REPORT BY THE

AUDITOR GENERAL

OF CALIFORNIA

THE STATE LACKS DATA NECESSARY TO DETERMINE THE SAFETY OF PESTICIDES

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REPORT BY THE

OFFICE OF THE AUDITOR GENERAL

TO THE

JOINT LEGISLATIVE AUDIT COMMITTEE

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AUGUST 1984

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Honorable Art Agnos, Chairman
Members, Joint Legislative
Audit Committee
State Capitol, Room 3151
Sacramento, California 95814

Dear Mr. Chairman and Members:

The Office of the Auditor General presents its report concerning the Department of Food and Agriculture's data to support the safety of registered pesticides. We reviewed files on 147 active ingredients in pesticides registered in California. The report concludes that 86 percent of the files lacked one or more of six types of health studies that show if exposure to the active ingredient causes chronic toxicity, cancer, birth defects, problems in reproduction, mutations, and nerve damage. However, the requirements for these health studies are not precise.

Respectfully submitted,

Thomas W. Hayes

THOMAS W. HAYES
Auditor General

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SUMMARY

The Department of Food and Agriculture (department) lacks data confirming the safety of many active ingredients in pesticides. Most of the active ingredients without complete data on file were registered prior to 1980, when the data requirements for registration were changed. We found weaknesses in the department's program for registering pesticides for use in the State and in the department's systems for reporting the use and sale of pesticides. We also report on the department's administration of the pesticide mill tax program. In fiscal year 1982-83, the department spent $18.3 million administering the State's pesticide regulatory program.

Pesticide Registration

When registering a pesticide for use in the State, the department may require applicants to furnish data from any of six types of health studies. These studies determine if exposure to the active ingredient in the pesticide causes chronic toxicity, cancer, birth defects, reproduction problems, mutations, or nerve damage. State law does not specify which of these studies are required for pesticide registration. Prior to 1980, the department required applicants to submit data on only health studies that the department considered necessary. Since January 4, 1980, however, department regulations have required summaries of the same health studies required by the Environmental Protection Agency (EPA) for federal registration.

We reviewed files for a sample of 147 of approximately 1,200 active ingredients used in pesticides registered in California. Files on 25 of 32 new active ingredients in pesticides registered after January 4, 1980, lacked summaries of one or more of the six health studies; files on 4 of the active ingredients did not contain summaries of any of the six health studies. Of our sample of files on 115 active ingredients in

pesticides registered before 1980, 102 lacked summaries of one or more of the health studies, and 26 did not contain summaries of any of the six health studies.

The department states that since January 4, 1980, it has received all data that the EPA requires; however, we could not verify precisely which data were required. Moreover, the department has not always verified that applicants have submitted summaries of all data required by the EPA. Furthermore, the EPA's requirements are not always precise, and the EPA may modify or waive its requirements as a result of negotiations with pesticide manufacturers. In addition, some of the summaries of health studies in the department's files are inadequate: some of the summaries are too brief; some summarize health studies that were performed prior to 1975 and may, therefore, be outdated; and some summarize health studies that were not conducted properly. We also found that the department does not always document its review of specific summaries of health studies and has not fully established its program to continuously evaluate the safety of pesticides registered in the State. Because of these weaknesses, there is no assurance that the pesticide regulatory program prevents the use of unsafe pesticides.

Sales and Use Reporting Systems

County agricultural commissioners monitor pesticide applications and forward information on pesticide use to the department, which summarizes the information in summary use reports. Although the department uses these summary reports as a management tool, it has no criteria specifying the use of the reports in achieving the department's goals. Without such criteria, we could not evaluate the department's use of the reports, nor could we determine the significance of the inaccuracies that the reports contain.

In addition, although the sale and the use of pesticides are reported in pounds of active ingredients, the reported amount of pesticides sold does not equal the reported amount of pesticides used for the same period. This discrepancy occurs because sales may be reported more than once, because not all uses of pesticides must be reported, and because pesticides are sometimes not used in the same year they are sold.

Administration of the Pesticide Mill Tax Program

The department collects a tax of 8 mills ($0.008) on each dollar of sales of pesticides registered for use in California. This "pesticide mill tax" partially finances the pesticide regulatory program at the state level and county level. In 1980, the Auditor General reported that the department did not collect sufficient data from those who have registered pesticides in the State (registrants) to permit its auditors to effectively monitor collection of the pesticide mill tax. According to the Legislative Counsel, the department lacked authority to require additional information. Since our 1980 report, the department has not obtained authority to require any additional information from registrants. However, the department has improved its performance in auditing registrants. In addition, a department document reported that in the 24 months prior to May 1984, its audit unit identified over 300 illegal pesticides that were being marketed in the State.

To provide other information the Legislature requested on the pesticide mill tax program, we determined that although the State Board of Equalization (board) could administer the pesticide mill tax program, estimates indicate that the board's costs would be higher than the department's. Finally, during the three fiscal years that ended June 30, 1983, the State paid California counties more than $12.6 million in pesticide mill tax revenue to fund enforcement of pesticide regulations. During the same period, the counties spent over $27.6 million enforcing state and county pesticide regulations.

Recommendations

To improve its program for registering new pesticides and for complying with requirements for continuous evaluation of registered pesticides, the Department of Food and Agriculture should clearly define data requirements for registering pesticides in California, determine which active ingredients in currently registered pesticides lack the required data, obtain the data, and thoroughly evaluate all data obtained. In addition, the department should develop procedures to document the specific data and scientific literature that the department evaluates in reaching its decisions on pesticide registration.

To further improve the department's efficiency in auditing the pesticide registrants, the Legislature should provide the department with the authority to require more detailed information from registrants.

INTRODUCTION

California uses millions of pounds of pesticides each year to control pests that attack agricultural products and threaten public health and welfare. Pesticides increase agricultural production and protect public health while safeguarding natural resources. If used improperly, however, or without sufficient knowledge of their side effects, pesticides can poison, cause cancer, birth defects, and other health problems in humans, and harm wildlife and the environment.

The Department of Food and Agriculture (department) has primary responsibility for regulating pesticides in the State. A "pesticide," as the term is used in this report, is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for defoliating plants, regulating plant growth, or artificially accelerating the drying of plant tissue; "pesticide" includes all fungicides, rodenticides, and herbicides. The department's pesticide regulatory program is intended to provide for the proper, safe, and efficient use of pesticides and to protect public health and safety. The program is also designed to protect the environment from harmful pesticides, assure workers of safe working conditions where pesticides are present, and monitor pesticide use. To accomplish these objectives, the department evaluates pesticides to determine that they are safe and effective and registers them for use in California. The department also monitors and regulates the use of pesticides in the State.

Pesticide Registration

The department is responsible under state law and under authority delegated to it by the United States Environmental Protection Agency (EPA) for registering prior to sale all pesticides used in California. Most pesticides are first registered by the EPA. An applicant for pesticide registration must submit to the department an application along with the required fee, proof of federal registration when applicable, three copies of the proposed label for the product, and scientific data showing that the product can be used safely. Depending upon the anticipated use of the pesticide, the applicant may also have to submit summaries of certain laboratory studies showing that the active ingredients in the pesticide are not harmful to health.* These studies report the results of exposing test animals, such as mice, rats, or rabbits, to the active ingredients under controlled conditions. The studies include four tests referred to as "chronic health studies" and two tests called "mutagenicity" and "neurotoxicity" studies.

Chronic health studies are laboratory tests designed to determine if the pesticide is likely to cause long-term health problems or interfere with the reproduction process. Chronic health studies include the following: "chronic toxicity," "oncogenicity," "teratogenicity," and "reproduction." Table 1 on the following page summarizes the purpose of these studies.

*Generally, laboratory tests are conducted on the active ingredients rather than on the pesticide itself, which includes inert ingredients such as water.

TABLE 1

CHRONIC HEALTH STUDIES

Type of Study	Purpose of Study
Chronic Toxicity	To determine if the pesticide causes changes in skin, eyes, respiratory and circulatory systems, and behavior.
Oncogenicity (Cancer)	To determine if the pesticide causes the formation of malignant or benign tumors.
Teratogenicity (Birth Defects)	To determine if exposure to the pesticide during pregnancy adversely affects the fetus or causes birth defects.
Reproduction	To determine if exposure to the pesticide decreases fertility, causes premature delivery, or results in smaller offspring.

In certain cases, the EPA requires health studies to verify that active ingredients in a pesticide are not likely to cause mutation problems (sudden variations in some inheritable characteristic of a plant or animal) or nerve damage. This verification is accomplished with mutagenicity and neurotoxicity studies. The mutagenicity study identifies changes in the genetic material in the nucleus of the cell that can be transmitted during cell division. If mutations are present in the genetic material in either the egg or the sperm at the time of fertilization, the resulting combination of genetic material may not be viable and death may occur in the early stages of embryonic cell division. Alternatively, the mutation in the genetic material may not affect early development of the embryo but may cause death of the fetus at a later developmental period, resulting in abortion. Congenital abnormalities may also result from mutations. The other type of health

study, the neurotoxicity study, is performed to detect nerve damage that results in unsteady reflexes and possible eventual paralysis.

The EPA determines what studies or data are required for federal registration of pesticides. For example, the EPA guidelines generally require data from chronic health studies if the pesticide is to be used on food crops or if humans would be exposed to the pesticide repeatedly or "over a significant portion of the human life span." In addition, the EPA generally requires data from neurotoxicity studies if the active ingredients are "organophosphates" (that is, chemicals that damage or destroy the enzyme necessary for nerve function in animals) or are chemically related to substances known to cause nerve damage.

Applicants for pesticide registration must conduct or have conducted the required health studies and provide the EPA with complete reports on the required tests. These reports contain three parts: a summary and evaluation of the test results; a description of the test procedures; and the test data and other information as required by the EPA for specific studies. The reports submitted to the EPA must contain information, analyses, and conclusions in sufficient detail to permit independent evaluation of the test results. The description of the test procedures should include information such as identification of substances tested, methodology, and ways in which the test procedures failed to meet applicable standards and reasons for such deviations.

Prior to 1980, California did not require the applicants to submit data on health studies when applying to register a pesticide for use in the State.* The department could, however, request such data from applicants when department scientists determined that the data for particular pesticides were necessary.

Since January 4, 1980, department regulations have required applicants seeking registration of pesticides containing new active ingredients to provide summaries of those health studies that the EPA requires. Each summary must include an adequate and accurate description of the data submitted to the EPA and must describe the methods and materials used, the results, and the conclusions.

State law requires the department to thoroughly evaluate the data submitted to it before registering the pesticide. Currently, more than 10,600 pesticides are registered for use in California; these pesticides contain approximately 1,200 active ingredients. Since January 4, 1980, the department has registered pesticides containing 32 chemical active ingredients not present in pesticides registered prior to 1980.

*The words "health studies" as used in this report refer to the following six studies: chronic toxicity, oncogenicity, teratogenicity, reproduction, mutagenicity, and neurotoxicity. There are additional health studies that we do not discuss in this report.

Enforcement of Pesticide Use

In addition to registering pesticides, the department regulates the use and the sale of certain pesticides. The department's program to monitor pesticide use primarily utilizes county agricultural commissioners for the day-to-day enforcement of pesticide regulations. The department's Pesticide Enforcement Unit provides coordination, supervision, training, and evaluation of the county officials through its district offices located in Sacramento, Los Angeles, Berkeley, and Fresno.

Applicators of pesticides report to the county agricultural commissioners the amount and kind of certain pesticides used; the commissioners forward this information to the department. The department then compiles this information, summarizes it, converts the amounts of pesticides used to pounds of active ingredients used, and produces monthly, quarterly, and annual reports (summary use reports) on the use of pesticides. The annual summary use report, entitled the Pesticide Use Report, lists the pounds of active ingredients used in California during the year for those pesticides that must be reported. The department estimates that it spends approximately $213,000 each year to produce the summary use reports.

The department also produces an annual report on pesticides sold; the report is entitled the Report of Pesticides Sold in California (generally referred to as the "sales report"). The manufacturers or

persons who registered pesticides for use in the State (registrants) must report to the department the amount and kind of active ingredients sold for use in California. The sales report, like the summary use reports, reports sales in pounds of active ingredients. The department estimates that it spends approximately $11,000 per year to produce the sales report.

Pesticide Mill Tax

The department is authorized to collect a "pesticide mill tax" of 8 mills ($0.008) on each dollar of sales of pesticides registered for use in California. The revenue from this tax partially finances the pesticide regulatory program. The department uses three-eighths of the tax to fund its cost of administering the program and uses the remaining five-eighths to partially reimburse the counties for their cost of administering the program.

Registrants must report to the department quarterly the dollar amount of registered pesticides sold during the quarter. Registrants provide this information on the "Report of Economic Poison (Pesticide) Sales and Assessment" and pay to the department the pesticide mill tax on the reported sales of the registered pesticides. The State's Food and Agricultural Code empowers the department to audit registrants to determine if they have paid the correct amount of mill tax.

Funding and Budget

California's pesticide regulatory program is administered by the department's Division of Pest Management, Environmental Protection, and Worker Safety. This division, created in 1977, is one of eight divisions in the department. Its fiscal year 1982-83 expenditures of approximately $18.3 million constituted about 19 percent of the department's total expenditures of approximately $97.6 million. Funds for the pesticide regulatory program come partially from the State's General Fund and partially from the Department of Food and Agriculture Fund. Other sources provide a small amount of funds for the program. The Department of Food and Agriculture Fund consists of money from the pesticide mill tax, application fees for pesticide registration, and other sources. Table 2 on the following page shows the expenditures for the pesticide regulatory program for fiscal years 1981-82, 1982-83, and 1983-84.

TABLE 2

EXPENDITURES FOR THE PESTICIDE REGULATORY PROGRAM FISCAL YEARS 1981-82, 1982-83, AND 1983-84

	Fiscal Year		
Source of Funds	1981-82	1982-83	1983-84*
General Fund	$ 9,068,000	$ 9,273,000	$ 9,338,000
Agriculture Fund	7,906,000	8,377,000	9,279,000
Other Sources	877,000	661,000	482,000
Total	$17,851,000	$18,311,000	$19,099,000

*Estimated Expenditures

Source: Governor's Budget

Previous Auditor General Report

The last Auditor General report on the State's pesticide regulatory program was published in 1980.* That report stated that the department's program to reevaluate the safety and effectiveness of registered pesticides did not ensure that the use of potentially harmful pesticides was being eliminated. The report also noted that county agricultural commissioners were unable to promptly and thoroughly investigate pesticide illnesses because the two notification systems were

*This report is entitled "Review of the California Department of Food and Agriculture's Pesticide Regulatory Program," Report P-934, August 1980.

inadequate. Finally, the report found that the department needed to increase its audits of pesticide registrants, require additional sales information from the registrants, and improve its system for documenting its registration decisions. (Appendix A summarizes the Auditor General's 1980 report.)

SCOPE AND METHODOLOGY

In this report, we review the Department of Food and Agriculture's administration of the pesticide regulatory program. We also respond to the Legislature's questions concerning the department's reports on the use and sale of pesticides and elements of the department's administration of the pesticide mill tax program.

We focused this review of the department's pesticide regulatory program on data from health studies conducted on active ingredients in registered pesticides. We determined if the department had on file and had reviewed data on six kinds of health studies that determine if exposure to a pesticide registered in the State results in chronic toxicity, cancer, birth defects, reproduction problems, mutations, or nerve damage. These studies show the extent to which the pesticides currently registered can be used safely. We also examined the summaries of health studies in the department's files and the guidelines that the department uses in requiring summaries of health studies.

We also address specific questions from the Legislature concerning the department's reports on the use and sale of pesticides. Specifically, the Legislature asked us to determine if the department is effectively administering the system for reporting pesticide use to ensure that California is protected from unsafe pesticides and if the department's reporting system is adequate to accurately monitor the use of hazardous pesticides. In addition, the Legislature asked us to explain why discrepancies existed between data reporting the sales of restricted pesticides in 1980 and data reporting the use of restricted pesticides in 1980.

Finally, the Legislature requested that we provide answers to the following questions about the pesticide mill tax:

- Does the Department of Food and Agriculture require the data necessary to accurately collect the mill tax?

- Is the Board of Equalization capable of collecting the mill tax more effectively than the Department of Food and Agriculture? If so, would such a change be cost beneficial?

- How do the counties spend the mill tax revenue they receive from the State?

To conduct our audit, we interviewed staff of the department's Division of Pest Management, Environmental Protection, and Worker Safety,

and we examined the health studies the department has on file in its data library and in its registration files. We reviewed data on the 32 new chemical active ingredients in pesticides registered after January 4, 1980, and data on a sample of 115 active ingredients in pesticides registered before 1980 that were the most widely used in 1982. We reviewed the department's files to determine if they contained data on the six types of health studies.

We requested the department to identify any additional studies we may have missed and to explain why data on health studies were not in the files. We also reviewed state laws and regulations as well as the federal laws, regulations, and guidelines for registering pesticides.

To determine the department's procedures for reporting the use and sale of pesticides, we examined the department's regulations and guidelines for monitoring the use of pesticides and its procedures for compiling the summary use reports.

Finally, to provide information the Legislature requested on the pesticide mill tax program, we examined the department's records supporting its audits of the pesticide registrants. We also interviewed staff of the Board of Equalization (board) and obtained an estimate of the costs to the board if it were to administer the pesticide mill tax program. We obtained data on the department's cost of administering the pesticide mill tax program and compared these with the board's estimate.

CHAPTER I

THE DEPARTMENT OF FOOD AND AGRICULTURE LACKS DATA CONFIRMING THE SAFETY OF MANY ACTIVE INGREDIENTS IN PESTICIDES

The Department of Food and Agriculture (department) lacks data showing that pesticides can be used safely. We examined the department's files on a sample of 147 active ingredients used in pesticides registered in the State and found that 127 (86 percent) of the files lacked data on one or more of six types of health studies. State law does not specify which health studies are required for registration of pesticides. Prior to 1980, the department required applicants for pesticide registration to submit data on only health studies that the department considered necessary. Since January 4, 1980, however, department regulations have required summaries of the same studies that the U.S. Environmental Protection Agency (EPA) requires for federal registration.

Although the department states that since January 4, 1980, it has received summaries of all health studies required by the EPA, the department has registered pesticides without verifying that the applicants have submitted summaries of all required studies. Further, some of the summaries of health studies in the department's files provide insufficient information, summarize studies that may now be outdated, or summarize studies that were improperly conducted. Moreover, EPA requirements are not always clearly defined, and the EPA can waive or modify its requirements during negotiations with applicants from the pesticide industry. The EPA has also registered pesticides that were

later found to be unsafe. Finally, the department does not always document specific summaries or other scientific literature it has reviewed when evaluating applications for pesticide registration, and it has not fully established a program for continuous evaluation of pesticides already in use. As a result of these problems, there is no assurance that the State's pesticide regulatory program protects California from unsafe pesticides.

SOME DEPARTMENT FILES ON ACTIVE INGREDIENTS IN PESTICIDES DO NOT CONTAIN DATA FROM HEALTH STUDIES

Our review of files on 147 of the approximately 1,200 active ingredients used in pesticides registered in California revealed that some of the department's files do not contain summaries of one or more of six types of health studies. These studies determine if exposure to the active ingredient causes the following: changes in skin, eyes, respiratory and circulatory systems, and behavior (chronic toxicity study); cancer (oncogenicity study); birth defects (teratogenicity study); problems in reproduction; mutations (mutagenicity study); and nerve damage (neurotoxicity study). However, the department states that since January 4, 1980, it has received all data required by the EPA. Prior to 1980, the department required applicants for pesticide registration to submit data on only health studies that the department considered necessary.

Health Data for Active Ingredients in Pesticides Registered After January 4, 1980

We reviewed files on 32 new chemical active ingredients in pesticides registered after January 4, 1980. Files on 4 of the 32 active ingredients did not contain summaries of any of the six health studies; files on 25 active ingredients lacked summaries for one or more of the health studies; files on 7 of the active ingredients contained summaries for all six health studies. Table 3 shows by type of health study the number of files without a summary of the health study, the number of files with one summary of the study, and the number of files that contained two or more summaries of the study. (Appendix B lists the 32 new active ingredients and details the summaries of health studies on file for each active ingredient.)

TABLE 3

HEALTH STUDY SUMMARIES IN THE DEPARTMENT'S FILES ON 32 NEW ACTIVE INGREDIENTS IN PESTICIDES REGISTERED SINCE JANUARY 4, 1980 (AS OF APRIL 27, 1984)

Type of Study	Files Without Summaries	Files With One Summary	Files With Two or More Summaries*
Chronic Health Studies			
Chronic Toxicity	9 (28%)	3 (9%)	20 (63%)
Oncogenicity (Cancer)	9 (28%)	4 (13%)	19 (59%)
Teratogenicity (Birth Defects)	8 (25%)	1 (3%)	23 (72%)
Reproduction	9 (28%)	15 (47%)	8 (25%)
Other Health Studies			
Mutagenicity (Mutations)	9 (28%)	5 (16%)	18 (56%)
Neurotoxicity (Nerve Damage)	22 (69%)	5 (16%)	5 (16%)**

*The proposed federal regulations would require two studies for chronic toxicity, cancer, and birth defects when chronic health studies are required. See "Environmental Protection Agency: Pesticides Registration; Proposed Data Requirements," The Federal Register, Part III, Vol. 47, No. 227 (November 24, 1982).

**The percentages do not total 100% because of rounding.

Table 3 shows that the department's files for nearly 30 percent of the new chemical active ingredients in pesticides registered since January 4, 1980, contained no data from chronic toxicity, cancer, reproduction, and mutation studies. Files on 25 percent of the active ingredients lacked data from birth defects studies, and files on

69 percent of the active ingredients did not include data from nerve damage studies. In total, files on 25 (78 percent) of the 32 active ingredients in pesticides registered since January 4, 1980, lacked summaries of one or more of the six health studies.

Health Data for Active Ingredients in Pesticides Registered Before 1980

We reviewed files on 115 active ingredients in pesticides registered before 1980 that were the most widely used in 1982. We found 26 files that did not contain any summary of any of the health studies and 13 files that contained one or more summaries of all six studies. Table 4 shows by type of health study the number of files that contained no summary of the particular health study and the number of files that contained one or more summaries of the study. (Appendix C lists the 115 active ingredients in the sample and details the summaries of health studies on file for each active ingredient.)

TABLE 4

HEALTH STUDY SUMMARIES IN THE DEPARTMENT'S FILES ON 115 ACTIVE INGREDIENTS IN PESTICIDES REGISTERED PRIOR TO 1980 (AS OF APRIL 27, 1984)

Type of Study	Files Without Summaries	Files With One or More Summaries
Chronic Health Studies		
Chronic Toxicity	38 (33%)	77 (67%)
Oncogenicity (Cancer)	54 (47%)	61 (53%)
Teratogenicity (Birth Defects)	46 (40%)	69 (60%)
Reproduction	46 (40%)	69 (60%)
Other Health Studies		
Mutagenicity (Mutations)	54 (47%)	61 (53%)
Neurotoxicity (Nerve Damage)	87 (76%)	28 (24%)

As Table 4 shows, department files on 33 percent of the active ingredients in our sample did not contain data from chronic toxicity studies. In addition, department files on 47 percent of the active ingredients in our sample lacked data from mutation studies, and files on 76 percent of the active ingredients lacked data from nerve damage studies. In total, files on 102 (87 percent) of the 115 active ingredients registered prior to 1980 lacked summaries of one or more of the six health studies.

Department Reasons for
the Lack of Health Studies

State law does not specify the requirements for chronic health studies and mutation and nerve damage studies. However, since January 4, 1980, department regulations have required applicants for pesticide registration to submit summaries of the same health studies required by the EPA. Although files on 25 of the active ingredients in pesticides registered since January 4, 1980, do not contain summaries of all six kinds of health studies and files on 4 active ingredients contain no summaries of health studies, the department maintains that it has received all data that the EPA requires. The EPA does not require that all health studies be conducted for all active ingredients in pesticides. According to registration supervisors at the department, EPA guidelines did not require data on the four chronic health studies for 10 of the active ingredients in pesticides registered after January 4, 1980, for several reasons. For example, the pesticides would not be used on food crops, and the use of the pesticide would not result in repeated exposure to humans or exposure "over a significant portion of the human life-span."

In addition, the registration supervisors identified 22 of the 32 active ingredients for which the EPA does not require nerve damage studies because the active ingredients are not "organophosphates" (that is, chemicals that damage or destroy the enzyme required for nerve function in animals) or are not chemically related to other substances known to cause nerve damage. The registration supervisors also said that

the EPA guidelines do not require any of the six health studies for 2 of the 32 active ingredients because they are "biorational pesticides," (that is, they occur naturally in the environment) and short-term tests did not indicate a need for further testing.

The file of one active ingredient, which was registered in June 1982, did not contain required mutations studies because the department had neglected to request them from the registrant. However, nearly two years later, the department found that the studies had been conducted and requested the studies during our review. The file on another active ingredient in a pesticide registered after January 4, 1980, contained summaries for all health studies except one of two cancer studies. The department's registration supervisors said that the EPA did not require a second cancer study because the pesticide was not used on food. The chief of the evaluation unit said that, although the same active ingredient is used in a well-known shampoo for humans, the specific product would be registered under different laws by the Food and Drug Administration.

In regard to the lack of data on health studies for the active ingredients in pesticides registered before 1980, the chief of the evaluation unit said that prior to 1980, state regulations did not require applicants for pesticide registration to submit data on the four chronic health studies and the mutations and nerve damage studies. Applicants were required to submit only data that department scientists considered necessary. However, some of the current criteria are more

stringent than the department applied prior to 1980. We found that if the department had used current criteria that generally require chronic health studies for active ingredients used on food crops, it would have required summaries of 159 additional studies for 65 active ingredients in our sample.

DEPARTMENT REGULATIONS MAY NOT REQUIRE SUFFICIENT DATA FROM HEALTH STUDIES TO PREVENT REGISTRATION OF UNSAFE PESTICIDES

To register a pesticide in the State, department regulations require summaries of the same data required by the EPA for federal registration. However, the department does not always verify precisely what data the EPA requires before the department registers pesticides for use in California. In addition, EPA requirements are not always precise, and federal guidelines allow the EPA to decide on a case-by-case basis which data will be required for federal registration of a pesticide. Moreover, the guidelines allow applicants to negotiate with the EPA on what data will be required. Further, some groups have identified reasons why the EPA should not be relied upon totally, and the EPA has registered some pesticides that were later found to be unsafe. As a result, the State has no assurance that department regulations require applicants to submit sufficient data from health studies to prevent registration of unsafe pesticides.

The Department Has Not Always Verified That Applicants Follow EPA Requirements

While state law does not specify requirements for data from chronic health studies and mutation and nerve damage studies, department regulations require applicants for pesticide registration to submit summaries that accurately reflect data that the applicant submitted to the EPA for federal registration. Each summary must include a description of the data submitted to the EPA, the methods and materials used in the required health studies, and the results and conclusions from each study. The regulations also require the director of the department to give special attention, when applicable, to factors that include evidence of chronic health effects, mutations, and nerve damage.

The department's procedures for registering pesticides, however, do not guarantee that it always receives summaries of all health studies that the EPA requires. The department relies on the EPA to notify applicants of the data required by the EPA. In addition, the department does not always verify that applicants have submitted summaries of all studies required by the EPA. Supervisors from the registration and evaluation units said they normally accept the summaries sent by the applicants and assume that the summaries they receive include all the data that the EPA requires.

Some EPA Requirements Are Not Precise

The EPA requirements for data on health studies lack precision. The EPA generally requires chronic toxicity studies if, for example, the pesticides are to be used on food crops or if humans may be exposed repeatedly to the pesticide or may be exposed "over a significant portion of the human life-span"; cancer studies are generally required if the pesticide has ingredients related to cancer-causing agents or if use of the pesticide is likely to result in "human exposure over a portion of the human life-span which is significant in terms of either the time of exposure or the duration of exposure." The EPA generally requires birth defects studies if "significant exposure of human females of child-bearing age may reasonably be expected"; reproduction studies may be required if anticipated exposure to the pesticide is significant in terms of "the human life span, frequency, magnitude, or duration." The EPA may require mutations studies if "significant human exposure" will result or if the ingredients belong to related compounds causing mutations or tumors. The EPA does not clearly define such important terms as "significant portion of the human life-span," "time of exposure," "duration of exposure," and "human females of child-bearing age."

The EPA Can Change Data Requirements

Although federal guidelines describe the health studies required for pesticide registration, the guidelines also provide exceptions when the EPA would not impose these requirements. For example, the guidelines state that "the data requirements for registration are flexible to meet the specific needs of the registration applicants and the Agency [EPA]." The guidelines also permit the EPA to waive data requirements when the physical or chemical properties of the pesticide or the proposed use of the pesticide make it impossible to fulfill the requirements.

The EPA's criteria for waiving data requirements are vague, as indicated by the following statement in the Federal Register: "When an applicant persuades the Agency [EPA] that producing an item of data generally required by this Part would not assist EPA to make a valid or useful decision, EPA will waive the data requirement."* The EPA also allows applicants to arrange private conferences with the EPA to determine specific data requirements on a case-by-case basis. The chief of the department's evaluation unit told us that the EPA has used considerable latitude in determining what data it requires from applicants.

*"Environmental Protection Agency: Pesticides Registration; Proposed Data Requirements," The Federal Register, Part III, Vol. 47, No. 227 (November 24, 1982).

Some Groups Question
Reliance on the EPA

Although the department has relied on the EPA to determine the data requirements for pesticide registration, other groups have identified reasons why the EPA should not be relied on totally. For example, in a statement before the House Committee on Agriculture in 1981, the American Farm Bureau Federation was critical of the EPA because, the federation claimed, the EPA failed to review older pesticides and failed to classify them as restricted or for general use. The statement also said "We believe EPA's record is one of failure to protect farmers, ranchers, and other users, the public, and the environment."

A 1982 report prepared by the staff of a subcommittee of the House Committee on Agriculture claimed that some of the EPA's reviews of test data submitted by applicants were superficial. The report criticized the EPA's Office of Pesticide Programs because, the report said, some agency reviews were nothing more than verbatim transcripts of applicant reports and the reviews failed to assess the accuracy and completeness of the "submissions." The same report described pressure on EPA scientists: "Strong pressures are being placed on agency scientists, reinforced by explicit ties to performance ratings and salary adjustments, to reduce the backlog of reviews, to shorten turn-around times, and to be more responsive to the concerns and scientific arguments expressed by the pesticide industry and pesticide users."

The EPA Has Registered Pesticides Later Found To Be Unsafe

Finally, the EPA has registered pesticides that were later found to be unsafe. The department's records provide examples showing that the EPA has registered pesticides based on inadequate data or on inadequate analysis of data that were submitted. For example, the EPA registered a pesticide that causes delayed nerve damage. The department recommended phasing out the pesticide after it obtained data confirming that the pesticide caused the death of cattle in Egypt.

In another case, the department suspended registration of a pesticide when workers in a plant manufacturing the pesticide and persons applying the pesticide in California experienced fertility problems. The EPA had registered the pesticide, but the department's files indicate that the EPA had accepted inadequate data.

SOME OF THE DEPARTMENT'S SUMMARIES OF HEALTH STUDIES ARE OF LIMITED VALUE

Some of the summaries of health studies in the department's files are of limited value because they are too brief. In addition, some of the summaries present data from health studies that may be outdated, and some present data from studies that were conducted by a laboratory that performed invalid health studies.

The Summaries of Health Studies Are of Varied Quality

Title 3, Section 2360, of the California Administrative Code, effective January 4, 1980, requires that applicants applying to the department to register pesticides that require EPA registration must provide summaries that accurately reflect the studies submitted to the EPA. Section 2360 of the code requires that the summaries contain a description of the data, methods and materials used, and results and conclusions.

In reviewing the files for the 147 active ingredients in our sample, we examined 972 summaries and found a wide variation in their content. While some summaries included detailed narratives, tables, statistical methods, and results, we also found summaries that were no longer than one paragraph, summaries that were composed solely of one or more studies from other researchers, and summaries that were simply copies of scientific literature.

Some of the Summaries Are Inadequate

Some of the summaries of studies on active ingredients in pesticides registered before 1980 are brief. If the current requirements contained in Section 2360 of the California Administrative Code were applied to the brief summaries, some would not meet the criteria. For example, one summary simply listed studies that the applicant had sent to

the EPA; one of the studies was listed as follows: "[Test Agency] Report 28-123. Two-year feeding of compound [identification number] in the diet of rats. 1965." Another test summary listed slightly more detail:

> Exhibit II - Mutagenicity of [identification number] Technical II-A - Ames Test with [identification number] Technical. Final Report, [company name and location]
> March 23, 1979.
>
> . . . . technical [batch] was examined in the Ames mutagenicity test. Negative results were obtained with five bacterial strains in both the Ames disc test and the Ames plate test at concentrations up to 1,000 mg per plate.

The chief of the department's Worker Health and Safety Unit told us that this statement, by itself, is not adequate to enable the unit to evaluate mutation effects of the pesticide .

Although EPA guidelines and department regulations require applicants for pesticide registration to submit adequate data to support the registration, the department has sometimes found it necessary to supplement the applicant's data. For example, two department toxicologists who are responsible for evaluating summaries said they relied on scientific literature to supplement the summary reports submitted by the applicants. Because the active ingredient files are not indexed to the registration toxicologist's files and to scientific files located in the Worker Health and Safety Unit and because the toxicologists had not always recorded which scientific literature they used to supplement the applicant's data, we could not identify specifically the scientific literature actually used.

Some of the Health Studies May Be Outdated

In addition to the summaries that are incomplete, some summaries report health studies that were conducted prior to 1975. Of the 972 summaries we reviewed, over 400 were dated prior to 1975 or were not dated. (Appendices B and C indicate the summaries that are dated before or after 1975.) Studies conducted prior to 1975 might not yield the same results as studies conducted with current practices and standards. In addition, the chief of the department's Worker Health and Safety Unit said that the formulation of ingredients in some of the older pesticides has changed over the years; such a change may affect the toxicity of the pesticide.

A 1982 staff report prepared for a subcommittee of the House Committee on Agriculture stated that "the agency [EPA] is directed [by the Federal Insecticide, Fungicide, and Rodenticide Act] to review past pesticide registrations to update and improve the scientific data bases supporting registered uses . . . and to remove a double standard which existed between the data on older and new pesticides." The report also said that "the scientific precision and sophistication of toxicological experiments done on pesticides have evolved markedly and rapidly in the last six to eight years." EPA documents also acknowledge that many products that have been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products.

Some of the Health Studies Are Invalid

Finally, some of the health studies summarized in the department's files on registered pesticides were not properly conducted. Fifty-four summaries in our sample, dated both before and after 1975, were conducted by the Industrial Bio-Test Laboratories (IBT). Audits by the EPA, which began in 1976, uncovered hundreds of questionable health studies performed by the IBT. As of March 1984, the department had identified in its files 75 invalid IBT health studies that needed to be replaced.

THE DEPARTMENT DOES NOT ALWAYS DOCUMENT ITS REVIEW OF SPECIFIC SUMMARIES OF HEALTH STUDIES

The department could improve its documentation of product evaluations by identifying specifically which test summaries it reviewed and specifically which scientific literature it used in reaching its registration decisions. When a product has been registered, the department maintains the registration application, product label, correspondence, and certificate of registration in files located in the registration information center. Two separate files, an active ingredient file and a pesticide file, which are located in the department's library, contain data on health studies and other data submitted by the applicant along with the department's evaluation forms and evaluation memoranda. Summaries are filed in specific volumes in the active ingredient file.

Although the department's evaluation forms and evaluation memoranda are contained in both of the library files, we could not always verify exactly which summaries the department had actually reviewed. Over 65 percent of the files for active ingredients we examined did not contain department evaluation forms or evaluation memoranda in the specific volume containing the summary. Although we found some forms and memoranda in other volumes indicating a review had been made, we could not specifically identify which summaries were actually used for the department's evaluation. We also reviewed the pesticide product files in the library. Each product file contained review forms and memoranda but seldom indicated the specific summary or volume used for the review.

The department could also improve the documentation of its reviews when it uses scientific literature to supplement the applicants' summaries. Neither we nor the department could document specifically which scientific literature the department used during an evaluation because the evaluation memoranda or other documents did not specify the exact articles reviewed. Also, as mentioned earlier, the scientific literature files in the Worker Health and Safety Unit and the registration toxicologist's files are not indexed to the active ingredient files. As a result, the active ingredient files do not contain all of the information that may have been used in the evaluations.

The department could overcome these deficiencies by stamping, dating, and initialing each volume of test summaries that it reviews and

by devising a form or other documentation to indicate which scientific literature, if any, it used to supplement the applicants' summaries.

THE DEPARTMENT HAS NOT FULLY ESTABLISHED A PROGRAM FOR CONTINUOUS EVALUATION OF REGISTERED PESTICIDES

The department has not established a continuous evaluation program for all pesticides that are registered in the State. The department has relied on investigations and reevaluations that it initiates after adverse effects involving registered pesticides either have already occurred or are likely to occur.

Section 2367(a) of the California Administrative Code requires the director of the department to investigate all reported pesticide problems that may have caused or are likely to cause a "significant adverse impact." If the director finds from the investigation that a "significant adverse impact" has occurred or is likely to occur, the pesticide will be reevaluated. Since our last audit of the department in 1980, the department has implemented a reevaluation program. The department's records indicate that it has completed 4 to 7 reevaluations a year since 1980. In addition, the department has investigated approximately 2,000 reports of illness each year.

In addition to requiring investigations and reevaluations of pesticides that may have caused or are likely to cause a significant adverse effect, Section 2367(g) of the California Administrative Code

requires the director to undertake a continuous evaluation of all registered pesticides. The purpose of continuous evaluations includes the elimination from use of any pesticides that prove harmful, are not effective, or have been misrepresented. Although state law has required the department to conduct continuous evaluations of registered pesticides since the enactment of Section 12824 of the Food and Agricultural Code, which became effective on November 10, 1969, the department did not draft a priority list of pesticides for the evaluation program until late 1981. Since that time, the department has evaluated about 10 fumigants out of approximately 220 active ingredients and chemical groups on the priority list. The 10 fumigants are used in approximately 280 pesticides. The focus of the review was on the label information, including instructions for use, protective equipment, storage and disposal, and information for physicians for treatment.

Three supervisors from the Division of Pest Management, Environmental Protection, and Worker Safety told us that the division has not emphasized continuous evaluations because evaluations have had low priority and because the department has not had enough staff positions to implement a more thorough program. During our audit, the chief of the Worker Health and Safety Unit prepared a proposal to request budget approval for additional staff. This proposal defines alternatives, scope of the program, schedules, and resources required.

CONCLUSION

Eighty-six percent of the files for our sample of 147 active ingredients in pesticides registered by the Department of Food and Agriculture lacked one or more of six health studies. State law does not specify requirements for these studies. Prior to 1980, the department required data only on health studies that it considered necessary. Since January 4, 1980, department regulations have required summaries of the same health studies required by the Environmental Protection Agency. The department maintains that it has received summaries of the same health studies required by the EPA. The department, however, does not always verify that applicants for pesticide registration have provided summaries of all health studies that the EPA requires. Moreover, some EPA requirements for data lack precision, and the EPA can change or waive its requirements for particular pesticides. Furthermore, reasons exist for not relying totally on EPA requirements. Finally, we found that some of the summaries in the department's files are too brief, may summarize outdated health studies, or summarize invalid studies.

As a result of these weaknesses, the State has no assurance that the department receives sufficient data on health studies to prevent the registration of unsafe pesticides. In addition, we could not determine if the department had evaluated

approximately 65 percent of the specific summaries we reviewed. Finally, the department has not implemented a program for the continuous evaluation of all pesticides registered in the State.

RECOMMENDATIONS

To improve the program for registering new pesticides and to comply with the statutory requirements for continuous evaluation of currently registered pesticides, the Department of Food and Agriculture should take the following actions:

- Clearly define what data applicants must submit when applying to register pesticides in California and determine if the State's requirements should be more stringent than EPA requirements. If the State's data requirements incorporate EPA requirements, the department should develop procedures for verifying precisely what data the EPA requires for registering each pesticide;

- Determine which active ingredients in currently registered pesticides lack the required health data, request the applicant to submit the required data, and thoroughly evaluate the required data; and

- Develop procedures to document which summaries and other scientific literature the department evaluates in reaching its decisions on pesticide registration.

To ensure that the department carries out these actions, the Legislature should require the department to submit periodic reports of its progress in implementing the recommendations. If the Legislature is dissatisfied with the department's progress in implementing these recommendations, the Legislature should amend the statutes to include minimum data requirements and timetables for obtaining and evaluating the data.

CHAPTER II

THE SYSTEMS FOR REPORTING PESTICIDE USE AND SALES

Information on pesticide use is reported to the Department of Food and Agriculture by county agricultural commissioners, who monitor and enforce pesticide regulations. The department then summarizes this information in reports on pesticide use (summary use reports). We could not, however, determine the effectiveness of the department's use of its summary use reports because the department has not specified how these reports should be used in achieving department goals. Moreover, the summary use reports are inaccurate, and the department does not know the extent of the inaccuracies. Without criteria specifying the use of the reports, the significance of these inaccuracies cannot be determined. Finally, the amount of pesticides used as reported in the annual summary use report does not equal the amount of pesticides sold as reported in the department's annual report on pesticides sold (sales report).

COUNTY AGRICULTURAL COMMISSIONERS MONITOR AND REPORT PESTICIDE USE

The department relies primarily on county agricultural commissioners for the day-to-day enforcement of pesticide use regulations. The agricultural commissioners' responsibilities include issuing permits for pesticide use, evaluating notices of intent to apply

pesticides, inspecting fields before pesticides are applied, collecting reports of pesticide use, and forwarding information on pesticide use to the department.

The department designates certain pesticides that are harmful to the environment as "restricted." The agricultural commissioners issue permits to persons who plan to apply certain restricted pesticides. In granting permits, the agricultural commissioners consider the qualifications of the applicant and the possible hazards of the pesticide to the environment. Permits include information on the types of pesticides to be used and may designate the time and place that the pesticide will be applied. Before selling a restricted pesticide, pesticide dealers must ensure that purchasers have a valid permit.

If the permit does not specifically designate the time and place of the pesticide application, the department requires the holder of the permit, or the person who is hired to apply the pesticide (pest control operator), to file with the agricultural commissioner a "notice of intent" to apply restricted pesticides. This notice must be filed at least 24 hours before applying the pesticide and must specify the date and place of application and the type and amount of pesticides to be applied. Agricultural commissioners must review all notices of intent to determine if environmental conditions have changed since the permit was issued.

The department requires agricultural commissioners to inspect 5 percent of the sites identified in permits or notices of intent to determine if the environmental conditions are the same as those described in the permit and the notice of intent. In addition, the agricultural commissioners may observe the mixing and applying of pesticides and may observe whether the permit holder or pest control operator stores and disposes of pesticide containers in compliance with department regulations.

Following application of restricted pesticides, the permit holder must report this use (use report) to the agricultural commissioner. This use report contains essentially the same information as the notice of intent and shows the date, location, type, and amount of the pesticide application. Generally, this report must be filed with the commissioner within seven days after the pesticide is applied. State law and department regulations also require pest control operators who apply pesticides to agricultural crops to report to the agricultural commissioners the use of all pesticides within seven days of the application. Generally, other pest control operators who apply pesticides, whether restricted or nonrestricted, must report the use of pesticides by the 10th of the month following the month of application.

The agricultural commissioners submit these use reports to the department, which compiles the information into the monthly, quarterly, and annual summary use reports. These summary use reports show the amount (in pounds) of the active ingredients in the pesticides applied, the number of applications, and the number of acres treated.

THE EFFECTIVENESS OF THE SUMMARY USE REPORTS CANNOT BE DETERMINED

State law requires the department to summarize the use reports and make these summaries available to the public. Although the counties use the individual use reports in regulating pesticide use, the department has not determined how the summary use reports should be used in achieving the department's goals. Without information specifying the purpose of the summary use reports, we could not determine the significance of inaccuracies in the reports or the effectiveness of the department's use of the reports.

The Department Has Not Specified the Purpose of the Summary Use Reports

The Food and Agricultural Code states that the department shall summarize the contents of the use reports and make these summaries available to the public. The department's regulations, however, do not specify how the department shall use the summary use reports in achieving department goals.

In a letter to a member of the State Assembly, the department stated that it uses the summary use reports as a management tool to help ensure worker health and safety, monitor the environment, and test for pesticide residues. For example, the department's Environmental Monitoring and Pest Management Unit uses the summary use reports to select sites for monitoring the quality of groundwater and air. The

residue testing program of the department's Pesticide Enforcement Unit routinely tests produce for residues of certain pesticides and selects one crop each month for testing for residues of pesticides not included in its routine testing. The unit uses information in the summary use reports to select for testing the pesticides not included in its routine tests. The department's Worker Health and Safety Unit investigates pesticides reported to have caused illness. This unit refers to the summary use reports to identify the crops that are treated with the greatest amount of pesticide that the unit is investigating.

Although the department believes the summary use reports contain helpful information, the department has no documents that specify the extent to which it should use the summary use reports or the importance of using summary use reports for achieving its goals.

The Department Does Not Know the Extent of the Inaccuracies in the Summary Use Reports

Although the department is aware of inaccuracies in the summary use reports, it does not know the extent of the inaccuracies. The department does not know how many of the use reports that it returns to the district offices for correction are not returned to the department, and it has not documented the number of use reports that are excluded from the summary use reports because they cannot be processed by the computer system. In addition, the department has used incorrect conversion factors for converting amounts of some pesticides used to

pounds of active ingredients used, and it does not know the extent to which it has underreported the use of active ingredients. The assistant director of the department told us, however, that more accurate data are not needed because the department relies on the summary use reports primarily to identify trends in pesticide use. However, without specific criteria for the use of the reports, the significance of the inaccurate data cannot be determined.

Reports Returned to District Offices

The department does not know the extent of the inaccuracies in the summary use reports because the department does not know the number of use reports that are not returned by the district offices and never included in the summary use reports. When the department receives a use report, the Information Services Unit reviews the report to determine if the information is complete and accurate. If the report is incomplete or inaccurate, the unit returns the report to the county through the appropriate district office.

Until our review, the department did not record the number of use reports it returned to the district offices for correction or the number of reports the district offices corrected and returned to the department. Without this information, the department cannot determine if the district offices are returning all of the use reports.

Reports Rejected by the Computer

The department has not documented the number of use reports that the computer system cannot process. The Information Services Unit codes and keypunches each record of a pesticide application included on the use reports. A computer system operated by the Franchise Tax Board compiles the data. The system checks the registration number of the pesticide to ensure that the number is valid, checks that the crop to which the pesticide was applied is a crop for which the pesticide is registered, and converts the reported number of pounds or gallons of pesticide applied into pounds of active ingredients. If the computer finds errors in the data, it rejects the record of that pesticide application and prints it out on an error listing. If the Information Services Unit cannot correct the error, the record of that application is not included in the summary use reports.

In a March 5, 1984, letter to a member of the State Assembly, the department reported that the computer rejects from 11 to 15 percent of the records it processes annually. However, when we asked the department about this figure, the department could not provide us with the calculations used as a basis for the information in the letter. The chief of the Information Services Unit told us that the unit's staff told her orally in weekly staff meetings the percentage of records the computer could not process. The department later provided us with the data to calculate the percentage of records the computer system rejects.

Unreported Use

We also examined the possibility that unreported pesticide use caused underreporting in the summary use reports. However, we found no evidence that this is a problem. Although state laws and regulations and the department's policies and procedures manual for county agricultural commissioners do not require the agricultural commissioners to identify those who apply a restricted pesticide without filing a notice of intent and a use report, we found that some agricultural commissioners do have systems in place to detect unreported applications of pesticides. We contacted the agricultural commissioners or members of their staff in the eight counties that process the highest number of applications for permits. Six of the counties reported that they do have systems in place to detect those who apply pesticides without filing a notice of intent or a use report.

The chief of the Pesticide Enforcement Unit stated that the department's district personnel can and do recommend that the counties develop systems to identify unreported applications of pesticides. He added, however, that the department has not identified unreported pesticide use as a problem.

Use of Incorrect Conversion Factors

When the department registers a new pesticide, the Information Services Unit is supposed to calculate the factor to be used for

converting pounds or gallons of the pesticide used into pounds of active ingredients used. The unit includes this factor and other information about the pesticide in the computer system at the Franchise Tax Board, which compiles the data from the use reports. The computer uses the factors to convert amounts of pesticides into pounds of active ingredients.

However, the department has used incorrect factors to convert gallons of pesticides into pounds of active ingredients. For example, from 1982 until our review, the Information Services Unit used the factor 8.33 instead of always calculating the correct conversion factor for a particular pesticide; the factor 8.33 is the factor for converting gallons of water into pounds of water. Prior to 1982, the unit used the factor 8.0 when it did not calculate the correct factor for converting gallons of a particular pesticide to pounds of active ingredients.

The department has been aware of the errors in these factors for more than two years. In a 1981 letter to the Governor's Office, the department reported that it had found errors in some of the factors used to convert gallons of pesticides to pounds of active ingredients. The department further added that it was working with the Franchise Tax Board and the Department of Finance to determine the feasibility of verifying the conversion factors. At the time of our review, however, the department had not corrected those errors.

Because the department uses the summary use reports to compare use of pesticides, the department needs to know the degree of inaccurate reporting for each pesticide. In the March 5, 1984, letter to the member of the Assembly, the department stated that the errors in the factors to convert liquid measures to pounds have resulted in underreporting of active ingredients in restricted pesticides by about 2.4 percent. We determined, however, that the underreporting of some active ingredients in restricted pesticides is much greater than 2.4 percent. For example, the department's summary use report for 1982 states that approximately 93,550 pounds of sodium arsenite were used that year. Two pesticides accounted for this figure. The department used the factor 8.0 to convert gallons of the two pesticides to pounds of sodium arsenite. However, these two pesticides have conversion factors of 12.121 and 15.0, respectively. When we applied the correct conversion factors to the gallons of pesticides used, we found that the department had underreported the total use of sodium arsenite in these two pesticides by at least 52 percent and as much as 88 percent.

In 1983, the department hired a part-time staff person to verify and recalculate the conversion factors. He recalculated some of the factors using data available in the department; he could not recalculate the correct factors for all pesticides because the department did not have sufficient data. At the time of our review, the department had not replaced any of the incorrect factors with the recalculated factors because, according to the assistant director of the department, the department wants to correct and replace all incorrect conversion factors at one time.

The department currently plans to send letters to all manufacturers asking them to provide the data necessary to calculate the correct conversion factors for all pesticides that have been registered in California. Following our review, the Information Services Unit initiated procedures to obtain the data necessary for correctly calculating conversion factors when the department registers pesticides.

THE ANNUAL REPORTS OF PESTICIDES USED AND SOLD CANNOT BE COMPARED

In addition to publishing data on the use of pesticides, the department publishes data on the sale of pesticides. The department requests pesticide registrants to report the total number of pounds of active ingredients in pesticides sold for use in California. The department compiles this information and publishes it annually in the Report of Pesticides Sold in California (sales report). Although the department reports both the use and sale of pesticides in pounds of active ingredients, the amount of pesticides sold does not equal the amount of pesticides used during the same period for three reasons.

The first reason that the data on the use and sale of pesticides cannot be compared is that the sales report may include double counting of the reported sale of active ingredients. The department instructs registrants to report the total pounds of each active ingredient sold for use in California. However, according to a program supervisor in the Pesticide Enforcement Unit, one registrant may sell an active ingredient to another registrant who resells the same active

ingredient. Both registrants may report the sale of the same active ingredient. The department does not audit or otherwise verify the information reported by the registrants for the sales report. However, the department, responding to a question from the Governor's Office, discovered that two registrants had reported the sale of over one million pounds of the same active ingredient in 1980.

A second reason that the data on the use of pesticides is not comparable to the data on the sale of pesticides is that an active ingredient sold in one year is sometimes not used until the following year. Therefore, an active ingredient that the department reports as sold for use in California in one year may not be included in the annual use report until the following year.

Third, although the sales report includes data on the sale of all active ingredients in pesticides sold for use in California, the annual summary use report does not include complete data on all active ingredients used. The Food and Agricultural Code requires persons who hold permits to use restricted pesticides to report each use. In addition, state law and department regulations require pest control operators to report the use of all pesticides. However, neither the code nor the regulations require persons other than pest control operators who use pesticides that are not restricted to report their use. Pesticides that are not restricted include household insecticides, flea collars, and home garden products. Use of these pesticides is not reported in the summary use reports.

In addition, not all uses of restricted pesticides must be reported. Although the department's regulations require persons who use restricted pesticides to obtain a permit for most uses, the regulations exempt some uses and quantities of restricted pesticides from the requirement for a permit. For example, the pesticide paraquat, when packaged only for home use, is exempt from the permit requirement. Pesticides containing some herbicides and packaged in quantities of one pint or less are also exempt from the permit requirement. Since persons who use these pesticides are exempt from the requirement for a permit, they are also exempt from the requirement to file a use report. Consequently, because restricted pesticides in certain quantities and for certain uses are exempt from the reporting requirement and because only pest control operators must report the use of pesticides that are not restricted, the summary use reports do not report all uses of pesticides.

Obtaining sufficient information to make sales data and use data comparable may be impractical. To make the published data on pesticides used and pesticides sold comparable, three changes must be made. First, to eliminate double reporting, the department would have to audit the sales information reported by registrants. Secondly, the department would have to determine how much of the pesticides sold in a given year are actually used in that year. To accomplish this, the department would have to conduct an inventory of pesticides purchased by individuals and pest control operators to determine the amount of pesticides on hand at the end of the year. Finally, to include all pesticides in the summary use reports, the department would have to

require reporting of the use of all pesticides, including those products used in households and in home gardens.

CONCLUSION

The Department of Food and Agriculture and the county agricultural commissioners regulate the use of pesticides. Applications of certain pesticides must be reported to county agricultural commissioners. The commissioners forward these reports to the department, which compiles the information into summary use reports. However, there are no criteria specifying the department's use of the summary use reports. Without such criteria, we cannot evaluate the department's use of the reports or the significance of the inaccuracies in the reports.

The annual data on pesticides used and sold are not comparable because the sale of the same pesticide might be reported by more than one manufacturer, pesticides reported as sold in one year are sometimes not used until subsequent years, and the department does not require reporting of all uses of pesticides.

If the Legislature or the department establishes criteria for using the summary use reports, the department can then determine how accurate the summary use reports should be and develop procedures necessary to improve the accuracy of the

reports. It may be impractical, however, to require sufficient information to make the annual use report and sales report comparable.

CHAPTER III

THE PESTICIDE MILL TAX

In collecting the pesticide mill tax, the Department of Food and Agriculture does not require more information from pesticide registrants on the pesticide mill tax assessment form than it did when we conducted our 1980 review. In addition, the department's criteria for selecting registrants for audit are similar to those used in 1980. However, the department currently audits more registrants each year than it was auditing in 1980. Moreover, a memorandum by the chief of the department's audit unit stated that in the 24 months previous to May 24, 1984, the department's audits had identified more than 300 illegal pesticides that were being marketed in California. Although the State Board of Equalization (board) can administer the pesticide mill tax program, cost estimates provided by the board indicate that it would cost $143,371 more per year for the board to administer the program than for the department to do so. Finally, for the three fiscal years that ended June 30, 1983, the State paid over $12.6 million from the pesticide mill tax to California counties for enforcing pesticide regulations; the counties spent more than $27.6 million. (Counties receive additional reimbursements from other sources.)

THE ASSESSMENT FORM IS UNCHANGED SINCE OUR 1980 REPORT

The Auditor General's 1980 report was critical of the form on which pesticide registrants report their sales of registered pesticides.

The "Report of Economic Poison (Pesticide) Sales and Assessment" (assessment form) required registrants to report only the total dollar sales of pesticides. For example, a registrant that sold several pesticides was required to report only the total dollar sales figure instead of sales of each pesticide. Consequently, without conducting a field audit, a department auditor had no means by which to determine whether a registrant had included the proper pesticide tax assessment for each registered pesticide.

The Auditor General report stated that additional information on the assessment form would enable the department's audit staff to better determine which registrants should be audited. This modification would increase the efficiency and effectiveness of the auditors in monitoring the reports. For example, if a registrant were required to report the sales of each registered pesticide for the quarter, the department could compare the number of pesticides registered by the registrant with the number of pesticides reported on the assessment form. This type of audit, used in conjunction with a field audit, could also increase the effectiveness of the auditor at the audit site.

In an opinion dated May 27, 1980, the Legislative Counsel concluded that the department "may not require a registrant . . . to report to the director the monthly volume and dollar amount of sales for each individual economic poison [pesticide] for which the registrant is required to pay an assessment." Consequently, the department did not have sufficient authority to require additional data on the assessment

form. The Auditor General report recommended that the Legislature consider providing the department with the necessary authority to require more detailed data on pesticide sales.

As of May 1984, the assessment form was the same as in August 1980. According to the Food and Agricultural Code, each registrant must pay the department an assessment not to exceed eight mills ($0.008) per dollar of sales for all sales of pesticides registered and labeled for use in the State. However, a registrant is not required to pay an assessment on pesticides registered and labeled for use in further manufacturing or formulating of pesticides. Since registrants are not required to disclose on the assessment form the amount of sales of each registered pesticide, the department still cannot determine without a field audit whether the registrant has reported and paid the full amount of the pesticide mill tax required.

THE DEPARTMENT HAS IMPROVED ITS EFFORTS TO AUDIT PESTICIDE REGISTRANTS

The department audits registrants to ensure that they comply with the applicable provisions of the Food and Agricultural Code. These provisions define the requirements for reporting sales of registered pesticides sold for use in California and for assessing the pesticide mill tax. In addition to being critical of the assessment form, the Auditor General's 1980 report noted that the department had not conducted enough audits of registrants to ensure their compliance with regulations

for reporting and assessing pesticides sales. The Auditor General's report also criticized the method by which the department selected registrants for auditing.

The department has improved its performance in auditing registrants. The 1980 report stated that over the previous five years, 197 audits had recovered more than $300,000 in additional tax revenues (approximately 10 percent above the amounts reported by the registrants). According to the department's audit reports and statistics that we reviewed for our current report, during the three fiscal years that ended June 30, 1983, the department conducted 595 audits and assessed more than $1.8 million in additional tax revenues.

The criteria for selecting registrants for audit, however, remain similar to those used in 1980. As stated in the 1980 report, the department initially selected a registrant for audit based upon such factors as a specific request from enforcement or registration officials, an irregularity in the registrant's mill tax payments, the density of companies in a geographical area, or information from other sources. In addition, some registrants requested audits. The department then selected additional registrants because of their proximity to the first registrant selected. The report stated that, although the department considered several factors in the auditee selection process, it selected most auditees based upon their geographical location.

Presently, the department selects a registrant for audit based upon the registrant's composite characteristics such as the dollar amounts of pesticide sales, the number of pesticides the registrant has registered, and the geographical location of the registrant. The chief of the audit unit stated that after selecting a registrant for audit, auditors also schedule visits of other registrants located in close proximity.

We concluded that, even though the department's current criteria for selecting registrants for audit are similar to those used in 1980, the criteria are now less important because the department now conducts more audits. The department's statistics indicate that it can audit all registrants within approximately six years; the 1980 report indicated the department would have required over 20 years to audit all registrants.

COST ESTIMATES INDICATE THAT THE STATE BOARD OF EQUALIZATION COULD ADMINISTER THE PESTICIDE MILL TAX PROGRAM BUT AT A HIGHER COST

The Department of Food and Agriculture and the State Board of Equalization (board) are both capable of administering the pesticide mill tax program. The board initially estimated that the development costs of administering the pesticide mill tax program would be $8,743 and the annual costs would be $373,838. On April 27, 1984, the board revised its estimates of the development costs to $14,743 and the annual costs to $299,463.

The board's analysis of the costs of administering the pesticide mill tax program assumes that while the program would initially be processed manually, the process would be automated within two years. The board administers 13 tax programs for the support of state and local governmental activities, more tax programs than any other state department.

The department presently operates the program manually. The department estimates its annual cost for administering the program at $156,092, based on its fiscal year 1982-83 actual expenditures. Thus, the revised estimate of annual costs of the State Board of Equalization and the figures from the Department of Food and Agriculture indicate that the board's annual cost for administering the pesticide mill tax program would be about $143,371 greater than the department currently spends.

The department's audit program has achieved certain benefits. During fiscal years 1981-82 and 1982-83, the department assessed registrants approximately $1.2 million more than the cost of auditing registrants during those two fiscal years. Furthermore, in a May 1984 memorandum, the chief of the audit unit reported results of the department's audits. During the 24 months preceding the memorandum, the audit unit identified over 300 illegal pesticides that were being marketed in California. Also, the chief told us that the department conducts other audits, such as the audits of commercial feed and commercial fertilizers, while conducting audits of pesticide registrants.

COUNTIES SPEND APPROXIMATELY $9 MILLION EACH YEAR ENFORCING PESTICIDE REGULATIONS

The Food and Agricultural Code requires the State to provide counties five-eighths of the pesticide mill tax revenue received by the State. We reviewed the data that California counties submitted to the department to determine how the counties spend the pesticide mill tax revenue they receive from the State. For the three fiscal years that ended June 30, 1983, the State paid California counties over $12.6 million as a partial reimbursement of their expenditures for enforcing pesticide regulations. During this same period, California counties spent about $27.6 million on pesticide regulatory programs.

County expenditures for enforcing pesticide regulations include the cost of enforcing county and state laws relating to injurious and restricted materials, injurious herbicides, and other pesticides; licensing agricultural pest control operators; inspecting pest control equipment and materials; and investigating complaints, injuries, damages, or losses resulting from applications of pesticides.

The allocation of pesticide mill tax revenue to counties is based on each county's enforcement activities, expenditures, workload, and performance. The criteria for allocation include evaluations by county personnel of pesticide application sites and inspections of pesticide use, the hours that county personnel spend enforcing regulations on pesticide use, and the effectiveness of the county's pesticide enforcement program, which is evaluated by the department.

As stated in the California Administrative Code, "no county shall be reimbursed an amount that is less than the amount it received as a reimbursement for pesticide enforcement expenditures for fiscal year 1978-79 unless the pesticide mill tax total revenue falls below the 1979 level." The total amount of pesticide mill tax paid to counties for fiscal year 1978-79 expenditures was $2.8 million. The amount of pesticide mill tax paid to counties in each of the past three fiscal years was greater than the 1978-79 reimbursement. Table 5 shows the counties' expenditures for enforcing pesticide regulations and the State's reimbursements to the counties during fiscal years 1980-81, 1981-82, and 1982-83.

TABLE 5

COUNTY EXPENDITURES FOR ENFORCING PESTICIDE REGULATIONS AND STATE REIMBURSEMENT FISCAL YEARS 1980-81, 1981-82 AND 1982-83

Fiscal Year	County Expenditures	State Reimbursement of Pesticide Mill Tax to Counties	Percent of County Expenditures Reimbursed From the Pesticide Mill Tax
1982-83	$ 9,978,094	$ 4,522,117	45.3
1981-82	8,729,078	4,236,421	48.5
1980-81	8,913,391	3,880,019	43.5
	$27,620,563	$12,638,557	45.8

Source: Department of Food and Agriculture.

CONCLUSION

The Department of Food and Agriculture has not changed the assessment form since the Auditor General's report in 1980; the criteria for selecting registrants for auditing are also similar to those in 1980. However, the department has increased the number of registrants it has audited. With the increase in the number of audits, the problems with the selection criteria have become less significant than in 1980.

Both the Department of Food and Agriculture and the State Board of Equalization are capable of administering the pesticide mill tax program, but cost estimates indicate that the State Board of Equalization's annual costs for administering the program would be $143,371 greater than the costs reported by the Department of Food and Agriculture.

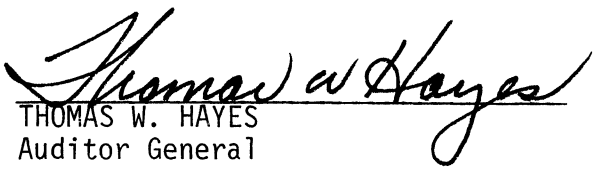
For the last three fiscal years, the State reimbursed California counties a total of over $12.6 million from the pesticide mill tax collections as reimbursement for their costs of enforcing pesticide regulations. The counties spent $27.6 million to enforce pesticide regulations.

RECOMMENDATION

To further improve the Department of Food and Agriculture's efficiency in auditing pesticide registrants, the Legislature should provide the department authority to require more detailed information on the assessment form.

We conducted this review under the authority vested in the Auditor General by Section 10500 et seq. of the California Government Code and according to generally accepted governmental auditing standards. We limited our review to those areas specified in the audit scope section of this report.

Respectfully submitted,



THOMAS W. HAYES
Auditor General

Date: August 6, 1984

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DEPARTMENT OF FOOD AND AGRICULTURE

1220 N Street
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July 17, 1984

Mr. Thomas W. Hayes
Auditor General
660 J Street, Suite 300
Sacramento, California 95814

Dear Mr. Hayes

Following is the Department's response to the recommendations in the July 1984 draft of the report entitled "The State Lacks Data Necessary to Determine the Safety of Pesticides."

In general, we are very satisfied with the accuracy and objectivity of your report. Of particular concern to us however, is the title, which we feel is misleading. We recognize that the Auditor General was required by the Joint Legislative Audit Committee to focus on the percentage of pesticides registered that were supported by the chronic feeding, cancer, birth defects, and reproduction health studies; however, as we explain below, these studies are not always necessary to determine the safety of pesticides. The title "The State Lacks Data Necessary to Determine the Safety of Pesticides" draws a conclusion that is not supported by the content of the report (1)*. This conclusion is drawn without the benefit of a scientific review to determine if these studies are needed or warranted or if they are required by regulation or law.

CHAPTER I

Your report makes three recommendations to improve the program for registering new pesticides and to comply with statutory requirements for continuous evaluation of currently registered pesticides.

RECOMMENDATION

° Clearly define what data applicants must submit when applying to register pesticides in California and determine if California requirements should be more stringent than EPA requirements. If the State's data requirements incorporate EPA requirements, the Department should develop procedures for verifying precisely what data the EPA requires for registering each pesticide.

RESPONSE

It is essential in the discussion of this recommendation and the understanding of this chapter of the report that the reader recognize that when the auditors indicate that studies are lacking (data gap), they are referring

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* The Auditor General's comments on specific points contained in the agency's response begin on page 71.

to six specific studies (chronic toxicity, oncogenicity, teratogenicity, reproduction, mutagencity, and neurotoxicity) without regard to whether these studies are relevant or required by law or regulation.

The Department considers a data gap to exist only when a study is not on file which is required by law or regulation, or the Department determines it is necessary to protect human health or the environment. California Administrative Code (CAC) Section 2360 requires registrants to submit to the California Department of Food and Agriculture (CDFA) summaries of the data required by EPA for federal registration. The specific definitions of required data are located in the federal guidelines.(2) Conversely, the auditors have indicated data was lacking when the active ingredient audited did not have tests on file in each of six categories, regardless of whether that test was required or necessary. The auditors therefore concluded, based on these findings, that pesticides registered in California may be unsafe without considering the relevancy or need for a particular type of study. To conclude that pesticides are unsafe only on the basis of an absent test is not practical.(3) Furthermore to develop rigid data requirements would subject numerous formulations to impractical and unnecessary testing.

The irrelevance of requiring all studies in all cases can be emphasized by the following extreme examples. It would be unnecessary to conduct a series of chronic tests on a sex lure taken from the sex glands of a female pink bollworm, and impractical to conduct a chronic feeding study in which animals were administered a formulation of sulfuric acid on a daily basis. Both sex lures and sulfuric acid formulations are currently registered as pesticides.

The auditors correctly point out the flexibility clause in the guidelines which allows the EPA some discretion in requiring data on an individual product basis. These same flexibility clauses were also in the Code of Federal Regulations prior to the development of the guidelines.

New pesticide formulations require evaluation on a case by case basis considering formulation toxicity, chemistry, use patterns and method of application. Decisions as to what data is necessary are made at the federal level in preregistration conferences using existing guidelines. Experience at the federal level indicates that rigid data requirements are neither practical or workable. For example, sodium chlorite, one of the active ingredients reviewed during the audit, was registered in California after the enactment of Section 2360 of the CAC. This product is a technical industrial microbiostat used for bacterial slime control in paper mills. The EPA did not require chronic toxicity data on this product because it is not used on a food crop or in a manner which would cause human exposure.

Products registered prior to 1980, although legally registered, will not normally have on file summaries of all of the studies required as of January 4, 1980. The Department strongly supports the need to evaluate products registered prior to 1980 to determine what additional chronic health studies may be needed. In the early 1980's, the EPA implemented a Data Call-In program requiring registrants to submit such chronic health data on old pesticides registered prior to the development of current federal data guidelines.

In a February 10 letter to George E. Brown Jr., Chairman of the Subcommittee on Department Operations, Research, and Foreign Agriculture Committee on Agriculture, John A. Moore, D.V.M., Assistant Administrator for the Pesticides and Toxic Substances Program of the EPA reports:

"To date (March 23, 1984), the Data Call-In Program has processed 197 chemicals representing an estimated 75 percent of the total pesticide production for use in agricultural and related areas or an estimated two billion pounds of chemicals. Add to that the fact that 70 chemicals have been reassessed for reregistration, which represents an estimated 37 percent of the total production of registered pesticide chemicals. This means that chronic data gaps have been identified and data are being generated for approximately 74 percent of the total production, and that, for approximately 37 percent of the production, data gaps in all scientific disciplines have been identified and the Agency is requiring the pertinent data to be generated. (This includes some overlap or double counting because some of the Data Call-In chemicals have gone through registration standard development.)" In the above paragraph, "data gap" is defined according to the requirements of the federal guidelines. By 1986, the EPA projects that chronic health data will have been called in on all pesticides produced for use on food crops; they expect to have called in chronic health data on all nonfood crops and other uses by 1988.

Whether California requirements should be more stringent than the EPA requirements is an issue that must be resolved by the Legislature. This would require duplication of the EPA efforts in that it would require additional toxicology and chemistry staff to conduct preregistration conferences with registrants to determine the data requirements for new formulations.

We concur with the auditor's assessment that the Department does not have a process for documenting precisely what data registrants have submitted to the EPA for registering each pesticide; however, existing regulation provides the Department the authority to enforce the data submission requirements. We will be interacting with the EPA and registrants to implement a system for such verification.

RECOMMENDATION

° Determine which active ingredients in currently registered pesticides lack the required health data, request the applicant to submit the required data, and thoroughly evaluate the required data.

RESPONSE

This recommendation is presently being implemented. Earlier this year, the Administration authorized $499,000 to initiate a one-year program beginning July 1, 1984 which includes an initial phase of cataloging and computerizing the test titles of data on file and identifying specified data gaps for each pesticide active ingredient. Pending legislation (SB 950), if adopted, will mandate submission and evaluation of such required data. Even if SB 950 is not adopted, the Administration and the Department are committed to implementing phase two which involves filling the data gaps for pesticides registered prior to 1980. Following the development of chronic health effects data, phase three will be implemented which will involve review and evaluation of these studies.

RECOMMENDATION

° Develop procedures to document which summaries and other scientific literature the Department evaluates in reaching its decisions on pesticide registration.

RESPONSE

The auditors dealt primarily with active ingredient test data volumes and did not thoroughly search product files for evaluation documentation. ④ Since the Department registers individual products and evaluation comments are filed by product, we understand the difficulty of auditing 11,000 to 12,000 individual files. However, the auditors make a valid point in that data found in the public literature is not cross referenced; is not always filed with the active ingredient volumes in the library; and is not always documented when utilized by evaluators to supplement the information submitted by the registrant.

We support this recommendation, and are taking steps to implement procedures to standardize documentation of data summary reviews.

The report further recommended:

° To ensure that the Department carries out these actions, the Legislature should require the Department to submit periodic reports of its progress

in implementing the recommendations. If the Legislature is dissatisfied with the Department's progress in implementing these recommendations, the Legislature should amend the statutes to include minimum data requirements and timetables for obtaining and evaluating the data.

RESPONSE

The Department supports this recommendation. Pending legislation, SB 950, mandates the Department to submit three reports to the Legislature.

By April 1, 1985, a list of currently registered active ingredients and the testing requirements for these ingredients must be submitted; by July 1, 1985, a list of health affects studies on file for each active ingredient is required; and by December 31, 1985, the Department must provide: (1) its determination of whether the health effects studies on file are valid, complete, and adequate; (2) a list of data gaps for each active ingredient; (3) the Department's determination if adverse reproductive effects are shown in each study; (4) a list of each active ingredient with data gaps or with studies showing adverse reproductive effects, and the amount sold in 1985 for home or agricultural use. (The December 31, 1985, report could be supplemented until April 1, 1986.)

In addition to responses to specific recommendations, other portions of the report require comment.

The report states that some of the summaries they examined did not meet the requirements of Section 2360 of the California Administrative Code.

The auditors do not indicate whether the studies they are referring to were submitted prior to 1980. This is important due to the fact that Section 2360 of the California Administrative Code was not adopted until January 4, 1980.⑤

The report also states that some of the health studies in the Department's files on registered pesticides were not properly conducted. Laboratory audits by the EPA which began in 1976 uncovered hundreds of questionable tests performed by the Industrial BioTest Laboratories (IBT). During 1983, the Department conducted a seven month study investigating the IBT health studies which support California registrations. As a result of that investigation, 17 active ingredients presently registered were placed into formal reevaluation. Further investigation and evaluation of the IBT health studies resulted in reducing the number in question to eight active ingredients. All other studies declared to be invalid on products presently registered in California have either been replaced or the studies have been initiated with projected completion dates on file with our Department. The Department's IBT report was made available to the public on March 9, 1984.

CHAPTER II

Although the Auditor General made no specific recommendations regarding the pesticide use and sales reporting systems, the Department has addressed those concerns expressed in the areas of (1) use reports returned to the counties; (2) exclusion by the computer from the summary use report due to error; and (3) conversion factors.

A weekly log is now being utilized which provides for the recording of both the number of reports returned to the Division's district office for correction at the county level and the corrected reports which are subsequently returned. Those reports which are returned are stamped, "Returned for Correction" so they may be easily identified when they are resubmitted for compilation.

A form has also been developed and utilized to document the number of use reports excluded from the summary because they cannot be processed by the computer.

The audit report refers to a March 5, 1984 letter to a member of the State Assembly in which the Department reported the computer rejects 11 to 15 percent of the records it processes.

Following are the percentages of errors on the work processed since the form has been utilized:

	Error Rate	
Month of Application	Individual	Monthly Summaries
August 1983	11.04	8.22
September 1983	10.74	8.54
October 1983	11.80	12.43
November 1983	12.33	12.11

In regards to conversion factors, on May 22, 1984, a letter was sent to the registrants (with forms for their completion) requesting the information to expedite entry of the correct factors necessary to convert liquid formulations from gallons used to pounds of active ingredients.

These factors will not be available in time for the 1983 Annual Report which should be ready for publication within the month. The 1984 report will reflect the corrected conversion factors.

Chapter III

Although the mill tax is the largest portion of funds reimbursed to the counties, other funding sources are considerable and should be noted. The following display provides an accurate reflection of the reimbursements to the counties:

Fiscal Year	County Expenditures	Reimbursement to Counties			Percentage of County Expenditures Reimbursed
		Mill Tax	General Fund	Federal	
1982-83	$ 9,978,094	4,522,117	$2,800,000	$151,000	74.9
1981-82	8,729,078	4,236,421	2,800,000	200,000	82.9
1980-81	8,913,391	3,880,019	2,400,000	200,000	72.7
	$27,620,563	$12,638,557	$8,000,000	$551,000	76.7

RECOMMENDATION

° To further improve the Department of Food and Agriculture's efficiency in auditing pesticide registrants, the Legislature should provide the Department authority to require more detailed information on the assessment form.

RESPONSE

The Department concurs with this recommendation and supports pending legislation (AB 3018 Klehs) which would require additional information from registrants. Specifically, the bill provides for information on the quarterly dollar sales of, and the quarterly pounds of each registered economic poison sold for use in this State.

Sincerely

Clare Berryhill

Clare Berryhill
Director
(916) 445-7126

AUDITOR GENERAL'S COMMENTS ON THE DEPARTMENT OF FOOD AND AGRICULTURE'S RESPONSE

The comments that follow address specific points made by the department. The numbers correspond to numbers we have placed in the department's response.

(1) We conclude that "the State lacks data necessary to determine the safety of pesticides" not only because the department does not have on file summaries of many health studies, but because some of the summaries it does have on file may not be adequate. As we point out in the report:

- Some of the summaries are very brief and may not be adequate. (pp. 27-28)
- Over 40 percent of the summaries in our two samples were either dated prior to 1975 or not dated. If the same tests were performed using current standards, the same results may not be obtained. (p. 29)
- The department identified 75 invalid studies that required replacement. (p. 30)
- The department has not fully developed a program of continuous evaluation of all pesticides as required by state law since 1969. (pp. 32-33)
- Most of the time, neither we nor the department could determine exactly which summaries and scientific literature were reviewed prior to the registration of pesticides. (pp. 30-31)

(2) As we point out on pages 23 and 24, the federal guidelines are general and imprecise, and the EPA can change the requirements on a case by case basis.

(3) See note 1.

(4) As indicated on page 31, we reviewed the department's product files for evidence that specific volumes of summaries had been reviewed prior to registering a pesticide. For the product files we reviewed, less than 10 percent of the available summaries were specifically identified in the product file as having been reviewed.

(5) Text changed.

APPENDIX A

SYNOPSIS OF THE 1980 AUDITOR GENERAL REPORT ON THE STATE'S PESTICIDE REGULATORY PROGRAM

Report P-934 -- Review of the California Department of Food and Agriculture's Pesticide Regulatory Program, August 1980.

The Department of Food and Agriculture has had limited success in establishing an ongoing reevaluation program. Certain pesticides currently registered have not been evaluated to ensure their safety and effectiveness for use in California in accordance with the Food and Agricultural Code and the California Administrative Code. Until the department establishes an ongoing reevaluation program, it cannot ensure that the use of potentially harmful pesticides is being eliminated.

We also found that county agricultural commissioners are unable to promptly and thoroughly investigate pesticide illness cases because the two systems that notify the commissioners of pesticide incidents are inadequate. Without prompt notification, the commissioners cannot obtain complete, accurate information that the department uses to detect and prevent pesticide use violations.

Our review of the department's audits of pesticide registrants disclosed that more audits and additional audit selection criteria could enable the department to more effectively monitor the collection of the pesticide mill tax. At its present rate of auditing, the department would require over 20 years to audit all pesticide registrants. Moreover, the "Report of Economic Poison (Pesticide) Sales and Assessment" form does not provide adequate sales information so that auditors can properly evaluate a prospective auditee prior to the field audit. Additional sales information would enable the audit staff to better determine which registrants should be audited. Lastly, the department's system for recording product registrations needs improvement so that the department can document registration decisions.

To address these problem areas, we recommend that the department institute ongoing reevaluation procedures. In addition, the department should monitor both systems that notify county agricultural commissioners of pesticide illness cases to ensure that the commissioners receive prompt notification. The department should also increase its audits of pesticide registrants and expand the criteria by which registrants are selected for audit. We also suggest that the Legislature consider providing the department with the necessary authority to require more detailed sales data. Finally, to better document registration decisions, the department should include evaluation comments with product files and note the registration number on the data files.

SUMMARIES OF HEALTH STUDIES FOR 32 CHEMICAL ACTIVE INGREDIENTS IN PESTICIDES REGISTERED AFTER JANUARY 4, 1980*

Active Ingredient	General Use (Food or Nonfood)***	Type of Health Study**: Chronic Toxicity†	Oncogenicity (Cancer)†	Teratogenicity (Birth Defects)	Reproduction	Mutagenicity (Mutations)	Neurotoxicity (Nerve Damage)	No Summaries On File	One or More Summaries Not on File	All Summaries On File
Acid Blue	Nonfood	X	X	UUUU	UU	-	-		+	
Acid Yellow	Nonfood	X	X	UUUU	UU	-	-		+	
Alpha Chlorohydrin	Nonfood	-	U	-	XX	XXUV	-		+	
Amdro	Nonfood	XXXX XXX	XXXX X	XXXU U	X	XXXU	-		+	
Ammonium Isobutyrate	Food	-	-	-	-	-	-	+	+	
Bromadiolone	Nonfood	-	-	-	-	-	-	+	+	
Butocarboxim	Nonfood	XU	XU	U	U	XXX	X		+	
Carbosulfan	Food	XX	XXX	XX	XX	XXX	XX			+
Chlorosulfuron	Food	XX	XX	XX	X	XXX	-		+	
Cuprous Thiocynate	Nonfood	-	-	-	-	-	-	+	+	
Cypermethrin	Food	XX	XX	UUU	X	-	UU		+	
Dimethipin	Food	XXXX XX	XX	XX	X	XXXX	-		+	
Dodemorph	Nonfood	-	-	OO	-	-	-		+	
Ethalfluralin	Food	XX	XX	XXX	X	XXX	-		+	
Thiodicarb	Food	XX	XX	XX	X	XXXX XX	XX			+
Fenarimol	Food	XXX	XX	XX	XXX	XXXX	-		+	
Fluazifop-Butyl	Food	UX	XXXU	XXXXX	XX	XUUU	U			+
Flucythrinate	Food	XXX	XX	XXX	X	XX	X			+
Fluvalinate	Food	XX	XX	XX	XX	XXXXX	X			+

Diiodomethyl Para Tolyl Sulfone	Nonfood	-	-	-	-	X	-			+	
Isobutyric Acid	Food	-	-	-	-	-	-		+	+	
Isofenphos	Food	XXXO	XXX	XXXO O	X	XXO	XXXO				+
Metalaxyl	Food	XXXX	XXXX	XXX	X	XXXX XX	-			+	
Propamocarb Hydrochloride	Nonfood	-	-	-	-	U	-			+	
Propetamphos	Nonfood	XX	XX	XXX	X	X	X				+
Pyridine-N-Oxide	Nonfood	OU	U	XXOO	XXX	U	XXOO			+	
Sethoxydim	Food	XX	XX	XX	X	XX	-			+	
Sodium Chlorite	Nonfood	O	-	-	-	-	-			+	
Sulfometuron Methyl	Nonfood	-††	-	XX	-	XXX	-			+	
Triadimefon	Food	XXX	XX	XXXX	X	XXXX	-			+	
Triclopyr	Nonfood	XX	XXX	XX	X	XXOO	-			+	
Vinclozolin	Food	XXX	XX	XX	X	X	-			+	
								Totals	4	25	7

*"Environmental Protection Agency: Pesticides Registration; Proposed Data Requirements," The Federal Register, Part III, Vol. 47, No. 227 (November 24, 1982). This proposal would require two studies for chronic toxicity, cancer, and birth defects when chronic health studies are required.

**For ingredients that show four or more summaries of a particular type of health study, the department may have additional summaries of that type of health study for the ingredient.

***Source: Pesticide Use Report for 1982, and the Farm Chemicals Handbook.

†Summaries of combined chronic toxicity and cancer studies are listed under both the chronic toxicity and the cancer columns.

††The department said a summary of one chronic toxicity study was received after we reviewed our sample, and a summary of another chronic toxicity study was due in June 1984.

Legend:

O = Summary dated prior to 1975
X = Summary dated 1975 or later
U = Summary date unknown
V = Various summaries and dates noted in one volume
- = No summary on file

SUMMARIES OF HEALTH STUDIES FOR 115 ACTIVE INGREDIENTS IN PESTICIDES REGISTERED BEFORE JANUARY 4, 1980

Active Ingredient	General Use (Food or Nonfood)**	Type of Health Study*								
		Chronic Toxicity***	Oncogenicity (Cancer)***	Teratogenicity (Birth Defects)	Reproduction	Mutagenicity (Mutations)	Neurotoxicity (Nerve Damage)	No Summaries On File	One or More Summaries Not on File	All Summaries On File
Acephate	Food	OO	XO	OOOOOX	OOO	OOOXX XX	OX			+
Alachlor	Food	OXXX	OX	OXXXX	OX	OXXUV	-		+	
Aldicarb	Food	OO	XX	-	-	-	-		+	
Alkarylpolyoxyethylene Glycol	Food	OX	OX	-	-	-	-		+	
Aluminum Phosphide	Food	O	-	-	-	-	-		+	
Amitrole	Food	U	OU	U		V	-		+	
Aromatic Petroleum Solvents	Food	-	-	-	-	-	-	+	+	
Atrazine	Food	O	OO	O	O	X	-		+	
Azinphosmethyl	Food	OO	XX	XX	O	-	O		+	
Barban	Food	OU	O	X	X	O	-		+	
Benomyl	Food	XX	X	OXX	OO	OXX	-		+	
Bensulide	Food	-	-	-	-	-	-	+	+	
Bentazon	Food	OOOOO	O	OO	OO	OOOO	-		+	
Bromoxynil Octanoate	Food	XXXX	XXXX	XXX	XX	XXXXX	-		+	
Calcium Hydroxide	Food	-	-	-	-	-	-	+	+	
Captafol	Food	OOXX	X	OXXX	O	X	-		+	
Captan****	Food	XXX	OOXXXXX	XXX	XXU	OXXX			+	
Carbaryl	Food	OU	-	OUUU	OU	-	O		+	
Carbofuran	Food	XXUU UUU	XXUU	XUUUU	XUUUU	OU	UU			+
Carbon Tetrachloride	Food	-	-	-	-	-	-	+	+	
Chlordane	Food	-	XX	O	O	X	-		+	

Chlorine	Food	-	-	-	-	-	-	+	+	
S-((4-Chlorophenyl)methyl) Diethyl Carbamothicate	Food	OOXX	XXX	OX	OU	OXX	XX			+
Chloropicrin	Food	-	XX	-	-	-	-		+	
Chlorothalonil	Food	OOX	XX	OXX	O	OXXXX	-		+	
Chlorpyrifos	Food	OOU	UUU	UU	UU	U	U			+
Copper	Food	-	-	-	U	X	-		+	
Cryolite	Food	-	-	-	-	-	-	+	+	
3-Cyclohexyl-6-(Dimethylamino) 1-Methy-S-Triazine- 2,4(1H,3H)-Dione	Food	XX	-	OX	XX	XXX	-		+	
Cyhexatin	Food	OX	X	OO	OO	X	-		+	
2,4-D Dimethylamine Salt	Food	-	-	-	-	-	-	+	+	
Dalapon, Sodium Salt	Food	UU	-	-	UU	-	-		+	
D-D-Mixture	Food	XXUU	X	U	U	OXU	-		+	
1-DEF	Nonfood	O	-	-	-	-	OOOX		+	
Diazinon	Food	X	X	O	-	-	-		+	
2,4-Dichloro-6- (O-Chloroanilino)- S-Triazine	Food	X	X	O	-	-				+

*For ingredients that show four or more summaries of a particular type of health study, the department may have additional summaries of that type of health study for the ingredient.

**Source: Pesticide Use Report for 1982, and the Farm Chemicals Handbook.

***Summaries of combined chronic toxicity and cancer studies are listed under both the chronic toxicity and the cancer columns.

****Additional summaries were noted in cancer, birth defects, and mutagenicity.

Legend:

O = Summary dated prior to 1975
X = Summary dated 1975 or later
U = Summary date unknown
V = Various summaries and dates noted in one volume
- = No summary on file

Active Ingredient	General Use (Food or Nonfood)**	Type of Health Study*						No Summaries On File	One or More Summaries Not on File	All Summaries On File
		Chronic Toxicity***	Oncogenicity (Cancer)***	Teratogenicity (Birth Defects)	Reproduction	Mutagenicity (Mutations)	Neurotoxicity (Nerve Damage)			
2,6-Dichloro-4-Nitroaniline Dichloran	Food	UUUUU	UUUU	U	OUU	UUU	-		+	
1,2-Dichloropropane,1,3-Dichloropropene and related	Food	XX	X	X	X	XUUU			+	
Dicofol	Food	OXX	XX	-	-	-	-		+	
Dicrotophos	Nonfood	UU	-	UU	UUU	UU	O		+	
Difenzoquat	Food	X	X	O	O	O	-		+	
Dimethoate	Food	-	XX	-	-	-	-		+	
Dimethyl Tetrachloroterephthalate	Food	-	-	-	O	-	-		+	
Diphenamid	Food	OOOUU	-	U	UUUU	-	-		+	
Diquat Dibromide	Food	OXUU	X	OOX	OOOXU	OOXU	-		+	
Disulfoton	Food	XX	-	OX	OOOO	OX	OOX		+	
Diuron	Food	OO	-	OX	O	-	-		+	
DNBP	Food	-	-	X	X	-	-		+	
Endosulfan	Food	-	XXX	UU	O	OO	-		+	
Endothall, Mono	Food	UUU	-	-	UU	-	-		+	
Eptam R	Food	X	X	O	XX	X	-		+	
Ethion	Food	X	X	U	O	-	-		+	
Ethylenebis (Dithiocarbumic Acid) Manganese Salt with Zinc Ion	Food	OO	-	X	O	X	-		+	
Ethylene Dibromide (EDB)	Food	-	XXX	XX	-	-	-		+	
O-Ethyl O-(4-(Methylthio) Phenyl)S-Propyl Phosphorodithioate	Food	XXX	XX	X	XX	X	X			+
Fensulfothion	Food	O	-	OX	O	OX	O		+	
Folex	Nonfood	-	-	-	-	-	-	+	+	

Folpet	Food	XX	XXX	XX	XX	X	-		+	
Formetanate Hydrochloride	Food	OOO	-	O	O	O	-		+	
Ammonium Soaps	Unknown	-	-	-	-	-	-	+	+	
Glyphosate, Isopropylamine Salt	Food	OO	O	OX	O	OX	X			+
Imidan	Food	-	-	-	-	-	-	+	+	
IPC	Food	O	OO	O	-	-	-		+	
Isopropyl Alcohol	Food	-	-	-	-	-	-	+	+	
Lime Sulfur	Food	-	-	-	-	-	-	+	+	
Malathion	Food	OO	XXX	OO	OOX	-	-		+	
Maleic Hydrazide, Diethanolamine Salt	Food	OX	XXX	X	UU	X	-		+	
Maneb	Food	OUU	-	X	O	X	-		+	
MCPA, Dimethylamine Salts	Food	-	-	-	-	-	-	+	+	
Meta-Systox	Food	OO	-	OX	OOO	OX	OO		+	
Methamidophos	Food	OO	-	X	O	X	OX		+	
Methiadathion	Food	OOO	XXX	-	U	XX	UU		+	
Methomyl	Food	UUUU	-	OX	OU	U	U		+	
Methoxychlor	Food	OO	XX	-	-	-	-		+	
Methyl Bromide	Food	OO	O	O	OV	XV	O			+
Methyl Parathion	Food	OO	XXXXX	OOXX	XX	X	-		+	

*For ingredients that show four or more summaries of a particular type of health study, the department may have additional summaries of that type of health study for the ingredient.

**Source: Pesticide Use Report for 1982, and the Farm Chemicals Handbook.

***Summaries of combined chronic toxicity and cancer studies are listed under both the chronic toxicity and the cancer columns.

Legend:

O = Summary dated prior to 1975
X = Summary dated 1975 or later
U = Summary date unknown
V = Various summaries and dates noted in one volume
- = No summary on file

Active Ingredient	General Use (Food or Nonfood)**	Type of Health Study*						No Summaries On File	One or More Summaries Not on File	All Summaries On File
		Chronic Toxicity***	Oncogenicity (Cancer)***	Teratogenicity (Birth Defects)	Reproduction	Mutagenicity (Mutations)	Neurotoxicity (Nerve Damage)			
Mevinphos	Food	OO	OO	O	O	OOOO	O			+
Mineral Oil	Food	-	-	-	-	-	-	+	+	
Molinate	Food	XX	-	O	XXXX	XX	-		+	
Monocrotophus	Food	UU	UU	U	U	U	U			+
Naled	Food	UU	-	X	U	-	X		+	
N-(2-Methyl-1-Naphthyl Maleimide)	Nonfood	-	-	-	-	-	-	+	+	
Ortho-Phenylphenol, Sodium Salt	Food	OUU	-	X	-	U	-		+	
Oryzalin	Food	XXX	-	OOOX	XXXX	-	-		+	
Paraquat Dichloride	Food	OUUUX	XX	XXU	OO	XX	U			+
Parathion	Food	OU	XXX	OOOO	OO	OOX	-		+	
PCNB	Food	OX	OXXUU	OXU	O	XX	-		+	
Permethrin	Food	XXXU	XU	U	U	UUU	U			+
Petroleum Oil	Food	-	-	-	-	-	-	+	+	
Phorate	Food	XX	XX	X	OU	X	O			+
Phosalone	Food	OO	O	X	O	V	O			+
Phosphoric Acid	Food	-	-	-	-	-	-	+	+	
Phthylaic Glycerol Alkyd	Food	OUU	OUU	-	-	X	-		+	
Polybutenes	Food	OX	-	-	U	-	-		+	
Poly-I-Para Menthene	Food	-	-	-	-	-	-	+	+	
Prometryn	Food	OO	-	O	O	XX	-		+	
Pronamide	Food	OO	U	-	O	O	-		+	
Propanil	Food	-	-	-	-	-	-	+	+	
Propargite	Food	O	X	OXX	O	X	-		+	
S-Propyl Butylethylthiocarbonate	Food	-	-	-	-	-	-	+	+	
Silvex, Propylene Glycol Butyl Ether Ester	Food	-	-	-	-	-	-	+	+	

Simazine	Food	-	U	-	-	U	-			+
Sodium Arsenite	Food	-	-	-	-	-	-		+	+
Sodium Cacodylate	Food	-	OX	XX	-	XU	-			+
Sodium Chlorate	Food	-	-	-	-	-	-		+	+
Sodium Metaborate	Nonfood	-	-	-	-	-	-		+	+
Sulfur	Food	-	-	-	-	-	-		+	+
Topsin M-R	Food	OO	0	0	0	XUUU	-			+
Toxaphene	Food	XV	XX	X	OO	-	-			+
Trichlorophon	Food	OUU	-	-	-	-	0			+
Trifluralin	Food	XXU	XX	OOOO	OOO	-	0			+
Vikane-R	Nonfood	-	-	-	-	-	-		+	+
Xylene	Food	-	-	-	-	XXXX	U			+
Zineb	Food	0	OXV	X	-	X	-			+
Ziram	Food	-	XX	-	-	-	-			+
								Totals	26	102	13

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