EPA

office of
pesticide
programs

STATUS REPORT AND ACTION GUIDE

DRAFT

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NOTE TO THE READER:

The attached document was intended for distribution for December 1976. Late in that month, two developments occurred which may prove to impact on program operations in ways not foreseen when the paper was originally prepared. First, the Senate Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary issued a draft report critical of the depth of data review undertaken by the Agency prior to reregistration. The report now before you has been rewritten since its previous draft to reflect the Agency's commitment to the Senate committee regarding data review. Secondly, a preliminary injunction recently issued by a United States District Court has required the Agency to consider basic modifications to its reregistration data requirements.

The Agency is now reviewing resources, adjusting program plans, and preparing to go before Congress for the FIFRA reauthorization hearings with these new developments in mind. The public will be kept informed throughout the next few months as events unfold through prepared statements, reports, and Federal Register notices.

Since a new Administrator will soon assume leadership of the Agency, this document may be a logical starting point to discussion of the operation of Pesticide Programs in the future. We would, therefore, welcome your comments and suggestions.

Although this is a draft document and the new Administrator has not had an opportunity to review it, the Office of Pesticide Programs intends to begin implementing the policy decisions and changes discussed herein except in those instances where they may conflict with existing formal policy statements or legal constraints.

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A STATUS REPORT AND GUIDE FOR ACTION
DECEMBER 1976

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I. BACKGROUND

A. Purpose. The deadline for full implementation of the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was originally set for October 1976, later extended until October 1977. Since the deadline is approximately one year away, this is an appropriate time to review what has been accomplished and what remains to be done. Significant progress has been made, but frustrating delays have also occurred. There is some confusion about just where we stand in implementing the Act, particularly in the effort to reregister and classify all the pesticides presently marketed in this country.

These have been active and controversial years. Although it may appear that progress has been tortuously slow, much forward movement has been made, despite unforeseen delays due to lengthy public debate on rulemaking, an in-depth Congressional oversight period during which the future of some major program elements were uncertain, and some unexpected discoveries affecting our fundamental assumptions for reregistration purposes.

Pesticide regulation affects many interests: the Congress, the regulated industry, farm groups, professional applicators, other pesticide users, our State and Federal colleagues, environmental groups, consumer groups, academia, and the general public. All these groups are the audience for this paper and we thus include basic background for those less familiar with the Agency's development of pesticide regulatory policy, while also providing specific discussions of problem areas and solutions. This paper is intended to provide a description of our goals, an historical perspective of pesticide regulation, a status report on some of the major areas of difficulty, and our proposed solutions to the problems.

We cannot provide all the answers now. Where we cannot, we can nevertheless propose pathways to decisions. We need your constructive thoughts on these issues. The challenges posed by this transition time between the "old" and "new" FIFRA must be met with patience and careful thought, and above all with a cooperative spirit between the regulators, the regulated, and the many interests affected by EPA's decision making.

This document is not a replacement for the long-range Pesticides Strategy paper. The Strategy, now being developed, will address in detail the Agency's objectives and plans for the entire regulatory program through 1981. This paper addresses immediate concerns and issues. It is a discussion of short-term problems (although some of the solutions may be extended over a period of time) to deal with the major current dilemmas which need prompt attention.

B. Program Objectives. The primary mandate of the Office of Pesticide Programs is to protect human health and the environment from unreasonable adverse effects of pesticide use. Pesticides are deliberately introduced into the environment to achieve a distinct benefit. Decisions on pesticides must thus consider not only the possible adverse effects from pesticide use, but also the potential effects on food production and health of the absence of these pest control tools. It would not serve this nation to restrict the use of pesticides to the point that an adequate supply of food and fiber could not be produced or protected, or that disease vectors or structural pests could not be adequately controlled. Nor would it be a service to permit the continued use of pesticides to the detriment of the health of our citizens. The heart of the regulatory objective, then, is to assess and determine the acceptability of risks as balanced against the benefits.

Social policy in this context requires that the benefits, or social utility, afforded by a pesticide be weighed against its undesirable consequences. The standard guiding all pesticide regulatory decisions is "unreasonable adverse effects on the environment." This is defined by law as "... any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Risk/benefit decision-making is not easy; there are no magic formulas for achieving the absolutely right answer. Neither side of the equation is known with certainty, since each involves some non-quantifiable inputs. The key question is simply, "What is an acceptable level of risk?" That determination is not based on science, economics, or social factors alone; all components and their interrelationships must be considered in the regulatory decision-making process. It is, in short, decision-making which most typically involves extrapolation beyond the strict bounds of scientific measurement: the very subjective area of trans-science.

Thus, in fulfilling our objective to protect the public from unreasonable adverse effects of pesticide use, we turn to three crucial elements: 1) obtaining the most up-to-date, complete, and accurate information available, 2) conducting a thorough assessment of risks and benefits and 3) making decisions in the open, with as much public participation as possible.

C. Historical Perspective. EPA assumed pesticide regulation responsibilities from the Department of Agriculture and the Federal Food and Drug Administration in 1970. All pesticides Federally registered before 1972 were subject to the 1947 FIFRA, an Act passed when the great benefits of pesticide use were first being recognized. It took many years to realize that some of these products, although efficient in pest control, could cause subtle long term adverse effects in man, wildlife, and the environment. In addition, overuse of certain chemicals was creating a resistance in some pests.

Congress responded to the need for a more comprehensive regulatory scheme with the passage of the Federal Environmental Pesticide Control Act to amend FIFRA in 1972. The amendments transformed FIFRA from a labeling Act to a comprehensive regulatory Act, affecting all aspects of pesticide use. EPA assumed responsibility for regulating pesticides from the early experimental stages, through premarket data review, to use in the environment. The Agency was assigned responsibility to monitor for long term effects and to respond to accumulated scientific knowledge. And we were to get underway with two giant tasks: the registration, reregistration, and classification of all pesticides marketed in the country; and the establishment with the States of programs to train and certify applicators who would need to use restricted pesticide products.

Several important factors were at work at the time the 1972 amended FIFRA was passed. They are still of critical importance:

- Rapidly advancing scientific knowledge and public interest which escalates the serious question of long-term effects -- cancer, mutagenesis, birth defects, and nervous system, blood and organ dysfunctions.

- Advancing monitoring technology that increased our ability to detect pesticides first in parts per million, then parts per billion, and now parts per trillion, beyond our ability to estimate significance;

- o The results of monitoring studies using such technology showing that pesticide residues are found in soil, water, air, and can accumulate in wildlife and man;

- o Increasingly complicated legal issues that are slow and costly to resolve;

- o Increasingly complicated economic and political factors that must be considered.

The Congress further amended the FIFRA in 1975 after a lengthy oversight process. The latest amendments are intended to ensure that all agricultural and scientific ramifications of proposed rulemaking or cancellation actions are explored. They require EPA to submit copies of proposed regulations or notices of intent to cancel to the Secretary of USDA and to a Scientific Advisory Panel 60 days before public notification. Final notices and rulemaking are to be submitted 30 days prior to public notification. EPA must also submit to USDA an assessment of the agricultural impact of proposed cancellation actions. The Senate and House Agricultural Committees are also informed in advance of our significant actions.

D. Accomplishments. Despite the complexities, progress has been slow but steady. Regulations began appearing in 1973 and most major rulemaking followed over the subsequent three years:

July 1973: Section 6, Administrative Review (cancellation and suspension procedures);

November 1973: Section 7, Registration of Establishments;

December 1973: Section 18, Emergency Exemptions;

May 1974: Section 19, Disposal and Storage;

May 1974: Farm Worker Protection Standards;

July 1974: Section 14(a), Assessment of Civil Penalties;

September 1974: Section 8, Books and Records;

October 1974: Section 4, Standards for Certification of Applicators;

March 1975: Section 4, State Plans for Certification of Applicators;

March 1975: Subpart D, Section 6, Reconsideration of Previous Cancellation Decisions;

April 1975: Section 5, Experimental Use Permits;

June 1975: Proposed Registration Guidelines;

May 1975: Section 17, Notice to Foreign Governments;

July 1975: Section 3, Registration, Reregistration, and Classification; and

September 1975: Proposed 24(c), Special Local Needs.

In addition, some significant policy statements have been issued under the new Act: two papers on the compensation for data provisions of the Act, Section 3(c)(1)(D) (November 1973 and January 1976); the categorization and call-in scheme for reregistration (February 1976); the procedures for handling problem chemicals through the Office of Special Pesticide Review (December 1975); the procedures for handling new registrations identical or substantially similar to already registered products (May 1976); and five Pesticide Enforcement Policy Statements regarding how the Agency will enforce "use inconsistent with the label" under Section 12(a)(2)(G):

#1, less than label dosage -- May 1975,

#2, unnamed structural pests -- September 1975,

#3, State registered products -- April 1976,

#4, preventive treatments — July 1976, and

#5, unnamed agricultural pests -- September 1976.

#6, use and labeling of service containers -- December 1976.

Twenty-nine Pesticide Regulation (PR) notices have been issued to registrants on a variety of policy issues. In addition, the Agency proposed an EPA-wide policy on addressing chemical carcinogens, including potential pesticide carcinogens, in May of 1976.

During this time, too, we have been processing the applications which come in daily. In the past 4 years, we have issued more than 145,000 supplemental registrations; 16,930 amended registrations, and 11,140 new registrations. More than 500 experimental permits, and more than 110 emergency exemptions have been processed. In addition, great progress has been made by joint effort with USDA Extension Service (ES), EPA Regions, and the States in starting applicator certification. As of this writing, 47 State Plans have been submitted for approval, and more than 225,000 applicators have gone through training programs.

E. Problems. Although we are pleased with these accomplishments, major program decisions must be made to complete the task of implementing FIFRA. Many of our problems are caused by the dynamics of the transition from the old law to the new law. Registrants knew where they stood under the old Act. They know where they will stand when the 1972 FIFRA is implemented. But they are confused and impatient about their status during this important in-between period. Industry, users, and environmentalists alike are equally concerned as we try to sort out an avalanche of complex and new variables.

To explain our policies and problems, this paper will systematically address two of the primary functions of the Office of Pesticide Programs in achieving program objectives: premarket review of pesticide products, and use regulations.

Part II will describe the foundation of the regulatory process and will discuss data requirements, the status of the data, the problems concerning the data, ways to convey requirements to registrants and the public, registration and reregistration procedures, and the problems being experienced during the transition between the old and new Acts. Part III will discuss the use aspects of the regulatory process, specifically applicator certification and training. Part IV will discuss the Office of Pesticide Programs staffing and organization to carry out program functions.

II. PREMARKET REVIEW

A. Background. Before a pesticide can be registered by EPA, the applicant must demonstrate to the Agency that the product will perform as claimed on the label, and that its use will not cause unreasonable adverse effects on man or the environment. A registration application, then, must be supported by data on efficacy, human safety, chemistry, fish and wildlife, and environmental effects.

We are presently engaged in two simultaneous processes under the new statute:

- registering pesticides not previously on the market, and
- reregistering those products already registered under the 1947 Act.

A system to reregister the more than 35,000 products which are already Federally registered was developed in 1973. Products will be grouped into "batches"; all products in a batch will be "called in" for reregistration according to chemical similarities in their active ingredients.

In taking this approach, the Agency is attempting to minimize potential confusion during the reregistration process, and to facilitate the submission of reregistration applications by clarifying what information is or will be expected for the applicant to achieve full registration. The entire onus for submitting a full and complete application with supporting data could have been placed squarely on the industry. The Agency chose the task sharing approach, however, which we believed would be the most equitable and orderly option.

Applications will be called in through the Guidance Package, a document which:

- informs the registrant of the proposed classification of his product (either general or restricted use),
- cites pertinent data already on file,
- provides label information, and
- specifies any additional data requirements to be filled.

When long-term data must be accumulated, presuming there are no data indicating adverse effects in our files, the registrant will receive a conditional registration for the specified period of time necessary to conduct the additional tests.

The primary purposes of reregistration are to:

- classify products,
- update labeling,
- identify and fill data gaps, and
- review data on hand to ensure that the problem pesticides will be identified and subjected to in-depth scrutinv.

The in-depth risk/benefit review procedure is triggered when the risk criteria enumerated in the Section 3 regulations are met or exceeded. The Agency then "presumes" that a reregistration will not be issued. The registrant, users and the public may "rebut" this presumption by submitting information showing that there is no risk, that the hazard can be reduced by special use directions, packaging, or other means, or that the benefits of the pesticide's use outweigh the risks.

This information-gathering and decision-making process, which will be discussed in greater detail later, is known as "rebuttable presumption against registration" (RPAR).

B. Priorities. The Agency has set registration/ reregistration priorities to provide the greatest public protection and best use of limited resources:

1. Classification and reregistration of those product uses most likely to be restricted.

2. Basic registration/cancellation decisions on those products triggering presumptions against registration on the basis of potential adverse health effects.

3. Making the basic registration process more workable by such efforts as improving data cataloging, data validation and regional support to help firms properly make application.

4. Reregistration of products destined for general use.

While we will not meet the statutory deadline of October 1977, devoting top resources to classification of restricted uses, reviewing pesticides which potentially cause unreasonable adverse effects, and smoothing the registration mechanisms, will be responsive to essential goals of the statute. An important point to note is that products will remain on the market regardless of the October 1977 date until action on reregistration is taken.

C. Data Requirements:

1. Background. There are three places where data requirements are articulated:

The Law: The statute requires under Section 3(c)(5) that the Administrator make a finding prior to registration that a product, among other things, will perform its intended function without unreasonable adverse effects on the environment. To make this finding the Act authorizes the Administrator to request test data in support of the application for registration.

The Regulations: To write regulations implementing that standard has been one of the biggest challenges before the Office of Pesticide Programs. Efforts to include the public in the decision making process for devising the registration, reregistration, and classification regulations were unprecedented. In July of 1974, a public meeting was held in Washington in which the first draft of the regulations -- which had previously been mailed to over 200 interested parties -- was openly discussed. That meeting was followed by the formally proposed regulations in October of that year. Because of the tremendous impact these regulations were to have, and the intense public interest, there was an extensive comment period on the proposals. Final regulations were not issued until July 1975, and were effective in August.

The regulations enumerate the basic registration requirements (§162.8) and establish criteria for identifying those products with potential for an "unreasonable adverse effect" (§162.11). The regulations reflect the Agency's concern about the potential chronic effects of pesticides on human health. They include requirements for oncogenic, mutagenic, teratogenic, and reproductive testing where appropriate to adequately assess health effects in addition to environmental chemistry, wildlife, phototoxicity, chemistry, and efficacy data.

The Guidelines: To more clearly define specific data requirements to support registration, Section 3(c)(2) of the Act instructs the Agency to issue Guidelines. The Guidelines will specify, among other things:

.data requirements for registration,
.characteristics of acceptable testing,
.examples of acceptable test methods, and
.the information required in test reports.

Proposed Guidelines were published in the Federal Register on June 25, 1975. The Agency is revising this document after careful review of the large number of comments received.

The Guidelines represent a difficult concept: the regulatory articulation of scientific requirements. In science, practically nothing is absolute. In regulatory affairs, clear-cut answers are required. In science, the search for knowledge never ends. In regulatory affairs, decisions must be made on the basis of the knowledge available. In science, the freedom to experiment and innovate is cherished. In regulatory affairs, a definitive method of measuring and judging must be established.

Competent regulatory decisions must, of course, be made largely on the basis of scientific information. EPA, therefore, must find a way to reconcile these differences. In the final Registration Guidelines, EPA will provide minimum standards for acceptable testing. Thus, with respect to many types of toxicity testing, the Registration Guidelines will not only indicate when the testing is required, but also specify such factors as reliability, preferred species of test animals and routes of administration, numbers of dose levels to be tested, reporting requirements and so on. In practically all instances, these specifications have been derived from, or are consistent with, test protocols already published in the scientific literature.

2. Data Requirements: PROBLEMS

PROBLEM #1: Should the Section 3 regulations be modified?

Discussion. The State-Federal FIFRA Implementation Advisory Committee (SFFIAC) has suggested several changes in the registration/reregistration/classification regulations. SFFIAC's major recommendations are to:

- .better define "use inconsistent with the label,"
- .increase flexibility in efficacy and hazard data requirements,
- .re-establish negligible residue concept,
- .clarify precautionary statement requirements, and
- .increase flexibility of the numerical toxicity indicators used to trigger an in-depth risk/benefit review or classify products.

Agency commitment. Amendments to the Section 3 regulations will be prepared for transmittal to USDA, Congress, and the Scientific Advisory Panel in early 1977 as the Agency deems appropriate.

PROBLEM #2: Will EPA insist that new testing conform -- without exception -- to the minimum standards specified in the Guidelines?

Discussion. Testing that meets the standards in all respects may not always be accepted without question, but testing that does not meet the standards is much more likely to run into problems.

When a prospective registration applicant believes that a particular testing standard is inapplicable or impractical in a particular case, or when the applicant wishes to deviate from the standards in any significant respect, consultation with EPA before testing begins will be strongly advised. Alternatively, the applicant can proceed with testing and take a chance that it may be accepted. In either case, it will be up to the applicant to spell out reasons why non-conforming tests should be accepted. Such reasoning will have to include a persuasive argument showing that the non-conforming testing will not (or did not) significantly reduce the likelihood of discovering any adverse effects that a pesticide may be capable of producing. In short, insofar as new testing is concerned, applicants will have to take the initiative in persuading EPA to accept testing that will not (or did not) meet the minimum standards.

Agency commitment. Taking into account the intricacies of toxicological testing and the diversity of scientific opinion on many aspects of such testing, EPA's position must be that while the minimum standards are designed to facilitate decision-making, testing that does not conform in all respects does not necessarily preclude decision-making. To the extent that EPA's scientists can reach reasoned conclusions from test results (even though the testing fell somewhat short of EPA's standards) without making extrapolations or assumptions that have no foundation in the test results or in other pertinent data, such test results will not be rejected. In such cases, of course, the EPA scientists performing the evaluation will thoroughly document their reasoning so that the public may be fully informed.

PROBLEM #3: How will the Registration Guidelines be applied to data submitted in years past?

Discussion. Thousands of tests performed over the past 25 years will be examined during reregistration. Many of them, however, do not satisfy the specific criteria of new testing standards in many respects. EPA could, of course, reject all such nonconforming tests. The testing standards set forth in the Registration Guidelines, however, are not an absolute prerequisite for decision-making. For instance, the results of a test performed with only 40 animals per dose level, when considered in light of both the remainder of the test protocol and other available information about the pesticide, may very well enable a scientist to reach sound conclusions regarding the pesticide's chronic toxicity.

Agency commitment. In the reregistration process, EPA will necessarily take the initiative in evaluating nonconforming testing. EPA will determine whether tests performed before the issuance of the Registration Guidelines -- if they do not meet the new minimum standards -- can be considered scientifically valid and provide the information needed for decision-making. Again, the EPA scientists who make such judgments will document their reasoning.

The key issue to consider in reviewing non-conforming tests is validity -- can the Agency have confidence in the results? In each case, EPA must assess the information present and determine if 1) the data are reliable and meet or exceed the "unreasonable adverse effects" criteria enumerated in the Section 3 regulations, and thus that an RPAR is triggered, 2) the data are reliable and show a negative effect, thus supporting registration or reregistration, or 3) the test was so poorly conducted that the results are meaningless, and thus that a data gap exists.

PROBLEM #4 How can the Agency successfully convey data requirements?

Discussion. It is not a simple matter to convey a complex set of data requirements to an applicant or any other interested party for the first time. But it is important to do so. It wastes company resources to submit and resubmit incomplete applications for registration. This is most important to the small manufacturer or formulator and to potential minor use registrants. And it wastes Agency resources to deal with procedural matters, when there are so many substantive issues which demand attention.

After the Section 3 regulations were published last year, the Agency sent a team across the nation to explain the new requirements and to assist registrants in understanding and preparing for reregistration. Nine workshops in 10 cities were attended by approximately 2000 registrants. The Agency found that it is very helpful to discuss requirements face to face with registrants, and we should thus not only be able to express data requirements in written form, but also be available for personal explanations. Because of the changes in the registration process since those workshops, further personal guidance should be available to registrants at the local level.

Agency commitment. To convey data requirements, the Agency will:

. issue the Guidelines. The schedule is as follows:

-- Hazard Evaluation and Chemistry Sections: first quarter 1977: through internal EPA review groups; second quarter 1977: to USDA, Congress, and the Scientific Advisory Panel; third quarter 1977: publish in Federal Register. A document with which the EPA staff can work will be complete by the first of March and will be available to registrants and the public and will be used while the Guidelines are under review by the rest of the Agency. Notice of availability will be published in the Federal Register after EPA working group approval, but before interagency review.

. train Regional personnel to assist registrants at the local level. The initial phase of this training program is near completion, and additional programs and instructions will follow.

. invite registrants to use the Regional expertise. PR Notice 76-2 was issued on June 21, 1976, notifying all manufacturers and formulators of the availability of Regional assistance.

D. Data Availability, Validity, and Applicability

1. Background

a) Company data files.

What data do we have, and how good is it? The data required by the Agency is received from individual manufacturers in support of product registrations. Most of the data on hand, therefore, is in data files submitted by companies. When the 1972 Act was passed, none of the data was cataloged. It was in different formats, and reflected the various regulatory standards acceptable at the time of submission. Data files thus go back many years and range widely in terms of quantity, quality, and organization.

Under the old FIFRA, products could be registered in accordance with "accepted patterns of use." In other words, a reviewer could issue a registration based on the fact that a similar product was already registered. An application did not have to be linked to specific data. Now, in accordance with Section 3 of the amended Act, the Agency must be able to identify specific data in support of any registered product. This does not mean that reams of duplicate data must be submitted nor that duplicate testing would be required; it does mean, however, that specific data references must be associated with each registration.

b) Data Validation.

This is an area of particular concern to the Agency. To discuss it properly, we must first establish the historical perspective for data examination for the reregistration process. In 1973, during the planning stages for the new registration/reregistration program, we were operating on the basis of certain important precepts and constraints:

- o first, there would be no significant increase in resources, particularly manpower;
- o there was a Congressional deadline to reregister some 35,000 Federally registered products and register for the first time an estimated 15,000 intrastate products by October 1976, now, of course, by October 1977;
- o the Agency had to maintain a reasonable response capability to continue handling applications for new registration, tolerance, and experimental use permits;
- o the Agency anticipated that data gaps would exist because of new data requirements. However, we made three very important assumptions about the data already on file;
  - -- data results were derived from testing which generally was properly performed and fully reported;
  - -- they were initially reviewed in accordance with scientific standards appropriate for today's decision-making; and
  - -- data problems were generally identified by prior reviewers and followed up in terms of resolving questions or obtaining additional studies as needed.

It was recognized that these assumptions would not hold for every case. However, it was anticipated that in those few instances when imperfect decisions had been drawn, the potential errors would appear when registrations had to be renewed (the law requires renewal every 5 years) and could be addressed then. All in all, we believed that our suppositions were sound, and our resources could be focused on the obvious problem products, label improvements, and the collection of additional data where gaps were discovered.

Our assumptions, as will be discussed in the problem section below, did not prove to be viable. Increased emphasis has been placed on validation during the past year. Data validation will consist of three primary elements in the regulatory context:

1. First, the data must be evaluated on a purely scientific basis to establish the scientific soundness of the conclusions.

2. If these studies are found to be scientifically sound, their applicability to the regulatory decision must be determined, after consideration of other supplementary data and the Guidelines.

3. Finally, validation consists of a statement of the scientific decision on the adequacy of the data to fulfill the standard and a summation of the basis for the decision.

One difficult concept relates to the absence of data as related to the presence of risk. Bad data or missing data, unless falsified to show opposite conclusions, does not equal a potential human or environmental risk. The presence or absence of a certain type of study reduces the certainty of making a proper finding of unreasonable adverse effect but does nevertheless not show a risk to be present. Data validity shows hopefully first, that studies are not fraudulently conceived or reported; second, that they are relevant or not; and, third, identifies where data gaps exist which must be filled in order to reduce the potential for a regulatory misjudgment.

c) Data Accessibility.

Company data files are accessible to the public and the industry to varying degrees. Section 3(c)(2) provides that the Administrator of EPA "shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision." However, the Agency is specifically prohibited in Section 10 from releasing "trade secrets or commercial or financial information" pertaining to registration applications.

Congress in deliberating on the 1972 FIFRA amendments grappled with the issue of whether companies who do not develop their own data should get a "free ride" by relying on data already submitted by another registrant. To equalize the costs of data development, a Section was incorporated into FIFRA which prohibits the Administrator from considering data submitted by one applicant in support of another application unless the originator of the data has given permission or the applicant has offered to pay reasonable compensation for use of the data. That is, of course Section 3(c)(1)(D). In part, this Section became effective with the issuance in the Federal Register of the Interim Policy Statement (IPS) of November 1973. According to the IPS, data first submitted on or after October 21, 1972, were eligible for compensation under 3(c)(1)(D). This policy pertained to all applications for registration submitted after November 19, 1973. However, in 1975 Congress further amended the FIFRA to specify that data submitted on or after January 1, 1970, were eligible for compensation and that the compensation provisions applied to all applications for registration submitted on or after October 21, 1972, and not approved before November 28, 1975, the effective date of the amendment.

The issue is further complicated because various segments of the pesticide industry are disagreeing as to what data are covered by Section 10, Trade Secrets. Data covered by Section 10 cannot be relied upon by the Administrator or released to the public without consent of the owner. In addition, small formulators are concerned about signing an offer to pay statement, or "blank check," which commits them to paying an unspecified sum in the future. Congress is concerned that the data compensation provisions may be encouraging a monopoly within the industry to the detriment of the small businessman. Many of these issues are now being considered in the courts, which will ultimately resolve some of the fundamental problems.

We have issued a second Federal Register notice (January 1976) stating our current policy with regard to data compensation and describing the changes to this Section brought about by the 1975 amendment. This amendment further provided that registration not be delayed pending the determination of reasonable compensation in the courts.

It has been EPA's position that the Agency should proceed with registration if an applicant either has permission to use data submitted by a previous registrant or has signed an offer to pay reasonable compensation for the use of the data, unless the Agency is specifically prohibited from utilizing the supporting data by court order.

2. Data Availability, Validity, and Applicability: PROBLEMS

PROBLEM #1: How and when will the Agency organize the data on file in suppport of registrations?

Discussion. As stated in the background section, company data have never been completely sorted or organized. This creates a problem for the industry in referencing data to support registrations and for the Agency in locating specific files.

Agency Commitment. EPA is now in the progess of cataloging all company data in the files.

The first step was to index the volumes of data currently in our data library. We have now identified 50,000 volumes of company data, i.e., we have an index of the physical description of each volume on hand.

The second major step in the cataloging process will be to identify the tests within each volume (each volume averages 20-22 tests). An OPP contractor is cataloging these tests at a steadily increasing rate. We have twice accelerated the contractor's schedule to obtain maximum speed: for the priority chemicals (those which may be subject to RPAR and the restricted classification), the job will be complete in January of 1977, the entire file to be completed by April 1977.

PROBLEM #2: Are data in EPA files reliable and properly reported?

Discussion. Based on the precepts developed when the new registration, reregistration, and classification regulations were written (see page 14), the Agency began sorting pesticides into three categories in 1974/75: those for which the rebuttable presumption against registration would likely be triggered; those potentially restricted to use by certified applicators; and those for general use candidacy. In looking into past files, the Agency sought what was missing, i.e., what now-required studies had not been completed, rather than what was on hand. Our primary purpose was to identify data gaps which could then be filled during the rerergistration process.

Then in 1976, new information came to light which questioned the assumptions of the registration and reregistration process. In January, it was disclosed in discussion with FDA and GAO officials and during Senate hearings that some toxicological data provided to FDA were of questionable reliability. An independent toxicologist was contracted to look into a sample of pesticide data. Based on his preliminary findings, the Office of Pesticide Programs established its own review force. In April 1976 we developed, in cooperation with FDA, a thorough auditing program to examine laboratory data validity. Serious questions were raised about the adequacy of the testing in EPA files, and the completeness of the Agency's own review and followup.

As a result of these efforts, we now know that it is not enough to determine whether a study is present. Preregistration review must go beyond that to determine what the study showed and whether proper follow-up was taken. Grossly inadequate and misreported previous testing will hopefully not be widespread; however, the problem cases already identified require us to go to the extra effort.

Agency Commitment. To resolve the reliability of data question, several important steps are to be taken:

First -- the Agency is initiating an auditing program in conjunction with FDA to determine if:

1. The testing in audited files was performed in accordance with the test protocol selected by the sponsor (i.e., pesticide company) or testing laboratory.

2. Any errors were made that may have materially affected the test results.

3. Any practices were followed that may have biased the test results or obscured the biological effect of the chemical.

4. Test procedures or results or any relevant data were materially altered during or after testing.

5. Test reports submitted to EPA (or predecessor agencies) fully and accurately reflected all material facts regarding the actual test procedures and results.

Second -- EPA published an advance notice of proposed rules on October 5, 1976, which would require toxicology test reports to include certain information to provide the Agency with a greater degree of confidence that the work has been properly conducted. Public comment has been solicited.

PROBLEM: #3: How deeply should data in EPA files be reviewed prior to reregistration?

Discussion: Just what "review of data" means has recently become a matter of some considerable concern. A Senate subcommittee report has stated that the Agency has misled the public as to the depth of review of data on file prior to reregistration. Obviously, there are several levels of data review -- each with specific implications regarding resources, timeliness, and public impact -- which are possible. The following logical review stages could be applied:

1) identify all the acute, subacute, and chronic toxicity data on hazard to humans, domestic animals, fish and wildlife and all environmental chemistry data currently in our files;

2) review any existing Agency summary and analyses of these data;

3) review summaries of use history, if any, including any accident reports;

4) review the full test report which was submitted by the applicant and validate the data in accordance with present day standards. The test report is the narrative and graphic description of the test method and results;

5) compile and review any articles and monographs readily available in the open literature and any Agency working documents which bear on the effects of the compound;

6) review the raw data and slides which were the bases for the test report which was submitted to the Agency. Raw data includes the laboratory workbooks and any other recorded material;

7) perform an extensive literature search and review any articles which bear on the effects of the compound.

When the Agency planned its original strategy for reregistration in 1973, it was decided that the best utilization of public resources in the alloted time would be to basically divide pesticides into two primary categories: suspected problems and those which the use history and the literature implied were not posing unreasonable adverse effects. Those suspected problem pesticides (those which had greatest potential for causing an unreasonable adverse effect)

would undergo a thorough data validation and risk/benefit review through the RPAR process. The other pesticides would be classified, their labeling upgraded, and data gaps identified and new testing required in accordance with the regulations implementing Section 3 of the amended Act. Our approach, then, was to screen out the "bad actors" to which our resources could be immediately devoted while further testing was being conducted on the other pesticides which could be more thoroughly reviewed after the new test results were received.

However, due to the discoveries made earlier in the year as discussed above regarding data on hand, our original approach was not affording adequate examination of data in our files for non-RPAR products.

A full review, including examination of every piece of paper in each file, data validation including recourse to tissue slides and raw data where needed, literature search and outside consultation on risk data as well as an assessment of economic and social importance of the compound's uses, alternatives, and use history would at best require about two man-years of effort per chemical. A basic de novo review of all the data on hand, then, could take between 10 - 20 years to accomplish at our current resource level, especially considering the scarcity of hazard evaluation scientists. At the other extreme, we could simply look at the first level of review and give primary priority to identifying data gaps. That kind of job could be accomplished in one or two years even with current resources. And in between those two options are various levels of review depth and resource commitments which could affect the thoroughness and timeliness of the task.

The more in-depth the data review prior to reregistration, the greater is the eventual certainty that the public will not be exposed to an unreasonable adverse effect based on all available knowledge. But on the other hand, the longer the Agency spends on reviewing data on hand, the longer it will be until Guidance Packages identifying data gaps and requiring additional testing are issued, and thus the longer it will be until the review of each product takes place. In actuality, there is no alternative but to sacrifice some degree of either certainty or timeliness. The policy question is then: is the public best protected by a thorough in-house review of those data in our files which delays filling data gaps, or is the public interest best served by a screening process which seeks to identify the "bad actors" and -- while these compounds are going through the RPAR process -- increase the data base from which a more complete assessment can be made? Clearly, this question comes down to how the public will be best protected.

Agency Commitment. The Agency will conduct a review on bioeffects and environmental chemistry data through level five as explained above. As far as efficacy data are concerned, we are considering relying on a certification either by the applicant or USDA that the pesticide will perform per label claims, provided that any new use will require efficacy data, and all efficacy data on disinfectants or other products related to public health will be reviewed and validated. General chemistry data will be required with each application.

The general reregistration strategy will remain the same, that is, products will be called in by batches and Guidance Packages will be issued. However, the internal review before the development of the Guidance Package will be substantially amended. The Agency will:

1. look at the files through level 5, and determine whether studies are valid and proper follow-up on reviewers' questions has occurred in the past;

2. develop standard procedure for our own reviewers to use in documenting their findings, so that the basis for the decision is clear;

3. consult with other Agencies in addition to looking to primary literature sources;

4. present all pertinent findings to an internal review panel before the issuance of the Specific Guidance Package to assure scientific, legal, and policy consistency and credibility.

The heart of the new procedures will be a chemical review file (CRF). The CRF will contain a summation of all supporting data, the use history of the pesticide, literature citations, and all other pertinent information. The review panel will examine the CRF for content and completeness, concur in the classification conclusions, the RPAR conclusions, and the action recommendations.

PROBLEM #4: What data are eligible for compensation, and can the Agency register in cases where a compensation dispute is outstanding?

Discussion. While 3(c)(1)(D) now provides clear direction as to what data are compensable, if used by another registrant in support of a subsequent registration, it is not certain what data are available

for use in this way. The trade secret provisions of Section 10 of the Act significantly affect the availability of data. Specifically, test data submitted before January 1970 may be relied on without consent of the owner firm, without an offer to pay compensation, and without regard to Section 10. (This does not mean such data may be released, but rather may be considered internally for purposes of reviewing registration applications). However, the right to rely on test data submitted on or after January 1, 1970, depends upon the applicability of Section 10. If the data are not confidential, the data may be relied upon by other applicants with or without the consent of the owner (although in this case the applicant must offer to pay reasonable compensation). If the data are confidential they may be relied upon only with the consent of the owner so long as the provisions of 3(c)(1)(D) are observed. There is thus a reciprocal relationship between 3(c)(1)(D) and Section 10. It is the Agency's position that data submitted by companies in support of registration (e.g., toxicity data, feeding studies, environmental chemistry data, etc.) may be compensable, and are not trade secrets. It is our view that upon a showing that the information has been maintained in confidence and that its public disclosure would likely cause substantial harm to the data submitter's competitive position, the confidential formula, financial information and data in support of an application not yet approved, should be accorded confidential treatment.

Ten cases involving data compensation/trade secret disputes are currently at issue in the courts. Pending any final decision on these trade secret issues, we have been enjoined from considering any of the data in question in support of other registrants' applications or have entered into stipulations to that effect. This is a significant problem, as it potentially can affect approximately 12,000 products on which no registration or reregistration actions may be taken until the courts make a final ruling. In the meantime the current registrations continue on the market and applications for new registrations cannot rely on that data without the consent of the owner.

An even more crucial trade secret problem concerns use of confidential formulas. The relevance of data in support of an application is generally determined by comparing one registrant's product with another. Product B cannot rely on Product A's data

unless the two products are the same. Some segments of industry claim that EPA cannot compare any application to a previously registered product without considering the formula of the two products in question, and thus all data are protected under Section 10. Litigation is also pending on this issue, which will have a major impact on the whole reregistration process.

Agency Commitment. EPA is taking several steps to help resolve data compensation complexities:

o a Federal Register notice was issued on October 18 relating to the determination of data compensation claims. In that notice, the Administrator authorizes the Chief Administrative Law Judge to hold hearings and issue Initial Decisions as to claims under Section 3(c)(1)(D).

o the proposed Section 3(c)(1)(D) regulations have been written and were transmitted to the USDA and the Agriculture Committees of Congress in November 1976. They were presented to the Scientific Advisory Panel when it convened in early December.

o a solution to the identicality question in some cases is the submission of complete chemical analyses on the two products showing practical identicality, thus demonstrating the relevancy of prior data to the current action without use of trade secret materials. Some applicants have requested that we accept these reports as evidence of identicality. Where such comparative analyses are not adequate to show relevance of prior testing, the problem remains.

o a paper is being prepared for the House Agriculture Committee which addresses the competitive aspects of FIFRA implementation, including the data compensation and trade secret issues. During the next oversight hearings early next year, we will discuss with the Committee the possibility of amending the Act to clearly define what information falls under the trade secret provisions of Section 10, and how the Agency can use this information during the registration and reregistration process.

E. TRANSITION IMPACTS

1. Background. Many of the problems now being faced by the Office of Pesticide Programs are attributable to the dynamics of changing from the 1947 statute to the new Section 3 regulations under the 1972 amendments. It has been obvious from the beginning that a certain amount of confusion and inconvenience would be experienced in this transition period; however, when it was anticipated that the transition would be but a year or two, the associated problems appeared to be tolerable. Now -- because of the data validity question -- the transition period will be considerably lengthened, and it is imperative that additional thought be given to the transition impacts, especially as they affect applications for new registration.

2. Transition Impacts: PROBLEMS

a) Registration

PROBLEM: How will the Agency treat registrations and conditional registrations now that all chemicals are back in Category V for purposes of data validation?

Discussion: It has been the Agency position that data requirements for registration and reregistration should be separate, and that applications for new registrations should for the most part fully comply with all the requirements of the Section 3 regulations prior to registration. On February 17, 1976, the Agency published in the Federal Register a description of the reregistration process, and placed all pesticides in five categories according to data status: I) compounds for which all supporting data were present, II) compounds for which long-term data were missing, III) compounds for which short-term data were missing, IV) compounds in the RPAR category, and V) compounds unreviewed. Data policy was further described in the May 1976 statement on conditional registration which allowed registrations of products identical or substantially similar to those already registered while long term data gaps were being filled so long as the parent compounds were placed in Categories I or II. With the data validity problem, however, all products are back in Category V (unreviewed) and thus the May statement is virtually inoperative.

The Agency must therefore come to grips with the question of processing new applications while the data validation efforts are underway. It is clear that all new chemicals must meet the new Section 3 requirements fully prior to registration. If the Agency were to insist that every data requirement of Section 3 be met

and validated prior to any new registration of old chemicals, however, (given the fact that data validation will take many years), we could virtually bring new registrations of old chemicals to a standstill. (The Administrator's Pesticide Policy Advisory Committee has passed the following resolution: "Old chemicals now registered will be treated alike regardless of whether they are now registered or will be conditionally registered in the future, while data are being gathered; the definition of old chemicals to include existing products with new formulations.") On the other hand, if we permit any registration of any old chemical without data validation, we would not be protecting the public health. Clearly, to best serve the public interest (which demands a balancing of pest control needs with potential adverse effects impacts), we must take a position intermediate to either extreme.

Several important factors must be noted in this regard:

- the Section 3 regulations require some chronic data which take years to accumulate; thus, while the regulations became effective overnight, the ability of registrants to comply with new data requirements did not;

- during a transition period, it is more logical and less economically and socially disruptive to get from point x to point y gradually rather than abrubtly -- the important thing is to get to point y, and to get there without creating havoc along the way;

- the absence of data does not preclude our ability to make an "unreasonable adverse effects" decision -- if, for example, the Agency has 95% of the studies on a certain pesticide but one long term study is missing, that final study will serve to only incrementally add to our knowledge about the product and our confidence that the product will not pose an unreasonable adverse effect. But that one increment may not prevent the Agency from making a Section 3 finding based on all the information which is available;

- any new uses of old chemicals during the transition period must be supported by validated data pertaining to the new use;

- our primary mandate is to protect public health and the environment; however, we should strive to assure that our registration policies do not disrupt pest control producers and particularly users without achieving environmental protection.

Agency Commitment. The Agency will develop a new registration policy which treats like chemicals in a like manner during the transition period. We plan basically to remove the distinction between registration and reregistration as far as data requirements are concerned. Any application involving a change in use pattern will be treated as a new chemical with respect to the new use, i.e., the full complement of data necessary to judge the environmental impact will be required prior to registration.

A policy statement implementing the new approach to registration and its implications for tolerance setting is being prepared, and will appear in the Federal Register in February 1977. A general description of the process is in Attachment II. Additionally, the Agency plans to exercise an open-minded policy with regard to Section 18 requests for use of new chemicals during the transition period in cases where there is an urgent need for pest control and most of the information needed for registration is developed and looks promising.

b) Status of Guidance Packages

PROBLEM: What is happening to the 72 Guidance Packages previously issued by the Agency?

Discussion. After the need to better review data on hand was discovered, a moratorium was declared on registration. At that time, 72 Specific Guidance Packages covering 2,527 pesticide products had been mailed. The following actions have since been taken with regard to these 72 packages:

-- an acute hazard profile has been built for the Chemical Review File. Most of the earlier packages were built from abbreviated chemical worksheets which are now considered inadequate;

-- external reviews have been added to a substantial number of CRF's;

-- a summary of chemical use history is being added;

-- documentation of the original classification decision has been added to each package.

Agency Commitment. The following actions require completion for the CRF covering the 72 Specific Guidance Packages:

-- use pattern summaries;

-- environmental chemistry summary;

- antidote statements which need to be reviewed and improved.

These problems complicate the following broader issues dealing with the Act, and/or Agency policy:

- current strict interpretation of 12(a)(2)(g), which according to many user groups gives rise to unnecessary problems of misuse;

- possible inadequacy of PEPS to meet long-term interpretations and/or specific cases on a broad policy basis;

- transition from old labels to reregistered labels;

- coordination of certified applicator training program with label classification changes.

Agency Commitment. To resolve these issues, we will:

1. Initiate improvement of use directions in the reregistration process as follows:

   A. develop a format for the elements found in use directions and the order in which they should appear.

   B. develop an internal training program to alert EPA reviewers to inconsistencies in labeling so that such problems can be addressed in future Guidance Packages.

2. Ask a special Chemical Specialities Manufacturers Association (CSMA) committee to help us develop a new class of labels for home products. A proposal from CSMA is expected within the next few months. Such labels would bear simplified, less technical use directions and general pest descriptions. The Agency could then consider whether or not home labels may serve as a prototype for similar approaches for agricultural labels.

3. Adopt the transitional scheme included as Attachment III for conversion of old labels to reregistered labels.

-- literature search;

-- completion of the use history summaries;

-- annotations of data bibliographies with abstracts of prior reviews.

Following the completion of the CRF's for the 72 packages these files will be reviewed for:

-- validation of the data

-- RPAR criteria

Recommendations for action will then be prepared and the CRF's will be submitted to the internal review panel.

Depending upon the changes indicated (if any), either a revision letter or a new package will be issued for each of the Guidance Packages.

c) Labeling

PROBLEM: What actions to improve the pesticide label will be taken during reregistration?

Discussion. While existing pesticide labels are undergoing considerable upgrading as a result of regulatory changes during the reregistration process, these improvements are largely confined to the warning and precautionary statements concerned with the safety aspects of the label. The label format has been standardized to make labels more uniform and easier to read.

Because of time and resource constraints, very little has been done to improve the use directions portion of the pesticide label. A number of problems exist with use directions:

- o inconsistency between directions for the same use on different product name labels of identical formulation;
- o lack of a standard format and nomenclature for presenting a given use direction to insure uniformity and inclusion of all the necessary elements such as method of application, site, timing, etc;
- o a high degree of specificity with regard to pests, which in some cases is considered too rigid;
- o extensive technical language which is too sophisticated for certain user audiences;

(d) Use Inconsistent With the Label

PROBLEM: Are all deviations from the label directions illegal?

Discussion: Part of the labeling problem is the issue of "use inconsistent with the label" as incorporated in Section 12(a)(2)(G) of the Act. The Agency has interpreted 12(a)(2)(G) in a "strict" manner, i.e., it is Agency position that any deviation from the label is at least technically a violation of the law. In a series of Pesticide Enforcement Policy Statements (PEPS), the Agency has exercised its prosecutorial discretion by defining those kinds of label deviations against which enforcement action will not be taken.

The PEPS are meant to be an intermediary tool during the transition period between the 1947 Act and the fully implemented 1972 amendments. As the transition period is extended, so is the question of PEPS viability.

Agency Commitment. To help alleviate this problem, registrants will be encouraged rather than discouraged to broaden label directions during registration and reregistration, e.g., the phrase "... and similar corn root pests" and "similar broadleaf weeds in the home lawn." This policy has been used in the herbicide area, and should be expanded to other areas where applicable. The basic difficulty to this approach is the reluctance of some registrants to broaden labels because of potential liability problems.

A more fundamental approach to the problem would be to develop a more flexible interpretation of "use inconsistent with the label." The Report of the House Agriculture Committee issued after the 1975 oversight hearings specified that not all deviations from the label should be considered a misuse, although the Report did not provide any definitive guidance in this regard. During the first half of the year, the Agency will give priority to reviewing the various views on use inconsistent with the label. PEPS were designed primarily with a relabeling completed in 10/76 or 10/77. If the process is to run on longer — we now expect to 1979-80 -- then other longer term alternatives must be considered including a process of before-use definition of what our reviewers have in mind when looking at label directions, and giving advisory guidance to growers before the use as to whether we consider it inconsistent or not.

It is likely that further Congressional direction will be forthcoming this Spring in the absence of a finite solution before that time.

e) Rebuttable Presumption Against Registration (RPAR)

Background

One of the most significant processes of registration/reregistration, which is particularly intensive during the transition period, is the screening of already registered products to determine if they meet the "unreasonable adverse effects" standard of amended FIFRA. Products which meet or exceed the risk criteria enumerated in the Section 3 regulations undergo an intense risk/benefit analysis under the auspices of the Office of Special Pesticides Review. If any of the risk criteria have been triggered, the Agency may "presume" that the product will pose unreasonable adverse effects on man or the environment. The registrant can rebut that presumption by demonstrating that the risk is not present or that the risk, while valid, can be mitigated so as to reduce actual hazard. Failing to establish that the risk is invalid or can be acceptably mitigated, the registrant also has the option of demonstrating that the benefits exceed the risks of the product's use.

A notice of rebuttable presumption is not tantamount to a notice of intent to cancel. It is rather a statement of the reasons why the Agency presumes against registration, and an invitation for the industry, other Government agencies, users, environmental groups, and the public to provide benefit and risk data. The process may last up to 180 days, during which time the pesticide in question may continue to be sold.

Basically, RPAR is a five-step process:

1. Preliminary review of EPA data files and the relevant literature to determine candidates;

2. Validation of the data to establish the trigger of the unreasonable adverse effects criteria;

3. Notification of the registrant and the public of the RPAR, via the Federal Register and solicitation of input;

4. Submission of rebuttal and/or supporting information by the registrant and interested parties regarding risks and and benefits; and

5. Determination as to whether to register or deny registration, or to initiate cancellation. If the decision is to proceed with a notice of intent to cancel, the Agency must submit the proposed notice to USDA and the Scientific Advisory Panel as mandated by the 1975 FIFRA amendments. If the decision is to proceed with reregistration, the public is notified of the decision and the reasons therefore in the Federal Register.

Seven RPAR's have been issued: Kepone, Chloroform, Chlorobenzilate, Endrin, BHC, 1080 and strychnine. Two chemicals (picloram and sperm whale oil) have been cleared and referred to the reregistration process.

RPAR Problem #1: What is an RPAR candidate & what is its status?

Discussion. RPAR candidates are those compounds which "appear" to meet or exceed the "unreasonable adverse effects" criteria enumerated in Section 3 regulations. They remain candidates until we examine the data which we feel may trigger the criteria. If that examination confirms that the data are good and do meet or exceed the criteria, an RPAR is issued. If, on the other hand, we find that the data are not good or do not meet the criteria, the product is returned to the registration process.

Candidates were identified from three primary sources:

1. the Mrak report ("Report of the [HEW's] Secretary's Commission on Pesticides and Their Relationship to Environmental Health", 1969);
2. "Bioassy of Pesticides & Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note" done in 1969 for the National Cancer Institute.
3. Referrals from chemical screening by the Registration and Criteria and Evaulation Division in preparation for reregistration.

Registrants have inquired as to the status of their products which are on the candidate list as far as registration and reregistration purposes are concerned.

Agency Commitment. The following policy applies to candidates on the RPAR list:

-- no RPAR candidate will be reregistered until it receives clearance from the Office of Special Pesticide Review.

-- no new registrations involving an ingredient on the RPAR candidate list will be issued unless the registrant can demonstrate that there would be a positive environmental or health benefit from the new registration.

RPAR PROBLEM # 2: Are too many candidates being identified through the acute triggers?

Discussion. The Section 3 regulations at §162.11(a)(3) set out three acute toxicity criteria which if met or exceeded, trigger the RPAR procedure. However, it has been discovered that the criteria are not serving their intended function as a screening mechanism to select out those pesticides which should be subjected to an intensive review. For example, one-third of the insecticides have triggered at least one of the criteria.

Agency commitment. We are presently preparing a proposed regulation change to modify the acute trigger criteria, which we plan to present to USDA and the Scientific Advisory Panel in early 1977.

RPAR PROBLEM #3: How will benefits data be collected and incorporated into the procedures?

Discussion. One important concern to the user community is that EPA receive proper information regarding benefits of a pesticide during the RPAR process. One of the primary purposes of the RPAR review is, in fact, the consideration of benefits data outside the adjudicatory process.

The Agency has been working with USDA to develop a system which will facilitate the collection of benefits data from the field. USDA recently announced the establishment of a national pesticide assessment program to provide input to pesticide decision making. This effort includes participation by seven USDA agencies, land grant colleges, and agricultural components of state governments

and other concerned organizations. Questionnaires will be sent to participators requesting information on the benefits and risk of RPAR candidates. The flow of information should also be augmented by a data use system, which USDA predicts will be operational by July 1977, and will be accessible through existing computer networks. This system will advise participators of the current registration status of pesticide products.

Agency Commitment. EPA has just completed a formal memorandum of understanding with USDA. The memorandum outlines the specific procedures for:

.exchanging existing benefits information,
.gathering new information where appropriate including that for minor uses,
.introducing this information into the RPAR process.

A copy of the memorandum of understanding is Attachment IV.

RPAR PROBLEM #4: Why is the process behind the original schedule and what does this mean in terms of the October 1977 date?

Discussion. According to the original schedule, 21 compounds were to have been reviewed by October to determine whether or not RPAR's should be issued. Unfortunately, the establishment and staffing of the Office of Special Pesticide Reviews took longer than anticipated. The Agency also found that the validation review was more complex than originally thought and that grouping of compounds on the list by major use patterns, e.g., fumigants, wood treatments, cotton insecticides, would provide for more efficient and logical decision making.

Agency Commitment. EPA has just published a new OSPR schedule. Decisions on whether or not to issue RPAR's on that list will be made by October 1977. A copy of the schedule is Attachment V.

f) Petroleum Distillates

PROBLEM: What will the Agency do in the reregistration of pesticides containing petroleum distillates given potential of risk from PNA's?

Discussion. Petroleum distillates are contained in thousands of pesticide products both as inert and active ingredients. Polynuclear aromatic hydrocarbons (PNA) can be found in petroleum distillates. Since some PNA's are carcinogens, the Agency is concerned about the PNA content in pesticide products, and the associated potential hazard.

On September 21, EPA published a proposed method for detecting PNA's through ultraviolet (UV) absorption. Each applicant for registration and reregistration of any product containing a petroleum distillate would be required to provide the Agency with information regarding the PNA content of the distillate as indicated by the UV absorption method. Registrants would also be required to keep records of the UV absorbance of subsequent batches, which shall be made available to EPA upon request. Public input to the proposed action was solicited in the Register notice.

The Agency is evaluating: (1) the risks which petroleum distillates may pose for man and the environment, (2) the type and amount of exposure to petroleum distillates which the public experiences as a result of pesticide products, and (3) the benefits accruing from use of petroleum distillates in pesticides.

Agency Commitment. Because more than 20,000 products are affected by the petroleum distillate question, it would unduly interfere with the production of food and fiber to deny registrations while the risk is being assessed. Therefore, the Agency is preparing a notice to appear in the Federal Register which in effect rebuts the presumption against registration for cetain products and outlines the data requirements which will be attached to conditional registrations.

The petroleum distillate question is but an example of an environmental problem which includes pesticides only marginally (less than 1% of petroleum distillates manufactured are used in pesticides). In all such cases, the Agency should have an overall policy to resolve the entire problem. This dilemma will be further explored as the Agency implements the new Toxic Substances legislation.

Petroleum distillates are also but an example of the general issue of inerts-contaminants (e.g., HCB, dioxin, nitrosamine) which fundamentally affects the registration/reregistration process. The Agency's general approach in this area will be consistent with the PNA situation, i.e., we will attempt to limit exposure while taking appropriate steps to assess the risk.

g) Minor Uses

PROBLEM: How can the Federal Government assist in the registration of needed products which are too minor to justify industry expense?

Discussion: The availability of pesticides for so-called "minor uses" has long been a topic of concern to growers. In general, a pesticide use is considered minor if its market potential is insufficient to economically justify the development of needed data required for registration by the manufacturer. Apart from data development, industry is also concerned about high liability risk in cases where damage may be great even though pesticide use is small.

Before 1972, FIFRA did not require all uses to be Federally registered and did not include penalties if label directions were not followed. Section 12(a)(2)(G) of the amended Act now makes it unlawful "to use any registered pesticide in a manner inconsistent with its labeling." Under the earlier Act, too, intrastate products were not regulated by the FIFRA, and many minor use needs were registered by States. The problem is, then, that it is now a violation of the law to approve minor uses via many of the former techniques and the industry cannot justify the expense of gathering necessary data to achieve Federal registration. It is also anticipated that registrants will drop some minor uses during the reregistration process rather than meet new data requirements. While Section 24(c) of the Act permits the States to register products for special local needs, which include minor uses, such registrations cannot be granted unless a tolerance for the food crop in question already exists. 24(c) thus is not a complete solution.

A cooperative effort to facilitate Federal registration of minor uses has been underway for several years through the Interregional Research Project group (IR-4) at Rutgers, sponsored by USDA and EPA. Just a few years ago thousands of minor use pesticide products needed to be registered. IR-4 liaisons at the various State Agricultural Experiment Stations analyzed and prioritized these needs, and now the current list for agricultural uses, which constitutes the major part of minor use requirements, includes about 700 requests.

Agency Commitment. As a regulatory agency, EPA does not have lead responsibility in obtaining the data needed to support registration; because of the difficulties in the minor use area, however, we will facilitate the resolution of the problems as best we are able. Toward this end, we will take several steps:

1. The Registration Division of OPP is assigning a special manager to "shepherd" minor uses exclusively and to address industry and user group concerns. The possibility of grower organizations becoming registrants will be explored. Instructional material to guide EPA reviewers will also be made available to industry and other interested parties outlining how minor use registrations will be handled.

2. A full time professional from the Registration Division has been assigned to work in IR-4 for the next year to assist in developing complete submissions to the Agency.

3. The 700 requests referred to above will, with the assistance of EPA Regions and the States, be prioritized by the end of January 1977. The prioritized list will be sent to industry representatives to determine their willingness to cooperate in registering/reregistering the proposed uses. Attempts will then be made to identify adequate

substitutes that will not be encumbered by minor use considerations. These combined efforts will permit USDA, EPA, IR-4 and the industry to focus their efforts in dealing with minor uses that are of priority importance.

4. A similar prioritized list will also be developed in January in cooperation with user groups for non-agricultural applications. Since tolerances are not involved, the difficulties in registering these uses are considerably less, although the liability issue remains.

5. EPA is working with USDA to accelerate the cataloging and release of registration use data. The data on registered uses via microfiche is the current mechanism used to convey this use information to the States and to user groups. The use computer system described on page 28 could assist in collecting efficacy and phytotoxicity data from the States. This combined system could well ease the minor use and 24(c) problem by ensuring that users have easy access to needed data on currently registered uses.

6. EPA will encourage Directors of State Experiment Stations to apply for and employ broad, one-year experimental use permits for uses related to those cited on the EPA, IR-4, USDA priority list.

7. Beginning in January 1977, EPA will begin providing brief quarterly progress reports in the minor use area for Congress and other interested parties.

8. EPA will discuss with the House Agriculture Committee the possibility of creating a liability fund for minor use pesticides and exploring such options as user group/non-EPA Federal Agency registration during the next oversight session in early 1977. This might be a means of relieving industry's concern about liability from expanding current labels.

h) Intrastate Pesticides.

PROBLEM: How will EPA register the products currently being marketed solely within a State without a Federal registration?

Discussion. On September 17, 1975, the Agency published a notice in the Federal Register advising all manufacturers of intrastate pesticides of the impending promulgation of new final regulations for the registration and classification of pesticides. To provide for an orderly transition from State to Federal regulation. The Agency has permitted a manufacturers of valid State registrations to continue marketing intrastate so long as they submitted a notice (within 60 days of the effective date of the Section 3 regulations) of this intent to apply for Federal registration. We would notify such registrants, at a later date, when to submit a full application for registration.

Agency Commitment. EPA will issue a Federal Register notice in April 1977 requesting manufacturers of intrastate products to submit an application for Federal registration.

F. Tolerances

Background. Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that a tolerance (allowable residue level) or tolerance exemption be established for a pesticide that is added to a raw agricultural commodity. A petitioner for such a tolerance must submit to the Agency data on the pesticide's toxicology, residue, and analysis. Toxicological data are also required by the Agency in evaluating whether a pesticide meets the standards for registration as set out in Section 3 of the FIFRA. Hazard evaluation performed to meet the standards of the FFDCA cannot be inconsistent with hazard evaluation performed to meet the standards of FIFRA. Thus, requirements for toxicological tests for pesticides which may result in residues in food or feed, as articulated in the Section 3 regulations and the Registration Guidelines, are equally applicable to registration and tolerance setting activities. Similarly, the data validation program which is aimed at reviewing the validity of data for purposes of reregistration will also pass comment on the validity of data for purposes of tolerance setting. The net result is that the enactment of the '72 FIFRA and the promulgation of Section 3 regulations have blurred the sharp distinctions between regulation and tolerance matters. FIFRA and FFDCA are intrinsically related and the Agency must act accordingly.

Although it would be most desirable to review tolerances for a chemical at the same time that its Chemical Review File is being prepared, two factors argue against doing so: lack of resources to perform both reviews simultaneously and the existence of uncertainties surrounding the tolerance question. Rather than beginning a tolerance review without full resolution of these uncertainties, it would be better to delay the review until a comprehensive set of procedures and policies is developed. Thus, we propose first to study the current procedures and if necessary to amend them; and also develop policies on how to handle interim tolerances, zero tolerances, temporary tolerances, and existing uses which result in residues on food or feed but for which no tolerances exist.

Agency Commitment. EPA intends to:

1. Complete a detailed description of present tolerance setting procedures by January 1977.

2. Perform a comprehensive evaluation of the principles underlying tolerance setting. The Environmental Health Advisory Committee of EPA's Science Advisory Board will be asked to undertake this task.

3. Issue new procedural tolerance regulations -- taking into account the Advisory Committee's findings -- by January 1978.

4. Systematically review tolerances chemical-by-chemical after January 1978 independent of the reregistration process.

As part of the reregistration process, however, some steps can be taken to improve the tolerance situation:

1. Labels will be reviewed to identify those uses which can be expected to result in food or feed residues and for which no tolerances exist. We will impose animal feeding or other restrictions on the label where corrective action is found to be appropriate.

2. Toxicology data will be reviewed in-depth as part of the data validation program for reregistration. If long-term data gaps are discovered and if the pesticide does not exceed any RPAR criteria, the pesticide will be conditionally registered for the length of time necessary to perform and report additional testing. During this period, the pesticide tolerances will remain in effect. They will be reviewed again after the missing data are submitted to the Agency.

III. USE REGULATION

A. Background

Congress, in passing the 1972 Act, recognized that pesticide use presented both benefits and risks to human health and the environment. One of the major additions to pesticide legislation was the strengthening of regulatory controls over the uses and users of pesticides.

The new Act accepts the premise that most pesticides, if correctly registered and properly labeled, can be used by the general public with the assurance that human health and the environment would be adequately protected. These are general use pesticides.

The Congress also recognized that there would be certain pesticides and certain uses of pesticides which, because of their potential hazard, should not be used by an applicator who does not have the needed level of skill or awareness. They determined, therefore, that such a use would be classified as a restricted use pesticide. Under the Act, a person applying restricted use pesticides would need to become a certified applicator or would have to use restricted use pesticides under the supervision of a certified applicator, or be subject to any other restriction deemed appropriate by the Administrator.

The Act provides that EPA shall establish standards for certification, and that States shall conduct certification programs. EPA published standards in October 1974 that must be met by private applicators (farmers) and 10 categories of commercial applicators: (1) agricultural pest control; (2) forest pest control; (3) ornamental and turf pest control; (4) seed treatment; (5) aquatic pest control; (6) right-of-way pest control; (7) industrial, institutional, structural and health-related pest control; (8) public health pest control; (9) regulatory pest control; and (10) demonstration and research pest control.

EPA published guidelines for use in developing State Certification Plans in March 1975. After considerable controversy over methods for certifying farmers, an amendment to the FIFRA was passed in 1975 authorizing training as an acceptable certification method. The program is now generally well received and commendable progress is being made.

A major advantage of certification is that it eliminates the "all or nothing" approach to registration and cancellation decisions. Rather than removing a pesticide from the market, or denying its access to the market, the Administrator can restrict the uses of the pesticide and be assured that the product will be used only by skilled applicators. This in turn provides the degree of human health and environmental safety needed to authorize the use of the pesticide.

B. Classification

The key to implementation of the State Certification Plans is the classification of pesticide uses. In the future, all new products will be classified restricted or general during the registration process. The reregistration and classification of the more than 33,000 pesticide products currently registered and on the market is underway.

Classification involves:

.establishing criteria for identification of restricted uses;
.evaluating the toxicity and the exposure from use patterns against these criteria;
.considering the use history in terms of reports of adverse effects involving the product;
.making an initial EPA determination;
.allowing registrants to consider this determination;
.discussing any disagreements; and
.making a final EPA determination.

This process will continually change the number of restricted uses. Uses will be added and removed as the registration and reregistration process moves forward.

Several issues discussed earlier have caused serious delays in registration. Consequently, classification, which is integral to the reregistration/registration process, is about to get underway.

C. Certification

As indicated above, the amended FIFRA, Section 4, calls for a cooperative Federal/State program to provide for the certification of applicators of restricted use pesticides. Through concerted technical and funding assistance from EPA to all States over the past 2 years, major progress has been made toward the goal of fully operational State plans nationwide by the October 21, 1977, deadline established by Congress. To date, 47 States have formally submitted plans to EPA for approval. Nine more States are expected to submit plans during the next several months. Applicator training programs have been established in all States and have achieved a generally high level of acceptance among private and commercial applicators alike.

Over the past two years, and in cooperation with the States and the USDA Extension Service, EPA has developed and published a host of training materials which can be used by the State Cooperative Extension Services which have the major responsibility for training applicators. The basic concept of this cooperative approach is that EPA would sponsor the development of training materials which would be an extension of our standards for certified applicators. These materials would, therefore, of necessity be minimal in terms of all the complex material that might be made available for presentation. The States would then add their more specific requirements to this "core" material. This concept has worked well and has led to reasonable and well developed training programs in almost all States.

It should be pointed out that training is not mandatory under the Act. All States, however, have recognized the value of training, education, and voluntary compliance, and have made training a major component of their certification program.

D. Use Regulation: PROBLEMS

PROBLEM # 1: How can the States certify applicators in the absence of a definitive list of restricted uses?

Discussion. Training and certification of applicators are intended to be directed at the proper and safe use of pesticides classified for restricted use. It can be assumed that for-hire commercial applicators will need to use one or more restricted use pesticides in the course of their normal operations. The same assumption cannot be made with respect to the so-called "non-commercial" and private applicators. The result is that for-hire applicators are participating in training and certification programs, while many non-commercial and private applicators are not, deferring participation until pesticides are classified and a determination can be made as to the necessity of becoming certified. EPA long ago recognized this likelihood, and in 1975 prepared and distributed a list of active ingredients which presumably would have one or more restricted uses. EPA intended that the list would provide information, pending actual product classification, sufficient to enable States to develop and implement programs which would reach maximum numbers of potential users of restricted use pesticides prior to October 21, 1977. However, there is still uncertainty among States and applicators as to the final result of classification, leaving training and certification programs in many States short of the necessary momentum.

Agency Commitment. In conjunction with States, industry, and user groups, EPA has for the past month been developing a more comprehensive listing of active ingredients likely to have one or more restricted uses. The list was completed and distributed in early December. It should provide greater certainty of classification and thereby increase the impetus of State training and certification programs.

It is important to note that a good "rule of thumb" to apply is that an applicator using pesticides with "danger"and skull and crossbones on the current label, labeled for use in aquatic environment or in forests, or registered as fumigants, should plan to be certified since these types of uses are most likely to be restricted.

EPA recognizes the difficulty in frequent changes in the number of uses that are restricted. Such changes create problems for the Extension Service training the applicators, for the State Lead Agency administering the program, and for the farmer who may or may not require certification, depending on which uses are restricted. To compensate for these difficulties, we have taken three steps: 1) ensured that certification of farmers is an uncomplicated administrative process with many options available to the States; 2) authorized an emergency program to allow an uncertified farmer to purchase a restricted use pesticide under circumstances beyond his control, and; 3) established a phasing concept in terms of label changes to reflect the restricted use determinations, and in terms of the date by which the purchaser must either be certified or be the agent of a certified applicator. It is the Agency's intent not to require a label change in the middle of a growing season which could disrupt or inconvenience applicators.

PROBLEM #2: What is the relevance of the October 21, 1977, date to those States whose plans have been approved on a contingency basis?

Discussion. Of the forty-six plans formally submitted to date, all but five have been or will be approved contingent upon passage of legislation and/or promulgation of regulations. Most of the remaining eight States will receive approval of their plans also on a contingency basis. In order to have a fully approved and therefore fully operational plan, a State must satisfy all contingencies; that is, it must enact any necessary legislation and promulgate all necessary regulations. Failure of any State to accomplish these actions by October 21, 1977, will leave such a State deficient in requisite legal authorities, thereby preventing EPA from granting full approval to that State's plan. The effect of this situation, in terms of law, may be the termination of that State's authority to carry out Section 4 of amended FIFRA.

Agency Commitment. EPA will continue to review and provide comments on all proposed legislation and regulations, testify at legislative and public hearings when requested by a State, and take other appropriate actions to ensure that all States have received information and assistance necessary to achieve full approval status.

PROBLEM #3: What will happen in a State without an approved plan by October 1977?

Discussion. Despite the best efforts of this Agency and the States, circumstances may arise in one or more States to prevent compliance with all requirements necessary for full plan approval by the October 21, 1977, implementation deadline for certification. It is EPA's legal opinion that in such a situation EPA has two available options: (1) to defer enforcement against use of restricted use pesticides by uncertified applicators in States without fully approved plans until such time as those States satisfy the requirements of, and are granted full plan approval; or (2) to make certification available through some other mechanism or combination of mechanisms such as:

-- developing a Federal certification program
-- relying on the certification apparatus of a neighboring State.

Agency Commitment. EPA is fully cognizant of the ramifications of these options. Decisions are being made, and policies developed, to structure programs necessary to take action under both. Circumstances will dictate whether one or both options will be exercised, but regardless of the course taken, the actions will be based not only in law, but also in equity. Restricted use pesticides will not be denied to those needing and qualified to use them.

PROBLEM #4: How will Federal employees be certified?

Discussion. In the State Plan Regulations published March 12, 1975, provision was made for the Government Agency Plan (GAP), through which Federal employees could become qualified for certification. The act of certifying Federal employees would be carried out by the individual States. The failure of GAP to generate much interest among Federal agencies, and recent Supreme Court decisions rendering tenuous the concepts underlying GAP, have caused EPA to consider other approaches. The most viable approach is to treat Federal agencies as States for purposes of certification. A Federal agency would thus certify its employees under a plan developed in accordance with the State Plan regulations and approved by EPA. Federal agencies not desiring to develop a plan would have the option to voluntarily submit to State jurisdiction for certification.

Agency Commitment. EPA will prepare amendments to the State Plan regulations to provide for Federal agency certification, and will work with agencies wishing to follow this course in the development of necessary programs and plans. These efforts are underway.

PROBLEM #5: How will applicators on Federal Indian reservations be certified?

Discussion. State jurisdiction on Federal Indian reservations varies widely. The State Plan Regulations take note of this fact and make provision for Indian governing bodies to develop their own certification plans or to enter into cooperative agreements with States for the purposes of carrying out certification under those States' plans. To date few Indian governing bodies have exercised either option or made their desires known. At the same time, little effort has been made by States or the Federal government to inform Indian governing bodies of the requirements of Section 4 and the available courses of action.

Agency Commitment. EPA will increase its efforts in working with the Bureau of Indian Affairs to contact Indian governing bodies and to ensure the development of appropriate certication programs on all Federal Indian reservations.

PROBLEM #6: How will EPA ensure that State certification and training programs are being carried out in accordance with approved plans, and that the purposes of FIFRA are being achieved?

Discussion. The submission and approval of State plans is only the first step in implementing Section 4. The heart of implementation lies in the conduct and quality of State certification and related training programs. To ensure attainment of the goals of certification, a system must be established not only to measure State adherence to the provision of approved plans, but also to evaluate the qualitative effectiveness of certification and training.

Agency Commitment. A guidance document is being developed to provide the basic structure for Regional Office evaluation of State certification and training programs. The evaluation will begin this winter. In addition, a Request for Proposal (RFP) will be issued for a major contract to provide base line data on quality of current pesticide use, and to evaluate the overall impact of certification and training. This second element of the contract will involve not only an evaluation of the relative improvement in the quality of pesticide use, but also an effort to determine the adequacy of various EPA and State certification requirements in achieving the purposes of FIFRA.

PROBLEM #7: Can States be expected to assume the full cost burden of certification and training programs?

Discussion. Prior to the passage of amended FIFRA in 1972, few States had in place or intended to establish comprehensive pesticide use control programs. It can be fairly said that many, if not a majority, of the States would not now be constructing such programs in the absence of the FIFRA requirement that they do so. The reasons are both political and economic. The Federal Government proceeded to urge States to participate on a cost sharing basis for start up costs, presuming that the States would then continue the program on a maintenance basis solely with State funds. The exact point of the termination of Federal assistance is difficult to determine precisely, but it appears that continued assistance at a reduced level is appropriate for FY '78 and perhaps FY '79.

Agency Commitment. EPA has received an appropriation of $4.6 million in FY '77 for certification and training assistance, and will request additional funds in FY '78 and consult with the States on FY '79. The amount of funds to be requested for the latter two fiscal years will be determined on the basis of joint EPA/States assessment of need.

IV. ORGANIZATION

It is clear from the preceding sections that there are two vital but nonetheless separate processes in pesticide regulation: the scientific evaluation and the regulatory decision. Scientific expertise is necessary to validate and interpret data; regulatory judgment is necessary to apply the scientific evaluation to risk/benefit decision making in which social and economic as well as scientific factors must be weighed to reach final conclusions. The scientist must be free to make scientific judgments and the regulator must be able to apply the findings of scientific reviews to the requirements of the law and regulations in drawing conclusions.

The most important tasks within OPP all require scientific support. The reregistration process must look to scientists for data validation and assessment of data gaps. The registration and tolerance setting process for new applications and petitions depends upon scientific evaluation of supporting data. The RPAR process looks first for the scientific validation of the information triggering the Section 3 162.11 criteria. In other words, there are three major program elements responsible for regulatory decisions which rely on scientific data validation and evaluation efforts:

1) registration/tolerances
2) reregistration;
3) OSPR

Presently, primary scientific support is divided up among the Criteria and Evaluation Division, the Registration Division, and the Technical Services Division. Because of the priority need for data validation and review which cuts across Division lines, it is only logical to reassemble the bulk of scientific personnel in a new Division which will be responsible for review of supporting and hazard data. During the recent past, OPP has not had adequate staff in certain critical skill pools to accomplish all of its objectives in a timely fashion, a condition that has been worsened by the fact that the program's human hazard and environmental effects analytical talent is scattered across three Divisions.

For these reasons, OPP management has decided to seriously pursue an organizational regrouping of some critical functions and activities. Principally involved are those scientists with the responsibility for hazard evaluation and hazard data validation, and those scientists involved in the aggregation of use data and the preparation of the benefits cases under RPAR. However, to complete that effort most responsibly, OPP must also look at the other segments of the organization as well and take this particular opportunity to make some necessary changes in location of some additional functions which are supportive of hazard assessment and benefits case preparation.

Accordingly, OPP has taken a first cut at some major changes which appear not only desirable, but essential. Stated somewhat simply, these changes would go generally as follows: The science directorate in the Registration Division, (RD) with one exception, along with the Metabolic Effects, and the Chemistry Branch, and a portion of the Ecological Effects Branch in the Criteria and Evaluation Division would be consolidated in a newly created Hazard Evaluation Division (HED). A portion of the staff in RD's Efficacy and Ecological Effects Branch would also be moved to HED. The Registration Division would retain its Pesticides Registration Office structure largely as is including the Special Registration directorate.

The pesticides use data expertise in the Technical Services Division (TSD) would be combined with similar expertise and functions now existing in the Plant Studies and Ecological Effects Branch in C&E into a use data/efficacy - RPAR benefits program within TSD. Just how that program would be actually organized is still very much an open question. The Economics Analysis Branch would be relocated to TSD, and would retain its Branch status.

The Technical Services Division would retain the Health Effects and Ecological Monitoring programs to which would be added the Pesticides Episodes Reporting System now located in the Operations Division. The laboratories now in TSD would remain in that Division with the addition of the laboratories and analytical reference program now run in the Registration Division. The System Support Branch and portions of the Information Branch would be transferred to a newly created Management Operations Division. That portion of the Information Branch which would remain in TSD are those functions with lead responsibility for use data collection and analysis vis a vis RPAR benefits cases.

The newly created Management Operations Division would have not only the responsibilities just mentioned but also those functions presently vested in the Office of Program Planning, Evaluation and Administration.

The Office of Special Pesticides Review would be given Division Status, but would remain essentially unchanged. The Operations Division would, except for the loss of the Pesticides Episode Reporting Program to TSD, remain as it is now.

Separating the scientific from the regulatory functions in each area will optimize the use of both scientific and management skills. A proposed reorganization chart is Attachment VI; OPP has asked for its employee's thoughts on this proposal, and management in pursuing it with Agency and Civil Service personnel experts.

LIST OF ATTACHMENTS

ATTACHMENT I

SUMMARY OF PROBLEMS AND COMMITMENTS

	PROBLEM	COMMITMENT	DISCUSSION PAGE #
I.	**PREMARKET REVIEW**		
A.	Section 3 Modification proposed by SSFIAC	Agency will make decision as to what proposed changes are deemed appropriate early '77	10
B.	Tests which do not meet minimum standards of guidelines	Agency will encourage applicants to consult before deviating from Guidelines. Agency scientists will judge on case-by-case basis and document decisions	10
C.	Applicability of Guidelines to past data	Scientific assessment on case-by-case basis	11
D.	Making data requirements widely understood	. Issue Guidelines . Regional assistance to registrants (PR Notice 26-2)	13
E.	Organizing data for reference	Catalogue data. Priority chemicals by February 1977, entire file by April 1977	17
F.	Data validity -- reliability	. Auditing program . Proposed rules published 10/5/76	17
	-- review depth	. Chemical Review File . Level 5 Review	19
G.	Data compensation disputes	. 10/18/76 FR Notice assigning ALJ authority to begin hearing disputes. . Proposed 3(c)(1)(D) regulations transmitted to Congress & USDA 11/76. . Assessing proposal to establish identicality by sampling from the marketplace. . Ask Congress to consider clarifying trade secret provision of Act	23
H.	Transition impacts on registration, reregistration, and tolerances	. FR notice by February '77 stating new policy	24

I. PREMARKET REVIEW	PROBLEM	COMMITMENT	DISCUSSION PAGE #
I.	Status of previously issued Guidance Packages	. Agency will complete use pattern summaries, data summaries, literature search, use history summaries, data validation.	26
J.	Labeling	. format label . internal training . development of new home use labels	27
K.	Use inconsistent with the label	. Broaden label directions where appropriate . reconsider "strict" interpretation of 12(a)(2)(G)	29
L.	Status of RPAR candidates	. No reregistrations until fully processed in OSPR . No new registrations containing candidate compound unless clear health or environmental advantage	31
M.	Benefits data input into RPAR process	. Memorandum of understanding with USDA signed 12/76	32
N.	RPAR behind schedule	. New schedule 12/76 . Decisions on whether to issue RPAR's by 10/77	33
O.	Petroleum distillates	. Method for detecting PNA's outlined in 9/21/76 FR Notice . New FR Notice explaining policy by February 1977	33
P.	Minor Uses	. Special contact for minor uses in Registration Division . Full time professional from Registration Division to IR-4 for 1 year . Prioritize needs of agricultural uses	34

PROBLEM	COMMITMENT	DISCUSSION PAGE #
I. PREMARKET REVIEW		
P. Minor uses (con't)	. Encourage Experiment Stations to apply for broad, one-year experimental use permits . Issue quarterly reports beginning 1/77 on minor use situation . Discuss with Congress the possibility of creating a liability fund	34
Q. Intrastate pesticides	. Will issue FR notice calling for applications for Federal registration 4/77	36
R. Tolerances	. New procedural regulations by 1/78	37
II. USE AND CERTIFICATION		
1. Restricted Use List	. New list issued 12/77	41
B. States which have contingency Plans as of 10/77	. Commit resources to help States achieve fully approval plans by 10/77	42
C. States which have no plans as of 10/77	. Defer enforcement or . Establish Federal plan	43
D. Federal applicators needing certification	. Treat Federal agencies like States and develop plans	43
E. Indian reservations	. Increase efforts to work with Bureau of Indian Affairs	44
F. Quality assurance	. Regional training . Contract study	44
G. Costs	. Assess needs with States	45

12/10/76

DRAFT

Summary of New Approach

to Registration/Reregistation

1. Data requirements for new registrations and reregistrations will be identical. Since the same finding of absence of unreasonable adverse effect must be made in each case, there really is no basis for distinguishing between the two.

2. Pesticides considered for reregistration will require, at time of application, general chemistry data and acute and subacute toxicity data for mammals, fish, and birds. If other required data are not available at time of application, the pesticide may be conditionally reregistered for the length of time necessary to perform the requisite testing if there is no indication that the product may otherwise pose an unreasonable adverse effect.

3. Old Chemical; Old use pattern: New registrations of products identical to currently registered products will be treated in a similar manner. The short term data described in 2 above will be required at time of application. All other required data must be cited by the applicant accompanied by a signed offer to pay statement. However, if any data other than that described in 2 above are not available for citation -- i.e., the tests have not been performed -- then the applicant will be granted a conditional registration allowing him the time necessary to perform the required tests.

4. Old Chemical; New use: New registrations of products which are not identical to currently registered products but which contain currently marketed active ingredients will be treated as follows. If the new pesticide is similar to a currently registered one -- i.e.,

adds a new pest to the label or involves a relatively minor change in formulation -- then in addition to the short term data described in 2 above, data to support the efficacy of the new formulation against the new pest will be required at time of application.

If the new pesticide includes a new food or feed crop on its label, the registration will be granted if the Agency determines that the available data can support the safety of the additional use, and there is enough data to support a tolerance under the FFDCA. Such factors as the percentage of the diet contributed to by the new crop, the percentage of the Allowable Daily Intake already taken up by other food uses of the chemical, and the results of recent Market Basket Surveys will be taken into consideration in making this determination.

Finally, if the new product involves a changed use pattern, its registration will be approved if data are available to evaluate the safety of any additional human or environmental exposure caused by the changed use.

In all cases, if data other than that necessary to make the above determinations are not available at time of application, the applicant will be given a conditional registration for a length of time necessary to perform the missing tests.

5. New Chemicals: Pesticide products with new ingredients or which otherwise do not fall into any of the above categories will require the full range of data at time of application -- no conditional

registrations will be approved.

6. Amendments will be treated according to the principles of 4 above for new registrations. That is, amendments including formulation changes of a minor nature, or additions of new pests or minor uses will be approved conditionally if short-term data and additional safety and efficacy data to support the amendment are available at time of application.

If the amendment involves a major crop or changed use pattern, a scientific and regulatory judgment will be made as to whether the additional risks incurred by the amendment are offset by the benefits for the period of time necessary for the applicant to fill data gaps.

CONVERSION SCHEDULE FROM NON-CLASSIFIED TO CLASSIFIED LABELS

ATTACHMENT III

Classification Decision Sent to Registrant	RD Label Approval to Registrant	Label in Effect for all Production	Label in Effect for all Channels of Trade
Reregistration	(60 days for submission 30 days for approval)		
RESTRICTED USES called in prior to May 21, 1977	3 mo. after call-in	October 21, 1977	December 21, 1977
May 21, 1977 - July 31, 1977 (assume all restricted called-in by 7/21/77)	no later than Oct 21, 1977	December 21, 1977	February 21, 1978
GENERAL USES called in after Jan. 21, 1977	3 mo. after call-in	6 months after receipt	Not Applicable
called in prior to Jan. 21, 1977	3 mo. after call-in, no later than April 21, 1977	October 21, 1977	Not Applicable
New Registrations before October 21, 1977	Upon completion of review	October 21, 1977	October 21, 1977
After October 21, 1977	Upon completion of review	Effective Immediately	Effectively Immediately
Case-by-case extensions may be granted upon submission of written justification to RD (cans, labels molded into plastics, etc.)			

ATTACHMENT IV

MEMORANDUM OF UNDERSTANDING
between
THE U.S. DEPARTMENT OF AGRICULTURE
and
THE U.S. ENVIRONMENTAL PROTECTION AGENCY

I. Purpose

The purpose of this Memorandum of Understanding is to formalize the working relationship between the United States Department of Agriculture (USDA) and the U. S. Environmental Protection Agency (EPA) that provides for improving the capability of both Agencies to conduct pesticide benefit/risk assessments. The Memorandum of Understanding identifies, consistent with existing statutory authority, the principles and policies of cooperation between the two Agencies and describes the general management and operational approaches that will govern the planning, approval, underwriting and conduct of the cooperative effort to accomplish mutually agreed upon objectives. This Memorandum is within the context of the overall Memorandum of Understanding as signed by the Secretary of Agriculture and the Administrator of EPA, July 31, 1974.

II. Background

The USDA is the prime Federal Agency with responsibility for assuring an adequate supply and efficient production of food, fiber, forest and other agriculturally-related products and improving the welfare of rural people. EPA has lead Federal responsibility in regulatory actions to protect the environment. The 1972 amendments to the Federal

Insecticide, Fungicide and Rodenticide Act provided EPA with the responsibility for regulating the use of pesticides. Additionally, the legislative amendments to the Act in 1975 (PL 94-140) provide that EPA must notify the Secretary of Agriculture 60 days prior to publication in the Federal Register of intent to cancel a pesticide product, except in cases where the Administrator of EPA determines that there is an imminent hazard to human health wherein notification is waived. USDA has 30 days to respond. This response is to be published jointly with the EPA notice.

With those pesticides that are presumed to present an unreasonable adverse effect on the environment, an accurate benefit/risk assessment is required to determine whether or not the pesticides should be registered. Such assessments are multi-disciplinary, involving input from biological, physical and social sciences. In this Memorandum, both Agencies recognize the importance of benefit/risk assessment, and the desirability of a viable cooperative working relationship to carry out designated responsibilities.

III. Policy

It is the policy of the two agencies that they work together to develop objective and accurate data and related information required for benefit/risk assessments of pesticide uses and use patterns subject to a presumption to refuse to register or to reregister. It is agreed that this will be done in a manner which recognizes and utilizes the capabilities of each agency to the greatest feasible extent in either making resources available to the other agency or for the joint

planning and execution of activities. Consistent with its broad agricultural responsibilities, USDA and States/universities are recognized as major sources of information on pesticide uses, relative effectiveness of pesticides and the importance of specific pesticide uses for agricultural and forestry purposes. When USDA notifies EPA that it is not able to supply the necessary information for uses such as industrial, home and garden, and agricultural, EPA may work with any available data source. EPA is recognized as a basic source of information on pesticide registration and environmental and health hazards associated with pesticide use. Both agencies have important contributions to provide on environmental aspects of pesticide use.

IV Organization and Policy Management

USDA will establish an appropriate mechanism to plan, manage, and conduct activities. This mechanism involves a Steering Committee composed of Associate or Deputy Administrators of key Departmental agencies and State/University representatives. This Committee will be chaired by the Coordinator of Environmental Quality Activities, Office of the Secretary.

The Steering Committee will draw upon the technical expertise of key agencies through a Technical Advisory Group. The Technical Advisory Group will be chaired by the USDA Pesticide Coordinator. The Steering Committee will establish Assessment Teams for pesticides or groups of pesticides requiring detailed assessments. The Assessment Teams will develop a plan of work. The individual agencies, through membership on the Steering Committee, will concur in plans of work and mutually approve the commitments required to implement the plans of work.

EPA will interface with the USDA Steering Committee in addressing policy issues, delineating specific joint activities, and to assure that both agencies are fully aware of ongoing efforts in the respective agencies. Additionally, EPA will identify a contact person to interface with the Technical Advisory Group and serve to facilitate information exchanges. When Assessment Teams are in existence, EPA will also identify a person at the technical level to interact with the Assessment Team Leader and to assign EPA members to assure that all information relevant to the data collection and assessment efforts are utilized.

It is understood that, as appropriate, individual sub-agreements to this general agreement will be developed to identify individual activities and resource commitments.

V. General Guidelines and Provisions

It is agreed that:

a. EPA and USDA will share all available data and analyses required for assessment work, but will be free to reach independent interpretations of the information.

b. EPA will channel its requests for agriculture and forestry related information and analyses initially through a central office in USDA to be designated. Information in central data banks will be made available. For other information needs not in central banks, consideration will be given to formation of assessment teams. Upon recommendation of the USDA/University Steering Committee, requests for information will be passed to the States. Each state system will be free to clarify the extent to which information is available and the ability of their system to be responsive to requests from assessment teams or EPA requests for other data. EPA will be advised within 15 days if requested data cannot be made available within the required time frame and/or when available data can be delivered.

c. USDA, States/Universities and EPA will continue joint efforts to determine data requirements and availabilities in order to identify data gaps and facilitate filling those gaps.

d. USDA and States/Universities will develop and provide to EPA new data to the extent possible, given resources available in the program.

e. EPA will share on a continuing basis with USDA its timetable of actions in the RPAR process and the bases for triggering RPARs.

f. EPA will inform USDA of decisions on pesticide uses which in turn may be assessed by the States and USDA.

g. EPA will appoint a contact person to channel information requests and exchange of information through the USDA Pesticide Coordinator as Chairman of the Technical Advisory Group.

h. In cases where an Assessment Team is assembled by USDA, OSPR/OPP, EPA will appoint an EPA technical person(s) to work with each Assessment Team as deemed appropriate.

i. EPA will advise USDA of its intentions to secure needed data or information in cases where an assessment team is not established by USDA.

Both agencies agree that:

1. Pesticide benefit/risk assessment is multi-disciplinary, in which inputs from biological, physical and social sciences are desirable;

2. Accurate, objective benefit/risk assessments are desirable for implementing certain provisions of FIFRA as amended;

3. The information flowing from the cooperative effort is subject to independent agency assessment;

4. This Memorandum does not inhibit in any way the participation of either agency in any hearing, litigation process or regulatory action initiated under FIFRA as amended, or other State or Federal statutes;

5. This Memorandum does not prohibit either Agency from obtaining additional data that will be available to both parties;

6. This Memorandum does not alter or negate any existing agreements, except as both agencies agree; and,

7. Working documents and/or clarifying statements regarding operational relationships will be developed, as appropriate, to facilitate the cooperation agreed to in this Memorandum.

VI. Funding

The specific details of the levels of support to be furnished one agency by another with respect to funding will be developed in specific sub-agreements.

VII. Procurement Policies

Any program or project activities undertaken by USDA for EPA or vice versa may involve contractual arrangements with non-governmental institutions. When such arrangements are necessary, they will be conducted in a manner consistent with policy, regulations and procedures of the contracting agency.

VIII. Public Information and Coordination

Timely release of information to the public regarding activities implemented under this Memorandum will be an objective of both agencies.

IX. Amendment and Termination

A. This Memorandum may be modified or amended by written agreement between USDA and EPA.

B. This Memorandum may be terminated by mutual agreement between USDA and EPA.

X. Effective Date

This Memorandum is in effect when signed by both agencies.

USDA

Deputy Assistant Secretary for Conservation, Research and Education

November 26, 1976

Date

EPA

Assistant Administrator for Water and Hazardous Materials

December 2, 1976

Date

ATTACHMENT V

REVISED RPAR DECISION SCHEDULE

December 8, 1976

MAJOR USE CATEGORY AND CHEMICAL OR CHEMICAL CLASS	PLANNED RPAR DECISION DATE
INSECTICIDES - CANINE Lead Acetate	January 1, 1977
LINDANE	January 15, 1977
HERBICIDES - FOOD Diallate Triallate Pronamide	February 15, 1977
RODENTICIDES Arsenic Trioxide	March 15, 1977
INSECTICIDES - COTTON Toxaphene EPN	March 15, 1977
WOOD PRESERVATIVES Arsenic Pentoxide Sodium Arsenate Ammonium Arsenite Sodium Pyroarsenate Pentachlorophenol and salts Creosote and related compounds	March 15, 1977
HERBICIDES - COTTON DESSICANTS Arsenic Acid Paraquat DEF Merphos	March 15, 1977
FUNGICIDES - FOOD EBDC Benomyl	March 15, 1977
DISINFECTANTS - DEODORANTS Safrole	March 15, 1977

GRAIN FUMIGANTS — April 1, 1977

- Ethylene Dibromide
- Ethylene Oxide
- Carbon Tetrachloride

HERBICIDES - WEED CONTROL — April 15, 1977

- Monuron
- Cacodylic Acid and its sodium salt
- Disodium Methanearsenate (DSMA)
- Monosodium Methanearsenate (MSMA)
- Calcium Acid Methanearsonate
- Monoammonium Methanearsonate (MAMA)
- Amine Methanearsonate (AMA)
- 2,4,5-T and related compounds

FUNGICIDES - NONFOOD — April 15, 1977

- Cadmium
- 2,4,5-Trichlorophenols
- 10,10'-Oxybisphenoxarsine

SOIL FUMIGANTS — April 15, 1977

- DBCP
- PCNB

INSECTICIDES - FOOD — May 1, 1977

- Dimethoate
- Carbaryl
- Trichlorfon
- Perthane
- Rotenone
- Calcium Arsenate
- Copper Arsenate
- Lead Arsenate (Standard)
- Lead Arsenate (Basic)

INSECTICIDES - NONFOOD — May 1, 1977

- Paris Green
- Sodium Arsenite
- Phenarsazine Chloride

INSECTICIDES - HOUSEHOLD — June 1, 1977

- DDVP
- Piperonyl Butoxide

RPAR'S ISSUED

CHEMICAL	DATE
Kepone	3/19/76
Chloroform	3/24/76
Chlorobenzilate	5/14/76
Endrin	7/19/76
BHC	10/12/76
Strychnine	11/22/76
Strychnine Sulfate	11/22/76
1080	11/22/76
1081	11/22/76

CHEMICALS RETURNED TO REGISTRATION DIVISION

CHEMICAL	DATE
Picloram	3/21/76
Sperm Oil	11/15/76

VOLUNTARY CANCELLATION - SECTION 6(a)(1)

CHEMICAL	DATE
OMPA	5/20/76
Strobane	6/18/76
Aramite	Pending
Chloranil	Pending
Copper Arsenite	Pending

FIFRA:
IMPACT ON THE INDUSTRY

EPA

office of
pesticide
programs

march 7, 1977

FIFRA: IMPACT ON THE INDUSTRY

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FIFRA: IMPACT ON THE INDUSTRY

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates all pesticides marketed in the United States. Statutory and regulatory requirements of the law naturally affect the industry which manufactures and distributes pesticide products. Congress has expressed interest in just how the administration of the FIFRA is impacting the industry as a whole, and particularly the small businessmen involved in the pesticide distribution chain. This paper addresses this Congressional concern, and will discuss the major impacts of the legislation since the 1972 amendments to date, especially those affecting the competitive atmosphere in the pesticide industry.

PROFILE OF THE INDUSTRY

Over 1.4 billion lbs. of pesticide are produced each year, encompassing some 1400 active ingredients. These 1400 active ingredients are contained in approximately 2500 technical products, which are in turn formulated in approximately 40,000 end-use products.

About 400 registrants produce technical material in a given year which is purchased and formulated into end-use products by about 4200 registrants. Some manufacturers of technical material also formulate their own end-use products. Some 90% of the active pesticide producers depend upon the other 10% for supply of the active ingredients.

The industry can be divided into two groups: those who gather their own data, and those who rely on data developed by others. Almost all data developers are large companies which can afford the long-term testing required under the Act. The bulk of the long-term data which form the basis for all these registrations is developed by the approximately 30 companies which contribute to innovative R&D in pesticides in the U.S. Most of these are large, multi-product firms for which pesticides comprise less than 20%, and in some cases less than 1%, of their total sales. Most formulators are small firms which lack the resources necessary to perform the required tests.

RELEVANT ISSUES

The registration regulations and guidelines impose costs through testing requirements; this overall impact has been considered in the preparation of the regulations implementing the registration, reregistration, and classification regulations, and a cost impact estimate of the proposed guidelines was published in the Federal Register on August 22, 1975. This issue is discussed briefly in the Appendix. However, the primary purpose of this paper is to address the two major issues affecting the ability of firms to register products and the amount of competition within the industry:

Availability of Data for Use and Disclosure -- to what extent can and should data developed in support of registration be shared among registrants and available to the public (this issue centers on Sections 3(c)(1)(D), 3(c)(2) and 10 of the Act).

Data Validity -- what is the quality of the data on file with the Agency, and can an applicant receive a registration for a product identical or similar to one already on the market without a validation of the entire data base.

These two issues are discussed at length in Parts I and II of the following paper. Other impacts of the FIFRA include areas where competition could be either stimulated or impaired by EPA actions: research and development, integrated pest management, application equipment and techniques, packaging, and application (commercial vs. private applicators). These are discussed in Part III. Results of some recent and on-going studies are summarized in the Appendix.

PART I
AVAILABILITY OF DATA FOR USE AND DISCLOSURE

Formulators of end-use products desire to purchase ingredients at reasonable prices. So long as a patent covers an active ingredient pesticide chemical, the developer controls the market and the price. Once the patent expires, however, the formulator could expect that other firms would begin to produce the chemical and thus the resulting competition would lower prices. For several years this was the pattern in the industry; competitors obtained "me-too" registration for technical-grade chemicals* after the patents expired.

The trade secrecy allegations recently raised by the data-developer firms have drastically changed this situation. Although a formulator-applicant who plans to use the technical-grade chemical sold by the data-developer can still obtain registration, a formulator who wishes to obtain technical-grade material from a different source will be stymied because his technical-grade source will be unable to furnish him access to the necessary data and he will not be able to obtain a registration. Thus, an essential question is whether the data developer firm should be able to control the market after his patent has expired by denying access to the data he submitted.

Equally controversial is the closely related issue of whether this data should be available to interested members of the public under FIFRA Section 3(c)(2) and the Freedom of Information Act. How these issues are resolved will, to a large extent, determine how the pesticide industry in this country is to be structured, how much the public will be allowed to know about the possible risks of pesticides, and perhaps how much research will be carried out on new pesticides.

EPA's interest in a speedy resolution of the various sub-issues that make up the use-of-data controversy stems from a desire to be able to conduct the registration and reregistration programs in an efficient manner, and to shift Agency resources now occupied with use-of-data matters to more environmentally-oriented tasks.

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* The basic chemicals sold for manufacturing use are often referred to as technical-grade chemicals, and normally contain some amount of impurities, ranging from less than 1% to, on occasion, 20% or more. The impurities are present because of the high cost and technical difficulty of producing commercial quantities of pure active ingredient.

This Agency believes that the issues should be resolved by Congress. This discussion is intended to describe how the controversy arose, and to indicate likely outcomes in terms of the amount of competition (and the range of public disclosure) with or without legislative changes.

BACKGROUND

The controversy has arisen because of the interaction between the patent law, the patterns of development and marketing of pesticides, the various provisions of FIFRA bearing on use and disclosure of data, and the changes in data requirements that have occurred.

Patent law considerations.

A patent may be issued to cover a newly-discovered chemical, a newly-discovered use for a previously-known chemical, or a new method for producing the chemical. New chemicals and new pesticidal uses are the kinds of patents with which we are concerned here.

A patent provides that during the 17-year period commencing with the issuance of the patent, no one other than the patent's owner can "practice" the invention without the owner's permission. The owner may license others to practice the invention.

After the 17-year period expires, the patent law provides no further protection; any firm can practice the invention, without needing the prior consent of the patent-holder. This does not necessarily mean that the patent owner has no remaining advantages; he may have acquired valuable "know-how" that he can still license, and he may have acquired marketing advantages due to his long association with the product. However, he can no longer prohibit unconsented competition in the market.

Developers of new chemicals or new pesticidal uses normally make prompt application for patents, to avoid the possibility of loss of rights through publication or independent invention by another. In the case of pesticide chemicals, the patent normally issues well before the developer has established, through long-term testing, that the chemical is safe and effective enough to be registered under FIFRA. Thus, there may be only 12 or so years of patent protection remaining when the initial FIFRA registration issues.

The great majority of the important agricultural pesticides were patented between 1945 and 1965. (Many of the products were developed as a result of military research begun during World War II.) Patents on many of the major pesticides have thus already expired, and more will expire in the next few years.

Patterns of pesticide development and marketing.

Development of new pesticides is not easy. Discovery of a chemical which is both effective against pests and adequately safe for use occurs only infrequently. The research and development costs are great, and must be absorbed by the sale of successful chemicals.

When a firm does develop a promising new chemical and obtains a FIFRA registration, there is every reason for that firm to promote its sale and use during the remaining period of patent protection. The firm will in most cases aggressively seek to develop and have approved new uses of the pesticide (on crops or pests not originally the subject of registration). Extensive advertising of the product is common.

A technical-grade pesticide chemical normally cannot be applied directly for pest control; it must be dissolved, diluted, or otherwise formulated into a product which is safe to the applicator, effective in pest control, and adapted to desired methods of application. The pesticide's developer may choose to formulate the chemical into end-use products himself; he may decide not to engage in formulation, instead reaping his profit from sale of the technical-grade pesticide to firms specializing in formulating end-use products; or he may choose to do both. Likewise, the patent-owner may choose to license other firms to manufacture and sell the technical-grade chemical. Each of these decisions will be made on the basis of profit maximization.

However, each technical-grade product which is to be sold in commerce (by the developer or his patent licensee), and each formulated product, must be separately registered under FIFRA. Each person who seeks registration must demonstrate that the product he will offer for sale is safe and effective. Unless formulators and license-seekers can obtain FIFRA registration for such products, neither patent licensing nor sale of technical-grade product will be feasible. Thus, the patent owner has a powerful incentive to encourage these other firms to use whatever data is necessary for the registration of their products.

Once the patent expires, however, everything changes. There are many firms which might find it economically attractive to commence production of a technical-grade product on which the patent has lapsed, and to sell it in competition with the original developer. Because these firms often do not maintain research operations, or have other cost advantages over the firms who do, they could in many cases undersell the original developer. And all things being equal, the formulators would prefer to purchase the lower-priced technical-grade chemical.

These potential competitors cannot enter the market until they can obtain FIFRA registration for their proposed products. And there is absolutely no incentive for the developer to consent to the use of his data for supporting these competitive registrations--instead, the incentives point in the opposite direction. Indeed, after patent expiration the chemical's developer may desire to curtail whatever competition already exists in the technical-grade market (from those firms which were the subject of patent licenses granted earlier). On the other hand, the developer has no reason to attempt to curtail the number of registrations of formulated (end-use) products, for each formulator represents an existing or potential customer. The developer merely desires to have control over the supply of the technical-grade chemical.

It is perfectly understandable that a developer firm would desire to lengthen the period of exclusive control of production of the chemical beyond the 17 years the patent law allows. This may be especially true when it is remembered that a portion of the 17-year period may have been lost to pre-registration testing.

One can equally easily understand the lack of enthusiasm over this kind of behavior on the part of the developer's potential competitors, those who desire to enter the technical-grade market. From their standpoint, the developer has obtained his due reward under the patent law; now he wants to start all over in reliance on a different kind of protection, that which can be obtained by denying access to the test data required for FIFRA registration. If a prospective competitor can be required to perform duplicate tests as a condition of market entry, in most cases the potential profits will not justify the expense of this duplicative testing and the developer will retain control over production and price levels.

Early regulatory practices and assumptions.

Some of today's problems concerning use of data can be traced to the practices and attitudes developed by both industry and Government during the period prior to the 1972 amendments.

The system of registering each product individually developed under the 1947 FIFRA, at a time when most of the important agricultural pesticides were still protected by patents owned by the major producing firms. For the reasons noted earlier, these firms were anxious to maximize production and use of their patented technical-grade chemicals, and many registrations were issued for formulated end-use products containing these chemicals. It became routine practice for developer firms to allow formulator applicants to rely on the data already on file concerning the composition of the technical-grade chemical.

(This composition data was not publicly disclosed by USDA, which treated it as trade secret.) USDA officials also routinely considered the other data (that pertaining to safety and efficacy) in support of formulator applications, without authorization of the technical-grade chemical's developer. This is understandable in the context of the times, because it normally would have been safe to assume that the data developer was anxious to have the formulated product registered, and to have the formulator as a customer. Moreover, during the early years of administering the 1947 FIFRA, the testing requirements were not nearly as stringent as they became starting in the mid-1960's. Thus, the data barrier would not have been formidable, even if the data developer objected to other firms' use of existing data.

But as time went on, two things changed: long-term testing requirements were imposed, and the patents began to expire. By the early 1970's, firms which had held the patents could see that their control over production would soon expire. These firms suddenly became very concerned about the use of their test data and composition statements by EPA in support of other firms' registrations.

EPA (like USDA before it) had continued to process registration applications on the assumption that it was proper to rely on any test data in its files. (The 1947 FIFRA, after all, made no mention of this practice, speaking only of the confidentiality of the formulas.)

In fact, under the 1947 FIFRA, products were routinely registered without any scrutiny of the underlying data, if there already existed a product registered for the same use patterns. Other prevalent assumptions at the time were also involved. One was that the potential hazard from a pesticide was associated only with the active ingredient of a product, not with the accompanying impurities. This led to the idea that if one firm's technical-grade product containing a particular active ingredient was safe, so was another firm's technical-grade product containing the same active ingredient.

Application of these various assumptions ultimately led to the registration of various technical-grade products made by firms other than the original developer, both those holding patent licenses and those which entered the market after the patent had expired. Many of these "me-too" registrations of technical-grade products now exist; the registrants have never performed their own tests on these products. All these products will be subject to fresh examination at reregistration.

Development of the present statutory provisions.

In 1971-1972, during the debate over the amendments to FIFRA then under consideration by Congress, the National Agricultural Chemicals Association (NACA) urged adoption of a provision that would have required the data developer's consent before test data could be used to support the registration of a pesticide product. NACA argued that the then-current EPA practice of allowing applicants to rely on data developed by the original registrant was causing pesticide firms to abandon their research and development programs. NACA argued that this trend would be accelerated by the public disclosure provisions of the amendments (which ultimately were enacted without change as §3(c)(2)). NACA did not oppose the disclosure requirements, but argued strongly for the "exclusive use of data" approach. The bill which passed the House in late 1971 contained an "exclusive use" provision, and the same approach was initially favored by the Senate Committee on Agriculture and Forestry. However, the Senate Committee on Commerce strongly opposed it, arguing that "exclusive use" would grant the original data developer a practical monopoly for a period extending well beyond the 17-year patent term. The two Senate committees arrived at a compromise that became law as §3(c)(1)(D). It provided that test data was to be available for use by all applicants (mandatory licensing), but required those applicants who had not obtained the data developer's consent to offer to pay the developer reasonable compensation.

In 1975, §3(c)(1)(D) was amended to provide that the limitations it placed on the Administrator's consideration of data did not apply to data received by EPA (or its predecessors) before 1970.

The 1972 amendments made both the public disclosure provision, §3(c)(2), and the mandatory licensing provision, §3(c)(1)(D), subject to one crucial exception: EPA could neither disclose to the public, nor consider in support of another firm's application, data which "contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential."

It is the meaning of this "trade secrecy" exception, and the interaction of it with §3(c)(1)(D) and §3(c)(2), which has served to frame the present controversy. Congress did not define what kinds of data were to be treated as "trade secrets."

The 1972 FIFRA amendments also put an end to the practice of issuing registrations based on "existing use patterns." FIFRA §3(c)(2) requires that EPA state publicly what data supports each registration action. The compensation provisions of §3(c)(1)(D) likewise assume that EPA will know just which items of data were relied on.

The large pesticide producers (the firms which generated most of the test data in EPA files) have argued, first to EPA and now in court, that the term "trade secrets," as used in FIFRA, encompasses any and all test data which the firms have not voluntarily disclosed to the public and which has competitive value. Most of the data has not been publicly disclosed. And the data does have one kind of competitive value: as long as it is considered "trade secret," other firms wishing to compete with the data developer will be practically excluded from the market because of their inability to obtain registration or reregistration. However, in EPA's opinion, it was this very element of value which was intended to be covered by the reasonable compensation plan of §3(c)(1)(D).

The data developers' primary concern appears to be control over the domestic technical-grade market. However, they have opposed not only use of data by other firms, but also disclosure of the data to the public. The sole argument against public disclosure of test data, insofar as EPA is aware, is the possible usefulness of such data to firms seeking to register products in other countries. (Toxicity data is apt to be most useful in foreign registrations. Data on efficacy and environmental chemistry may be of little use, because of the different weather and soil conditions, pest strains, crop varieties, and application methods prevalent in other countries.) Thus, the value of this data for purposes of preserving market shares in foreign countries must be balanced against the right of this country's citizens to critically examine the toxicity data and other information concerning pesticides used here. The Toxic Substances Control Act, it should be noted, requires that health and Safety data on marketed products must be publicly disclosed.

ISSUES REQUIRING RESOLUTION

1. <u>What safety, efficacy, and environmental chemistry data should be available for use by competitors under FIFRA?</u>

The kinds of hazard-related data that must be submitted or cited by an applicant for reregistration or new registration include short-term, acute toxicity studies; 90-day subacute toxicity studies; and often long-term (normally 2-year) feeding studies designed to show whether prolonged dietary exposure to the product produces cancer or other adverse health effects. Such studies are performed using rats, mice, or other test animals. In some cases, depending on the proposed use

patterns, studies must be done of the effect of the pesticide on fish and wildlife, and on the "environmental chemistry" of the product (its behavior in soil, degradation time, etc.). Efficacy studies, showing that the pesticide is useful against pests but not unduly harmful to desirable life forms, must be furnished. Finally, in the case of products for use on agricultural commodities, or to which livestock or poultry will be exposed, studies must be performed dealing with such things as how the chemical is metabolized (chemically changed) by food plants or feed animals, studies of pesticide residues which result from the product's use, and studies showing the waiting periods which must be employed after use of the pesticide to avoid unacceptably high pesticide residues in food plants, meat, poultry, milk, or eggs.

EPA has taken the position that it was Congress' intent to make this information subject to the mandatory licensing procedure of §3(c)(1)(D), and that Congress did not therefore intend that data of these types should be regarded as trade secrets. 1/* However, most of the major pesticide firms have commenced litigation alleging that this data is trade secret. If these firms are successful, and the test data is held to be immune from the mandatory licensing provisions, true competition in the technical-grade pesticide market in the future will be greatly diminished. The expense and delay incident to duplicative testing may effectively preclude market entry; only those firms which "own" the data, or are able to come to terms with the data owners and obtain permission to rely on the data, will be able to either enter or stay in the market.

If Congress desires not to promptly encourage competition, it need do nothing; the present law will continue in effect, and the cases will wend their way through the courts. During the year or more that the litigation will require, EPA will be able to register only those products which have the blessing of data developers. EPA anticipates that it will prevail in the litigation, but this result cannot be guaranteed.

On the other hand, if Congress desires to resolve the matter promptly in favor of increased competition in the production and sale of technical-grade pesticides on which the patents have expired, it should amend FIFRA §3(c)(1)(D) by deleting the prohibition on the Administrator's consideration of trade secret data. This will facilitate competitive registrations, whether or not the data may be publicly disclosed. 2/

* Footnotes are found at the end of the paper.

2. What safety and efficacy data should be available for examination by the general public?

This Agency firmly believes that Congress, in enacting FIFRA §3(c)(2) in 1972, intended to make it possible for interested members of the public to examine the actual data which is submitted in support of the safety and efficacy of registered pesticides, and therefore to encourage public understanding and criticism of Agency decision-making as well as to increase the knowledge of risks and benefits of pesticide use.

Public disclosure to supporting test data is fully consistent with the licensing-and-compensation scheme of §3(c)(1)(D). Disclosure of data does not in any way diminish the right of a data developer to be paid reasonable compensation for the use of the data by another. In fact, by allowing a prospective user of the data to examine it, disclosure of the data would facilitate data-sharing and would make more likely the negotiation of acceptable compensation terms.

Some have suggested that only summaries of this data should be disclosed. This would not assist those interested in assessing the validity of the data; it is the detailed data which must be examined if public scrutiny is to serve any useful purpose.

EPA's position is that trade secret status should be routinely afforded only to truly secret information concerning manufacturing processes (and, perhaps, to the list of deliberately-added inert ingredients in formulated, end-use products). The remaining data needed to support a registration, including the data describing the toxicity of a product, its environmental behavior, and its efficacy, should be routinely available to the public once registration has been granted. This approach would be consistent with that recently adopted under the Toxic Substances Control Act.

The procedural aspects of data disclosure are nearly as important as the substantive issue of which data may be disclosed. The present law, which requires disclosure of all data except that which is trade secret (but does not define what data <u>is</u> trade secret), encourages judicial review. At present, most of the large data-developing firms are engaged in litigation seeking to enjoin EPA from disclosures of data. Some of these firms are arguing that they are entitled to a complete evidentiary trial in court to establish the facts concerning the confidentiality and the value of each item of data in question. It is EPA's position that the data is publicly available as a matter of law, i.e., that the statute, properly construed, requires disclosure of the data. However, if EPA does not prevail on that issue, full evidentiary hearings will be the result whenever EPA proposes to disclose any item of data against the data developer's desires.

If Congress desires to clarify the matter in favor of disclosure, it should amend FIFRA 10(b) to state that all data pertaining to the properties, safety, behavior, or efficacy of a registered pesticide is publicly available, except for those specific portions of an item of data identified by the submitter as information which, if disclosed, would divulge details of secret manufacturing methods or quality control procedures having competitive value to the data developer.

3. Should information concerning the impurity content of technical-grade pesticide chemicals be available for use by prospective competitors and disclosure to the public?

Some large data-developing firms have recently argued that toxicity test data pertaining to one firm's product (even if it is not trade secret) is simply irrelevant, in a scientific sense, to the question of the safety of another firm's product containing the same active ingredient, because of the possible presence in the second product of toxic impurities. Thus, they allege, Firm B should be required to perform a complete battery of toxicity tests on its product, and should not be granted registration on the basis of tests on Firm A's product. If accepted, this argument would tend to severely limit competition in the technical-grade pesticide market.

Traditionally, toxicity testing has focused on the possible adverse effects of the pesticidally-active ingredient which composes the bulk of a technical-grade chemical. (Most toxicity testing is performed using technical-grade chemical as the substance fed to test animals.) However, this Agency has become increasingly concerned about the possible adverse health effects attributable to the impurities that are present in technical-grade chemicals. These toxic effects may be either of an acute or chronic nature. Certain dioxin compounds (present as impurities in some herbicides unless very careful manufacturing precautions are taken) are among the most acutely toxic substances known, and also have chronic adverse effects. Some nitrosamine compounds, present as impurities in various pesticide products, are highly potent carcinogens, and there are other highly carcinogenic pesticidal impurities. It is likely that this concern with impurities' toxicity will continue to grow as more becomes known about their presence in pesticides.

Because of this concern, EPA has concluded that in the future its registration decisions must take into account the toxicity of possible impurities that may be present in marketed quantities of pesticides. Applicants will be required to state the maximum limits for the various impurities that they will allow to be present in marketed products, and the Agency will base its health evaluations in part on the impurity limits the applicant furnishes. Enforcement action will be taken against firms whose marketed products are found to contain impurities in excess of the limits the applicant prescribed in its application.

The various toxicity studies required for registration differ in their ability to demonstrate the toxicity of impurities. A highly acute toxic impurity may demonstrate its effects even though it is present in a test substance at very low concentrations. On the other hand, the long-term animal feeding studies (especially studies designed to show the possible carcinogenicity of the pesticide) probably are only marginally useful in demonstrating the safety of impurities. For one thing, these tests are, for reasons of economy, designed to produce evidence of possible toxicity by use of relatively small "test populations" of animals; to do this, it is necessary to provide the test animals very high daily dosages of the technical-chemical test substance. But the test substance is, of course, mostly comprised of the active ingredient. Impurities are often present in the test substance at very low concentrations, and therefore a finding that tested animals showed no chronic adverse effects may demonstrate very little about the toxicity of the impurity even though it says a great deal about the safety of the active ingredient. Higher dosages of the impurity might demonstrate that it is indeed chronically toxic.

Moreover, any given sample of a technical-grade chemical, including the lot used as the test substance in long-term feeding studies, may happen to be free of impurities that would be found in other lots of the same firm's technical-grade product. In short, a "negative" long-term feeding study is much more persuasive of the safety of the principal active ingredient than of the innocuousness of the various possible impurities in the marketed product.

Limitations on availability of test facilities, as well as cost considerations, make impracticable the theoretically-desirable requirement of complete testing of impurities. EPA's hazard evaluations of impurities will sometimes have to be made in the absence of hard data, and will have to be based in some cases on the presence or absence of chemical characteristics known to be indicators of hazard.

Assuming that, using modern hazard criteria and evaluation methods, EPA has concluded that Firm A's technical-grade product (with its certified impurity limits) is safe enough to warrant registration or reregistration, how should EPA respond when a potential competitor, Firm B, requests registration for its own technical-grade product containing the same active ingredient? As already noted, Firm A may argue that EPA should deny registration until Firm B has thoroughly tested the new product. There is some merit to this argument, if one assumes that Firm B's product will contain more or different impurities than Firm A's. A new battery of tests just might demonstrate that Firm B's product is more toxic, because of impurity differences.

There are, however, counter-arguments, aside from the obvious limiting effect on competition that required new testing would have. First of all, Firm A's own product may contain impurities that were not present in the test substance used for Firm A's tests; thus, the logic of the alleged need for testing by Firm B would lead one to conclude that Firm A must also perform a complete new set of tests on his current product.

Second, it will be remembered that the safety decision concerning Firm A's product was based on an EPA evaluation of the likely hazard of all the impurities that Firm A indicated might be present in its product as marketed. If EPA could be assured by Firm B that its product's impurity levels would fall within the limits already found safe with respect to Firm A's registered product, the hazard decision would be easy to make. However, Firm B cannot easily make this certification unless it is able to ascertain what those approved limits are and whether its quality control methods allow it to conform to those limits.

Under the present law, EPA cannot routinely disclose information on the formulas of products. Such formula information would be available to Firm B only in the event that Firm A, when queried, is unable to demonstrate that the formula is in fact "secret" or unable to show likely competitive harm in the event of the formula's disclosure. Each such determination must be made individually and can be appealed in court, where Firm A would probably be entitled to a full evidentiary hearing. Because of the startling advances in analytical methodology, most commercially-useful formula information is probably not truly "secret" anymore; but establishing this in court can be an arduous process under present law.

Accordingly, if Congress desires to encourage competition in the production of technical-grade pesticides, it should amend FIFRA §10(b) to make clear that, as a matter of law, EPA may routinely disclose to the public the impurity limits which a firm has stated may be present in commercial quantities of its technical-grade product (or at least those that pertain to any product no longer protected by a U.S. patent).

EPA believes that requiring disclosure of impurity content would also serve the general public's interest in knowing which chemicals reach the environment as a result of pesticide use.

PART II

DATA VALIDITY

Before registering a pesticide, the Administrator is required under §3(c)(5) of the Act to find, among other things, that the product will not pose "unreasonable adverse effects" on man or the environment. In order to apply this standard prior to registration or reregistration, the Agency must determine:

- how much data are required in order to make a §3(c)(5) finding;
- to what depth should those data be reviewed prior to a reregistration decision; and
- in registering a product, is the Administrator making a determination that the active ingredient is not posing an unreasonable adverse effect, or that the individual product -- considering that the environmental burden of that active ingredient is actually posed by the aggregate of all products on the market -- will pose an unreasonable adverse effect. In other words, should the Agency consider the whole hazard of the active ingredient, or consider the incremental hazard of the product for which registration is pending.

All these considerations are important to the competitive situation among pesticide registrants, and particularly to pesticide formulators who do not submit their own data to support product registrations. With full reregistration, and the accompanying data review, being stretched years into the future, the Agency is at a critical juncture in deciding how to treat applications for pesticides which utilize active ingredients that are also found in products already on the market.

If, on the one hand, the Agency requires all the data on the active ingredient, the formulator may find it impossible to comply, since some of the data may never have been generated by any registrant. Meanwhile, since the Act contemplates that registrants already on the market should have time to gather missing data, they enjoy a distinct competitive advantage. Even if a formulator can cite data submitted in the past, it may be that EPA will be unable to validate the data for reregistration purposes for three or more years. Because of the Agency workload, it would not be reasonable to take the data in question out of its scheduled review sequence; but neither is it desirable to inform an applicant that his application cannot be processed for three years. From his standpoint that would be unreasonable.

On the other hand, the Agency could permit new registrations of products utilizing active ingredients already on the market until such time as all products containing the active ingredient are scrutinized during the reregistration process. This option would favor a competitive situation within the industry; further, it can be argued that this option would not jeopardize environmental quality in that it is the active ingredient as a whole from all sources of its use which is or is not posing an unreasonable adverse effect, and thus all products containing that ingredient should be evaluated at the same time. The legality of the latter option has been questioned by one Congressional Committee. The Agency is pursuing development of an approach incorporating conditional registration. This consideration is at the heart of the resolution of the so-called "double standard" problem: should products registered under the 1947 Act have the advantage of remaining on the market while their data base is being verified, when identical or similar products are denied access to the marketplace until the 1972 FIFRA standards are fully met. Congressional affirmation of the Agency position would help break the registration logjam.

BACKGROUND

Why has data validation become an issue and what does it mean in terms of competition?

The original reregistration program was based on the assumption that data on file were accurate and reliable and had been reviewed internally in a thorough manner according to still valid scientific principles. The section 3 regulations thus made a distinction in the data requirements for new registrations and reregistrations in order to ease the administrative burden of reregistering 30,000+ pesticides (by October 1976). While a full range of data would be necessary to support an application for a new registration, a much more limited range of data would be sufficient to support an application for reregistration. It was felt that given a product's prior registration and its use history, the §3(c)(5) safety finding would be adequately met until full compliance with the data requirements could be achieved.

To ensure that reregistration would proceed in an orderly and systematic manner, products were grouped into batches on the basis of similarity of formulation and broad use patterns. At a scheduled time an entire batch would be called in for reregistration. In addition, active ingredients were assigned to one of five categories based on a review of data to determine simply whether data existed to meet the data requirements: Category I, all data requirements filled; Category II, long-term data gaps; Category III, short-term data gaps; Category IV, rebuttable presumption against registration (RPAR) (presume not to reregister); Category V, unreviewed. Because of our assumption that the data were generally reliable, the review did not actually

examine the quality of the data on hand. A preliminary call-in schedule for the batches and a list of active ingredients in the five categories were published in the Federal Register on February 17, 1976.

However, as reregistration began, it became increasingly apparent that the distinction between data requirements for new registrations and reregistrations was creating serious inequities for producers of new products. Registered products could be conditionally reregistered and marketed pending the completion of long-term testing but identical new products could not be registered without full submission of data, some of which have not yet been developed. To alleviate this situation to some extent, the Agency issued a General Statement of Policy - Data Requirements for Registration in the Federal Register on May 27, 1976. This notice provided for the conditional registration of new pesticide products which were identical or substantially similar to currently registered products which had been reviewed and found eligible for a full or conditional reregistration (that is, products with no data gaps or only long-term data gaps). Products not identical or substantially similar to presently registered products still required the complete submission of data prior to registration. Like full and conditional reregistration, conditional new registration relied fundamentally on the reliability of the data in Agency files.

However, early in 1976 new information came to light which questioned the assumptions of the registration and reregistration process. Senate hearings, discussions with GAO and FDA concerning the reliability of certain data submitted to FDA, and a subsequent preliminary report of an independent toxicologist on a sample of pesticide data raised serious doubts about 1) the adequacy of the testing in EPA files, and 2) the completeness of the Agency's own review and follow-up. Since then, in December 1976, the staff of the Senate Subcommittee on Administrative Practice and Procedure has issued a report stating that the Agency has, in fact, been negligent in its public duty by not reviewing all data in depth prior to reregistration.

In August 1976, reregistration was halted because the Agency decided it was now necessary to actually review the data in our files. There are several important consequences of the Agency commitment to this review.

. The May 27, 1976, policy statment is basically inoperable, because all products are back in Category V (unreviewed). New products utilizing chemicals already on the market are thus not eligible for conditional registration, since the supporting data are not reviewed.

. Reregistration will take far longer than was originally anticipated. A recent zero-based program analysis indicates that, at current resource levels, the task will take 10 years or more.

. It is no longer reasonable to have different requirements for registration and reregistration. Policies which would have worked during a short transition period will not be equitable in a lengthy transition. The removal of the distinction between registration and reregistration requirements has also been recently required by a recent Federal District Court injunction.

. Because of the large amounts of efficacy data which are on file, considerable resources would have to be dedicated to complete validation of those tests. EPA believes that except for public health and disinfectant type products, the user community can best judge a product's efficacy, based on local conditions and pest resistance. Because of this and because a manufacturer would not find it in his best interests to go to the expense of registering a product which did not work, public resources can most effectively be put to use in hazard rather than efficacy evaluation of products other than public health/disinfectant uses.

. The length of time necessary for reregistration and the complexities of handling individual registration actions resulting from the trade secret disputes have led the Agency to the conclusion that a new approach for regulating pesticides in this country is in order. Specifically, Agency resources could best be utilized if devoted to intensively reviewing technical products rather than end-use products.

CURRENT PENDING DECISION

Currently registered products may remain registered and on the market pending completion of data review and registration; in this respect, they are not seriously affected by data validation problems. Similar new products are in a much more difficult situation. On the one hand, we could ask registrants of new products utilizing old chemicals to provide all required data. On the other hand, we could just request data corresponding to the difference (e.g., new target pest, new site, new method of application, new formula, etc.) between the new products and those already on the market. The choice of one of these two general options (or some combination of each) will have a significant effect on the structure of the pesticide chemical industry.

IMPACTS OF TWO BASIC OPTIONS

Option 1: Require full data submission or data citation for every application for registration.

. For individual pesticide producers, this means that where long-term data gaps exist new applicants will not be able to register products similar or even identical to those which current registrants are selling for several years. While current registrants are able to continue to market such

products for up to three years while the data gaps are filled, there will be no data for a "new registrant" to cite and it will not be impossible for him to complete required tests should he be willing and able to do so.

- For the industry as a whole, the requirement of full data submission will, to a large extent, preserve the status quo. Those now marketing registered products will continue to do so. But few new competitors, in particular small formulators, will be able to enter the market for at least three years, and probably much longer than that.

- Registrations for minor uses will be impeded.

- The total environmental burden of particular pesticide chemicals may remain substantially the same until assessments of their hazards can be completed. However, current registrants are limited mainly by the elasticity of demand, and their own capital formation abilities, from substantially increasing production and sales. Thus, the environmental burden of a particular pesticide may be more directly affected by marketing strategies than regulatory controls.

- On the other hand, the approach provides the greatest assurance that each product will be assessed for safety thoroughly before entering market.

Option 2: Generally require full data for new chemicals. However, for old chemicals, require only the data pertinent to the incremental differences between the new product registration and those already on the market to achieve conditional registrations. Products thus conditionally registered would have to meet the full requirements of the amended FIFRA when the active ingredient as a whole is evaluated during reregistration.

- "Double standard" would be removed; all products containing the same active ingredient would be treated fairly.

- Competition would thus be served in that a barrier would be removed for registrants of "me too" products and other new products formulated with old active ingredients.

- The interests of the environment can be served in that a) the environmental burden of the chemical may not, it can be argued, be appreciably increased by encouraging competition for the existing market or by legalizing minor uses; and b) the decision as to the environmental safety or being posed can most efficiently and systematically be made on the chemical as a whole.

- The legality of such a conditional registration scheme may be open to question. FIFRA does not specifically provide for conditional registrations; its silence on

this subject could be interpreted to mean that the Agency should not proceed in this direction.

AGENCY POSITION

The Agency believes it is in the best public interest to devote its currently scarce resources to assessing the effects of pesticide chemicals from a generic standpoint rather than laboriously processing thousands of individual product actions. This approach, would

- focus attention on the broad risks and benefits of any pesticide, encompassing all uses and all formulations;
- limit the primary data compensation arena to registrants of technical, rather than end-use, products;
- provide a simple registration mechanism for formulators who utilize an already-registered technical material, in which only data pertinent to the individual product which has not already been submitted to support the technical registration would be required, which would thereby
- free EPA reviewers from complex paper work and record keeping so that resources could be best utilized in assessing the larger risk and benefits issues.

Regardless of whether the Agency maintains the current product-by-product approach, or adopts the generic chemical approach, there will be a transition period of many years before all data are validated and reregistration is accomplished. What to do with new applications during this time is crucial to the competitive situation in the industry. Generally speaking, the Agency subscribes to the philosophy articulated in the second option above, i.e., that it is the incremental hazard which should be assessed during the transition period, and that registrants of like products generally should be treated alike. Our overriding concern will be to answer several fundamental questions:

- will the product pose a risk additional to that posed by products already on the market?
- if so, are data available on the additional hazard?
- has an RPAR or intent to cancel notice been issued on the active ingredient?
- is there a known inert or contaminant problem?
- will public health or the environment benefit by denying the product access to the market place, or would denial simply affect the structure of the industry?

SPECIFIC TREATMENT OF CLASSES OF APPLICATIONS

Application For New Chemical

. Generally, all data required by Section 3 must be present.

-- For exceptional circumstances on a case by case basis -- in reliance on the chemical structure of the pesticide, the exposure expected from use of the pesticide, and short term indicator tests -- a conditional new registration may be granted where one long term study has been completed with negative results and the second is underway.

Application For Old Chemical, Old Use Pattern ("ME-TOO")

. Register product if all requisite data are submitted or cited (with appropriate permission or offer to pay reasonable compensation) for active ingredients not subject to an RPAR or intent to cancel notice.

. Provide a conditional registration when long-term data are missing, so long as registrant provides or cites short-term data (and offers to pay reasonable compensation if applicable) supporting registration of product already on the market which is not subject to an RPAR or intent-to-cancel notice. Full data requirements will have to be met by all like products at the time of reregistration.

. Conditional registration may be granted if active ingredient is an RPAR candidate, since the risk has not been validated and in any event is not greater than that already being posed by like products already on the market.

Application For Old Chemical, New Use Pattern

. Registration will be granted if all required data are submitted or cited (along with permission or offer to pay where applicable).

. Conditional registration will be granted if

-- long term data are missing but all short term data are submitted or cited;

- data supporting the efficacy and safety of the new use, i.e., the incremental difference between the already registered uses and the proposed new use, can support a §3(c)(5) finding;

- if a food crop is added, pertinent data required to support a tolerance under the Federal Food, Drug, and Cosmetic Act must be provided if a tolerance is not already established; and

- the active ingredient is not subject of an RPAR notice or notice of intent to cancel.

- Products utilizing active ingredients which are in the RPAR process will be eligible for conditional registration but the burden of justification for the §3(c)(5) finding for the use will bear more heavily on the applicant.

The Agency believes that this approach would be conducive to eliminating many of the current regulatory and statutory roadblocks to registrations as formulators and other new registrants of products utilizing chemicals already in use could enter the market on the same footing as old registrants. This would eliminate the "double standard" by equalizing registration requirements for products containing the same active ingredient.

POTENTIAL CONGRESSIONAL ACTION

The Congress could either sanction or disagree with the Agency position through a specific statement in the law or the Committee Report regarding Congressional intent on conditional registrations. The Agency would welcome discussion and instruction in this area.

PART III

OTHER IMPACTS

The primary impacts on competition of FIFRA and its administration by EPA were dealt with in the previous two sections. Those were primarly negative impacts, and ways to alleviate those negative effects were described. This section describes five other areas where effects can be identified -- on new product research and development, on integrated pest management, on application technology, on child protective packaging, and on users and applicators.

NEW PRODUCT R & D

How has FIFRA affected new product research and development? A look at history shows that most new product research and development has been done by larger firms. Therefore, although small businesses are not presently a major factor in the innovation of new chemicals, it does not appear that FIFRA has contributed significantly to this situation. 3/

Although some firms have left the pesticide research and development field in recent years, about an equal number have entered the field. High profits and profit potential have kept the industry interested. 4/ There has been some trend to consolidation of business in the larger firms. Since few small firms have ever been in the field, however, this trend is making very little change in the situation. Chemical research and development, synthesis, screening, production, and marketing have always required some substantial size for success.

As suggested by studies conducted by outside organizations for EPA and the investment community, 5/ as well as by EPA's own contacts with the regulated industry, the pesticides industry expects that opportunities for innovators to be fewer in number than in the past, but that a big success will be relatively more spectacular. In addition, the industry will continue to build on its existing research and development base with changes in use patterns and formulations of previously-registered products, and new chemicals within already successful classes of compounds.

One segment of the industry, however, is adversely affected by increasingly stringent regulatory requirements -- those firms currently or potentially pursuing products with inherent limitations on market size. This applies to pesticides for minor crops, to biological controls (predators and pathogens), and to such chemical agents as insect growth regulators, pheremones, attractants, repellants, antimetabolites and antifeeding agents. Many of these products are attractive from an environmental point of view because of their low volume of use, specificity of action to a small number of species, low toxicity to humans and other non-target organisms, and lack of persistence. 6/.

But to determine these desirable characteristics requires testing costs of a magnitude similar to products with much larger production and profit potential. The Agency is able to waive all or part of the $10,000 tolerance petition fee if the applicant can show financial hardship or if waiving of the fee would be in the public interest. Considering product development costs running into the millions of dollars, it cannot be expected that waiving tolerance fees would be much of an inducement to potential developers of such products.

INTEGRATED PEST MANAGEMENT

Integrated Pest Management (IPM) is an approach to pest management that utilizes all suitable techniques and methods in as compatible a manner as possible, to maintain pest population at levels below those causing unacceptable economic or aesthetic injury. It usually employs a means of scouting or monitoring; use of "action thresholds" to trigger treatment; consideration of the dynamic interactions among pests, weather, parasites or predators, and costs of treatment; consideration of a series of strategies; and selection of the most appropriate tools, with high priority given to long-term human health and environmental concerns.

This is an area where opportunity exists for the entry, expansion and prospering of small businesses. The primary responsibility for the development and promotion of IPM lies with USDA, but the Agency's actions could encourage or discourage the growth of IPM. Therefore, it is worthwhile to examine the consequences for small businesses and competition from a growth in IPM.

Characteristics of the IPM Industry

IPM is a knowledge industry. It operates by collecting and analyzing information about crops, pests and their interactions, and providing guidance for actions by the growers or managers of agricultural crops, structures, parks, lawns, rights-of-way, etc. Practitioners come by their knowledge via long experience in the field, by formal training (associate degree to Ph.D.), informal in-house training courses or a combination of these.

There is a high degree of decentralization of the delivery of services, since advice, to be useful, must be tailored to the particular circumstances prevailing at the growers' sites. However, some demonstration projects have utilized centralized data analysis, in order to incorporate weather projections and other data more amenable to a regional approach (eg., the Purdue system for alfalfa, the Michigan State University system for apples, and a model for cotton at the University of California.)

IPM is currently fairly labor intensive because of the reliance on scouts in the fields. Some technology is evolving to reduce this reliance, such as satellite or airplane surveillance for presence of plant pathogens or weed infestations, but there are limits on this development -- there will probably always be a need for scouts in the field, not only for the detailed information they can produce, but to act as an effective human interface between the provider of the information and the grower users. Likewise, there are opportunities for more efficient means of information collection and processing, but IPM represents a small move away from the current trend in capital intensive farming.

In considering the potential acceptability of IPM, it should be noted that the infrastructure and traditions exist in some areas (eg., in California, where private farm advisors have become established, consistent with the high degree of regulation of agricultural activities), but IPM services delivered by private parties would be seen as a new idea in other areas.

There is some set-up cost involved in developing and testing out IPM techniques. This work has primarily been carried out by university and USDA sponsored researchers, but some small firms have been successful in developing their own techniques and adapting those developed with public funds. In addition, some pesticide manufacturers have developed parts of IPM programs as vehicles for the commercialization of their products (such as the information provided by the Zoecon Corporation for effective use of their insect lures.)

These characteristics create an environment particularly suited to small, localized firms, providing services via high-labor and low-capital mechanisms, and dealing in information and innovation.

Experience to Date

Government sponsored or run programs have predominated, reflecting the unique capabilities of the land grant system for developing and proving out new ideas of use to the farmer. Among the scouting and pest management projects examined by APHIS and EPA, the program participants experienced a decline in pesticide use and production costs, and increases in yield and profits, and must therefore be deemed successes. 7/

Studies conducted for EPA's Office of Research and Development on farmers' considerations of risk have indicated the preferability of information, as opposed to insurance or other mechanisms, as a means for reducing growers' uncertainties. 8/ In this context, pest infestation information and other components of IPM programs can be cost effective means for maintaining profits and productivity, while reducing environmental exposure to pesticides.

Results from a Ph.D dissertation from the University of California suggest that the spread of IPM can best be promoted by focusing support on the providers of information (as opposed to the users of the information.) 9/ Governmental policies to encourage an expanded supply of information services might include price subsides to the information providers, training of potential IPM practitioners, or cooperative development of pest management techniques for particular crop/pest situations. Although the limited crop and geographical bounds on that study restrict the ability to generalize from it, it is worth noting, however, that this finding is consistent with the long-established practice of USDA providing area specialists to deal with particular crop production problems.

Over the past few years, numerous pest control advisors or farm management firms have achieved recognized success. 10/ Success is measured not only in their own financial well-being, but in their ability to improve their clients' profit situation.

EPA Mandate

Conduct of the pesticides registration scheme requires EPA to understand IPM well enough to make intelligent regulatory decisions. In addition, Section 20(a) directs EPA to conduct a research program, giving "priority to research to develop biologically integrated alternatives to pest control." Finally, Sec. 4(c) directs EPA to provide information on IPM to those pesticide users requesting it.

EPA Actions

EPA is evolving a statement on its stance and programs on IPM, with particular attention to the research needs and where the research should be conducted. EPA is looking into the development of IPM in urban settings. EPA is also providing materials potentially useful to persons interested in applying IPM to their pest control problems to USDA, for distribution through the Cooperative State Extension Service. IPM will be considered among alternative pest control practices in RPAR, cancellation and suspension decisions. Through its research, information distribution and regulatory actions, EPA intends to help create a climate that is conducive to the further development of a healthy vigorous system of private providers of IPM services.

APPLICATION TECHNOLOGY

The Agency feels that its actions may also have an effect on the portion of the pesticide industry which is concerned with application technology. EPA regulations should stimulate changes in methods of application, since more efficient application can reduce the amount, and therefore the risks, of pesticides applied. This is not a big push, but the pressure is there. The industry seems aware of the need to refine application techniques, and users, of course, are interested.

As an illustration of the potential savings involved, it has been estimated that for a typical application of an agricultural foliar insecticide, 40% of the quantity applied winds up away from the target area through drift, misapplication, volatilization, leaching and surface transport. Another 15%, although falling in the target area, does not land on the target crop. Of the remaining 45%, only 4 % is typically applied near the target insect, and the bulk of that makes no contact with the insect. Thus, less than 1% of the amount applied is absorbed by the insect through contact, inhalation and ingestion. The details are different for different crops and pesticide types, but sizable opportunities exist for reducing the quantity of pesticides applied without sacrificing any benefits through the reduction of drift, improvement of placement within the target area and attracting target pests to pesticide deposits. 11/ Innovations in recent years include ultra-low volume (ULV), microencapsulation and time-release formulations and their attendant application equipment; chemicals and devices for improved baits, lures and traps; and other improvements stemming from an increased understanding of the aeronautical and physical principles underlying pesticide applications. 12/

Any market created for innovations in application methods need not be restricted to large companies. Small firms are as viable a source for new approaches to research, development and production of application equipment as are larger firms.

CHILD PROTECTIVE PACKAGING

The Agency is planning to publish proposed child protective packaging regulations early in 1977. Use of child protective packaging will enable some products to be used in the home that otherwise would not have been available. These are products with an inherent toxicity making them candidates for restricted use.

A recent study showed that the total annualized incremental cost of child protective packaging will be less than $6 million, which is less than 8 cents per container subject to the regulations. This cost should not be a serious problem for manufacturers or formulators, particularly since it means that these products can be kept in the home market. 13/

Developers and vendors of child protective packaging and closures include a variety of large and small firms. The regulations will expand the market for special packaging and both large and small companies will be stimulated to compete on the basis of innovative designs, price, and performance.

USERS AND APPLICATORS

Certification and training of applicators, as a condition on the use of restricted use pesticides, is not expected to deny agricultural users the benefits of such products, nor to make them more dependent on commercial applicators than in the past. The certification and training program has ample provision to allow such agricultural users to qualify as private applicators.

Section 3(c)(5) provides that the Administrator "shall not make any lack of essentiality a criterion for denying registration of any pesticide." This allows multiple products to be introduced to compete for the same use patterns. When considering products for cancellation or suspension, EPA weighs the costs and benefits of the products' uses, particularly the effects on productivity in the affected agricultural sector. A cancellation decision typically has different impacts on agricultural users in different parts of the country, and some minor uses may be adversely affected. Where cancellation occurred, the Agency's judgment was, however, that these disadvantages were outweighed by the advantages of the cancellation. 14/

Some products intended for home use will be available only as restricted use products, although the exact numbers depend on re-registration decisions between now and October 1977. This probably will cause some increased reliance on professional applicators in these instances, creating some benefit to that sector of the industry. Contacts with the professional applicator industry show optimism that classification of pesticides into restricted and general use will be good for business.

APPENDIX
STUDIES

Several studies done in recent months have given the Agency a more accurate idea of the side effects of our actions and some suggestions for how the negative effects might be lessened.

ECONOMIC IMPACT OF REGISTRATION DATA REQUIREMENTS

EPA is in the process of revising the Guidelines for Registering Pesticides, proposed in June 1975. Concurrent with the development of the Guidelines is an assessment of the cost impacts of the testing requirements. EPA estimates on the Guidelines as proposed in 1975 amounted to an incremental one-time cost of $68 million. 15/ Industry's own estimates have been much higher. A recurring problem has been to identify what increased costs are due to data requirements made progressively more stringent in the 1960's and 1970's and which are attributable to the Guidelines themselves. As the Guidelines stood in mid-1976, the incremental one-time costs were roughly estimated at $97 million or $29 million annualized over a 5 year period. As the Guidelines reach the point of re-proposal in 1977, the costs will be summed up and reported.

INCENTIVES AND DISCENTIVES

A study has recently been completed on incentives in the pesticide industry. A working conference took place in October 1976 and EPA received the final report in January 1977. 16/ The study concluded that although action by EPA, USDA, and the industry cannot be expected to bring about a major change in pest control innovation, EPA and others could take some incentive measures to improve the likelihood of pest control research and development. Steps recommended for implementation as soon as possible included specific actions to:

* Decrease regulatory hindrances to research and development
* Reduce the risk of product development by industry
* Increase the availability of minor use pesticides
* Lengthen patent life
* Advertise safety on product labels
* Increase use of integrated pest management
* Increase information and training for pesticide users.

A STUDY OF SMALL BUSINESSES

A study was conducted in 1975 for the Experimental Technology Incentives Program and the Small Business Administration on "The Impact on Small Business Concerns of Government Regulations that Force Technological Change." 17/ Although FIFRA and the FFDCA are laws which bring about technological change, the effects of these statutes were not examined directly in this study. The statutes considered were of the "minimal standard" or "allocation/distribution" type, and not "permission/prohibition" variety which characterizes FIFRA and FFDCA. In spite of the lack of direct applicability of the study to the specifics of the pesticide regulatory situation, some of the findings are worthy of mention:

Among the firms studied, the costs of compliance (per unit of output) with the statutes under consideration rose as size of the firm decreased (reflecting economics of scale,) except for the very smallest firms. This is related to exceptions that are made for smaller firms (in the form of extension, modifications and exemptions), and to flexibility of enforcement. In the opinion of the contractor, flexible enforcement is more common among the older, more established regulatory bodies, but even the "younger, brasher outfits like EPA" have "confronted and accepted the impossibility of total enforcement."

Smaller firms face higher interest changes, less advantageous terms of payment, and less availability of money to finance spending required by regulatory demands than larger firms. There is a tendency to be able to pass through either nearly all or nearly nothing of the costs incurred. The further down the production - distribution chain a company is located, the less likelihood of cost pass-through.

The small firms studied also had non-financial problems with compliance which seem to be shared to some degree with pesticide registrants -- time and paperwork burdens, confusion over regulatory requirements, difficulties in dealing with agency personnel and in the formulation of legislation and regulations.

The study notes the benefits partly off-setting the costs of regulation, citing "a wide range of industries, including many small businesses, (which) receive indirect benefits through sales of materials, equipment, supplies, and services to manufacturers of pollution control equipment and the like."

The report recommends several kinds of action to the Small Business Administration, including intervention and advocacy in the federal legislative and regulatory process; financial assistance via Regulatory Economic Injury Assistance Loans and the like; technical assistance of several types; and programs to foster cooperative action among similarly-affected small businesses.

NEW, INNOVATIVE PESTICIDES

A study on "New, Innovative Pesticides: An Evaluation of Incentives and Disincentives of Commercial Development by Industry," is being conducted for OPP. Tentative findings include the expectation that, over the next ten years, there will be a steady flow of products from the chemical industry for pesticide uses, but that innovative products (such as bacterial, pheromonal and viral pesticides) will not be registered and available in sufficient quantities to dramatically substitute for conventional chemical products, although some are expected to complement the use of chemicals in selected markets. These conclusions are based both on analysis of economic factors and on the views of pesticide users.

By viewing profit as incentive for product development by private industry and risk as disincentive, two limiting factors on the development of innovative products are their generally narrow spectrum (limiting the ultimate market size) and the lack of proprietary protection. Therefore, the government should consider the following changes to encourage develoment of innovative products.

* Means to give some measure of proprietary protection to firms seeking to market naturally-occurring agents.

* Means to reduce risk to the developers, possibly through support for R & D costs and modification of performance liability constraints.

These are preliminary conclusions, but it is worthwhile to note that the measures seen as helpful in encouraging development of innovative products are to some degree in conflict with the promotion of an atmosphere of competition.

CHILD PROTECTIVE PACKAGING

Another recent study looked at the cost of the child protective packaging which will be required later in 1977. 18/ It showed that the total annualized cost will be less than $6 million and less than 8 cents for each container subject to the regulations. The effects of the special packaging regulations were discussed further in the text.

Footnotes

1. Memorandum, March 5, 1976, to Deputy Assistant Administrator for Pesticide Programs from EPA General Counsel.

2. The "data validation" problems will not be solved by this legislative action.

3. Incentives for Research and Development in Pest Control, Volume II, Appendices, 1976, EPA-540/9-77-009, pp. 1-12.

4. The Pesticide Industry -- An Overview, William Blair and Company, July 7, 1975, p. 15.

5. Ibid., and Incentives for Research and Development in Pest Control,op. cit.

6. Contemporary Pest Control Practices and Prospects, Vol.I of Pest Control: An Assessment of Present and Alternative Technologies, National Academy of Sciences, 1975, pp. 340-386.

7. An Evaluation of the Scouting Activities of Pest Management Programs, 1974, EPA-540/9-75-014, pp. 34-38.

8. Crop Insurance and Information Services to Control the Use of Pesticides, draft final report, 1974.

9. The Diffusion of Pest Management Information Technology, Wayne Richard Willey, Ph.D. dissertation in economics, University of California, Berkeley, 1973.

10. Contemporary Pest Control Practices and Prospects, op. cit., p. 397, and volume III, Cotton Pest Control.

11. Production, Distribution, Use and Environmental Impact Potential of Selected Pesticides, 1974, EPA 540/1-74-001, pp. 106-108.

12. Incentives for Research and Development in Pest Control,Volume II, op. cit., pp. 8-12, and Contemporary Pest Control Practices and Prospects, op. cit., 365-380.

13. Economic Impact of Child-Proof Packaging Regulations on the Cost Of Pesticide Containers in the United States, draft screening study, Office of Pesticide Programs, U.S. EPA, 1977.

14. DDT: A Review of Scientific and Economic Aspects of the Decision to Ban Its Use as a Pesticide, prepared for the Committee on Appropriations, U.S. House of Representatives, by the U.S. EPA, July 1975.

15. Incremental Cost Impacts of the 1972 FIFRA, 1976, EPA-540/9-76-002, p. 41.

16. Incentives for Research and Development in Pest Control, volumes I and II, op. cit.

17. September 1975, CAI-800-F-2R.

18. Economic Impact of Child-Proof Packaging Regulations on the Cost of Pesticide Containers in the U.S., op. cit.

STATEMENT OF
HONORABLE DOUGLAS M. COSTLE
ADMINISTRATOR
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON AGRICULTURE AND FORESTRY
UNITED STATES SENATE
MARCH 11, 1977

Good morning, Mr. Chairman, and Committee members. I am very pleased to be here with you this morning for this hearing on the Federal Insecticide, Fungicide, and Rodenticide Act.

As you know, the Senate voted my confirmation as Administrator of the Environmental Protection Agency last Friday. I am to be formally sworn into office by the President this afternoon. I am present before your Committee today to listen and learn, and Dr. Breidenbach, who is serving as Assistant Administrator in charge of the pesticide regulatory program, will present the Agency's statement.

Although I had some involvement with pesticide regulation as Deputy Commissioner and then Commissioner of the Connecticut Department of Environmental Protection from 1972 to 1975, the

issues which have arisen in the implementation of the 1972 Amendments to FIFRA are for the most part new to me. I know that pesticide regulation is an extremely complex and important area of EPA responsibility. I also know that there are difficult problems which have to be solved. I am pleased to be here today to learn directly from you and from the discussion that will follow.

I would like to emphasize my desire to work closely with this Committee. I regret that I have not yet had the opportunity to meet with you, and hope that I can do so before too long.

With your permission, Mr. Chairman, I will call on Dr. Breidenbach to present the Agency's testimony.

STATEMENT OF
HONORABLE ANDREW W. BREIDENBACH
ASSISTANT ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON AGRICULTURE AND FORESTRY
UNITED STATES SENATE
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Mr. Chairman, administration of the Federal Insecticide, Fungicide, and Rodenticide Act is a tough job. The law charges EPA with the responsibility to protect health and the environment from the adverse effects of toxic chemicals manufactured for the very purpose of adversely affecting pests, while assuring that the great good they can perform remains a productive part of the national economy. The law provides us with the basic rationale and tools needed to make decisions on pesticide use which strike the necessary balance between environmental and economic concerns. As I will describe, the job is made difficult by issues having less to do with that balance than with rival economic interests, paperwork, and problems inherited from the past.

We are making progress. Major rulemaking has been conceived and promulgated with full participation from many interested parties. Most of the States have done a magnificent job in cooperating with EPA to establish workable and sensible applicator training and certification programs; 49 State Plans have been submitted to EPA for approval, and over 330,000 applicators have participated in training programs. A system has been developed for intensely

reviewing pesticides that may be posing an unacceptable hazard to the environment or the public. The system includes receiving and considering both benefit and risk information received from the public. The new Scientific Advisory Panel established by the 1975 FIFRA amendments has met three times to consider proposed Agency rulemaking, and promises to be active and informative. The Administrator's Pesticide Policy Advisory Committee, established to provide input from a wide spectrum of interested agricultural, industrial, environmental and governmental vantage points, has been extremely helpful in identifying and discussing significant issues. Hundreds of thousands of individual actions, including experimental use permits, emergency exemption requests, tolerance petitions and requests for new, supplemental and amended registrations have been handled over the past four years. It has been a busy and productive time.

But all is not well. The two major tasks assigned by the 1972 amendments were, as you are certainly aware, the reregistration and classification of all pesticides presently marketed in the United States, and the certification of applicators to use restricted pesticides. The former task has encountered serious difficulties, and is still -- over four years after the enactment of the 1972 law -- not close to completion. In looking over those four years and the chronology of events in the reregistration effort, several impressions particularly strike me:

-- the complexity of the task was originally underestimated, and further complicated by a series of new developments in 1976;

-- Agency resource needs were thus also underestimated, another problem exacerbated by the 1976 developments;

-- the problems encountered have been patched by the "bandaide" approach, and a thorough review of the situation, with long term, thoughtful resolution, is in order.

There are two primary problems impeding reregistration: data validity and trade secret litigation. I believe a brief discussion of these issues would be helpful.

One major problem is that of data compensation and trade secrets. It was always our belief that the mandatory data licensing provision of the Act was intended to be a mechanism to share costs of data development among all users of those data, and thus an incentive to research in the producing industry. Section 3(c)(1)(D) prohibits the Administrator from considering data developed by one manufacturer in support of subsequent registrations without permission of the data developer, or an offer to pay reasonable compensation by the subsequent applicant for use of the data. Section 10 of the Act specifies that trade secret data cannot be released nor, under 3(c)(1)(D), is it to be used in support of subsequent registrations regardless of the willingness

of an applicant to pay reasonable compensation. EPA's position has been that trade secret information should be narrowly defined, e.g., the manufacturing process and confidential formula. However, several registrants have asserted that all data in support of registration -- such as toxicity, chemistry, fish and wildlife, and efficacy -- are trade secrets, and thus are not eligible for use by any other registrant without express permission. This position, if correct, would leave little data subject to the compensation scheme under section 3(c)(1)(D). Ten cases are now pending in the courts, with injunctions or stipulations preventing the Agency from using the disputed data for registration or reregistration purposes without consent of the data developer.

This issue has an especially profound impact on the small formulator, who is generally incapable of developing data and has historically relied on that already submitted by another registrant. What this comes down to is a matter of how many pesticide formulators will stay in business, and who will control which formulators are in and which are out. Also at issue is the public's right to have access to data supporting pesticide registrations.

The second major problem concerns reregistration and classification. The original strategy for reregistration was to screen and separate pesticides into two basic categories:

(1) those suspected of posing an unreasonable risk to man or the environment; (2) those for which no evidence of potential unreasonable adverse effects was known. Pesticides falling into the first category were to be subjected to an intensive review with full data validation (scientific review and confirmation of results by EPA technical staff). Those in the second category were to be classified, their labeling updated, and examined for data gaps -- tests required to meet today's standards which were not performed in the past. The data supporting registrations of products in that category were not to be individually evaluated and validated, the assumption being that, for the most part, tests had been performed properly, results had been honestly reported, and testing deficiencies had been detected and resolved at the time of registration. Utilizing this strategy, the Agency believed the job could be done by the October 1976 (not October 1977) deadline.

Those underlying assumptions were proven invalid in 1976. Investigations by the Food and Drug Administration, the GAO, and a Senate Committee revealed questionable, even fraudulent, practices in laboratories conducting animal studies. In addition, an internal EPA review disclosed problems with the data in Agency files. Reregistration was halted in August of that year to consider the proper data validation approach. In December, the Senate Subcommittee on Administrative Practice and Procedure issued a draft

report concluding that Agency review of data was insufficient, and that the public was not being properly protected from the hazards of pesticides. Former Administrator Train made the commitment at that time to review test reports in Agency files before reregistration.

Because we must undertake the immense job of validating bio-effects data related to risks to health presented by pesticides, our job is correspondingly greater. It is not possible to accurately assess the amount of time this task will add to our other jobs, but we estimate -- after a thorough zero-based resource exercise -- that reregistration including data validation for all products will take, at the current resource level, 10-15 years.

This extended period forces us to readjust our thinking about accomplishing program goals. Policies developed on the assumption that reregistration would be accomplished quickly must be reevaluated, and new strategies planned. We are considering the following several ways to streamline our program and deal with the longer reregistration period:

Separate Classification From Reregistration

Although reregistration will not be completed for many years, most of the States are ready to begin implementing the applicator certification provision of the Act. The Agency

thus desires to classify products, apart from the reregistration process, by regulation. Classification could be accomplished on or near the October 1977 deadline, and take effect during the 1978 growing season. This approach would help minimize the hazards associated with the restricted products, and put to good use the hard work accomplished by the States, EPA Headquarters and Regions, and the Extension Service in training and certification.

Permit Conditional Registrations

A problem corollary to the lengthier transition period between old and new FIFRA is the matter of granting new registrations. Where trade secrets and data compensation are not at issue and applicants can submit or cite data to meet current requirements, registrations can be granted. However, there are certain data gaps which preclude a new registration from either submitting or citing now-required information. Many "new" products are actually just like products on the market ("me too" registrations) or utilize an "old" active ingredient in a different way than the products already registered. The question is, is it fair to keep "new" products utilizing old chemicals off the market until long-term data requirements (which current registrants are being given time to fill) are met? The Act clearly allows the current registrants to remain registered until reregistration or an intent to

cancel decision is made. I think it is important to establish whether or not Congress wishes current registrants to enjoy a competitive advantage over companies desiring to compete with like products "grandfathered" by the 1972 Act pending re-registration. The law does not specifically permit or specifically preclude conditional registrations, so Congressional direction in this matter would be welcome.

Define "Trade Secret"

The trade secret dispute could be clarified if the Congress specified which information should not be considered trade secrets. Clarification as to whether or not the Agency can use trade secret information "in camera" for purposes of comparing formulas of registered products and those of applicants is also needed.

Diminish Efficacy Review

It has become increasingly apparent that our scarce resources should be applied where they can do the most public good. One area in which we have devoted much time and attention is the review of efficacy data. In practice, especially for agricultural chemicals, efficacy is of limited duration, affected by geography, climate and regionalized pest resistance. Agencies such as the USDA Extension Service and even farmers themselves are in a better position to assess efficacy of particular products. With reregistration and attendant data validation demanding priority, it seems an

unwise use of our resources to spend the time to examine efficacy data while more important issues and registration activities suffer. EPA is therefore considering proposals which would require examination of efficacy data only for certain products or when required by special circumstance.

New Approach To Registration

Above all, I would like to broach for discussion the idea of regulating pesticides by a generic rather than a product-by-product approach. It became clear after grappling with the complexities of FIFRA for over four years, that there was far too much paperwork and attendant time devoted to individual product registrations, without commensurate public advantage. If the Agency were to adopt a technical-product-intensive registration scheme (for example, X technical-grade product is registered for A uses against B pests on C sites at D formulations), and most data, including the expensive long term animal feeding studies, were associated with the technical registration, several important benefits would accrue:

-- the data compensation issues would be largely confined to disputes between the hundred or so producers of technical material;

-- formulators utilizing a registered technical product in a manner consistent with the registration would have to cite much less data, and formulator registrations could be issued quickly with minimum review time;

the public interest would he best served in that Agency resources would be devoted to assessing the risks and benefits of all uses of a chemical at one time, more efficiently using scarce scientific and technical talent.

These are all important broad issues I have raised, and I urge the Committee to give them a thorough public airing to develop sound and responsive legislative direction.

That concludes my prepared remarks, Mr. Chairman.