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CONTROL OF PESTICIDE RESIDUES IN FOOD PRODUCTS

**A Review of the
California Program of Pesticide Regulation**

MARCH 1985

CONTROL OF PESTICIDE RESIDUES IN FOOD PRODUCTS

A Review of the California Program of Pesticide Regulation

A Report of the
COMMISSION ON CALIFORNIA STATE GOVERNMENT
ORGANIZATION AND ECONOMY

March 1985

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March 18, 1985

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President pro Tempore of the Senate
and Members of the Senate

Honorable Patrick Nolan
Assembly Minority Floor Leader

Honorable Willie L. Brown, Jr.
Speaker of the Assembly
and Members of the Assembly

Dear Governor and Members of the Legislature:

In August 1984, our Commission initiated a major study of the State's programs to regulate pesticide residues in food and water. The study was undertaken in part because our Commission, through an earlier study of State toxic programs, had become aware of the potential dangers from letting toxic substances in our environment go undetected. The scope of our study was also designed to be responsive to a request we had received from members of the Legislature to conduct a study of pesticide regulatory programs as managed by the Department of Food and Agriculture.

The use of pesticides and the potential dangers from exposure to them has become of great concern to the public in recent years. Events in Bhopal, India and recent news stories regarding pesticide and selenium contamination of the Kesterson Reservoir and Wildlife Refuge in Merced County have served to heighten the public's awareness and sensitivity to government programs created to regulate pesticide manufacturing, registration, and use.

The State of California in fiscal year 1984-85 will spend more than \$22 million to register pesticides, monitor and enforce their use, monitor the environment, and oversee certain aspects of related worker health and safety. It was the objective of our study to determine how effective the Departments of Food and Agriculture (CDFA) and Health Services (DHS) are in fulfilling their responsibilities including the protection of public health. Additionally, our Commission evaluated the operations of these programs to identify opportunities for improved efficiencies and associated cost savings.

During the course of our study, the Commission conducted public hearings in Los Angeles and Sacramento; interviewed in excess of 70 government and industry officials and noted experts in the field; attended major conferences and seminars on pesticide issues; and conducted extensive research and analysis.

Our study revealed that great uncertainties in science as well as inadequate practical knowledge of how, when, where, and by whom pesticides are used prevent government regulators from making perfect regulatory decisions in all cases. We also learned, on the other hand, that to the extent scientific assumptions are correct and pesticide use is reported, the California program of pesticide regulation is a leader in the country, and is in many ways exemplary in comparison to other states.

Nevertheless, this Commission in our attached report entitled "Control of Pesticide Residues in Food Products: The California Program of Pesticide Regulation," has identified over 30 findings and presents more than 40 recommendations which, if implemented, will result in important improvements and increased efficiencies in the management of these regulatory programs.

Our findings include the following:

- While setting general management priorities, the CDFA lacks an articulated, overall priority setting discipline for identifying "pesticides of greatest concern."
- CDFA has inherited significant weaknesses from the Federal government's statutes and programs to regulate pesticides.
- Funding for pesticide regulatory activities is inadequate to maintain state-of-the-art regulatory capability; the General Fund is supporting too large a portion of these regulatory programs.
- CDFA's program of public information is inadequate to give the public access to sufficient non-technical data on the programs.
- Certain Federal and CDFA data bases critical to State monitoring and enforcement activities are inadequate.
- For some pesticides used on foods, CDFA lacks the residue data necessary for estimating risk.
- In some cases, CDFA lacks adequate data to enable it to predict the environmental effects of either previously or newly registered pesticides.
- CDFA's residue monitoring program could be better designed to identify public health problems more efficiently.
- CDFA lacks detection methods for many pesticides in common use in California.
- The State lacks an effective program of residue monitoring for foods destined for processing and for processed foods.
- Current enforcement sanctions are cumbersome, ineffective, and inadequate.

- CDFA and DHS have inherited a serious data gap on the "inert ingredients" in pesticide formulations. Furthermore, there are no practicable analytical residue detection methods for many inert ingredients.
- The Federal Food and Drug Administration's program for monitoring residues in imported foods is not equivalent to California's monitoring program.

To improve the efficiency, effectiveness, organization, and management of pesticide regulatory programs, the Commission has developed over forty recommendations including the following:

1. CDFA management should begin work on selecting criteria to identify the "pesticides of greatest concern" and integrate the priority pesticides with program management priorities already established.
2. Current law should be amended to specify that the contribution from the Agriculture Fund shall equal the General Fund contribution to support pesticide regulation.
3. The Legislature and Governor should authorize the establishment of an Office of Pesticide Ombudsman within CDFA's Pest Management Division.
4. CDFA should automate its pesticide toxicological data files and establish data sharing networks between other State departments, EPA, and other states.
5. CDFA should require manufacturers of "older" pesticides to provide updated data necessary to predict residues. Registrants should also provide the State laboratories with coded samples containing residues.
6. The Legislature should specify that no pesticide which is applied directly to water be registered in California until DHS has set an "action level" for it.
7. CDFA should implement a pesticide-based monitoring program to supplement its crop-based deterrence program.
8. The responsibility for monitoring residues in raw agricultural produce destined for processing should be transferred from DHS to CDFA.
9. The Legislature should amend current law to expand enforcement sanctions against agricultural pest control operators to parallel those to which structural pest control operators are subject.
10. CDFA should require pesticide registrants to provide analytical methods for detecting residues of inert ingredients identified as being hazardous.

11. CDFA should establish a monitoring station at the Mexican border to monitor imported produce until such time as significant improvements in Federal monitoring and enforcement are attained.

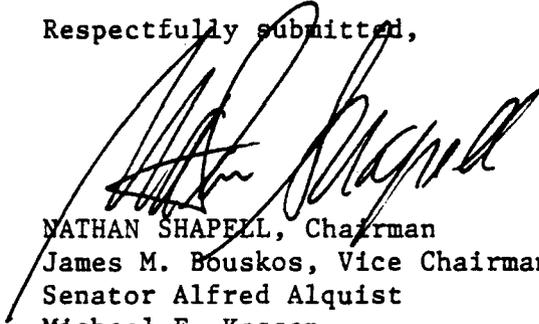
Further findings and specific recommendations to address them are discussed within the attached report.

Respectfully submitted,



Albert Gersten, Jr., Chairman
Pesticide Regulatory Study
Subcommittee

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CONTROL OF PESTICIDE RESIDUES IN FOOD PRODUCTS
A Review of the California Program of Pesticide Regulation

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CONTROL OF PESTICIDE RESIDUES IN FOOD PRODUCTS
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SUMMARY

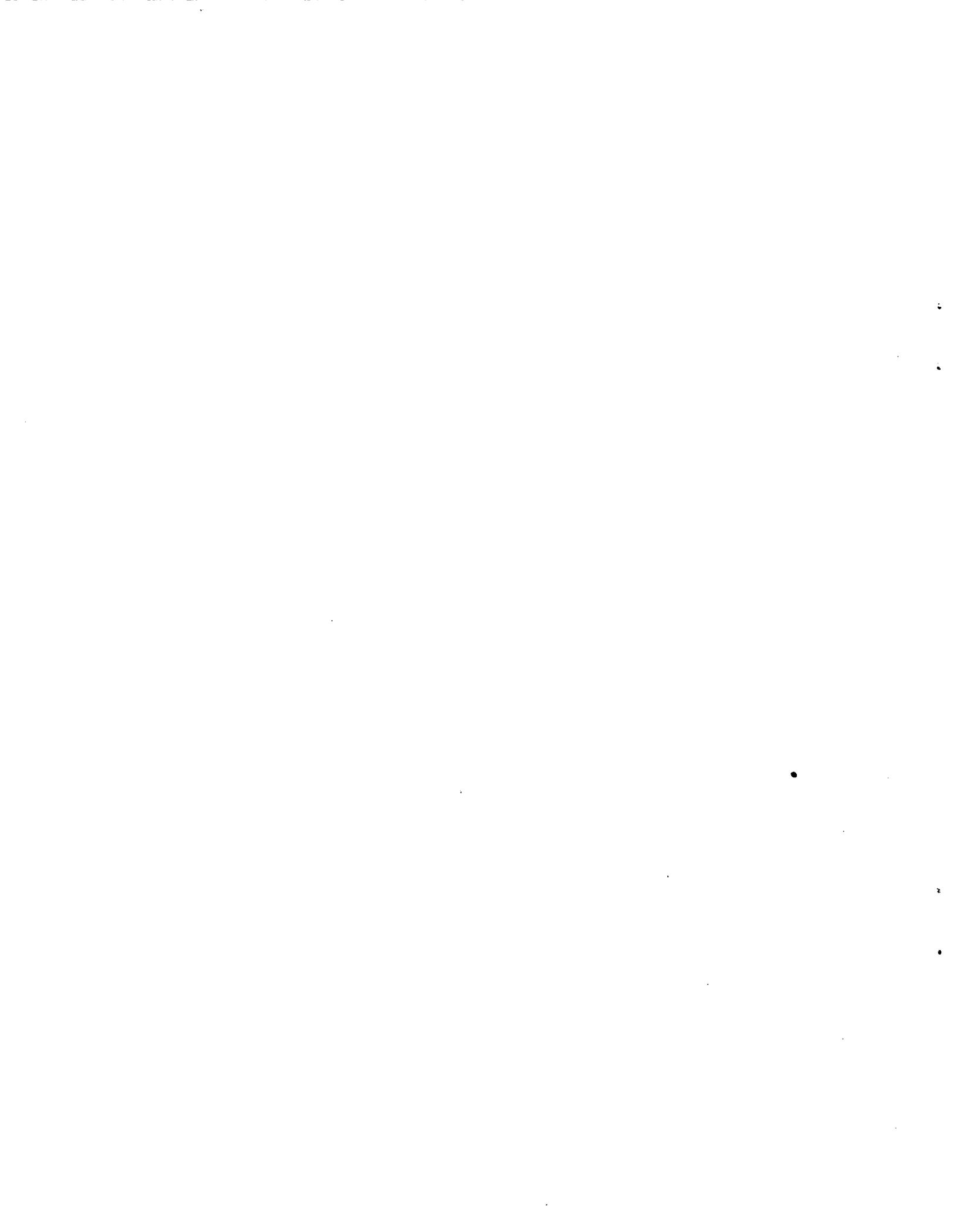
The Commission on State Government Organization and Economy (the "Little Hoover Commission") decided to undertake a study of pesticide residues in food in response to several factors: (1) several Commission members were personally interested in and concerned about this issue; (2) through a study of toxic waste dumps completed early in 1984, the Commission had become aware of the potential dangers from letting toxic substances in our environment go undetected; and (3) the Commission received a request from members of the State Legislature that the Commission examine issues having to do with pesticide residues in food.

Recent news stories regarding pesticide and selenium contamination of the Kesterson Reservoir and Wildlife Refuge in Merced County illustrate the danger of failing to take corrective action early on in the development of toxic hazards. By this time, so much is at stake economically in maintaining existing patterns of land and water use in the area that responding to the toxic hazard problem will require extraordinary political will. The Commission wanted to find out whether pesticide residues in food products or pesticide contamination of drinking water may represent analogous situations.

Over the course of our study, we learned that great uncertainties in science as well as inadequate practical knowledge of how, when, where, and by whom pesticides are used prevent government regulators from making perfect regulatory decisions in all cases. We also learned, on the other hand, that to the extent scientific assumptions are correct and pesticide use is reported, the California program of pesticide regulation, compared with programs in other states, is in many ways exemplary. Nevertheless, our Commission believes that California can substantively improve the efficiency and effectiveness of its regulatory program by implementing the more than 40 recommendations we have outlined in this report.

In Chapter I of our report, we have provided an extensive background on the existing regulatory program in place to control the availability and use of pesticides and to take corrective action whenever pesticides are found to be leaving unpredicted residues in food and/or water. We encourage our readers to give Chapter II -- THE SIGNIFICANCE OF "UNCERTAINTY" IN PESTICIDE REGULATION -- a careful reading, because a thorough understanding of how uncertainty undermines the regulatory decision making process is a prerequisite to understanding the findings and recommendations in this report.

Controversy. The nature of controversy inherent in



pesticide regulation may be stated briefly as follows:

*Pesticides make it possible to grow more food for people, rather than pests, to consume. They also reduce bacterial damage to human health and termite damage, for example, to buildings. In this sense, pesticides are "good," even though by design all pesticides are toxic to biological organisms.

*Some pesticides leave toxic residues in food and water, sometimes at levels that cause adverse effects on human health and the environment. In this sense, pesticides are in some cases "bad."

*Because no foolproof methodology exists to distinguish between "good" and "bad" pesticides, the registration of each new product -- and some of the older ones as well -- becomes the subject of controversy.

The culprit in pesticide regulation, if there is one, is uncertainty. Uncertainty means no one can be absolutely sure that pesticide use decisions will prove to be safe. What is at issue, then, is how to make decisions when we cannot predict with certainty what the consequences of our decisions will be.

In controlling the availability and use of pesticides, regulators draw upon three resources in making decisions: (1) scientific knowledge -- knowing which substances, under which conditions, and in which concentrations pose a threat to human health or the environment; (2) practical knowledge -- records of which substances are in fact being applied, by whom, at which geographic locations, how often, and on which crops (or buildings); and (3) will to act -- overcoming the inertia inherent in regulatory processes when action is necessary to protect human health and the environment.

The Commission's having conducted this study should not be taken to imply that the uncertainties inherent specifically in pesticide use and regulation involve threats to human health or the environment of unique magnitude. Indeed, there is great uncertainty as to the possible effects on human health and the environment of countless natural and synthetic chemicals to which people are exposed in various combinations for prolonged periods, albeit usually in minute doses.

SUMMARY BY CHAPTER OF FINDINGS AND RECOMMENDATIONS

Chapter III: PESTICIDE REGULATION: THE ROLE OF CALIFORNIA'S LEAD AGENCY

Chapter III examines the Department of Food and Agriculture's regulation of pesticides as practiced by the Division

of Pest Management, Environmental Protection, and Worker Safety. The division's activities to meet its twin missions of preventing harm to human health and the environment while at the same time promoting agricultural productivity are outlined. Chapter III includes a discussion of California's program of regulation for "structural pest control," meaning pesticides used to kill pests that attack and destroy buildings, clothing, stored food, and manufactured goods.

The general theme of Chapter III is that CDFA needs to institute a clearly articulated discipline for priority-setting. This same finding and our recommendations for addressing the problems that emanate from it are repeated throughout the remainder of the report.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA's Pest Management Division sets management priorities within each subdivision in order to comply with statutory requirements, but the division lacks an articulated, overall priority-setting discipline for identifying "pesticides of greatest concern."

Recommendation: We recommend that the Pest Management Division in CDFA appoint all subdivision managers to begin work on selecting criteria to identify the pesticides of greatest concern and to integrate the "priority pesticides" with priorities already established for activities in each of the discrete regulatory functions.

Finding #2: CDFA inherits the weaknesses in EPA's programs, despite having state-level statutory authority in some cases to compensate for EPA's deficiencies.

Recommendation: We recommend that CDFA ask the Pesticide Advisory Committee to establish a policy for determining when the department should not wait for EPA to act before taking and/or coordinating state level action to prevent or mitigate a problem that has been identified in California.

Finding #3: Funding for pesticide regulatory activities is often inadequate to enable CDFA to maintain a state-of-the-art regulatory capability. Furthermore, the General Fund is supporting more than half the budget for the pesticide regulatory program.

Recommendations: We recommend that:

A. The Legislature amend current law to specify that the contribution from the Agriculture Fund shall equal the General Fund contribution to the support of pesticide regulation. Adjustments in the pesticide mill tax and/or the annual pesticide registration fee to meet this standard should be

adopted in the annual Budget Act.

B. The Legislature request from the Franchise Tax Board by July 1, 1985 a report on the amounts collected in "voluntary contributions" from California taxpayers in response to lines 86 through 92 on Form 540. The purpose of this report is to enable the Legislature to consider adding a line to this section of the state tax return to give taxpayers an opportunity to increase spending for pesticide regulation.

Finding #4: CDFA's program of public information is inadequate to give the public access to non-technical information on hazards associated with pesticide use and/or how the regulatory program works at the point such information is most needed.

Recommendations: We recommend that:

A. The Legislature authorize the establishment within CDFA's Pest Management Division of an Office of the Pesticide Ombudsman. We further recommend that the Pesticide Ombudsman institute a toll-free "hotline" to enable the office to receive calls from anywhere in the state. We also recommend that the Legislature memorialize Congress and the Governor work with the Reagan Administration to require pesticide registrants to include EPA's pesticide hotline number on all pesticide labels.

B. CDFA solicit the assistance of health and environmental advocacy groups and affected pesticide manufacturers in the planning, development, and scheduling of a series of seminars to be made available to public groups, including schools, upon request. We further recommend that pesticide manufacturers support this effort financially, especially when problems caused by a particular pesticide product trigger the need for a program of targeted public information services.

Chapter IV: REGISTRATION

Registration represents the gatekeeper in the regulation of pesticides. Registration processes provide the opportunity to generate the toxicological, environmental, and use data required by government and industry to verify the efficacy of each pesticide in its intended use and the likely levels of pesticide residues that will be left on target crops.

Both the federal government, through the Environmental Protection Agency (EPA) and the State of California, through the California Department of Food and Agriculture (CDFA), maintain comprehensive pesticide registration programs. EPA currently has approximately 60,000 pesticides registered; CDFA has registered nearly 12,000 of those pesticides for use just in California.

FINDINGS AND RECOMMENDATIONS

Federal Program

Finding #1: Certain EPA data bases critical to state monitoring and enforcement activities are inadequate. As a result, EPA and CDFA may in some cases make inappropriate regulatory decisions which impair their ability to effectively fulfill all regulatory responsibilities. Three specific problems are as follows:

A. EPA's toxicological data base on certain pesticides registered before 1972 is inadequate for assessing risk.

B. EPA's residue and monitoring data base is inadequate to enable EPA to determine whether registered pesticides are "behaving" as the registrants predicted at the time of registration.

C. EPA has initiated new efforts to establish a program of data requirements, scientific analysis, and enforcement activities to prevent pesticide contamination of groundwater. Prevention is late, however, as contaminated wells are being discovered throughout the country, including in California.

Recommendation: We recommend that the Legislature memorialize Congress and the Governor work with the Reagan Administration to require EPA to:

A. Establish toxicological and environmental data-sharing networks with the states.

B. Establish a residue data-sharing network with the Food and Drug Administration (FDA) and the states.

C. Coordinate efforts with manufacturers to create models for predicting environmental effects of pesticide use, especially with respect to potential for groundwater contamination.

D. Sponsor research to develop clean-up procedures to mitigate the effects of pesticide-contaminated groundwater.

E. Sponsor research for developing safe alternatives to soil and grain fumigants which may pose unreasonable risks to health and environment.

Finding #2: CDFA's data bases are inadequate. They reflect not only the inherited weaknesses of EPA's data bases but certain state-level deficiencies as well. Specifically:

A. CDFA's inheriting of EPA's inadequate toxicological data bases exacerbates uncertainty in risk assessment at the state level.

B. CDFA relies on manually maintained data files to catalogue information on approximately 12,000 registered pesticides.

Recommendations: We recommend that:

A. CDFA automate its pesticide toxicological data files.

B. CDFA establish toxicological data-sharing networks between departments of California state government, EPA, and other states.

C. CDFA articulate its criteria for setting priorities in selecting pesticides for special review.

D. CDFA co-sponsor with pesticide manufacturers a series of seminars intended to identify cost-sharing alternatives to pay for health effects testing of "older" pesticides.

Finding# 3: For some pesticides used on foods, CDFA lacks the residue data necessary for estimating risk.

Recommendations: We recommend that:

A. CDFA require manufacturers of "older" pesticides to provide updated data used to predict residues. Updated residue detection procedures, where these do not now exist, must also be made available.

B. CDFA require registrants to provide state laboratories with coded samples containing residues of the pesticides to be registered.

Finding #4: In some cases, CDFA lacks adequate data to enable the department to predict the environmental effects -- in particular, the likelihood of drinking water contamination -- of either previously or newly registered pesticides.

Recommendations: We recommend that:

A. The Legislature specify in new legislation that no pesticide which is applied directly to water -- such as rice field herbicides -- shall be registered in California until the Department of Health Services has set an "action level" (an advisory trigger for enforcement action) for it.

B. CDFA require registrants of pesticides which are injected into the soil, or applied directly to the water, to provide evidence in the form of statistical models that the pesticides will not pose a threat to public health or the environment.

C. Local water districts and county agricultural commissioners assemble names and telephone numbers of area laboratories equipped to analyze water samples from private wells and able to interpret the significance of the detection of pesticide traces.

Chapter V: RESIDUE MONITORING AND ENFORCEMENT

California state law divides the responsibility for monitoring pesticide residues in foods between the Departments of Food and Agriculture and Health Services on the basis of whether the food is a raw agricultural product, a processed food, or a food destined for processing. Produce distributed in fresh fruit and vegetable markets is monitored by CDFA. A food product altered chemically or physically before distribution -- other than sorting or cleaning -- is a "processed food" and is assigned to DHS for monitoring.

The federal government also monitors pesticide residues in raw produce and processed foods through the Food and Drug Administration (FDA). FDA's authority encompasses foods imported from other countries -- such as produce from Mexico -- as well as domestically grown food products distributed across state lines.

In general, the Commission found that the design of CDFA's pesticide residue monitoring program fails to enable the department to predict the likelihood that certain pesticides of concern will leave residues. This is so because the program focuses on crops rather than pesticides. If traffic controllers want to detect speeders, they patrol highways where speeding is most likely to occur, rather than busy streets where speeding is a practical impossibility. By designing residue monitoring to be crop-oriented rather than pesticide-based, CDFA cannot make use of information on residue-leaving behavior to prevent higher than tolerance pesticide residues in food. In other words, using the idiom of our analogy, it isn't the crops that may be "speeding" -- it's the pesticides.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA's residue monitoring program is not designed to identify public health problems efficiently.

Recommendation: We recommend that CDFA implement a pesticide-based monitoring program to supplement its crop-based surveillance (deterrence) program.

Finding #2: The state lacks certain information on pesticide use which is essential for development of a pesticide-based monitoring program.

Recommendation: We recommend that CDFA develop a list of pesticides for which all agricultural users must keep detailed records of use.

Finding #3: Coordination among the Pest Management Division's internal units is inadequate to support priority-setting to identify the pesticides of greatest concern.

Recommendation: We recommend that the Pest Management Division's unit managers establish internal communications procedures designed to facilitate priority-setting for identifying both the pesticides and the crops which should be most carefully scrutinized in the residue monitoring program.

Finding #4: Laboratory resources for analyzing food samples to detect pesticide residues are inefficiently administered and poorly coordinated with the information needs of scientists in the Pest Management Division.

Recommendations: We recommend that:

A. Administrative control over laboratory testing for pesticides be transferred to the Pest Management Division.

B. A scientific advisory panel, which should include a lay person and a UC Cooperative Extension pest management specialist, be established to assist CDFA in setting priorities for the monitoring of pesticides and the operation of monitoring and enforcement programs.

C. The Legislature appropriate and the Governor approve additional funding for CDFA's pesticide residue laboratories to enable them to acquire state-of-the-art technology for chemical analysis and more space in which to conduct testing for pesticide residues.

Finding #5: CDFA lacks detection methods for many pesticides in common use in California.

Recommendation: We recommend that as part of the re-registration program mandated by Chapter 669, Statutes of 1984 (SB 950), data gaps on residue detection procedures be identified and filled.

Finding #6: The state lacks a trigger for taking enforcement action upon finding residues from certain pesticides known to cause adverse health effects.

Recommendation: We recommend that DHS, in conjunction with CDFA, set a food tolerance (or an action level) for pesticides which, because of their toxic potency, their likeli-

hood of leaving residues in foods, and the current absence of food tolerance-settings for them, may pose a significant risk to public health.

Finding #7: The state lacks an effective program of residue monitoring for foods destined for processing and for processed foods. The existing division of monitoring responsibility between CDFA and DHS is not conducive to effective enforcement of residue tolerances for processed foods.

Recommendations: We recommend that:

A. The responsibility for monitoring residues in raw agricultural produce grown in California, whether destined for produce markets or processing plants, be vested in CDFA.

B. DHS, in conjunction with CDFA, FDA, and EPA:

1. Identify those pesticides most likely to leave residues in processed foods and the food items in which they are most likely to be found; and
2. Set aside a portion of its monitoring program to ascertain the safety of post-harvest applications on foods in storage, in restaurants, or other locations where pesticides may be used in or around foods.

Chapter VI: USE MONITORING AND ENFORCEMENT

Federal law permits states to regulate the sale or use of all registered pesticides or devices within the state, provided the regulations do not permit sales or uses prohibited by federal law. In California, the county agricultural commissioners are the primary enforcement officers in the pesticide use monitoring program.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA has little knowledge of the rate of compliance with laws and regulations for growers and applicators.

Recommendation: We recommend that CDFA continue its efforts to develop a system for estimating compliance among growers and applicators.

Finding #2: CDFA conducts only sporadic monitoring of non-restricted pesticides and incomplete investigations of illegal residues in foods.

Recommendations: We recommend that:

A. CDFA create a new use category called "use by prescription" for non-restricted pesticides whose improper or even legal use could lead to health and/or environmental problems.

B. The Legislature require a joint investigation by CDFA and county agricultural commissioners to produce a report on every incidence of illegal residues in foods.

Finding #3: Current enforcement sanctions are cumbersome, ineffective, and inadequate.

Recommendation: We recommend that the Legislature amend existing law to parallel recent changes provided for in Chapter 766, Statutes of 1984 (AB 294), which gave county agricultural commissioners the authority to suspend licenses and/or impose fines immediately upon detecting a violation by a structural pest control operator.

Chapter VII: INERT INGREDIENTS

The term "inert" as used by the pesticide industry and government regulators is misleading. The dictionary definition of inert is: "exhibiting no chemical activity, totally unreactive, or exhibiting chemical activity under special conditions only." In contrast, "inert" in pesticide jargon refers to the substances added to the formulation for a purpose other than to kill the target pest (e.g., adhesives or emulsifiers).

Inert ingredients are virtually unregulated. They are not subject to routine residue monitoring nor formula verification testing to ensure correct labelling. Inerts are generally exempt from food tolerances. Roughly 1,000 to 1,200 chemicals are used as inert ingredients in pesticide formulations.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA and DHS have inherited a serious data gap on the inert ingredients in pesticide formulations.

Recommendations: We recommend that:

A. The Legislature memorialize Congress and the Governor work with the Reagan Administration to require that formulators of pesticides provide justification as to why an inert ingredient should not be listed on the pesticide label. Inert ingredients that are identified as likely to pose a health hazard if the pesticide is misused should have their technical name (or names) included on the label.

B. The Legislature memorialize Congress and the Governor work with the Reagan Administration to change the designation of ingredients of pesticide formulations currently defined in federal law as "inert ingredients" to "non-pesticidal ingredients," or some other less misleading term.

C. CDFA integrate the regulation of inert ingredients into the re-registration program mandated by Chapter 669, Statutes of 1984 (SB 950).

Finding #2: There are no practicable analytical residue detection methods for many inerts.

Recommendation: We recommend that CDFA require pesticide registrants to provide analytical methods for detecting residues of inert ingredients identified as being hazardous pursuant to Section 2378 of Title 3 of the California Administrative Code.

Finding #3: The level of residues in foods which may pose a significant risk to human health has not been determined for the inert ingredients identified as being of health concern.

Recommendations: We recommend that DHS, in conjunction with CDFA:

A. Set tolerance levels for inert ingredients that (1) have been identified pursuant to Section 2378, (2) are known to leave residues in foods, and (3) may pose a significant health risk when not used in accordance with label instructions.

B. Be given responsibility for setting food tolerances for the small number of inert ingredients of concern.

Chapter VIII: MONITORING OF IMPORTED FOODS AND FOODS IN INTERSTATE COMMERCE

The Federal Food, Drug, and Cosmetics Act grants FDA the authority to collect and inspect -- for purposes of monitoring pesticide residues -- samples of foods imported from foreign countries, or grown domestically but shipped across state lines. Adulterated products may be seized or refused entry, or both. Within California, FDA lacks embargo authority, relying on EPA to be the prosecuting agency. In such a situation, EPA would notify the state to take appropriate enforcement action.

Nationwide, FDA samples approximately 10,000 shipments each year. Of this number, 4,000 samples are collected in

California. FDA samples only a small number of processed foods and only on an exception basis. FDA relies on communication from EPA regarding those pesticides or foods which should be targeted for special monitoring.

FINDINGS AND RECOMMENDATIONS

Finding #1: FDA's program for monitoring pesticide residues in imported foods is not equivalent to California's monitoring program.

Recommendations: We recommend that:

A. The Governor and the Legislature petition FDA to expand its monitoring program to the level of California's for foods imported from Mexico.

B. CDFA establish a monitoring station at the Mexican border to monitor imported produce until such time as significant improvements in federal monitoring and enforcement are attained.

products or drinking water may represent just such a situation and decided to conduct a study.

Finally, the Commission received a request from members of the Legislature that the Commission undertake an examination of issues having to do with pesticide residues in food. Sharing the Legislature's concern that Californians may not be adequately protected against the hazard of chemical poisoning from pesticide residues on foods, the Commission began this study in August 1984.

Pesticide Use in California

"Pest" is a generic term for any life form that attacks food or fiber crops, including livestock. Pests also jeopardize human health and attack residences and public and commercial buildings. Pests include insects, nematodes (microscopic worm-like organisms), weeds, fungi, bacteria, and rodents and other vertebrates. A "pesticide," then, is any material used to kill pests. Pesticides include insecticides, herbicides, fungicides, fumigants, disinfectants, rodenticides, and so forth. This report is concerned specifically with the regulation and use of chemical pesticides.

The California Department of Food and Agriculture (CDFA) has reported that more than 743 million pounds of chemical pesticides were sold in California during 1983. Approximately half that total were purchased for agricultural uses. Another major category of pesticide use is water purification. The department estimates 330 million pounds of chlorine-based

products were used for that purpose in 1983.

Other non-agricultural uses of pesticides include: home and garden applications; landscape and right-of-way maintenance; public health programs such as mosquito abatement, treatment of tree diseases, and rodent control; and "structural" pest control such as termite and cockroach extermination in public, private, and commercial buildings.

Benefits of Pesticide Use

While it is prudent to remain concerned about potential harm from the long-term health and environmental effects of using pesticides, it is also important to understand how all of us benefit from their use. Even at today's volume of pesticide usage, annual worldwide food losses to pests are estimated to be approximately 45 percent. Pre-harvest losses alone -- from insects, plant diseases, and weeds -- are estimated at 30 percent. Additional post-harvest losses from microorganisms, insects, and rodents range from 10 to 20 percent. (Pest damage in forms other than crop loss is unknown.)

Photographic images from Ethiopia are painful reminders of the consequences of food shortages. The U. S. Department of Agriculture (USDA) and the United Nations estimate that already one-half billion human beings in the world today are protein- or calorie-malnourished. Current projections are that world population will reach 6 to 7 billion by the year 2000. With pests consuming or destroying nearly one-half of the world's food supply, the importance of controlling pest

damage is clear enough. Scientists are not able in all cases to determine, however, whether chemical pesticides can be used to control pest damage without also causing adverse effects on human health.

Pesticide Residues on Food

Pesticide "residues" are traces -- usually very small -- of chemical pesticides that have been applied to food crops at some point during the growing cycle. Some pesticides leave no traces; others can leave potentially toxic residues. These latter pesticides are approved for use because they assure maximum yields and are considered safe when used according to instructions on the label. Food crops treated with these products must be carefully monitored, however, for detection of residues.

The Federal Insecticide, Fungicide, and Rodenticide Act, or "FIFRA," requires that pesticide manufacturers, prior to marketing their products, register pesticides with the U. S. Environmental Protection Agency (EPA). For each pesticide that is to be used on food, EPA reviews data on acute and chronic toxicity and use patterns submitted by the registrant and cross refers this evaluation with data collected by the U.S. Department of Agriculture (USDA) on American patterns of food consumption. This process is known as "risk assessment" and is performed in order to determine whether a pesticide, if properly used, will have unreasonable adverse effects on human health or the environment. Based on the risk assessments, EPA sets a food tolerance level which, if exceeded when the crop

is harvested, will cause the contaminated food lot to be quarantined.

The tolerance represents EPA's and the registrant's prediction of maximum residue levels a pesticide will leave on crops at the point of harvest. Enforcing the tolerances through residue monitoring programs becomes the responsibility of both the state in which the pesticide is applied and, in the case of imported foods or domestically grown foods transported across state lines, the Federal Food and Drug Administration (FDA).

Appendix A provides details of existing federal and state laws and regulations pertaining to control of pesticide residues in food.

Safety Factor. EPA can predict under most circumstances the levels of residues on food when pesticides are used according to label instructions, but it is harder to estimate the levels at which particular residues may cause adverse health effects from repeated exposures over a lifetime. EPA divides the dosage at which pesticides cause a toxic effect in laboratory animals by a safety factor, usually 100 -- the first factor of 10 for differences in body size and weight between animals and humans, the second factor of 10 for variations in human sensitivity. In principle, estimating exposure levels believed to be safe for humans creates a safe margin for error. In practice, only a case-by-case analysis can determine whether these assumptions apply for every pesticide.

Most tolerances are based on results in animal tests

involving chronic, long-term exposure to pesticides. It is therefore unlikely that a person who consumes food containing pesticide residues somewhat over tolerance would become ill from a single exposure, or even several exposures. In general, pesticide residues detected in food are far below the tolerances set by EPA.

EPA's process for protecting public health and safety is based on estimating methods which are designed to create a safe margin for error. It may never be possible to guarantee that the margin for error is safe enough in every case to prevent adverse effects from chronic, or even a single, exposure to pesticide residues in food. This is especially so because present methods cannot take into account synergistic effects of exposure to two or more pesticide residues in one or more foods -- that is, health effects which are greater when they occur in combination than when they occur singly.

Pesticides in Drinking Water

Pesticides used in agricultural production can enter drinking water supplies by a variety of routes but usually in the "run-off" from farm fields. Pesticide traces are found in agricultural drainage channels, for example, which empty into rivers, lakes, and reservoirs.

Until recently -- within the past decade -- scientists believed that pesticides did not "migrate" through soil into underground water supplies. The theory was that soil and the chemical properties of the pesticides themselves combined to protect groundwater from pesticide intrusion. In 1977, the

discovery in California wells of DBCP (1,2-Dibromo-3-chloropropane), a nematocide, triggered a re-evaluation of scientific assumptions that previously had supported the predictions of environmental effects from pesticide use.

The extent of the presence of pesticide traces in groundwater is unknown, but a monitoring program newly established in the Department of Health Services (DHS) is beginning to generate a profile on the situation in this state. Similarly, the early results in other states with monitoring programs show traces of pesticides are present in those states' drinking water supplies as well.

The simple presence of pesticide traces in drinking water does not necessarily represent a danger to human health. For example, fluoride is intentionally added to public drinking water supplies throughout the country to prevent tooth decay. In appropriate doses, fluoride is actually beneficial to human health although, in other doses and different circumstances, the same substance is used as a rat poison. It is also the case that potentially harmful chemicals occur naturally in all types of drinking water sources, including groundwater. In short, determining whether pesticide traces in drinking water pose a danger to human health requires analysis and interpretation on a case-by-case basis.

BACKGROUND ON PESTICIDE PRODUCT DEVELOPMENT, USE DECISIONS, AND REGULATION

The manufacture, testing, regulation, and use of pesticides are individually and collectively complex subjects. To

assist our readers in better understanding the findings and recommendations in this report, we are providing an extensive background section.

The Role of Pesticide Manufacturers

The primary role of manufacturers is to develop effective pest control products to meet agricultural and other pest control needs. Ideas for new pesticides come from many scientific disciplines. Useful products have been developed from discoveries in such areas as organic chemistry (the study of carbon compounds); plant, animal, and insect physiology (the study of living organisms); biochemistry (the study of the chemistry of biological substances and processes); and pharmacology (the study of drugs).

Manufacturers, in both laboratory and field experiments, test their discoveries first to detect whether a particular compound will in fact be effective in controlling the pest it was developed to control. Such tests also reveal whether soil type, soil structure, rainfall, and other field conditions affect the compound's performance, its "persistence" in the environment, and its breakdown characteristics (that is, how the parent compound and its decomposition products -- metabolites -- interact with naturally occurring chemicals, in the process possibly becoming toxic).

Having established a new product's efficacy, the manufacturer then begins a series of required toxicological tests to determine the compound's potential effect on animal systems. The principal criterion a pesticide must meet in

order to be registered by EPA is that its use will not result in "unreasonable" harm to humans or the environment -- in proportion to the benefits of its use. EPA uses the manufacturers' test data as the basis for evaluating the likelihood that any given product will cause unreasonable harm. This process is referred to as "risk-benefit analysis."

Apart from federal and state governments' residue monitoring programs, many pesticide manufacturers conduct their own market basket studies. They purchase "typical" quantities of foods that surveys have determined Americans are consuming. In laboratory tests, they attempt to verify predictions of whether specific pesticides leave excessive residues in food products when the pesticides are applied according to label directions.

Finally, manufacturers must provide a proposed method of analysis for the detection of residues from particular pesticides. This proposed analytical method is to be validated in government laboratories before EPA establishes a tolerance for the candidate pesticide.

The Role of Growers

The role of growers in pesticide use is to decide which products to use under which circumstances. In making these decisions, individual farmers rely on advice from a variety of sources. Pest control advisors are licensed by the state and may be either sales representatives for pesticide manufacturers or independent consultants. In addition, growers have access to the University of California's

Cooperative Extension Service, which disseminates information on pest control techniques, strategies, and products.

The Role of Food Processors

The National Food Processors Association and its member associations, such as the California League of Food Processors, maintain a "Protective Screen Program: A Program to Prevent Illegal Contamination of Raw Agricultural Products with Pesticides." The major elements of this program are as follows:

- *Growers are required to provide written assurances that crops purchased by food processors are free of illegal pesticide residues.
- *Contractual agreements between growers and food processors require the growers to use only approved pesticides and to apply them according to directions on the labels.
- *The National Association's Environmental Affairs Division keeps the industry informed regarding pesticide registration regulations and important new knowledge regarding hazards associated with specific pesticides.
- *Some food processors make an effort to test finished food products for the presence of illegal pesticide residues.

Federal Responsibilities in Regulating Pesticide Residues on Food

The federal role in pesticide regulation is multifaceted and carried out by multiple agencies. We refer throughout this background section to these many functions as they interface with state regulatory responsibilities. To recapitulate very briefly, the U. S. Environmental Protection Agency (EPA) is the federal agency with the most direct responsibility for pesticide regulation: registration, evaluation of health and

environmental effects data, and setting of food tolerances.

USDA produces the survey data for the dietary assumptions upon which EPA's residue tolerances in food and water are based. The Federal Food and Drug Administration (FDA) completes this program by monitoring for pesticide residues in both imported foods and domestically grown crops transported across state lines.

State and County Roles and Responsibilities in Regulating Pesticide Residues on Food

Under federal law, states are given the primary enforcement authority for any pesticide use violations. The responsibility for devising training programs to certify pesticide applicators is also delegated to the states. Certain categories of pesticide registration are submitted first to state rather than federal regulators (in cases of special local needs and emergency exemptions), but all registrations require final EPA approval subject to conditions defined in the law.

Department of Food and Agriculture

The Division of Pest Management, Environmental Protection, and Worker Safety in the California Department of Food and Agriculture has the primary regulatory responsibility for pesticide use in California. In addition to its overall responsibility to register all pesticides that are to be used in California, CDFA monitors raw produce for pesticide residues and has the authority to remove contaminated food lots from sale. Four other state departments are also involved in pesticide regulatory decisions through their

review of CDFA's registration decisions: the Departments of Health Services and Industrial Relations, and the Air Resources and Water Resources Control Boards.

County agricultural commissioners (CAC's) are county employees and simultaneously agents of CDFA's pesticide regulatory program at the local level. The CAC's issue permits and monitor reporting of the use of restricted pesticides. These requirements apply whether restricted use pesticides are used for agricultural, structural, or other pest control purposes. Non-restricted pesticides are exempt from the permit and reporting process.

Department of Health Services

The Department of Health Services is responsible for monitoring pesticide residues in processed foods, including raw produce that is destined for food processing plants. The Food and Drug Branch of DHS's Environmental Health Division is the unit responsible for developing a sampling strategy to test processed foods for pesticide residues.

DHS also is involved in a range of activities to support risk assessments of health effects from human exposure to toxic substances in general, including pesticides. The department has written a state cancer policy, for example, which all state departments conducting risk assessments of health effects will utilize. DHS's Epidemiological Studies Section conducts studies to identify possible links between human exposure to toxic substances and observed health effects.

Roles and Responsibilities in Regulating Pesticide Residues in Water

Any analysis of pesticide regulation would be incomplete without some mention of existing water quality regulatory processes concerned with pesticides. A complete analysis of water quality regulation, however, is beyond the scope of this report. The information that follows is a summary of California's activities to regulate water quality. Our goal is to offer a view of the necessarily symbiotic relationship between agencies concerned with pesticide residues in food and water.*

Planning a response to the dangers posed by pesticides in drinking water is even more difficult than reacting to dangers posed by pesticide residues in food. Whereas the regulatory process can prevent a contaminated food lot from reaching the market, the public's access to pesticide-contaminated drinking water is much harder to control. A single grower's pesticide-contaminated crop of a particular food can be disposed of, but pesticide contaminants in water -- groundwater in particular -- may remain there for many years.

Greater progress has been made in monitoring surface water than groundwater. Surface water is monitored more often and at more locations because it is easier to get to and monitors know more about how to interpret what they find. For

* Readers wanting more detailed information about water quality control are referred to Water Quality and Pesticides: A California Risk Assessment Program, a report issued on December 20, 1984 by the State Water Resources Control Board's Toxic Substances Control Program.

example, they can assess cumulative contamination in fish. Groundwater is more difficult to monitor because its "flow" is measured in centuries -- rather than days, weeks, or months for surface water -- and because a single aquifer in which contamination may be isolated in only a small part may extend underneath vast areas of land ("aquifer" refers to water-bearing rock formations). Consequently, even a periodic and wide-area monitoring program might fail to detect the "worst case" levels of actual contamination.

The Role of Federal Agencies

Under the Safe Drinking Water Act of 1974, EPA is responsible for assessing health risks associated with the presence of various chemical residues found in drinking water and identifying in new regulations maximum contaminant levels (MCL's) for both primary (health hazards) and secondary (appearance, odor, or taste) contaminants. The National Academy of Sciences is EPA's advisor on identifying chemical residues in drinking water which are either known or suspected to be health hazards. Twenty-one such contaminants have been so identified to date, some of which are pesticides, or pesticide ingredients.

The Role of State and Regional Agencies

The responsibility for preventing pesticide contamination of drinking water is shared by several state departments, including CDFA and DHS. Since the discovery of DBCP in groundwater, the State Water Resources Control Board (SWRCB) and its nine Regional Water Quality Control Boards (RWCQB's) have also become more directly involved in monitoring public

and private water systems to assess potential contamination from pesticides.

Department of Food and Agriculture. One of the many purposes of the data requirements the Registration Unit in CDFA's Pest Management Division imposes on pesticide registrants is to enable scientists in CDFA and other state departments to assess the risk that new products will contaminate water supplies. The accuracy of these assessments is essential to the success of the contamination prevention effort.

Department of Health Services. DHS has identified more than 100 chemicals used in California that show some tendency to get into water supplies and may have adverse human health effects if ingested in sufficient quantities. Chapter 881, Statutes of 1983 (AB 1803) took effect on January 1, 1984. This new state law requires DHS to identify public water systems with contamination or potential contamination problems and to develop a program for ongoing local monitoring.

DHS also establishes "action levels" pertaining to chemical residues in drinking water. The action levels specify detectable amounts of given chemicals that should trigger regulatory action. Although the action levels are strictly advisory, DHS reports that local water districts are cooperative in notifying their communities in a timely fashion of possible contamination, once possibly hazardous chemicals have been detected in the drinking water.

State Water Resources Control Board. SWRCB, operating

under the broad powers assigned to it originally in the 1969 Porter-Cologne Act, supervises the discharge of wastes into California's waterways. This includes the "rinsing" of agricultural pesticides from fields and from the equipment that is used to apply pesticides. Regional Water Quality Control Boards (RWQCB's) set limits on how much of which materials can be discharged under specified conditions and have authority to issue waste discharge permits. The regional boards also require self-monitoring reports from those responsible for waste discharges and specify timetables for water treatment if needed.

SWRCB's "Priority Chemical Program" has developed a list of suspected problem chemicals; staff in that unit have prepared detailed reports on individual "priority chemicals." In these reports, each subject chemical is evaluated for its toxicity, impact on fish and wildlife, current use patterns, residues in the environment, and known geographic trouble spots. Each report, which is circulated in scientific, regulatory, and industrial communities before SWRCB releases it, contains recommendations for action.

Local Public and Private Water Systems

Most municipal water districts spend the majority of their resources on dependable drinking water delivery systems and non-contaminating sewage disposal facilities. They lack additional funds to do extensive monitoring for pesticide residues in drinking water sources. Regardless of size, nearly all municipal water systems depend on RWQCB's to

monitor pesticide residue levels at intake sites. In agricultural communities, regional boards work with county agricultural commissioners to identify possible sources of pesticide releases, such as field applications, pesticide storage sites, and sites where application equipment is cleaned. County commissioners are invaluable to this monitoring activity because of their program's comprehensive records on long-term local pesticide usage.

Well construction and abandonment standards are administered at county and city government levels by Environmental Health branches of County Health Departments. State monitoring programs do not systematically include private wells, although certain studies and environmental monitoring efforts have included samples from private wells that were located at or near sites thought to be sources of pesticide contamination. Screening for residues of pesticides known to be in general use in a particular county, county environmental health agencies may monitor private wells that serve as drinking water sources for as few as two or three people. As a general rule, however, most private well owners must purchase testing services themselves. Private sector laboratories -- many of them extensions of manufacturers' research facilities -- are capable of detecting pesticide residues in water samples, but their services can be very expensive, depending on the number of chemicals screened for and how often samples are taken. Recognizing the need for accurate and detailed data on harmful trace residues, many manufacturers offer to pay for screenings of private water

sources suspected of contamination by any of their pesticide products.

BENEFITS OF PESTICIDE REGULATION

The regulation of pesticides benefits the public, the pesticide manufacturers, and the users of pesticides. The primary benefit to the public is protection of public health. Protecting health also benefits the manufacturers and users, whose exposure to the chemical agents is generally greater. To a great extent, manufacturers rely on government, through its activities to evaluate the effectiveness and safety of pesticide products, to assure adequate quality control.

Effectiveness and Safety Considerations

Pesticide regulation began as an effort to assure users of the efficacy of pesticide products -- in other words, the federal government undertook (in 1910) to monitor pesticide manufacturing to verify that pesticides did in fact kill the pests the product labels promised they would. Pesticide registration was not required until 1947, when FIFRA was first enacted (see Appendices B and C for chronologies of changes in federal and state law). FIFRA required the U. S. Department of Agriculture (USDA) to assure farmers, as the primary pesticide users, of product efficacy.

Amendments to FIFRA in 1972 reflected public health concerns. In response to public awareness of environmental hazards, the registration function had been reassigned in 1970 from USDA to EPA. Throughout the 1970's, advances in

toxicology that enabled scientists to estimate adverse effects from exposure to toxic substances compelled EPA to increase its requirements for more complete health effects testing by the pesticide manufacturers. Whether similarly comprehensive data will be provided by manufacturers of "older" pesticides for which little or no such testing data exist remains a controversial and contested point.

The use of pesticides has increased dramatically since the end of World War II, but only in the last 20 years has the regulation of pesticides benefitted from accelerated scientific understanding of the toxicological effects of pesticide use. Nevertheless, while pesticide testing can determine easily enough whether a substance is acutely toxic -- how much it would take to cause an immediate ill effect or death after a short-term exposure -- it remains difficult to assess the chronic toxicity of pesticides: how much exposure over how long a time would result in some form of damage to human health.

Liability Concerns

Responsible manufacturers are concerned about incurring liability for unforeseen health problems resulting from use of their products. These firms make substantial investments in investigating the potential health risks of their products. Government regulations protect these responsible firms from having to compete against firms more concerned with short term profits than with the long term health effects and environmental consequences of their actions. Government

regulation of pesticides insures that the marketplace does not offer rewards to those firms which lower costs by discounting legitimate health and safety concerns.

Pesticide regulation also reduces the manufacturers' business uncertainty. EPA's participation in determining the safety of a new pesticide supports a manufacturer's decision to begin identifying potential markets and to plan production of the new product. Government also assists manufacturers by helping to determine the precautions necessary to the safe manufacture, handling, and use of a possibly hazardous compound. These considerations include the need for protective garments, wording for label instructions and warning statements, limitations on re-entry of farmworkers into treated fields, and safety training.

Benefits to Agriculture

The quality control benefits of pesticide regulation are also very important to the agricultural industry. Access to effective pest control technology assures farmers of maximum crop yields. The additional responsibility of government regulators to protect public health -- provided the public trusts in government's commitment and ability to provide this protection -- assures farmers that consumers will be confident in the wholesomeness of farm products. The protection of farmers' and farmworkers' health and safety in the handling and use of pesticides is an additional benefit of regulation -- one of increasing importance to agribusiness. In California and other states, government regulators have been effective in systematically upgrading these protections.

Protection of Public Health

Government processes for protecting public health in the pesticide regulation scenario are the primary focus of the findings and recommendations in this report. The process consists of:

- *scientific review of toxicological and health effects data submitted by pesticide manufacturers to determine the potential for products to damage human health and/or environmental quality;
- *setting of food tolerances representing residue levels which are not expected to be exceeded if pesticides are used according to label instructions;
- *monitoring of actual residues in food and water; and
- *removal of contaminated food crops from the marketplace as needed.

The "Informal" Network of Regulation

Supplementing the official regulatory process, there also exists an "informal" network of regulation comprised of public health and environmental advocacy organizations, groups of concerned citizens, independent scientists and researchers, and representatives of the mass media. All of these people play an invaluable, frequently unpaid "watchdog" role by keeping themselves informed regarding the actions and effectiveness of government regulators in implementing the laws that are intended to protect public health. These individuals and organizations frequently act to stir public concern when they believe the official regulators are not being responsive enough or concerned soon enough in the face of a particular problem.

SCOPE OF AND METHODOLOGY FOR THE STUDY

In July 1984, the Little Hoover Commission issued a request for proposals (RFP), seeking a contractor to conduct a study of "Pesticide Residues on Food Products." The RFP specified that the study would evaluate state programs and policies for (1) setting pesticide tolerance levels, (2) monitoring and regulating the use of pesticides, (3) enforcing pesticide residue tolerance levels, and (4) evaluating potential health effects of pesticide residues. (At mid-point in the course of the study, the scope was expanded to include pesticide contamination of drinking water.)

The Chairman of the Commission appointed Commissioner Albert Gersten, Jr. to serve as Chairman of the subcommittee responsible for the project. Commissioners Jean Walker and Lester O'Shea served as subcommittee members, as did Commission Chairman Nathan Shapell.

The Pesticide Study Subcommittee evaluated the proposals and the Commission subsequently awarded the contract to Troubleshooters. The project team selected by Troubleshooters consisted of:

*Deanna J. Marquart, M.P.P., and Andrew P. Manale, M.S., M.P.P. -- two policy analysts with experience in (1) evaluating program effectiveness (including toxic substances control programs), (2) developing recommendations to improve management systems and program operations, (3) statistical analysis, and (4) organizing and staffing public hearings.

*Joyce C. McCann, Ph.D. -- a research biochemist at

Lawrence Berkeley Laboratory, University of California, Berkeley, who specializes in genetic toxicological testing strategies and has served as a science advisor on toxic substances control policy at both federal and state levels.

*Timothy J. Sullivan, Ph.D. -- an assistant professor at U.C. Berkeley's Graduate School of Public Policy, specializing in environmental policy and quantitative methods for decision making.

*Patrick W. Weddle, M.S. -- a registered professional entomologist and agricultural consultant specializing in integrated pest management, with extensive knowledge of the agricultural industry and the federal and state programs that have been created to regulate the use of pesticides.

Work on the project began in August. The initial phase of the project consisted of a literature search, review of existing documents and analyses, and an interviewing process to gather information on California's existing program of pesticide regulation -- specifically as it pertains to pesticide residues on food products (and, later, pesticide contamination of drinking water).

The Pesticide Study Subcommittee was responsible for overseeing the study from start to finish. The subcommittee reviewed all documents -- such as proposed agendas for hearings, study scope and methodology, and background papers on issues -- and approved the draft report before it was submitted to the full Commission for final approval.

In addition to attending project-related hearings and

briefings, which were scheduled to coincide with the Commission's monthly meetings, the Pesticide Study Subcommittee members toured a state laboratory where food samples are tested for pesticide residues and a pesticide manufacturer's laboratory where animal tests are conducted to generate data on the chronic toxicity of pesticide ingredients. They attended the National Governors' Association's three-day conference on "Environmental Health Issues in Pesticide Management" (September 19-21, 1985 in San Diego) and the Western Agricultural Chemicals Association's residue seminar on "Groundwater Issues in Agriculture" (November 13, 1985 in Sacramento). They also toured farm product inspection stations and food processing plants.

Two public hearings were held to focus attention on:

1. The setting of residue tolerances, pesticide residue monitoring and enforcement, and alternative pest control strategies (September 26, 1984/Los Angeles); and
2. Pesticide contamination of drinking water and problems associated with the regulation of inert ingredients (November 29, 1984/Sacramento).

A list of the witnesses who testified at each hearing is attached as Appendix D. Individuals interviewed in the course of the study are listed in Appendix E.

Chapter II

THE SIGNIFICANCE OF "UNCERTAINTY" IN THE REGULATION OF PESTICIDES

INTRODUCTION

In the best of all possible worlds, the laws and organizations created by society to protect public health and the environment would in all situations produce the correct decisions. In the case of pesticide regulation, a "correct" decision is one which (1) prevents human exposure to unsafe levels of pesticide residue in food or water, and (2) guarantees the availability of pest control materials that minimize losses from pest damage.

If law and regulatory practice alone were sufficient to produce correct decisions, public confidence in food and water safety would be completely justified. Current law is well-conceived and is updated periodically to reflect new scientific knowledge and shifts in social priorities. Similarly, current regulatory practice in California provides a high degree of control over the availability and use of pesticides.

The source of controversy in pesticide regulation may be simply stated as follows:

*Pesticides make it possible to grow more food for people, rather than pests, to consume. They also reduce bacterial damage to human health and termite damage, for example, to buildings. In this sense, pesticides are "good," even though by design all pesticides are toxic to biological organisms.

*Some pesticides leave residues in food and water, sometimes at levels that cause adverse effects on human health and the environment. In this sense, pesticides are in some cases "bad."

No foolproof methodology exists to distinguish between "good" and "bad" pesticides in the abstract, because "good" or "bad" depends on use, the availability of safer alternatives, and consideration of benefit as well as risk. Because of the inherent trade-offs in approving the use of pesticides, the registration of each new material -- and re-registration of some of the older ones as well -- becomes the subject of controversy. The culprit in pesticide regulation, if there is one, is uncertainty. Uncertainty means no one can be absolutely sure that pesticide use decisions will prove to be safe and/or effective.

Making correct decisions regarding the management and control of toxic substances draws on three resources. First is scientific knowledge -- knowing which substances, under which conditions, and in which concentrations pose a threat to human health or the environment. Second is practical knowledge -- records of which substances are in fact being applied, by whom, at which geographic locations, how often, and on which crops (or buildings). The third resource is having sufficient will to act whenever scientific and practical knowledge indicate action is required.

Figure II-1 summarizes potential interactions of uncertainty with the three resources necessary for making correct regulatory decisions.

Figure II-1

Possible Adverse Effects of Uncertainty
on Resources for Pesticide Regulatory Decision Making

	SCIENTIFIC KNOWLEDGE	PRACTICAL KNOWLEDGE	WILL TO ACT
UNCERTAINTY Can Lead to and/or Re- sult from:	*Flawed as- sumptions *Inaccurate risk assess- ments *Inappropri- ate regis- tration ap- provals	*Incomplete records of actual use, actual resi- dues *Imperfect knowledge of rate of vol- untary com- pliance with instructions for use	*Delays *Weak enforce- ment response *Inappropriate product bans *Inappropriate demands for formulation changes

In each case, uncertainty undermines the ideal state of the decision making resource. As a result, regulators cannot know whether basic assumptions are sufficient for judging whether to allow use of a particular pesticide product, under which specific restrictions, and so forth. What is at issue is how to make decisions when we cannot predict with certainty what the consequences of our decisions will be.

Understanding the significance of uncertainty in the regulation of pesticides is a prerequisite to understanding the findings and recommendations in this report. As a matter of public policy, a realistic decision making approach must be to try to reduce uncertainty -- recognizing it can never be eliminated entirely -- and to allow for retroactive changes in decisions as new scientific information becomes available.

We have selected two specific categories of uncertainty as examples of the general significance of uncertainty in

pesticide regulation. These examples help to explain how it is possible -- and legitimate -- for informed individuals to disagree on the prudence or desirability of particular regulatory decisions.

UNCERTAINTIES THAT UNDERMINE PESTICIDE REGULATORY DECISION MAKING

Uncertainty #1: The ability of toxicologists and other environmental scientists to predict the "environmental fate" of pesticides is imperfect.

In theory, the data submitted to EPA and CDFA in pesticide registration applications should enable scientists to predict a compound's "environmental fate" -- in other words, how will the compound interact with naturally occurring chemicals in the soil? Will it break down into undesirable compounds? How "persistent" is it -- meaning how long will it remain potent as a toxic substance in the environment? And, of critical importance, what possibility is there that the chemical will migrate through soil into groundwater?

Impact on Scientific Knowledge

Uncertainties such as those itemized above undermine the usefulness of scientific knowledge as a decision making resource. It is unclear, for example, whether the levels of pesticides now present in food and water always pose a human health risk. In general, toxicology cannot conclusively determine the risk posed to people from detectable traces of pesticides in food and water. Most evidence on carcinogens comes from animal tests and indicates that some chemicals

which are used as pesticides can, at high rates of exposure, cause cancer in humans. Toxicologists know that certain substances, even in minute doses, are highly carcinogenic (or cause other deleterious health effects) in animal tests. What is usually not known is the "potency" of these substances in humans -- that is, the concentrations at which the substances will produce an adverse effect on human health.

Pesticides are present in food usually in very small amounts, resulting in doses to humans that are much smaller than doses administered to laboratory animals. Risk from exposure to these low doses is estimated based on extrapolation models which involve a number of assumptions, some of which are of uncertain validity.

DBCP

In certain specific cases, predictions based on incorrect scientific assumptions have failed to prevent pesticide contamination. Until recently, for example, scientists believed that groundwater was protected from pesticide contamination by the filtering capacity of soil and by the chemical properties of pesticides themselves which cause them to break down into harmless compounds or to dissipate entirely. Since 1977, however, when DBCP was discovered in California wells, early assumptions about the environmental fate of particular types of pesticides have been disproved.

DBCP was used on grapes and fruit trees in California starting early in the 1950's. Scientists know that at high levels of exposure DBCP causes male sterility; it is suspected

of causing cancer and birth defects as well. In 1982, the Department of Health Services reported positive correlations between consumption of DBCP-contaminated water and cancer mortality rates in Fresno County -- the area of most intensive use of the product. (The average amount of five parts per billion (5 ppb) detected in the contaminated wells is 1,000 times the amount EPA predicted would be found if the compound were used according to label instructions.) When DBCP was registered, no one considered it likely that human health would be harmed by its use because, on the basis of knowledge available at that time, regulators assumed DBCP would not persist in the environment as a toxic substance.

Fumigants

Initial assumptions about the behavior of fumigants also have turned out to be flawed. Most soil and grain fumigants such as ethylene dibromide (EDB) and methyl bromide are exempt from EPA's food tolerance requirements because, at the time they were registered, scientists believed these products deteriorated completely within 24 to 72 hours of application and, thus, would not leave residues. Because tolerances were not set, FDA and the states did not monitor foods to find out whether residues could be detected. In fact, registrants were not required to develop residue detection procedures specific to these products.

But EDB does in some cases leave high levels of residue in processed foods. This discovery caused concern because the data submitted in support of the registration application for EDB indicated that in animal tests the chemical causes cancer,

heritable genetic damage, and reproductive disorders. On the assumption that EDB did not leave residues, scientists believed the health effects from residues were of no consequence: if there is no exposure, there is no risk. The discovery that initial assumptions regarding the behavior of fumigants were in error was made after years of use.

The consequences of regulatory error are potentially seriously harmful. Thus, the high degree of uncertainty in scientific knowledge upon which regulatory decisions are based is not just of academic concern.

Impact on Practical Knowledge

Uncertainty also arises from faulty regulatory practice. The failure to set a tolerance for EDB, for example, and to follow up with monitoring to ascertain that a product known to have adverse effects in fact did not leave residues on food added uncertainty in the practical knowledge available on the behavior of fumigants. Decisions regarding residue and use monitoring priorities are based only partly on scientific knowledge of chemical properties that would cause pesticides, if improperly used, to have adverse effects on human health and the environment. In the case of DBCP and EDB, the assumptions that caused monitors to overlook the potential for problems prevented the development of a data base on these products that would have made it possible to compare the predictions of chemical behavior with actual evidence of residues.

An error emanating from uncertainty continues to

reverberate throughout the regulatory process.

Impact on the Will to Act

If regulatory agencies had foreseen the potential for DBCP to contaminate groundwater or for EDB to contaminate processed foods, public outrage would be a justifiable response to the failure of regulators either to deny registration of these products or to specify restrictions for their use in order to prevent these adverse effects. At the time, however, regulators lacked scientific or practical information which would have supported a decision to ban or restrict the use of DBCP or EDB. To have done so without evidence would have been an extension of remarkably uncommon foresight or intuition, or both -- as well as an unacceptable extension of authority.

Given the large number of registered products, state regulators necessarily, even if not systematically, focus their attention on only a subset of chemicals at any given time, rather than all 12,000 at once. Even the most rigorous discipline for setting priorities, however, can fail to identify the "pesticides of greatest concern" unless predictions of chemical behavior are always accurate.

Uncertainty #2: Patterns and trends in pesticide use are so dynamic that it is hard to say whether regulation promotes or prevents the wisest use of pesticides.

Regulation is far from the only source of decisions regarding pesticide use. A host of decision makers is

involved in an uncoordinated battle against pest damage. Manufacturers, for example, decide which problems to tackle and which new products to develop. Because certain pests cause severe damage more in one year than another, pest control advisors must decide which particular products to recommend against particular pests in particular years. Growers decide which advice to accept.

Government can control its own regulatory decisions and it can influence other pesticide use decisions. The overall patterns and trends in pesticide use, however, are only partly an artifact of regulation. The forces that create trends in pesticide use are outside the control of government regulation. These forces are a source of uncertainty in regulatory decision making.

Impact on Scientific Knowledge

In the area of scientific knowledge, the phenomenon of "pest resistance" challenges the assumptions dominant at any given time as to which pesticides will be effective in controlling particular pests. Historical patterns reveal that certain pests develop resistance to very potent chemical pesticides. Cockroaches are notorious for their resilience, as are certain pest species that attack field crops -- citrus thrips, for example, and boll weevils.

The usual response to pest resistance has been to increase the dosage and/or potency of chemical pesticides. In some cases, however, pest resistance escalates along with the dosage and/or potency of the pesticides, creating a situation

in which chemical traces in the environment may be increased with no additional benefit in pest control.

Resistance management -- the process of keeping pests from building up an immunity to pesticides -- is an emerging and complex pest management specialty. As this branch of knowledge and practice develops, its theorists and practitioners are devising strategic alternatives to simply increasing chemical use. But it is too early to tell which approaches will turn out to be effective in addressing every pest resistance problem.

Meanwhile, pesticide regulators must respond on the basis of existing scientific and practical knowledge to the need for agricultural, structural, and other pest control materials. It is uncertain, at best, that the decisions made now in every case will successfully reconcile concern for health and environmental effects with concern for, say, optimal agricultural productivity.

Impact on Practical Knowledge

Dynamic patterns and trends in pesticide use create a special category of uncertainty for regulation in the form of anomalies in available methods for conducting cost/benefit analyses. Federal law requires that pesticide regulators give equal weight to costs and benefits when deciding whether to permit the use of a compound for which the risk of use may be unknown or uncertain. A practical uncertainty related specifically to pesticides is that more is known about how to measure the economic costs and benefits of pesticide use than

about how to measure the social costs and benefits.

The economic benefits of pesticide use for agricultural purposes are measured by the increases in crop yield that controlling pest damage produces. Because pesticides are expensive -- i.e., their economic cost is high -- trends in choice of particular products vary, depending on product cost (and, of course, effectiveness). Economic considerations require growers to be aware of pesticide use at whatever levels simultaneously minimize both production costs and crop loss and to maintain the pattern which is most beneficial to them.

The responsibility of regulators is to promote agricultural productivity and to protect human health and the environment. Their decisions aim to benefit individual growers in the sense of allowing use of pesticides that are effective and affordable. Their decisions must also benefit the public by preventing unreasonable adverse health and environmental effects.

The proof of "unreasonable" in this particular situation would be that costs exceeded benefits. The problem is that the costs of potential adverse health and environmental effects are largely unmeasurable and, furthermore, are spread among the entire population. Thus, the average per person social cost of adverse effects is much smaller than the average cost of crop loss to individual growers.

Similarly, the average per person social benefits of preventing adverse effects are much smaller than the average per grower benefits of pesticide use in the form of increased

crop yields. The public as a whole also benefits from pesticide use in that food supplies are abundant and affordable. Whether this measurable social benefit exceeds the unmeasurable social cost of pesticide use is uncertain.

Impact on the Will to Act

Fluctuations in patterns and trends in pesticide use -- and in the conditions and factors that create patterns and change trends -- make it hard to say whether regulation promotes or prevents the wisest use of pesticides. Pest management techniques change over time, with or without regulatory action. For example, certain chemical pesticide manufacturers are currently researching biological control methods for pest management. Uncertainty regarding the appropriate allocation of regulatory resources in a dynamic environment can undermine the will to act, because there is no way of knowing in advance whether new types of pest control materials and/or pest management techniques will be more or less harmful to people and the environment than current use of chemical pesticides.

Regulation always follows the invention and development of new products and technologies; prior to development, there is neither basis nor opportunity for regulation. Because regulation waits for the targets of regulation to come into existence, so to speak, there is always a degree of inertia in regulatory agencies deriving from uncertainty as to the point at which regulatory intervention is appropriate. When action is required, such inertia must be overcome by

sheer force of will.

That drastic regulatory actions are taken when drastic actions are called for proves that the will to act can overcome the inertia that is inherent in the regulatory process. But uncertainties endemic to regulatory decision making also do undermine the will to act and thereby weaken the regulatory process according to the varying degrees of uncertainty in different situations.

ADDITIONAL SOURCES OF UNCERTAINTY

For the sake of clarity, we have limited our discussion of the impact uncertainty has on the three resources needed for correct regulatory decisions to two categories of uncertainty. Clearly, many additional categories exist and influence decision making in unique ways. Without completing a full exegesis of each one, we simply mention the following three additional sources of uncertainty which we have arbitrarily selected from the full complement of possibilities: "trade secrets," fraudulent testing data, and non-compliance.

"Trade Secrets"

Certain specified categories of information required for pesticide registration are exempted by federal law from public disclosure. Among these is the category of "trade secrets." In the manufacture of pesticides, trade secrets generally pertain to the identity of all chemical ingredients in a product and their proportions. Depending on whether the

manufacturer and the pesticide "formulator" are one and the same, the company submitting a registration application may itself not know the chemical contents or the precise formulation for which it seeks approval. The protection extended by the government to patented information limits the ability of environmental scientists to assess the hazardous potential of particular pesticides.

Fraudulent Testing Data

In 1976, the federal Food and Drug Administration uncovered a major scandal at Industrial Bio-Test (IBT) Laboratories in Northbrook, Illinois. IBT had falsified and fabricated data from toxicology tests used to support the registrations of hundreds of pesticides. The Natural Resources Defense Council, in a report issued in March 1984, cited the following details of the IBT scandal:

This one lab was estimated to be responsible for between 35-40 percent of all toxicology tests in the country. The registration of over 200 pesticides has since been found to be based to some degree on IBT data. Of the 801 chronic health risk studies which IBT submitted to EPA, only three percent have been determined to be valid and sufficient to support registration. ... At least 90 of the pesticides registered with IBT data are intended for use on food crops. (NRDC;1984)

The data gap created at the Environmental Protection Agency by the IBT testing scandal is also a data gap at CDFA to the extent any of the pesticides registered by EPA on the basis of fraudulent data have also been registered in California.

Noncompliance

Predictions of environmental fate necessarily assume a very high rate of voluntary compliance with instructions for and restrictions on pesticide use. Clearly, government regulators cannot always be present when pesticides are being applied to assure that label instructions are being strictly adhered to. Monitoring programs can keep track of only a very small percentage of cases.

A farmer confronted with a pest resistance problem may be tempted to use more of a pesticide than is recommended -- either apply a more concentrated solution or apply the product more often or closer to harvest than recommended, or some combination of all these possibilities. Instructions for use are derived so as to avoid the possibility that pesticides will leave residues that exceed food tolerances. Consequently, noncompliance heightens the chance that illegal residues will be left on crops. There is no guarantee, of course, that the residue monitoring program will detect every incidence of illegal residues -- or that monitors will know when noncompliance is responsible in the event they do find residues over tolerance.

Unintentional Noncompliance

In non-agricultural use, potent pesticides are available "over the counter" for home and garden use. Occasionally, consumers may purchase even restricted materials (in small amounts) to deal with difficult pest problems. Who can say whether consumers fully understand the potential risk to which they are being exposed through the use of these

pesticides? Just because restricted pesticides are available for purchase does not mean they are safe to use without taking the precautions that are specified on the label.

Certain pesticides available for home and garden use -- chlordane, for example -- must be carefully disposed of, sometimes requiring the assistance of the manufacturer or the county agricultural commissioner. The extent to which home and garden pesticide users are aware of the need to take such special precautions is unknown. Thus, the potential for unintentional noncompliance with pesticide regulatory decisions creates yet another special category of uncertainty.

CONCLUSION

Uncertainty means no one can be absolutely sure decisions made by pesticide regulatory agencies or individual pesticide users will prove to be safe. Seriously harmful consequences can follow from faulty decisions. For example, daily doses of some chemicals that may cause cancer over long-term exposure can cause reproductive disorders and/or birth defects from short-term or even single exposures. Clearly, pesticide regulators must remain alert to such information as it becomes available in order to prevent adverse health effects from exposure to pesticides.

The information that would allow affected regulatory agencies to discern in every case which course of action best serves the public interest sometimes just isn't available. The significance of this uncertainty is that it deepens the

obligation of government to be vigilant: to do whatever is necessary to reduce uncertainty at every point at which the well-being of the public and the wholesomeness of our environment are vulnerable to the harmful consequences of preventable error.

The regulation of pesticides is perched between two economic giants: the chemical industry and agriculture. Effective action to protect public health requires that regulators have clear direction from policymakers, plus the flexibility and resources necessary to upgrade staff and equipment to match the ever increasing technological and scientific sophistication of the chemical industry.

Twin constraints of budgets supported with tax dollars for which there are competing demands and staffing decisions controlled by personnel policies designed to protect the continued employment of existing staff tend to thwart the periodic modernization needed for effective regulation. A government agency lacking state-of-the-art tools is necessarily weaker than the industry it regulates and cannot act in the public interest with the decisiveness most people would prefer.

The findings and recommendations in this report are concerned with: (1) identifying what is at stake in any system of pesticide regulation -- that is, defining why it is necessary to maintain a modern regulatory capability -- and, (2) proposing ways of reducing the uncertainty that undermines definitive and timely regulatory decision making.

Chapter III

PESTICIDE REGULATION:
THE ROLE OF CALIFORNIA'S LEAD AGENCY

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA lacks an overall priority-setting discipline for identifying "pesticides of greatest concern."

Recommendation: Integrate "priority pesticides" with management priorities."

Finding #2: CDFA inherits the weaknesses in EPA's programs.

Recommendation: Establish policy for determining when the department should not wait for EPA to act.

Finding #3: Funding is inadequate to enable CDFA to maintain a state-of-the-art regulatory capability.

Recommendations:

A. Amend current law to specify that the Agriculture Fund and General Fund contributions to pesticide regulation shall be equal.

B. Consider giving taxpayers the option on state tax returns to contribute voluntarily to pesticide regulation funding.

Finding #4: Public information on pesticide hazards and regulation is inadequate.

Recommendations:

A. Establish an Office of the Pesticide Ombudsman within CDFA and institute a toll-free "hotline."

B. Develop materials, with the assistance of health and environmental advocacy groups and participation and financial support from the pesticide manufacturers, for use in a program of targeted public information services.

Chapter III

PESTICIDE REGULATION: THE ROLE OF CALIFORNIA'S LEAD AGENCY

INTRODUCTION

California's program of pesticide regulation has a long history because of the importance of pesticides to one of California's major industries -- agriculture. In 1983, gross income from crop sales amounted to \$13.5 billion. The total contribution agriculture makes to California's \$400 billion economy is speculative, but many economists assume it is at least three times the income from crop sales.

For 35 straight years, California has been the nation's top agricultural producer. We grow more of 48 separate crops than any other state; we grow more different types of crops than any other state. We grow 10 percent (in dollar value) of all agricultural products produced in the United States and fully half of the nation's supply of fruits and vegetables. In addition, California produces 90-100 percent of ten specialty crops such as almonds, figs, and pomegranates. Appendix F lists the 25 commodities of which 50 percent or more are grown in California.

California became the nation's number one agricultural producer by developing our water resources into irrigation systems that complement California's unique climate. This combination of resources enables the industry to continue agricultural diversification. It also has led to the use of more and increasingly specialized varieties of pesticides, some of which are used almost exclusively in California. The

need for a comprehensive state program of pesticide regulation grew along with these advances in agricultural practice and pesticide use.

It became apparent over the course of our study that, compared with other states' programs, California's pesticide regulatory program is in many ways exemplary. While we did find deficiencies and have recommended improvements in management and operations, we also feel confident in recommending the "California model" to other states which have more recently begun programs of pesticide regulation.

THE DEPARTMENT OF FOOD AND AGRICULTURE:
CALIFORNIA'S LEAD AGENCY

This chapter provides the reader a brief overview of the California Department of Food and Agriculture -- designated the lead agency for promoting the state's agricultural business as well as regulating agricultural use of pesticides. This chapter also sets forth broad findings and recommendations which cut across many of the issues addressed in more detail in later chapters.

Over the years, a complex system of regulation has evolved to enable CDFA to meet its statutorily defined objectives of: (1) preventing "unreasonable harm" from pesticide use to people and the environment, and (2) promoting agricultural productivity. The uncertainty surrounding the use of pesticides requires that complex systems be created to coordinate activities and to make the most efficient use of existing resources.

In concept, the department's program is structured as follows: the Division of Pest Management, Environmental Protection, and Worker Safety is divided into five branches: (1) Registration and Agricultural Productivity, (2) Pesticide Use Enforcement, (3) Environmental Monitoring and Pest Management, (4) Worker Health and Safety, and (5) Information Services. The Environmental Monitoring Unit is further subdivided into (a) Environmental Hazards Assessment, (b) Pest Management Analysis and Planning, and (c) Biological Control Services. Figure III-1 (next page) illustrates this organizational structure. Appendix G details the activities of each subdivision in meeting the division's two objectives.

Preventing Harm

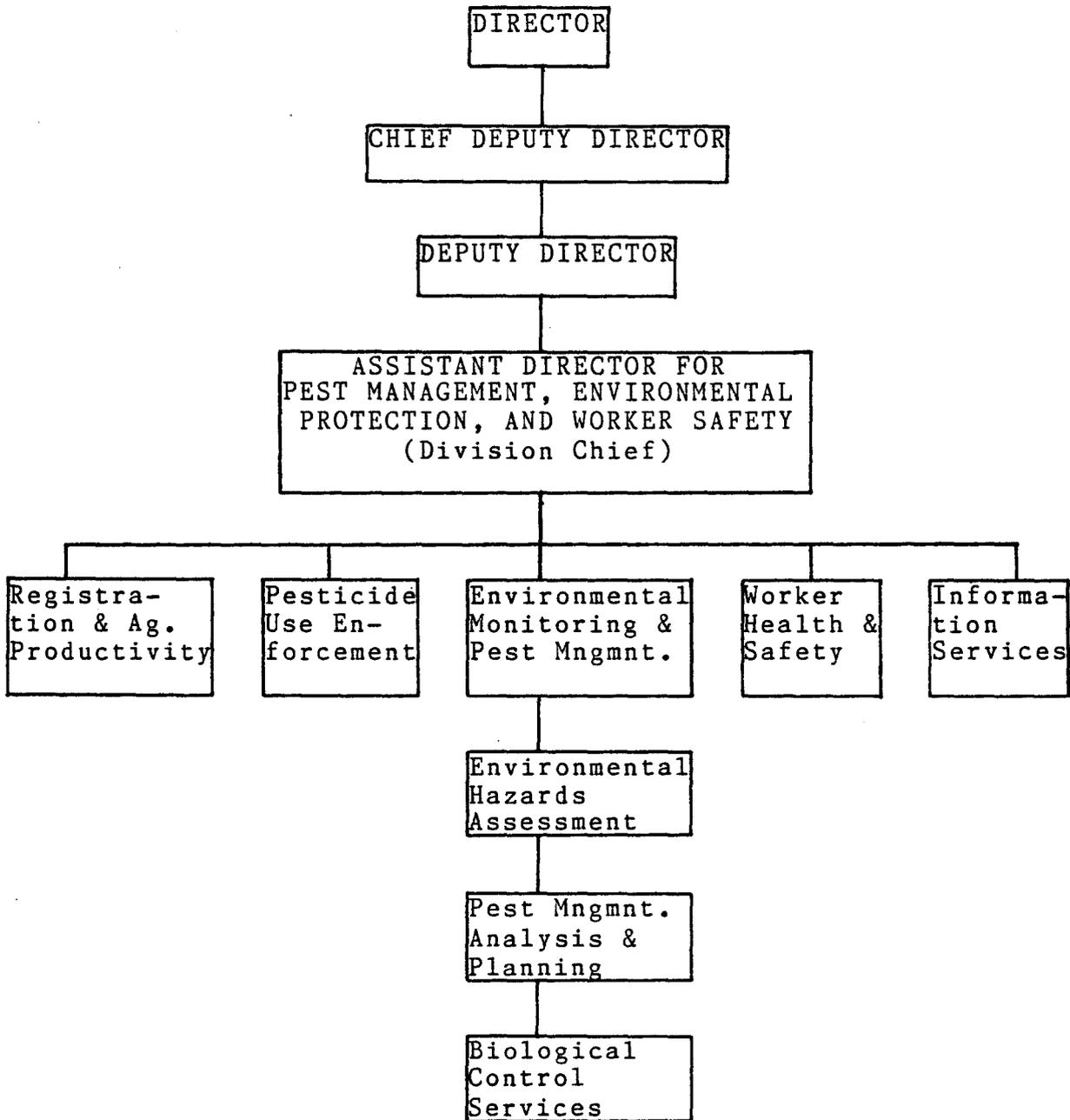
CDFA's regulation of pesticides through the five branches of the Pest Management Division is a collective effort that focuses on preventing harm and promoting agricultural productivity. Specifically, CDFA's regulation of pesticides attempts to prevent adverse health and environmental effects from pesticide use by:

- *conducting scientific evaluations of toxicological and environmental data;
- *denying registration of pesticides for which the risks of use exceed the benefits;
- *de-registering pesticides found to pose unreasonable harm;
- *checking pesticide formulations for misbranding and embargoing pesticides found to be misbranded;
- *conducting use monitoring to assure compliance with label instructions and restrictions on use set by the Registration Unit;

Figure III-1

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
Division of Pest Management, Environmental
Protection, and Worker Safety

Organization Chart



*sampling randomly-selected food lots to find out whether (1) residues above tolerances set by EPA can be detected, and (2) pesticides are "behaving" as Registration and industry scientists predicted;

*removing from sale food lots found to contain illegal pesticide residues;

*conducting special studies of the environmental impact of the use of particular pesticides;

*investigating reports of pesticide-related illnesses and other incidents;

*monitoring pest eradication projects in urban and suburban areas;

*developing requirements for precautions to be taken during use to protect worker safety; and

*maintaining an extensive data base on the sale and use of pesticides throughout California.

Promoting Agricultural Productivity

As previously discussed, promoting high agricultural productivity is an equally important objective. CDFA strives to fulfill this mandate by:

*requiring and evaluating efficacy testing data to assure that pesticides registered in California are effective in killing target pests;

*protecting farmers against crop loss or quarantine by preventing illegal or improper use of pesticides;

*conducting special studies to determine the impact of pesticide use on agricultural productivity;

*assessing crop losses from air pollution;

*preparing efficacy assessments of proposed alternative pest control methods;

*developing mitigation measures when a pesticide needed by agriculture is found to be causing adverse effects;

*promoting activities to improve worker safety; and

*assuring the supply of an adequate work force and the continued availability of particular pesticides.

Mechanisms for Coordination

In addition to task forces and advisory committees, CDFA has formalized several mechanisms to assure a high level of coordination in the state's activities to regulate pesticides. Under the terms of a memorandum of understanding with the Department of Industrial Relations (DIR), CDFA and DIR share data and conduct cooperative investigations of pesticide-related occupational injuries or illnesses or other workplace incidents. In addition, CDFA, DIR, and the Department of Health Services (DHS) make joint oversight inspections of reported or discovered pesticide problems. If the problems meet the criteria of the Priority Incident Reporting System, appropriate federal, state, and local agencies are notified immediately and asked to participate in developing mitigation measures.

Structural Pest Control

California's pesticide regulatory program includes the regulation of non-agricultural pesticide use. "Structural pest control" refers to methods and materials used to kill pests that attack and destroy buildings, clothing, stored food, and manufactured goods. CDFA controls the availability of products for structural as well as agricultural pest control through its registration process. Pesticides used for structural pest control must be used in accordance with the same statutes and regulations that apply to pesticides in

C. Articulate priority-setting procedures to select pesticides for special review.

D. Conduct seminars to identify cost-sharing alternatives to test "older" pesticides.

Finding #3: For some pesticides used on foods, CDFA lacks residue data necessary to estimating risk.

Recommendations:

A. Require updated data and residue detection procedures.

B. Require registrants to provide state laboratories with coded samples containing residues of pesticides to be registered.

Finding #4: CDFA lacks adequate data for predicting environmental effects.

Recommendations:

A. Require DHS to set "action levels" prior to registration for pesticides applied directly to water.

B. Require evidence in form of statistical models that pesticides injected into soil or applied to water do not threaten health or environment.

C. Ask local water districts and county agricultural commissioners to provide information to private well owners on locally available water analysis services.

Chapter IV

REGISTRATION

FINDINGS AND RECOMMENDATIONS

Finding #1: Certain EPA data bases critical to state monitoring and enforcement activities are inadequate. Specifically:

A. EPA's pre-1972 toxicological data base is inadequate for assessing risk.

B. EPA's data base for determining whether pesticides are "behaving" as predicted is inadequate.

C. EPA's failure to prevent pesticide contamination of groundwater is partly due to the agency's inadequate data analysis capability.

Recommendations:

A. Establish toxicological and environmental data-sharing networks with the states.

B. Establish a residue data-sharing network with FDA and the states.

C. Coordinate efforts with manufacturers to create statistical models for predicting environmental effects of pesticide use.

D. Sponsor research to develop groundwater clean-up procedures.

E. Sponsor research to develop safe alternatives to soil and grain fumigants now in use.

Finding #2: CDFA's data bases are inadequate. Specifically:

A. Toxicological data inherited from EPA exacerbate uncertainty in state-level risk assessment.

B. CDFA manually maintains data files on 12,000 pesticide registrations.

Recommendations:

A. Automate data files.

B. Establish data-sharing networks.

general, with additional safety precautions appropriate to pesticide applications made directly to environments inhabited by people. Usually, restricted pesticides must be applied by licensed pest control operators.

The chief regulatory mechanism for assuring compliance with structural pest control regulations is licensing. In 1935, a Structural Pest Control Board was established in the California Department of Consumer Affairs to issue licenses and mediate consumer complaints of ineffective or illegal work. The board receives more complaints about failure to fulfill contractual agreements than about exposure to hazardous pesticides.

County agricultural commissioners oversee all uses of restricted pesticides, including those in structural pest control. The commissioners also perform random inspections of pest control operators' storage areas to determine whether necessary safety and application equipment are on hand and to inspect pesticides in stock to assure they meet CDFA standards. Upon discovery of violations of law or regulations by structural pest control operators, county agricultural commissioners are authorized to suspend an operator's license for up to three days and may levy fines up to \$500.

CDFA's involvement in structural pest control monitoring is limited to responding to the board's requests to investigate problems. The Pest Management Division's Environmental Hazards Assessment Team is called in to inspect sites where excessive use or other misapplications of pesticides are suspected. The team samples air and fabric,

wood, or other surfaces to which a pesticide was applied and completes laboratory analyses to determine whether hazardous chemical residues have deteriorated in potency to the point of not posing a threat to health. Representatives from the Structural Pest Control Board sit on several of CDFA's advisory committees and the two entities also confer on a case-by-case basis when special problems arise.

Appendix H of this report provides additional details of California's structural pest control regulatory program.

Budget Summary

For 1985-86, the Governor has proposed a total budget of \$25,675,000 for the Division of Pest Management, Environmental Protection, and Worker Safety. This is an increase of \$3,590,000, or 16.3 percent, over estimated 1984-85 expenditures.

Not all funds supporting the pesticide regulatory program come from the general taxpayer. California collects a mill tax on pesticide sales (\$0.008 per dollar of sales). The revenue from the pesticide mill tax is deposited in the Agriculture Fund which, during the current fiscal year, is providing approximately \$9,850,000, or 44.6 percent, of this year's \$22,085,000 program cost. Three-eighths of the revenue from the mill tax is used to off-set CDFA's administrative costs and the remaining five-eighths is given to the counties to reimburse them for expenses related to the regulation of pesticides by county agricultural commissioners. Revenue from the collection of an annual registration fee of \$40 per

pesticide also contributes to the Agriculture Fund.

Table III-1 shows variations in budgeting for the subdivisions of Pest Management over three years.

Table III-1

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
Division of Pest Management, Environmental
Protection, and Worker Safety

Budget by Subdivision
(Dollars in Thousands)

	1983-4 ^a	1984-5 ^b	1985-6 ^{c, d}	<u>Change</u> <u>Amt/Pct</u>
Registration/ Agricultural Productivity*	\$2,529	\$3,410	\$4,178	+\$768/+22.5%
[% of Total]	[13.5%]	[15.4%]	[16.3%]	
Pesticide Use Enforcement	11,590	12,800	13,055	+ 255/+2.0%
[% of Total]	[62.0%]	[58.0%]	[50.8%]	
Environmental Monitoring	2,729	3,581	5,034	+1,453/+40.6%
[% of Total]	[14.6%]	[16.2%]	[19.6%]	
Worker Health and Safety	1,842	2,294	3,408	+1,114/+48.6%
[% of Total]	[9.9%]	[10.4%]	[13.3%]	
TOTALS	\$18,690	\$22,085	\$25,675	+\$3,590/+16.3%

a. Actual

b. Estimated

c. Proposed

d. Does not include proposed state employee salary and benefit increases

* Includes Information Services

Source: Governor's Budget for 1985-86

FINDINGS AND RECOMMENDATIONS

The findings and recommendations in Chapter III serve as the themes for the variations which recur with greater specificity and in more detail in subsequent chapters.

Finding #1: CDFA's Pest Management Division sets management priorities within each subdivision in order to comply with statutory requirements, but the division lacks an articulated, overall priority-setting discipline for identifying "pesticides of greatest concern."

We recognize that the Pest Management Division does set priorities. Neither the Assistant Director for Pest Management nor the individual unit chiefs would be able to manage monitoring activities or assure compliance with other statutory requirements if they did not set goals in priority order and then proceed to administer the pesticide regulation program according to those priorities. Given the very large number of pesticides registered for use in California, however, the varying degrees of uncertainty in scientific knowledge of health risks posed by each one, and the inevitably limited resource allocations for pesticide regulation, it is essential that CDFA also have a priority-setting discipline to identify the "pesticides of greatest concern."

Certain pesticides need to be integrated into every subdivision's established management and activity priorities -- whether for sampling programs to detect residues, monitoring programs to deter misuse, or scientific evaluation to compare actual with predicted chemical behavior in the environment.

This approach would superimpose particular pesticides on the division's already established priorities for sampling, monitoring, and scientific review.

The State Water Resources Control Board has implemented a process to select criteria for identifying chemicals of greatest concern with respect to their potential for contaminating California's water supplies. Having set priorities, the board can begin systematically to monitor the behavior of the priority chemicals in order to add to existing knowledge of those particular chemicals' toxicity and persistence. At the same time, when a crisis occurs, the board has an interpretive framework available to facilitate the assessment of relative risks posed by new concerns in relationship to already established priorities. Thus, the board can be flexible in giving a crisis the attention it deserves without neglecting the priority chemicals it has identified for routine monitoring.

As the lead agency for regulating pesticide use, CDFA must have the capacity to identify the pesticides which bear the most careful scrutiny by residue and use monitors -- not just within CDFA, but in other affected state departments as well. But the department has not yet articulated an overall discipline for consistently determining which pesticides are of greatest concern. Consequently, re-registration reviews are to some extent pro forma and fail to fill data gaps in order of highest priority. Furthermore, because they cannot anticipate CDFA's priorities, pesticide manufacturers are not able to plan for additional testing to meet the department's

needs for additional data.

Priority setting in environments of great uncertainty and limited resources is essential to effective performance. All other components of an effective regulatory program are in place at CDFA, but the department remains vulnerable to the negative effects of crisis management because it lacks a clearly articulated policy and process for priority-setting to identify the pesticides of greatest concern.

RECOMMENDATION

We recommend that the Pest Management Division in CDFA appoint all subdivision managers to begin work on selecting criteria to identify the pesticides of greatest concern and to integrate the "priority pesticides" with priorities already established for activities in each of the discrete regulatory functions.

The most compelling reason to identify pesticides of greatest concern is to minimize harm to public health and the environment. To meet this mandate, the department must be able to identify which pesticide ingredients persist in the environment or on food and to maintain current data bases on the acute and/or chronic toxicity of those ingredients. Lack of knowledge of any of these characteristics is of equal importance in identifying which pesticides the department needs to monitor in actual use in order to gain practical knowledge of their environmental fate.

Once having identified the pesticides of greatest concern, we recommend that CDFA develop a data base on the

crops to which those pesticides are applied. Cross referencing pesticides of greatest concern with the crops on which they are used would clearly establish priorities for residue and use monitoring. Such a system of "management by exception" would allow the department -- at no additional cost -- to make more productive use of its scientific, laboratory, and monitoring resources.

Finding #2: CDFA inherits the weaknesses in EPA's programs, despite having state-level statutory authority in some cases to compensate for EPA's deficiencies.

CDFA currently has the statutory authority to set tolerances for pesticide residues in food whenever EPA has not yet set a tolerance for a particular product. Certain types of pesticides, particularly fumigants, were exempt from food tolerances when they were registered because scientists believed they did not leave residues on food. Practical knowledge of actual residue-leaving behavior has determined that earlier assumptions were in error. Under these or similar circumstances which clearly indicate a need for regulatory action, how long should California wait before preceding EPA?

Data gaps that have persisted through multiple re-registrations are another weakness in the regulatory program inherited from EPA. If EPA had succeeded in getting registrants to fill the data gaps it had identified over the years, California's data base would be less uncertain by this time. Under existing law, CDFA is empowered to request

additional health and environmental effects data, so it is not the lack of authority that has perpetuated the present data gap at the state level. In this situation, CDFA's will to act appears to be undermined by EPA's legacy of inertia as well as by uncertainty as to which pesticides to consider of greatest concern.

Projections by long-time observers of EPA that the Agency will increasingly resort to giving new and possibly even older pesticides a restricted use classification make it all the more important for California to be prepared to precede EPA. Under this policy at the federal level, the states' enforcement activities to protect public health and the environment will take on greater urgency. At present, however, the department lacks a priority setting structure for imposing this self-discipline to exercise without hesitancy the authority with which it has been entrusted.

RECOMMENDATION

We recommend that CDFA ask the Pesticide Advisory Committee to establish a policy for determining when the department should not wait for EPA to act before taking and/or coordinating state level action to prevent or mitigate a problem that has been identified in California.

We believe that CDFA should continue to work closely with EPA in the regulation of pesticides so as to avoid taking action that would be truly duplicative of federal responsibility and action. We also believe, however, that CDFA needs to establish criteria, priorities, and standard

operating procedures to facilitate state level decision making when, for whatever reason, EPA fails to take definitive action in a timely manner.

Finding #3: Funding for pesticide regulatory activities is often inadequate to enable CDFA to maintain a state-of-the-art regulatory capability. Furthermore, the General Fund is supporting more than half the budget for the pesticide regulatory program.

Regulatory programs rarely are entirely self-supporting, nor do we think necessarily they should be. In the case of pesticide regulation, however, the proportion of the contribution from sources intended to share the costs of regulation has been steadily diminishing. Table III-2 (next page) shows, for example, that the Governor is requesting a 32.1 percent increase in General Fund support for the regulation of pesticides in 1985-86, while the request for an appropriation from the Agriculture Fund is only \$230,000, or 2.3 percent, more than 1984-85 expenditures.

Over the course of our study, we found that inadequate funding contributes to the uncertainty of decision making in the pesticide regulatory program. Existing laboratory resources are inadequate, for example, to allow for any expansion of residue sampling. This particular problem is unfortunately not just a matter of inadequate numbers of staff or outdated equipment. Rather, CDFA is unable to offer salaries competitive with private industry in order to recruit top of the line scientists. Furthermore, the buildings

themselves in which the laboratories are located are not large enough to accommodate increases in staff or additional, state-of-the-art analytical equipment. At CDFA's food residue analysis laboratory in Sacramento, the chemical reference library also houses analytical equipment, producing an environment which is no more conducive to chemical analysis than it is to research.

Table III-2

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
 Division of Pest Management, Environmental
 Protection, and Worker Safety

Funding by Source
 (Dollars in Thousands)

	1983-4 ^a	1984-5 ^b	1985-6 ^{c, d}	<u>Change</u> <u>Amt/Pct</u>
GENERAL FUND	\$9,337	\$11,414	\$15,079	+\$3,665/+32.1%
[% of Total]	[50.0%]	[51.7%]	[58.7%]	
AGRICULTURE FUND	8,834	9,850	10,080	+ 230/+2.3%
[% of Total]	[47.2%]	[44.6%]	[39.3%]	
FEDERAL FUNDS	470	806	501	- 305/-37.8%
[% of Total]	[2.5%]	[3.7%]	[2.0%]	
REIMBURSEMENTS	49	15	15	---/---
[% of Total]	[0.3%]	[0.07%]	[0.06%]	
TOTALS	\$18,690	\$22,085	\$25,675	+\$3,590/+16.3%

a. Actual

b. Estimated

c. Proposed

d. Does not include proposed state employee salary and benefit increases

Source: Governor's Budget for 1985-86

Control and management of pesticides will continue to improve only to the extent that regulators are able to keep up with advances in scientific and practical knowledge and to maintain a state-of-the-art analytical capability. The responsibilities of government in the regulation of toxic substances change as knowledge of both the benefits and adverse effects of the use of these chemicals becomes more sophisticated. Preparation to meet the demands of the future requires adequate funding.

RECOMMENDATIONS

We recommend that:

A. The Legislature amend current law to specify that the contribution from the Agriculture Fund shall equal the General Fund contribution to the support of pesticide regulation. Adjustments in the pesticide mill tax and/or the annual pesticide registration fee to meet this standard should be adopted in the annual Budget Act.

The impact of pesticides on human health and the environment requires costly regulation in order to put important preventive measures and other protections in place. Pesticide producers and users should participate in paying for regulation as a reflection of the true cost of pesticide use. The public benefits from this regulation and should therefore also bear a portion of its cost.

The pesticide mill tax generated \$7.2 million on sales of \$903.4 million in 1983. Increasing the present tax would have to be done carefully because it is difficult for farmers to pass along the costs of food production to consumers. Thus,

an imprudent increase would be one that, in the search for new revenue for the pesticide regulatory program, put California farmers at a competitive disadvantage with farmers from other states. The current annual registration fee per pesticide is \$40. This fee generates approximately \$480,000 from annual renewal of nearly 12,000 registrations.

The selection of standards to identify appropriate share of costs is ultimately a political rather than analytical decision. But, from our point of view, there is no acceptable reason during a time when public sentiment consistently resists new taxation that the industry share of the costs of regulation should be allowed to decline. As Table III-2 indicated, the Agriculture Fund paid 47.2 percent of the cost of regulation in 1983-84, but is proposed to pay 39.3 percent in 1985-86.

We recommend that the Legislature authorize sufficient flexibility in assessments of both the agricultural and chemical industries through annual adjustments of the pesticide mill tax and/or the annual pesticide registration fee to meet the standard that the Agriculture Fund and General Fund share of CDFA's budget for pesticide regulation shall be equal. By requiring approval through the annual Budget Act, the Governor and Legislature can be assured these changes will receive adequate review.

B. The Legislature request from the Franchise Tax Board by July 1, 1985, a report on the amounts collected in "voluntary contributions" from California taxpayers in

response to lines 86 through 92 on Form 540. The purpose of this report is to enable the Legislature to consider adding a line to this section of the state tax return to give taxpayers an opportunity to increase spending for pesticide regulation.

A recent development in raising private money for public purposes is to give taxpayers an opportunity to contribute donations of unspecified amounts (\$1 or more) to campaign funds, senior programs, rare and endangered species preservation, child abuse prevention, and the U.S. Olympics Committee. Actual amounts raised through this method should give some indication of public willingness to utilize this device to support certain causes. It is certainly possible that current tax dollar support for control of toxic substances, including pesticides, does not completely satisfy public preferences and that more money could be raised for these purposes through voluntary contributions collected and administered by the government.

Finding #4: CDFR's program of public information is inadequate to give the public access to non-technical information on hazards associated with pesticide use and/or how the regulatory program works at the point such information is most needed.

The Information Services Unit in the Pest Management Division is focused primarily on the division's internal needs for assistance with data gathering and compilation and coordination of data processing required to prepare statistical reports. Thus, while Information Services

meets the needs of technical and scientific audiences, CDFA lacks a program of information services appropriate for use by the public.

The department's media office is expected to provide assistance with press relations for all the department's internal divisions, but there is no staff person in the media office presently assigned on a regular basis to the Division of Pest Management. Quite apart from media concerns, evidence suggests that CDFA is ill-prepared simply to respond to queries from concerned citizens trying to get information on a particular pesticide problem. At the Commission's public hearing in Sacramento in November 1984, for example, a representative of a Sacramento-based health and environmental advocacy organization made the following comments:

The Sacramento Toxics Alliance felt management at the California Department of Food and Agriculture to be biased on the side of the rice growers and chemical companies. We felt that CDFA was and still is more concerned about production of rice than protection of public health. They were impossible to work with and made information difficult to receive. Exchanging valid concerns and comments to management level was impossible. We found the public involvement process took considerable energy and coordination with no effect on CDFA. (Commission on State Government Organization and Economy; 1984)

Whether or not this organization's experience with CDFA is representative is less important than the fact that the organization's spokesperson openly expressed strong dissatisfaction with the response received from a state regulatory agency. We understand CDFA may be expanding the availability

of media relations services to the Pest Management Division. In general, however, information on pesticides is a category of information that only the people most directly affected need at the time they happen to hear or read about it in the news. Being prepared to provide information about particular pesticides to people who have specific concerns or questions would provide a beneficial supplement to any additional media relations services the department has planned.

Californians deserve to know that our state has an effective pesticide regulatory program that is capable of preventing adverse effects from pesticide use, provided the scientific assumptions upon which the regulatory program is based are correct, the practical knowledge of actual pesticide use is adequate, and the will to act is sufficiently strong and supported by the public.

RECOMMENDATIONS

We recommend that:

A. The Legislature authorize the establishment within CDFA's Pest Management Division of an Office of the Pesticide Ombudsman. We further recommend that the Pesticide Ombudsman institute a toll-free "hotline" to enable the office to receive calls from anywhere in the state. We also recommend that the Legislature memorialize Congress and the Governor work with the Reagan Administration to require pesticide registrants to include EPA's pesticide hotline number on all pesticide labels.

Currently, EPA does have a "pesticide hotline" into its Office of Pesticide Programs in Washington, D. C. We believe

it would greatly enhance the usefulness of this service to make the telephone number for the hotline readily available by printing it on all pesticide labels. Eventually, the volume of calls might create enough pressure to encourage EPA to respond by coordinating the relay of calls over its own hotline to places within states where callers could receive assistance or information on local problems.

B. CDFA solicit the assistance of health and environmental advocacy groups and affected pesticide manufacturers in the planning, development, and scheduling of a series of seminars to be made available to public groups, including schools, upon request. We further recommend that pesticide manufacturers support this effort financially, especially when problems caused by a particular pesticide product trigger the need for a program of targeted public information services.

In addition to improving routine public relations, CDFA needs to make a special effort to educate affected segments of the public regarding how the pesticide regulatory program works in California. On a case-by-case basis, CDFA could begin to meet the public's needs for information by explaining the dimensions of a problem identified with a particular pesticide, the actions the state is taking to mitigate the problem, and the precautions that citizens most likely to be affected can take to protect themselves against adverse health effects. Such a program is badly needed right now to address the concerns of private well owners, for example, whose

drinking water supplies may be contaminated by DBCP. We predict pest eradication projects (e.g., Medfly) also would run more smoothly if a coordinated effort were made by CDFA, advocates, and pesticide manufacturers to inform the people living in affected areas of what to expect from the project and what is known regarding health and environmental risks.

Participation of health and environmental advocacy organizations in the development of these educational programs would assure that the materials and plans developed by the department would meet the informational needs of these groups' members. Advocates could also be extremely helpful in scheduling seminars for their members to attend, thereby reducing the costs associated with publicizing the availability of this service.

It is in the best interests of the pesticide manufacturers to supply informational materials and financial support for this kind of targeted public education, especially with respect to one of their products. Therefore, we recommend that manufacturers take it upon themselves to provide the financial support necessary to make this effort a success, particularly when a special program must be developed in order to address the adverse effects from particular pesticides.

Finally, county agricultural commissioners may find they would be welcome in classrooms in their areas -- in science classes, for example -- to educate students to the potential hazards of careless pesticide use and to inform them of what California does now to prevent and address problems associated

with the use of pesticides. We encourage the county commissioners to look for such opportunities.

Chapter IV

REGISTRATION

FINDINGS AND RECOMMENDATIONS

Finding #1: Certain EPA data bases critical to state monitoring and enforcement activities are inadequate. Specifically:

A. EPA's pre-1972 toxicological data base is inadequate for assessing risk.

B. EPA's data base for determining whether pesticides are "behaving" as predicted is inadequate.

C. EPA's failure to prevent pesticide contamination of groundwater is partly due to the agency's inadequate data analysis capability.

Recommendations:

A. Establish toxicological and environmental data-sharing networks with the states.

B. Establish a residue data-sharing network with FDA and the states.

C. Coordinate efforts with manufacturers to create statistical models for predicting environmental effects of pesticide use.

D. Sponsor research to develop groundwater clean-up procedures.

E. Sponsor research to develop safe alternatives to soil and grain fumigants now in use.

Finding #2: CDFA's data bases are inadequate. Specifically:

A. Toxicological data inherited from EPA exacerbate uncertainty in state-level risk assessment.

B. CDFA manually maintains data files on 12,000 pesticide registrations.

Recommendations:

A. Automate data files.

B. Establish data-sharing networks.

C. Articulate priority-setting procedures to select pesticides for special review.

D. Conduct seminars to identify cost-sharing alternatives to test "older" pesticides.

Finding #3: For some pesticides used on foods, CDFA lacks residue data necessary to estimating risk.

Recommendations:

A. Require updated data and residue detection procedures.

B. Require registrants to provide state laboratories with coded samples containing residues of pesticides to be registered.

Finding #4: CDFA lacks adequate data for predicting environmental effects.

Recommendations:

A. Require DHS to set "action levels" prior to registration for pesticides applied directly to water.

B. Require evidence in form of statistical models that pesticides injected into soil or applied to water do not threaten health or environment.

C. Ask local water districts and county agricultural commissioners to provide information to private well owners on locally available water analysis services.

Chapter IV

REGISTRATION

INTRODUCTION

Registration represents the gatekeeper in the regulation of pesticides. Registration processes provide the opportunity to generate the toxicological, environmental, and use data required by government and industry to verify the efficacy of the pesticide in its intended use and the likely levels of pesticide residues on target crops. Precautions that may be necessary to ensure the pesticide minimizes risk to public health and the environment when used properly may become obvious in this examination. Initially perceived as a "consumer protection" program -- a certification of the efficacy of the product -- registration increasingly serves as a preventive mechanism against adverse health and environmental effects.

Toxicological, environmental, and use data provide the basis for a "risk assessment:" the estimate of the likelihood of adverse effects under presumed conditions of exposure. By identifying unreasonable risks which in turn may result in recommendations to deny registration, risk assessment can serve to screen out pesticides that cannot be used properly in some or all cases without posing undue human health and/or environmental risk.

Both the federal government, through the Environmental Protection Agency (EPA), and the State of California, through the California Department of Food and Agriculture

(CDFA), register pesticides for various uses. EPA currently has approximately 60,000 pesticides registered, while CDFA has registered nearly 12,000 pesticides for use in California. Following is a brief summary of both registration processes.

Federal Registration of Pesticides

Federal responsibility for pesticide registration is legally mandated to the U. S. Environmental Protection Agency (EPA). The federal registration process is schematized in Figure IV-1 (next page). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that all pesticides distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received for shipment, or offered to be delivered be registered with the EPA (7 USCA Sec. 136(a)). Exceptions are pesticides for which experimental use permits have been granted or those being transferred from one registered establishment to another operated by the same producer, for packaging or for use as a constituent part of another pesticide produced at the second establishment. The EPA may deny registration if the requirements for registration have not been met.

EPA categorizes registration of a pesticide into six groups, five of which correspond to sections of FIFRA. These five categories address factors such as testing, emergency use, experimental use, special local need, and "full registration" for all uses outlined on the label. The sixth registration category provides for a "conditional" authorization when the data base used in making the

Figure IV-1

FEDERAL REGISTRATION PROCESS

<u>MANUFACTURER</u>	new -----> <u>EPA</u>	-----> <u>ACTION</u>
A) Conducts testing of the pesticide active ingredient and to a lesser extent the pesticide formulation	registra- tion or new use	A) Approves unconditional registration B) Grants conditional registration contingent upon the generation of additional data to support a full registration
1) to ensure efficacy	for an existing	C) Grants experimental use permits whereby conditions for granting are met
2) to determine persistence on foods (residues) or in the environment (contamination of soils, surface water, and groundwater and "good" plants and animals)	registra- tion	D) Denies registration
3) to satisfy EPA data requirements for the purpose of conducting risk assessments (40 CFR 158 data requirements)	A) Reviews submitted statement and data B) Sets labelling requirements C) Classifies pesticide general use, restricted use, or both D) "Sets" tolerance level if pesticide is to be used in or on food based on estimated risk to the public or exempts from tolerance requirement if the chemical is	
B) Submits statement which includes information necessary for registration to EPA	1) on the list of exempted chemicals (the so-called "inerts" list) or 2) is unlikely to leave a residue on foods	

Note: Already registered pesticides are subject to data call-ins whereby information that may exist on the pesticide and is known to the registrant must be sent to the EPA. Information suggestive of adverse effects may trigger a "special review" whereby more information may be required of the registrant to ascertain the safety of the pesticide.

registration request is incomplete. Conditional registrations are granted generally to older pesticides whose available data bases are viewed as inadequate by today's standards.

Food Tolerances

In order to assure that foods to which pesticides have been applied are safe for human consumption and that pesticides are used in accordance with state and federal laws regulating use, the EPA sets a food tolerance for pesticide residues. If the pesticide is used in accordance with label instructions, a food tolerance level should never be reached. Crops containing residues at or exceeding the food tolerance are not acceptable for public distribution.

Verification that tolerance levels do not pose significant risk to public health is based on various data, including the results from health effects tests conducted by the manufacturer and projections of the percentage a single commodity or commodity group represents in the "average American's" total diet. A safety factor of 100 is generally incorporated into the calculations, although this was not always the case. For some pesticides registered during the early years of the regulatory program -- organophosphates, for example, which are believed to break down rapidly into harmless chemicals -- a safety factor of 10 was used.

Dietary Intake

The potential dietary intake of a pesticide from consumption of all commodities to which it may legally be applied must be determined before a requested food tolerance can be evaluated. If a pesticide leaves a certain amount of residue

on an avocado and a different amount on an eggplant, the volume of avocados and eggplants a person consumes normally -- daily or annually -- must be estimated to arrive at an approximation of the total average residue ingested in a year.

Pesticides found to induce cancer in animals may be used on raw agricultural food products if the maximum residues likely to be found on the intended food crop pose a sufficiently low level of risk -- generally less than one additional cancer death in a million from lifetime exposure to the pesticide. Only if the pesticide has been found to induce cancer when ingested by animals and is intended to be used on foods destined for processing is no food tolerance established -- in compliance with the Delaney Clause, which prohibits cancer-causing food additives (21 USCS Section 348(c)(3)).

An exemption to the requirement of a tolerance level may be granted if the EPA determines that the total quantity of the residue likely to be present in or on raw agricultural commodities under current usage conditions will involve no hazard to human health. Federal regulations do not specify how such a determination shall be made, but they do list those pesticides which are exempt from tolerance settings along with conditions for their use.

Data Requirements

Federal law delegates to EPA the authority to require health and safety test data in support of registration. The EPA in its Registration Guidelines specifies the kinds of data that are required to support the registration of new or

existing uses of pesticide active ingredients. These data requirements have only recently been set in regulation in Title 40 of the Code of Federal Regulations, Part 158. A data requirement may be waived by the EPA if "the data so required is [sic] not necessary in order to determine whether a specific pesticide product will generally cause unreasonable adverse effects on man or the environment" (40 CFR Part 162.45).

Use Classification

Recognizing that all pesticides do not pose the same degree of environmental and health risk, FIFRA classifies pesticides according to the degree of hazard associated with their use. Acceptable pesticides must be classified for general or restricted use, or both. A pesticide is classified for general use if it causes no unreasonable adverse effect on human health or the environment. Pesticides whose application may cause unreasonable adverse effects are classified as "restricted" and may require application by a certified applicator.

Re-registration

An additional oversight and control mechanism is the re-registration process. A pesticide must be re-registered every five years. Existing supplies may be sold and used, however, even when registration has expired. Recognizing that present registration requirements are considerably more stringent than those which existed when most pesticides were originally registered, FIFRA allows older pesticides to be conditionally registered until new data requirements are satisfied.

De-registration

Federal law provides the EPA two methods for "de-registering" a pesticide: suspension and cancellation. The EPA can suspend the registration which immediately imposes a ban on the use and sale of the pesticide, or it can cancel the registration which initiates a series of administrative proceedings to determine whether to deny either the registration or a particular use of the pesticide. During the the time required for a determination, existing supplies of the pesticide may be sold and used.

California's Registration Program

Federal law permits states to regulate the sale or use of federally registered pesticides or devices within the state, provided that state regulations do not permit sales or uses prohibited by federal law. States are not allowed to impose additional labelling requirements but may provide registration for additional uses and distribution solely within the state, provided these uses are in accord with the purposes of FIFRA. Such uses shall not have been previously denied, disapproved, or cancelled by the EPA. Where a pesticide is used on food or feed crops, a tolerance or exemption must exist under the Federal Food, Drug and Cosmetic Act permitting residues of the pesticide on food products.

In theory, assessing the risk of a particular pesticide should be necessary only once, if the assessment is conducted properly. Given the scientific imprecision of estimating the risk posed by pesticides, however, federal law recognizes that

each individual state may have to decide for itself the level of risk, or presumed risk, it is willing to tolerate. Individual states, especially California, have assumed the responsibility for reviewing the safety of pesticides used within the state, in particular the likely extent and degree of exposure from residues on foods and in water.

In California, CDFA has the sole responsibility for the registration of pesticides. All pesticides must be registered in accordance with California statutes. Pesticides to be registered for the first time must meet standards specified in Section 12824 of the Food and Agriculture Code. A new pesticide must:

- *not have demonstrated serious uncontrollable adverse effects either within or outside the agricultural environment;
- *result in greater public value than detriment to the environment in its use;
- *not have reasonably effective or practicable alternative material or procedure which is demonstrably less destructive to the environment;
- *not be detrimental to vegetation, except weeds, to domestic animals, or to the public health and safety, when properly used;
- *not be the subject of any false or misleading statement made or implied by the registrant or agent, either verbally or in writing, or in the form of any advertising literature.

Although EPA sets food tolerances for all pesticides, California statutes authorize CDFA to set its own food tolerances when it deems it appropriate. To date, CDFA has not exercised this authority for foods. Similarly, the Department of Health Services, which is responsible for

monitoring and enforcing food tolerances in processed food, may prescribe tolerances for pesticide residues in processed foods.

As in the federal registration process, state government can require additional health and environmental effects testing by the manufacturer of a pesticide. California regulations require that data submitted in support of a federal registration must also be submitted in support of a state registration, including data waived by the EPA. The state registration process also requires submission of data on the residue testing method, efficacy of the pesticide, hazards from inert ingredients, general toxicity, and other information. Like EPA, CDFA classifies a pesticide as "restricted" to regulate its usage. Currently, over 80 pesticides are designated as restricted in California.

Unlike the federal government, California requires each pesticide to be re-registered annually. In renewing the registration, the department is required by law to screen out any pesticide which endangers "the agricultural or non-agricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented."

FINDINGS AND RECOMMENDATIONS

Federal Program

It is important to note that certain deficiencies in federal registration are inherited by the states. The most serious deficiency in the federal pesticide program is the "data gap" for many pesticide ingredients.

Finding #1: Certain EPA data bases critical to state monitoring and enforcement activities are inadequate. As a result, EPA and CDFR may in some cases make inappropriate regulatory decisions which impair their ability to fulfill all regulatory responsibilities.

Optimal regulatory decision-making and careful management of the registration process require complete and accurate data bases. As discussed in Chapter II, the regulation of pesticides involves imperfect knowledge with many unknowns in areas of toxicology, agriculture, and patterns of use, to name only a few. These uncertainties increase the importance of proper management of resources over which regulatory agencies can maintain control. Following are discussions of three specific cases:

A. EPA's toxicological data base on certain pesticides registered before 1972 is inadequate for assessing risk.

The registration process produces a compendium of critical information on registered pesticide ingredients, the year in which they were registered and/or de-registered, and the results of various tests required by EPA. Maintenance of this compendium, in addition to a data base on projected

pesticide use and predictions of residues, is critically important. Knowledge of the long-term effects of nearly all pesticides needs to be updated constantly to reflect (1) advances in chemical analytical techniques, (2) dynamic patterns of use of agricultural pesticides over the past forty years, and (3) advances in scientific knowledge of toxic effects. Data on when a pesticide was registered and which kinds of information were used to support the registration can help determine which information on a pesticide is no longer predictive and, thus, where new "data gaps" have occurred.

New knowledge regarding human health effects from exposure to certain chemicals, and of the kinds and quality of information necessary to make a determination regarding these effects, has led to more stringent testing requirements of pesticides registered today than for those registered even ten years ago. Numerous active ingredients (those pesticide ingredients which are included in the formulations specifically to kill target pests) that were registered in the early 1970's, including ingredients that were fraudulently or inaccurately tested, remain in common use today even though they lack the toxicological data base upon which to assess adequately their likelihood of causing chronic health effects. Examples of pesticides whose health effects are unclear are methyl bromide, herbicides such as paraquat, and fungicides such as the ethylene bis dithiocarbamates (EBDC) and their conversion product ethylene thiourea (ETU). The consequence of the toxicological data gap is that some pesticides are approved for use on foods without reasonable certainty that

they pose no significant risk to human health.

In some cases, chemicals produced through reaction of the original (parent) pesticide with air or water or through enzymatic conversion by bacteria in the soil, or by plants, are overlooked. The toxicity of these "breakdown" products often is not taken into account in the original evaluation of risk. Evaluation of tolerances for EBDC's, for example, failed to consider the fact that EBDC is readily converted into ethylene thiourea (ETU) -- a suspected carcinogen. The EPA in its new registration guidelines requires a more extensive scrutiny of breakdown products.

B. EPA's residue monitoring data base is inadequate to enable EPA to determine whether registered pesticides are "behaving" as the registrants predicted at the time of registration.

For many older pesticides, little information exists on the amount and frequency of residues left on different commodities, especially for those pesticides brought into commercial use before 1972. Most of the soil and grain fumigants such as ethylene dibromide (EDB) and methyl bromide fall into this category. Fumigants were exempt from food tolerance requirements because scientists believed they deteriorated quickly or dissipated completely and therefore did not leave residues on foods. Since tolerances have not been identified for them, these agents are not routinely monitored for in foods. For many of these chemicals, in fact, practicable residue detection procedures have not been developed.

Inadequate residue data also limit the effectiveness of the state's regulatory program. An effective regulatory program must be able to predict those pesticides which are most likely to leave residues on foods even under proper and legal use so that those pesticides can be closely monitored for. In addition, pesticides whose capacity to leave residues is not clearly understood should be systematically monitored to collect data on their actual residue-leaving behavior. Generation of such information enables a regulatory agency to determine whether a pesticide behaves as the registrant predicted it would: whether it leaves more or fewer residues on food than indicated in initial field studies conducted for registration purposes, or whether it persists on food or in the environment in its toxic state (see Chapters V and VI).

The importance of such information is underlined in situations where few chronic toxicity data exist -- for example, for pesticides such as methyl bromide, which is being used as an alternative to the banned EDB. Without tolerances and, hence, without data on public exposure, regulators cannot judge the health risk associated with use.

C. EPA has initiated new efforts to establish a program of data requirements, scientific analysis, and enforcement activities to prevent pesticide contamination of groundwater. Prevention is late, however, as contaminated wells are being discovered throughout the country, including in California.

Before EPA began implementing new data requirements, the agency had been requesting few data for use in assessing the

likelihood that a pesticide will reach and contaminate ground or surface water. New guidelines require many more tests to allow estimation of a chemical's potential for getting into drinking water supplies. Examples of inadequately evaluated pesticides are the soil fumigants -- such as telone, methyl bromide, and chloropicrin --- which are injected into the soil in great quantities to control nematodes. The EPA currently is conducting a general request for all data on the environmental effects of soil fumigants, including indications of the likelihood of their migrating into groundwater. In many places around the country, however, including California, the damage appears already to have been done.

The scientific consensus seems to be that little or nothing can be done to "remove" pesticide contamination from groundwater. Many contaminants presently found in California wells are expected to remain there for years.

RECOMMENDATION

We recommend that the California State Legislature memorialize Congress and the Governor work with the Reagan Administration to require the U.S. Environmental Protection Agency to:

A. Establish toxicological and environmental data-sharing networks with the states. The benefits of data-sharing would be (1) more efficient use of toxicological and environmental data by all levels of government, and (2) less duplication in data-gathering efforts. A cooperative approach would expedite overall efforts to close data gaps and could result in cost savings for both the federal

government and regulatory agencies in affected states, including California.

B. Establish a residue data-sharing network with the Food and Drug Administration (FDA) and the states. Such a system has been established for pesticide residues in feed crops under the purview of feed crop growers' associations, with FDA financial assistance. The advantages from establishment of such a system are:

- *efficient use of data on pesticide residues in different food crops;

- *less likelihood of duplicative monitoring; and

- *greater likelihood that problem pesticides (those which in actual use do not behave as predicted in field studies) will be identified early enough to allow for imposition of use restrictions or cancellation, if necessary, to prevent an unreasonable threat to public health and the environment.

C. Coordinate efforts with manufacturers to create models for predicting environmental effects of pesticide use, especially with respect to potential for groundwater contamination. By law, the responsibility for generating data necessary for evaluating the health and environmental risks lies with the pesticide manufacturers. This information should include statistical models for estimating pesticide concentrations at different times and under varying soil or water conditions. By providing such statistical models themselves, manufacturers could avoid substantial delays in the registration of newly developed pesticides. (Later in this chapter, we make a similar recommendation regarding CDFA's program.)

D. Sponsor research to develop clean-up procedures to mitigate the effects of pesticide-contaminated groundwater.

E. Sponsor research for developing safe alternatives to soil and grain fumigants which may pose unreasonable risks to health and environment. A pesticide cannot always be banned from use even when it poses a known threat to human health or the environment. Sometimes not controlling the pest, or using a more hazardous alternative pesticide, poses even greater risk of adverse effects. Banning EDB, for example, did not eliminate the pest problem for which EDB was being used. Scientific knowledge of health effects from fumigants now being used as substitutes for EDB is even more uncertain.

California State Program

Finding #2: CDFA's data bases are inadequate. They reflect not only the inherited weaknesses of EPA's data bases but certain state-level deficiencies as well. Specifically:

A. CDFA's inheriting of EPA's inadequate toxicological data bases exacerbates uncertainty in risk assessment at the state level.

Nearly twelve thousand different pesticide products are registered for use in California. According to one of CDFA's staff toxicologists, only about 5 to 10 percent of the pesticides for which either known health risks or health effects data gaps cause concern are registered on the basis of toxicological and environmental data that meet present California standards. This problem is partly inherited from the Environmental Protection Agency, which bears the primary

responsibility for requiring that adequate toxicological data exist prior to registration, and partly is the result of increased emphasis on having chronic health effects data for adequately assessing risk.

Chapter 669, Statutes of 1984 (SB 950) addresses the problem of data gaps, but CDFA estimates it will need roughly ten years to complete the program which seeks to fill critical information gaps on all registered pesticides. Despite the magnitude of effort necessary to review "old" pesticides in order to assure that they meet current standards, the department has yet to articulate how it will set priorities for product review. No assurance has been given that pesticides posing the greatest risk to public health and the environment will be reviewed first.

B. CDFA relies on manually maintained data files to catalogue information on approximately 12,000 registered pesticides.

The Auditor General of California recently conducted an audit of CDFA's data to determine the department's capacity to judge the safety of registered pesticides. The study revealed that data on CDFA's registrations are maintained and stored manually, in filing cabinets, and that information is poorly cross-referenced. Tracking the existence of specifically required information is extremely difficult. Given the size of the data base supporting the registration of 1,200 active ingredients in nearly 12,000 pesticides, it is difficult to update annually even a small percentage of

ingredients without access to an automated information system.

The shortage of data on exposure is a problem in all states, not just California. The ability of pesticide regulatory programs everywhere to assess the risk of harmful effects from a pesticide discovered to be leaving hazardous residues depends on knowing the extent to which people will be exposed to the compound. Even if CDFA had adequate exposure data, it would be impractical to share them with other states from a manual system containing that many files.

RECOMMENDATIONS

We recommend that:

A. CDFA automate its pesticide toxicological data files. Given the amount of data stored on pesticide active ingredients and their formulations, having to rely on manual manipulation of data files is time consuming and inefficient -- and therefore costly. Computer storage of important pieces of information would facilitate cross-referencing and tracking of data and save staff time and personnel costs.

B. CDFA establish toxicological data-sharing networks between departments of California state government, EPA, and other states. The advantages of this recommendation are the same as those discussed with regard to recommendations we made earlier in this chapter for improving EPA's information and data management.

C. CDFA articulate its criteria for setting priorities in selecting pesticides for special review. Government regulation represents a major source of uncertainty for industry. Government actions can alter market structures or

change the rules by which an entire industry must operate. The state can assist pesticide manufacturers to achieve efficient use of their resources, at the same time it can promote the goal of protecting public health, by articulating how it decides which pesticides are to undergo special scrutiny for unreasonable health effects. Knowing these priority-setting criteria would help manufacturers to plan with reduced uncertainty. A pesticide manufacturer could determine whether to devote its toxicological testing resources to the health effects testing and development of new pesticides or whether it must reserve these resources to assure the safety of an existing pesticide which meets the department's criteria for special review.

We suggest that CDFA adopt a priority-setting system similar to that used by the State Water Resources Control Board -- as described in the Board's report on Water Quality and Pesticides: A California Risk Assessment Program (Appendix I). The only significant modification to the Water Board's system should be to assign weights to pesticides with detectable residue levels on food. Absence of residue information through lack of monitoring, or inability to monitor, also should trigger consideration for review.

D. CDFA co-sponsor with pesticide manufacturers a series of seminars intended to identify cost-sharing alternatives to pay for health effects testing of "older" pesticides. At the federal level, the major stumbling block to the testing of "older" pesticides and chemicals has been the problem of

determining who is to pay for such research. Current law requires registrants to assume this responsibility. However, there may be many manufacturers of a single chemical, with no one manufacturer enjoying sole proprietary rights to the substance. Deciding how to share costs can be extraordinarily complex and might take years of litigation to resolve. The alternative to court-imposed solutions is to create a situation in which all parties most directly affected have an opportunity to negotiate a course of action they can all accept.

The success of California's new re-registration mandate in Chapter 669, Statutes of 1984 (SB 950) depends in part on the voluntary efforts of the pesticide industry to resolve this cost-sharing dilemma. We recommend a series of jointly sponsored seminars on this issue in order to create a decision making process which is open to public view. Neither CDFA nor the pesticide manufacturers can afford to overlook opportunities to encourage public confidence in the re-registration process.

Finding #3: For some pesticides used on foods, CDFA lacks the residue data necessary for estimating risk.

All pesticides with California registration that the EPA has exempted from food tolerances also enjoy an exempt status in California. Most of these exemptions were granted under the assumption that the pesticide would not leave residues on foods. As in the case of EDB in grain products, the state failed to test many of these assumptions more carefully as

residue detection methods improved. For other, mainly "older" pesticides, but including some newer pesticides such as thiobencarb (Bolero), glyphosate (Roundup), and permethrin, residue levels in foods are not being monitored for because of the absence of practicable analytical techniques. Such techniques have not been devised despite California's requirement for 24-hour residue detection procedures to be developed by registrants. Residue predictions are lacking for "inert" ingredients especially (see Chapter VII).

The lack of residue and, hence, exposure data on pesticides in foods is of particular importance. The state monitoring and enforcement programs, not having the resources to test for every pesticide that could conceivably be present on foods, must test for those "pesticides of greatest concern" -- those having the greatest likelihood of leaving residues in a particular food. In other words, monitoring must establish testing priorities consistent with its resources. Without valid residue data, however, the department cannot produce a risk assessment even should accurate toxicological data become available.

Risk = [hazard x exposure]. As discussed earlier, considerable uncertainty surrounds the estimation of hazards to human health. Exposure data weigh heavily in the equation, because they represent the most accurate and reliable information upon which an estimation of risk may be based. If exposure is very low, or non-existent, then risk -- regardless of the degree of hazard -- will, in turn, be relatively low.

If exposure is very high, however, risk becomes a concern because of the uncertainty regarding hazard.

Ethylene dibromide (EDB) in grain products perfectly illustrates the problem of lack of valid data on residues on foods. EDB was widely used to fumigate stored grains on farms and in grain elevators. When the pesticide was originally registered, it was believed not to leave residues in grain products at all. Consequently, no food tolerance was set for it, nor was it routinely monitored for in foods.

Since 1977, EPA has conducted reviews of EDB to determine whether its registration should be cancelled. Data then available indicated that the chemical causes cancer, heritable genetic damage, and reproductive disorders. The State Department of Health Services, which is responsible for monitoring pesticide residues in foods destined for processing, did not routinely test for it because of the absence of a food tolerance. The extent of the problem with EDB residues in food products was not apparent until Florida officials discovered high levels of the fumigant in cake mixes. The EPA did not take action to limit exposure to EDB until the State of California threatened to ban its use.

EPA's banning of EDB for use as a fumigant, however, has not eliminated the uncertainty regarding the safety of stored grain products. Methyl bromide is being substituted for EDB as a grain fumigant. Even less toxicological information is available on methyl bromide than for EDB but it, too, is not being routinely tested for in food products. The risk posed to the public by the use of such pesticides is unknown.

RECOMMENDATIONS

We recommend that:

A. CDFA require manufacturers of "older" pesticides to provide updated data used to predict residues. Updated residue detection procedures, where these do not now exist, must also be made available. By law, registrants are responsible for developing the data necessary to assess risk and to assure the safe use of a pesticide. They are also required to develop residue detection methods which regulators have the capability to utilize. We recommend that CDFA aggressively enforce these requirements.

B. CDFA require registrants to provide state laboratories with coded samples containing residues of the pesticides to be registered. Pesticide registration applications submitted to CDFA, by law, must be accompanied by proposed residue-detection techniques that can be used to complete an analysis within 24 hours. Not only may the state lack the equipment necessary to do the analysis, however, it may also lack the expertise either to detect certain complex molecules at very low concentrations or to determine the chemical identity of detected residues, or both.

It may be useful for the lay reader to be advised that residue detection is a process which involves interpretation of findings. The laboratory tests do not identify particular chemical residues which may be present in food samples. Rather, the laboratory scientists must interpret the results of tests in order to determine the chemical identity of

pesticide residues.

To assure that residue-detection techniques are consistent with the state's analytical capability, the state laboratory should be provided with a coded sample to which a given concentration of the pesticide has been applied. Failure to detect the residue would indicate a need -- before registration is granted -- for closer cooperation between the state and the registrant in developing a usable procedure.

Finding #4: In some cases, CDFA lacks adequate data to enable the department to predict the environmental effects -- in particular, the likelihood of drinking water contamination -- of either previously or newly registered pesticides.

The Registration and Agricultural Productivity section at CDFA has not always required data from registrants to assess a pesticide's potential to contaminate the environment. Although the Environmental Monitoring section of the Pest Management Division developed a list of data necessary for assessing a chemical's likelihood of getting into groundwater, for example, Registration was not requiring registrants of new products to provide this information.

Another deficiency is that Registration sometimes fails to respond to the findings generated by Environmental Monitoring. The department continues to register pesticides containing inorganic and organic arsenic, for example, despite substantial evidence of these chemicals' potential to contaminate the groundwater and to persist in the soil.

RECOMMENDATIONS

We recommend that:

A. The Legislature specify in new legislation that no pesticide which is applied directly to water -- such as rice field herbicides -- shall be registered in California until the Department of Health Services has set an "action level" (an advisory trigger for enforcement action) for it. Under ideal use conditions, pesticides which are applied directly to water should break down to harmless levels before reaching sources of public drinking water. Rates of decomposition may differ in accordance with meteorological conditions, however, or accidents may occur. For example, water treated with a pesticide may be prematurely released into a river.

Local water districts, which are responsible for the safety of public drinking water, need the guidance that DHS's "action levels" provide. Water district officials are dependent on state assessments of when contamination of the water supply poses a health problem. Unless DHS establishes action levels before affected pesticides are registered, the present system of reacting to the existence of a health threat, rather than taking precautions to prevent one, will continue.

B. CDFA require registrants of pesticides which are injected into the soil, or applied directly to the water, to provide evidence in the form of statistical models that the pesticides will not pose a threat to public health or the environment. By law, the responsibility for generating data

necessary for evaluating the health and environmental risks lies with the manufacturer. This information should include statistical models for estimating pesticide concentrations at different times and under varying soil or water conditions. By providing such statistical models themselves, manufacturers could avoid substantial delays in the registration of newly developed pesticides.

C. Local water districts and county agricultural commissioners assemble names and telephone numbers of area laboratories equipped to analyze water samples from private wells and able to interpret the significance of the detection of pesticide traces. Individual owners of private wells may need assistance in finding out whether their own drinking water supplies contain unsafe levels of pesticides. Local water districts and county agricultural commissioners would be providing a valuable public service simply by maintaining a list for each county of reliable laboratories. The labs should be capable of analyzing water samples for pesticide contamination and interpreting the test results to assist well owners in deciding whether they are being exposed to an unacceptable health risk.

Chapter V

RESIDUE MONITORING AND ENFORCEMENT

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA's residue monitoring program does not focus on public health risks.

Recommendation: Implement pesticide-based monitoring to supplement crop-based monitoring.

Finding #2: Information needed to develop pesticide-based monitoring is lacking.

Recommendation: Identify pesticides for which all agricultural users must keep detailed records of use.

Finding #3: Internal coordination within the Pest Management Division is inadequate.

Recommendation: Establish standard procedures to improve internal communications.

Finding #4: Laboratory resources are poorly coordinated with needs for scientific information.

Recommendations:

A. Transfer administrative control over pesticide lab services to the Pest Management Division.

B. Establish scientific advisory panel.

C. Increase funding for pesticide residue labs.

Finding #5: CDFA lacks residue detection methods for many pesticides in common use in California.

Recommendation: Identify and fill data gaps on residue detection procedures.

Finding #6: CDFA lacks a trigger for taking enforcement action in cases involving pesticides known to cause adverse health effects.

Recommendation: Require DHS to set food tolerance or action level when specified conditions apply.

Finding #7: Division of monitoring responsibility is not conducive to effective enforcement.

Recommendations:

A. Assign all raw agricultural product monitoring to CDFA.

B. Require DHS, in conjunction with CDFA, FDA, and EPA to (1) identify pesticides likely to leave residues in processed foods and (2) monitor pesticide applications on foods in storage.

Chapter V

RESIDUE MONITORING AND ENFORCEMENT

INTRODUCTION

California state law divides the responsibility for monitoring pesticide residue tolerances in food grown in California between the Department of Food and Agriculture and the Department of Health Services on the basis of whether the food is a raw agricultural product, a processed food, or a food destined for processing. Produce distributed in fresh fruit and vegetable markets is classified in Section 12504 of the Food and Agriculture Code as raw agricultural products and thus is monitored by CDFA. A food product altered chemically or physically before distribution -- other than sorting or cleaning -- is classified as a "processed food" and is monitored by DHS. Many agricultural products, however, defy this particular conceptual classification. Grapes, for instance, are distributed as fresh produce but also are distributed in their processed state as raisins.

The federal government also monitors pesticide residues in raw produce and processed foods through the federal Food and Drug Administration (FDA). FDA's authority encompasses foods imported from other countries and domestically grown food products distributed across state lines. Chapter VIII of this report provides more details on the federal residue monitoring effort.

Pesticide Residue Monitoring Programs Conducted
by CDFA and DHS

According to state statutes, the CDFA "may inspect and take samples of any produce grown, processed, packed, stored, shipped, transported, delivered for shipment, or sold" for purposes of testing for compliance with tolerance levels. Produce suspected of carrying pesticide residues may be seized and held by CDFA until sampling and testing for residues are completed. If pesticide residues exceed permissible tolerances, the department may, "upon the request of the owner, permit the lot of produce to be reconditioned or disposed of for byproduct purposes which may lawfully contain the pesticide residues found." The department must obtain a court order to condemn and destroy produce containing unlawful levels of pesticide residues.

The stated objectives of the food monitoring and enforcement programs, as given in response to questions asked during the Commission's public hearing are:

- *to assure the consumer that California produce is within legal pesticide residue tolerances established by EPA;
- *to monitor pesticide residue levels in selected ready-to-harvest crops in order to prevent illegal residues from reaching the marketplace; and
- *to compare detected residues with established tolerances for new pesticides, and new uses of existing pesticides, in order to determine whether they exceed tolerance levels.

CDFA has established a dual program of "compliance" and "surveillance" monitoring to meet these objectives. Compliance monitoring is an immediate response to an allegation or suspicion that a particular lot of commodities

contains illegal pesticide residues. Surveillance monitoring refers to the routine, ongoing testing of randomly selected crop samples to determine residue levels. For surveillance purposes, crops are selected on the basis of whether CDFA has detected illegal residues in them in the past (crops with no record of illegal residues are rarely sampled), and on the department's projections of public consumption of a given food product. CDFA bases food volume assumptions on 1977 consumption estimates for the state of California. The department has also established a "Crop of the Month" program in which high volume, seasonal commodities are tested for pesticides which are not routinely monitored. Field monitors determine which crops and pesticides are to be tested.

When testing for pesticide residues, the number of items (subsamples) to be tested depends on the size of the lot. Fractions of each subsample are combined to form a composite specimen which is tested for residue traces. Laboratory analysts routinely use a standardized series of tests --the multiresidue screen -- to evaluate detectable traces of pesticides from the three major chemical pesticide groups: organophosphates, chlorinated hydrocarbons, and carbamates. The field monitors may request additional tests but do not often do so. For special tests, samples generally have to be sent to CDFA's pesticide laboratory in Sacramento. If laboratory test results reveal residue levels above tolerance, however, CDFA scientists must test another portion of the composite sample, this time using different analytic

procedures. If results are positive again, the field monitor must initiate enforcement action.

As previously mentioned, the DHS shares in the total responsibilities for monitoring pesticide residues. DHS is authorized to secure food samples for testing from a factory, establishment, vehicle, or store where processed foods are processed, distributed, or sold (Health & Safety Code Sections 26230-35). The department may prohibit the transfer or sale of any food found to be adulterated and may remove contaminated food to a place of safekeeping. (Tainted food may not be condemned, however, without the consent of a supervisor or lower court in lieu of agreement and authorization by the grower.

Summary of Recent Findings in the Residue Monitoring Program

In fiscal year 1983-84, CDFA tested 7,859 samples of food and feed while the DHS tested 273 samples in calendar year 1983. Of those tested by CDFA, 58 samples -- or 0.7 percent -- were contaminated by illegal pesticide residues. No illegal residues were found by DHS. As of August 1984, DHS had collected and tested 1,990 samples of grain-based products for EDB; 380 were found to be positive with 64 of those exceeding EPA/DHS action levels.

Monitoring Conducted by Food Processors

To offset monitoring gaps in government regulatory programs and to avoid product liability for contaminated foods, segments of the food processing industry set up monitoring programs to track pesticide residue levels in their

products. Members of the League of California Food Processors, for example, require growers to provide records of pesticides applied to produce destined for their facilities, regulate which pesticides may be used on shipments, and do limited residue testing on suspect shipments. Such precautions supplement but cannot serve as a substitute for definitive regulatory monitoring of all pesticides applied to crops destined to become processed foods.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA's residue monitoring program is not designed to identify public health problems efficiently.

The current pesticide residue monitoring program serves largely a deterrent function. To be effective, deterrence monitoring has to be aimed at the area where abuse is most likely to occur. To use an analogy from enforcement efforts to control speeding, if traffic controllers seek to detect speeders, they will more likely schedule patrols of streets and highways where speeding is common than on a busy street where speeding is a practical impossibility.

CDFA's surveillance monitoring -- by being entirely crop-oriented, rather than pesticide-based -- makes no such distinction. The department's monitoring does not generate a data base that will enable the department to predict the likelihood that pesticides containing certain active and/or inert ingredients* will consistently leave higher than legal residues or that they will be misused. To use our control analogy again, it isn't the crops that may be "speeding" -- it's the pesticides.

To deter unsafe levels of excessive residues in foods, the enforcement effort has to discourage the registration, sale, and use of pesticides that are most likely to leave illegal residues and identify misuses of pesticides. The current ef-

* The term "inert ingredients" refers to chemicals added to pesticide formulations for some purpose other than to kill the target pests. Examples are solvents or adhesives. (See Chapter VII.)

fort is largely limited to deterring the retailing of crops that contain illegal residues. The number of pesticides tested for is limited.

By being focused on the crops (the street in our analogy) rather than the pesticides (the car), the existing monitoring strategy prevents CDFA from predicting a problem and taking steps to prevent it before it can occur. It also prevents the department from meeting its third stated objective: to monitor pesticides whose residue-leaving behavior is not well understood.

The pesticide methomyl serves as an illustration of the need for systematic monitoring. One-half million pounds of methomyl were applied to over 45 different California food crops in 1983. According to CDFA's computer print-outs containing residue data, methomyl left detectable residues on nearly all spinach and leaf lettuce crops to which it was applied. Average levels of 21 percent of tolerance for spinach and 25 percent of tolerance for leaf lettuces indicate that roughly 1 percent of commodities sprayed with methomyl -- based on a normal statistical distribution -- would contain illegal levels under presumably normal use. Such high levels, confirmed in tests by Federal Food and Drug laboratory officials, should trigger either an investigation by enforcement personnel or a review of the registration, or both.

Without a system for setting priorities for the monitoring of pesticides and crops in which they may leave residues, CDFA lacks a mechanism for triggering change in its

monitoring program. If pesticide use in California were static, this would not be important, but each year over 30 new active ingredients are registered and nearly 5,000 new uses of existing pesticides are approved. The CDFA multiresidue screen is updated only once every five years. As a consequence, the department employs the bulk of its resources in testing crops for pesticides for which the residue levels are of minimal importance instead of focusing its monitoring resources on the behavior of newly registered ingredients, or newly approved uses, and pesticides of proven concern. There is no built-in, systematic means for anticipating health risks.

To illustrate, an emerging area of undefined risk to public health is the currently increasing use of a wide variety of sophisticated herbicides. These herbicides are used before and after the emergence of the food crop to control weeds that interfere with plant growth. Most are applied before the edible portion of the food crop develops. Their environmental fate, however, is not well understood. Environmental specialists at CDFA explained that their persistence "depends upon many factors; not all are controllable or predictable." Under certain circumstances they could be taken up by plants and they, or their breakdown products, may leave residues in food.

Examples of herbicides that do leave residues in root crops under certain conditions are linuron and prometryn. Neither one is regularly tested for by the residue monitoring

laboratory. Residues may be present in crops which do not display the tell-tale leaf damage normally found in leafy vegetables. Paraquat, which has a pernicious tendency to drift onto non-target crops, leaves residues in root crops such as rutabagas, radishes, and carrots. It is also found in spinach, though it poses no health risk if the spinach is cooked. Unfortunately, Californians often eat spinach raw. Finally, chlorsulfuron, which is hazardous because of its great persistence, should be monitored for in grain products.

RECOMMENDATION

We recommend that CDFA implement a pesticide-based monitoring program to supplement its crop-based surveillance (deterrence) program. The number of additional samples that would have to be taken and laboratory tests that would have to be performed in implementing this recommendation would not necessarily be large. The efficiency of focusing residue testing on specific pesticides as well as specific crops would offset the additional start-up workload of instituting a pesticide-based residue detection program.

Finding #2: The state lacks certain information on pesticide use which is essential for development of a pesticide-based monitoring program.

Development of a pesticide-based monitoring program requires knowledge of which pesticides have been applied to which crops, when, and where the crops are. For pesticides which have been designated as restricted, such information is available because CAC's must be notified when a restricted

pesticide is going to be used. For non-restricted pesticides, such information is scanty or costly to develop because growers must be individually queried. Though sales records can indicate which pesticides have been sold in a particular area and to whom, they do not indicate when or whether they were used or on which crops.

Without such information, a pesticide-based residue monitoring program would reveal that a pesticide had been used only if residues were detected on the crop. The monitors would not be able to determine whether the pesticide had been used on a sample upon which residues were not detected. Statistics on the results of monitoring would therefore be misleading because they would underestimate the actual average residue levels on foods to which a particular pesticide had been applied. Variations in residue amounts could not be readily interpreted; results from proper use could not be distinguished from results from improper use without a formal investigation.

RECOMMENDATION

We recommend that CDFA develop a list of pesticides for which all agricultural users must keep detailed records of use. Upon selection of a shipment of produce for sampling, the field monitor need only inquire of the shipper, or wholesaler, the name of the farmer from whom he/she should request pesticide use information. The alternative is to require pesticide use records to accompany all shipments of produce. This would result in considerably more paperwork and

the possibility that shipment and use records would become confused.

In addition, there are advantages to the growers to keeping such use records. If growers are to minimize their costs for pest control, they must know when and how much of which pesticides they have used over time. This information is also valuable in assessing the effectiveness of a particular pest management strategy. The introduction of microcomputers into agriculture is already easing the burden of maintaining this kind of information for heavy users of pesticides.

Finding #3: Coordination among the Pest Management Division's internal units is inadequate to support priority-setting to identify the pesticides of greatest concern.

The Pesticide Use Enforcement and Environmental Monitoring Units of CDFA's Pest Management Division possess the monitoring apparatus to develop an accurate and reliable data base on pesticide residues. This information, as discussed in Chapter IV with regard to the registration program, is vital for alerting the Registration and Agricultural Productivity Unit to potential risks and the need to set priorities for the special re-registration review of particular pesticides. The Worker Health and Safety Unit, which assists Registration in assessing risks associated with pesticide use, also requires immediate access to results of monitoring activities and special studies.

CDFA has established a "Crop of the Month" program to

identify which pesticides are being used on various food commodities and at what levels. Between February and August 1984, for example, CDFA conducted investigations of 32 pesticides on eight agricultural commodities. How the kind of information generated by such projects can be used in a systematic pesticide monitoring program remains unclear. Without the ability to test for every pesticide residue possible, better information could have been gleaned less expensively simply by asking the growers which pesticides they had applied.

Conducting a "Pesticide of the Month" program is needed so as to test assumptions that were made when the product was registered. Selecting the pesticides for such a program would require guidance from scientists in the Registration Unit in order to identify those pesticides for which residue data are either lacking or questionable.

In deciding which crops and which pesticides to monitor for, the field monitors base sampling decisions on information from merchants' records and reports provided by county agricultural commissioners of pesticides used on particular crops in certain areas. No direct information channel between field monitors and the Registration Unit has been established. Field monitors would not necessarily know which new pesticides -- or old pesticides in new uses -- scientists in the Registration and Worker Health and Safety Units consider most likely to leave residues in foods or those representing the greatest threat to public safety if improperly used.

RECOMMENDATION

We recommend that the Pest Management Division's unit managers establish internal communications procedures designed to facilitate priority-setting for identifying both the pesticides and the crops which should be most carefully scrutinized in the residue monitoring program.

Having in place the residue data base and priority-setting and information-handling systems recommended earlier in this report would facilitate the setting of priorities for re-registration as well as residue monitoring. That is, the resulting expanded data base would support the division's decision making process by clearly identifying the pesticides of greatest concern in the category of pesticides which leave residues in foods.

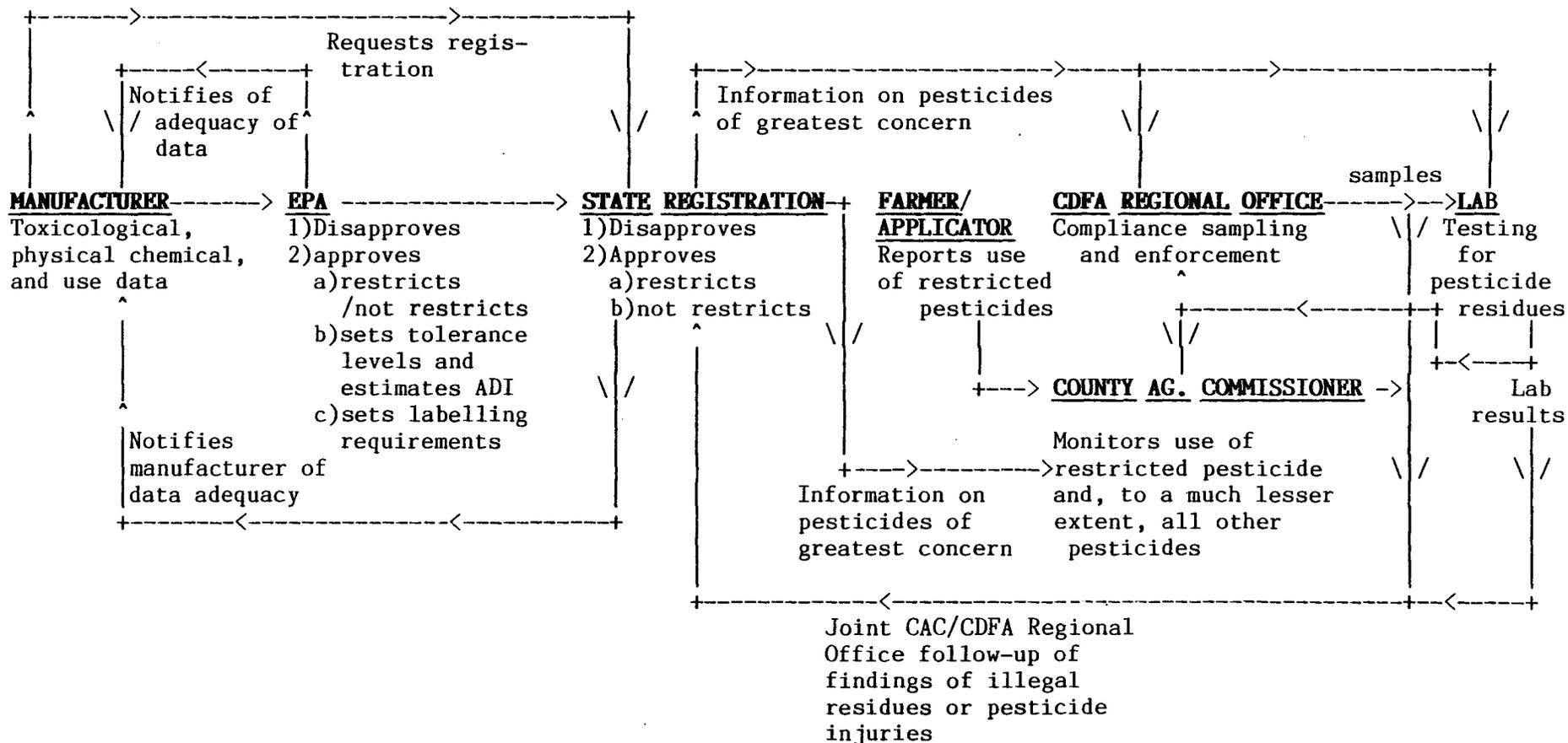
This process could lead to lower costs for industry as well as government by eliminating the immediate need to conduct additional toxicological tests in order to fill existing data gaps -- except for those pesticides which leave residues in foods. In other words, filling the data gaps on pesticides which do not leave residues in foods would clearly be of secondary importance.

Effective utilization of large data bases -- as a regular and ongoing operating procedure -- requires a structured internal communications network. Figure V-1 (next page) illustrates the information flow necessary for effective and efficient internal communications. Before this information exchange can occur, the Pest Management Division must identify:

Figure V-1

INFORMATION FLOW ON PESTICIDES

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- *the kinds of information needed for each component of the process;
- *the source of the information; and
- *the individuals or units responsible for generating or collecting the data.

With this information in hand, the Pest Management Division could undertake minor organizational changes as necessary to facilitate communication.

Finding #4: Laboratory resources for analyzing food samples to detect pesticide residues are inefficiently administered and poorly coordinated with the information needs of scientists in the Pest Management Division.

CDFA's pesticide residue-testing laboratories are located administratively in the Division of Inspection Services while the pesticide registration and monitoring programs, of course, are located in the Division of Pest Management. Decisions regarding laboratory services are made at a higher bureaucratic level than the Pest Management subdivisions which use the information generated by the laboratories. Testing priorities at the labs are sometimes inconsistent with those of the Pest Management Division.

Because of the field monitors' demands that laboratory results be made available to them before the end of the working day in which samples were taken, the choice of tests is limited to those which can be completed in four to six hours. The laboratories also eliminate tests which make excessive demands on their analytical capabilities. The chief of laboratory operations concedes that CDFA laboratories

cannot test for more pesticides without increases in space and equipment.

The Pest Management Division lacks administrative discretion under the existing arrangement to set laboratory analysis priorities for the pesticide regulatory program. Because of the potential risk of adverse health and environmental effects from pesticide use, the division requires authority over laboratory resources in order to assure that laboratory practices conform to the overall goals of pesticide regulation. The extent to which not having this authority can be a problem is illustrated by the data presented in Appendix J of this report.

In Appendix J, we present a comparison of 45 active and inert ingredients of pesticide formulations. The particular pesticides were chosen on the basis of their toxicity (especially their potential to cause chronic health effects at low doses), the lack of toxicological data currently available on each, and the volume of their reported use on food crops in California. Nineteen are routinely monitored for in CDFA labs, but the remaining 26 are rarely if ever tested for. Only seven of the pesticides not routinely monitored for have been designated as restricted.

The inert ingredients of principal concern to the Pest Management Division -- such as the glycol esters, aromatic petroleum distillates, benzene, or xylene -- are not tested for in CDFA labs. Either limited resources prohibit use of the procedures that are necessary to detect these compounds

or, in some cases, a residue detection method has not yet been developed.

Detection of residues from certain pesticides -- such as benomyl (whose registration is currently being reviewed by EPA due to questions regarding its safety) and most of the herbicides -- exceeds the analytical capability of CDFA laboratories. Either the labs lack the equipment or level of skill necessary to perform the analysis or available procedures cannot be completed within the 4-6 hour time constraint.

RECOMMENDATION

We recommend that:

A. Administrative control over laboratory testing for pesticide residues be transferred to the Pest Management Division. Having laboratory personnel directly responsible to the Pest Management Division will facilitate communication between staff scientists in Pest Management who are involved with collecting and review of technical information on pesticides, and laboratory personnel who generate residue data. The transfer will also allow for greater consistency in setting residue monitoring priorities.

B. A scientific advisory panel, which should include a lay person and a UC Cooperative Extension pest management specialist, be established to assist CDFA in setting priorities for the monitoring of pesticides and the operation of monitoring and enforcement programs. A scientific advisory panel comprised of members from academia, the chemical industry, and the public and including a UC Cooperative Ex-

tension pest management specialist can assist the Pest Management Division in deciding which pesticides to test for, and on which crops. For pesticide ingredients, both active and inert, which are at present exempt from food tolerances, the advisory panel can assist the department just as EPA's Science Advisory Panel assists the EPA -- by helping to evaluate the quality of data supporting registration.

A complete advisory role might include advising that food tolerances be set by CDFA when necessary. Academic scientists can facilitate the exchange of knowledge regarding chemicals between CDFA scientists and the universities, where research continually expands basic understanding of the health and environmental effects of pesticides. Industry scientists can contribute their knowledge of specific chemicals and toxicological analysis methodologies. Including a representative of the general public would provide an avenue of communication between government decision making and public concern.

C. The Legislature appropriate and the Governor approve additional funding for CDFA's pesticide residue laboratories to enable them to acquire state-of-the-art technology for chemical analysis and more space in which to conduct testing for pesticide residues. Laboratory resources are too limited for advanced tests to be completed quickly enough to clear a ripening food crop for marketing without serious product deterioration. Inadequate laboratory space and equipment prevent analytical scientists from conducting more tests for

more pesticide residues. New generation pesticides tend to be chemically complex molecules which are difficult to test for in a reasonable period of time. For compliance enforcement purposes, results must be obtained within a few hours of the receipt of the sample. To provide such results in time to prevent product deterioration before release to retail markets, sophisticated equipment and expert personnel are required. If industry is to develop efficacious and safe pesticides, the state's laboratory capabilities must progress commensurately.

Finding #5: CDFA lacks residue detection methods for many pesticides in common use in California.

Numerous pesticides were registered before laws were enacted to require that all registrations be accompanied by a residue detection procedure that can be performed within 24 hours. As an illustration, glyphosate, though heavily used as a herbicide in California, cannot be tested for by CDFA. For other pesticides, the testing methodologies call for state-of-the-art analytical equipment and scientific sophistication which the department frequently lacks. In lieu of government analysis, consequently, public safety is entrusted to the accuracy and thoroughness of the manufacturers' initial residue testing completed for registration purposes. In pesticides registered before 1972, the manufacturers' testing program failed to identify the residue-leaving behavior of some of the fumigants.

RECOMMENDATION

We recommend that as part of the re-registration program mandated by Chapter 669, Statutes of 1984 (SB 950), data gaps on residue detection procedures be identified and filled. The arguments for identifying and filling data gaps have been presented in detail in Chapter IV.

Finding #6: The state lacks a trigger for taking enforcement action upon finding residues from certain pesticides known to cause adverse health effects.

As discussed in Chapter IV, exemptions from food tolerances were granted to certain pesticides registered before 1972. Some of these, like the fumigants and the petroleum distillates, have subsequently been shown to cause acute and chronic health effects and may leave residues in foods. Other pesticides may share these characteristics, but, if food tolerances have not been set for them, CDFA does not test for residues from these pesticides. Lacking a trigger for enforcement action, the state cannot seize food lots that contain excessive residue levels.

RECOMMENDATION

We recommend that DHS, in conjunction with CDFA, set a food tolerance (or an action level) for pesticides which, because of their toxic potency, their likelihood of leaving residues in foods, and the current absence of food tolerance-settings for them, may pose a significant risk to public health.

The nature of uses of the chemicals that are likely to

require food tolerances makes DHS the logical choice as the lead agency to assume responsibility for setting tolerances or action levels. Many of the older pesticides which were exempted from tolerance levels contain ingredients which have uses other than as active ingredients in pesticide formulations. Carbon tetrachloride, methyl bromide, and chloroform, for example, also have industrial applications for which they are used in much greater quantities than in pesticides. In these other uses, they may pose risks to health and the environment through contamination of the air and water or through direct worker exposure in the industrial setting.

The procedure for assessing risk should not differ according to the manner of exposure: the toxicological data used in assessing risk are the same, even though uses vary. The variable in the risk assessment equation -- $\text{risk} = [\text{hazard} \times \text{exposure}]$ -- is exposure.

Having the risk assessment performed independently by different agencies according to the manner or location of exposure is justified only if there is social utility in having the data variously interpreted by different groups of scientists. Given the general uncertainty inherent in risk assessment, it is possible that independent reviews of the data may generate insights that would not otherwise occur. On the other hand, the confusion caused by conflicting interpretations undermines the credibility of the effort. Scientific differences which are unavoidable because of the

uncertainty surrounding toxicology should be addressed through coordinated scientific evaluation prior to the point at which key policy decisions must be made.

A single state agency should have the lead responsibility for risk assessment in order to facilitate accountability and consistency in government decision making. The setting of an action level may be necessary when a public health emergency has been identified, in which case there would be insufficient time to complete a formal regulatory process.

Finding #7: The state lacks an effective program of residue monitoring for foods destined for processing and for processed foods. The existing division of monitoring responsibility between CDFA and DHS is not conducive to effective enforcement of residue tolerances for processed foods.

The Department of Health Services' effort to monitor pesticide residues in processed foods or food crops destined for processing is so minimal that it could not be said to be "routine." DHS laboratories test for pesticide residues in processed foods strictly by request, a practice referred to as "custom" monitoring. If a manufacturer, regulatory agency, or consumer suspects a processed food to be contaminated, DHS will test samples for residue levels, but "routine" monitoring of residue levels is triggered only if excessive levels of residue are discovered in a particular product line -- and then only temporarily. Consequently, some of the pesticides that leave residues in processed foods and may pose risks to

public health -- such as the grain fumigants EDB, methyl bromide, and carbon tetrachloride -- are monitored for only episodically.

In 1984-85, the department plans to conduct 2,000 sample analyses. The program that DHS is planning appears to duplicate CDFA's and FDA's monitoring efforts. Pesticides for testing are to be chosen on the basis of their acute toxicity and to a lesser extent their potential to cause chronic health effects. Insufficient regard is paid to their residue-leaving behavior. The lack of automated and shared data bases further assures that DHS's residue monitoring will remain episodic. A large percentage of the present staff involved in laboratory testing has been temporarily drawn from other assignments to conduct this monitoring program. The Food and Drug Branch of the Environmental Health Division has received no new funding for staff.

Although a budget request to purchase a gas chromatograph/mass-spectrophotometer was granted in the 1984 Budget Act, the department did not receive approval for its request for positions for the highly trained personnel necessary to operate the machine. Training for existing staff is offered by the manufacturer of the equipment -- outside California -- but the lab's requests for out-of-state travel authorization to send chemists to conferences and training events have been routinely denied. Given the anomalies of state cost control procedures, it is unlikely in the foreseeable future that DHS could bring its monitoring program for

pesticide residues in processed foods up to a par with CDFA's food testing program.

Drawing a distinction between a raw agricultural product destined for the dinner table and one destined for a food processing plant is conceptually convenient, but it fails to result in a consistently administered residue monitoring program. The responsibility for monitoring pesticides applied to the same commodity in adjacent fields often falls under the separate administrative authorities of CDFA or DHS. The organizational arrangement of having one agency collect and develop information that will be used by another imposes inordinately high transaction costs: it takes extra time, staff, memoranda of understanding, meetings, and coordinated travel to achieve the level of cooperation that would be required for two bureaucracies to produce the same consistency and efficiency that one department acting alone can produce.

RECOMMENDATIONS

We recommend that:

A. The responsibility for monitoring residues in raw agricultural produce grown in California, whether destined for produce markets or processing plants, be vested in CDFA. Residue monitoring responsibilities vested in DHS should be restricted to actual processed foods, grain products in storage, and foods in locations where processing occurs.

B. DHS, in conjunction with CDFA, FDA, and EPA:

1. Identify those pesticides most likely to leave residues in processed foods and the food items in which they are most likely to be found; and

2. Set aside a portion of its monitoring program to ascertain the safety of post-harvest applications on foods in storage, in restaurants, or other locations where pesticides may be used in or around foods.

A monitoring gap exists at present for stored food products and for foods in restaurants, supermarkets, and stores. Directing at least a portion of its monitoring effort to these areas can provide DHS with data on whether pesticides registered for use in these locations can in fact be used safely.

Chapter VI

USE MONITORING AND ENFORCEMENT

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA knows little regarding the actual rate of compliance.

Recommendation: Continue efforts to estimate compliance among growers and applicators.

Finding #2: Monitoring of non-restricted pesticide use and investigations of illegal residues are sporadic.

Recommendations:

- A. Create new "use by prescription" category.
- B. Investigate all incidences of illegal residues.

Finding #3: Current enforcement sanctions are cumbersome, ineffective, and inadequate.

Recommendation: Give CAC's authority to suspend licenses and/or impose fines on the spot.

Chapter VI

USE MONITORING AND ENFORCEMENT

INTRODUCTION

Federal law permits states to regulate the sale or use of all registered pesticides or devices within the state provided that the regulations do not permit sales or uses prohibited by federal law. In California, the primary responsibility for monitoring and enforcement of the laws and regulations regarding the use of pesticides is shared by the Department of Food and Agriculture (CDFA) and the County Agricultural Commissioners (CAC's).

The Director of the Department of Food and Agriculture may adopt regulations circumscribing the use of pesticides. The department also has the responsibility for licensing pest control operators and pesticide dealers, certifying pest control aviators, and licensing pest control advisors. Agents of the Department have the authority to order violators of state or federal laws and regulations to cease and desist pesticide uses that are not in compliance.

As a complement to state use monitoring and enforcement activities, county agricultural commissioners assume the responsibility to register and certify pest control operators, pest control aircraft pilots, and pest control advisors. Commissioners also have the responsibility for issuing written permits for the use of restricted pesticides. They may, upon discovery of a violation, order the violator to cease and desist from any application that, if allowed to proceed, would

present an immediate hazard or cause irreparable damage. The commissioners may also prohibit the harvest of any produce which may pose a threat to public health.

State regulations specify that restricted pesticides may be applied only under the direct supervision of a certified pesticide applicator or by growers to whom a written permit has been granted by the commissioner. A user of a restricted pesticide must obtain a written permit to use a restricted material and file a notice of intent to apply the pesticide. The commissioners review the notices of intent and are required by state law to inspect 5 percent of the applications. Criteria by which commissioners decide which applications of restricted pesticides to inspect are:

- *the category of material -- i.e., acute or moderate toxicity;

- *who is applying the pesticide -- i.e., whether an employee or the certified applicator him/herself; and

- *where the application is to occur -- i.e., whether next to a garden or source of water.

State law requires investigation of incidences of pesticide related illnesses or injuries. In 1983, county commissioners investigated 110 such incidences.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA has little knowledge of the rate of compliance with laws and regulations for growers and applicators.

The current monitoring and enforcement process shared between CDFA and CAC's does not have a system for evaluating the effectiveness of the program or for ensuring compliance with federal and state laws and regulations. The chief of Pesticide Use Enforcement at CDFA concedes: "We do not have a good handle on the compliance rate by farmers. Counties monitor applicators of pesticides, but we don't know how effective counties are in doing this. We are trying to develop a compliance evaluation program with standards for user compliance."

Although CDFA collects extensive information on use and reported violations and the incidence of illegal residues on foods, it has not developed a procedure by which this information can be reliably used to measure compliance. Without a measure of compliance, the department lacks a procedure to anticipate problems in order to prevent them.

Information on compliance would enable CDFA to focus its resources on pesticides of greatest concern and to initiate actions to help reduce whatever level of non-compliance now exists. Compliance information can also be used to evaluate the performance of county agricultural commissioners. The chief of Pesticide Use Enforcement has described these objectives: "We want to standardize the work [of the CAC's] and rate it. We want this in terms of compliance by the [pesticide] user."

RECOMMENDATION

We recommend that CDFA continue its efforts to develop a system for estimating compliance among growers and applicators.

Pesticide residue data might be analyzed as a possible indicator of the compliance rate. Since food tolerances are set on the basis of the maximum residue level expected under proper (legal) use, an instance of a residue exceeding the food tolerance may imply non-compliance. Under certain circumstances, the pesticide itself may not be "performing" as expected. Unforeseen conditions may affect its residue-leaving behavior or the pesticide may have been misbranded. Isolating causal factors requires complete data. Field monitors should be trained in statistical sampling procedures to help compile these data.

Finding #2: CDFA conducts only sporadic monitoring of non-restricted pesticides and incomplete investigations of illegal residues in foods.

CAC's are required to monitor only a certain percentage of the applications of all pesticides designated as restricted. Applications of all other pesticides are monitored sporadically, if at all. Because CAC's are not required to be notified when and where non-restricted pesticides are being applied, these pesticides are difficult to monitor.

Not all pesticides of health or environmental concern are restricted, however. In fact, only about 80 pesticides have

been so designated. Pesticides are generally classified as restricted on the basis of their acute toxicity and their persistence in the environment, including their potential to contaminate drinking water. Some pesticides are not restricted even though they show a likelihood of leaving residues in certain foods at levels approaching tolerance -- dacthyl, for example. Pesticides whose use currently is restricted are those which rate high in terms of:

- *the likelihood of environmental contamination through frequent or excessive use (e.g., compounds containing arsenic);
- *the likelihood of developing biological resistance in target pests; and
- *the likelihood of leaving toxic residues on foods.

This ranking illustrates again the need to set priorities for the monitoring program so as to focus monitoring on those pesticides which pose the greatest risk to human health and the environment.

In addition to more comprehensive monitoring of non-restricted pesticides, CDFA and the CAC's need to coordinate and conduct more complete investigations into the causes of pesticide contamination. The current program does not require a report on findings of illegal residues. In 1983, for example, the pesticide formulation causing the illegal residue was not determined in five of the 27 cases of overtolerances in food for human consumption. Nor did an investigation to determine the causes of the contamination follow.

A residue in excess of the food tolerance does not necessarily imply non-compliance. Only by investigating the

causes of contamination in every finding of illegal residues can monitoring and enforcement officials generate the information to determine:

- *the performance of the pesticide under use conditions;
- *the adequacy of label instructions;
- *the adequacy of CAC inspection and monitoring activities where drift of a restricted pesticide may have caused contamination; and
- *the rate of compliance with use requirements.

Therefore, an investigation should follow every finding of an illegal residue.

RECOMMENDATIONS

We recommend that:

A. CDFA create a new use category called "use by prescription" for non-restricted pesticides whose improper or even legal use could lead to health and environmental problems.

Restricting all pesticides of public concern is impracticable. Restricting pesticides leads to considerable paperwork and administrative expense, but does not guarantee that the pesticide will be monitored even when registered as restricted. Requiring that certain pesticides be used only through prescription by a certified pest control advisor adds an additional level of control. The greater expertise of pest control advisors increases the likelihood that state-of-the-art knowledge of pesticides and pest problems will help prevent problems before they can occur. Such prescriptions could also generate accurate usage records of suspect non-restricted pesticides.

B. The Legislature require a joint investigation and report by CDFA and county agricultural commissioners on every detected incidence of illegal residues in foods.

The information necessary for determining whether a pesticide behaves as predicted and whether farmers and applicators are complying with rules and regulations cannot be generated without a follow-up on every finding. As the chief of Pesticide Use Enforcement acknowledged: "Follow-ups of findings of illegal residues are a joint state/county responsibility which are a necessary element in the pesticide enforcement program."

Finding #3: Current enforcement sanctions are cumbersome, ineffective, and inadequate.

When illegal residues or other violations are discovered, a county agricultural commissioner has three enforcement options available. First, the CAC can simply notify the violator of the nature of the violation and inform him/her of the requirements of current laws and regulations. Second, the CAC can require the guilty party to forfeit his permits, county registrations, and/or state licenses. Finally, judicial sanctions such as civil or criminal penalties can be assessed. CAC's do not have the authority to levy fines for violations by agricultural pest control operators -- only structural pest control operators. The kind of action taken will depend on the severity of the violation and the history of the offender.

The enforcement sanctions available to CDFA and county agricultural commissioners are not always sufficient to deter violations of state laws and regulations. CAC's must request local district attorneys or the State Attorney General to prosecute violators of the Food and Agricultural Code. As the department concedes, however: "Quite often, we have found local district attorneys are burdened by high case loads of more violent and pressing crimes, and, consequently, they must place a lower priority on violations of the Food and Agricultural Code. Often in these situations, the case is referred to the Attorney General or back to the county or CDFA for consideration of administrative actions."

RECOMMENDATION

We recommend that the Legislature amend existing law to parallel recent changes provided for in Chapter 766, Statutes of 1984 (AB 294), which gave county agricultural commissioners the authority to suspend licenses and/or impose fines immediately upon detecting a violation by a structural pest control operator.

In structural pest control enforcement, recent changes in legislation have made punitive action more direct by placing it directly in the hands of county agricultural commissioners. Detecting a violation, a commissioner can suspend an operator's license immediately for up to three days and may levy fines up to \$500.00. An appeals procedure is available to the operator through the Department of Food and Agriculture; extreme cases of violations can still be referred to the Attorney General for further investigation and prosecution.

Chapter VII

INERT INGREDIENTS

FINDINGS AND RECOMMENDATIONS

Finding #1: Data on inert ingredients are inadequate.

Recommendations:

A. Require justification for not listing inert ingredients on pesticide labels.

B. Change designation of "inerts" to less misleading term.

C. Integrate inert ingredients into SB 950 re-registration program.

Finding #2: Residue detection methods for inerts are lacking.

Recommendation: Require registrants to provide residue detection methods for inert ingredients.

Finding #3: Residue levels that pose health risks have not been determined for inerts.

Recommendations:

A. Set tolerance levels for inerts when specified conditions obtain.

B. Set tolerance levels for small number of other inert ingredients of concern.

Chapter VII

INERT INGREDIENTS

INTRODUCTION

The term "inert" as used by the pesticide industry and government regulators is quite misleading. The New American Heritage Dictionary defines inert as "exhibiting no chemical activity, totally unreactive, or exhibiting chemical activity under special conditions only." In contrast, in pesticide jargon, "inert" means only that the substance which has been intentionally added to the formulation is not the active ingredient -- that which destroys the pest -- in that formulation. Due to the nature of pesticide formulations, an inert ingredient in one formulation may be an active ingredient in another. Examples include aromatic petroleum distillates, methyl bromide, and chloroform.

To date, inert ingredients have been virtually unregulated. As a result, some chemicals banned as active ingredients -- such as benzene, or even the recently banned ethylene dibromide (EDB) -- are still listed as acceptable "inert" ingredients for pesticide formulations. As "inert" ingredients, these chemicals may be present in significantly greater concentrations than as active ingredients. Moreover, "inerts" are not subject to routine residue monitoring nor formula verification to ensure correct labelling. They are generally exempt from food tolerances and are not monitored for in foods.

Inert ingredients must be closely scrutinized if the safety of pesticide formulations is to be ensured. In addition to their own inherent toxicity, differences in the amounts of inerts may affect the toxicology and efficacy of the products, the residues of the active ingredients left on food, and the behavior of the active ingredients in the environment.

Roughly 1,000 to 1,200 chemical inert ingredients are contained in pesticide formulations. About 500 inerts are cleared by exemption from the requirement of food tolerances although in some cases the tolerance exemption specifies a limited percentage of the inert in each formulation to ensure zero or near zero residues. Many inert compounds used on foods, however, were exempted from the requirements of a tolerance before the 1969 FIFRA procedures were established.

FINDINGS AND RECOMMENDATIONS

Finding #1: CDFA and DHS have inherited a serious data gap on the inert ingredients in pesticide formulations.

In general, the EPA has little toxicological or residue chemistry information on file for inerts. It also does not know precisely which inerts are in many pesticides. During the 1972 petroleum shortage, the EPA issued a notice allowing registrants flexibility in the purchase of scarce solvents and emulsifiers for their formulations. This policy enabled registrants to declare multiple inerts in their confidential statements of formula so long as the substitutions did not lead to changes in label warnings or directions. Many confidential statements on file are out of date or incomplete by current standards. New federal regulations now require that inert ingredients be subjected to acute toxicological testing as components of formulations, as well as complete product chemistry characterization (40 CFR Part 158). Much of the current product chemistry information on file is insufficient for validation of the chemical makeup of active or inert ingredients, or identification of important impurities. In the past, mandatory updates of formulation changes have not been required to support continued registration, although proposed regulations would require updating of confidential statements of formula.

Recently, the EPA Science Advisory Panel "concluded that there is insufficient information available on the intentionally added inert ingredients of pesticide products and how EPA regulates these substances." The panel

recommended that EPA develop a better regulatory program than now exists for inert ingredients in pesticide products. In response, the EPA has announced that it is planning an ambitious program for inerts in 1985, including requests for confidential statements of formula and relevant product chemistry data for all registered pesticides. Even if this program does get underway in 1985, it may take years before the toxicological data bases are complete.

Despite the scarcity of toxicological data on inerts, 85 inerts have been identified as hazardous. Of these, 35 had been previously cleared by exemption for use on food. Their environmental effects are unknown. Of particular concern are the aromatic petroleum distillates, which occur in about 80 percent of all pesticide formulations as either inert or active ingredients. Petroleum distillates may have highly variable chemical composition. Polynuclear aromatic components of petroleum distillates have a high potential for carcinogenicity and the aliphatic content may pose other health problems as well. Without data or the ability to generate data, CDFA cannot assess the health risk that these ingredients may pose or take action to prevent unnecessary exposure -- short of banning the chemicals.

CDFA does not have information on inert ingredients in most pesticide formulations for the same reasons that the EPA does not. CDFA's data gap is further exacerbated by EPA's failure to develop routine procedures for sharing information that it does have with the states. CDFA maintains a list of

inerts for which health effects testing is required. According to the chief of Worker Health and Safety, however, "it has been very difficult for the Registration Unit to acquire the requested data." CDFA has had to review each pesticide formulation individually to ensure that the inerts of concern are not resulting in a health hazard.

RECOMMENDATIONS

We recommend that:

A. The Legislature memorialize Congress and the Governor work with the Reagan Administration to require that formulators of pesticides provide justification as to why an inert ingredient should not be listed on the pesticide label. Inert ingredients that are identified as likely to pose a health hazard if the pesticide is misused should have their technical name (or names) included on the label.

Inert ingredients of pesticide formulations are currently not listed on the label because they are regarded as "trade secrets" and, hence, confidential. The concept of "trade secrets" is misleading. Manufacturers of pesticides generally possess the expertise and equipment to analyze nearly every pesticide product on the market. Not listing the ingredients on the label may delay, but will not prevent, discovery of the true identity of the substances. Furthermore, patent rights will protect most unique combinations of ingredients.

B. The Legislature memorialize Congress and the Governor work with the Reagan Administration to change the designation of ingredients of pesticide formulations currently defined in federal law as "inert ingredients" to "non-pesticidal

ingredients," or some other less misleading term.

The meaning of the term "inert" as used in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and on the labels of pesticides does not correspond to standard English usage. Consequently, it is misleading and could cause users to fail to identify a health hazard. A more appropriate term -- not necessarily "non-pesticidal" would be helpful.

C. CDFA integrate the regulation of inert ingredients into the re-registration program mandated by Chapter 669, Statutes of 1984 (SB 950).

Inert ingredients, like pesticide active ingredients, are chemicals posing varying degrees of hazard to the public. Setting higher priority upon the review of either inert, or non-pesticidal ingredients, or the active ingredients of formulas is unlikely to result in better protection of public health and the environment. Instead, all pesticide chemicals of concern should be reviewed in a systematic way under the program called for by SB 950.

Finding #2: There are no practicable analytical residue detection methods for many inerts.

For many inerts, including those which have been identified as being of concern, there are no analytical residue detection methods which the state can use to monitor for their residues in foods. Consequently, the state cannot assess the risk which at present they may pose to public health.

Nevertheless, the Pesticide Use Enforcement Branch could develop the data needed to make rough estimates of risk by actually monitoring for residues of inert ingredients in foods. This information could then serve to rank the substances with regard to their need for registration review. Without a practical laboratory detection procedure, officials cannot identify an unreasonable health hazard and take the necessary enforcement actions to mitigate it: it must await the generation of residue data when and if it occurs. Because the aromatic petroleum distillates, for example, were exempted from food tolerances, registrants were not required to provide data on the amount, if any, of residues likely to be left on crops.

RECOMMENDATION

We recommend that CDFA require pesticide registrants to provide analytical methods for detecting residues of inert ingredients identified as being hazardous pursuant to Section 2378 of Title 3 of the California Administrative Code.

Without an analytical detection method for non-pesticidal ingredients of health concern, the government agencies charged with verifying pesticide formulations, enforcing food tolerances, and assessing risk from exposures cannot execute their responsibilities. The responsibility for generating information to allow government to assess the safety of the use of a pesticide ingredient lies with industry.

Finding #3: The level of residues in foods which may pose a significant risk to human health has not been determined for the inert ingredients identified as being of health concern.

The uncertainty regarding risk in the use of pesticides on food crops cannot be better illustrated than in the case of inerts. Of the 1,000 to 1,200 chemicals used as inert ingredients in pesticide formulations, a good data base on toxicology and the potential to leave residues is available for relatively few. Manufacturers generally base decisions on which chemicals to use as inert ingredients not on toxicological data but on efficacy and history of use.

The presence of residues in foods does not necessarily imply a health hazard. Hazard depends upon the toxicological potency of the substance. Saccharin and EDB are both animal carcinogens, for example, but EDB causes cancer at much lower doses. Thus, EDB is much more likely to pose a significant health threat than saccharin. The differences in toxic potencies of chemicals which may leave residues in foods illustrate the importance of setting priorities in the monitoring of pesticides.

Monitoring and enforcement officials must know when detectable residues of a chemical represent a threat to health, or a violation of the law, if they are to carry out their responsibility to protect public health. Otherwise they must either seize all produce with detectable residues or merely report the residues detected without taking any enforcement action.

RECOMMENDATIONS

We recommend that DHS, in conjunction with CDFA:

A. Set tolerance levels for inert ingredients that (1) have been identified pursuant to Section 2378, (2) are known to leave residues on foods, and (3) may pose a significant health risk when not used in accordance with label instructions.

Food tolerances are enforcement tools. Setting a food tolerance (or a maximum residue level) should not imply that the chemical is hazardous to health in any use or in any amount on foods. On the contrary, a food tolerance means that the chemical ingredient can be used safely and does not pose an unreasonable risk to human health if it is used in accordance with label instructions. Without food tolerances for pesticides which do leave residues on food, safe use can be neither demonstrated nor enforced. The alternative to setting food tolerances for chemicals that are toxic at moderate levels of exposure is prohibiting their use.

B. Be given responsibility for setting food tolerances for the small number of inert ingredients of concern that are used on food.

Most inert ingredients are used primarily as industrial chemicals. Regulation to assure their safe use falls within the purview of numerous state agencies. To ensure consistency in risk assessment and to reduce duplication of effort, DHS in conjunction with CDFA (which has the authority to register pesticides) should set food tolerances for inert ingredients of concern that are used on food.

Chapter VIII

MONITORING OF IMPORTED FOODS
AND
FOODS IN INTERSTATE COMMERCE

FINDINGS AND RECOMMENDATIONS

Finding #1: FDA's monitoring is not equivalent to California's.

Recommendations:

A. Petition FDA to expand monitoring for foods imported from Mexico.

B. Establish state monitoring station at the Mexican border.

Chapter VIII

MONITORING OF IMPORTED FOODS AND FOODS IN INTERSTATE COMMERCE

INTRODUCTION

The Federal Food, Drug, and Cosmetics Act grants the Food and Drug Administration the authority to collect and inspect, for the purposes of monitoring pesticide residues in foods, samples of foods in interstate commerce or foods imported from a foreign country. Distributors and manufacturers are prohibited from refusing to permit entry or inspection. Adulterated products may be seized or refused entry, or both. For intrastate produce, FDA lacks embargo authority. Consequently, it requests that the EPA become the prosecuting agency. The EPA, in turn, notifies the State to take appropriate enforcement action.

Nationwide FDA samples approximately 10,000 shipments each year. Five thousand of these samples are from shipments of imported foods, mostly raw agricultural products. Domestic samples are generally drawn from wholesale distribution centers. In California, about 4,000 samples are collected and tested annually, of which 2,700 are of imported produce. The samples collected in California are generally collected from farms at the time of harvest. Sampling from the point of origin complements CDFA's program which draws most of its samples from wholesale markets and supermarket distribution centers. The FDA tests only a small

number of processed foods and only on an exception basis.

Like CDFA, the FDA generally employs a multi-residue screen in testing for pesticides. Unlike CDFA, however, the agency uses different screens depending on the crop that is being analyzed for pesticides. According to laboratory officials from the FDA office in Los Angeles, nearly all of the 300 pesticide active ingredients in common use in California can be, and are, tested for depending upon the kind of crop sampled and the pest history of the crop.

The FDA also relies upon "Surveillance Index Reports" in deciding which pesticides to test for on produce. "Surveillance Index Reports" are technical reports on pesticides in widespread use which assist enforcement officials in ranking pesticides with regard to their need for surveillance. Pesticides are ranked in order of descending importance according to whether they:

- *are no longer produced;
- *are of little toxicological concern;
- *degrade rapidly; or
- *are used in ways that make the presence of residues unlikely.

The FDA also relies on communication from EPA regarding pesticides and foods which require special monitoring.

Upon the recommendation of EPA, FDA sets action levels to define the residue level at which regulatory action will be considered against pesticides for which there is no food tolerance and the presence of the residue is unavoidable. Since the levels of the pesticide in the environment should

diminish over time, the regulatory trigger must be periodically lowered. Action levels, rather than food tolerances, are set due to the relative ease of revising action levels. Food tolerances require lengthy laboratory testing and decision making procedures. In setting action levels, FDA draws upon the authority derived from Section 306 of the FFDCFA which permits FDA to refrain from taking regulatory action for minor violations. As of 1981, the FDA had set action levels for nine pesticides.

In addition to its regular monitoring of domestic and imported shipments of foods, FDA conducts a total diet study of pesticide residues in foods. The purpose of the study is to measure levels of pesticide residues actually consumed and to compare these levels with acceptable daily levels of intake which are established by the World Health Organization. About 800 foods representing over 200 different kinds of foods are collected from four locations every year. Over 120 different contaminants are tested for. Because of budget limitations, however, results of these studies are not published promptly. Results from fiscal year 1977 and 1978 Total Diet Studies were published in the January/February 1984 issue of the Journal of the Association of Official Analytical Chemists. FDA anticipates that articles on studies covering fiscal years 1979 through 1982 will be published in 1985.

FDA Enforcement Actions for Imported Foods

FDA collects about 5,000 samples from shipments of imported food each year. Four to five percent of samples from

both compliance and surveillance monitoring programs are found to contain illegal residues. Discovery of a violative sample in a shipment flags all subsequent shipments from the same grower causing those shipments to be seized and held at the border. If a second violative sample is found, the grower must certify that subsequent shipments do not contain illegal residues before that grower's products are admitted into the country.

FINDINGS AND RECOMMENDATIONS

Finding #1: FDA's program for monitoring pesticide residues in imported foods is not equivalent to California's monitoring program.

Surveillance monitoring is intended to deter growers and applicators from misapplying pesticides on foods. The greater the likelihood of having a shipment monitored, the less likelihood that an applicator will violate laws and regulations and risk having a crop destroyed.

California employs three strategies to assure compliance. First, CDFA conducts surveillance monitoring of food crops for illegal levels of residues. Second, county agricultural commissioners inspect pesticide applications, sales, and use records, ascertain the competency of persons who apply and advise the use of pesticides, and generate the information on pesticide use required to focus an effective residue monitoring program. Finally, through educational programs, and competency requirements and standards, the state seeks to raise the level of public consciousness regarding the proper use of pesticides. The intent of this combined effort is to promote voluntary compliance.

FDA, on the other hand, relies almost exclusively upon surveillance monitoring to assure compliance in shipments of foods imported from other countries. Its primary, if not exclusive, instrument for deterring misuse is monitoring for residues and refusing entry to shipments containing violative samples. If too few samples are tested, a surveillance monitoring program may not represent a sufficient deterrent to

insure that shipments of imported foods do not contain unacceptable levels of residues.

In order to estimate the adequacy of FDA's monitoring of foods imported from Mexico, we have compared FDA's program with CDFA's surveillance program for domestic produce. The comparison is shown in Table VIII-1 (next page).

The sampling ratio is arrived at by dividing the number of samples collected from a particular crop by California's consumption of the crop in tons. The deterrence ratio represents the likelihood that a shipment of produce will be sampled and is calculated by multiplying the sampling ratio by the maximum tonnage of the respective crop that can be transported in a piggy-back van (most fruits and vegetables in California are transported by truck rather than rail). The amount of produce transported in a piggyback van is assumed as the average shipment. The data are the most recent that FDA and CDFA have made available.

The average deterrence ratio for FDA is roughly 0.0705. In other words, FDA is likely to sample, on average, only 1 in 14 shipments of Mexican produce. CDFA, on the other hand, monitors an average of slightly more than 1 in 8 shipments of Mexican produce (0.13). Thus, under CDFA's monitoring program, growers generally face a 75 percent greater likelihood of having their produce sampled than under FDA's monitoring program.

Table VIII-1

COMPARISON OF FDA'S AND CDFA'S SAMPLING PROGRAMS

Crop	'82 Calif. Production (tons ¹)	'77 CA Consumption ₂ (tons ²)	Net Wt. # Samples Piggyback Taken ₄ in Van '83	Sampling Ratio	Deter- rence Ratio	Mex. Produce Imported into US in '81 (tons ³)	# Samples Taken ₃ in '81	Sampling Ratio	Deter- rence Ratio	
Apples	17,275	185,000	20	230	0.0012	0.0249	--	--	--	
Asparagus	29,675	3,000	17	76	0.0253	0.4307	3,776.3	16	0.0042	0.0720
Avocados	140,415	13,000	16.5	98	0.0075	0.1244	--	--	--	
Bananas	--	195,000	20	64	0.0003	0.0066	20,557.9	17	0.0008	0.0165
Beans (green)	--	15,000	16	99	0.0066	0.1056	13,553.1	49	0.0036	0.0578
Broccoli	230,840	13,000	12.5	99	0.0076	0.0952	8,668.0	30	0.0035	0.0433
Brussel sprouts	--	1,000	22.5	46	0.0460	1.0000	2,346.3	11	0.0047	0.1055
Cabbage	90,170	85,000	20	228	0.0027	0.0536	1,135.2	15	0.0132	0.2643
Cantalopes	469,725	--	20	--	--	--	89,434.0	61	0.0007	0.0136
Carrots	489,415	54,000	20	151	0.0028	0.0559	3,048.1	35	0.0115	0.2297
Cauliflower	122,330	11,000	12	108	0.0098	0.1178	2,388.1	16	0.0067	0.0804
Celery	640,120	71,000	24	163	0.0023	0.0551	--	--	--	--
Corn	52,235	76,000	16	127	0.0017	0.0267	91.3	1	0.0110	0.1752
Cucumber	28,065	40,000	17.5	161	0.0040	0.0704	169,616.7	179	0.0011	0.0185
Eggplant	--	6,000	17.5	67	0.0112	0.1954	23,205.6	90	0.0039	0.0679
Endive-escarole	--	5,000	14	82	0.0164	0.2296	184.8	1	0.0054	0.0758
Garlic	--	6,000	15	55	0.0092	0.1375	--	--	--	--
Grapefruit	60,600	78,000	20	82	0.0011	0.0210	6,773.8	5	0.0007	0.0148
Grapes (table)	585,655	31,000	18	126	0.0041	0.0732	8,486.0	3	0.0004	0.0064
Lemons	268,560	21,000	18.5	93	0.0044	0.0819	--	--	--	--
Lettuce	2,210,275	251,000	21.5	781	0.0031	0.0669	3,603.6	10	0.0028	0.0597
Mangoes	--	6,400	17.5	30	0.0047	0.0820	17,397.6	21	0.0012	0.0211
Nectarine	175,405	12,000	19	67	0.0056	0.1061	--	--	--	--
Onions (dry)	245,435	79,000	22.5	138	0.0017	0.0393	--	--	--	--
Onions (green)	41,935	35,000	12	121	0.0035	0.0415	60,149.1	14	0.0002	0.0028
Oranges	1,267,915	130,000	20	292	0.0022	0.0449	39,598.9	18	0.0005	0.0091
Other peppers	--	14,000	18	80	0.0057	0.1029	93,674.9	336	0.0036	0.0646
Papaya	--	2,600	14	12	0.0046	0.0646	1,197.9	3	0.0025	0.0351
Peaches	127,175	54,000	17.5	83	0.0015	0.0269	--	--	--	--
Pears	81,820	27,000	20	121	0.0045	0.0896	--	--	--	--
Peas (green)	--	1,000	12	51	0.0510	0.6120	3,760.9	51	0.0136	0.1627
Peppers (bell)	59,695	20,000	18	209	0.0105	0.1881	--	--	--	--
Pineapple	--	13,000	15	21	0.0016	0.0242	49,388.9	15	0.0003	0.0046
Plums	118,780	16,000	18.5	87	0.0054	0.1006	--	--	--	--
Potatoes (table)	646,495	1,240,000	20	255	0.0002	0.0041	--	--	--	--
Radishes	22,615	16,300	21	127	0.0078	0.1636	4,195.4	18	0.0043	0.0901
Spinach	17,480	7,000	12.5	222	0.0317	0.3964	487.3	6	0.0123	0.1539
Strawberry	199,430	20,000	12	97	0.0049	0.0582	45,843.6	99	0.0022	0.0259
Sweet Potatoes	43,100	49,000	20	91	0.0019	0.0371	--	--	--	--
Tomatoes	374,315	125,000	18	331	0.0026	0.0477	331,703.9	604	0.0018	0.0328
Average					0.0080	<u>0.1301</u>			0.0043	<u>0.0705</u>

1 USDA/CDFA Agricultural Marketing Service, Market News Branch, CA Fresh Fruit and Vegetable Shipments, Calendar Year 1982

2 CDFA, Memo from Ken Park to James Frank, "Review of Residue Sampling Plan" (24 September 1984)

3 FDA, "Compliance Program Report of Findings: Pesticides in Mexican Produce (FY 81)"

4 USDA Agricultural Marketing Service, Memo, "Revised Tables of Net Weights -- January 1, 1984" (28 December 1983)

RECOMMENDATION

We recommend that:

A. The Governor and the Legislature petition FDA to expand its monitoring program to the level of California's for foods imported from Mexico.

B. CDFA establish a monitoring station at the Mexican border to monitor imported produce until such time as significant improvement in federal monitoring and enforcement are attained.

A food monitoring station at the Mexican border and the increased level of sampling it could provide would serve to deter the importation of foods containing illegal residues into California. Although CDFA does not have the legal authority to prevent entry of violative shipments, the State of California could form a cooperative agreement with the federal government, asking FDA to take enforcement actions whenever necessary.

APPENDICES

- A. Summary of Laws and Regulations Pertaining to the Control of Pesticide Residues in Food
- B. Federal Regulation of Pesticide Use: Chronology
- C. California Laws to Regulate Pesticide Use: Chronology
- D. Public Hearing Witnesses
- E. Individuals Interviewed in Course of the Study
- F. 25 Foods of Which California Produces 50 Percent or More of the United States' Supply
- G. California Department of Food and Agriculture/Division of Pest Management, Environmental Protection, and Worker Safety: Summary of Functions and Activities
- H. Regulation of Structural Pest Control in California
- I. California State Water Resources Control Board's Process for Selecting "Priority Chemicals"
- J. Comparison of Pesticides Used on Food
- K. Glossary
- L. Bibliography

Appendix A

SUMMARY OF LAWS AND REGULATIONS PERTAINING TO THE CONTROL OF PESTICIDE RESIDUES IN FOODS

There are two main divisions in the body of law and regulations pertaining to the regulation of pesticide residues in food: (1) registration, and (2) monitoring and enforcement.

I. REGISTRATION

A. First-Time Registration

1. Federal Program

a. **Unconditional Registration:** The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that all pesticides distributed, sold, offered for sale, held for sale, shipped, delivered, offered for delivery, or received for shipment be registered with the EPA (7 USCA, Section 136(a)). EPA may deny registration if the requirements for registration have not been met. Meeting registration requirements entails presenting evidence to verify that:

*the efficacy of the pesticide supports labelling claims;

*labels meet regulatory specifications (40 CFR 162.10);
and

*the pesticide performs its intended functions without "unreasonable adverse effect on the environment" when used in accordance with widespread and commonly recognized practice (7 USCA Section 136(a)(c)(5) and 40 CFR Part 162.6).

If the pesticide is to be used on or around food crops, a tolerance must exist for such pesticide in or on the raw agricultural commodity or processed food or an exemption from the requirement of a tolerance must be obtained in order to register the pesticide for such use (21 USCS Sections 346, 346(a), and 348 and 40 CFR Part 162.7). If the pesticide has been found to induce cancer when ingested by humans or animals, no tolerance level may be set for its residues in processed foods -- the so-called Delaney Clause (21 USCS Section 348(c)(3)). An exemption to the requirement of a tolerance level for the presence of residue on raw agricultural (and processed foods, provided that the pesticide is not carcinogenic) is granted when the EPA determines that the total quantity of the residue likely to be present in or on raw agricultural commodities under conditions of use currently prevailing will involve no hazard to public health. Federal regulations do not specify how such a determination

shall be made but rather list those pesticides which are exempt, along with conditions for their use (40 CFR Part 180.1001). The so-called "inert" ingredients of pesticides are generally drawn from this list.

A registration is valid only for the use applied for. Each registration specifies the pests and the crops for which the pesticide is to be used. It must be re-registered after five years, whereupon additional data to support the registration may be requested by EPA (97 USCS Section 136(d)(a)).

b. Experimental Use Permits: An experimental use permit for a pesticide or for a particular non-registered use of a pesticide may be granted if the experiment is necessary to "accumulate information necessary to register a pesticide" (7 USCS Section 136(c)(a) et. seq.). If the use of the pesticide is likely to leave a residue on foods, a temporary tolerance level for the residue may be required (7 USCS Section 136(c)(b)). States may issue experimental use permits if the state has submitted, and had approved by EPA, a state plan designating a responsible state agency for detailing the procedures for reviewing permit applications and supervising use in accordance with the provisions of these permits. State permits may not be issued for longer than three years (40 CFR Part 172). There is no time limit for federally issued experimental use permits.

c. Exemption from Registration Requirements: Pesticides may be exempted from federal registration requirements if they are:

- *pesticides transferred between establishments;
- *pesticides transferred under experimental use permits;
- *pesticides transferred for purposes of disposal;
- *pesticides intended solely for export to any foreign country;
- *pesticides granted an emergency exemption, such as those being transferred for use by a federal or state agency under the provisions of 40 CFR Part 166;
- *pesticides that are adequately regulated under other federal laws; and
- *pesticides that are "of a character which is unnecessary to be subject to the Act in order to carry out the purposes of the Act" (40 CFR Part 162.5).

Certain biological agents may also be exempted.

d. **State Authority Specified in Federal Law:** Federal law permits states to regulate the sale or use of federally registered pesticides or devices in the state provided that the regulations do not permit sales or uses prohibited by federal law (40 CFR Part 136(v)(a)). States are not allowed to impose additional labelling requirements (40 CFR Part 136(v)(b)). States may provide registration for additional uses of federally registered pesticides for use and distribution solely within the state to meet special local needs in accord with the purposes of FIFRA. Such uses shall not have been previously denied, disapproved, or cancelled by EPA. Where a pesticide is used for a food or feed crop, a tolerance must be set or an exemption to tolerance requirements under the Federal Food, Drug, and Cosmetic Act must be obtained.

e. **Data Requirements:** Federal law (7 USCS Section 136(a)(c) and 21 USCS Section 346(a), as interpreted in 40 CFR Part 162.8) gives EPA the authority to require health and safety test data in support of registration. The EPA in its Registration Guidelines specifies the kinds of data that are required to support the new or continued use of a pesticide active ingredient. An active ingredient is the ingredient which brings about the desired pesticidal action. All other ingredients are considered "inert" or simply not the "active" ingredients. A pesticide formulation may contain numerous active and inert ingredients.

Data requirements include studies on the potential for:

- *short term exposure effects, such as acute poisoning or skin and eye irritation;
- *long-term exposure effects, such as tumor formation, birth defects, genetic damage and other adverse reproductive effects;
- *hazards to non-target organisms and wildlife;
- *behavior of the chemical in the environment after application; and
- *the quantity and the nature of residues likely to occur in food or feed crops as a result of its use.

These data requirements constitute Part 158 of Title 40 of the Code of Federal Regulations.

According to 40 CFR Part 162.45, a data requirement may be waived by the EPA if "the data so required is [sic] not necessary in order to determine whether such specific pesticide product will generally cause unreasonable adverse effects on man or the environment."

f. **Use Classification:** Recognizing that all pesticides do not pose the same level of environmental and

health risk, FIFRA allows for the classification of pesticides in accordance with the degree of hazard associated with their use. Pesticides, other than those exempted from registration or granted an experimental use permit, are classified for general or restricted use, or both. A pesticide use is classified general if its use in accordance with labelling requirements will not cause unreasonable adverse effects on the environment. A pesticide that will cause unreasonable adverse effects without additional regulatory restrictions is to be classified for restricted use. In this case, the pesticide in its restricted use, or uses, may be applied only under the direct supervision of a certified applicator (7 USCS Section 136(a)(d)).

2. State Program

a. **Unconditional Registration:** State law requires pesticides to be registered with the California Department of Food and Agriculture (7 F&AG Section 12811). A pesticide to be registered for the first time must meet additional standards in accordance with 7 F&AG Section 12824. The pesticide must:

- *not have demonstrated serious uncontrollable adverse effects either within or outside the agricultural environment;

- *generate greater public value than detriment to the environment in its use;

- *not have a reasonably effective or practicable alternative material or procedure which is demonstrably less destructive to the environment;

- *not, when properly used, be detrimental to vegetation, except weeds, to domestic animals, or to the public health and safety; and

- *not be the subject of any false or misleading statement made or implied by the registrant or agent, either verbally or in writing, or in the form of any advertising literature (7 F&AG Section 12825).

b. **Data Requirements:** State law (7 F&AG Section 12824) gives the department the authority to require health and environmental effects testing which are to be conducted or financed, or both, by the manufacturer. Regulations (Title 3 of the California Administrative Code, Article 5) state that data submitted in support of a federal registration must also be submitted in support of a state registration, including data waived by the EPA (3 CAC Section 2369).

Additional data requirements for state registration include:

*A Residue Test Method. Each applicant must provide a method for accurately determining residues of each active ingredient and each metabolite that may result from the active ingredient, for which a tolerance has been set. A registrant has up to two years to submit a procedure for determining the residue within a continuous 24 hour period for pesticides to be used on food crops (3 CAC Section 2371).

*Efficacy Determination. Data must be submitted on a pesticide's efficacy under Californian or similar environmental conditions (3 CAC Section 2373).

*Inert Ingredient Toxicity Data. Applications for pesticides containing an inert ingredient not included on a list of inert ingredients approved for registration must be accompanied by chronic toxicity data. California has not compiled a list of acceptable inert ingredients. Instead, it generally accepts chemicals listed in 40 CFR Part 180.1001, which are exempt from tolerances except for inert ingredients appearing on an unofficial "unlist" developed by CDFA in 1980. Where animal feeding study data are not available, a battery of short term tests for mutagenicity may be submitted. Where such data indicate mutagenicity, data from animal feeding studies on two species will also be required (3 CAC Section 2378).

*General Toxicity Data. Data or summaries from acute toxicity and irritation studies must accompany each application. In addition, where a federal unconditional registration did not so require, an applicant must submit:

- (1) results from a two year feeding study on oncogenicity on the active ingredient in at least one animal species;
- (2) results of a teratogenicity study and one generation of a two-generation combined male-female reproductive study on the active ingredients; and
- (3) results of three mutagenicity studies on active ingredients that detect gene mutations, chromosomal aberrations, and DNA damage/repair (3 CAC Section 2379.5).

The department may also request other health and environmental effects data of the applicant as needed (3 CAC Section 2380).

c. **Use Classification:** The department has the legal authority to designate pesticides as "restricted" and to regulate their use (7 F&AG Section 14001 et. seq.). The major criteria to be used to determine a pesticide registration as restricted include:

- *danger of impairment of public health;
- *hazards to applicators and farmworkers;
- *hazards to domestic animals, including honeybees, or to crops from direct application or drift;
- *hazards to the environment from drift onto streams, lakes, and wildlife sanctuaries;
- *hazards related to persistent residues in the soil resulting ultimately in contamination of the air, waterways, estuaries or lakes, with consequent damage to fish, wild birds, and other wildlife; and
- *hazards to subsequent crops through persistent soil residues (7 F&AG Section 14004.5).

Regulations governing the use of restricted material must prescribe "the time when, and the conditions under which, a restricted material may be used or possessed in different areas of the state, and may prohibit its use or possession in such areas" (7 F&AG Section 14006). An applicator must obtain a permit from the county agricultural commissioner to use a restricted pesticide except for:

- *any pesticide used under an emergency exemption pursuant to Section 18 of FIFRA "when possessed or used by or under the supervision of a certified commercial applicator unless otherwise required by the commissioner (3 CAC Section 2452(c)). (According to 7 F&AG Section 14006.5, all pesticides designated as restricted materials can be used only with a written permit from the commissioner. A permit may be denied for unacceptable local conditions such as weather or timing.)
- *any pesticide on a designated list of restricted pesticides when used under the supervision of a certified commercial applicator (3 CAC Section 2452).

Persons required to register pesticides and who sell or transfer any restricted material must keep accurate records of the amount and type of the material involved in every sale or transfer (7 F&AG Section 14012). Finally, the user of a restricted pesticide must keep a record of each restricted use for at least two years and report such use to the commissioner (7 F&AG Section 14011.5 and 3 CAC Section 2452.5).

B. Re-Registration

1. Federal Program

A pesticide must be re-registered every five years or the registration expires (7 USCS Section 136(d)(a)). Even should the registration expire, existing stocks may be sold and used, provided that such use will not have unreasonable adverse effect on the environment.

a. **RPAR Process:** Because present registration requirements are considerably more stringent than those which existed when most pesticides were originally registered, pesticides coming up for renewal face a contested re-registration process termed "Rebuttable Presumption Against Registration" (RPAR). Pesticides that result in post-harvest residues in or on food or feed crops must be given priority in the re-registration process (7 USCS Section 136(a)(g)).

Part 162.11 of Title 40 of the Code of Federal Regulations sets forth criteria with which failure to comply leads to a rebuttable presumption against registration. Risk criteria apply to the ingredient(s), metabolite(s), or degradation product(s) of the pesticide and address:

- *acute toxicity;
- *chronic toxicity; and
- *lack of emergency treatment.

The burden of rebutting a presumption against registration falls upon the registrant.

b. **Conditional Registration:** Since "old" pesticides may have been registered originally on the basis of data which would be considered inadequate when measured against current standards, FIFRA permits "conditional" registration (7 USCS Section 136(a)(c)(7)). Under conditional registration, pesticides may be registered pending full data development. Circumstances under which a pesticide, or a proposed use of a pesticide, may be conditionally approved are if:

*The pesticide and its proposed use are identical or substantially similar to a currently registered pesticide and use thereof.

*Additional use of the pesticide is satisfactorily supported by submitted data. (If risk criteria are exceeded by any other use of the pesticide, and the proposed use is on a food crop which is not minor and for which there is no satisfactory alternative, a conditional registration for such use may not be granted while a risk-benefit evaluation is pending.)

*Sufficient time has not elapsed for the generation of necessary data in support of registration, provided that the data do not meet or exceed risk criteria.

In all cases, the EPA must determine that use of the pesticide during the period of conditional registration will not have any unreasonable adverse effects on the environment. Finally, if the pesticide is to be used on a food crop, a food tolerance -- temporary or otherwise -- must be established (40 CFR Part 162.18-4).

2. State Program

According to state law, "every license and registration expires on December 31st of each year except when renewal is applied for within one month thereafter in the manner which is provided for registration and licensing" (7 F&AG Section 12817). In renewing the registration of a pesticide and its use(s), the department must screen out a pesticide which endangers "the agricultural or non-agricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented (7 F&AG Section 12824). Hence, pesticides facing renewal must satisfy the same registration criteria as new pesticides. In reviewing a registration, the department must "investigate all reported pesticide episodes and information received by the director indicating that a pesticide may have caused, or is likely to cause, a significant adverse impact, or which indicate that there is an alternative that may significantly reduce an adverse environmental impact from a pesticide" (3 CAC Section 2367). Any significant finding triggers a re-evaluation.

C. De-Registration

1. Federal Program

There are two avenues by which a pesticide might become de-registered: cancellation and suspension. The two terms have specific meanings in pesticide regulation. Suspension refers to an immediate ban on the use and sale of a pesticide. Cancellation indicates only the initiation of possibly protracted administrative proceedings on whether to deny or terminate registration of a pesticide (7 USCS Section 136(d)). Existing stocks of pesticides for which the registration has been cancelled may continue to be sold and used under certain conditions. In announcing a cancellation proceeding, the EPA must consider social and economic factors which could affect the decision to issue a cancellation notice, including the impact on prices of agricultural commodities, retail food prices, and the agricultural economy in general.

2. State Program

The state program for terminating a registration

parallels the federal program (7 F&AG Section 12825 et. seq.). In addition, the department must provide justification for cancelling the registration or refusing to register a product registered with the EPA (7 F&AG Section 12827.5).

II. MONITORING AND ENFORCEMENT

A. Food Monitoring

1. Federal Program

21 USCS Sections 372-4 grant the Food and Drug Administration the authority to collect and inspect samples of foods in interstate commerce or being imported from a foreign country for the purposes of monitoring pesticide residues. Distributors and manufacturers are prohibited from refusing to permit entry or inspection by regulatory agents (21 USCS Section 331). When a product is adulterated, it may be seized, refused entry, or both (21 USCS Section 342(a)(1)).

2. State Program

California state law allocates the responsibility for monitoring food tolerances on the basis of whether the food is a raw agricultural product (the responsibility of the Department of Food and Agriculture) or a "processed food" (the responsibility of the Food and Drug Branch of the Environmental Health Division in the Department of Health Services). The two departments have agreed that a "processed food" is food to which something physical or chemical has been done (other than sorting and cleaning) or any food destined for such processing. A food destined for the fresh fruit and vegetable market is a raw agricultural product, or produce, as defined in Section 12504 of the California Food and Agriculture Code: "produce means any food in its raw or natural state which is in such form as to indicate that it is intended for consumer use without any further processing."

a. **Department of Food and Agriculture Program:** For purposes of testing for compliance with tolerance levels, the Department of Food and Agriculture "may take and inspect samples of any produce grown, processed, packed, stored, shipped, transported, delivered for shipment, or sold" (7 F&AG Section 12581). If produce is suspected of carrying pesticide residues, the department may seize and hold the lot for the purpose of sampling and testing for residues (7 F&AG Sections 12601-15). If pesticide residues on the produce exceed permissible tolerances, the department may, "upon the request of the owner, permit the lot of produce to be reconditioned or disposed of for byproduct purposes which may lawfully contain the pesticide residues found" (7 F&AG Sections 12607-9). The department must obtain a court order to condemn and destroy the produce containing unlawful levels of pesticide residues

(7 F&AG Sections 12641-43).

b. **Department of Health Services Program:** An authorized agent of the Department of Health Services may secure food samples for testing from a factory, establishment, vehicle, or store where processed foods are processed, distributed, or sold (Health & Safety Code Sections 26230-35). The Department of Health Services may prohibit the removal or sale of any food found to be adulterated and may remove the embargoed food to a place of safe-keeping (H&S Sections 26830-33). Any food found to be adulterated may not be condemned without the consent of a lower court in lieu of authorization by the owner (H&S Sections 26830-37).

B. Regulatory Powers

The state regulates the use of registered pesticides insofar as regulations are consistent with federal law (7 USCS Section 1360). Primary responsibility for enforcement rests with Department of Food and Agriculture agents and county agricultural commissioners (7 F&AG Sections 11501-13, 12977, 12982, and 14004).

1. Department of Food and Agriculture Agents

The Director of the Department of Food and Agriculture may adopt regulations circumscribing the use of pesticides (7 F&AG Sections 11502-11, 12971-7, and 14001-12). The department issues licenses to pesticide dealers and pest control operators and advisors and certifies pest control aviators. The department may order applicators in violation of state laws and regulations to cease and desist unlicensed activity.

a. **State Licensing of Pest Control Operators:** Persons engaged in the business of pest control must obtain an agricultural pest control license from the Department of Food and Agriculture (7 F&AG Section 11701). Licensing requires the applicant to demonstrate his/her competence to conduct pest control operations safely (7 F&AG Sections 11702-11).

b. **Certification of Pest Control Aviators:** Persons operating aircraft in pest control applications must hold pest control aircraft pilot certificates issued by the Department of Food and Agriculture (7 F&AG Sections 11901-7). Certification requires demonstrating ability to legally and safely conduct pest control applications and knowledge of pesticides (7 F&AG Section 11905).

c. **Licensing of Agricultural Pest Control Advisors:** Persons acting as agricultural pest control advisors must be licensed by the department (7 F&AG Section 12001). All recommendations regarding pesticide use made by the pest control advisor must be put in writing (7 F&AG Section 12003).

and recommendations must include the following information, when applicable:

- *the name and dosage of each pesticide to be used and description of recommended method of application;
- *the identity of each pest to be controlled;
- *the owner or operator, location of and acreage to be treated;
- *the suggested schedule, time, or conditions for the pesticide application or other control method;
- *a warning of the possibility of damages by the pesticide application when known;
- *the signature and address of the person making the recommendation, the date and the name of the business such person represents; and
- *any other information the department may require.

A copy must be furnished to the dealer and applicator when a pesticide use is recommended (7 F&AG Section 12003).

2. County Agricultural Commissioners

The county agricultural commissioners have the responsibility to register and certify pest control operations (7 F&AG Sections 11732-41), pest control aircraft pilots (7 F&AG Sections 11920-25), and pest control advisors (7 F&AG Sections 12031-36). Commissioners also are responsible for issuing written permits for the use of restricted materials (7 F&AG Section 14006 et. seq.). A commissioner may, upon discovery of a violation of state law or regulation, order the violator to cease and desist any activity that might result in an immediate hazard or cause irreparable damage to the environment (7 F&AG Sections 11897 and 13102). The commissioners may also prohibit the harvest of any produce which may pose a threat to public health (7 F&AG Section 12672).

Appendix B

FEDERAL REGULATION OF PESTICIDE USE

Chronology

- 1910 Federal Insecticide Act Passed. Specified the percentage of certain ingredients for Paris green and lead arsenate (arsenical pesticides) and set general standards for other insecticides or fungicides. Established enforcement in U. S. Department of Agriculture to be triggered by user complaints or random plant inspections. Legislative intent was to protect farmers from being sold adulterated goods.
- 1938 Amendment to Federal Food, Drug, and Cosmetic Act (FFDCA). Introduced the concept of legally regulated food tolerances for chemical residues.
- 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Required for the first time that pesticides be registered by U.S.D.A. before they were marketed and that pesticide labels specify the contents. A "rational user" was assumed, and legislative intent was to require sufficient information for the user to make an informed choice. FIFRA allowed a manufacturer whose chemical was challenged to obtain a "protest registration," thereby placing the burden of proving a pesticide ineffective or unsafe on the government and allowing the challenged chemical to remain on the market.
- 1954 Miller Amendment to FFDCA. Required the FDA to establish food tolerances in raw agricultural produce. Required USDA to establish efficacy of registered pesticides.
- 1962 Rachel Carson's book, SILENT SPRING, published.
- 1964 Amendments to FIFRA. Eliminated protest registrations and expanded the definition of a misbranded pesticide to include pesticides that would injure invertebrate animals, as well as vertebrates and plants.
- 1970 "Reorganization Plan #3:" FIFRA. Environmental Protection Agency (EPA) assumed administration of FIFRA.

- 1972 Federal Environmental Pesticide Control Act (FEPCA). Required EPA to refuse to register a pesticide unless it could be determined that "when used in accordance with widespread and commonly accepted practice, it will not cause unreasonable adverse effects on man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In other words, required EPA to weigh the benefits and the risks of a particular pesticide's use without bias, although legislative intent appeared to be to supplement the consumer protection thrust of earlier legislation with recognition of the potentially harmful effects of pesticide use.
- 1975 Amendments to FIFRA. Established a Science Advisory Panel to EPA and conditional registration of pesticides.
- 1976 Toxic Substances Control Act (TSCA). Regulated chemical substances and mixtures. Until such time as chemical substances become components of pesticides or other compounds, they are subject to TSCA requirements and regulation.

Appendix C

CALIFORNIA LAWS TO REGULATE PESTICIDE USE

Chronology

- 1881 County Agricultural Boards Established. State law enacted to authorize any county board of supervisors upon petition establish a county board of horticultural commissioners to deal with infestations of "noxious insects." These boards evolved into the offices of county agricultural commissioners.
- 1901 Quality Control Act for Paris Green. First California legislation to control quality and prevent fraud in the manufacture and sale of a pesticide.
- 1911 Labeling Requirements Enacted (repealed 1921). Established labeling requirements and forbade the manufacture or sale of an adulterated poison. The University of California was delegated the responsibility for monitoring compliance.
- 1921 Registration Requirement Enacted (repealed 1968). Required that all pesticides manufactured and sold within the state of California be registered with the Director of Agriculture. Delegated all authority for monitoring pesticide use to the Director of Agriculture instead of the University of California. Provided for revocation of registration if the director determined the poison was dangerous to animals and the public health even when used properly.
- 1949 Licensing of Pest Control Operators. Authorized the Director of Agriculture to license all pesticide operators. Previously, county agricultural commissioners had been solely responsible for the direct control of pesticide applications.
- 1949 Regulation of "Injurious" Agricultural Materials. Delegated to the Director of Agriculture the authority to regulate all agricultural materials found to be "injurious to persons, animals, or crops, other than the pest or vegetation they were intended to destroy."
- 1968 Revision of California Agricultural Code. Required that both pesticide manufacturers and dealers be licensed by the Director of Agriculture. Required anyone who engaged in pest control for hire to have

a pest control license for the current year. Defined a pesticide as any economic poison as described in Section 12753:

(a) any spray adjuvant; and

(b) any substance or mixture of substances which is intended to be used defoliating plants, regulating plant growth, or for preventing, destroying, or mitigating any and all insects, fungi, bacteria, weeds, rodents, or predatory animals or any other form of plant or animal life which is, or the director may declare to be, detrimental to vegetation, man, animals or households, or be present in any environment whatsoever.

1969 Comprehensive Regulation Enacted. Directed the Director of Agriculture to "develop an orderly program for the continuous evaluation of all economic poisons actually registered in order to endeavor to eliminate from use in the state any economic poison which endangers the agricultural or nonagricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented."

1972 Reorganization of the Department of Agriculture. The California Agriculture Code was renamed the California Food and Agriculture Code. Changed nomenclature of "economic poison" to "pesticide." Established statutory criteria for classification of pesticide materials. Authorized agricultural commissioners to cancel a pest control operator's county registration for cause. Required a full system of pest control advisor licensing including that such advisors be registered with the county agricultural commissioner of each county wherein they work.

1978 Health and Environmental Concerns. Required the director, in carrying out evaluations of pesticide registrations, to consider whether there are other, less destructive methods of pest control available, and whether the public benefits to be derived from the use of the pesticide under review outweigh the detriment to the environment. Required the director to forbid the use of any pesticide found to endanger the environment.

Appendix D

PUBLIC HEARING WITNESSES
(In Alphabetical Order)

Hearing #1:

Pesticide Residues on Food Products
Los Angeles City Council Chambers
September 26, 1984

<u>Name/Title</u>	<u>Representing</u>
Chambers Bryson, Chief, Food & Drug Branch	California Department of Health Services, Environmental Health Division
Harvey F. Collins, Chief	California Department of Health Services, Environmental Health Division
Hon. Gray Davis	California State Assembly
Paul Engler, County Agri- cultural Commissioner	Los Angeles County
Merlin Fagan, Director, Environmental Affairs	California Farm Bureau Federa- tion
Dan Galbraith, Grower and Pest Control Advisor	Samuel Edwards Associates (Commercial Orchard), Ventura County
George R. Hawkes, Advisor, Product Environmental Affairs	Chevron Chemical Company, Agricultural Chemicals Division
Lori Johnston, Assistant Director for Pest Management, Environ- mental Protection, & Worker Safety	California Department of Food & Agriculture
Alexander Kelter, Chief, Epidemiology & Toxi- cology Branch	California Department of Health Services, Health Protection Division
Joyce C. McCann, Research Biochemist	Biology and Medicine Division, Lawrence Berkeley Lab, U.C.
Keith T. Maddy, Staff Toxicologist and Chief, Worker Safety	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety

Phil Phillips, Pest Management Specialist	University of California, Cooperative Extension
D. Lawrie Mott, Project Scientist	Natural Resources Defense Council
James W. Wells, Chief, Pesticide Enforcement	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
E. D. Yates, Vice President	California League of Food Processors

Hearing #2:
Pesticide Contamination of Drinking Water,
Regulation of Inert Ingredients
State Capitol, Room 437
November 29, 1984

<u>Name/Title</u>	<u>Representing</u>
Hon. Lloyd G. Connelly	California State Assembly
Dennis P. Corcoran, President	Corcoran Associates, Drinking Water Consultants
Solange Goncalves, Staff Attorney	California Rural Legal Assistance
John Harris, Manager, State Environmental Regulatory Affairs	Dow Chemical USA, Midland, Michigan
John Harrison, State Pesticide Regulatory Coordinator	Shell Oil Company, Houston, Texas
Kenneth Kizer, Deputy Director for Preventive Health Programs	California Department of Health Services
Diane Koenigshofer, Director	Sacramento Toxics Alliance
Peter Kurtz, Medical Coordinator	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety

Olaf Leifson, Chief,
Registration &
Agricultural Pro-
ductivity

California Department of Food
& Agriculture, Division of Pest
Management, Environmental Pro-
tection, & Worker Safety

Keith Schneider, Free
Lance Writer

Appendix E

INDIVIDUALS INTERVIEWED IN COURSE OF THE STUDY
(In Alphabetical Order)

<u>Name/Title</u>	<u>Representing</u>
William S. Aldrich, Manager, Performance Audit Division	Auditor General's Office
C. E. Bailey, Regional Manager	Heinz U.S.A., West Coast Agriculture
Georgene L. Bailey, Senior Auditor	Auditor General's Office
John Batchelder, Chief, Toxic Substances Standards Section	California Air Resources Board, Research Division
Clare Berryhill, Director	California Department of Food & Agriculture
William Betts, Minority Policy Consultant	Assembly Committees on Agriculture and Water, Parks, & Wildlife
Marsha Bradley, Staff Scientist, Residue Chemistry Branch	U.S. Environmental Protection Agency, Office of Pesticide Programs
Chambers Bryson, Chief, Food & Drug Branch	California Department of Health Services, Environmental Health Division
Barbara Bunn, Chief, Information Services	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
Robert Burns, Special Assistant	Secretary for Environmental Affairs, Hazardous Substances Task Force
Ann Carberry, Program Analyst	Legislative Analyst's Office
Catherine Carnevale, Assistant Director, Contaminant Policy Staff	U.S. Food and Drug Administration, Office of Regulatory Affairs

Name/Title	Representing
Christine Chaisson, Project Officer, Toxicology Branch	U.S. Environmental Protection Agency, Office of Pesticide Programs, Hazard Evaluation Division
Van H. Cheney, Program Supervisor, Registra- tion & Agricultural Productivity	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety
Harvey F. Collins, Chief	California Department of Health Services, Environmental Health Services
Dennis P. Corcoran, Presi- dent	Corcoran Associates, Drinking Water Consultants
Thomas J. Dawson, Public Intervenor	Department of Justice, State of Wisconsin
Lyle Defenbaugh, Program Analyst	Legislative Analyst's Office
Kathleen K. Dougherty, Toxicologist, Product Evaluation	Chevron Environmental Health Center, Richmond, California
D. F. Dye, Coordinator, Registration Research	Chevron Chemical Company, Agricultural Chemicals Division
Clyde Elmore, Extension Weed Scientist	University of California, Cooperative Extension Services
Anna Fan, Staff Toxicolo- gist, Environmental Toxics Unit	California Department of Health Services, Epidemiological Studies Section
Judith A. Feldman, Coordina- tor, Government Affairs	Chevron Chemical Company, San Francisco
Wally Fung, Chief, Food & Drug Lab Section (Emeryville)	California Department of Health Services, Environmental Health Division
Donna Gilmore, Environmental Chemist	O. H. Materials Company
Daniel T. Halverson, Agri- cultural Statistician	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety

Name/Title	Representing
Cynthia Harmon, Chief, Bureau of Pesticides	New York Department of Environmental Conservation
George R. Hawkes, Advisor, Product Environmental Affairs	Chevron Chemical Company, Agricultural Chemicals Division
Lyndon S. Hawkins, Pest Management Specialist	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety
Robert Hughes, Super- visory Evaluator	U.S. General Accounting Office
Richard J. Jackson, Chief, Environmental Toxics Unit	California Department of Health Services, Epidemiological Studies Section
Lori Johnston, Assistant Director for Pest Management, Environ- mental Protection, & Worker Safety	California Department of Food & Agriculture
Pamela Jones, Director, Alliance for Food and Fiber	Council of California Growers
Norman Kado, Toxicolo- gist, Toxic Substances Standards Section	California Air Resources Board, Research Division
Hiroshi Kanda, Manager, New Product Develop- ment	Takeda Chemical Industries, Ltd. (Tokyo), Agricultural Chemicals Division
Charles Karnopp, Field Representative	Heinz U.S.A., West Coast Agriculture
Meg Kelly, Analyst	U.S. Environmental Protection Agency, Office of Policy and Planning
Alexander Kelter, Chief, Epidemiology and Toxi- cology Branch	California Department of Health Services, Environmental Health Division
Kenneth Kizer, Deputy Director for Preven- tive Health Programs	California Department of Health Services

Name/Title	Representing
Abraham Kleks, District Director	U.S. Food and Drug Administration, Los Angeles
Peter Kurtz, Medical Coordinator	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
Olaf Leifson, Chief, Registration & Agricultural Productivity	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
Paul E. Levingston, Program Supervisor, Registration and Agricultural Productivity	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
Ralph Lightstone, Staff Attorney	California Rural Legal Assistance
Donald O. Lyman, Deputy Director for Health Protection	California Department of Health Services
Jake Mackenzie, Western Regional Compliance Representative	U.S. Environmental Protection Agency, Region IX, San Francisco
Keith T. Maddy, Staff Toxicologist and Chief, Worker Safety	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
D. Lawrie Mott, Project Scientist	Natural Resources Defense Council
Hiroaki Nakamura, Director	Japanese Agricultural Chemicals Inspection Station, Tokyo
Sherman Nash	California Department of Food & Agriculture, Division of Pest Management, Environmental Protection, & Worker Safety
Ray Perkins	Yolo County Agricultural Commissioner
Barbara Petersen, President	Petersen and Associates, Inc., Washington, D. C.
Daniel Rabovsky, Principal Program Analyst	Legislative Analyst's Office

Name/Title	Representing
Nancy J. Rachman, State Regulatory Specialist	Chevron Chemical Company, Agricultural Chemicals Division
George A. Reese, Then- Chief, Registration & Agricultural Productivity	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety
George Root	California Department of Food & Agriculture, Chemistry Laboratory Services
Charles Shulock, Special Consultant	Secretary of Environmental Affairs, Hazardous Substances Task Force
Susan Sherman, Deputy Director	Environmental Protection Agency, Office of Pesticide Programs, Washington, D. C.
Richard Steffen, Senior Consultant	Assembly Select Committee on Job Development and Economic Productivity
George Stein, Field Representative (Retired)	Heinz U.S.A., West Coast Agriculture
Peter J. Stoddard, Pest Management Specialist	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety
George R. Tichlaar, Chief	California Department of Food & Agriculture, Chemistry Laboratory Services
K. C. Ting, Supervisor, Pesticide Residue Laboratory	California Department of Food & Agriculture, Division of Inspection Services
Peter Troast, Administra- tive Assistant	Assembly Member Lloyd G. Connelly
James W. Wells, Chief, Pesticide Enforce- ment	California Department of Food & Agriculture, Division of Pest Management, Environmental Pro- tection, & Worker Safety
Robert L. Wilkenfeld, Toxicologist	Chevron Environmental Health Center, Product Evaluation Division

<u>Name/Title</u>	<u>Representing</u>
Wray Winterlin, Professor of Residue Chemistry	University of California, Cooperative Extension Service
E. D. Yates, Vice President	California League of Food Processors
Zachary A. Wong, Supervising Toxicologist	Chevron Environmental Health Center, Richmond, California

Appendix F

25 Foods of Which California Produces
50 Percent or More of the United States' Supply

Food	Percent of Nation's Supply Produced in California
Almonds	99.9%
Apricots	95.7
Avacados	85.3
Broccoli	89.9
Carrots	51.3
Cauliflower	72.1%
Celery	68.0
Dates	99.9
Figs	99.9
Grapes	88.9
Kiwi	100.0%
Lemons	79.8
Lettuce	69.4
Honeydew Melons	71.7
Nectarines	97.2
Olives	99.9%
Peaches	58.9
Pistachios	100.0
Plums	88.4
Pomegranates	99.9
Prunes	100.0%
Safflower	75.0
Strawberries	70.0
Tomatoes	75.8
Walnuts	99.0

Source: California Department of Food and Agriculture

Appendix G

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
Division of Pest Management, Environmental
Protection, and Worker Safety

Summary of Functions and Activities

Prevention of "Unreasonable Harm"	Promotion of Agri- cultural Productivity	Mechanisms for Coordination
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1. REGISTRATION AND AGRICULTURAL PRODUCTIVITY

Maintains data files on health & environmental effects data, evaluates data so as to assure adverse effects will not occur if pesticides are used according to label instructions	Maintains data files on efficacy testing, evaluates data to assure registered pesticides are effective in killing target pests	In charge of regulating access to data files by scientists from other state departments, universities, others Pesticide Registration and Evaluation Committee (PREC), with representatives from DHS, DIR, DFG, ARB, SWRCB* (Technical Advisors) Pesticide Advisory Committee (Policy Advisors)
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*Departments of Health Services, Industrial Relations, Fish & Game and Air Resources and State Water Resources Control Boards

2. PESTICIDE USE ENFORCEMENT (Also County Agricultural Commissioners)

CAC's monitor pesticide use at selected sites to assure compliance with label instructions	Protects farmers against crop loss or quarantine due to illegal or improper use of pesticides	Unit Chief represents CDFA on Food Protection Committee: CDFA/DHS cooperative effort to monitor residues on fresh and processed foods
CAC's issue permits for use of restricted materials, require filing of Notices of Intent prior to application		MOU with DIR specifies procedures for information sharing and cooperative investigations
CAC's review NOI's to compare proposed use with use(s) approved under terms of restriction		

Prevention of "Unreasonable Harm"	Promotion of Agricultural Productivity	Mechanisms for Coordination
<p>State-level use enforcement unit enforces residue tolerances set by EPA by sampling food crops; illegal residues trigger quarantine; unit technicians follow up on illegal residues to correct improper practices</p>		<p>CDFA, DIR, DHS make cooperative oversight inspections</p> <p>Priority Incident Reporting System: pesticide "incidents" meeting specified criteria (e.g., harm to human health, wildlife, etc.) are reported immediately to federal & state agencies; cooperative decision making determines actions to be taken</p>

3. ENVIRONMENTAL MONITORING AND PEST MANAGEMENT

A. Environmental Hazards Assessment

<p>Evaluates extent of environmental contamination from pesticides</p>	<p>Determines impact of pesticides on agricultural productivity</p>	<p>Compiles, disseminates information on pesticidal methodologies</p>
<p>Recommends mitigation methods to minimize or eliminate potential or existing threats to environmental quality</p>	<p>Identifies sensitive and resistant plant varieties</p>	<p>Provides monitoring data necessary for human exposure evaluation by DHS, CDFA (Worker Health and Safety), and DIR, as well as university and independent researchers and other states</p>
<p>Monitors applications of pesticides targeted for special attention</p>	<p>Develops methods to assess air pollution related crop losses</p>	<p>Research advisory committee meets quarterly to design research strategies specific to newly identified problems with pesticides</p>
<p>Collects, analyzes samples of soil, water, air, vegetation so as to identify off-target movement and fate in the environment</p>		
<p>Monitors pest eradication projects</p>		

Prevention of
"Unreasonable Harm"

Promotion of Agri-
cultural Productivity

Mechanisms for
Coordination

Recommends restric-
tions on use to be
imposed by Regis-
tration and en-
forced by Pesticide
Use Enforcement

B. Pest Management Analysis and Planning

Provides information
on new developments
in integrated pest
management (IPM) to
other units in the
Division

Plans mitigation
measures specific
to certain pests or
pesticides (e.g.,
rice herbicides)
to extend use of
pesticide needed
by agriculture, but
discovered to be
causing adverse
health or environ-
mental effects

Promotes new IPM
delivery systems

Provides informa-
tion and recommen-
dations to other-
units in the
Division, especial-
ly Registration
and Environmental
Hazards Assessment

C. Biological Control Services

Promotes awareness
of non-chemical pest
control alterna-
tives

Prepares efficacy
assessments of bio-
control methods
available for
specific crops

Prepares inventory
of short/long range
needs for bio-control
of agricultural
pests

Develops funding
sources for con-
tracts with other
agencies to con-
duct research

Develops bio-con-
trol methods

Maintains rearing
facilities to test
and provide specif
bio-agents

Trains CDFA and
other state staff,
CAC's, and others
how to use bio-
control

Serves public and
state government as
bio-control informa-
tion center

Prevention of
"Unreasonable Harm"

Promotion of Agri-
cultural Productivity

Mechanisms for
Coordination

4. WORKER HEALTH AND SAFETY

Provides increased protection for workers, public from harmful effects of pesticides by:

*upon review of toxicological and exposure data, recommending actions to mitigate hazards

*conducting tests of pesticide residues on plant surfaces in soil, water, air

*establishing worker re-entry periods (after pesticide applications in farm fields)

*developing regulations re: requirements for safe working conditions

*evaluating medical supervision provided by employers of workers who produce, handle, or use pesticides

*assisting CAC's to investigate pesticide incidents of all kinds (e.g., misuse, disposal)

Assures availability of farmworkers by working to protect farmworker safety

Assures continued availability of pesticides by working to make use of pesticides safe

Monthly meetings of Worker Safety Advisory Committee are open to and regularly attended by members of the public and the press

Routinely reviews data submitted in applications to register new pesticides; recommends precautions to be observed during use in order to protect worker safety

Coordinates Pesticide-Related Illness Reporting System:

*physician treating anyone suspected of suffering from pesticide related illness must report case within 24 hours to county health officer

*county health officer notifies CAC, CDFA (Worker H/S), and DHS (Epidemiological Studies)

*if occupational injury, special form filled out by physician goes to CAC, CDFA, and DHS, as well as county health officer

Prevention of
"Unreasonable Harm"

Promotion of Agri-
cultural Productivity

Mechanisms for
Coordination

5. INFORMATION SERVICES

Drafts new regula-
tions

Prepares news re-
leases related to
changes in policy,
regulations, and
problems Division
is addressing

Compiles data for
preparation of an-
nual pesticide use
and sales reports

Responds to re-
quests from public
for information

Coordinates data
gathering, compila-
tion, and process-
ing within the
Division

REGULATION OF STRUCTURAL PEST CONTROL
IN CALIFORNIA

INTRODUCTION

Structural pest control refers to the coordinated application of pest control technology to the eradication of pests which attack and destroy buildings and other structures, clothing, stored food, and manufactured and processed goods. Pest control technology includes the application of chemical agents through baiting, fumigation, fogging, spraying, dusting or soil application to suppress or destroy pest organisms such as termites, cockroaches, fleas, ants, clothes moths, or rats and mice. Application of pesticides used in structural pest control technology must be comply with the same statutes and regulations applying to uses of pesticides in general. Additional safety precautions must also be observed since the pesticides are used in the immediate vicinity of people. Restricted pesticides used in structural pest technology must be applied by professional pest control operators.

The chief regulatory mechanism for assuring compliance is licensing. For this purpose, a Structural Pest Control Board was established in the California Department of Consumers Affairs in 1935 to issue licenses and to mediate customer complaints of ineffective or illegal work. The work of pest control operators includes making estimates of pesticide damage and the costs of remedial steps to correct it. The board receives more complaints involving estimates, remedial suggestions, and failure to fulfill contractual agreements than about adverse effects from pesticide applications.

Types of License. The Structural Pest Control Board issues three types of licenses:

1. Fumigation: the practice relating to the control of household and wood-destroying pests or organisms by fumigation with poisonous or lethal gases;
2. General Pest: the practice relating to the control of household pests, excluding fumigation with poisonous or lethal gases; and
3. Termite: the practice relating to the control of wood-destroying pests or organisms by the use of insecticides, or structural repairs and corrections, excluding fumigation with poisonous or lethal gases.

A pest control operator licensed in only one practice may not perform pest control operations in the other two categories, although operators may be licensed in any

combination of categories. Frequently, operators are licensed in all three categories.

Licensing for structural pest control often overlaps with licensing for agricultural applicators. Structural pest control operators may apply pesticides only inside a structure. Any restricted pesticides applied in yards, gardens, and lots must be applied by licensed agricultural applicators. Many structural pest control operators are therefore also licensed as agricultural applicators.

Licenses expire every three years but are renewed automatically if the board has registered no verified customer complaints against the operator.

MONITORING

The responsibilities of the Structural Pest Control Board include:

- *Monitoring pest control inspections;
- *Monitoring reports from pest control operations;
- *Mediating customer complaints; and
- *Setting minimum standards and requirements to assure safe structural pesticide use.

Although the board occasionally receives complaints of illness related to improper structural pest control operations, the board itself is not equipped to assess the possible hazard from improper pesticide applications. The board refers complaints of improper use to the Department of Food and Agriculture, which responds with an investigation by the Environmental Hazard Assessment Team. Investigators inspect the site and may take samples of air and fabric, wood, or other surfaces to which the pesticide was applied. These samples are analyzed to determine whether detectable chemical residues have deteriorated in potency to the point of no longer posing a threat to public health.

The Structural Pest Control Board works closely with the Department of Food and Agriculture in all aspects of its regulation, not only because its operators often carry concurrent licensing as agricultural applicators but also to avoid duplication of the pesticide use monitoring program at the state level. A representative of the Structural Pest Control Board is a member of the Pesticide Advisory Committee of CDFA to furnish information and suggestions about pesticide use practices in structural pest control, but monitoring residues is done almost exclusively by CDFA.

In 1979-80, the Los Angeles County Agricultural Commissioner's office did conduct a residue monitoring study of the pesticide chlordane. The study was funded by an EPA urban pest control grant. Soil samples were taken near foundations prior to applications of the pesticide and periodically after the application to determine residue persistence. Data from the study were shared with CDFA. The study was discontinued when funding was cut by the EPA.

Recordkeeping. Although neither the SPCB nor county agricultural commissioners maintain branches for monitoring pesticide residues, county commissioners do monitor carefully records of the types and uses of pesticides for structural pest control. Such monitoring is accomplished through three major tracking steps:

1. Notice of Intent: each application of a restricted pesticide requires the operator to notify the county agricultural commissioner of an intent to apply a restricted agent. Such notification must include the name of the pesticide to be applied, the amount, the location, and the time of application. Although commissioners cannot inspect each application, notices of intent allow them to spot-check applications randomly as time and resources allow. Such spot-checks occur frequently enough to promote compliance generally.
2. Inspection of Storage Areas: commissioners also spot-check operators' storage areas randomly to determine whether necessary safety and application equipment are available and to inventory pesticide stock to determine that pesticides used in applications meet CDFA standards.
3. Record Verification: operators are required to keep careful records of pesticide applications: time, location, and amounts of pesticides applied, names and certifications of applicators, and, in the case of fumigants, name, dates, times, test methods and levels of residues detected at the time buildings were cleared for occupancy after being fumigated. Not only must these records be available for inspection by the public for up to two years, they are monitored by county commissioners for compliance.

Data derived from these investigations are shared with CDFA.

ENFORCEMENT

The Structural Pest Control Board's complaint-investigation program of the SPCB functions primarily to resolve consumer complaints about unsatisfactory work performed by licensed structural pest control operators. The board attempts to mediate complaints to the satisfaction of both the consumer and the operator; its on-site investigations aid in this process. When operators have violated the law, their licenses may be suspended or civil penalties may be assessed in lieu of suspension. In extreme cases, the board reports an operator to the Attorney General for further investigation and prosecution.

The chief enforcement officers for structural pest control, as for agricultural pest control, are the local county agricultural commissioners. Through their monitoring of all pest control operations, commissioners detect non-compliance at the point of the violation. Prior to new state legislation which took effect January 1, 1985, CAC's were required to report their findings of non-compliance in structural pest control to the SPCB. Chapter 766, Statutes of 1984 (AB 294) authorizes commissioners, upon detecting a violation, to suspend an operator's license immediately for up to three days and to levy fines up to \$500.00. An appeals procedure is available to the operator through the Department of Food and Agriculture; extreme cases of a violation of the law can still be referred to the Attorney General for further investigation and prosecution.

HEALTH CONCERNS IN STRUCTURAL PEST CONTROL

The chief public health concern in structural pest control operations is the process of fumigation. Fumigants are gaseous pesticides used in closed spaces such as homes, warehouses, grain elevators, and vaults to completely destroy pest infestations. When used at sufficient dosage under prescribed conditions, fumigants are generally lethal to all insect populations. Most fumigants are also highly toxic to humans, thus generating concern for their safe use.

As with all applications of restricted pesticides, operators must file notices of intent (NOI's) with county agricultural commissioners 24 hours prior to all fumigations. Commissioners consider these notices an excellent compliance enforcement tool because they can spot-check the NOI's to verify the information reported. Myriad details must be recorded which are susceptible to verification: (1) the building must be double locked after a fumigation, with one lock to which neither the owner nor tenant has a key; (2) fumigant levels must be measured to verify the fumigant is being applied per label requirements; (3) fumigant levels must be determined when the building is cleared for public use again; and (4) names, dates, times, and fumigant levels must

be recorded and must match corresponding information in the notice of intent filed with the commissioner's office.

Only in some rural counties where fumigations are infrequently performed are commissioners able to monitor every application, but most commissioners believe enough applications are monitored to guarantee nearly complete compliance. Commissioners frequently monitor recently licensed operators on a regular basis until they are satisfied that the operator has demonstrated competence.

Safety Precautions. Fumigants are required by EPA regulations to contain chloropicrin, a tear gas chemical that functions to identify a fumigant to anyone inadvertently entering a fumigated building. An exception is made when instruments or equipment may be damaged by exposure to the compound. Buildings housing computer equipment, for example, are exempted from the chloropicrin requirement but, in such exempted cases in which no odor-identifying agent is present in the fumigant, a guard must be physically posted at the location until such time as the site is cleared again for public occupancy. When the fumigation site is cleared, information as to who cleared it, what tests were performed to determine the fumigant had dissipated, its potency, and results and times of these tests must be recorded and kept as public records. The property must be posted with the names and amounts of the fumigant applied and the dates and times of application.

Other recent legislation has also strengthened posting requirements. Chapter 459, Statutes of 1984 (AB 3916) requires structural pest control operators or their representatives or employees to provide the owner and/or tenant of the premises to be treated, a notice which contains the following information:

1. the pest to be controlled;
2. the pesticide(s) and active ingredient(s) to be applied;
3. a specific statement that the structural pest control operators are licensed by the SPCB and that the pesticides are registered by the EPA and CDFA; and
4. a statement which addresses general pesticide poisoning symptoms, the telephone numbers of the poison control center, county health department, the county agricultural commissioner, and the Structural Pest Control Board.

When fumigations are checked by agricultural commissioners, tests for residues of the fumigant on surfaces in the treated building are rarely performed. Usually

commissioners repeat the same tests performed by the operator who cleared the site only to verify results. In other words, the applicator's work is monitored but the pesticide itself is not. County commissioners simply lack the resources and laboratory facilities for further testing. When contamination is suspected, an Environmental Hazard Assessment Team from CDFA may be called in to test for hazardous residues.

PUBLIC INFORMATION

Like all agencies and boards of the Department of Consumer Affairs, the Structural Pest Control Board is mandated to provide and disseminate information to the public about the board, its activities, and the operations it is mandated to license and regulate. To fulfill this requirement, the board has distributed over 70,000 information pamphlets over the past three years alone. Newsletters are provided as warranted to all licensees to inform them of changes in laws, regulations, and board policies. Brochures currently being prepared by the SPCB include a general household pesticide brochure that explains to interested persons how they can find out whether the pesticide being applied by any licensed structural pest control operator is appropriate and has been approved for the proposed use.

Appendix I

CALIFORNIA STATE WATER RESOURCES CONTROL BOARD'S PROCESS FOR SELECTING "PRIORITY CHEMICALS"

(See Endnote)

DEVELOPMENT OF THE PRIORITY PESTICIDE PROGRAM

Criteria Selection Process

The priority chemical program was developed to provide an early warning system for California regulatory agencies charged with protecting surface and ground waters from agricultural and industrial chemical pollution. The first step in developing this program was the selection of criteria that would identify, from among the thousands of potential priority chemical candidates, those compounds posing the highest risk of adverse impact to water quality in California.

State Board staff took several approaches to identify priority toxic substances. The first approach involved identifying compounds which had one or more distinguishing features of concern. For example, a pesticide may be so toxic to fish that it probably should not be in water even in concentrations below current detection limits. Toxaphene fits this description, because concentrations over 35 parts per trillion impair fish growth and development.

Another feature of concern was the presence in a toxic compound of contaminants several orders of magnitude more toxic than the main constituent. For example, the very toxic chlorinated dibenzodioxins and dibenzofurans were found to be contaminants of

the herbicide 2,4,5-T, and the wood preservative pentachlorophenol.

Some toxic substances are distinctive because they "degrade" into products which are as toxic as the parent compound, or more so. Endosulfan and its breakdown product, endosulfan sulfate fit this category.

A second approach in developing criteria for priority toxic chemicals was based on lists of international scientific advisory groups and regulatory agencies. Toxicities and other properties of individual compounds appearing on these lists were compared in detail, compounds common to several lists were noted, production and use data for California were obtained, and the potentially highest risk chemicals selected for in-depth risk assessment.

A third approach recognized that certain substances must be given priority attention because of the special nature of their toxicity (e.g. carcinogens, teratogens, and mutagens).

A fourth approach involved identifying classes of compounds that have properties similar to those known to have caused serious water quality problems. For example, soil fumigants with properties similar to DBCP (e.g. 1,2-D/1,3-D and EDB) must be considered as potentially threatening to ground water quality because of their persistence and leaching potential.

All of these approaches were used by staff to develop an integrated chemical selection approach. The highest priority

chemical candidates were then identified as described in the following section.

The first step involved developing a matrix for comparing priority chemicals with the appropriate selection criteria. Thirteen criteria were selected, based on a thorough review of toxic chemical risk assessment literature.

1. Human toxicity (acute/chronic);
2. Aquatic toxicity (acute/chronic);
3. Carcinogenicity, mutagenicity, teratogenicity;
4. Bioaccumulation potential
5. Persistence;
6. Public concern;
7. California use;
8. Detection in California;
9. Detection worldwide;
10. Fish and wildlife kills;
11. Potential for ground water contamination;
12. Potential for surface water contamination;
13. Actions by other agencies and countries.

The next step was to screen the top one hundred highest reported use agricultural chemicals in California since 1971 (Table 1-1). The highest reported use criterion could not be applied for industrial chemicals, as no mandatory use reporting system presently exists for them. A semi-quantitative (HIGH - MEDIUM - LOW) ranking scale was developed for all criteria. The high, medium, and low rankings were further defined for those criteria

Table 1-1. Top 100 pesticides used in California
(1971-1981).

<u>RANK</u>	<u>CHEMICAL</u>	<u>TOTAL POUNDS</u>
1	Sulfur	217,188,584
2	Inert ingredients	214,366,310
3	Petroleum oil, unclassified	177,627,326
4	Petroleum hydrocarbons	136,198,145
5	Mercury treated seed - not included in state or county totals	101,004,901
6	Methyl bromide	84,298,029
7	D-D mixture	66,545,635
8	Sodium chlorate	45,745,348
9	Aromatic petroleum solvents	38,692,128
10	Carbon disulfide	34,603,088
11	Chloropicrin	24,910,854
12	Mineral oil	20,247,698
13	Petroleum distillates	19,526,371
14	Xylene	14,933,300
15	Toxaphene	14,695,777
16	Calcium hydroxide	14,028,338
17	1,2-Dichloropropane, 1,3-Dichloropropene and related C3 compounds	13,435,780
18	Methomyl	11,274,736
19	Propargite	11,137,100
20	Blue vitriol	11,106,164
21	Carbaryl	10,587,766
22	Parathion	10,586,361
23	Molinate	10,435,221
24	Malathion	8,518,090
25	DNBP	7,878,692
26	DEF	7,731,389
27	Cryolite	7,345,580
28	Methyl parathion	6,680,327
29	Dicofol	6,405,700
30	2,4-Dimethylamine salt	6,245,684
31	Dimethoate	5,827,578
32	Phorate	5,781,024
33	Dimethyl tetrachloroterephthalate	5,580,876
34	DBCP	5,495,122
35	Endosulfan	5,487,838
36	Maneb	5,419,216
37	Chlordane	5,214,127
38	Ethylene dibromide	5,161,417
39	Captan	5,079,511
40	Copper sulfate (basic)	4,773,984
41	Azinphosmethyl	4,733,394
42	Desulfoton	4,510,262
43	MCPA, dimethylamine salt	4,350,456
44	Vicane-R	4,318,577
45	Xylene range aromatic solvent	4,249,168
46	Mitrofen	4,171,729
47	PCNB	4,122,921
48	Sulfuric acid	4,116,648
49	Diazinon	4,099,290
50	Captafol	3,823,438

Table 1-1. Top 100 pesticides used in California
(1971-1981).

<u>RANK</u>	<u>CHEMICAL</u>	<u>TOTAL POUNDS</u>
51	Paraquat dichloride	3,710,648
52	Naled	3,548,755
53	Alkylaryl poly/oxyethylene/glycol	3,534,929
54	Chlorothalanil	3,231,980
55	Simazine	2,997,794
56	Diuron	2,913,066
57	Strazine	2,856,024
58	Maneb with zinc ion	2,836,399
59	Methamidophos	2,737,803
60	Mevinphos	2,729,123
61	Petroleum distillate, aromatic	2,710,902
62	Borax	2,618,716
63	Monocrotophos	2,600,399
64	Dalapon, sodium salt	2,441,741
65	Copper hydroxide	2,424,833
66	Aldicarb	2,348,820
67	Trichlorophon	2,338,275
68	Acephate (orthene-R)	2,185,153
69	2,4-D, alkanolamine salts (ethanol and isopropanol amines)	2,104,510
70	Copper oxychloride sulfate	2,075,780
71	Folex	2,046,798
72	Trifluralin	1,956,825
73	Ziram	1,935,141
74	Copper	1,861,768
75	IPC	1,845,923
76	Meta-systox	1,803,141
77	Terrazole-R	1,795,544
78	Methidathion	1,784,982
79	CDEC	1,709,006
80	Ethion	1,652,152
81	2,4-Dichloro-4-nitroaniline	1,644,484
82	Sodium arsenite	1,602,676
83	Sodium cacodylate	1,586,420
84	Magnesium chloride	1,472,493
85	Amitrole	1,467,429
86	Imidan	1,432,674
87	MSMA	1,424,100
88	Copper-zinc sulfate complex	1,343,531
89	Disodium octaborate tetrahydrate	1,293,336
90	Benomyl	1,289,230
91	Diphenamid	1,277,310
92	2,4-D propyleneglycolbutyl	1,244,151
93	Chlordimeform	1,240,646
94	Poly-1-para-menthene	1,023,774
95	Chlorpyrifos	972,151
96	Isopropyl alcohol	951,474
97	2,4-D	920,391
98	Free fatty acids and/or amine salts	910,053
99	Carbophenthion	888,017
100	Paraquat (cation)	861,320

that dealt with a quantifiable continuum of values, e.g. acute and chronic toxicity (Table 1-2). The results of this screening process are shown for the top 12 agricultural and industrial chemicals having the highest cumulative ranking (Table 1-3).

Six of the 12 priority chemicals shown in Table 1-2 are agricultural chemicals discussed in this report. The remaining six industrial chemicals are, or will be, described in other SWRCB publications.

Scientific Assessment Process

Each of the priority chemicals selected was assigned to staff for scientific risk assessment. The sequential steps in this process are described in Figure 1-1. Initial review of the world literature focused on each specific compound's physical and chemical properties, environmental fate, aquatic and human toxicology, existing water quality and other criteria and standards, monitoring information, and potential best management practices. A review of the monitoring data frequently indicated that more site-specific information for California was needed. When such a data gap was identified, a field monitoring program was developed to document "worst-case" conditions. Sites selected for priority chemical field monitoring were carefully restricted to those areas with the greatest likelihood of finding highest concentrations in soil, water and aquatic organisms.

A draft staff report was then prepared which integrated literature review, field monitoring and analytical information.

Table 1-2. Criteria matrix for ranking the toxicity of chemicals

Criteria	Rating		
	Low	Medium	High
Carcinogen	None or Marginal Evidence	Suspect	Documented
Tumor Promotion (Benign)	"	"	"
Mutagen	"	"	"
Teratogen	"	"	"
Reproduction/Fertility	"	"	"
Immunotoxic	"	"	Low threshold level indicated
Hematotoxic	"	"	"
Neurotoxic	"	"	"
Cumulative Effect	"	"	"
Behavior Modification	"	"	"
Bioaccumulation	Log P < 2	Log P 2-3	Log P > 3
Acute Oral LD ₅₀ (mg/kg)	> 500	50-500	< 50
Metabolic Activation/Other Potentiation	None or Marginal Evidence	Suspect	Documented
Structure-Activity Relationship	"	"	"

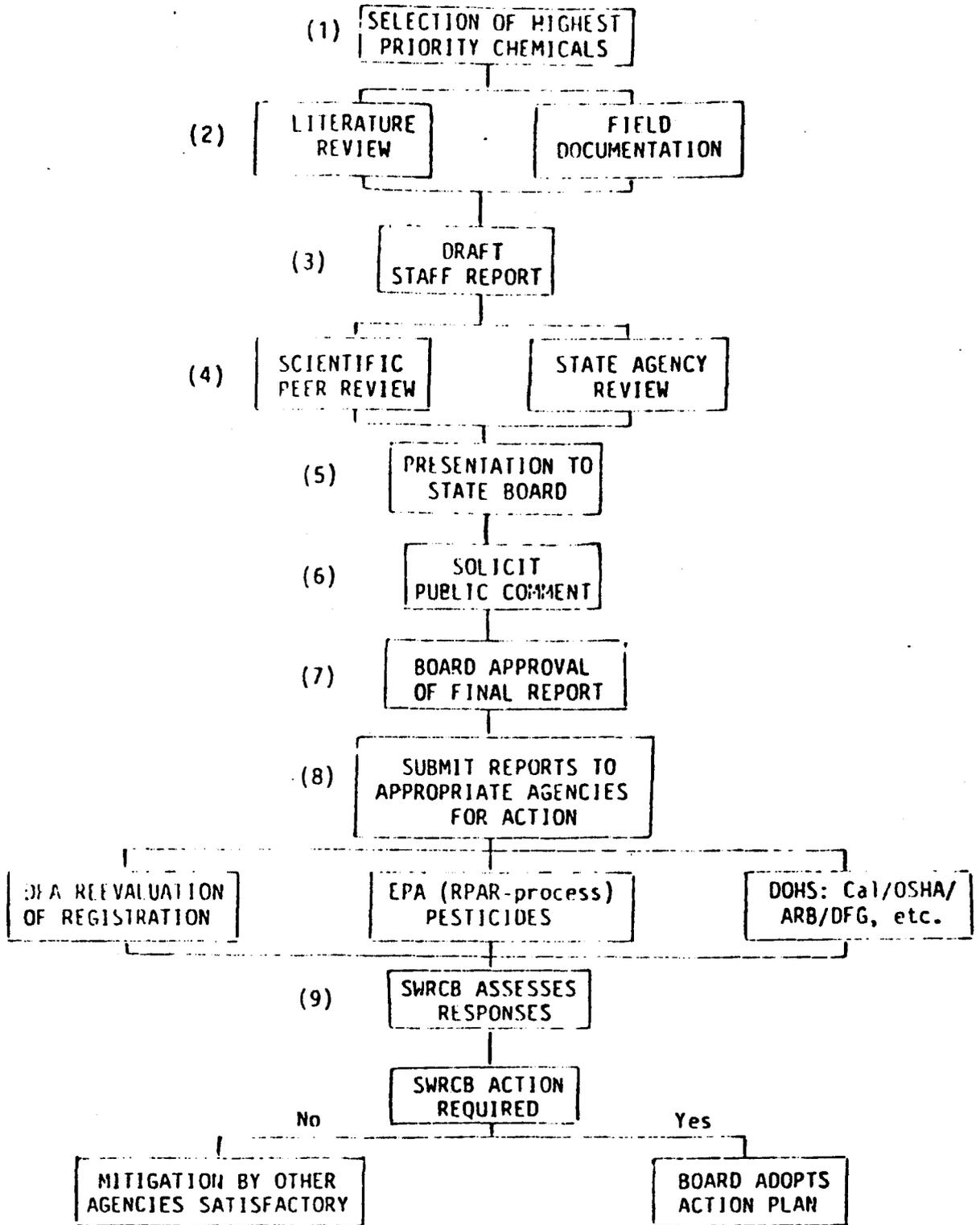
Table 1-3. Top twelve chemicals with a cumulative high hazard ranking

	Human Toxicity Acute/Chronic	Aquatic Toxicity Acute/Chronic	Carcinogenicity/ Mutagenicity	Bioaccumulation Potential	Persistence	Public Concern	California Use	Detection in California	Detection Worldwide	Fish/Wildlife Kills	Potential for Ground Water Contamination	Potential for Surface Water Contamination	Action by Other Agencies, States or Nations
<u>AGRICULTURAL CHEMICALS</u>													
1. Toxaphene	M	H	M	H	H	M	H	M	M	L	L	M	M
2. 1,2-Dichloropropane/ 1,3-Dichloropropene (D-D)	M	L	M	L	M	L	H	L	L	L	H	L	L
3. Ethylene dibromide (EDB)	H	M	H	L	M	L	M	M	L	L	H	L	L
4. Endosulfan	H	H	L	L	L	L	M	M	L	H	L	H	L
5. Arsenicals	H	L	H	H	H	L	M	M	M	L	L	H	L
6. Rice herbicides (Molinate and Thiobencarb)	M	H	L	M	L	M	H	H	L	H	L	H	L
<u>INDUSTRIAL CHEMICALS *</u>													
1. Polychlorinated biphenyls (PCBs)	H	H	H	H	H	H	H	H	H	L	L	H	H
2. Pentachlorophenol (PCP)	M	H	L	M	M	M	H	M	M	M	M	M	O
3. Trichloroethylene (TCE)	H	H	H	M	M	H	H	H	O	O	H	M	O
4. Chlorinated ethanes	H	H	H	M	M	H	H	H	O	O	H	M	O
5. Cyanide	H	H	M	M	H	H	H	H	O	O	H	H	O
6. Chromium (hexavalent)	H	H	H	M	H	M	H	H	H	O	H	M	O

O = Little information available
 L = Low rating
 M = Moderate rating
 H = High rating

* Industrial chemicals are assessed by a separate program of Toxics Special Project

Figure I-1. Scientific assessment process of priority chemicals
(SWRCB Toxic Substances Control Program)



Leading experts in the fields of environmental fate and toxicology were solicited for their peer review comments. The report was also circulated among affected state and federal agencies for technical and policy review. Scientific and government agency peer review comments were incorporated into a subsequent draft report which was presented to the State Board at a public hearing for approval.

Public comments were solicited prior to the hearing from an extensive number of interested citizens and public interest groups on SWRCB mailing lists. Board approval of the report and its recommendations followed satisfactory incorporation of the peer review and public comments. After the report was approved, its recommendations were submitted to affected state and federal agencies for appropriate actions. State Board staff then worked cooperatively with other agencies to evaluate the effectiveness of the recommended mitigation measures.

Note: Appendix I is an excerpt from the following report:

California, State Water Resources Control Board,
Toxic Substances Control Program, Water Quality and Pesticides:
A California Risk Assessment Program, by David B. Cohen and
Gerald W. Bowes, 20 December 1984, pp. 1-10.

APPENDIX J

COMPARISON OF PESTICIDES
USED ON FOODS

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
2,6-dichloro-4-nitroaniline	150	No	12:grapes, lettuce	Yes	equivocal cancer data ⁶		3.7 ppm on potatoes	0.2 ppm	generally 10 ppm	fungicide ⁵
Acephate	210	No	>10:beans, celery, citrus	No			not routinely monitored for		ranges from 3 - 10 ppm	organo-phosphate; insecticide ⁵
Alachlor	40	No	beans, corn	Yes	moderate carcinogen ⁷				.05 to 0.1 ppm	groundwater threat ⁸ ; herbicide ⁵
Aldicarb	20	Yes	11:beans, carrots, lemons	Yes		additional mutagenicity tests ⁹			ranges between .05 and 5 ppm	insecticide ⁵
Inorganic arsenic	75? (CEA admits that the data are incorrect)	Yes	grapes	No	carcinogenic, genetic effects ⁶		not tested for		3.5 ppm	soil/groundwater threat ¹⁰ ; insecticide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Atrazine	20	No	corn	No	equivocal cancer data ⁶	inadequate data on chronic effects ⁹	not routinely tested for	.25 ppm	pre- and post-herbicide ⁵ ; persists in soil ¹¹	
Benmyl	167	No	30:fruit, cabbage, peppers	No	potential to cause chronic toxicity being re-assessed ¹²	in special review ¹²	not routinely tested for	ranges from .2 to 15 ppm	carbamate; systemic fungicide ⁵	
Bentazon	97	No	4:rice, corn, pea bean	No	no observed chronic effects ¹³		not routinely tested for	.05 ppm	herbicide ⁵	
Bromoxnil octanoate	135	No	7:grain, onion, garlic	Yes				.1 ppm	carbamate; herbicide ⁵	
Captan	935	No	over 30: wide variety	Yes	very weak carcinogen (neoplasm only) ⁶	data base complete, though under special review	17 ppm: cherry	0.045 ppm	ranges from from .25 and 100 ppm	food tolerances are likely to be reduced to 5 ppm for most crops ¹⁴ ; fungicide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Carbaryl	720	Yes	most crops	Yes	equivocal cancer data ⁴ (in RPAR)	inadequate chronic data ⁹	13.8 ppm: avocadb	0.015 ppm	ranges from 1 to 10 ppm	insecticide ⁵
Carbofuran	750	No	>4: grapes, rice, strawberries	Yes					.2 and .5 ppm	insecticide ⁵
Chloropicrin	1500	Yes	51 crops	No	equivocal cancer data ⁶	inadequate data base ¹⁴	not tested for		exempt	fumigant ⁵
Chlorothalonil	300	No	24 different crops	Yes	very weak carcinogen ⁶		1.5 ppm: oriental vegetables	0.04 ppm	ranges from .5 to 5 ppm	fungicide ⁵
Chloroxuron	30	No	>5: carrot, celery, strawberry	No		chronic data base complete ¹⁵	not routinely tested for		.1 ppm	pre- and post-emergent herbicide ⁵
Chlorpyrifos	200	Yes	22: orange, sugarbeet	Yes		data base complete ¹⁵	0.1 ppm: rutabaga	0.025 ppm	ranges from .1 to 3 ppm	insecticide ⁵
Dichlone	6	No	tomatoes, wheat	No	moderate carcinogen ⁶		not routinely tested for		3 ppm	fungicide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Dicofil (kelthane)	150	No	22:corn, bean, tomato	Yes	weak carcinogen ⁶				5 ppm	contains DDT contaminant ¹⁶ ; insecticide ⁵
Dimethoate	300	No	33:beans, grapes lemon	Yes	moderate carcinogen, genetic, reproductive effects ⁶ (in RPAR) ¹³		6 ppm: lettuce	0.02 ppm	2 ppm	insecticide ⁵
Endosulfan	280	Yes	34:artichoke lettuce	Yes	strong carcinogen (neoplasms only) ⁶		1.13 ppm: kale	0.04 ppm	2 ppm	insecticide ⁵
Ethephon	27	No	8:tomatoes	No			not routinely monitored for		2 ppm	plant growth regulator ⁵
Ethion	67	Yes	19:oranges, melons	Yes	?	chronic data base inade- quate ¹³	0.66 ppm: lime	0.03 ppm	ranges from .1 to 2 ppm	insecticide ⁵
Ethylene bis dithiocarbamic acid (EDBC)	280	No	26:fruit, carrot, lettuce	No	carcinogen, teratogen. under special review ¹²	chronic data being generated ¹³	not routinely monitored for		generally .1 ppm	fungicide ⁵ ; EIU-breakdown product ¹²

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Folpet	62	No	10: onions, lettuce, garlic	Yes	birth defects, equivocal cancer data ⁶ (in RPAR) ¹³	in data call-in ¹³	5.5 ppm: lettuce	0.009 ppm	ranges from 15 to 50 ppm	fungicide ⁵
Lindane	25	Yes	14 crops	Yes	weak carcinogen (neoplasms only) birth defects ⁶ (in RPAR) ¹²		0.13 ppm: peach	0.034 ppm	generally 3 ppm	insecticide ⁵
Maneb	500	No	35: almonds, lettuce, melon	No	weak carcinogen, birth defects ⁶ (in RPAR) ¹²	chronic data base complete ¹³	not routinely monitored for		ranges from .1 to 10 ppm	fungicide ⁵ ; EIU/EBIS are breakdown products ¹⁴
Methamidophos	130	Yes	11: broccoli lettuce, potato	Yes		chronic data base complete ¹⁵	.23 ppm: eggplant	0.14 ppm	generally 1 ppm	insecticide ⁵
Methyl bromide	5300	Yes	51: nuts, fruits, vegetables	No	?	chronic data base inadequate ¹³	not routinely monitored for		exempt	fumigant ⁵
Mevinphos	260	Yes	40: artichoke, berry, lettuce	Yes	?	currently under data call-in ¹³	.15 ppm: lettuce	0.01 ppm	.25 and 1 ppm	insecticide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Naled	80	No	32: strawberry, grapes	No	does not exceed risk criteria ¹³	chronic data being generated ¹³	.18 ppm: zucchini	0.01 ppm	ranges from .5 to 3 ppm	organophosphate; insecticide ⁵
Permethrin (synthetic pyrethroid)	60	Yes	14: primarily lettuce	No	equivocal cancer data ¹⁷	chronic data base complete ¹⁷	not routinely monitored for	20 ppm		insecticide ⁵
Petroleum distillates - aromatic	140 (as active ingredient)	No	50: broccoli, brussel sprouts	No	some evidence of chronic effects ¹⁴	everything ¹⁴	not routinely monitored for	exempt		generally used as inert
Phorate	80	Yes	8: wheat, sugarbeet, corn	Yes	?	chronic data base inadequate ¹³			.05 and .1 ppm	insecticide ⁵
Propargite	600	No	21: nuts, corn, grapes	No			not routinely monitored for		.1 to 10 ppm	acaricide ⁵
Simazine	80	No	16: grapes, oranges	No	equivocal cancer data ⁶	carcinogen, birth defects (chronic data deferred) ¹³	not routinely monitored for		.25 ppm	pre- and post-emergent herbicide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Thiophanate	1.5	No	7 crops	No			not routinely monitored for		.05 ppm	carbamate; fungicide ⁵
Thiram	7	No	5:wheat, strawberry	No	neuro- toxicity, equivocal cancer data ⁶	chronic data base complete ¹³	not routinely monitored for		7 ppm	carbamate; fungicide ⁵
STN Trifluralin	70	No	31:tomato, melon, bean	Yes	very weak carcinogen, mutagen ⁶				.05 ppm	pre-emergent herbicide ⁵
Xylene	1100	No	54:nut, artichoke, lettuce	No	under special review	chronic data base incomplete ¹⁵	not routinely monitored for		exempt	inert ⁵
Zinab	32	No	17:grapefruit, lettuce	No	weak carcin- ogen; birth defects ⁶ (in RPAR) ¹³	chronic data being generated ¹³	not routinely monitored for		generally between 7 and 25 ppm	carbamate; fungicide ⁵
Ziram	1200	No	>6:almonds, apricots	No	weak carcin- ogen ⁶	inadequate chronic data base (currently data call-in) ¹³	not routinely monitored for		ranges from .1 to 7 ppm	fungicide ⁵

PESTICIDE	IBS USED (X 1000) ¹	RESTRICTED? ²	MAJOR CROPS ²	ROUTINELY MONITORED FOR? ^{2a}	CHRONIC TOXICITY?	DATA GAP?	HIGHEST RESIDUE FOUND ⁴	AVERAGE RESIDUE WHEN RESIDUES ARE FOUND ⁴	FOOD TOLERANCE ⁵	COMMENT
Glycol esters	?	No	?	No	some suggestion of genetic and reproductive effects ¹⁶	chronic data base inadequate or non-existent ¹⁶	not routinely monitored for		exempt	inert ⁵ ; risk is undefined ¹⁶
Carbon tetrachloride	20	Yes	grain crops	No	foetotoxic, very weak carcinogen ⁶		not routinely monitored for		exempt	fumigant ⁵
Chloroform	?	No	grains	No	weak carcinogen, reproductive effects ⁶		not routinely monitored for		exempt	fumigant ⁵
D-D mixture (Telone)	10,000	Yes	51:broccoli, cabbage	No	mutagen, carcinogen ¹⁸		not routinely monitored for		exempt	pre-emergent nematocide ⁵

Key

Toxic potency (for carcinogens and neoplastic agents):

- > 1 mg of pesticide/kg of animal bodyweight/day fed to rodent over its lifetime -- strong carcinogen
- 10 mg to 1 mg/kg/day -- moderate carcinogen
- 100 mg to 10 mg/kg/day -- weak carcinogen
- > 100 mg/kg/day -- very weak carcinogen

Equivocal cancer data: When some evidence of tumorigenic activity is presented but one or more of the criteria considered essential for an adequate study are lacking, as defined by the Registry of Toxic Effects of Chemical Substances.⁶

Neoplastic agent: Neoplasms, i.e., non-malignant or invasive cancers, are considered a lesser form of evidence of carcinogenic potential.

Footnotes

- 1 California Department of Food and Agriculture, Pesticide Use Report: Annual 1983, 1984.
- 2 Letter from George Reese (former Chief), CDFA Pesticide Registration and Agricultural Productivity Unit, to Andy Manale (October 31, 1984).
- 2a CDFA, Pesticide Use Monitoring and Enforcement Unit, "New List of Pesticides Detected by Screens", August 1984.
- 3 CDFA, Pesticide Use Report: Annual 1983; number corresponds to the number of food crops for which the pesticide is used to control pests; the indicated crops are those for which the pesticide is primarily used.
- 4 CDFA, "Pesticide Residue System Sample Summary Report," 1983.
- 5 40 CFR 100.
- 6 U.S. Department of Health and Human Services, Center for Disease Control, National Institute for Occupational Safety and Health, Registry of Toxic Effects of Chemical Substances, 1981-82 edition edited by R.C. Tatkin and R.J. Lewis, Senior (June 1983).
- 7 Telephone conversation with Dr. Amal Mahfong, USEPA, Office of Pesticide Programs, Hazard Evaluation Division.
- 8 USEPA, Hazard Evaluation Division, Office of Pesticide Programs, "Assessment of Groundwater Contamination by Pesticides prepared for FIFRA Scientific Advisory Panel Meeting June 21-23, 1983, Arlington, Virginia" (June 7, 1983).
- 9 USEPA, Office of Pesticide Programs, Hazard Evaluation Division, "Chemical Information Fact Sheet" (undated).
- 10 Conversation with Dr. Raye Hinterline, Department of Environmental Toxicology, University of California, Davis.
- 11 Conversation with Dr. Clyde Elmore, University of California Davis Extension Services.
- 12 49 FR 45486 (November 16, 1984).
- 13 USEPA, Office of Pesticide Programs, March 1984 Status Report on Rebuttable Presumption against Registration (RPAR) or Special Review Chemicals, Registration Standard Program and Data Call-in Program (March 31, 1984).
- 14 Telephone conversation with Dr. Christine Chaisson, Hazard Evaluation Division, Office of Pesticide Programs, USEPA.
- 15 Telephone conversation with Dr. Frank Sanders, Special Review Unit, Office of Pesticide Programs, USEPA.
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Appendix K

GLOSSARY

ACARICIDE	A pesticide that kills ticks and mites.
ACUTE TOXICITY	Acute toxicity is determined by measuring the adverse health effects of a single exposure.
BREAKDOWN PRODUCT	A relatively stable substance resulting from the decomposition of the parent compound.
CARCINOGEN	A substance that causes cancer.
CHRONIC TOXICITY	Chronic toxicity is determined by measuring the adverse health effects of repeated or continuous exposure over a period of at least one half the lifetime of the organism.
EFFICACY	The ability of a pesticide to bring about the desired effect on the target pest when it is used according to label instructions.
FUNGICIDE	Any substance which kills or inhibits the growth of fungi.
HAZARD	The likelihood that use of a pesticide will result in an adverse effect on humans or the environment.
HERBICIDE	A substance used to control weeds or other unwanted vegetation.
INSECTICIDE	A pesticide used to control insect life that is harmful to humans.
METABOLITE	A substance produced in or by living organisms by biological processes and derived from a pesticide.
MUTAGEN	A chemical substance that causes changes in genetic material.
NEMATOCIDE	A pesticide that kills nematodes, i.e. soil worms that attack the roots of beneficial plants.

NEOPLASM	An abnormal new growth of tissue in plants or animals; a tumor.
PEST	A generic term for any life form that attacks food crops. Pests include insects, weeds, fungus, mildew, mold, disease, and rodents.
PESTICIDE	Any substance used to destroy or inhibit the action of plant or animal pests.
PLANT REGULATOR	A chemical which accelerates or retards the rate of growth of a plant.
RESIDUE	The amount of pesticide remaining on or in the crop to which it has been applied.
RODENTICIDE	A substance used to kill rats and other rodent pests.
SUBACUTE TOXICITY	Subacute toxicity is determined by measuring the effects of repeated or continuous exposure within less than one half the lifetime of the organism.
TERATOGEN	A substance that causes abnormalities in embryos or fetuses.
TOLERANCE	A number (usually in parts per million or ppm) that is determined to be the maximum permissible level of pesticide residue remaining on the crop at the time of harvest, when the pesticide has been used according to label instructions.
TOXICITY	The potential of a substance to cause adverse health effects.
TOXICOLOGY	The branch of medical science devoted to the study of poisons.

Appendix L

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