

REVIEW OF EPA'S REGIONAL PESTICIDES PROGRAM

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Program Evaluation Division

Office of Planning and Evaluation

Office of Planning and Management

I. INTRODUCTION

A. Background

Since December 1974, the Program Evaluation Division has been conducting a long-term review of the Agency's pesticide program under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). The review has already produced a number of short, operationally relevant issue papers on various aspects of the program. This report was initiated by a joint memorandum from Messers. Alm, Breidenbach and Legro. It was undertaken in response to a request to review the current role of the Regional Offices in implementing the pesticide program and to formulate appropriate recommendations. The study was conducted by a Review Team composed of representatives from the Office of Pesticide Programs (OWHM), the Pesticide Enforcement Division (OE), and the Program Evaluation Division (OPM). Pesticide program managers at Headquarters and all ten Regions were interviewed. In addition, the Team visited six State pesticide offices. On Regional and State visits, the Team was accompanied by a Pesticide Branch Chief from a Region other than the one being visited.

The next section of this report summarizes our general conclusions. Chapters II-IV detail our findings and recommendations on the Regional role in the major areas of program activity. The final Chapter V provides some perspectives on the allocation of Regional pesticide manpower resources.

B. General Conclusions

The pesticide strategy document identifies three major areas of program activity: supply control, use control, and hazard evaluation. The main elements of supply control are registration, suspension and cancellation of registrations, tolerance setting, and producer and market place surveillance. Use control involves training and certifying applicators, ensuring appropriate labeling, regulating storage and disposal, investigating accidents, and enforcing against improper pesticide use. Hazard evaluation is the accumulation and assessment of data regarding the impact of pesticides on man and the environment.

In general, the Review Team was favorably impressed by the Regional pesticide programs. Despite meager resources, the Branches do a good job of fulfilling their major responsibilities. This is particularly true of supply enforcement activities, which have historically been the focus of the Regions. Not only are inspection and surveillance commitments met, but the Branch Chiefs point to an overall decrease in the number of unregistered establishments and pesticides. Generally, the Branches achieve good coverage of manufacturers and products, although some improvements are necessary in the development of the inspectors' work plans. In most Regions the necessary enforcement actions are taken in a timely fashion. Branch Chiefs report very few repeat episodes dealing with the same firm and the same problem.

Much of the success of the enforcement effort results from the decentralized nature of the program. The Pesticides Enforcement Division provides general guidance, but the Branches do most of their own planning and decision making. Some of the success also stems from the fact that the supply enforcement effort is a well established program with precisely defined objectives and experienced personnel.

Further along these lines, it is our conclusion that the Regional organizational structure apparently has little to do with program success in general. The programs in Regions II and IX, where enforcement and technical assistance are separated, do not work perceptibly better or worse than the other eight Regions where all pesticide activities are in one Branch. Much more important than structure is function. The Regions that are most effective have considerable overlap between enforcement and program activities. Personnel perform a variety of tasks which may extend into either sphere of responsibility. Inspectors are not just enforcement agents but educators and State liaison assistants as well. Technical assistance staffs provide aid and support in ensuring that pesticide manufacturers and users understand and do not break the law. The Review Team encourages all Regions to follow this coordinated approach in carrying out their responsibilities.

The 1972 amendments to FIFRA, however, added new responsibilities to the control of pesticides, largely elements of use control and the hazard evaluation function. Regional activities in these areas are less well established. This is, at least in part, a function of the fact that Headquarters has not fully articulated the Agency's policy in these areas. As more emphasis is given to these newer responsibilities, the Regional role will change rapidly. The potential policy and methodological problems will have to be solved through a joint Headquarters/Regional effort.

An example of the problems with the 1972 Amendments is that the technical assistance goals of the Pesticide Branches are less specific than are the supply control goals. The primary Regional objective has been to foster the development of State enabling legislation and operational programs that will fulfill the requirements of amended FIFRA. Under the best of circumstances, persuading States to set up new regulatory programs is not easy. Unfortunately, the Regional

Branches have been hampered by inadequate and shifting guidance from Headquarters offices. This poor guidance results partly from Congressional uncertainties and partly from a failure of all Headquarters units involved to meet deadlines and to coordinate decision making activities. Other technical assistance activities have had additional problems. The Branches generally lack both the information and authority to make decisive policy judgments in technical assistance areas. This minimizes their effectiveness and consequently impairs their relations with States, pesticides manufacturers, and pesticides users, all of whom expect the Branch to represent the Agency. Furthermore, most Regions do not have sufficient scientific expertise to respond to technical issues or environmental problems that arise with respect to pesticides, although in some cases (e.g., participation in the National Monitoring Program) Regions themselves have failed to respond to opportunities to participate. Nevertheless, most technical assistance sections of the Pesticide Branches are not well equipped to provide required technical assistance, let alone be active in data gathering, pesticide education or related activities.

The Review Team found that the technical assistance potential of the Regional Offices is not being fully utilized. Given more responsibility and greater resources, they could better handle duties still tightly controlled by Headquarters, for example, supplying basic registration information, doing some types of product registration, approving State certification plans, and providing adequate support for accident and use investigation. Admittedly, at this stage of the implementation of amended FIFRA, technical assistance activities are much more dependent on Headquarters policy guidance than are enforcement activities. Consequently, immediate decentralization of the major activities of the Office of Pesticide Programs may not be possible. Nevertheless,

certain additional responsibilities should be delegated to the Regions at this time, and much more should be Regionalized in the future. The Review Team is hesitant to recommend too much registration decentralization until after reregistration has been completed. On the other hand, delegating to the Regions the responsibility for making the final decision on State plans for Section 4, 5f, and 24c should be a very high priority, since the Regions have done much of the work and are the main lines of communication to the States. There is no question that once October 1977 is passed, Regional capabilities should be strongly augmented, especially in the area of scientific expertise for registration and enforcement ID review. In the meantime, the Review Team urges that no reductions be made in total Regional pesticide manpower. While not all Branches are equally constrained, some seem to be understaffed in relation to their responsibilities. If any action is taken with regard to resources, it should probably be a reallocation among Regions. Chapter V offers some perspectives in this regard.

One area of weakness was clearly apparent during the Review Team's visits: the Regions must make a much greater effort to involve States in program planning and implementation. To date Regions have met with mixed success in obtaining cooperative agreements with States for enforcement and other activities. The problem is that often the Regions ask the States to cooperate without first indicating their willingness to cooperate in return. For example, some Regions do not usually discuss their workplans with the States, and few routine attempts are made to coordinate enforcement inspections and surveillance.

With the expansion of activities under FIFRA, fostering State cooperation is imperative. EPA pesticide resources will never be great enough to do everything desirable; they must be programmed to avoid unnecessary duplication of State efforts.

II. SUPPLY CONTROL

The Agency's objective with respect to pesticide supply is to ensure that available products are safe and effective when used as directed. The activities dealing with supply control include registration of pesticide products, registration of producer establishments, surveillance of producers and retailers, control of imports, experimental use permits, special local need registrations, and emergency exemptions. This chapter briefly describes the activities now performed by the Regional Offices, discusses the relationships of the Regional Offices and Headquarters and makes several recommendations.

A. Product Registration.

Section 3(a) of the FIFRA, as amended, requires that all pesticides used in the United States be registered with EPA. The conditions of registration are contained in Section 3(c)(5) and explained in detail in EPA's Section 3 regulations. Recent extensions of the Act have given the Registration Division (OPP) until October 1977 to complete the registration or reregistration of an estimated 30,000 products.

Regional Role. As presently organized, the Regional Offices have been delegated only minimal registration responsibilities. Agency management has reasoned that: (1) existing data cannot be duplicated and stored in each Regional Office at a reasonable cost; (2) the minimum necessary level of expertise can not be developed in each Region; and, (3) a centralized operation is needed to ensure a consistent national registration policy.

Originally the study team recommended that OPP immediately transfer an additional position to each Regional Office to serve as the reregistration specialist. A subsequent evaluation of the reregistration process has revealed that even though this recommendation is desirable, it is not now feasible. A process for registering /reregistering the 30,000 pesticides has now been

established in which the Product Manager is the focal point. A notice was published in the February 17, 1976 Federal Register directing applicants to address all inquiries to the Product Manager responsible for the product's active ingredient. The notice published Product Manager telephone numbers and active ingredient assignments. If there is to be a chance of meeting the October 1977 deadline, OPP must stick with the current process. Until the reregistration workload is completed the Regional Office should refer manufacturers and applicants to the appropriate Product Manager.

After October 1977 the possibilities for decentralization (particularly the approval of distributor labels and minor label changes) should be further investigated. A demonstration project, as was at one time proposed for FY 77, would be the best way to determine what changes would be efficient and effective. In the meantime, OPP should know that Regions are spending considerable time (up to 30 hours per week in some places) answering basic questions concerning registration. Adequate provision should be made to enable Regions to handle routine inquiries and dealings with local people and companies.

Recommendation 1: OPP should complete a pilot program in FY 1978 to assess the feasibility and cost-effectiveness of decentralizing certain registration functions.

Headquarters Support. The Pesticide Branches in the Regional Offices depend on Headquarters for policy guidance and assistance to answer questions directed to the Regional Office and to perform assigned duties properly. Regional personnel interviewed by the Review Team reported that the support received from the Office of Pesticide Programs (OPP) has been inadequate. Inconsistent policy guidance, processing delays and lack of response were mentioned often as problems which adversely affect the Regional Offices and the Pesticide Branch staff. At the same time the service which the Agency should be providing to the

public has suffered. Delays due to Congressional uncertainty, changed rules and internal inconsistencies have adversely influenced the effectiveness of the Regions and given EPA an unnecessarily bad public image.

Recommendation 2: Regulations and policies should be promulgated on schedule. The Office of Pesticides Programs should complete the following items by the designated deadline.

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|-------------------------------|-------------------|
| - microfilm of product labels | August 1, 1976 |
| - disposal regulations | August 15, 1976 |
| - §5(f) regulations | September 3, 1976 |
| - §24(c) regulations | November 1, 1976 |
| - packaging regulations | January 15, 1977 |

The Standards and Regulations Division of the Office of Planning and Management should provide assistance as necessary and help to ensure that these deadlines are met.

A common complaint in the Regions is that getting answers from OPP is difficult, if not impossible. (PED, on the other hand, always is quick to help.) Frequently OPP "authorities" are not able to provide answers, and in many cases the person contacted is not responsive at all. One Region finds that obtaining information from the Registration Division is so hard that the first thing they now do is call their Headquarters Pesticides Enforcement Division coordinator for assistance. Notwithstanding the designation of the Product Manager as the contact for reregistration questions, Regions still must be able to get responsive answers to other kinds of questions that arise.

Recommendation 3: OPP must design a process for ensuring that Regional inquiries are promptly answered and that all responses are definitive and consistent. The Operations Division Regional coordinators, like their counterparts in the Pesticides Enforcement Division, should have the authority, capability, and responsibility to help Regional personnel get answers from all OPP personnel to their questions, and stand behind the decisions given.

Currently, the Regions lack basic data--chemical formulation, toxicity, target pests, usage sites--about most pesticides they are regulating. This is a major reason why they remain so dependent on OPP (particularly the Registration Division) for information. The Pesticides Analysis and Retrieval Control System (PARCS) has been designed to provide to the Regions not only

copies of all product labels, but also cross-referenced materials about pesticide composition and intended use. It is imperative that the Regions receive the basic system components as soon as possible.

Recommendation 4: The Technical Services Division should complete a plan for making PARCS microfiche available not only to the Regional Offices, but to other groups involved in pesticides use as well (e.g., State agricultural officials, County extension agents). The plan should include considerations for providing the necessary microfiche readers and recommend financial arrangements for microfiche distribution. A user manual should be ready to go with each shipment of the microfiche.

B. Surveillance of Producers and Retailers.

Section 7(a) of FIFRA, as amended requires registration with EPA of all establishments producing pesticides for use in the United States. Section 7(c) requires producers to inform the Agency annually of the types and amounts of pesticides produced, sold and distributed. Section 9 authorizes EPA employees to enter producing establishments to inspect and obtain samples of pesticides released for shipment and to examine the collected samples to determine whether they comply with the provision of the Act.

Inspection Strategy - Marketplace inspections and producer surveillance appear to operate efficiently and have been effective in securing industry compliance with the new registration regulations. Most Regions have completed the initial effort to inspect every establishment in the last two years. Now that this first step is past, the industry compliance effort must be more carefully directed by a system of priorities based on four factors:

- 1) Hazard of the product.
- 2) Volume produced.
- 3) Violative history of the firm and/or product.
- 4) Sampling history of the product.

Information about these factors is only partially available to the Regions in a usable form. For factor #1, hazard generally relates to toxicity, persistence, and availability of antidotes. Specific information of this sort is on each product

label, but complicated and careful manual searching would be required to develop specific hazard information. In any case, most Regions don't have a complete set of the labels. OPP has begun distribution of the PARCS microfiche list which indicates relative toxicity on a 1-5 scale.

For factor #2, annual production reports (§7c) are being coded into the Establishment Registration Support System (ERSS) which is already available to and utilized by Regional enforcement programs.

For factor #3, PEMS Violative History Reports are available, but they are frequently not kept up to date by the Regions. In fact most Regions use their own files as the primary source for company violative histories.

For factor #4, the Pesticides Enforcement Management System (PEMS) "Quarterly Sampling Report" lists all the dates when a particular product was sampled. This report is widely used to assure regular sampling of individual products.

These four basic pieces of information are provided to the Regions through four different printouts, with the result that the Regions must make 120,000 separate manual references (30,000 products x 4 criteria) to assemble the basic data for development of a Regional sampling strategy. Better coordination of the references for the design of sampling strategy is needed if the sampling program is to be effective.

Recommendation 5: The Pesticides Enforcement Division, with increased support from the Office of Pesticides Programs, must assure that the Regions have all the necessary data to develop comprehensive inspection strategies. Specifically, the Quarterly Sampling Report should be improved by the addition of three pieces of data: first, the 1-5 toxicity code from PARCS, second, some simple code (A-H?) for relative volume of production from the §7C reports*, and third, some reference to products on the Suspect Products List. Data from the Violative History Report should not be factored automatically into the Quarterly Sampling Report until it is up-to-date and accurate. Meanwhile, the Regions should continue to rely on their files for this information.

*Volume of production is confidential information. Care will have to be taken to ensure that the Quarterly Sampling Report is used for internal planning purposes only.

Data support - As noted above, PEMS is intended to support the supply enforcement effort, including the development of the inspection strategy. However, it has been the subject of controversy for some time. In theory PEMS provides a nationwide record of all inspection visits made, all pesticides samples collected, violations, and the resulting enforcement actions taken. In practice, effective implementation of PEMS has been hampered by its design, which provides too much unused information and spreads important data over too many printouts. If PEMS is to be retained it must have: 1) complete, current, and accurate data input from all Regions; 2) computer programs which will serve as significant Regional as well as Headquarters tools; and, 3) close coordination and clear understanding between the Regional pesticides programs and PED on how PEMS is to be utilized.

PED currently has a contractor revising PEMS. This effort is focused on both cost reduction and systems improvement. Of course the most important first step is to create a simple process that will support basic Regional information needs without unnecessary data base maintenance.

Every Region stated that the PEMS Violative History Report was "all input and no output." Even Regions that are conscientious about entering data to the system utilize their hard copy files to determine a company's violative history. This is because:

- 1) Data is not always accurately coded into the system and sometimes is garbled by the computer program.
- 2) It takes much longer to request and receive a print-out in the Region than to go to the hard-copy files and manually obtain the violative history.
- 3) There are many gaps in the data base because some Regions are unable or unwilling to input required information on a timely basis.
- 4) Computer programs for data interpretation are not currently available to the Regions. Thus much of the data is not utilized.

The Review Team agrees with the necessity of continuing ADP support for the pesticide enforcement effort. This ADP support must, however, be based on legitimate Headquarters oversight and Regional management needs. There is no reason for it to include all data associated with the program.

Recommendation 6: The current redesign of PEMS should focus on developing a streamlined system that will be of practical use to all pesticides enforcement managers. For example, the violative history report could be simplified to contain only the following useful information: Establishment registration number, product number, ID number and date sampled, violation, action taken, and date of permanent abeyance.

Recommendation 7: Information in PEMS that is not useful to the Regional pesticides program should be deleted. The Scientific Support Branch must assure that the modifications come from the suggestions of pesticide program managers, and not just ADP specialists.

Recommendation 8: The Scientific Support Branch must develop computer programs for accessing and evaluating the data that will be in the streamlined PEMS.

Recommendation 9: Once PEMS is revised, PED should develop a user's manual that discusses the services and information PEMS can provide. This handbook should go beyond a technical description of how to enter data into the system, which is the purpose of the PEMS Regional Operations Guide and the PEMS Data Collection Manual. It should explain for the benefit of program personnel how PEMS can be utilized and what types of analyses can be performed.

Inspection Workload: Table 1 shows a wide variation among the Regions in the percentage of establishments inspected, and the number of products picked up at each establishment. In FY 75, 40% of all producer establishments in the Nation were inspected (2274 of 5590 total). The FY 76 Regional Guidance directed that establishment inspection activities are to be deemphasized.* The commitment by the Regions for FY 76 is to inspect only 1713 establishments (31% of the total).

* The FY 76 Regional Guidance instructions for establishment inspection include the statement "...the number of producer establishment inspections may be reduced with concurrent reduction in the number of samples taken." (P. 15) This reduction of effort was recommended because of improvements in the sampling system and greater emphasis on misuse enforcement.

TABLE I
Regional Producer Surveillance

<u>REGION</u>	<u>No. of Inspectors</u>	<u>No. of producing estabs.</u>	<u>No. Estab. inspected</u>	<u>% of all estab. inspected in FY 75</u>	<u>No. of products reviewed</u>	<u>Average No. of products reviewed per estab.</u>
I	3	185	116	62	184	1.6
II	8*	513	236	46	802	3.4
III	4	395	213	53	765	3.6
IV	8	1202	497	41	1136	2.3
V	7	983	357	36	1568	4.4
VI	5	590	245	41	942	3.8
VII	4	546	241	44	489	2.0
VIII	3	145	89	61	279	3.1
IX	5**	762	227	29	756	3.3
X	<u>3***</u>	<u>269</u>	<u>53</u>	<u>19</u>	<u>202</u>	<u>3.8</u>
TOTAL	50	5590	2274	40%	7123	3.1

* Does not include 2 import inspectors and 3 clerical.

** One additional inspector does case preparation full time.

*** The inspectors have extensive State technical assistance responsibilities.

*SOURCE: FY 75 FPRS data and ERSS information

However, in the first half of FY 76, establishment inspections were 38% greater than planned, 1145 actual vs. 831 commitment. (In the first half of FY 75 the Regions exceeded their commitment by only 13%). Apparently most Regions are continuing their efforts at the same level, in spite of the guidance.

Recommendation 10: Those Regions that have not as yet done so should reduce the man-years applied to establishment inspections and focus on higher priority needs.

In no Region did we observe a sufficient coordination of inspection activities with States. A 1974 GAO* recommendation that EPA make better use of State resources apparently has had little impact. Where adequate State pesticide enforcement programs exist, the Regional Offices should prepare a unified, non-overlapping sampling strategy. The activities to avoid needless duplication should be specified in formal enforcement agreements.

Recommendation 11: Regional Offices should base their strategies on the States' capabilities. As a first step, copies of the Regional Guidance, Regional commitments, and monthly or quarterly workplans and summaries, as appropriate, should be sent to the States.

Chemical Analysis- The four Product Analysis Labs (PAL) appear to be serving the program well. Every Region indicated PAL efficiency and reliability. Although not organizationally "clean," having four labs serve 10 regions is currently working satisfactorily. In some cases, the PAL's and manufacturers use different testing methods, which has caused some difficulties. These preliminary conflicts will be reduced as standard methods are defined as part of

*General Accounting Office, Pesticides: Actions Needed to Protect the Consumer from Defective Products. May 1974. p. 40-44.

the reregistration process. Also, a manual of chemical methods is now being jointly prepared by TSD and the Association of Official Analytical Chemists. However, to date there has not been a successful challenge to PAL evidence in hearings.

All four PAL's report to a Regional Surveillance and Analysis Division Director. Agreement on "quotas" for sampling must come from the PAL Director and the various Regions served. The Regional sampling program currently picks up about 5000 samples each year. Supposedly this is the laboratory testing capacity. However, it is obvious from Table 2 that lab output varies considerably. The high disparity in the number of samples analyzed per man year by each PAL should be reviewed.

Table 3 shows that the "quotas" match up reasonably well with the relative number of registered products in each Region, although Region IV is considerably short of its relative share. Table 3 also shows that those Regions served by

TABLE 2

Product Analysis Laboratory Workload for FY 76

<u>PAL</u>	<u>Man-years</u>	<u>Total Samples*</u>	<u>Samples per MY</u>
New York	10	1775	177.5
Bay St. Louis	8	1152	144
Denver	4	1000	250
San Francisco	<u>6</u>	<u>750</u>	125
TOTAL	28	4677	

* The number of samples the PAL's committed to do. Actual number of tests performed may vary.

SOURCE: Regional interviews

the New York or Denver PAL's have a larger relative share of tests run than those Regions served by the Bay St. Louis or San Francisco PAL's.

Recommendation 12: PED, in consultation with the Technical Services Division, the PAL Directors, and the Regional Pesticide Branch Chiefs, should develop guidance for the PAL's on quotas, priorities, residuals analysis, Headquarters support needs, manpower requirements, and related issues.

Scientific Support- Once a labeling violation, chemical discrepancy or efficacy problem has been identified during the inspection or subsequent product testing, the Regional Pesticide Branch is responsible for taking appropriate enforcement action. In many cases, before any prosecutorial decisions are made, the Branch requires scientific opinion about the seriousness of the violation. Through what is known as the ID review process the Branch sends the laboratory report and other pertinent data to Headquarters for review. Ideally, the Branches should have the scientific expertise to make their own determinations without having to go through Headquarters. Such expertise would also enable the Branches to assume more registration responsibilities and other technical duties. However, as mentioned earlier, resource constraints preclude the acquisition of such expertise at the present time.

Currently, the ID's are sent by the Branch to PED which transmits the package to the Registration Division for review. PED is creating a new scientific support section to do the ID review without routinely having to go through the Registration Division. This change should reduce the delays in the ID review process noted by the Regions.

Recommendation 13. Until the full development of the Scientific Support Branch capabilities, the Registration Division should follow more closely the progress of the ID through the review process to reduce delay. A simplification of the Division's current ID logging system would be extremely beneficial. On the fifteenth working day that the ID is in the Division the ID coordinator should contact the Region by phone and explain what is holding up the review and how much longer it is expected to take.

TABLE 3

Regional Product Analysis Quotas for FY 76

<u>REGION</u>	<u>Sample "Quota"*</u>	<u>% of Total Quota</u>	<u>% of Products</u>	<u>% of Producers</u>	<u>PAL Responsible</u>
I	250	5%	2%	3%	NY
II	625	13%	12%	9%	NY
III	300	6%	7%	7%	NY
IV	600	13%	24%	21%	BSL
V	1025	22%	17%	18%	Den-250, NY-600, SF-175
VI	552	12%	9%	10%	BSL
VII	500	11%	10%	10%	DEN
VIII	250	5%	2%	3%	DEN
IX	400	9%	13%	14%	SF
X	<u>175</u>	4%	4%	5%	SF
TOTAL	4677				

* The negotiated number of samples each Region is to send to its PAL.
Actual number sent may vary.

SOURCE: Regional interviews and ERSS data.

A few Regions mentioned problems in completing enforcement actions because of inconsistent procedures by OPP. The person who conducts a scientific review should sign the report and testify at any hearing or trial. Apparently supervisors of the scientists now sign-off on the findings, and they are frequently not prepared or qualified to appear in support of the conclusions in subsequent hearings on trials.

Recommendation 14: OPP should develop procedures with PED to ensure that whenever feasible the individual who reviews a product suspected of violating FIFRA is the same one who participates in subsequent enforcement procedures. However, to the extent possible Regions should be the primary source of expert witnesses for enforcement actions.

Some friction has occurred between at least one Region and the Chemical and Biological Investigation Branch (CBIB) laboratories. There is no mutually satisfactory standard operating procedure for resolving conflicts between EPA and a registrant's test data. Consequently, the Region was frustrated in attempting to prosecute a registrant for a product that EPA labs found ineffective but that the registrant's own tests showed met the performance criteria. CBIB contends that its evidence was conclusive enough to stand up in court. The Region did not agree. Although this case was eventually settled, the need exists for specific procedures to prevent future misunderstandings.

Recommendation 15: Representatives from the Technical Services Division of OPP, the Pesticides Enforcement Division, the Office of General Counsel, and the Regions should establish formal procedures for dealing with conflicting test results. A process for resolving any future Regional/CBIB disagreements or problems should also be prepared.

C. Experimental Use Permits

Section 5 of FIFRA provides for the issuance of experimental use permits to prospective registrants for the purpose of gathering or developing necessary data. Regional personnel are responsible for monitoring the permits to ensure that all conditions are met. Currently all permits submitted pursuant to §5(f) are approved in OPP, although the responsibility may be delegated to the States. The development and approval of State §5f plans must be a Regional responsibility as well as the monitoring of the subsequent permit program. The Act required publication of §5f regulations by October 1973. They are expected in the summer of 1976.

Recommendation 16: When States submit plans for State issuance of experimental use permits, the Regional Offices should have the lead responsibility for review and approval. Minimum acceptable standards for the State plans should be clearly set forth in the Section 5 guidelines.

D. Registration for Special Local Needs

Section 24(c) of FIFRA allows authorized States to register pesticide products for special local needs. This provision enables States to secure a needed product when no nationally registered product is available. The authority to approve §24c plans has not been delegated by the Administrator.

Recommendation 17: Regional Administrators should be delegated the authority to approve State special local use registration plans.

Recommendation 18: During the ninety day period when EPA can reject a State registration, both the Regional Office and the Registration Division should evaluate the proposed registration. The Regional Office should be responsible for assessing the local problem and economic impact of denial, while the Registration Division should evaluate safety and effectiveness. This latter responsibility should be delegated to any Region with a qualified scientific support staff.

E. Emergency Exemptions

Section 18 of FIFRA allows the use of nonregistered products under an emergency exemption. Currently, §18 exemption requests are made by the head of a Federal Agency, a State Governor, or other official designee and go directly to the Administrator. It is important that the Administrator make the final decision because of the controversial nature and/or national implications of granting an exemption. However, the Region should be consulted for its own assessment as soon as the request is received. In the past State/Regional/Headquarters coordination of exemption requests has not always been acceptable.

Recommendation 19: In any future §18 exemption request, the Regional Office must have major responsibility in assessing the problem and finding solutions. They must receive a copy of the request as soon as it arrives in Headquarters. Final action on the exemption should be based on the Regional Office recommendation with Registration Division concurrence. Copies of all State/Headquarters correspondence relating to the request should be sent to the Regional Office.

Recommendation 20: No §18 exemptions, under any circumstances, should be granted without Regional Office participation.

Recommendation 21: Exemption requests should not be renewed by the Administrator without a review to determine if the product should be registered for the use in question. The repeated exemption is, in effect, a de facto registration. Either the use should be registered formally or it should be disallowed except for extreme emergencies.

III. USE CONTROL

EPA's use control objective is to ensure that pesticides are handled in accordance with label directions. Activities undertaken in support of this objective include applicator training and certification, accident investigations and use surveillance. These activities are discussed in this section.

A. Certification of Applicators

FIFRA gives EPA the authority to classify especially dangerous pesticides "for restricted use." Only an applicator who has been certified as competent to handle them may do so. Each State is responsible for the certification of its applicators. The Pesticide Branches' highest priority activity for the past two years has been to assist States in developing acceptable certification programs. Progress has been slow for a variety of reasons, but with the extension of the implementation deadline from October 1976 to October 1977, enough time remains to finish the job in every Region.

The current pesticides strategy indicates that the Regions should provide final review and approval of State plans. However, this authority has not been delegated formally from the Assistant Administrator for Water and Hazardous Materials to the Regional Administrators. A draft change order (1255.3 change 2) providing for the transfer of this authority was once prepared but never issued. Because the Regions have had the lead responsibility and have worked long, hard and closely with their States, and because they are obligated to ensure that the plan is properly implemented, the Regional Administrator should be delegated the authority for final plan approval. OPP concurrence should be obtained, although even the concurrence requirement could be waived in the case of capable Regions.

Recommendation 22: Draft change order 1255.3 change 2, delegating certification plan final approval to the Regional Administrator, should be completed and issued by July 1, 1976.

Operation Division Support: The Operations Division (OD) in OPP established the basic requirements for an acceptable State certification plan. The Division now performs a vital support function in assisting the Regions with the certification problems that arise with certain States. While OD must be ready to provide timely help when requested, it must not initiate direct State contact without first contacting the Region. Such unilateral action can cause embarrassment to or difficulties for the Pesticide Branch.

Recommendation 23: The Operations Division, or any other Headquarters pesticide office, should not deal directly with a State on substantive issues without prior Regional consultation.

Recommendation 24: The Operations Division should provide comments on any draft State plan within ten working days. Although this has been a standing promise in the past, the deadline has rarely been achieved.

Funding Control. Federal funds are available to support State management of the certification program. EPA is administering grants totalling over \$5 million per year for this purpose. Another \$5 million of EPA funds have been transferred to USDA/Cooperative Extension Service for applicator training. Criteria for monitoring of these funds must still be established. The issue of who is accountable for funds channeled through CES has yet to be resolved.

Recommendation 25: The Operations Division and the Office of Program Development and Evaluation (in OPP), after consultation with the Regions, should specify who is accountable for each category of expenditure and what means should be taken to ensure that the certification and training objectives attached to the grants are accomplished.

B. Accident Investigations

Accident investigations are conducted by Regional personnel to provide OPP with necessary substantiation of the magnitude and characteristics of pesticide problems and to gather information for product labelling and registration decisions.

Unfortunately, the existing system (PERS: Pesticide Episode Review System) does not serve either purpose. Almost every Region indicated that accident investigation was its least productive activity. Although one work year of effort was ostensibly devoted to accident investigation in each Region, few were able to use it productively. Several Regions used the accident investigator as an additional consumer safety officer to make inspections of producer establishments.

Three fundamental problems with PERS were reported. First, the coverage of the system is spotty. Regional Offices receive accident reports from only a very few sources. Accuracy is often questionable, and, therefore, interpretation or extrapolation of the data is likely to result in misleading or meaningless conclusions. Second, the reporting forms (PERF: Pesticide Episode Reporting Form) were designed to minimize possible enforcement uses. The intention was to keep accident investigation a "blind" data gathering system to reduce the concern that reporting accidents would lead to enforcement actions. The result has been the exclusion of substantial amounts of vital information, thereby reducing the utility of the system. Third, the data entered into the system has rarely been used, probably because of the previous reasons. Therefore, submitting quality data has been a low priority activity in the Regions.

The output of PERS is minimal compared with the energy and resources that are required to run the system. A fundamental restructuring of PERS is needed. This remodeling should be done in the context of related data gathering activities. After all, accident investigation is only one way of collecting hazard information. Epidemiological studies, formal hospital or household surveys and use observations may be more effective and efficient methods for obtaining the same information.

PERS should operate in conjunction with other pesticide monitoring and assessment programs. The Technical Services Division is now developing a system to provide a structure for the collection and evaluation of pesticides hazard data. PERS should be a complimentary element of this system.

Recommendation 26: Responsibility for the management of PERS should be transferred immediately from the Operations Division to the Technical Services Division to insure its integration with the hazard evaluation system.

Recommendation 27: The utility of PERS vis-a-vis other hazard information collection alternatives should be assessed at the earliest possible time and appropriate revisions initiated.

C. Use Surveillance

A program of use surveillance is necessary to ensure that all applicators follow label directions and that only certified applicators use restricted products. Section 15B of the PED inspectors' manual explicitly describes the purposes of inspections. The range of goals extends from enforcing compliance with use directions to determining whether product label changes are needed. There are two parts to use surveillance activity: use observation and misuse investigation. Use observation consists of an EPA inspector being present during the application of a pesticide to determine if label directions are properly followed. Applicator consent is required, since EPA has no authority to enter private property unless a violation is suspected. Misuse inspections are investigations of specific alleged violations of the law. They are initiated when a possible breach of the law comes to the attention of the Regional Office. Misuse investigations are made to determine if an enforcement action is warranted.

The FY 76 Headquarters Guidance to the Regions indicated that forty percent of pesticides enforcement resources should be devoted to use surveillance activities. While the Regions all agreed that increased emphasis on use enforcement was desirable, there was strong sentiment that Headquarters was

trying to move too fast. The certified applicator provisions of the law do not come into effect until October 1977, so no enforcement in this area is yet required. More importantly, the Agency has just begun to deal with the complexities of pesticide use. Until the "rules of the game" have been codified in the Pesticides Enforcement Policy Statements (PEPS) series, Regional enforcement efforts will be fragmented and inconsistent.

The FY 77 Guidance recommends a reduction in use surveillance activity to thirty per cent of Regional pesticides enforcement resources. Increased emphasis is to be placed on establishing cooperative enforcement agreements with the States. The Review Team believes that strong State participation is essential for a successful use control program since EPA's resources are too limited to assure adequate local coverage and since State personnel often have better access to use information. Region X has taken the initiative in developing a mutually beneficial division of labor with its States. The Region will have responsibility for a strong supply control program, while the States will emphasize use enforcement. If a problem is too big or complex for one party to handle, the other will assist. Region IV (with North Carolina) and Region IX (with California) also have developed programs. These approaches are illustrative of the direction in which all Regions must head, namely, getting the States involved.

Recommendation 28: Before FY 77, a national meeting of all Pesticide Branch Chiefs should be held to discuss use enforcement. Representatives from the Denver NEIC, OPP, and PED should attend. Within one month of the meeting, PED should have prepared a document that summarizes the discussions held, and describes in detail appropriate strategies and activities for use surveillance.

Recommendation 29: In the time remaining before the applicator certification requirements go into effect pesticide inspectors should spend as much time as possible on use observation and acquainting applicators with the use requirements. Familiarizing potentially affected applicators with the Pesticide Enforcement Policy Statements should be a high priority for both Regional and Headquarters personnel in FY 77.

The law empowers EPA to respond to use by issuing either a non-punitive §9c warning or a §14(a)(2) warning which is the first step towards a civil action. In egregious cases, criminal proceedings can be instituted. All misuse enforcement cases currently have to be cleared by the Pesticides Misuse Review Committee (PMRC), consisting of members from PED, the Registration Division, and the Office of General Counsel.

Misuse review has been slow and cumbersome, partially because PED has provided no standard format for submission. Actions have been referred by the Regions in stages of preparation ranging from brief summaries to entire case files without any recommended action. Before the PMRC can conduct a review, it must summarize the file. Often the review that takes place after the paperwork is done is purely routine. In many cases, the PMRC review adds nothing of substance to the enforcement process.

Recommendation 30: The Regions should have the primary responsibility for handling use enforcement cases. PED should waive concurrence on §9c and 14(a)(2) warnings for most Regions now, and for all Regions as soon as they gain sufficient experience. During this period of use enforcement policy development, the Regions should provide PED with a simple one page "fill-in-the-blanks" summary of use warnings sent out.

Recommendation 31: Regions should submit misuse cases in a standard format that includes a proposed action. The standardized format should eliminate the need to make summaries in Headquarters. The PMRC should review submitted case summaries and make a recommendation within ten working days. The Regional offices must be given copies of any additional information that is provided on the case by the Registration Division.

Recommendation 32: The Scientific Support Branch of PED should revise the PMRC Manual to reflect recent policy and organizational changes and to prescribe formatting and procedural changes that will eliminate process delays.

Laboratory Support - The Regions require adequate laboratory support to discharge use control responsibilities effectively. The laboratories must provide analysis of residues, environmental monitoring of specific incidents, and scientific evaluation of the impact of suspect pesticide uses. The Regions do not receive

this necessary assistance now. For example, no clear policy indicates where Regions are to send use related samples for analysis (to a PAL, the NEIC, the Regional S&A laboratory, to TSD labs, or to a contractor).

Recommendation 33: The Directors of the Technical Services Division, the Pesticides Enforcement Division and the Denver NEIC should establish policy for the evaluation of residue samples. Analytic needs and priorities should be clarified, catalogued, and then communicated to the Pesticide Branches.

Most Regional Pesticide Branches are unaware of the technical and analytical support services offered by the National Enforcement Investigation Center (NEIC) at Denver. The NEIC, in turn, seems somewhat unaware of some of the problems involved in pesticide use enforcement. One possible cause of this problem is that the NEIC responds first to requests from the Regional Enforcement Division Directors, while the lead responsibility for pesticides enforcement is generally in the Air and Hazardous Materials Division.

In FY 76 the NEIC has 14 man-years for pesticide programs. To date, most effort has focused on support to the Office of General Counsel for the Chlordane/Heptachlor cancellation and to the Regions on NPDES permits associated with water discharges by pesticides manufacturers.

Recommendation 34: The Office of Enforcement, in consultation with PED, NEIC, and the Regions, should develop clear guidance on the NEIC's pesticides responsibilities and capabilities. This should include an understanding of priorities among the appropriate decision-makers in PED, the NEIC, and in each Region.

IV. HAZARD EVALUATION

Although the identification and assessment of the possible dangers inherent in pesticide use is one of EPA's most important responsibilities, hazard evaluation has not been emphasized as much as supply control and use control.

Recently, however, OPP has placed greater priority on the development of a Hazard Evaluation System (HES). The objective of HES is to provide a mechanism for structuring, interrelating, and evaluating data about the hazards of pesticides use in order to produce information useful for policy development

Regional participation in the design and operation of the HES is imperative since the Regions should be a continuous source of information about pesticide products and uses. Accident investigation is the only Regional activity which currently provides a formal hazard assessment input. Other Regional activities, e.g. enforcement and applicator training, generate useful information about pesticide problems. Also, the Regions may acquire an important role in monitoring pesticides in the environment, as is recommended in the National Pesticide Monitoring Plan. The Regions need a clear statement of their evaluation responsibilities. The Branch Chiefs from Regions V and IX have been selected to coordinate and integrate Regional inputs to HES. However, major features of the plan should be sent directly to all Regions for review. Regions have the responsibility to respond promptly and carefully to all requests for comments.

Recommendation 35: The DAA for Pesticides should complete the Hazard Evaluation planning effort by November 1976.

Recommendation 36: The Pesticides Enforcement Division should be involved in developing the HES. Pesticides inspectors are an important source of pesticide field information. Their experience and knowledge about product uses and problems should be a major input into the HES.

Recommendation 37: The Regions should be involved in the design, implementation, and operation of HES.

Recommendation 38: As HES requirements for ambient monitoring become defined, appropriate resources and directions should be provided by OPP to ensure close Headquarters/Regional/State coordination of effort.

The Pesticide Branches could conduct their enforcement and other regulatory activities more efficiently if they had the suspect chemical, suspect product, and suspect use lists prepared by the Technical Services Division and Criteria and Evaluation Division. The Branches report that nothing from these lists has ever been communicated to them. It is extremely important to distribute all available information. Furthermore, intelligence and advice from the Pesticide Branches themselves should be inputs to the development of the listings

Recommendation 39: The Operations Division should send immediately all available suspect chemical, suspect product or suspect use information to the Regions.

V. Manpower Resources

One of the major thrusts of this report is that Regional responsibilities for pesticide programs should be expanded. The Review Team believes that a greater decentralization of the program is desirable once the currently pressing legal deadlines have been satisfied. Only one out of five pesticides positions is now in the Regions (see Tables 4 & 5). On the other hand, air programs have nearly one of every two people in the Regions, and water programs over four out of five. This concentration of position at Headquarters is not in the best interests of the program. We recommend that the Agency begin now to manage the manpower resources devoted to pesticides in such a way as to make the implementation of a decentralization strategy possible. In the interim any reductions mandated in overall pesticides resources should be absorbed by Headquarters elements, rather than the Regions.

Some workload problems were noted during our Regional visits, although in several cases pesticide resources were not devoted to pesticide activities. A few Regions appear overworked, while others seem to be relatively over-staffed. The Review Team has compared in each Region the allocated personnel and the expected relative workload.

The assumption was made that the manpower for each pesticide activity should be proportional to the level suggested in the FY77 draft Regional Guidance. This model does not determine optimal position allocation (for example, the number of inspectors necessary to cover 1000 establishments). It only shows the preferred distribution of currently available manpower resources. Accordingly, the following weighting factors were used:

Technical Assistance (81 positions)

Two positions allocated to each Region (20 positions) the 61 remaining positions allocated as follows:

66.67% for applicator training and certification (40.66 positions)

22.22% for Section 24(c) and Section 5(f) responsibilities (13.55 positions)

11.11% for integrated pest management and accident investigation (6.77 positions)

Enforcement (111 positions - 2 import positions in Region II were not included)

Three positions allocated to each Region (30 positions) the 81 remaining positions allocated as follows:

33.33% for State cooperative enforcement (27 positions)

33.33% for producer surveillance (27 positions)

33.33% for use observations and enforcement (27 positions)

Criteria were then selected for apportioning available positions in each category among the ten Regions. The following parameters were used in determining the workload of each Region and the number of positions to be assigned.

Technical Assistance

Applicator Training and Certification (40.66 total positions)

--60% (24.4 positions) allocated on the basis of the number of

States in the Region (e.g. if a Region has 10% of all U.S. States

it would get 10% of these 24.4 positions: $10\% \times 24.4 = 2.44$ positions).

--20% (8.13 positions) allocated on the basis of the percentage of all

U.S. farmers and farm managers in the Region (e.g., if a Region has

14% of U.S. farmers and managers it would get 14% of these 8.13 positions: $14\% \times 8.13 = 1.14$ positions).

--20% (8.13 positions) allocated on the basis of the percentage of U.S. population located in the Region.

24(c) and 5(f) (13.55 total positions)

- 100% (13.55 positions) allocated on the basis of the percentage of all experimental use permits issued in the Region in 1975.
(This may not be a completely accurate projection of future 24(c) and 5(f) workload).

Integrated pest management and accident investigation (6.78 total positions)

- 33.33% (2.26 positions) allocated on the basis of the percentage of U.S. farmers located in the Region.
- 33.33% (2.26 positions) allocated on the basis of the percentage of the U.S. population located in the Region.
- 33.33% (2.26 positions) allocated on the basis of the percentage of involuntary pesticide poisoning hospital admissions in the Region.

Enforcement

State Cooperative Enforcement (27 total positions)

- 100% (27 positions) allocated on the basis of the percentage of States located in the Region.

Producer Surveillance (27 total positions)

- 66.67% (18 positions) allocated on the basis of the percentage of all U.S. pesticide producers located in the Region.
- 33.33% (9 positions) allocated on the basis of the percentage of all pesticide products made in the Region.

Use Observations and Enforcement (27 total positions)

- 16.67% (4.5 positions) allocated on the basis of the percentage of all U.S. farms located in the Regions.
- 16.67% (4.5 positions) allocated on the basis of the percentage of U.S. farmers and farm managers located in the Region.

--33.33% (9 positions) allocated on the basis of the percentage of the U.S. population located in the Region.

--33.33% (9 positions) allocated on the basis of the percentage of all involuntary pesticide poisoning hospital admissions located in the Region.

The results are displayed in Tables 6, 7, and 8 (Table 9 presents the Regional percentages used in the computation). More staff appear needed in Regions III and IV. The greatest single reduction is suggested for Region II, where, allowing for 2 customs and 10 Pesticide Analysis Laboratory personnel, the analysis indicated a loss of 6 positions.

Admittedly, any allocation formula is open to objections. However, the Review Team believes that this methodology represents a reasonable first step. More importantly, it is generally in accord with the impressions developed by the Team in the course of its Regional visits. We believe that any adjustments in Regional resources should be guided by the distribution ratios presented above.

TABLE 4

Headquarters/Regional Personnel Allocations
Air, Water, Pesticides

	<u>AIR</u> Reg.	HQ	TOTAL	<u>WATER</u> Reg.	HQ	TOTAL	<u>PESTICIDES</u> Reg.	HQ	TOTAL
A/C	293 (36.5%)	510 (63.5%)	803	1584 (78.5%)	435 (21.5%)	2019	81 (11.5%)	624 (88.5%)	705
ENF	309 (66.9%)	153 (33.1%)	462	737 (88.1%)	100 (11.9%)	837	113 (76.9%)	34 (23.1%)	147
TOTALS	602 (47.6%)	663 (52.4%)	1265	2321 (81.3%)	535 (18.7%)	2856	194 (22.8%)	658 (77.2%)	852
TOTAL MANPOWER	4937								
	AIR		1265	25.4%					
	WATER		2856	57.4%					
	PESTICIDES		852	17.2%					

TABLE 5

Total Pesticides Program Personnel

Regions

Abatement and Control	-	81
Enforcement	-	113
Pesticide Analysis Labs	-	28
TOTAL		<u>222</u>

Headquarters

. <u>Pesticides Enforcement Div</u>	-	34
. <u>Office of Pesticides Programs</u>	- current ceiling	
(by Program Sub-Element)		
Accident Investigation		10
Technical Support		42
Substitute Chemicals		35
Registration		224
Criteria & Standards		164
Epidemiological Studies		13
Residue Profiles		37
Technical Information		63
Program Management		33
EIS Preparation		<u>3</u>
TOTAL		624

The current OPP distribution by Division is approximately:

Immediate Office of the DAA	52
Operations Division	41
Technical Services Division	186
Registration Division	226
Criteria & Evaluation Div.	<u>140</u>
TOTAL	645

TABLE 6

Model for Regional Pesticide Manpower Allocations*

Abatement and Control**

81 Positions**

Regions	I	II	III	IV	V	VI	VII	VIII	IX	X
20 positions evenly	2	2	2	2	2	2	2	2	2	2
Of 61 remaining positions -										
60% states	2.71	1.81	2.71	3.61	2.71	2.24	1.81	2.71	2.24	1.81
66.67% Cert. 20% farmers	.12	.32	.46	1.33	2.04	.91	1.62	.72	.30	.30
app. prog. 20% pop.	.42	1.10	.89	1.23	1.72	.78	.44	.21	1.11	.24
22.22% 5(f) and 24(c)	.81	.68	1.22	2.71	2.03	1.76	1.36	1.22	.95	.95
IPM 33.33% farmers	.03	.09	.13	.37	.57	.25	.45	.20	.08	.08
+ ACC 33.33% pop.	.12	.30	.25	.34	.48	.22	.12	.06	.31	.07
11.11% 33.33% Hosp. Ads.	.05	.06	.23	.51	.38	.38	.13	.08	.36	.09
TOTAL	6.26	6.36	7.89	12.10	11.93	8.54	7.93	7.20	7.35	5.54
Present Allocation	7	6	6	8	10	10	7	10	9	8
DIFFERENCE***	-.74	+.36	+1.89	+4.10	+1.93	-1.46	+.93	-2.80	-.1.65	-2.46

* See Table 5 for regional percentages used to compute man years.

** These numbers do not include Product Analysis Laboratory, or import inspectors (Region II)

*** .12 man years lost due to rounding

TABLE 7
Enforcement
111 Positions*

Regions	I	II	III	IV	V	VI	VII	VIII	IX	X
30 positions evenly	3	3	3	3	3	3	3	3	3	3
Of 81 remaining positions -										
33.33% co-op enf. (States)	3	2	3	4	3	2.5	2.0	3.0	2.5	3
33.33% 66.67% producers	.59	1.66	1.28	3.87	3.17	1.89	1.76	.45	2.47	.86
indus. surv. 33.33% products	.18	1.08	.63	2.16	1.53	.81	.90	.18	1.17	.36
16.67% farms	.05	.10	.28	1.08	1.03	.68	.72	.27	.15	.14
33.33% 16.67% farmers use	.07	.18	.26	.74	1.13	.50	.90	.40	.17	.17
33.33% pop.	.47	1.22	.98	1.36	1.90	.86	.49	.23	1.22	.27
33.33% Hosp. Adms.	.19	.24	.91	2.01	1.50	1.50	.54	.30	1.45	.35
TOTAL	7.55	9.48	10.34	18.22	16.26	11.74	10.31	7.83	12.13	7.15
Present Allocation	6	17	10	17	21	9	12	5	10	4
Difference	+1.55	-7.52	+.34	+1.22	-4.74	+2.74	-1.69	+2.83	+2.13	+3.15

* * See Table 8 for regional percentages used to compute man years.

These numbers do not include Product Analysis Laboratory, or import inspectors (Region II)

TABLE 8

Total Regional Position Differentials**
(Difference Row of Tables 6 & 7 Combined)

I	II	III	IV	V	VI	VII	VIII	IX	X
+ .8	-6.2	+2.2	+5.3	-2.8	+1.3	- .8	even	+ .5	+ .7

** .4 man years lost from rounding error

TABLE 9

Percentages Used To Model The Regional Personnel Distribution

Regions	I	II	III	IV	V	VI	VII	VIII	IX	X
States per Region (54 Total)	11.1	7.4	11.1	14.8	11.1	9.2	7.4	11.1	9.2	7.4
Farmers and Farm Managers	1.5	3.9	5.7	16.4	25.1	11.2	19.9	8.9	3.7	3.7
Population	5.2	13.5	10.9	15.1	21.1	9.6	5.4	2.6	13.6	3.0
Producers	3.3	9.2	7.1	21.5	17.6	10.5	9.8	2.5	13.7	4.8
Products	2.0	12.0	7.0	24.0	17.0	9.0	10.0	2.0	13.0	4.0
Farms	1.1	2.2	6.3	23.9	22.9	15.1	15.9	6.1	3.3	3.2
Exp. Use Permits	6.0	5.0	9.0	20.0	15.0	13.0	10.0	9.0	7.0	7.0
Involuntary Hosp. Admissions	2.1	2.7	10.2	22.4	16.7	16.7	6.0	3.3	16.1	3.9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 8 1976

OFFICE OF
PLANNING AND MANAGEMENT

SUBJECT: Pesticides Regional Operations Review

FROM: Alvin L. Alm, Assistant Administrator
for Planning and Management (PM-208)

Andrew W. Breidenbach, Assistant Administrator
for Water and Hazardous Materials (WH-556)

Stanley Legro, Assistant Administrator
for Enforcement (EN-329)

TO: Russell E. Train, Administrator (A-100)

On September 15, 1975, we initiated a review of Regional operations in the pesticide program that was conducted by the Office of Pesticide Programs, the Pesticide Enforcement Division, and the Program Evaluation Division. The final report of the Review Team is attached. In conducting this review, the team interviewed pesticide program managers at Headquarters and visited all ten Regional Pesticide Branches, as well as six State pesticide offices. The report has been circulated among Headquarters and Regional Offices and the recommendations made in this memorandum take their comments into account.

The Review Team was favorably impressed by the Regional pesticide programs. Despite meager resources, the Branches do a good job of fulfilling their important responsibilities. Other major findings of the Review Team are:

- Regional Pesticide Branches generally have strong and effective enforcement programs, particularly for pesticide supply control. Much of the past success of enforcement efforts may be attributed to program decentralization. Currently there is a shift in emphasis to use control. The FY 77 Regional Guidance and the Inspector's Manual provide the basic instructions for use observation. The overall use control strategy will have to evolve from the experience of the Regions and continued follow-up by the Pesticides Enforcement Division.

- Controlling the supply and use of pesticides is a massive task which could legitimately consume far greater resources than will ever be available. But most Regions have not effectively coordinated their efforts with those of the States to get the most out of resources that are available.
- The role of the Pesticide Branches in program operations and technical assistance can and should be greater. Now that the uncertainty with respect to Section 4 of FIFRA has been resolved by Congressional amendment the Branches can move ahead in helping States to establish operational certification programs. Better OPP Headquarters support in providing the Regions with consistent policy information and guidance as well as increased authority in all program areas is essential. However, a concentrated attempt by each Region to understand, complement and utilize that guidance is also required, even with limited Regional staff.

These general conclusions, along with the other more specific observations detailed in the report, led the Review Teams to four major recommendations:

- 1) A strategy for decentralizing pesticide responsibilities should be developed, particularly in abatement and control.
- 2) The Agency should manage the manpower resources devoted to pesticides in such a way as to make the implementation of a decentralization strategy possible. The Headquarters/Regional personnel balance should be evaluated on a case specific basis whenever manpower reductions become necessary. Every effort should be made to minimize personnel cutbacks in the Regions.
- 3) Pesticide Branch Chiefs can make the most effective use of their resources by encouraging more interaction between enforcement and abatement and control activities.
- 4) Pesticide Branches must make a greater effort to coordinate with the States by involving States in program planning and implementation, reaching agreements on inspections and surveillance, and fostering State assumption of some regulatory responsibilities.

To ensure these broad-based recommendations are implemented and to improve the overall efficiency and effectiveness of program planning, operations, and management, we submit, for your approval, the following list of actions suggested by the Review Team:

The Review Team recommends that the Administrator:

- Delegate responsibility for approving State certification plans to Regional Administrators.
- Delegate responsibility for approving State plans for special local use registrations to Regional Administrators.
- Delegate authority to the Regional Administrator to veto, when necessary, an experimental use permit granted by a State pursuant to the conditions set forth in Section 5(f).

The Review Team recommends that the Deputy Assistant Administrator for Pesticide Programs:

- Initiate a pilot program in late FY 77 or early FY 78 to assess the feasibility and cost-effectiveness of decentralizing certain registration functions.
- Ensure promulgation of the following items by the identified deadline.
 - disposal regulations August 15, 1976
 - §5(f) regulations September 3, 1976
 - §24(c) regulations November 1, 1976
 - packaging regulations January 15, 1977
- Instruct Headquarters pesticide personnel not to deal with a State on substantive issues without prior Regional consultation, except under emergency conditions.
- Complete by October 1, 1976 a review of the Pesticide Episode Reporting System to determine its value and its organizational relationship to the Hazard Evaluation System.
- Finish the Hazard Evaluation planning effort by November 1976.

The Review Team recommends that the Director of the Registration Division (OPP):

- Improve the system for tracking the progress of ID's through the registration review process. This will include identifying specific responsibility for contacting the Regions by phone if a review takes longer than 15 days.
- Develop procedures to ensure that the individual who reviews a product suspected of violating FIFRA, is the same one who participates in subsequent enforcement procedures. However, Regions should be the primary source of expert witnesses for enforcement actions.

- Ensure that during the ninety day period when EPA can reject a State registration made under §24(c) authority, information relating to the local problem and the economic impact of denial is obtained from the responsible Region.
- Grant a §18 emergency exemption only after obtaining Regional input.
- Renew an emergency exemption only after a review to determine if the product should be registered for the use in question.

The Review Team recommends that the Director of the Technical Services Division (OPP):

- Prepare a Pesticide Analysis Retrieval and Control System User's Manual and consider options for distributing the PARCS microfiche to non-EPA groups.
- Take the lead in establishing formal procedures for dealing with conflicting efficacy test results and resolving Regional/CBIB disagreements.
- Develop, with the advice of the Pesticides Enforcement Division, guidance on manpower requirements for the Product Analysis Laboratories, as well as analysis quotas and priorities.
- Ensure the participation of the Pesticides Enforcement Division and all of the Pesticide Branches in the design and implementation of the Hazard Evaluation System.
- Provide guidance to ensure close Headquarters/Regional/State coordination of ambient monitoring efforts.
- Establish, in cooperation with PED and the Denver NEIC, a policy for the analysis of residue samples.

The Review Team recommends that the Director of the Operations Division (OPP):

- Design a system, using the Regional Coordinators, to ensure that inquiries from the Regions are promptly answered and that all responses are definitive and consistent.
- See that all available suspect chemical, suspect product or suspect use information is distributed to the Pesticide Branches.
- Provide comments on any draft State plan within 15 working days.
- Develop criteria for determining when applicator training funds are to be transferred to a State Cooperative Extension Service.

The Review Team recommends that the Director of the Pesticides Enforcement Division (OE):

- See that the Regions have all the data necessary to develop comprehensive inspection strategies, including toxicity classification and information on production, violations and previous sampling.
- Streamline the Pesticide Enforcement Management System so that it will be of greater practical use to the Pesticide Branches and the Office of Pesticide Programs. Unused information should be dropped and programs for accessing and evaluating the remaining data should be prepared.
- Prepare a PEMS user's manual that goes beyond technical descriptions of the system and discusses the services and information PEMS can provide.
- Lead a session long enough to adequately discuss and cover the Regional use enforcement strategy at the next scheduled Branch Chiefs' meeting.
- Waive concurrence on §13 Stop Sale notices and non-use related §9(c) and §14 (a)(2) warnings in the case of Regions that have demonstrated the competence to handle these actions on their own. Concurrence will be relaxed on use related warnings once the Regions have had experience dealing with use violations.
- Standardize the format for submissions to the Pesticides Misuse Review Committee and expedite the PMRC review. The PMRC Manual will be revised to reflect policy and organizational changes.
- Develop and transmit to the Pesticide Branches clear guidance on the National Environmental Investigation Center's pesticides responsibilities and capabilities.

The Review Team recommends that the Regional Pesticide Branch Chiefs:

- Re-examine resources committed to establishment inspections making shifts to higher priority activities where appropriate.
- Send to the States copies of the Regional Guidance, work plans and other strategic documents as appropriate.

- Emphasize use observation and acquainting applicators with use requirements, particularly those contained in the Pesticides Enforcement Policy Statements.
- Make special efforts to acquaint manufacturers and formulators with registration guidelines, and to provide them with information bearing on registration matters.

The Review Team recommends that the Director of the Standards and Regulations Division (OPM):

- Provide assistance necessary to get the following regulations promulgated by the identified deadline.
 - disposal regulations August 15, 1976
 - §5(f) regulations September 3, 1976
 - §24(c) regulations November 1, 1976
 - packaging regulations January 15, 1977

Approve John Zuñiga Acting

Disapprove _____

Other _____

Date July 20, 1976