authority to impose administrative civil money penalties on registrants for the submittal of data after any applicable deadline, or for the submittal of data (even if timely) the inadequacy of which can be demonstrated by reference to clear data standards adopted by EPA.[186]

3. Congress should consider changing the incentives of registrants for reasonably expeditious reregistration by imposing an essentially automatic suspension of List A pesticides for which there still remain, by a date certain,

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[185]It is not a forgone conclusion that regulators will always, or even ever, move quickly to cancel an existing pesticide entirely simply because there is a safer alternative. There will always be pest resistance possibilities to contemplate that may make it reasonable to maintain at least some uses of pesticides that are more risky in only some respects.

[186]*See* Administrative Conference Recommendation 93-1 "Use of APA Formal Procedures in Civil Money Penalty Proceedings," 1 CFR §305.93-1.

outstanding significant data gaps within the registrant's control. Once suspended, pesticides could subsequently be reinstated through a petition process.

4. Congress should eliminate the provisions in FIFRA allowing for formal adjudicatory hearings and provide instead an informal procedure that affords registrants notice of the grounds on which EPA bases its proposed suspension or cancellation actions and reasonable opportunities to file written comments. Only upon cause being shown, would the agency grant the registrant the right to introduce oral testimony or to subpoena and cross-examine witnesses in individual cases.

5. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through pesticide label changes. EPA should inform the public, through a Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

6. EPA should ensure compliance with label changes. After a label change, the agency should establish and publicize the availability of a "compliance docket," for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. In addition, EPA's Office of Pesticide Programs (OPP) should communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes and any material information received by OPP in its compliance docket.

7. Congress should consider providing EPA the authority to order a phase down in the use of any registered pesticide through an informal rulemaking procedure in which EPA considers such factors as the relative risks and benefits of the pesticide at issue when compared with alternative pest management products and practices.

APPENDIX

FIFRA And the Politics of Proceduralism

Perhaps the most revealing aspect of pesticide regulation under FIFRA and FFDCA is that its critics seem to see in it two entirely different things. One broad criticism is that the scheme allows for public hysteria over pesticides to displace a more scientific approach. Arguments urging the need for more scientific decisionmaking were launched against EPA for its suspension in 1979 of the herbicide 2,4,5-T;[1] for its regulatory actions in 1984 against the nematicide ethylene dibromide (EDB);[2] and for its cancellation in 1989 of the growth regulator daminozide (Alar).[3] Currently, the argument is reflected in criticism of the Ninth Circuit's literal interpretation of the Delaney Clause in *Les v. Reilly*[4] where critics argue the scientific "irrationality" of a zero-risk interpretation of FFDCA Section 409 because it would preclude the registration of new pesticides posing less risks of cancer than currently registered "older" pesticides.[5]

On the other hand, there is an equally long tradition of criticizing pesticide regulation under FIFRA and FFDCA for being overly cautious and methodical. EPA was criticized for dragging its feet on both EDB[6] and Alar,[7] as well as for its more general failure to consider a broader range of risks posed by pesticides such as risks to farmworkers,[8] particular risks to children,[9] the risks of inert

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[1]*See* R. Jeffrey Smith, *"EPA Halts Most Uses of Herbicide 2,4,5-T,"* 203 *SCIENCE* 1090-1091 (1979)("an example of government at its worst—basing a hasty product suspension on data which have not been subjected to scientific review") (quoting Ethyl Blair, spokesperson for 2,4,5-T's producer, Dow Chemical Company); *see also* Sheila Jasanoff, *The Fifth Branch* 24-26 (1990).

[2]*See* William B. Havender, *EDB and the Marigold Option*, January/February 1984 REGULATION 13, ("extremists controlled the momentum of these events"); Jasanoff, *supra* note 1, at 130-133.

[3]*See* advertisement, *New York Times*, April 5, 1989, at A11 (full page advertisement signed by sixty-five scientists decrying EPA's "unfounded attacks on the safety of our food supply"); Jasanoff, *supra* note 1, at 141-151.

[4]No. 91-70324.

[5]*Id.*

[6]*See* Jasanoff, *supra* note 1, at 135 (criticizing EPA for having authority to investigate substitutes to EDB for six years before acting).

[7]*See* Linda M. Correia, *"A" is for Alar: EPA's Persistent Failure to Promptly Remove Hazardous Pesticides from the Food Supply*, 16 Chem. Reg. Rep. (BNA), No. 20, 868, 878 (Aug. 14, 1992) ("The Alar case illustrates EPA's timid approach to the enforcement of the pesticide laws").

[8]*See, e.g.*, 15 Env. Rep. (BNA), No. 47, at 1689 (Feb. 28, 1992) (General Accounting Office critique of EPA's "cursory protection" of farmworkers from pesticide dangers); 14 Env. Rep. (BNA), No. 7, at 251 (May 18, 1990) (critique by Office of Technology Assessment that EPA's focus on carcinogenicity has downplayed neurotoxic effects that may pose an even greater threat to human health, especially among farmworkers); 13 Env. Rep. (BNA), No. 23, at 725 (Sept. 8, 1989) (no excuse for ignoring 313,000 cases of pesticide-related illness among farmworkers).

[9]*See, e.g.*, 15 Chem. Reg. Rep (BNA), No. 49, at 1784 (Mar. 13, 1992) (EPA failed to protect children from dangers associated with aldicarb application to citrus crops); 15 Chem. Reg. Rep. (BNA),

ingredients,[10] ecological risks,[11] and the risks of groundwater contamination.[12] In recent congressional hearings on FIFRA reform, the statute was characterized as having "simply...failed to assure that there will be timely and appropriate action taken to protect human health and the environment from pesticides."[13] The National Research Council's June 1993 report on pesticide residues in the diets of infants and children has provoked renewed concern that EPA's risk assessments are inadequately framed to reflect real risks.[14]

One of the major conclusions reached in this Report is that these twin criticisms, rather than reflecting only administrative missteps by EPA, reveal statutory tensions that have been designed by Congress, in some cases advertently and in other cases inadvertently, into FIFRA itself. Although FIFRA has been reported as having freed pesticide regulation from the provincialism of agricultural interests in both Congress and USDA, procedurally FIFRA was set free only to wander in a complex labyrinth of risk-based decisionmaking in which slow-going was often a statutory requirement.

A. The Early History of Pesticide Regulation

In its earliest years, pesticide regulation was desultory at best under both the 1906 Federal Food and Drug Act,[15] which delegated to USDA's Bureau of Chemistry the duty to protect consumers from impure food, and the 1910 Insecticide Act,[16] which delegated to USDA the authority to protect farmers from false advertising and nonefficacious pesticides. After lax regulation by the Bureau of Chemistry caused USDA in 1925 to dissolve the Bureau and transfer

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No. 15, at 461 (July 12, 1991) (residue limits do not always reflect safe levels for everyone, especially children, because of the composition of their diet and their low body weight relative to exposure).

[10]*See, e.g.*, 14 Chem. Reg. Rep. (BNA), No. 20, at 789 (Aug. 17, 1990) (some inert ingredients are known to be more toxic than the active ingredients, and the public, because EPA has not required labeling of inerts, has no way of taking adequate precautions); 13 Chem. Reg. Rep. (BNA), No. 45, at 1436 (Feb. 16, 1990) (EPA faulted for not considering potential health effects of inert ingredients).

[11]*See, e.g.*, 21 Env. Rep. (BNA), No. 4, at 266 (May 25, 1990) (SAB Report criticized EPA for placing too much emphasis on human health issues and ignoring broader ecological issues); 13 Chem. Reg. Rep. (BNA), No. 18, at 632 (Aug. 4, 1989) (bird mortality from pesticides indicates that there is broader ecological damage occurring).

[12]*See, e.g.*, 18 Env. Rep. (BNA), No. 4, at 438 (May 22, 1987) (EPA's piecemeal approach to groundwater protection from various sources including pesticides needs to be integrated); 17 Env. Rep. (BNA), No. 40, at 1672 (Jan. 30, 1987) (calling for end of "regulatory patchwork" governing protection of ground water from pesticidal and other forms of contamination).

[13]*See* Subcommittee on Department Operations, Research and Foreign Agriculture, House Committee on Agriculture, *Hearings on Pesticide Safety Improvement Act of 1991*, 102d Cong., 2d Sess. 176 (1992) (statement of Erik Olson, Senior Attorney, Natural Resources Defense Council).

[14]*See* National Research Council, *Pesticides in the Diets of Infants and Children* 8-10 (Nat'l Academy Press 1993).

[15]Federal Food and Drug Act of 1906, 34 Stat. 768 (repealed 1938).

[16]Pub. L. No. 61-152, 36 Stat. 331 (1910).

its functions to USDA's newly created Food Drug and Insecticide Administration (later renamed the Food and Drug Administration)("FDA"),[17] there began an effort by FDA scientists in the 1930's to use animal experiments and extrapolate from them the possible long-term effects of pesticides on humans.[18] These incipient efforts were stymied in 1937 by Representative Clarence Cannon, chair of the House Subcommittee on Agricultural Appropriations and a former apple grower (who once proclaimed, "lead arsenate on apples never harmed a man, woman, or child"),[19] in a USDA appropriations bill that prohibited the FDA from using funds "for laboratory investigations to determine the possibly harmful effects on human beings of spray residues on fruit and vegetables."[20] In one of the first political efforts to shape science in support of pre-conceived social conclusions about pesticides, Cannon assigned research jurisdiction over the health effects of pesticides to the Public Health Service ("PHS") which used the far less discriminating analytical approach of merely questioning farmers and field hands about their health.[21] Although, in 1938, the Food, Drug and Cosmetic Act[22] gave FDA the authority to set legal "tolerances" for pesticide residues, the tolerances still had to be based on PHS methodology and the new statute gave judicial appeal rights to any parties who might be "grievously affected" by even the inadequate tolerances that FDA could establish.[23] FDA was moved out of USDA and into the new Federal Security Agency in an executive reorganization in 1940, but its pesticide-related work remained firmly within the jurisdiction and watchfulness of congressional appropriations committees that were dominated by senior farm bloc legislators.[24]

The development of inexpensive, synthetic chemical pesticides between 1940 and 1945 led to enactment in 1947 of the original Federal Insecticide, Fungicide, and Rodenticide Act[25] as a mechanism for regularizing the market for these new chemicals.[26] The original FIFRA required USDA to "register" pesticides whenever their "labels" contained sufficient "directions for use which ...if complied with [were] adequate for the protection of the public."[27] Pesticides without such labels were considered "misbranded"[28] and, although producers

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[17]*See* Christopher J. Bosso, *Pesticides and Politics* 50 (1987).

[18]*Id.* at 50.

[19]See Thomas R. Dunlop, DDT: Scientists, Citizens and Public Policy 50 (1981).

[20]*See* Bosso, *supra* note 17, at 50.

[21]*Id.* at 50.

[22]Food, Drug & Cosmetic Act of 1938, Pub. L. No. 717, ch. 675, 52 Stat. 1046.

[23]*See* Bosso, *supra* note 17, at 51-52.

[24]*Id.*

[25]Pub. L. No. 80-104, 61 Stat. 163 (1947).

[26]*See* Bosso, *supra* note 17, at 55-56 (industry sought a labeling statute to prohibit "fly-by-night" producers of imitations of the new synthetic chemicals).

[27]*Id.* 2(u)(2)(c).

[28]*Id.*

could insist that USDA register a product "under protest" (even when USDA had rejected a registration application or had proposed to cancel an existing registration),[29] an action could be brought by the appropriate United States Attorney alleging that these "under protest" pesticides inadequately protected the public.[30] In such a case, the government shouldered the burden of proving its allegations.[31] None of this was controversial. FIFRA came into the world by voice vote without "significant comment or debate,"[32] reflecting the widely shared political perception that pesticide policy was mostly a matter of accommodating the interests of growers and the emerging chemical industry.[33]

During the 1950's, public positions on pesticides did take shape with most, but not all, policies decidedly supportive of pesticide use. The only skeptical policies stemmed from congressional investigations chaired by New York Representative James Delaney into the growing use of synthetic chemicals in agriculture and the pharmaceutical industry,[34] and resulted in the addition of Sections 408 and 409 to the FDCA in 1954 and 1958, respectively.[35] Apparently mindful of the way scientific methodology might be manipulated to shade the effects of pesticides, Representative Delaney explained that the prohibition in Section 409 of any pesticide residues found to induce cancer in humans or animals (the so-called "Delaney Clause") had "slammed shut and locked" the door to allowing even small amounts of carcinogens in food.[36] Yet, despite such

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[29]*Id.* Section 4(c).

[30]*Id.* at Section 6(c).

[31]*See* Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 593 & note 34 (D.C. Cir. 1971) (the effect of the "under protest" provision in the original FIFRA made it incumbent upon the government to prove the pesticide unsafe before the product could be removed from the market).

[32]*See* Bosso, *supra* note 17, at 58 (noting that passage of the Act was mentioned only in passing in the *New York Times* Food Section).

[33]*Id.* at 59.

[34]*See* Hearings Before the House Select Comm. to Investigate the Use of Chemicals in Foods and Cosmetics, 81st Cong. 2d Sess. and 82nd Cong., 1st & 2d Sess. (1950-1952).

[35]*See* Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171, 179-180 (1978).

[36]Food Additives: Hearings on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food Before a Subcommittee of the House Interstate and Foreign Commerce Committee, 85th Cong., 2d Sess. 498 (1958). Delaney was speaking specifically about a 1955 FDA decision that had approved a one part-per-million tolerance for residues of the pesticide Aramite after concluding that such a residue level "would offer no hazard to the public." Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, 20 Fed. Reg. 7301 (1955). *See* Food Additive Hearings, *supra*, at 498. As Professor Richard Merrill has further chronicled, Delaney later supplemented his view of Section 409 by mentioning the Aramite decision by name: "Mr. Speaker, the significance of FDA's former ruling on Aramite was that for the first time a precedent was set that might give legal sanction to the introduction of so-called 'safe' quantities of cancer-inciting additives into food.... [It is the] firm purpose [of the Delaney Clause] to slam shut and lock [the door that the ruling had opened]." 104 Cong. Rec. 7783 (1958), *cited in* Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific*

bold rhetoric, the Delaney Clause in fact became one of the least-used provisions of the FDCA[37] and the enactment of Sections 408 and 409 attracted little popular attention from a public who viewed the congressional debate as "esoteric and technical."[38]

In contrast, there were far more visible public policies that openly supported pesticide use with almost unrestrained enthusiasm. In addition to subsidizing pesticide development in the country's land-grant colleges,[39] USDA organized several highly publicized "eradication" campaigns against the gypsy moth in the Northeast and the fire ant in the South. So supportive of these efforts was Representative Jamie Whitten, then Chair of the House Subcommittee on Agricultural Appropriations (and known for two decades in Washington as the "permanent Secretary of Agriculture"),[40] that Whitten insisted on providing USDA with more funds for the campaigns than it had requested.[41] When mounting evidence of fish and wildlife losses from these campaigns began to dissuade state officials from further cooperating, USDA offered literally to give away the fire ant insecticide heptachlor to any private property owner willing to use it.[42] Despite a growing scientific consensus that the fire ant's dangers had been overblown,[43] USDA redoubled a "barrage of government press releases, motion pictures, and government inspired stories portraying the fire ant as a despoiler of southern agriculture and a killer of birds, livestock, and man."[44]

Ironically, it was USDA's intransigent support for the increasingly unpopular eradication campaigns in the 1950's that created the receptive public that Rachel Carson addressed in 1962 and that ultimately prompted amendments to FIFRA in 1964 and 1972. Before focusing on those amendments, however, it is important to highlight one last aspect of what is often viewed as the political "republican moment" that transformed pesticide regulation in the 1960's and early 1970's.[45] Among other things, Carson questioned the government's

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Progress?, 5 YALE J. ON REG. 1, 55 n.288 (1988) (noting, however, other evidence indicating the language may in fact be ambiguous).

[37]*See* Merrill, *supra* note 35, at 178.

[38]*See* Bosso, *supra* note 17, at 80.

[39]*See* Board on Agriculture, National Research Council, *Alternative Agriculture* 77 (1989)(most federal research funds to land grant colleges for pest control supported work on chemical technologies aimed at boosting yields).

[40]*See* Bosso, *supra* note 17, at 67.

[41]*Id.* at 82.

[42]*Id.* at 102.

[43]*Id.* at 20 (National Research Council found that the ant's sting was no worse than a bee's); *id.* at 86 (many USDA entomologists worried little about the agricultural impact of the fire ant).

[44]*Id.* at 88.

[45]According to the concept of "republican moments," environmental statutes are enacted not during the "normal" political periods that are typically responsive to conventional interest group pressures, but rather during "extraordinary moments" when broad segments of the population become intensely interested in environmental issues, often due to well-publicized environmental "crises" or other attention-getting

manipulation of science to support the toxicological safety of pesticides by attacking the government's reliance on a National Academy of Sciences-National Research Council ("NAS-NRC") pesticide panel that, in Carson's view, was dominated by industry-sponsored experts.[46] When *Silent Spring* itself ignited a public controversy, President Kennedy bypassed NAS-NRC and sought policy advice from the President's Science Advisory Committee ("PSAC"), which issued a report in 1963 that largely supported Carson.[47] There followed counter-studies from NAS-NRC attacking the PSAC,[48] counter-counter-attacks on the NAS-NRC for itself being "unscientific,"[49] and a further "proliferation of 'expert' studies, each claiming to be the definitive analysis on pesticides and debunking claims propagated by rival studies."[50] It was against the backdrop of this quite politicized science that over a dozen separate committees or subcommittees of the 88th Congress held pesticide-related hearings in 1963 and 1964 on six different FIFRA reform bills that had been introduced into the House and three that had been introduced into the Senate.

B. The 1964 FIFRA Amendments: The Beginnings of Proceduralism

The 1964 FIFRA Amendments are most widely noted for eliminating the ability of producers to compel USDA "under protest" to register a pesticide or to continue a pesticide's registration.[51] Although it was generally acknowledged that few producers had used this provision,[52] its elimination was interpreted as signaling an important shift in the burden of proof needed by the government to

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"symbolic" events. *See generally* Daniel A. Farber, *Politics and Procedure in Environmental Law*, 8 J. L. ECON. & ORGAN. 59, 59-66 (1992), referring to James Pope, *Republican Moments: The Role of Direct Popular Power in the American Constitutional Order*, 139 U. PA. L. REV. 287, 291-93 (1990) ("And if history is any indicator, the legal system's response to these "republican moments" may be far more important than its attitude toward interest group politics").

[46]*See* Rachel Carson, *Silent Spring* (1962).

[47]*See* President's Science Advisory Council, *Use of Pesticides* (Washington, D.C. May 15, 1963); *see* Bosso, *supra* note 16, at 121-122 ("The PSAC panel acknowledged the benefits to society from chemical use, but overall concluded that 'the decisions on safety [were] not as well-based as those on efficacy,' and that 'until publication of *Silent Spring* by Rachel Carson, people generally were unaware of the toxicity of pesticides'").

[48]*See* National Academy of Sciences-National Research Council Report 920A, B, & C, *Pest Control and Wildlife Relationships* (1962-1963).

[49]*See* Bosso, *supra* note 17, at 124 (citing Audubon Society policy analyst Frank Graham).

[50]*Id.* at 121.

[51]*See, e.g.*, John D. Conner, Jr., et al, *Pesticide Regulation Handbook* 2-3 (3d ed. 1991).

[52]*See* U.S. Senate, Committee on Government Operations, Subcommittee on Reorganization and International Organizations, *Hearings on Interagency Environmental Hazards Coordination* 15, 88th Cong., 1st Sess. (1963) (Only 23 of some 50,000 products were registered "under protest" between 1947 and 1963); *see also* Bosso, *supra* note 181, at 126.

keep pesticides off the market.[53] Whereas the "under protest" provision of the original FIFRA effectively required the government to prove the dangerousness of a pesticide in a judicial "misbranding" action,[54] the 1964 Amendments gave USDA final authority to refuse registration or to cancel existing registrations without going to court,[55] with judicial review of the agency's factual determinations limited to the familiar "substantial evidence" test.[56] In addition, USDA was given the authority to "suspend" a pesticide's registration immediately "to prevent an imminent hazard to the public."[57] The 1964 Amendments have been interpreted as sending a warning shot over the bow of the "pesticide subgovernment," the entrenched pro-pesticide interests on the congressional agriculture committees and at USDA, that policymaking must become more responsive to the public concerns that had been articulated by Rachel Carson.[58] This is the "republican moment" explanation for the 1964 FIFRA Amendments.

There is another perspective, however, with which to view the 1964 FIFRA Amendments. Political economists Matthew McCubbins, Roger Noll, and Barry Weingast (known collectively as "McNollGast") have argued that Congress, when it enacts statutes that delegate policymaking tasks to agencies, will rationally design administrative structures and processes that lead to the types of substantive policy outcomes that are desired.[59] The underlying dynamic that forces Congress to think so strategically about administrative form, McNollGast argue, is that agencies can to some extent ignore *with impunity* the substantive policy preferences implied in legislation; agencies can play a "game" within a reasonably broad "policy space" in which policy moves away from that envisioned in the enabling legislation but toward a new point that so benefits either the

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[53]*See* 110 Cong. Rec. 2948-2949 (1964) (remarks of Congresswoman Sullivan) ("I am strongly in favor of the legislation now before you to require industry, rather than the Federal Government, to shoulder the burden of proof in connection with the marketing of pesticides which may be unsafe for use as intended"); *see also* H. Rep. No. 1125, 88th Cong., 2d Sess. (1964), *reprinted in* 1964 USSCAN 2166, 2167 ("[A]t present, the Secretary can be required to register a product even though he is convinced that it is ineffective and dangerous to human health. He can proceed against it...only after it has moved in interstate commerce, and he then has the burden of proving that it violates the law").

[54]*See* text accompanying notes 30-32, *supra*.

[55]*See* 78 Stat. 190(3).

[56]*See* 78 Stat. 190(4)(d).

[57]*Id.* at Section 3.

[58]*See* Bosso, *supra* note 17, at 125 ("The transformation in the pesticides debate was so swift that those promoting the use of pesticides were unprepared to deal with new sets of policy claimants. The twin blows delivered by *Silent Spring* and the PSAC report made it obvious to all save the most recalcitrant defenders of the status quo that *some* change would emerge as the debate moved from the front pages to the committee rooms and the federal office buildings").

[59]*See* Matthew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 VA. L. REV. 431 (1989).

House, Senate or President that one or more of these players will rationally choose not to support (or will choose to veto) any corrective legislation.[60] From the point of view of the enabling legislative coalition—the President (assuming he supports the bill) and the winning majorities in the House and Senate—the prospect of such "policy drift" is especially unnerving. Because neither the President nor the winning coalition in the House or Senate knows *ex ante* at whose expense (policy-wise) the agency's game will be played, each of them faces the dreary post-enactment prospect of "getting" to the agency before the others do.[61] Yet this defeats the purpose of banding together into a legislative coalition in the first place. So, McNollGast predict, rational players will find it in their best interest to design into the enabling legislation *ex ante* administrative structures that protect against agency noncompliance.[62]

For the purposes of analyzing FIFRA, the significant aspect of the "McNollGast Hypothesis" is its tenet that administrative structures and processes can play distinctly political roles. First, Congress can design administrative structures and processes in such a way as to create informational requirements that affect the difficulty (or ease) of agency policymaking and that can give significant advantages to a favored constituency by increasing "the dependence of the agency on information the constituency supplies."[63] Second, Congress can require agencies to act only after observing certain procedural complexities in part to create "fire alarms" that signal Congress sufficiently early of agency action to allow for congressional intercession before the agency can put together an uncorrectable "fait accompli."[64]

The 1964 FIFRA Amendments offer both some support and some difficulties for the McNollGast model. On the one hand, it is plain that Congress gave careful attention to the administrative structure and processes that USDA was to follow; indeed, these processes seemed to have been crafted by Congress to *undermine* the ostensible relaxation in the burden of proof for which the amendments are most widely known. This was accomplished in two ways. First,

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[60] *Id.* at 435-439.

[61] *Id.* at 439 (although "each of the three wants to minimize the chance that one of the other two will influence the agency against its interests...all have an ex post incentive to spend resources persuading the agency to sway policy their way. This is a negative sum game....").

[62] McNollGast explain:

> First, if political actors are risk averse, all three will prefer greater certainty in policy implementation as compared to random noncompliance (that is, noncompliance that may drift away from the preferred outcome of each of the three. Second, each of the three wants to minimize the chance that one of the other two will influence the agency against its interests.... Third, none of the parties wants to let the agency choose which political actor to favor.

Id. at 439.

[63] *Id.* at 440.

[64] *Id.* at 441.

although USDA could now refuse to register or cancel a registration without worrying about protest registrations, it could do so only after a formal "public hearing" if requested by the disappointed party.[65] Formal cancellation proceedings soon became the most time-consuming adjudicatory proceedings in the federal government.[66] Second, even before demanding a public hearing, disappointed parties were given the right to have USDA's proposed decision "referred to an advisory committee" composed of experts "*selected by the National Academy of Sciences*"—which at the time was the single most visible scientific body associated with public criticism of Rachel Carson and public support for the safety of pesticides.[67] Although the advisory committee's reports were not binding on USDA, the 1964 Amendments seemed to specify with unusual clarity that courts were to affirm USDA's decisions "if supported by substantial evidence when considered on the record as a whole, *including any report or recommendation of an advisory committee*."[68]

On the other hand, for all the evidence of Congress's understanding that process can affect substance (one of McNollGast's central premises), McNollGast predicted that the winning coalition would use process to safeguard—not undermine—the substantive gains made in the statute. This suggests either that process "losses" are traded off against substance "gains," a bargaining strategy that has been suggested by others[69] but is not consistent with the McNollGast model, or that, contrary to the "republican moments" explanation for the 1964 Amendments, it actually is not particularly clear whether the pro-pesticide or anti-pesticide side really won.[70]

C. The 1972 Amendments: Attempts to Shift the Burden of Proof

Events between 1964 and 1972, surprisingly, provide support for both the McNollGast Hypothesis *and* a republican moments theory of legislation. The defining event during this period was a "jolt" to business-as-usual politics caused by rising public concern about the pesticide DDT and by the emergence of

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[65] *See* 78 Stat. 190(3).

[66] *See* Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L. J. 729, 730 n.11 (1979).

[67] *See* Bosso, *supra* note 17.

[68] 78 Stat. 190(4)(d).

[69] *See* Terry M. Moe, *Political Institutions: The Neglected Side of the Story*, J. L. ECON. & ORGAN. 213, 230 (1990) ("public agencies will tend to be structured in part by their enemies—who want them to fail").

[70] *See* Bosso, *supra* note 17, at 125-132 (noting the competing "successes" of pro-pesticide and anti-pesticide forces in the 1964 Amendments).

environmentalism as a national political force. In a series of lawsuits in state courts between 1966 and 1969, the newly formed Environmental Defense Fund effectively put DDT "on trial" before a national audience.[71] As evidence of DDT's risks mounted, there arose numerous state and local prohibitions on DDT use[72] and, in 1969, a federal task force's recommendation for a phased elimination of all but essential uses of DDT over two years.[73] Given the predictable ineffectiveness of FIFRA, and the USDA's pro-pesticide mindset, it is not surprising that FIFRA played almost no role in these events; indeed in early 1969 the General Accounting Office issued a report severely criticizing the lethargic track record USDA had developed under FIFRA.[74] Following that most quintessential of republican moments, Earth Day 1970, President Nixon sought to capitalize on rising voter support for environmental issues by creating EPA and transferring to it all responsibility for administering FIFRA, for pesticide tolerance-setting under FDCA, and for several other pesticide-related research functions that had been scattered across the federal government.[75] In 1971, the D.C. Circuit interpreted FIFRA's cancellation provision to require the initiation of cancellation proceedings against a pesticide when the Agency had expressed "substantial questions concerning [its] safety."[76] The combined effect of all this activity was plainly a shift in pesticide policymaking toward more regulation. And, as the McNollGast model predicts, because the shift worked to the advantage of some of the political principals (for example, President Nixon), it was impossible for others to budge the new equilibrium point through corrective legislation.

But, although the status quo ante could not be completely regained (that is, FIFRA could not be immediately returned to USDA), the 1972 FIFRA Amendments demonstrate a major conceptual limitation of the McNollGast Hypothesis. The limitation stems from the fact that legislators and agencies rarely view statutes as *all* good or *all* bad; some provisions are preferred over others. And, when policy "drifts" during implementation, it usually occurs one provision at a time (typically through a rulemaking). Accordingly, if the agency plays McNollGast's implementation game, it has no guarantees that the

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[71] *See* Bosso, *supra* note 17, at 135-137 (describing litigation and the role it played in forming the Environmental Defense Fund as well as environmentalism generally).

[72] *Id.* at 138 (collecting state and local statutes).

[73] U.S. Dept. of Health, Education & Welfare, Report of the Secretary's Commission on Pesticides and Their Relationships to Environmental Health (the "Mrak" Commission) 5 (1969).

[74] *See* U.S. General Accounting Office, Need to Improve Regulatory Enforcement Procedures Involving Pesticides (Sept. 10, 1968).

[75] *Id.*

[76] *See* Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 595 (D.C. Cir. 1971); *see also* Angus MacIntyre, *A Court Quietly Rewrote the Federal Pesticide Statute: How Prevalent is Judicial Statutory Revision?*, 7 LAW & POL'Y 249 (1985).

disaffected principals will not be able to form retaliatory coalitions to change other provisions which the agency would prefer to leave alone or to withhold from the agency something that it doesn't have but wants. Knowing this, one wonders why the agency will attempt to get away with what it can on any *one* policy; to paraphrase McNollGast, if an agency is risk averse it will prefer certainty in its delegated authority to random retaliation by its principals.[77]

Just such retaliation happened in the politics of FIFRA in the 1972 Amendments. In 1972, environmentalists pressed the political advantages given them by the public's heightened anti-pesticide sentiment by insisting on rescission of the registrant's "right" to refer agency decisions to the NAS advisory committee; after 1972, such referrals became discretionary with the EPA hearing examiner.[78] Next, environmentalists also gained a much-desired "classification" system for registering pesticides either as "general use" or "restricted" pesticides, with restricted-use chemicals allowed to be used only under the supervision of "certified applicators."[79] Finally, the standard for registration became no "unreasonable adverse effects on the environment" rather than a more demanding "substantial environmental effects" test that had been proposed in a competing bill,[80] and, moreover, EPA could now require registrants to support their registrations with specified types of data.[81] All of these provisions can be viewed as collectively relaxing EPA's burden of proof for regulating pesticides and, to give McNollGast credit, they can also be viewed as examples of legislative victors "hardwiring" administrative structures and processes into legislation to ensure that the "right" substantive policy choices will subsequently be made.

The problem, however, is that other provisions in the 1972 Amendments plainly made it *more* difficult for EPA to regulate pesticides. Most significantly, an indemnification provision was added which required EPA to indemnify "any person" who suffers financial losses "by reason of a pesticide's suspension or cancellation"[82]—a provision which hung around the Agency's neck until 1988, forcing it to contemplate depletion of its operating budget any time it began efforts to protect public health. In addition, a new Section 3(c) provided that a pesticide's "lack of essentiality" could not be used as a criterion for denying registration[83]—despite strenuous arguments from EPA that essentiality should be a primary criterion to reduce what was then viewed as a "glut of available products."[84]

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[77]*See* McNollGast, *supra* note 59, at 439.

[78]*See* Pub. L. No. 92-516, Section 6(d), 86 Stat. 973.

[79]*Id.* Section 3(d).

[80]*See* Bosso, *supra* note 17, at 160 (Table 7)(describing competing legislative proposals).

[81]*See* Pub. L. No. 92-516, Section 3(c)(1), 86 Stat. 973.

[82]Pub. L. 92-516, 86 Stat. 973, Section 15(a).

[83]*See* Pub. L. No. 92-516, Section 3(c)(5).

[84]*See* Bosso, *supra* note 17, at 163.

D. EPA Implementation: 1972-1976

Almost immediately after the 1972 Amendments were in place, EPA's Office of General Counsel ("OGC") intensified its efforts to cancel the registrations of several organochlorines including DDT, Aldrin/Dieldrin, Heptachlor/Chlordane, and Mirex.[85] OGC attorneys, however, soon learned how demanding the "unreasonable risk" standard could be; the bellwether proceeding against DDT became mired in the endless evidentiary possibilities for asserting, and challenging, the extent of all the various risks (to wildlife, to farmworkers, to consumers) posed by DDT.[86] To streamline the cancellation proceedings, OGC attorneys streamlined the analysis. Rather than an open-ended inquiry into the universe of risks and benefits, the Agency began to focus its case on animal data showing a pesticide's carcinogenicity, on evidence of widespread human exposure to the pesticide, and on evidence of increasing pest resistance from which the Agency could downplay the pesticide's benefits.[87] Using this formula, EPA prevailed in each of its cancellation proceedings, although even under the streamlined inquiry the adjudicatory proceedings each took over two years to complete.[88]

As EPA successfully began to ban pesticides, however, it only highlighted the immensity of the Agency's regulatory task: the enormous effort required by the handful of cancellation proceedings hardly made a dent in the Agency's statutory duty to reregister the entire inventory of 50,000 existing products, containing hundreds of active ingredients.[89] The 1972 Amendments had required EPA to promulgate implementing regulations within two years and to complete reregistration of all existing pesticides within four years.[90] Although this task belonged to the Agency's scientists in OPP rather than to the OGC attorneys, OPP staff borrowed the streamlined analytical approach pioneered by OGC in the cancellation proceedings and crafted an innovative regulatory device, the "rebuttable presumption against registration" ("RPAR") for use in the Agency's registration and reregistration programs.[91] If a pesticide ingredient was found to

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[85]*See* Angus MacIntyre, Administrative Initiative and Theories of Implementation: Federal Pesticide Policy, 1970-1976, 1985 PUBLIC POL'Y AND THE NATURAL ENVT. 205, 215 (1985).

[86]*See id.* at 215 ("in many respects the first hearing, against DDT, was a disaster for EPA...the proceeding was unfocused and the adversaries could adopt a strategy of evidentiary all-inclusiveness which obscured the central questions").

[87]*See id.* at 216.

[88]*Id.*

[89]*See* Staff Report to the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, The Environmental Protection Agency and the Regulation of Pesticides, 94th Cong., 2d Sess. 11 (1976) (hereafter the "Kennedy Report") (35,000 products had been registered under prior federal laws and 15,000 under various state laws).

[90]Pub. L. No. 92-516, Sec. 4, 86 Stat. 998-99 (1972).

[91]*See* MacIntyre, *supra* note 85, at 217.

be oncogenic in test animals, it automatically triggered a RPAR process under which the burden of proof formally shifted to manufacturers to submit data rebutting the presumption to avoid Agency issuance of notices of intent to cancel.[92] If further data were not required, products were eligible for full reregistration.[93] The RPAR was viewed as a promising regulatory initiative that "proffered a substantial reduction of [the reregistration] caseload by providing a screening device that would rapidly isolate, and focus available evaluation capacity on, the worst chemicals while the safer ones underwent pro forma reregistration."[94]

E. The 1975 FIFRA Amendments: Proceduralism and the Burden of Proof

These EPA initiatives, however, provoked a political backlash that demonstrates both the strengths and fragility of the McNollGast Hypothesis in constructing a positive political theory of environmental legislation. To begin, the 1972 Amendments contained a sunset clause which required reauthorization of FIFRA before October 1975.[95] Concerned that EPA's initiatives reflected too risk averse an attitude toward pesticides, the agrichemical industry complained to Congress that EPA's pesticide programs had been wrenched away from scientists by agency lawyers.[96] FIFRA approached expiration several times, to be extended only for pointedly short periods of time while the House Agriculture Committee held hearings excoriating EPA Administrator Russell Train for acting "unscientifically" and extracting a pledge from Train to "demote" OGC attorneys and elevate OPP scientists as the "primary" office at EPA in charge of pesticide policy.[97] Not content with this concession, Congress amended FIFRA in 1975 to establish a Scientific Advisory Panel ("SAP") which EPA was required to "consult" prior to making cancellation decisions or promulgating regulations affecting registration.[98] In addition, the 1975 Amendments required EPA to notify USDA of proposed cancellations, changes in classification, or proposed regulations (an amendment that would have granted USDA "veto" power over all

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[92]*See* 40 CFR §162.43(f)(1)(i)(A)(3) (1976).

[93]*Id.* 162.43(f)(1)(i)(A)(1).

[94]*See* MacIntyre, *supra* note 85, at 215-216.

[95]*See* Pub. L. No. 92-516, 86 Stat. 973. Although a sunset clause might be rationalized by McNollGast as a warning device designed to prevent policy drift at EPA, its existence is otherwise difficult to square with McNollGast's prediction that legislators try to "hardwire" administrative procedures into statutes so as to make it unnecessary for Congress to rely on its oversight capabilities.

[96]*See* MacIntyre, *supra* note 85, at 219-220.

[97]*Id. See also* House Comm. on Agriculture, Business Meetings on FIFRA Extension, June-November 1975, 94th Cong., 1st Sess. (1975).

[98]*See* Pub. L. No. 94-140, 89 Stat. 751 (1975).

EPA pesticide decisions came within eight votes of passing the House),[99] and required EPA to "take into account the impact of major regulatory action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."[100]

Although these changes are described in the legislative history merely as securing good science[101] and balanced consideration of risks and benefits,[102] one observer of FIFRA has concluded that the 1975 Amendments "gave back to the agriculture lobby a little of the ground it lost when pesticide regulation was removed from the U.S. Department of Agriculture and placed within the newly established EPA."[103] Another commenter has stated, "[t]he 1975 amendments...were the result of agribusiness dissatisfaction with EPA's attempts to take effective, forceful action to protect public health and the environment."[104]

The 1975 Amendments demonstrate both the limits and usefulness of the McNollGast Hypothesis. Although, as McNollGast predict, the new legislative coalition tried to "hardwire" into legislation administrative structures and processes (SAP and USDA consultation) that reflected the coalition's substantive preferences (which had now plainly shifted to the agriculture side of pesticide policy), Congress in 1975 retaliated against EPA by "unwiring" the administrative features of the 1972 Amendments that had made aggressive regulation of pesticides possible in the first place. At least as to pesticide regulation, McNollGast overemphasize the singular importance of administrative structure as a political device and underestimate the more traditional policing function of legislative oversight and correction. On the other hand, consistent with the McNollGast Hypothesis, the 1972 and 1975 amendments together indicate the usefulness of administrative procedures in telegraphing to Congress significant agency action that Congress might choose to police. What seems clear in any case is that, by 1975, the republican-moment aspect of pesticide regulation could not alone provide a political theory of FIFRA. As political scientist Angus MacIntyre concludes, "[a]t the very least, 'the environment' lost its aura of sacrosanct national priority...[as] industries [began] challenging the environmental carte blanche in a manner that was infeasible before the 1972 presidential elections."[105]

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[99]*See* Pub. L. No. 94-140, 89 Stat. 751 (1975) (consultation requirements); 121 Cong. Rec. 9190-91 (daily ed. Sept. 16, 1975) (remarks of Representatives Young and Latta) (USDA "veto power" amendment).

[100]*See* Act of November 28, 1975, Pub. L. No. 94-140, Sec. 1(2), 89 Stat. 751, *amending* 7 USC §136(d) (1988).

[101]*See* FIFRA Extension Hearings, *supra* note 97, at 125, 138, 146.

[102]*Id.* at 125.

[103]See Sheila Jasanoff, The Fifth Branch: Science Advisors as Policymakers 124 (1990).

[104]William E. Reukauf, *Regulation of Agricultural Pesticides*, 62 IOWA L. REV. 909, 918 (1977).

[105]MacIntyre, *supra* note 85, at 218.