REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Federal Pesticide Registration Program: Is It Protecting The Public And The Environment Adequately From Pesticide Hazards?

Environmental Protection Agency

Food And Drug Administration (HEW)

GAO found the following conditions:

- --Safety and efficacy data has not been submitted to support marketing many pesticides. (Safety data include information on cancer, genetic changes, birth defects, and reproduction.)
- --Safety and efficacy data is not required for the pesticides as marketed, only for individual active ingredients.
- --Reviews of inert ingredients (such as vinyl chloride) are not subjected to the full range of safety testing.
- --Many labels do not comply with requirements.
- --Pesticide residue tolerances are not monitored or reviewed.
- --The safety of pesticide residues in some foods has not been determined.
- --Statutory registration requirements are not carried out on a timely basis.

RED-76-42

DEC. 4, 1975

ABBREVIATIONS

BHC	Benzene hexachloride
EBDC	Ethylene bisdithiocarbamate
ETU	Ethylene thiourea
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FEPCA	Federal Environmental Pesticide Control Act
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
ppm	parts per million
PCNB	Pentachloronitrobenzene
PR	Pesticide regulation

Contents

Glossary

Acceptable daily intake	Man's daily intake of a substance during his lifetime which appears to be without appreciable health risk on the basis of all facts known at the time.
Active ingredient	An ingredient in a pesticide which will (1) prevent, destroy, repel, attract, or mitigate any pest, (2) accelerate or retard the growth rate or maturation rate or otherwise alter the behavior of ornamental or crop plants or the product thereof (plant growth regulator), (3) cause the foliage to drop from a plant (defoliant), and (4) artifically accelerate the drying of plant tissue (dessicant).
Acute toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism through a single exposure.
Adulterated	Food or a pesticide formulation containing chemicals or substances at variance with the amounts prescribed by law.
Carcinogenic	The property of a substance or a mixture of substances which produces or incites cancer in a living tissue.
Cholinesterase inhibitor	A substance that inhibits action of cholinesterase, a nervous system enzyme, thereby disrupting nerve activity which can result in death.

Chronic feeding study	A study during the lifetime of test animals involving multiple exposures to substances in their food. The study's purpose is to find a maximum level that induces no toxicological effect and to determine the nature and degree of long-term toxic effects.
Compendium of Registered Pesticides	A compilation of pesticide chemical uses registered by EPA.
Disinfectant	An agent or substance that frees from infection; especially, a chemical that destroys vegetative forms of harmful microorganisms excepting bacterial spores.
Effective	As applied to pesticides the composition of a pesticide product is such to warrant the proposed claims for it.
FEPCA registration program	A program to reregister all existing pesticides registered by EPA (interstate pesticides), as well as those not previously registered by EPA (intrastate pesticides) during the 2-year period ended October 1976. The program was required by the Federal Environmental Pesticide Control Act (FEPCA) of 1972.
Fungicide	Preparations intended for preventing, destroying, repelling, or mitigating any fungi (mushrooms, molds, mildews, rusts, etc.).
Herbicide	Preparations intended for preventing, destroying, repelling, or mitigating unwanted plants or weed plants declared to be pests.

Insecticide	All preparations intended for preventing, destroying, repelling, or mitigating insects.
Inert ingredient	An ingredient in a pesticide other than an active ingredient. Such ingredients are usually added as a solvent, thickener, propellent, or other such uses to enhance the effectiveness or to facilitate the use of the pesticide.
Mrak Commission	A commission established by the Secretary of HEW in 1969 to study pesticides and their relationship to environmental health.
Mutagenic	The property of a substance or mixture of substances which induces genetic changes in subsequent generations.
Negligible residue	An amount of a pesticide residue that is regarded as toxicologically insignificant. EPA has considered this to be less than .1 ppm.
Nontarget species	Those plants and animals (including man) that are not intended to be controlled, injured, killed, or detrimentally affected in any way by a pesticide.
Oncogenic	The property of a substance or a mixture of substances which produces or incites tumor formations in living tissue.

Pesticide tolerance	A scientifically and legally established limit for the amount of chemical residue permitted to remain in or on a harvested food or feed crop as a result of the application of a chemical for pest-control purposes.
Residue	Active ingredient(s) and dissimilation products that can be detected in crops, soil, food, water, and other components of the environment following the use of the pesticide.
Rodenticide	Preparations intended for preventing, destroying, repelling, or mitigating rodents and closely related species declared to be pests.
Safe	As applied to pesticides, a pesticide product which will perform its intended functions without unreasonable adverse effects on man and the environment, that is, without any unreasonable risk to man or the environment, considering the economic, social, and environmental costs and benefits of the use of the pesticide.
Subacute toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism on repeated exposure within 90 days of the initial exposure.
Synergism	The cooperative action of separate substances so that the total effect is greater than the sum of the effects of the substances acting independently.

Teratogenic	The property of a substance or mixture of substances which produces or incites birth defects, ordinarily not hereditable, in or on an animal embryo or fetus.
Translocation	The attachment of a broken-off segment of one chromosome to another; especially, the exchange of parts between dissimilar chromosomes.

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133192

To the President of the Senate and the
Speaker of the House of Representatives

This is the third in a series of GAO reports issued to alert the Congress to the shortcomings in the Environmental

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT PROTECTING THE PUBLIC AND THE ENVIRONMENT ADEQUATELY FROM PESTICIDE HAZARDS?

Environmental Protection Agency
Food and Drug Administration
Department of Health, Education, and Welfare

D I G E S T

The American consumer has not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws regulating pesticides which require that

--only effective pesticides be registered (those that will not cause unreasonable adverse effects on human health and the environment) and

--residues of pesticides in food be adequately checked so that consumers are not exposed to harmful levels.

GAO has issued three other reports on shortcomings in the Environmental Protection Agency's program to regulate the use of pesticides.

[redacted]

Registrants have not submitted required studies on such issues as pesticide effects on reproduction, birth defects, and permanent genetic changes for many registered pesticides. The absence of information on pesticides to which much of the population is exposed daily--such

as those in foods and in the environment--means that the Environmental Protection Agency cannot be sure that human health or the environment is being adequately protected.

The Environmental Protection Agency should require this information for all future registrations and registration renewals. (See pp. 7 to 10 and 13 to 15.)

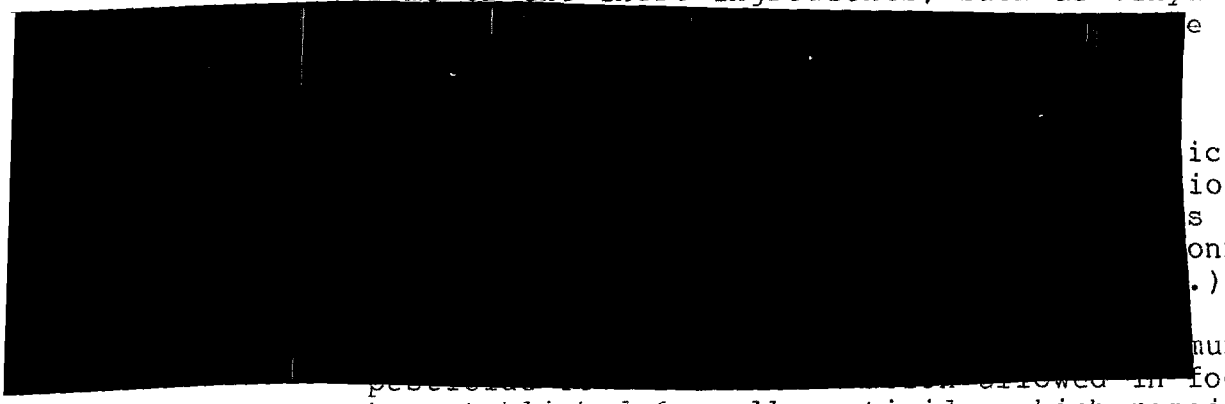
The Agency assesses a pesticide's safety by studying individual active ingredients, not the pesticide as marketed.

There is little or no information on the long-term effects of the pesticide as marketed on human health and the environment, particularly when the formulation contains two or more ingredients which, when combined, may be more toxic than the individual ingredients.

The Environmental Protection Agency should determine whether testing pesticides as marketed should be required. (See pp. 11 to 13.)

Also, its testing requirements for inert ingredients in pesticide formulations are less stringent than those for active ingredients.

Some of the inert ingredients, such as vinyl



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be established for all pesticides which remain in or on a treated food. Although the Environmental Protection Agency establishes all tolerances for pesticides remaining in food, the Food and Drug Administration is responsible for making sure that residues do not exceed tolerances. (See p. 38.)

Many pesticide tolerances were established before certain safety testing was required. The Environmental Protection Agency does not review periodically the adequacy of data supporting tolerances for pesticide residues on food to insure that such residues are not injurious to consumers.

Consequently, many types of safety data have not been obtained for pesticides with food tolerances. (See pp. 38 to 44.)

Many tolerances, currently in effect, were established in the 1950s without residue data, and therefore, total human exposure to residues of certain pesticides is not known and may exceed safe levels. (See pp. 42 to 44.)

The Food and Drug Administration's residue testing program is limited to about 90 of the approximately 230 active pesticide ingredients for which the Environmental Protection Agency has established tolerances. Food should be periodically tested for all pesticides which might enter the food chain.

The Environmental Protection Agency has registered pesticides for uses resulting in residues on food products, although tolerances for the residues have not been established. (See pp. 44 to 47.)

The Environmental Protection Agency has established a system of interim tolerances to allow using a pesticide while reviewing the tolerance petition. Interim tolerances were sometimes established in cases where (1) questions of safety existed, (2) inadequate data on residue levels was provided, and (3) petitioners submitted no data to support the safety of the proposed uses. (See pp. 51 to 64.)

Under present legal requirements of the Federal Environmental Pesticide Control Act, the Environmental Protection Agency must register about 46,000 pesticides by October 1976 and in addition must process its normal workload. Presently, the Agency does not have the necessary staffing or funding to sufficiently review and register these pesticides within the time frame provided or to assure the public that these pesticides are safe and effective when used according to label directions.

To compound the problem, the Agency was about 9 months late in issuing regulations to be followed in registering the pesticides. (See pp. 67 to 70.)

Pesticide registrations are valid for 5 years and must, by law, be renewed or canceled at the end of this period. However, the Environmental Protection Agency has not been renewing pesticide registrations as required; many pesticides whose registrations are over 5 years old still are being marketed. (See pp. 70 to 72.)

The Environmental Protection Agency stated that the report is an exhaustive and generally excellent study of pesticide registration and tolerance setting. The Agency noted that GAO's observations of the program covered a period during which major changes were made in organization, procedures, and regulations and that many of the problems would be corrected by its new registration regulations or by changes to existing programs in line with recommendations in the report.

However, the Environmental Protection Agency said it would not require the full range of data to support registration under the 1972 act because of limited staff and time. Data including mutagenicity or permanent genetic changes, environmental chemistry, and efficacy (for agricultural pesticides) will not be required. (See pp. 23 and 24.)

The Environmental Protection Agency did not agree to require the full range of safety testing of inert ingredients (see p. 25) or to consider further the need for testing of pesticides as formulated (see pp. 25 and 26). GAO does not concur with the Environmental Protection Agency's waiver of required data for registration under the act or with its intention to require only limited data for inert ingredients and for pesticides as formulated. GAO believes this data necessary for the Environmental Protection Agency to carry out its mandate to register only effective pesticides which will not cause unreasonable adverse effects to man or the environment.

The Department of Health, Education, and Welfare agreed to coordinate future pesticide residue testing with the Environmental Protection Agency out did not concur with GAO's recommendation that the pesticide surveillance program be expanded to include periodic testing of food for all pesticides with tolerances. Health, Education, and Welfare said that its surveillance program detects over 90 of the more persistent and toxic pesticides which for the past 10 years have been well within prescribed limits in food.

GAO recognizes Health, Education, and Welfare's need to concentrate its monitoring activities on those pesticides presenting the greatest hazard. However, GAO does not believe that residues of the more persistent and toxic pesticides are reliable indicators of other pesticide residues. The existing surveillance program should not preclude the periodic testing for other pesticides. (See pp. 49 and 50.)

CHAPTER 1

INTRODUCTION

Pesticides are substances used to control harmful insects, diseases, rodents, weeds, bacteria, and other pests that attack man's food and fiber supplies and threaten his health and welfare. In 1973 (the latest year of available data), 1,289 million pounds of pesticides with a value of $1,493 million were produced in the United States. About 1 billion pounds are used domestically each year--55 percent for agriculture; 30 percent for industrial, institutional, and governmental use; and 15 percent for home and garden use.

Approximately 29,000 pesticide products--including insecticides, rodenticides, herbicides, fungicides, and disinfectants--made from 1 or more of about 1,800 chemicals were registered with the Environmental Protection Agency (EPA) as of January 1975. These pesticides are identifed as follows.

	Number	Percent
Insecticides	14,210	49
Rodenticides	928	3
Herbicides	5,046	17
Fungicides	4,002	14
Disinfectants	4,814	17
Total	29,000	100

Pesticides are a mixed blessing. They are beneficial in that they save lives by controlling disease-bearing insects; minimize crop damage due to insects, weeds, and other pests; and protect households from infestations of flies, roaches, rats, mice, and other pests. Because of these benefits, pesticides have become increasingly important in agriculture production, public health and sanitation, protection of natural resources, and improvement of man's well-being. However, they are also hazardous because they are poisonous to people, animals, and the environment if used improperly or without sufficient knowledge of their side effects. Pesticides can contaminate water, air, or soil and can accumulate in man, animals, and the environment. In addition, persistent pesticides can create potential future hazards to man and wildlife because residues may build up in the food chain and cause widespread contamination of the environment.

The basic legal authority for regulating pesticides is in (1) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135), as amended by the Federal Environmental Pesticide Control Act (FEPCA) of 1972 (7 U.S.C. 136), and (2) the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938, as amended (21 U.S.C. 301). Authority for administering FIFRA was transferred from the Department of Agriculture along with the responsible organizational elements to EPA on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA.

Because our earlier reports[1] indicated weaknesses in EPA's and FDA's efforts to protect man and his environment from the effects of harmful pesticides and because of the widespread concern about these effects, we reviewed EPA's policies and practices for pesticide registration and establishment of tolerances.

PESTICIDE REGISTRATION

Pesticides are regulated by the Federal Government to insure that quality products are available to the public and that when properly used, these products will provide consumers with effective pest control without unreasonable adverse effects on man or the environment. EPA is the Federal agency with primary responsibility for regulating pesticides.

EPA registers a pesticide when it determines that

--the pesticide's composition is such as to warrant its proposed claims (product efficacy),

--the pesticide's labeling and other material required to be submitted comply with requirements,

--the pesticide will perform its intended function without unreasonable adverse effects on the environment (product safety), and

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[1] Reports on "Environmental Protection Agency Efforts to Remove Hazardous Pesticides From the Channels of Trade" (B-133192, Apr. 26, 1973); "Pesticides: Actions Needed to Protect the Consumer from Defective Products" (B-133192, May 23, 1974); and "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (B-133192, Oct. 23, 1974).

--when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse effects on the environment.

(FEPCA defines unreasonable adverse effects as any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.) EPA also requires the registration number on the label to indicate that EPA has accepted the pesticide.

Registration is valid for 5 years and must, by law, be renewed at the end of this period, or it is canceled. EPA is required to review registered pesticides to determine if they are still safe and effective in the light of developing scientific data.

On October 21, 1972, FEPCA amended FIFRA to provide for more effective registration, regulation, labeling, manufacture, distribution, and use of pesticides. All FEPCA provisions must be effective by October 21, 1976. The most important change was that all pesticides, except those intended solely for export, be registered with EPA before distribution or sale rather than, as previously required, that only those sold in interstate commerce be registered. FEPCA provisions discussed in this report require EPA to

--establish regulations and guidelines for registering and classifying pesticides,

--register all intrastate and new pesticides and reregister currently registered interstate pesticides by October 21, 1976, in accordance with the newly established regulations,

--classify all pesticides for general or restricted use on the basis of the degree to which they adversely affect the environment.

PESTICIDE TOLERANCES

If a pesticide remains in or on food or feed, FFDCA requires that a tolerance (the maximum pesticide residue allowed in food) be established for that pesticide. Tolerances are established on the basis of data submitted by the petitioner on the nature, level, and toxicity of the pesticide's residues. The Registration Division in EPA's Office of Pesticide Programs establishes all tolerances for pesticide residues remaining in food either

under section 408 (pesticide chemicals in or on raw agricultural commodities) or section 409 (pesticide food additives) of FFDCA. A pesticide is classified as a food additive if it is applied to processed foods or if the concentration of the pesticide increases as the raw agricultural commodity is processed. Before EPA's existence, tolerances were established by the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare (HEW).

FDA is still responsible under FFDCA for enforcing tolerances. FDA tests samples of food to determine if any residues exceeding tolerance levels remain on the food, rendering the food adulterated. Adulterated foods may not be sold in interstate commerce.

SCOPE OF REVIEW

We reviewed EPA's policies and practices for registering and establishing tolerances for pesticides. We examined pertinent legislation, documents, reports, and records on evaluating pesticide safety and effectiveness; setting tolerance and residue levels; and registering, labeling, and residue testing of pesticides.

We interviewed responsible agency officials at EPA and FDA headquarters in Washington, D.C. We also obtained information from agency officials at EPA regional offices in Philadelphia, Atlanta, and San Francisco and from the Department of Agriculture headquarters in Washington, D.C.

In addition, we randomly sampled product files of 100 registered pesticides to determine the adequacy of EPA registration actions. A breakdown of our sample according to the type of pesticide follows.

	Number and percent
Insecticides	48
Rodenticides	3
Herbicides	16
Fungicides	11
Disinfectants	22
Total	100

The percentages are similar to those for all registered pesticides as shown on page 1 of this report. Our review of the sampled pesticides included

--an evaluation of their labels to determine if they complied with EPA regulations,

--an examination of the registration and tolerance files to ascertain whether the registrant provided sufficient data to show that the pesticide was not hazardous to man or the environment if used correctly, and

--a review to determine the timeliness and type of EPA reviews.

CHAPTER 2

ADEQUATE SAFETY AND EFFICACY DATA NOT AVAILABLE AT EPA

A pesticide's registration is required by law to be supported by sufficient evidence to show that it is safe and effective when used as directed. Before a pesticide can be registered, EPA requires the manufacturer-formulator to provide to EPA for its review various studies on the active ingredients in each type of pesticide to insure the pesticide's safety to man and the environment and its effectivess. EPA permits registration of pesticide products which are similar to previously registered products without submission of additional safety or efficacy data.

EPA does not have adequate assurance that man and the environment are protected because:

--The required studies for many registered pesticides being marketed have not been submitted to EPA.

--Studies are not required for pesticides as marketed, only for the active ingredients. There is little or no information on the long-term effects on man and the environment of those pesticides that combine two or more active ingredients.

--Some inert ingredients used in pesticide formulations may be hazardous to man or the environment,but EPA's testing requirements for inerts are less than those for active ingredients. Vinyl Chloride which was recently found to be a carcinogen is an inert ingredient.

EPA should evaluate the hazards associated with pesticides containing more than one ingredient as a basis for determining if pesticides as marketed should be tested. Also EPA should (1) reassess its policy on inert ingredient and develop appropriate guidelines for testing those that may present a health hazard and (2) require mutagenicity testing for pesticides processed under the FEPCA registration program.

SAFETY TESTING DATA NOT SUBMITTED

Our review of files of 100 randomly sampled pesticides showed that, contrary to EPA requirements, manufacturers have not submitted to EPA safety studies on many active pesticide ingredients. Without such studies EPA does not have adequate assurance that man is being adequately protected from possible pesticide hazards.

A primary purpose of the pesticide regulation program is to protect the public from injury and to avoid subjecting the public to the dangers of experimentation. EPA's policy is to evaluate the hazards associated with a pesticide's use to insure that only those that can be handled and used safely are registered. Some hazards evaluated include the pesticide's degree of toxicity (poison) and whether it may be oncogenic (causing cancer or other tumors), mutagenic (causing permanent genetic changes), or teratogenic (causing birth defects). It is also EPA's policy to evaluate whether a pesticide could (1) affect reproduction, (2) make another pesticide hazardous, or (3) combine with other chemicals to create a compound more hazardous than any of the resultant compound's original components. Because different formulations of the same pesticide behave differently, one formulation could be relatively safe while another could be toxic.

EPA officials said that the burden of proof is on the registrant for showing a pesticide's safety; consequently, EPA relies primarily on test data submitted by the registrant. To determine potential adverse effects on man, the registrant generally tests the pesticide on laboratory animals.

EPA requirements for safety testing to support pesticide registration have increased over the years to better protect man and the environment. The more important safety testing requirements are detailed in the table below.

Testing requirement	Date first required	Purpose of requirement
Acute toxicity	1954	Single exposure of animals to a chemical to determine the level that will result in mortality in 50 percent of the animals exposed.

Testing requirement	Date first required	Purpose of requirement
Subacute toxicity	1954	Multiple exposure of animals to a chemical to determine its toxicity over a period of 30 to 180 days, the most common period being 90 days.
Chronic feeding-oncogenicity (note a)	1963	Multiple exposure of the chemical during most of the animal's life to determine long-term toxic effects and whether the chemical will result in an increased number of tumors. The periods range as follows: 18 months for mice, 2 years for rats, and 2 to 7 years for dogs.
Reproduction	1963	A three-generation study with rats to determine if multiple exposure of the animals to a chemical will affect their ability to reproduce.
Teratogenicity	1970	A test to determine if exposure to the chemical will cause birth defects.
Mutagenicity	1972	A test to determine if exposure to the chemical will cause permanent genetic changes.

Many additional safety tests may be required depending on the circumstances under which the pesticide is used and its frequency and length of exposure to nontarget species such as man.

[a]Oncogenicity previously referred to by EPA as carcinogenicity.

Chemicals for which tolerances were set for residues in food were subject to all the requirements set out above from the date of the first requirement. There were 36 active-ingredient chemicals in our sample of 100 pesticides for which residue tolerances in food had been established. Our review of EPA's various toxicology and registration files and literature references for the 36 chemicals indicated that safety data was lacking as follows.

Type data	Chemicals lacking data	Percent of total
Acute toxicity	0	0
Subacute toxicity	0	0
Chronic feeding	7	19
Reproduction	7	19
Teratogencity	14	39
Mutagenicity	23	64

We provided a list of the sampled chemicals to EPA officials who verified that the data was not in their files. (See examples of pesticides with insuffient data on pp. 39 to 42.)

According to EPA, oncology data can, with suitable testing procedures, generally be obtained as an adjunct to the chronic feeding study; hence there should be oncology data for those chemicals with chronic feeding studies. However, the Registration Division's pesticide science officer said many available chronic feeding studies may not be sufficient for oncology review. He said that this is particularly true of feeding studies which use dogs. He explained that these studies usually cover only 2 years, whereas the possibility of an increase in tumor incidence could not be excluded unless the study covered most of the animal's life, or about 7 years.

The Registration Division's pesticide science officer said that he had formed a task force in January 1975 to determine what long-term tests EPA lacked for each active ingredient used in pesticide formulations. He said that registrants would be told which of their products lacked safety data and that these products would receive temporary registration for a period sufficient to satisfy data requirements. This means that an entire safety evaluation may not be completed until 2 or 3 years after a registrant is notified if tests such as a 2-year chronic feeding study are required.

Although pesticides without food tolerances are subject to some but not all of the safety data requirements

described on pages 7 and 8, required data for these pesticides was also lacking. For example, 23 active-ingredient chemicals were in the disinfectants in our sample. According to EPA's current testing requirements, disinfectants usually require both acute and chronic toxicity data. Although we found acute toxicity data on 20 of the 23 chemicals (neither we nor EPA officials could locate the file for 1 chemical) only 5 of the 23 had the required chronic toxicity studies. Thus, the effects, including cancer potential, of long-term exposure to these pesticides are not known.

EPA officials said that required safety data may not be available because (1) the pestcide was registered before establishment of the requirement, (2) an inadequate renewal review (required at 5-year intervals) was made and the data was not requested, or (3) the data could have been submitted but later lost during various moves and/or reorganizations.

Because of the absence of safety data for many chemicals which much of the population is exposed to daily in their food and environment, EPA cannot insure that the public is being adequately protected from possible pesticide hazards. We believe that EPA should not wait for FEPCA registration review to notify affected registrants that required safety data on their products is missing but should do so as soon as EPA identifies the deficiency and should set a deadline for submission. The registration of those pesticides for which data is not submitted by the deadline should be canceled until data is provided. In August 1975 an EPA official said that a list of pesticide chemicals lacking required data for FEPCA registration will be published in the Federal Register in the near future. He also said that a reasonable time will be allowed for each type study. If the data is not submitted within that time, the affected pesticide registrations will not be renewed.

Need for mutagenicity testing under FEPCA registration program

Although EPA has required mutagenicity testing since 1972, this data was not available for 64 percent of the agricultural pesticides in our sample (see p. 9), and EPA is not, except in unusual cases, requiring this testing under the FEPCA registration program. Because of the hazards presented by mutagens, we believe that mutagenicity testing would be necessary to protect the public and should be a requirement for FEPCA registration.

The Registration Division pesticide science officer said the mutagenicity testing requirment was not included under the FEPCA registration program because most independent laboratories do not presently have the capability to do such testing in live animals. However, it seems unlikely that independent laboratories would develop this capability without EPA enforcing this requirement.

The problem of mutagens in the environment was described in the Mrak Commission's report. The report stated that exposure of individuals to mutagens may lead to cancer and to birth defects. However, the report expressed greater concern for the descendants of exposed individuals, because changes caused by mutagens may lead to a wide range of abnormalities, mental retardation, physical and mental diseases, or many other inherited weaknesses and debilities to which man is susceptible. Since these effects may appear only in future generations when the damage is already irreversible, the Mrak Commission recommended (1) prompt identification of chemical mutagens to which the population is exposed and (2) that pesticides with mutagenic properties be rigorously restricted or banned unless thorough and impartial study convincingly demonstrates that the benefit outweighs the risk.

The Director of EPA's Criteria and Evaluation Divison said that live animals should be tested for mutagenicity. He explained that the best test involves feeding chemicals to test animals and determining if translocations result within the chromosomes of the animal's sperm. Translocation in the chromosomes would cause genetic changes in the animal's offsprings. The Director said that testing animals overcomes most of the objections to previous tests using cells in culture or insects; these test results cannot be readily related to man. He also said that the major objection to this test is its cost--about $23,000 per test. He added that he did not believe this cost excessive in light of the potential hazard to exposed populations.

We believe that EPA should expand its requirements under the FEPCA registration program to include live-animal or other suitable mutagenicity testing of appropriate pesticides.

PESTICIDES AS MARKETED ARE NOT BEING TESTED

Our review showed that, for the most part, EPA is requiring safety testing for only individual active ingredients and not for the pesticide as marketed which usually contains several ingredients. The combination of several

ingredients may cause harmful effects whereas the ingredients by themselves do not.

In our sample of 100 pesticides were 60 formulations containing 2 or more active pesticide ingredients. Except for some acute and subacute toxicity tests, EPA requires that safety testing be done on the individual ingredients only and not on the combined ingredients. Such testing does not insure that the pesticide as formulated will have the same long-term effects on man as do the individual ingredients.

EPA recognizes that chemicals in combination may have toxic effects which are greater than the effects of the individual chemicals. These are referred to as synergistic effects. For example, a 1972 study done for EPA by the National Academy of Sciences showed the following active ingredients when used in combination had synergistic effects on fish.

DDT --------- BHC	Parathion --- Malathion
Parathion --- Copper Sulfate	Carbaryl --- Malathion
Parathion --- Diazinon	Carbaryl --- Copper Sulfate
Parathion --- Methoxychlor	

In another test synergistic effects were demonstrated when mixtures of malathion, Phosdrin, and carbaryl were injected into chicken eggs. The mixture (1) caused deformed embryos at levels where single pesticides generally do not and (2) reduced the hatchability of eggs far more than did the individual pesticides.

EPA officials said that acute (short-term) studies in nonmammals, such as the foregoing, cannot be reliably correlated to results in man. One said there is no evidence to conclude that one chemical may combine with another to produce carcinogenic, teratogenic, or mutagenic effects in man or other mammals. The official also stated that he did not know of studies which would prove or disprove such interaction. He believed that little effort had been expended in this area to date.

Another official said that the cost of testing and the infinite number of chemical combinations that man is exposed to in his food and environment each day would preclude any possibility of testing all combinations. This official said that the burden for additional testing would fall primarily on the small manufacturer who generally would not be able to absorb the additional cost.

We believe that EPA has not sufficiently considered the area of synergistic interactions of pesticides. EPA should determine on a test basis whether chemicals that have proven to be synergistic in acute toxicity tests --such as those done on fish--may have long-term effects in mammals that are not revealed by testing the individual compounds. The result of this work would provide a basis for determining whether tests should be done on other chemicals which are combined in pesticide formulations.

EFFICACY DATA NOT IN EPA FILES

Efficacy data was not available in EPA files for many of the 100 pesticides reviewed. When data was available, it was often on individual active ingredients rather than on the pesticide as marketed. To carry out its responsibility to insure that only effective pesticide products are registered, we believe that EPA should have efficacy data on each pesticide product, not just on the individual active ingredients. Data on the pesticide product is necessary because different combinations of active and inert ingredients can change the efficacy of a product. EPA laboratory officials responsible for testing the efficacy of pesticides said that efficacy of a pesticide could be affected by such factors as the order in which chemical ingredients are combined, minor changes in the purity of the ingredients, and differences in the inert ingredients.

Pesticide Regulation Notice 69-8, issued on April 21, 1969, specified that for agricultural pesticides:

> "***Data are required to show that the proposed formulation can be used effectively and safely without resulting in illegal residues in or on food or feed. Data on the use of the active ingredients in other formulations will not serve as a basis for registration for mixtures."

Since the notice was issued, EPA has included in its draft guidelines, a similar but less specific requirement for all pesticide formulations.

We found efficacy data on only 42 of 93 (45 percent) pesticides sampled (efficacy data was not required for 7 of 100 because they were to be combined with other chemicals into a new pesticide which would then require efficacy data). We provided EPA a list of the 51 pesticides lacking data to determine if additional data could be found. These officials could provide us with no additional data on the

specific products sampled. One official said some data on similar products may be available for 12 of the 51 pesticides. He also said that many product files would have to be searched to determine if data was available.

The Chief, Efficacy Review Section, said that on several occasions he had been unable to locate efficacy data that he personally knew was previously available. He said that this necessitated writing to the registrant and having the data resubmitted. The official stated that he believed such data had been misplaced or destroyed as a result of a program to reorganize the registration files into files on efficacy, toxicology, and registration documents and correspondence. Another official said this program began in 1966.

An EPA official said that EPA does not plan to require efficacy data on currently registered agricultural pesticides because of the extent of data requirements and the limited registration period allowed by FEPCA. The official said that this waiver was made because of extensive use data on agricultural pesticides and because EPA believed that testing efforts should be concentrated on higher priority safety testing. The officials also stated that efficacy data would be required on other products such as home and garden products, and on new uses for existing pesticides.

Due to the variability of toxicity when various active and inert ingredients are combined, we believe that it is necessary for EPA to have efficacy data on registered pesticide products. EPA should take steps to insure that efficacy data is available. Currently, EPA has no evidence that at least 51 of the 100 pesticides in our sample are effective. Although EPA officials state that such data will be required during FEPCA registration for all but agricultural pesticides, efficacy data is not required in the registration regulations which became effective August 4, 1975.

Efficacy data on animal repellents

Before 1972 EPA registered animal repellents on the basis of testimonials--statements of satisfied users. Beginning in December 1972 this policy was changed, and registrants were required to submit objective data on the efficacy of their products. Registrants were given 1 year from the date of notification to provide efficacy data or the registration would be canceled.

Our random sample of 100 pesticides contained two animal repellents. The registrants had been notified of the new efficiacy requirement; however, neither had submitted satisfactory data as of March 1975.

One registrant was notified of the requirment during December 1972. The latest letter in the registration file is dated June 20, 1973. Adequate efficacy data had not been submitted at that time, and there was no indication that EPA followed up to obtain the data since that date.

The other registrant was not notified of the requirement until February 4, 1974. On December 9, 1974, the registrant submitted an efficacy study for a similar (not identical) repellent. In January 1975, EPA told the applicant that an efficacy study must be made using the registered product. No time limit was placed on submitting the study. As of June 1975, efficacy data had not been submitted. We believe EPA should not continue registrations of those products for which adequate data is not submitted within a reasonable time.

An EPA official said that more aggressive action had not been taken on the efficacy requirement for repellents because satisfactory test procedures were not available. He said that EPA is currently developing test procedures which may be satisfactory for general use in the near future.

PESTICIDES LACK ENVIRONMENTAL TESTING DATA

Test data necessary to insure that a pesticide will not adversely affect the environment has not been provided for many pesticides currently registered and marketed, and EPA does not generally require the submission of this information for pesticide uses registered before June 1970. Pesticides which have greatest impact on the environment are those that are applied to fields, pastures, and forests and which leach into ground water or which run off into waterways.

Requirements for environmental chemistry data were defined in Pesticide Regulation (PR) Notice 70-15 which was issued on June 23, 1970. An EPA official stated that environmental chemistry reviews are currently required for new pesticide registrations and for approving new uses for registered pesticides that are markedly different from existing uses. Environmental chemistry reviews were not made on registration renewals or on new registrations involving previously registered pesticide chemicals used for similar purposes. Also, these reviews will not be made under

the FEPCA registration program. EPA officials said this data will be required in subsequent registration renewal reviews. An EPA official stated that EPA has no system to follow up a registrant's compliance with EPA requests for environmental chemistry data and has no policy to cancel pesticide registrations when data is not provided.

Thus, according to EPA policy, environmental chemistry data is not required to be submitted for those pesticides registered before June 23, 1970, for use on fields, pastures, and forests and which may get into water, unless approved uses are added.

We selected certain of the PR Notice 70-15 requirements to determine if pesticides in our random sample of 100 complied with requirements. The requirements selected were studies to determine:

--The pesticide's degradation or decomposition (1) in soil, (2) in water, and (3) when exposed to light (photochemical degradation).

--Whether the pesticide destroys beneficial micro-organisms and the micro-organisms' effect on the toxicity and efficacy of the pesticide (micro-biological studies).

--Whether the pesticide leaches through the soil into ground water.

--Whether the pesticide moves from the application site in runoff water.

There were 32 pesticide chemicals in our sample for which environmental chemistry data was required. The extent to which environmental chemistry data has not been provided for these 32 chemicals is summarized in the following table.

Type of data	Number lacking studies	Percent of total
Degradation:		
Soil	11	34
Water	17	53
Photochemical	17	53
Microbiological	16	50
Leaching	24	75
Runoff	24	75

The absence of required data is illustrated for the following pesticide chemicals.

2,4-D dimethylamine salt--This is a widely used herbicide primarily for controlling weeds along canals and irrigation ditches. During 1972, about 22.5 million pounds were produced in the United States. An EPA environmental chemistry review of this pesticide completed in April 1973 showed that several studies were lacking or inadequate, including

--a microbiology study under anaerobic (oxygenless) conditions,

--a photochemical degradation study with lake water,

--leaching, adsorption, and runoff studies for ditchbanks, and

--adsorption studies with hydrosoil (mud).

The writeup on this review stated that additional data was needed to support the registration but could not be requested from the registrant at that time and referred to an internal EPA policy memorandum dated April 28, 1972. The writeup further stated that EPA hoped to ask for PR Notice 70-15 (requirements for environmental chemistry) data in the future. The April 1972 memo states that:

> "The requirement of any necessary data on established chemicals is to be done on a blanket basis through direct communications to the manufacturer. Requirements of this type should be handled as a separate issue from individual product registration. The acceptance of additional products or additional uses for established chemicals is not to be held up pending development of such data."

An EPA official said that as of March 1975, this data had not been requested for 2,4-D dimethylamine salt.

Also, we found that even when EPA did request data for previously registered pesticide chemicals, it often was not furnished as indicated in the following example.

Guthion--Guthion is a broad spectrum insecticide which is used to control insects in over 50 food or animal feed crops. During 1971 about 2.7 million pounds were applied to crops in the United States. In 1972 EPA reviewed a request to register guthion for a new use. An EPA letter dated March 27, 1972, advised the registrant

that an environmental review indicated that chemistry data was inadequate. The letter stated that the data, including the 6 studies listed above, should be submitted within 1 year. Two environmental chemistry reviews completed during January and March 1975 showed that none of the requested guthion data had been provided.

Many pesticides have never been reviewed

Because of the foregoing examples, we requested that the Environmental Chemistry Review Section review a list of the chemicals which have tolerances for pesticide residues in food and animal feeds and identify those that have never undergone environmental chemistry data review. From this list of approximately 250, EPA identified 120 chemicals (about 50 percent) which have never undergone review.

The 120 pesticide chemicals represent a significant volume of pesticides used in the United States. Failure to obtain environmental data on many widely used pesticides does not insure that EPA is fulfilling its mandated responsibility to protect the environment from unreasonable adverse effects. We believe EPA should revise its policy and require complete environmental chemistry data for all pesticides applied to fields, pastures, and forests, regardless of the date of the pesticides' original registration.

NEED TO ESTABLISH POLICY FOR REGULATING INERT INGREDIENTS

In addition to the active ingredients in pesticide formulations, there may also be other ingredients, which are described as inert--ingredients which by themselves will not prevent, destroy, repel, or mitigate a pest. These ingredients are generally added as solvents, thickeners, propellents, or other uses to enhance the effectiveness or to facilitate the use of the pesticide. Inert ingredients range from innocuous substances, such as water, sugar, and salt, to toxic chemicals, such as vinyl chloride and formaldehyde.

FFDCA requires that toxic substances which remain in or on food or feed must have a tolerance or must have been exempted from the requirement of a tolerance. Many inert ingredients with varying degrees of toxicity have been exempted from the requirements of tolerances. EPA does not require the same safety evaluation for inerts as are required for active ingredients even though residues may remain in or on food or feed. Also, FDA does not test food for residues of inert ingredients.

The necessity for thoroughly evaluating the potential danger of inert ingredients is demonstrated by the disclosure in 1974 by 2 pesticide manufacturers that vinyl chloride, an inert propellent used in some pesticide aerosols, causes a rare form of liver cancer. After the disclosure of vinyl chloride's carcinogenicity, EPA evaluated its use in aerosols and found that it presented an imminent hazard in the home, food-handling establishments, hospitals, or enclosed areas. During April 1974 EPA requested manufacturers to recall pesticides containing vinyl chloride. This recall was followed in January 1975 by a cancellation order for 32 pesticides containing vinyl chloride.

Vinyl chloride has been produced commercially in the United States since 1939; by 1974 production was in excess of 7 billion pounds annually. The public has been exposed to this compound in the work environment of chemical plants and from pesticide and cosmetic aerosols.

The overall health effects of this exposure will not be fully known for several years because the cancer incubation period is believed to be 15 years or longer. The chances of eliminating potentially hazardous inert ingredients in pesticides would be enhanced if satisfactory long-term testing were required.

EPA is not developing regulations or guidelines governing safety evaluation of inert ingredients equivalent to those being developed for active ingredients. (See pp. 7 and 8.) The review process for inert ingredients used on food and feed crops was described in an internal Toxicology Branch memo dated October 1972 as follows:

> "Toxicologists in the past have not considered the inerts to be in the same class of poisons as are pesticides; accordingly they have tended to be much more lenient in their requirements for the demonstration of safety of residues of these compounds. A determination of exemption is made more on the basis of lack of demonstrated hazard than of demonstrated safety.
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> * * * * *
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> "***the process for exempting materials from the requirements of tolerances is still a seat-of-the-pants operation. I think we should either set up a Standards Committee to develop criteria, or we could promulgate [the criteria described in] this memo***."

The criteria discussed in the memo included a determination of safety on the basis of the material's

--structural similarity to a compound whose toxicity has been adequately defined,

--tolerance under food additive regulations,

--presence on FDA's "generally recognized as safe" list,

--low residue level on food or feed, and

--small percentage of the total pesticide formulation.

An EPA official told us that the foregoing criteria were used to evaluate inert ingredients.

If the inert ingredient could not be exempted under the foregoing criteria, the registrant might have to provide EPA with 90-day subacute (in 2 species) and 2-year chronic feeding (in 2 mammalian species) studies.

Provisions for other types of tests, such as 3-generation rat reproduction, teratogenicity, and mutagenicity studies, which are required for active ingredients, are required only on a case-by-case basis.

Some of the exempted inert ingredients are relatively toxic and EPA requires that they be applied a number of days before harvesting to allow the pesticide residue to dissipate. For example, EPA requires that the inert ingredients maleic acid and maleic anhydride be applied no later than 21 days before harvest; some active ingredients have no limitations on when they can be applied and in some cases can be applied after harvest. An EPA official said that if the preharvest interval was not observed, the residues may be greater than the submitted safety data would justify. Another EPA official said that FDA does not test for such residues, and in many cases residues for inert ingredients could not even be determined because analytical methods have not been developed.

The Chief, Chemistry Branch, stated that exemptions should be limited to those materials whose toxicity allows safe use under a wide range of conditions with widely varying residue levels. He also said that tolerances should be established for those relatively toxic inert ingredients whose safe use is predicated on imposing a rigid use pattern to insure that residues will be below a certain level.

--The report does not recognize that, generally, standards of efficacy and safety are not clear cut and that EPA must therefore exercise reasonable judgment in developing standards and regulations while considering the social and economic costs of regulation to all affected sectors of society.

--GAO's observation of the program was during a period of tremendous change and the report does not adequately reflect major changes in organization, procedures, and regulations which, although too new to evaluate, should correct many of the problems identified by GAO.

The Federal Government regulates pesticides to insure that quality products are available to the public and that when used properly, these products will provide consumers with effective pest control without unreasonable adverse effects on human health or the environment.

We agree with EPA that generally standards of efficacy and safety are not clear cut and consequently judgment is needed in regulating pesticides. Questions in the report pertain to instances where, although required, sufficient data has not been obtained to enable EPA to make a reasoned judgment on whether the potential adverse effects are outweighed by economic considerations.

We acknowledge that our review was made during a period of change, but appropriate reference has been made in the report to any changes affecting the matters discussed therein. Also, most if not all the requirements discussed in the report and contained in the new regulations dated August 4, 1975, had been in effect before that time. Furthermore, in view of EPA's past performance where requirements were ignored or circumvented, we agree with EPA's comment that, it is too early to evaluate the success of changes made.

EPA generally agreed with our recommendations and pointed out certain corrective measures which had already been taken. With regard to deficiencies in supporting data, EPA stated that

"***in accord with the requirements of amended FIFRA,***guidelines have been developed 'specifying the kinds of information which will be required to support the registration of a pesticide...' ***in preparation for reregistration, the data base supporting the safety of each registered active

ingredient has been reviewed, and any gaps have been identified. If there are gaps which require studies of short duration, products containing an affected chemical will not be reregistered until the gap is filled. If missing data require long-term studies, affected products will be granted non-renewable reregistration for a period reasonable to allow development and review of the missing data.

"If the data are not submitted, the registrations involved will lapse. If data are submitted, then the acceptability of the registration will be judged on the basis of the data."

As for requiring the full range of data to support reregistration, EPA stated that it had considered and rejected this approach because EPA itself and industry were faced with severe resource and time constraints for reregistration. EPA said that it had thus determined to concentrate resources in the area of highest priority, which is potential human hazard. EPA also stated that the remaining, less critical gaps in efficacy and environmental data will be addressed in the course of future renewals, at which time all products will be subject to all data requirements current as of the renewal date.

If properly implemented, EPA's new registration regulations and procedures should correct many of the data deficiencies noted in the report. However, collecting mutagenicity safety testing data (see p. 10), as well as efficacy and environmental chemistry data, will be considerably delayed. This delay is not desirable because of:

--The potential health hazards of public exposure to pesticides where the mutagenicity effects have not been assessed.

--Past exemptions granted registrants subject to these data requirements; for example, environmental chemistry data has been a requirement for pesticides used on fields, pastures, and forests and which may get into water, since 1970; however, EPA has waived the requirement for pesticides registered before that date.

The time required to develop the data which is being waived is relatively short compared to the 2- to 3-year period which will be required to obtain chronic feeding studies for some pesticides. In waiving the data requirement until the product comes up for 5-year renewal could result in such data not being obtained for a period of 7

to 8 years (for example, 2 to 3 years to complete a chronic feeding study and up to an additional 5 years before the 5-year renewal review anniversary is reached). This does not appear consistent with EPA's mandate to register pesticides which will not cause unreasonable adverse effects to man or the environment, because potential adverse effects cannot be evaluated until appropriate studies have been done.

In response to our comments on inert ingredients, EPA stated that

> "***many substances that appear as inert ingredients in pesticides are extremely common in other uses as well, and there is a potential interface with other existing regulatory programs which must be considered. If Toxic Substance legislation is passed, it may well provide the most appropriate mechanisms for regulating many substances which occur as inert ingredients in pesticides. There is, in any case, a possibility of significant regulatory overlap.
>
> * * * * *
>
> "***the Agency has the authority to require, on a case-by-case basis, testing of inert ingredients which may be hazardous. This authority has been exercised frequently, and during just the past six months in connection with***[11] inert ingredients,***"

Although EPA's assertion that inert ingredients may be more appropriately regulated under other legislation may be correct, this legislation has not been passed, and until it is and such a program becomes operable, inert ingredients must be regulated under the existing pesticide program. We agree that EPA has authority to require testing of potentially hazardous ingredients. The data requested by EPA on the 11 inert ingredients mentioned above was not the full range of tests that would be required of active ingredients used on food or feed crops. Only subacute (90-day) feeding studies were requested on nine inerts and chronic (2-year) feeding studies were requested on two. No teratogenicity, reproduction, or mutagenicity studies were requested on any of the 11 inert ingredients. Again, we do not believe that EPA can assess the hazards associated with a chemical's use unless appropriate studies are performed.

On our recommendation concerning safety and environmental testing of pesticides as marketed, EPA stated that it had

considered such an approach but had rejected it because of the economic impact that would result. EPA pointed out that combinations of ingredients in formulated products are by no means the only combinations of pesticide chemicals to which man and the environment are chronically exposed. As soon as a pesticide is released into the environment, complex processes of chemical combination and transformation begin. As is stated in the National Academy of Sciences 1975 publication, Principles for Evaluating Chemicals in the Environment, "there are so many different possibilities for potential interactions that it is unrealistic to demand that all of them be tested in advance."

EPA's acknowledgement that the interaction of pesticides and other chemicals in the environment is a matter of concern, we believe, supports our recommendation that EPA needs to consider testing pesticides as marketed. EPA's statement that all interactions cannot be tested should not be a basis for total inaction. The acute testing that EPA currently requires for some formulated pesticides does not address the problem of long-term effects such as cancer, mutagenicity, or impairment of reproductive capacity. The logic of not testing pesticides as marketed is far from convincing, particularly from the aspect of consumer protection.

In considering the need for long-term testing of pesticides as formulated, EPA should minimize overall economic impact to the pesticide industry by establishing guidelines which control the need for testing. Factors that should be considered are the pesticides' persistence, use patterns, and volume of use.

CHAPTER 3

MANY LABELS DO NOT COMPLY WITH EPA REQUIREMENTS

Many pesticide products on the market are misbranded. By law, a pesticide is deemed to be misbranded when the label does not contain precautionary statements adequate to protect man and the environment. Also, it is unlawful for any person to hold, distribute, sell, or offer for sale misbranded pesticides. EPA is responsible for enforcement of the law.

In our sample of 100 registered pesticides, we found many instances where required precautions were not included on the labels or where final printed labels had not been submitted to EPA. In some cases the absence of required material did not permit EPA to determine if precautions for bees, birds, fish, and wildlife were required. EPA officials advised us that (1) statements missing from the labels resulted from oversights or (2) registrations and/or labels were approved on the condition that required label statements would be added.

EPA officials also said that EPA did not have sufficient manpower to follow up and insure tnat requested labeling changes were made.

PESTICIDE LABELS LACK PROPER BEE, BIRD, FISH, AND WILDLIFE PRECAUTIONS

EPA guidelines require that if a pesticide may cause a hazard to bees, birds, fish, and/or wildlife, precautionary statements are required which specify the nature of the hazard and how to minimize or prevent injury, damage, or death to these nontarget species. The type of precautionary statements required are dependent on the toxicity of the pesticide to exposed species. The toxicity of the pesticide is determined by tests conducted by the applicant/registrant or from data available from published studies.

Our random sample of 100 pesticides contained 28 agricultural pesticides whose use would result in considerable environmental exposure and, therefore, would require bee, bird, fish, and other wildlife precautions. Of the 28 agricultural pesticides, we found and EPA officials agreed that 22 (79 percent) had one or more of the following shortcomings.

	Bee	Fish	Bird	Other wildlife
Precaution missing	5	3	6	2
Precaution was inadequate	3	1	5	0
No data in EPA files to determine precaution requirements	[a]2	1	8	0
	10	5	19	2

[a]No data on one chemical which was in two pesticides.

Bees

Bees are of economic importance as honey producers and crop pollinators. Pesticide poisoning of bees is a major problem of beekeepers. The importance of bees was discussed in a 1973 report prepared by the House Appropriations Committee investigative staff. The report stated:

> "***Loss of honeybees, for whatever reason, means a loss in pollination; and at least 90 important crops grown in the United States are dependent, to a large degree, on honeybees for pollination. Severe loss of bees resulting from pesticide poisoning can, therefore, mean a serious reduction in yield of those crops.***
>
> "Without the honeybee, melon growers would have no crops to harvest. Producers of alfalfa seed and other seed crops would have very poor seed set without bees to pollinate their plants. Deciduous fruit and nut crops are dependent also upon bees for pollination.***"

Deciduous fruits and nuts include apples, peaches, plums, pears, cherries, almonds, and walnuts.

Bees may roam up to 5 miles from their hives. The extent of pesticide damage to a colony is affected by such factors as the number of bees from the colony in or near a treated area, the time of day the pesticide is applied, the method of application, the wind drift, and the toxicity of the pesticide.

To prevent and reduce damage to honeybees and other pollinating insects, Pesticide Regulation Notice 68-19, issued on November 29, 1968, required registrants to include labeling statements for designated pesticides which were toxic to bees. This notice required that the bee statement

be added to approved labels as they were revised or, at the latest, when the labels were submitted for registration renewal.

Honeybees killed by accidental exposure to the pesticides parathion and carbaryl, North Collinston, Utah.

CREDIT: Agricultural Research Service, Department of Agriculture, M.D. Levin.

The identification and proper labeling of pesticides toxic to bees should help minimize the Government's expenditures under the Beekeepers Indeminity Payment Program authorized by the Agricultural Act of 1970 (7 U.S.C. 135b note). This program provides for reimbursing beekeepers who, through no fault of their own, lose bees exposed to pesticides registered by EPA. As of June 30, 1974, about $13.3 million had been paid under the program. Estimated obligations for fiscal years 1975 and 1976 were $1.8 and $3.0 million, respectively.

EPA identified 87 pesticide chemicals which were highly or moderately toxic to bees and which required label precautionary statements. One precaution states that the pesticide is "highly toxic to bees exposed to direct treatment or residues on crops," whereas the other states that the product is "toxic to bees and should not be applied when bees are actively visiting the area." Thirteen of the 28 agricultural pesticides in our random sample contained chemicals which required bee toxicity precautions. Labels for 5 of the 13 (38 percent) did not contain a bee toxicity precaution and 3 others (23 percent), although they contained bee statements, did not, according to EPA officials, contain the proper precaution.

The types of label statements required for each chemical in a pesticide product are summarized in EPA's Compendium of Registered Pesticides. EPA officials said its reviewers used the compendium to insure that required statements are included on each pesticide's approved label. We found that the compendium did not have bee toxicity precautions for 28 of 63 listed chemicals and that 1 that was listed had the wrong precaution. We also found that another 22 chemicals used in pesticides which are toxic to bees were not listed in the compendium. EPA officials told us that if the bee statement were not included in the compendium, the reviewers would probably overlook the need for the statement. These officials also stated that the compendium is deficient in certain data areas because there is insufficient assigned staff--a total of six--to keep it updated in a timely manner.

We informed EPA officials about the eight pesticides in our sample which did not contain the required bee statement or which contained an incorrect bee statement. As a result, EPA sent letters to registrants requiring that the proper bee statement be placed on the labels of five sampled pesticides. An EPA official said the Agency did not send letters to the other three because EPA has not reviewed the products since Pestidice Regulation Notice 68-19 was issued.

When EPA establishes a new requirement, it does not review those pesticides already registered to insure compliance with the requirement until EPA renews these pesticides' registrations; renewal may not occur for several years. For example, EPA had not reviewed 40 percent of the pesticides in our sample for over 6 years and, therefore, it could not insure that changes were made. We believe that EPA should implement a procedure requiring that pesticides reviewed before the effective date of a labeling requirement be reviewed within 1 year of the effective date for compliance with the new requirement.

Bird, fish, and other wildlife

FIFRA requires precautionary statements on the labels of pesticides which may cause a hazard to birds, fish, and/or other wildlife. The statements define the nature of the hazard and appropriate precautions to warn of potential accident, injury, or damage to nontarget species.

In the 28 agricultural pesticides included in our sample, 15 were not properly labeled. Of the 28, 10 (36 percent) did not have 1 or more required bird, fish, and wildlife precautionary statements, and 6 (21 percent) had inadequate precautionary statements. In addition, EPA files on eight (29 percent) lacked bird and/or fish data necessary to determine whether precautionary statements were needed. EPA officials stated that missing or incorrect precautionary statements on pesticides on which data was available were probably due to errors on the part of the reviewers.

In May 1975 an EPA biologist said that bird and fish toxicity data was not available on many chemicals used in pesticide formulations which were required to have such data. We requested EPA to review the list of about 1,800 pesticide chemicals; EPA officials identified 230 and 170 chemicals on which EPA did not have required bird and fish data, respectively.

Although EPA's policy has been to require fish, bird, and wildlife data, this requirement was waived before August 5, 1975, for those chemicals which

--are ingredients in pesticides that have been marketed for several years or

--are ingredients in new pesticides which are registered because of their similarity to previously registered products. (These are known as established use pattern registrations.)

EPA officials said that this waiver of requirements has been EPA policy for several years. The policy was formalized in an internal memo dated September 5, 1974, which stated:

> "***unless the data lack is serious enough to pull similar products from the files and impose the same requirements on all registrants, we cannot legally require the second or hundredth registrant to compile such data."

Adherence to such a policy appears to be at variance with FIFRA, as amended, which states that

> "The Administrator shall register a pesticide if he determines that***when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

Such a determination cannot be made if the registrant is not required to submit necessary data.

The biologists responsible for determining whether fish, bird, and wildlife statements are needed on a pesticide's label rely primarily on an EPA Biologists Compendium (not the same compendium previously discussed) in their work. EPA biologists said the compendium was the quickest and most convenient reference source. They also said the compendium contained many errors and had not been significantly updated in the last 2 years. One biologist estimated that it would take two biologists working 6-day weeks about 6 months to correct and update the compendium. EPA currently does not have any professional or clerical staff assigned to do this work. It would appear that an accurate and up-to-date compendium would be a necessity for EPA to effectively insure that all pesticides registered are properly labeled and contain appropriate precautionary statements on potential hazards to birds, fish, and other wildlife. An EPA official said that bird and fish data will be a requirement for FEPCA registration.

OTHER LABELING DEFICIENCIES NOTED

We also reviewed the registration files and labeling of the sampled pesticides to determine the extent of compliance with certain requirements. We noted several deficiencies which we discussed with EPA officials. These deficiencies and the number on which EPA took action are detailed below. EPA officials said the Agency did not act on the remaining deficiencies because they were not considered serious or because the products were being canceled.

Type of deficiency	Number of pesticides: Subject to requirement	Number of pesticides: With discrepancies	Percent with discrepancies	Number on which EPA took action
No container disposal statement	64	15	23	5
Inappropriate disclaimer	100	8	8	1
Confusing or contradictory statement	100	5	5	1
No statement for residual insecticide	5	3	60	0
Final printed label not furnished	100	32	32	0

The lack of followup capability in EPA is demonstrated in two areas. The first relates to EPA's procedure of approving pesticide registrations on condition that certain defects in the label will be corrected. EPA's form letter for such labels states that:

> "***certain defects, given below, have been noted. These corrections must be incorporated when the finished labeling is prepared. Five copies of the finished labeling must be submitted."

As noted in the table above, files of 32 percent of the pesticides included in our sample did not contain the final printed label as required. EPA does not maintain followup files to insure that periodic and timely followup action can be taken. Also, EPA officials stated that they do not have sufficient manpower to follow up and insure that requested labeling changes were made.

Secondly, EPA has no system to insure that PR notices issued by it or its predecessor, the Department of Agriculture, have been complied with. PR notices are statements directing the manufacturers, formulators, distributors, and registrants of economic poisons (pesticides) to take certain action on their pesticide registrations. For example, PR Notices 68-14 and 70-12, respectively, provide:

PR Notice 68-14

"***Because of the likelihood of contamination of food, residual type insecticides should not be used in the edible products area of food processing plants.

"Labeling for products containing residual insecticides with directions for use in any food processing plant whether stated in general terms or specifically must bear the following statement in a prominent position: 'Do not apply in the edible products areas of food processing plants'."

PR Notice 70-12

"In reviewing formula data submitted for sterilizers, sporicides, germicides, disinfectants and sanitizers, it is apparent that certain manipulations, both physical and chemical in nature are required for successful compounding. In many cases these are not described with sufficient clarity, so that reliable evaluations as to precise replications can be made insofar as efficacy and safety are concerned.

"As an added public protection measure, all applications for the registration of new sterilizers, sporicides, germicides, disinfectants and sanitizers must be accompanied by:

a. a complete statement of formula listing the percentages by weight of all ingredients present as set forth in PR Notice 67-3 and on the reverse side of PR Form 9-199;

b. a complete description of the production control procedures employed; and

c. the analytical chemical methods used therein and shown to be applicable to each formula proposed.

"This same information must be submitted for existing registrations on such products within six months from the date of this notice."

As noted in the table above three of the five pesticides in our sample subject to PR Notice 68-14 did not contain the

(c) The product of this review is a 'Label Guidance Package', specific to the particular batch, itemizing label text and format requirements.

(d) The Label Guidance Package for each batch will be sent to all registrants of affected products, to aid them in developing acceptable labels for submission.

(e) The Label Guidance Package will also be provided to the reviewers to use as a reference standard in considering applications for products in each batch.

"Another significant change has been made in the regulations, which now require submission of final printed labeling prior to acceptance of the application, whether for new or amended registration. This should eliminate altogether the problem addressed by GAO's second recommendation."

We recognize that EPA is in the process of changing requirements for the FEPCA registration program. However, as of August 1975 we were not able to evaluate these changes because they had not been implemented. Also, a list of pesticide chemicals lacking required data had not been published by EPA and the Label Guidance Package for each batch was not completed or available for GAO review. Furthermore, the labeling deficiencies discussed in this report were items which were at variance with EPA written policy. We cannot conclude from our review that a written requirement in EPA regulations or guidelines will be appropriately enforced.

CHAPTER 4

BETTER ASSURANCES NEEDED THAT PESTICIDE RESIDUES IN FOOD ARE SAFE

FFDCA requires that a tolerance (the maximum pesticide residue concentration allowed in food) be established for all pesticides which remain in or on a treated food. While EPA is responsible for establishing these tolerances, FDA is responsible for insuring that residues do not exceed tolerances.

Pesticide residues in food and feed may be unsafe because EPA established residue tolerances without enough safety or residue data and because EPA does not require the submission of test data when new test requirements are established. In addition our review showed that:

--Tolerances were not periodically reviewed to insure that they were supported by data meeting current EPA requirements.

--Human exposure to a pesticide from all foods may have exceeded the acceptable daily intake--daily intake of a substance which appears to be without appreciable health risk.

--FDA tests for about 90 of the over 230 residues in food. FDA could not insure that the remaining 140 do not exceed approved tolerance levels.

In addition, many pesticide tolerances were established before several important safety tests were required. EPA does not periodically review the adequacy of data supporting already established tolerances and does not require the submission of test data when new safety test requirements are established. Thus, safety data such as teratogenicity, mutagenicity, and reproduction studies have not been provided by the registrants to support the safety of some established tolerances.

NEED TO PERIODICALLY REVIEW TOLERANCES

Although requirements for safety data required from registrants for establishing more recent tolerances have been steadily strengthened (see pp. 7 and 8), EPA has not implemented a program to periodically reevaluate the adequacy of existing tolerances in terms of current requirements. The acting Chief, Toxicology Branch, said that tolerances

are reassessed only when a petition is filed by a registrant requesting additional tolerances for new uses of the pesticide or as new studies become available. EPA does not normally require registrants to submit test data for existing tolerances when it establishes new safety test requirements.

Consequently, adequate data is not available to establish the safety of many current tolerances, and data on the residues themselves remaining in or on food may be inadequate or lacking. Also, we found instances where total human exposure to a pesticide in food may exceed the acceptable daily intake; this may be the case for many other pesticides. Missing safety and residue data are not always required and tolerances exceeding the acceptable daily intake are not reduced when subsequent tolerance petitions are reviewed.

Inadequate safety data

Carcinogenic, teratogenic, and mutagenic tests have not been completed to support the tolerances for many of the 36 pesticide chemicals with food or feed tolerances included in our sample. (See p. 9 for listing.) In addition, we noted several cases where tolerances for additional uses have been granted for a pesticide after a new data requirement was established without submission of such data. The following examples illustrate this point.

Example 1

As of February 1975, residue tolerances for the insecticide carbophenothion had been granted for over 50 foods. Carbophenothion tolerances were first established in the 1950s when mutagenicity and teratogenicity studies were not required. EPA did not, however, require that the manufacturer/registrant submit teratogenicity or mutagenicity studies when other carbophenothion tolerances were established after requirements for these studies were adopted; as a result, studies have never been submitted.

In addition, EPA did not establish a finite (measurable) residue tolerance for carbophenothion in milk even though its policy is to do so. Tolerances were established in 1963 for carbophenothion in almond hulls, sugar beet tops, citrus, and forage, all of which may be fed to diary cattle. EPA was aware that residues of 0.002 parts per million (ppm) would occur in the milk of dairy cattle eating feed containing as little as 3 ppm carbophenothion.

In October 1973 an EPA chemistry reviewer said feeding data showed that appropriate residue tolerances were required to cover residues that may occur in milk, meat,

and meat by-products. Tolerances were established in meat, but no tolerance has been set in milk. EPA regulations state that when data shows that finite residues may occur in milk from feeding a treated raw agricultural commodity to dairy cattle, a tolerance will be established on the raw agricultural commodity only if, on the basis of toxicological and other data, a tolerance can also be established for the finite residues in milk.

We believe EPA should enforce its requirements for the submission of mutagenicity and teratogenicity studies for carbophenothion. We also believe that EPA should establish a finite tolerance for carbophenothion in milk if supported by toxicological data, or the tolerance for residues in feed for dairy cattle should be canceled.

Example 2

Many tolerances for arsenical (arsenic-containing) pesticides were established in March 1955 as a result of FDA hearings--known as the Spray Residue Hearings of 1950. These included tolerances for lead arsenate, calcium arsenate, sodium arsenate, magnesium arsenate, and copper arsenate, which are used on a variety of crops.

In December 1969 the Mrak Commission recommended that exposure to certain persistent pesticides, including arsenicals, be restricted to specific essential uses which will create no known hazard to man. PR Notice 70-8, issued in March 1970, stated that additional teratogenic studies were needed for the arsenical pesticide, cacodylic acid (dimethylarsenic acid).

EPA established tolerances for residues of cacodylic acid in cottonseed and cattle in January 1972. Teratogenic data was required beginning in 1970. An EPA toxicologist reviewing the petition discounted the existing teratogenic studies because they were done on tadpoles rather than on a mammal. Although teratogenic studies were not submitted, EPA established a tolerance for cacodylic acid without requesting submission of such studies. Our review of the tolerance petition indicates that no additional teratogenic studies or references to such studies were submitted by the petitioner.

The above toxicology review was completed in July 1971, 2 months after publication of an article in a scientific periodical, the Archives of Environmental Health, linking sodium arsenate to birth defects in golden hamsters. EPA apparently was not aware of the study until a citizen submitted it in February 1973 as the basis for objections

to setting permanent tolerances for sodium and potassium arsenite in cattle and horses. After reviewing the submitted study and an earlier study also involving hamsters, an EPA toxicologist stated that "there is no doubt that relatively high doses of sodium arsenate. . .injected intravenously on the 8th day of gestation to pregnant females induced malformations in the golden hamster." He discounted the significance of the report, however, because the compound was not administered in a manner parallel to the normal human intake--oral ingestion. In spite of its own requirement for teratogenic study and the question of arsenical exposure causing birth defects, EPA again did not request additional data. EPA established permanent tolerances for sodium and potassium arsenite in cattle and horses on June 6, 1973.

In a letter to GAO dated April 1, 1975, EPA said the exposure level at which cacodylic acid will cause birth defects is not known, and that on the basis of available information, cacodylic acid does not appear to be an essential chemical for any of its registered uses. EPA stated that technically it was at fault in granting a registration in March 1972 for cacodylic acid on cotton and that a moratorium on the registration of arsenical pesticides should have been in effect.

EPA also wrote that:

> "Based solely on scientific grounds, as of March 22, 1972, the PRD [Pesticide Registration Division] apparently had insufficient evidence to object to the registration of CA as a cotton defoliant. However, it is also reasonable to conclude that EPA should have considered this action in light of (1) PR Notice 70-8 and (2) that the Special Pesticide Review Group had just made its recommendations as to the status of uses of arsenic containing pesticides. In the final analysis however, all presently registered uses of arsenical pesticides will be examined and evaluated, with recommendations set forth, by an in-depth review [being] made by our Criteria and Evaluation Division."

The continued registration of arsenical pesticides for nonessential uses is highly questionable, particularly in light of disclosures by two large chemical companies that employees in their arsenic-producing plants have an increased incidence of cancer. We also believe that EPA's position that it "had insufficient evidence to object to the registration" is contrary to the intent of FIFRA which

places on the registrant the burden of proving that a pesticide is safe. Because EPA believed that a valid teratogenic study had not been made, EPA could have denied registration until the study was provided. If EPA, in its review of cacodylic acid and other arsenicals, finds that continued registration is required, we believe that complete safety studies should be obtained by October 1976 before the pesticides are reregistered.

Inadequate residue data

During 1950 the Spray Residue Hearings were held to review data on the safety of, need for, and residues of pesticides used on raw agricultural commodities. As a result of the data accumulated during the Spray Residue Hearings, tolerances were established on March 11, 1955, for 28 pesticides used on about 50 crops.

Our review of the residue data submitted in support of the tolerances established for residues on 10 crops showed that at the time tolerances were established, residue data was not available for most of the crops. Also, some tolerances were established without considering technical and research advances in residue testing made between 1950 and 1955. As shown by the following table, few of the tolerances established accurately reflected the available residue data.

Crop	Total tolerances	Residue data not available	Tolerance differs from data		Tolerance reflects residue data
			Above	Below	
Apples	20	8	5	5	2
Beans	16	10	3	3	0
Celery	12	8	1	3	0
Corn	13	11	1	0	1
Lettuce	13	11	1	0	1
Peaches	16	8	3	4	1
Peas	12	10	2	0	0
Spinach	11	8	2	1	0
Strawberries	15	13	2	0	0
Tomatoes	15	4	7	3	1
	143	91	27	19	6

Of the 52 crop uses for which some residue data was available, 27 tolerances were set at residue levels above the corresponding data. For example, tolerances for methoxychlor were established at 14 ppm in beans and lettuce--about 100 times greater than expected residues which were 0.15 ppm or less. It is EPA's policy to set tolerances at the maximum

residues likely to occur from proper application provided they do not exceed acceptable safety levels. Tolerances set at artificially high levels may unnecessarily subject the public to pesticide residues resulting from misapplication. The possibility of excessive residues is of added importance because the safety of the higher levels has not been assessed, and FDA does not always test for residues in their enforcement program.

In contrast, 19 tolerances were established at levels lower than the maximum residues found. For example, a tolerance of 7 ppm combined fluorine was established on apples, although residue data indicated that residues on washed fruit could be as high as 31.4 ppm. Setting tolerances at levels considerably below the maximum residues found may result in residues that exceed the tolerance even though the pesticide was applied according to label directions.

Acceptable daily intake of pesticides not considered

EPA determines the acceptable daily intake for residues of each pesticide which may be present on agricultural commodities. Acceptable daily intake for man is usually 1 percent of the pesticide concentration which was found to have no toxic effect in the most sensitive animal species tested. Because inhibition of cholinesterase by organophosphate and carbamate pesticides is a more sensitive indicator of toxicity, the acceptable daily intake for man is set at 10 percent of the no-toxic-effect level. The acceptable daily intake is set at only a fraction of the no-effect level to allow for variations in the toxicity within animal species and man.

EPA determines the total possible exposure to pesticide residues that could be present in each food commodity in the average diet of a 60-kilogram (about 132 pounds) man. The residues from each food commodity are then totaled and compared to the acceptable daily intake. If the total residues from all commodities are below the acceptable daily intake, then the tolerances established are considered to be safe.

We found instances where the total pesticide exposure exceeded acceptable daily intake as shown by the following example. (Another example is discussed on p. 63.)

Example 3

Available toxicity data indicates that the acceptable daily intake for parathion, an organophosphate insecticide,

is 0.3 milligrams per day for a 60-kilogram man. Tolerances for residues of parathion have been established for about 70 agricultural commodities which comprise over 34 percent of a 60-kilogram man's diet. Total exposure to parathion from these uses could be 0.51 milligrams per day--0.21 milligrams above, or almost twice, the acceptable daily intake.

It does not appear that total exposure to parathion from all sources was considered when some tolerances were established. The acceptable daily intake of parathion had already been exceeded when EPA established interim tolerances for parathion residues in sugarbeets, sugarcane, sweetpotatoes, and rye in August 1972.

FDA DOES NOT TEST FOR MOST PESTICIDE RESIDUES IN FOOD

In addition to the questions on the adequacy of supporting documentation for pesticide tolerances established by EPA, FDA does not effectively test for most pesticide residues for which EPA has established residue tolerances in food.

FDA has two major programs to monitor the amount of pesticide residues in food products and performs special purpose tests initiated by itself or when requested by other agencies, such as EPA. An FDA official told us that in addition to its testing, residue testing is also performed by the Department of Agriculture (for meat and poultry), various State agencies, and the food industry; therefore, a substantial portion of the Nation's food supply routinely undergoes pesticide residue examination.

The primary FDA regulatory program for enforcing pesticide tolerances is the pesticide surveillance program which is conducted on a continuing basis at all 17 FDA district offices. Samples of food commodities are collected at the grower or shipper level. Program objectives are to

--determine on a geographical basis pesticide levels of individual food commodities,

--survey on a nationwide basis total pesticide residue levels of selected food commodities,

--monitor imported food commodities and deny entry to those with illegal pesticide residues, and

--identify pesticide residues occurring in excessive levels as a basis for compliance followup.

The second program, called the total diet study, is an information-gathering program and does not serve as a basis for regulatory action against specific products. Market baskets, each containing 117 food items, are collected 6 times a year by FDA inspectors in 4 areas of the United States. FDA collects 20 market baskets representing the diet for an adolescent male--usually the biggest eater in the general population--and 10 market baskets each representing the diets of a 6-month infant and 2-year toddler. The items in each market basket are separated into commodity groups, and each composite group is blended into a homogeneous slurry--a uniform mixture of similar food commodities. The slurries are then analyzed for over 90 various pesticide residues.

Under both the total diet study and the pesticide surveillance program, FDA uses a multiresidue test which is capable of detecting 54 parent-compound pesticide chemicals--primarily organochlorine and organophosphate chemicals--and about 90 of their metabolites in almost any type of food. An FDA official stated that these pesticides are highly toxic or quite persistent in the environment and could pose a potentially serious threat to public health.

FDA also emphasized that using the multiresidue test does not preclude testing foods for other pesticides if there is evidence or suspicion of misuse or special interest in the incidence and levels of a certain pesticide residue. For example, the total diet study measures lead, mercury, zinc, and arsenic residues in all samples.

An FDA official told us that FDA does not test for all pesticide residues because the results of FDA's surveillance program over a period of years has indicated that pesticide levels found in most raw agricultural commodities are generally well below established tolerances. He said FDA believes that the results of this testing should indicate the overall seriousness of the pesticide residue problem because FDA concentrates its efforts on widely used and persistent pesticides which are found to be violative in only about 3 percent of the samples. He also stated that FDA relies on programs of its own, EPA, State, and local agencies to insure that good agricultural and manufacturing practices are followed in using pesticides because it is generally recognized that use of a pesticide in a manner consistent with label directions greatly limits the occurrence of violative levels of pesticides in food.

While we do not question (1) the emphasis placed on testing food for organochlorine and organophosphate insecticide residues because of their toxicity, persistence,

and/or widespread use and (2) efforts to insure good agricultural and manufacturing use of pesticides, we do not believe that this should preclude periodic testing of other pesticides for which tolerances have been established. The 3 percent rate of violative samples noted in FDA's comments above indicates that illegal residues occur despite efforts to the contrary. We believe that this occurrence demonstrates a need for FDA to initiate a systematic procedure to insure that all pesticides with tolerances are tested in FDA's surveillance program over a period of years.

Limited testing of herbicides and fungicides

As of July 1, 1974, 233 permanent tolerances were in effect. In nonfatty foods, FDA's multiresidue test would measure either partial or complete residues of only 54 of the 233 pesticides. As shown by the table below, FDA's detection capabilities were primarily limited to insecticides.

Type of pesticide	Number of tolerances	Detection capabilities		
		Complete	Partial	None
Insecticides	93	27	8	58
Herbicides	72	5	4	63
Fungicides	40	2	4	34
Other	28	3	1	24
Total	233	37	17	179

The absence of reliable data on herbicide residues is important because herbicide usage is greater than insecticide usage. Only 9 out of 72 herbicide tolerances can be detected and enforced using the multiresidue test.

Similarly, the most widely used fungicides, the ethylene bisdithiocarbamates (EBDC's), are not detected by the multiresidue test. In 1973 an EPA Special Pesticide Review Group labeled a decomposition product of the EBDC's, ethylene thiourea (ETU), a potential carcinogen. It also stated that ETU may be present in a wide variety of agricultural commodities, including milk. Because FDA does not test for ETU and because EPA has not requested testing, the exposure to this possible carcinogen is unknown.

Because testing in both the pesticide surveillance program and total diet study is limited primarily to organophosphate and organochlorine insecticides, total public exposure to pesticide residues is unknown. For example, 47 permanent tolerances have been established for residues in

problems. In the recent past our emphasis on the implementation of FIFRA has allowed for insufficient attention to the problems identified here. Now that the necessary regulations for registration have been promulgated, we can turn more of our attention to review of the tolerance regulations and procedures, to reassessment of tolerances already regulated, and to a comprehensive evaluation of the whole scientific basis for tolerance setting. We accept and will implement GAO's recommendations in this area."

In commenting on our report (see app. II), HEW concluded that:

"We do not concur with the proposed expansion of the pesticide surveillance program at this time. In essence, we do not believe there is a significant need for surveillance of all pesticides since there are means other than residue testing for ensuring the safe use of pesticides and our current assessments of the total food supply do not indicate the presence of excessive pesticide levels.

"In assessing FDA's surveillance program it is essential to understand that the control of pesticides in food encompasses more than merely testing samples of food for the presence of illegal residues. The relationship of good agricultural and manufacturing practices to the regulatory control of pesticides in food is an equally, if not more important consideration. It is generally recognized that if food is treated with a pesticide in a manner consistent with its labeled directions, there is only a very remote possibility that violative levels of residues would occur. It is for this reason that FDA, EPA, State and local agencies conduct establishment inspections to make certain that pesticides are being properly used."

HEW did not believe that expansion of residue testing addressed the relative seriousness of pesticide residues in food because:

--Pesticide residues for over 90 of the more persistent and toxic pesticides (or their metabolites) are found

in less than 3 percent of the 7,000 to 8,000 shipments of food and feed tested each year.

--The results of the FDA total diet studies for the past 10 years indicate that the consumer's average daily dietary intake for over 90 of the more persistent and toxic pesticides or their metabolites is well within established acceptable daily intake limits.

--A fiscal year 1974 examination of 500 food samples for 32 pesticides not recovered in the routine surveillance program detected only 4 samples with residues above tolerance.

HEW further stated that, on the basis of the foregoing, there is little reason to expect that residues of less persistent pesticides are occurring in the Nation's food supply to any major degree.

Although pesticide control encompasses more than testing food for residues, we believe that this is a very important part of control. The fact that FDA is detecting violative residues in the small number of shipments sampled indicates that other aspects of pesticide control in food are not altogether effective. In fact the 3 percent rate of violation appears high when considering that FDA is testing for less than one-fourth of the pesticides with tolerances.

Further, we do not agree with FDA's inference that organochlorine and organophosphate residues are reliable predictors of the residues which will result from other pesticide uses. Nor should this testing preclude periodically testing other pesticides.

In commenting on our recommendation that FDA coordinate with EPA on all future samplings of pesticide residues in food, HEW stated:

"We agree with this recommendation. In fact, the June 12, 1975 Memorandum of Understanding on Pesticide Enforcement contains provisions along these very same lines. Accordingly, it is FDA's intention to formally request that EPA review and comment on the scope and overall adequacy of the FDA surveillance program and total diet studies including the types of foods and pesticides covered by these activities. FDA would then modify these programs as appropriate, based on EPA suggestions."

CHAPTER 5

SAFETY OF INTERIM TOLERANCES NOT ESTABLISHED FOR REGISTERED PESTICIDES

Under the law any pesticide residue on food shall be deemed unsafe unless a tolerance--or an exemption from the requirement of a tolerance--has been established and the amount of residue remaining is within the limits of that tolerance. A permanent tolerance is to be established only after EPA is satisfied that the data submitted by the petitioner is adequate to support the safety of the proposed tolerance.

Any food product containing residues of a pesticide for which a tolerance has not been established or containing residues in excess of established tolerances is adulterated under FFDCA. FFDCA prohibits the movement of adulterated foods in interstate commerce and provides for removing such products from interstate commerce and for penalties for violators. However, FDA's residue testing program is primarily limited to insecticides, and many pesticides, particularly those with interim tolerances, are not monitored.

EPA has permitted the registration of pesticides resulting in residues on food without establishing tolerances, usually because the safety and/or amount of residues remaining have not been determined. For example, some uses of chlordane result in residues in milk; however, tolerances for such residues have not been set. Thus, using the product according to label directions could adulterate milk.

EPA has established a system of interim tolerances to allow using a pesticide while the review of the tolerance petition is in progress. Interim tolerances were usually established when (1) questions of safety existed, (2) inadequate data was provided on residue levels, and (3) petitioners submitted no data to support the safety of the proposed uses. Such tolerances are not consistent with EPA's mandate to protect human health.

"NO RESIDUE" TOLERANCES

Before April 1966 registrations were granted for agricultural pesticides on a "no residue" basis if data was submitted to show that no detectable residue remained on the crop or food product as a result of the proposed use. Any detectable residue of such pesticides would render the crop adulterated and subject to seizure under FFDCA.

Advances in analytical chemistry made it possible to detect minute amounts of residue which were previously undetected. As a result, residues were detected for pesticides previously registered on a no-residue basis.

In June 1965 a committee appointed by the National Research Council, National Academy of Sciences, recommended eliminating the no-residue method of registering pesticides. The committee recommended that the existing no-residue tolerances be converted to "negligible" (generally less than .1 ppm) residue tolerances if their use resulted in residues of a negligible or permissible fraction of the pesticide's acceptable daily intake. In April 1966 the Departments of Agriculture and Health, Education, and Welfare in implementation plans published in the Federal Register agreed that:

> "***new uses of pesticides on food crops which may reasonably be expected to result in small residues in or on food should not be registered ***unless a finite residue level is formally provided for by tolerances***.
>
> * * * * *
>
> "***If the available data do not establish the safety of a pesticide for a particular use, such use will be deemed to be hazardous and ***[EPA] would not register the pesticide for such use."

They concluded that:

> "***The changeover, including processing of petitions, should be effective as soon as possible, but in no event should such no-residue***registrations be continued later than December 31, 1970."

Because many tolerance petitions were filed shortly before the December 31, 1970, deadline, the deadline was extended to December 31, 1971. No action was taken to formally extend the deadline between January and March 1972. To avoid further extensions of the no-residue registrations, EPA began issuing interim tolerances in April 1972; as of February 1975 there were interim tolerances for 22 pesticides in or on over 50 crops. Interim tolerances permit continuing no-residue registrations while petitions for permanent tolerances are pending.

In addition to pesticides with interim tolerances, some pesticide registrations were extended beyond the

December 31, 1971, deadline without either a permanent or interim tolerance. Available safety data was inadequate for determining tolerances for these pesticides.

PESTICIDES MARKETED WITHOUT A TOLERANCE

Although interim tolerances were established for most of the no-residue uses for which petitions were still pending, the Toxicology Branch recommended against establishing interim tolerances for certain uses of chlordane, endrin, heptachlor, silvex, meta-systox R, and morestan because of unanswered questions about the safety of the proposed uses. Most of these pesticides are widely used. In a memo dated June 2, 1972, the Chief, Toxicology Branch, stated the following objections to the proposed interim tolerances.

> "Chlordane: The requested milk tolerance for chlordane, 0.3 ppm in milk fat, is at least twice as high as available toxicity data can support as safe to the young infant on all-milk diet. Moreover, maximum residues which could occur in average daily diet, if all tolerances requested in PP# 0F0935 are granted, will be at least twice as high as available toxicity data can support as safe to the adult.
>
> "Endrin: All tolerances for endrin are established at zero. The present request for 0.05 ppm of endrin in milk and eggs may not be adequate to cover residues from proposed uses. The no-effect level for endrin is 0.5 ppm in the dog, and 1 ppm in the rat and there is concern over the effects of endrin on the reproductive capacity in dogs. Further toxicity studies are recommended before this request can be judged safe.
>
> "Heptachlor/heptachlor epoxide: The requested milk tolerance, 0.3 ppm in milk fat, if expressed only in terms of residues of heptachlor/heptachlor epoxide, is appreciably higher than the available toxicity data can support as safe to the young infant on an all-milk diet. Furthermore, maximum residues which could occur in average daily diet, if all tolerances requested in PP#CF0935 are granted, exceed those that available toxicity data can support as safe to the adult.

* * * * *

'Silvex: This is an ester of 2,4,5-T and the presence of 2,3,7,8-tetrachlorodibenzo-p-dioxin[1] has not been ruled out with certainty. The toxicity data in our files will only support tolerances for residues at the negligible level. Data available to Chemistry Branch does not enable them to estimate whether the levels in milk from use of Silvex on pasture grass are negligible or not. An interim tolerance for this compound is not in the best interest of the public health.

"Meta-systox R: The no-effect level for this cholinesterase inhibiting compound is 1 ppm based upon 90-day feeding studies. The level which could be supported in the total diet would be 0.005 ppm. Chemistry Branch states that a tolerance higher than the requested 3 ppm on alfalfa and clover is necessary to cover expected residues from proposed uses. Since CB [Chemistry Branch] has insufficient data at hand to estimate the level of Meta-systox R that might transfer to milk, it is my opinion that an interim tolerance for this use of Meta-systox R is not safe. Neither chronic studies nor a reproduction study which is generally recommended, if residues appear in milk, are available.

"Morestan: Tolerances requested are not negligible and this cannot be considered as falling under the 'no residue registration' category for issuing tolerances. The toxicity data available does not support the safety of the requested tolerances for this compound."

On August 16, 1972, the Acting Director, Pesticide Tolerance Division, recommended that the Pesticide Registration Division cancel the registration of pesticide uses on crops for which setting interim tolerances was not recommended because of unresolved safety questions. EPA did not act on the recommendation and these pesticide uses were not covered by tolerances. Only meta-systox R and morestan eventually were covered by a tolerance.

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[1]A highly toxic contaminant which causes birth defects.

Because of the strong objections of EPA's Toxicology Branch to setting even interim tolerances for these uses and the possibility of adulterating food products by using the pesticides, in a letter dated September 17, 1974, we asked EPA to justify the continued registration of these pesticides.

EPA, in its October 31, 1974, response, stated that

> "***The fact that pesticide residues in a crop may render it adulterated under the FFDCA in the absence of a tolerance or exemption from the requirement of a tolerance does not require***the institution of cancellation proceedings under FIFRA. ***The Seventh Circuit Court of Appeals in Continental Chemiste Corporation v. Ruckelshaus, 461 F. 2d 331 (1972), held that 'adulteration' of a food due to pesticide contamination does not foreclose registration of that pesticide under FIFRA, because the definition of product safety under FFDCA is not incorporated in FIFRA."

EPA further stated that it agrees with the position on tolerances taken by the former Chief, Toxicology Branch (see page 54), except for meta-systox R and morestan for which interim tolerances were established on August 16, 1972. Permanent tolerances for meta-systox R and morestan were established in November 1972 and July 1974, respectively.

The former Chief, Toxicology Branch, recommended (1) canceling endrin, chlordane, and heptachlor because the available toxicity data did not support the tolerances and (2) canceling 2,4,5-T and silvex because the chemistry data was insufficient to determine appropriate tolerance levels. EPA maintains, however, that

> "***Since the hazard was no greater than had occurred throughout the years of registration under 'zero tolerance' (no residue) there seemed to be a weak case for cancellation."

EPA's contention that the hazard is no greater is immaterial, because the extent of the hazard has not been determined and prevents EPA from fulfilling its mandate to protect human health.

We believe that the Continental Chemiste case does not preclude canceling or suspending pesticide registrations

for which tolerances have not been established. Further, the United States Circuit Court of Appeals for the District of Columbia in Environmental Defense Fund v. United States Department of Health, Education and Welfare, 428 F. 2d 1083 (1970) stated:

> "If Congress intended that either department [formerly HEW and the Dept. of Agriculture but now only EPA] defer to the other, the House and Senate reports suggest that ordinarily Agriculture's decisions as to whether to register a pesticide under FIFRA for use on food crops should depend upon HEw's decision to grant a tolerance." (Material in brackets supplied.)

In footnote 11 of the opinion the court further referred to the legislative history of section 346a (section 408 of FFDCA) showing a linkage between tolerances under the section and registration.

> "The Congressional Committee Reports summarized the departmental responsibilities as follows:
>
> > Under this bill [the present FFDCA provisions], a regulation establishing a tolerance for a pesticide chemical used on raw agricultural commodities may be initiated by an applicant for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act or by the Secretary of Health, Education, and Welfare. It is anticipated that, in the usual case, registration of a new economic poison would be withheld by the Department of Agriculture pending the issuance of the tolerance.
>
> H.R. Rep. No. 1385, supra Note 8, at 3, U.S. Code Cong. & Admin. New 1954, p. 2628. * * * Similarly, the Department of Agriculture should presumably deregister a pesticide for use on food crops if HEW revokes an existing tolerance. Precisely this pattern was followed recently when Agriculture revoked registrations of lindane and benzene hexachloride for use on certain crops because HEW had cancelled tolerances for these pesticides. USDA Release No. 943-70, March 25, 1970." (Underscoring supplied.)

The House and Senate reports (House Report No. 1385, p. 3, and Senate Report No. 1635, p. 3, 83d Congress, 2d Sess.) anticipated that registration would be withheld pending issuance of a tolerance in the ordinary case, leaving open the possibility of registration without a tolerance in exceptional cases. Also, cancellation ("deregistration") would presumably be required, according to the court, if an existing tolerance were revoked.

We believe the foregoing decisions clearly demonstrate that the Congress intended that pesticide registration resulting in residues in or on food or feed would be withheld or canceled unless required tolerances could be established. EPA should revise its policy accordingly.

Subsequently, on July 30, 1975, the EPA Administrator suspended the manufacture of chlordane and heptachlor as an imminent human cancer hazard. In his order the Administrator stated:

> "I have found that these compounds cause cancer in laboratory animals and that laboratory tests are reliable indications of the human cancer hazard. In addition, although any single component of human exposure--such as intake through poultry--may not appear to be significant, it alone poses a cancer hazard to certain of the more susceptible individuals and together with the several other components of human exposure presents a serious human cancer threat. This threat is made even more alarming by evidence that human exposure begins in the mother's womb and continues without interruption throughout life. In addition, because these chemicals are ubiquitous, the major sources of human exposure are largely unavoidable by individual action."

QUESTIONABLE INTERIM TOLERANCES ESTABLISHED

Some interim tolerances were established in cases where (1) questions of safety existed, (2) inadequate data was provided on residue levels, and (3) petitioners submitted no data to support the safety of the proposed uses. EPA has not established guidelines governing interim tolerances.

Questions of safety

As shown by the following examples, interim tolerances have been set for pesticide uses on which questions of safety exist involving the carcinogenicity or teratogenicity of the pesticides.

Example 1

In December 1969 the Mrak Commission recommended that human exposure to pentachloronitrobenzene (PCNB) be minimized because of tests showing PCNB to be both a carcinogen and a teratogen. Although EPA notified manufacturers that additional carcinogenicity and teratogenicity studies were required, a manufacturer refiled a petition for PCNB tolerances on peanuts and 10 other agricultural commodities in December 1970 without submitting additional studies.

In December 1972 EPA established an interim tolerance for PCNB. The interim tolerance was established because (1) additional studies on carcinogenicity and teratogenicity were being conducted, and (2) the purity of the pesticide used in the earlier test and produced by another manufacturer was unknown.

Because the available data did not indicate the safety of the proposed uses, we question EPA's establishing an interim tolerance before additional carcinogenicity and teratogenicity studies were completed. In addition, PCNB produced by the petitioner contained hexachlorobenzene impurities. EPA's residue chemists said the proposed uses would result in residues in meat and milk and would require tolerances of 0.2 ppm in milk and in meat, fat, and meat by-products of cattle, goats, horses, and sheep. They stated that these residues would be almost entirely hexachlorobenzene. Any residues of PCNB or hexachlorobenzene in meat and milk would render the product adulterated because neither an interim nor a permanent tolerance have been established for these ingredients.

Because the petitioner did not propose tolerances in meat and milk, the Toxicology Branch did not review the safety of the probable residues in meat and milk, even though the crops for which tolerances were granted were fed to animals and would have resulted in such residues. Thus the public, through the establishment of interim tolerances for PCNB use on certain agricultural commodities, may be exposed to products adulterated with residues of a possible carcinogenic and teratogenic pesticide.

Example 2

In September 1970 a petition was filed requesting the establishment of a permanent tolerance for the fungicide dithane M-45 in potatoes and milk, and in meat, fat, and meat by-products from dairy and beef cattle. Because of questions about the carcinogenic properties of ETU, an impurity and metabolite of dithane M-45 and other EBDC pesticides, in November 1971 EPA notified the petitioner that it was unable to complete its toxicology review until the question of ETU residues was resolved.

However, in May 1972 the Toxicology Branch recommended establishing interim tolerances for dithane M-45 and two other EBDC pesticides because of higher tolerances in other EBDC pesticides. The Toxicology Branch justified this recommendation on the basis that the requested interim tolerances were less than permanent tolerances granted for similar EBDC pesticides, and, consequently, "although toxicity data does not completely support the safety of these compounds, TB [Toxicology Branch] must recommend them for interim tolerance." EPA would be better fulfilling its mandate to protect human health by canceling those tolerances not supported by safety data rather than by justifying additional tolerances on the basis of those established without adequate data.

On December 2, 1972, interim tolerances were established for the three EBDC pesticides. Although an interim tolerance of 1 ppm was established for dithane M-45 in potatoes, no interim tolerance for dithane M-45 or ETU was established in milk, even though dairy cattle are fed potatoes. The Chemistry Branch of EPA's Registration Division concluded that residues of ETU in milk would likely be between 0.01 and 0.02 ppm and could run as high as 0.05 ppm.

Because of the serious questions concerning the safety of EBDC fungicides, it seems inappropriate to approve additional tolerances for dithane M-45 until these questions are resolved. Rather, it would seem more appropriate to eliminate all nonessential uses of EBDC fungicides until the question of safety is resolved.

The Department of Agriculture indicated that EBDC fungicides are probably the most important single fungicide group and that many of the uses have no alternatives. There are alternatives for the two EBDC fungicides for which interim tolerances have been set and for the use of dithane M-45 on potatoes. The interim tolerance for

dithane M-45 is especially questionable because of the expected ETU residues in milk and the inability to detect ETU residues.

Inadequate residue data

The Chemistry Branch reviews the residue data submitted with tolerance petitions to determine whether the proposed tolerance levels are adequate to cover the expected residues. In several cases EPA set interim tolerances at levels requested by the registrant even though the Chemistry Branch found that residues would be higher. EPA's Toxicology Branch did not evaluate the safety of consuming foods containing residues at the higher level and, consequently, the public may be exposed to pesticide residues exceeding safe levels. If the residues occurred at levels above tolerances, the food would be adulterated. However, since most of the pesticides and/or crops for which interim tolerances were established are not included in FDA's pesticide monitoring program, such adulterated foods will not be detected and removed from commerce.

The following examples illustrate these points:

Example 3

In December 1967 a petition was submitted requesting tolerances for the herbicide 2,4-D on a number of agricultural commodities including grasses and milk. The petition was rejected because expected residues for some commodities, including meat and milk, would exceed the requested tolerances. After repeated resubmissions and rejections, an interim tolerance of 300 ppm was established for 2,4-D residues in grasses in 1972. The interim tolerance did not, however, cover residues of 2,4-D in meat and milk.

EPA's Compendium of Registered Pesticide Uses places no time restrictions on meat animals' grazing on 2,4-D treated grasses; however, dairy animals may not be grazed until 7 days after treatment. In a June 1972 review of the tolerance petition, an EPA residue chemist estimated from the data provided that the maximum 2,4-D residues on grasses would be about 2,000 ppm at the time of application and 400 ppm 7 days later. As a result, the residue chemist concluded that 2,4-D residue levels in meat and milk would exceed the proposed tolerance levels of 0.1 ppm in meat, 1 ppm in kidney, and 0.05 ppm in milk but did not estimate what the residues would be.

In a subsequent review dated December 14, 1973, the residue chemist concluded that:

> "After reevaluation, we now find a tolerance level of 0.2 ppm will be needed for combined residues of 2,4-D and 2,4-DCP (a metabolite of 2,4-D) in milk. This adjustment is based upon the residue data for grasses, which indicate up to 700 ppm residues could be present after 7 days at the maximum proposed use rate of 6 lbs ai/A [active ingredient/ acre]. If the maximum proposed rate for overall applications were to be reduced to 3 lbs. ai/A (by specifying the 6 lbs ai/A rate was only for spot treatment), a 0.1 ppm tolerance level for combined residues (2,4-D/2,4-DCP) in milk would be adequate.
>
> * * * * *
>
> "The petitioner now proposes meat tolerances of 1 ppm for liver and kidney and 0.1 ppm for other tissues. A 7-day PSI [Pre Slaughter Interval]***for livestock is also proposed; this limitation should be added to the label.
>
> "The proposed tolerance levels are adequate to cover combined residues of 2,4-D/2,4-DCP in meat from the feed uses of grasses per se, provided there is a 7-day PSI; however, these tolerance levels are not adequate to cover residues from ingestion of grass hay; and, we have no residue data on alfalfa and clover and/or their hays with which to judge what levels of tolerances will be needed to cover secondary residues in livestock incurred from their ingestion.
>
> * * * * *
>
> "This deficiency remains unresolved pending the petitioner's response. At present we can draw no final over-all conclusions re the levels of tolerances for meat which will be needed."

Although EPA's Toxicology Branch reviewed the safety of the proposed tolerances, they did not review the safety of the residue levels which the chemist said would likely occur. The former Chief, Toxicology Branch, told us,

however, that the toxicity of 2,4-D is so low that she would not hesitate to approve the higher tolerance level.

We question establishing an interim tolerance for 2,4-D on grasses at 300 ppm when EPA expects residues to be as much as 6 times that level. Such action is especially questionable because FDA was not requested to monitor the tolerance. In addition, because tolerances were not set for milk and meat, the presence of 2,4-D in meat or milk at any level would render them adulterated; meat and milk from livestock grazed on treated grasses contain 2,4-D residues.

Example 4

In December 1970 a pesticide manufacturer submitted a petition requesting a tolerance for toxaphene in alfalfa hay and in milk. An interim tolerance of 0.05 ppm in milk and 1 ppm in alfalfa hay was established in August 1972.

In a June 6, 1972, letter, EPA notified the manufacturer to

> "Revise label restrictions to flatly prohibit the feeding or grazing to livestock of feed items which now bear the restrictions, 'Do not feed to dairy animals or animals being finished for slaughter'."

In a letter dated November 2, 1972, EPA explained its objections and stated that with the precautionary labeling currently on the product "excess residues may result in meat or milk." In that letter EPA also stated that toxaphene residues found by FDA and Agriculture in meat and milk were of low order.

FDA notified EPA in December 1972 that the State of Arizona and the Los Angeles District of FDA were alledgedly finding toxaphene in milk at 3 to 4 times the established 0.05 ppm interim tolerance. FDA wanted to know whether the tolerance petition contained any gas chromatograms of what toxaphene looks like after being fed to cows.

An EPA residue chemist indicated that the above data was not available in the petition but agreed that it was needed, stating in a December 1972 memo that:

> "In view of the above recent problem of toxaphene in milk, the petitioner should be informed that in addition to data already requested, we need to know what changes, if

any, occur in toxaphene after ingestion by the dairy animal. Also, we will need a validated analytical method for toxaphene in milk. Gas chromatographs of both samples and standards should be submitted."

Since that time EPA has, at the request of the manufacturer, extended the deadline for responding to EPA's June 1972 rejection on seven occasions; the latest extention placed the petition in abeyance until September 11, 1975. On September 15, 1975, the manufacturer submitted the requested data which was still under EPA review as of October 21, 1975.

In evaluating the safety of the proposed milk tolerance, EPA's Toxicology Branch allowed total public exposure to toxaphene residues from agricultural commodities to exceed the acceptable daily intake. Toxaphene tolerances are established for over 50 agricultural commodities comprising about 32 percent of the diet of a 60-kilogram man. Total exposure to toxaphene residues from these uses could exceed 2.79 milligrams a day--almost 4 times the acceptable daily intake of toxaphene which is only 0.75 milligrams.

We believe that tolerances should not be permitted--even on an interim basis--which in the aggregate could exceed the acceptable daily intake.

No safety data provided

Some interim tolerances currently in effect were not established as extensions of no-residue registrations. These interim tolerances were established because of special requests and frequently did not contain any safety data or references to data to prove the safety of the proposed uses. In such cases EPA's toxicologists had to obtain data to support the safety of the proposed tolerances from other sources (such as earlier petitions and published articles). In so doing, however, we believe EPA assumed the responsibility of proving the safety of the proposed uses rather than having the registrants supply the safety data. This is illustrated in the following examples.

Example 5

Because of an expected shortage of 2,4-D during the 1974 growing season, three States filed requests for a temporary tolerance for the herbicide picloram in barley and wheat. None of the requests contained any data or references to data on the safety of the proposed uses.

The Toxicology Branch determined, on the basis of toxicity data submitted in a 1967 petition, that residues of 0.5 ppm picloram in barley and wheat would be safe. After the review by the Toxicology Branch, however, the Chemistry Branch determined that tolerances would also be required in horses, hogs, poultry, and eggs. The Toxicology Branch found the tolerance levels proposed by the Chemistry Branch in hogs, horses, poultry, and eggs to be safe, and interim tolerances were approved on June 19, 1974.

Example 6

On August 29, 1973, a petition was filed requesting an interim tolerance for benzene hexachloride (BHC) in imported paprika. The petition was filed because FDA was detaining several lots of imported paprika found to contain BHC residues. The paprika was considered adulterated because no tolerance had been granted for BHC in paprika.

The Director of the Registration Division required the Toxicology and Chemistry Branches to complete their reviews of the paprika petition in 2 days. The petition contained neither data on the safety of BHC nor references to studies in earlier petitions or published articles. The petition contained residue data on only five lots which FDA found to be in excess of the 1 ppm tolerance. Despite the lack of data provided with the petition, the Toxicology Branch completed their review in 1 day, the Chemistry Branch in 2 days. On the basis of these reviews, EPA established an interim tolerance for BHC in paprika.

Accepting submitted petitions without proper supporting data and placing unreasonable time constraints on reviewers could create a potentially hazardous situation. Although the level of BHC entering the diet from paprika is minor, BHC is on the list of suspected carcinogens of the National Institute for Occupational Safety and Health. Establishing interim tolerances without proper safety data, even for minor uses, sets a bad precedent.

CONCLUSIONS

EPA has permitted registration of pesticides for use on food crops without adequate data to support the safety of the resulting residues. Also, we found instances where commonly used pesticides were registered for use on crops resulting in residues on food for which tolerances had not been established. In allowing the continued use of chlordane, endrin, heptachlor, and silvex on food crops

CHAPTER 6

STATUTORY REGISTRATION REQUIREMENTS NOT CARRIED OUT IN A TIMELY AND ADEQUATE MANNER

FEPCA, enacted on October 21, 1972, required EPA, among other things, to register all pesticides during the 2-year period ending October 1976 (FEPCA registration program), regardless of any previous registration. EPA must register about 46,000 pesticides in addition to processing its normal workload during this 2-year period. Presently, EPA does not have the necessary capability to review and register these pesticides within the time frame provided or to assure the public that these pesticides are safe and effective. To compound the problem, EPA was late in issuing regulations and guidelines for registering and classifying pesticides.

Pesticide registrations are valid for 5 years and must, by law, be renewed or canceled at the end of this period. However, EPA has not renewed or canceled pesticide registrations as required, and, as a result, many pesticides whose registrations are over 5 years old are being marketed, although their registrations have not been renewed.

ALL PESTICIDES CANNOT BE ADEQUATELY REGISTERED BY OCTOBER 1976 AS REQUIRED BY FEPCA

In addition to the 46,000 FEPCA registrations, EPA's projected workload during the 2-year period includes 13,000 anticipated new pesticide registrations and 14,000 amended registrations (applications for changes, such as changes in product formulations, uses, or labeling).

EPA estimates that the net effect of the FEPCA registration program on the normal workload will be an increase of approximately 35 percent over the levels of fiscal years 1973 and 1974.

The FEPCA registration program workload of about 46,000 pesticides is composed of about 29,000 currently registered pesticides that must be reregistered and 17,000 intrastate pesticides that were not previously required to be registered by EPA.

EPA's Registration Division staff was increased from 217 to 222 positions between fiscal years 1973 and 1976, an increase of only 5 positions. Of these positions, there were 156 professional staff positions as compared to 138 at

the beginning of fiscal year 1974. According to EPA, position increases in fiscal years 1974 and 1975 were moderate and were not adequate to handle the burden of FEPCA registration. Moreover, no increase in positions has been approved for fiscal year 1976.

According to EPA officials, EPA has had difficulty in keeping up with its normal workload at the current staffing level even after the registration renewal process was suspended. EPA officials said that the recent reorganization of the Registration Division had improved its efficiency and effectiveness in processing registration applications.

Our review of EPA's weekly workload reports showed that there were about 1,550 registration applications on hand awaiting review on July 1, 1972, when EPA suspended the renewal program. As of April 25, 1975, about 1,720 registration applications on hand were awaiting review, an increase of approximately 370 applications over the backlog on hand when the Registration Division was reorganized in December 1974. EPA officials said the time needed to process an application has been reduced as a result of the reorganization. Because the reorganization was only recently implemented, we did not review this aspect of the program.

FEPCA required that by October 21, 1974, EPA establish regulations for registering and classifying pesticides in accordance with provisions of the act and that all pesticides be registered under such regulations. Regulations issued by an executive authority of the Government have the same effect as laws. Guidelines, used in conjunction with regulations, provide information necessary to clarify and implement the regulations. Also, guidelines provide registrants with specific information on what kind of data is needed to support pesticide registrations.

EPA's proposed regulations did not appear in the Federal Register for public comment until October 16, 1974--just 5 days before the mandated deadline for completing the regulations. EPA is required to solicit public comment on the proposed regulations before they can be finalized. After public comments were received and evaluated by EPA, the final regulations were published in the Federal Register in final form on July 3, 1975, and became effective August 4, 1975. Proposed guidelines for registering pesticides were published in the Federal Register on June 25, 1975.

An EPA official said that regulations and guidelines were not completed in time to meet the legislative deadline because difficulties were encountered in (1) resolving

questions on technical aspects of registration requirements, such as the controversy over whether mice or rats should be used as the test animals for pesticide toxicity testing, (2) determining if a clause similar to the Delaney Clause[1] should be included, (3) determining the precise wording of various sections of the regulations and guidelines, and (4) reaching accomodation with other Federal agencies and various interest groups.

An EPA official also said that establishing the final regulations and guidelines was further delayed because of recent court decisions on EPA's responsibility for canceling pesticide registrations. Because of these decisions which dealt with questions of safety and "risk versus benefit," certain changes had to be incorporated into the regulations. EPA could not start the FEPCA registration program until the regulations were issued and, consequently, EPA lost about 9 months of the 2-year period provided by the act.

FEPCA requires that all intrastate pesticides not previously required to be registered by EPA must be registered with EPA between October 22, 1974, and October 21, 1976. EPA estimated in April 1974 that it would be requested to register about 14,700 intrastate pesticides; however according to an EPA official, this data was based on preliminary information from EPA's regional offices and represented their best guess based on their knowledge of the area.

In November 1974 we contacted EPA region III, IV, and IX officials to determine how many intrastate pesticides were registered with the States and Territories in those regions but not with EPA. Officials in regions IV and IX said about 14,300 pesticides in 12 States and single Territory in their regions will have to be registered. A region III official was not able to provide us with an estimate of the number of pesticides in his region which were not registered with EPA. EPA's rough estimate of April 1974 was 9,970 for these two regions.

EPA completed a study in March 1975 which showed that about 17,370 intrastate pesticides were registered by the States which were not previously registered by EPA. This figure was relatively close to EPA's original estimate for the entire country--a difference of about 15 percent. We did not make a detailed analysis of EPA's latest study.

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[1]The Delaney Clause is an amendment to FFDCA which prohibits using chemicals in food which are known to cause cancer in man or animals by any type of exposure.

REGISTRATIONS NOT RENEWED AT REQUIRED 5-YEAR INTERVALS

Pesticide registrations are valid for 5 years. At the end of this period the registrant may request renewal of the pesticide's registration or the registration is to be canceled. Before a product registration can be renewed, EPA requires that the pesticide undergo a complete review to insure that it complies with all current labeling and data requirements. This includes a chemical, a human safety, a use-effectiveness, and an environmental safety review.

EPA does not currently have a formal pesticide registration renewal program; since December 1970 it has had one in only 15 months. The registration renewal program was first suspended for a 4-month period between May and August 1971 because of backlogs in registration work.

In July 1972 EPA again suspended registration renewals and they have not been resumed. EPA officials told us that this suspension occurred because all pesticides currently registered must be reregistered between October 22, 1974, and October 21, 1976, and renewing the registration after July 1972 would serve no purpose because they would have to be reregistered again within a 2- to 4-year period. Also, the suspension would allow EPA to reduce its backlog of new, amended, and supplemental registrations. This backlog, however, was not appreciably reduced.

We reviewed the registration files for 100 randomly selected pesticides as of June 30, 1974, to determine the timeliness of renewal reviews made by EPA. Of the 100 sampled pesticides, 78 should have been renewed within the 5-year period ending June 30, 1974. Of the 78 pesticides, 14 were renewed within the proper time frame; however, the remaining 64 pesticide registrations had not been renewed at the end of the 5-year period as required. Also, 48 pesticides registered for 6 or more years have not received renewal reviews since their initial registration; 33 of these were initially registered before July 1967 and should have undergone renewal reviews before July 1972 when EPA suspended its renewal program. Thus, although EPA had a renewal program before July 1972, it was not effective in insuring that required registration renewals were being conducted.

EPA officials said it had been their policy to automatically extend a pesticide's registration for 5 years each time the pesticide's label is reviewed. EPA officials stated that generally a label review would not have included all four reviews required in the registration or

the registration renewal reviews as previously mentioned. There were 18 pesticides in our sample of 100 that had not had a registration renewal review in over 10 years but each had received a label review which EPA used to renew the 5-year registration period.

An EPA official stated that a request to add an additional use to the label generally required only a use review to insure that the pesticide will be effective for the new pest usage; as a result of this review, EPA considered the pesticide registration as having been renewed.

Of the 100 sampled pesticides, 40 had not undergone any type of review for 6 or more years. Also, 48 pesticides in our sample registered for 6 or more years had not received a renewal review since their initial registration; however, 39 of these had received label reviews which may have substituted as a renewal review.

We examined the record jackets of these pesticides to determine what types of reviews were made. However, these files do not contain evidence showing the type of review that was conducted during each label and/or renewal review. Consequently, we could not determine what reviews were made or the basis on which the reviewers judged that the registrant complied with all current EPA requirements.

Our review of the adequacy of labeling and data submissions (human and environmental safety, use-effectiveness, and chemistry data) indicated that these reviews were not thorough and that registrants were not requested to comply with current EPA requirements. These areas are discussed in greater detail in chapters 2 and 3. We believe that these inadequacies emphasize the need for EPA to eliminate its practice of extending the 5-year renewal data at each label change.

As shown in chapter 2 of this report, many studies are required by EPA before a product can be registered. Many of these studies have not been submitted by the registrants of currently registered pesticides. Some of these studies, including chronic (long-term) feeding and oncogenic studies, take 2 or more years to complete. Consequently, if EPA had reviewed these pesticides as they came up for renewal, it could have notified the registrants that such studies would be required before their product could be reregistered, thereby expediting the FEPCA registration program.

As outlined in its issued regulations, EPA will grant temporary registrations for less than 5 years for those products which lack certain required studies. If EPA had

notified the manufacturers of these requirements, studies might have been available before the FEPCA registration period expires in October 1976. Many products (40 percent in our sample) have not been reviewed for excessive periods of time and will probably require extensive safety and label reviews to insure that they comply with current requirements. In chapter 2 we question whether establishing temporary registrations will afford the consumer protection against unsafe and ineffective pesticides.

CONCLUSIONS

EPA is experiencing an increase in its registration workload, particularly during the FEPCA registration program--October 1974 to October 1976. EPA's workload during the 2-year period will total about 73,000 pesticide registrations and renewals. This is 3 times the normal workload. There will be a permanent increase in EPA's registration workload of about 35 percent due to the requirement that all pesticides must now be registered rather than only those shipped in interstate commerce as was the case before the passage of FEPCA. However, EPA has not taken adequate measures to provide for additional personnel with appropriate backgrounds to properly handle this increased workload.

EPA did not complete the required registration regulations and guidelines--a prerequisite for the FEPCA registration program--until 9 months of the 2-year period had expired. Registrants or potential registrants could not prepare the required data for submission until they knew what was required. Such requirements are contained in the completed regulations. However, there were some steps that EPA could have taken to speed up the registration process. For example, several pesticides lacked basic data requirements which were included in the final regulations and guidelines. EPA should have identified those pesticides which lacked these studies--some of which take 2 years to complete--and should have notified the registrant that studies would be required or their registration would expire by October 1976.

We believe that EPA cannot accomplish the required registrations and reregistrations by the October 1976 deadline because it

- --lost more than one third of the 2-year registration period as a result of delays in completing the regulations,
- --has not increased its staff enough to handle the increased workload, and

APPENDIX I

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

SEP 17 1975

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Resources and Economic
Development Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

This letter is in reply to your letter of July 18, 1975 to Mr. Train accompanying copies of the proposed report entitled "Federal Pesticide Registration Program: Is It Adequately Protecting the Public and the Environment from Pesticide Hazards." We appreciate the opportunity to review and comment on this report prior to its issuance to Congress. The report was very well done and was a great help in reviewing the directions and priorities of our program.

I am enclosing the comments prepared by the Office of the Deputy Assistant Administrator for Pesticides Programs for the Agency.

If there is any additional information desired, please let us know.

Sincerely yours,

Alvin L. Alm
Assistant Administrator
for Planning and Management

Enclosure

APPENDIX I

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

SEP 11 1975

SUBJECT: OPP Comments on Draft GAO Report Entitled: "Federal Pesticide Registration Program: Is It Adequately Protecting the Public and the Environment from Pesticide Hazards" B-133192

FROM: Deputy Assistant Administrator
for Pesticide Programs (WH-566)

TO: Malcolm Stringer
Director, Office of Audit (PM-209)

General Comments:

The subject report is an exhaustive and generally excellent study of pesticide registration and tolerance setting. There are, however, two broad respects in which the EPA mandate and program are not fairly represented.

First, the report is based on the concept that pesticides are regulated to assure their effectiveness and safety without regard to the cost of regulation, and that there are generally recognized, clear-cut standards of efficacy and safety. Neither efficacy nor safety is an absolute, either-or quality. When finite standards are set, they cannot be precise or invariable; they serve simply as useful indicators. A regulatory agency, such as EPA, is faced with a demand for floating standards, which become stricter and more extensive as our knowledge grows concerning pesticides, their effects, and their environmental fate. As such standards become stricter, compliance becomes increasingly more expensive, so that society finds itself faced with ever-increasing costs to achieve decreasing increments of safety and efficacy. Reasonable judgment must be exercised in the development of standards and regulations, bearing in mind the social and economic costs of regulation to all affected sectors of the society. This need for judgment is not adequately recognized in the draft report.

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The second respect in which the report is weak stems from GAO's observation of the program during a period of tremendous change. GAO's review began shortly after the 1972 amendments to FIFRA became law, and lasted through the point of issuance of new regulations for virtually all aspects of pesticide regulation. During this period, major changes have been made in organization, procedures, and regulations. One result of all these changes was some apparent confusion on the part of GAO concerning registration requirements, demonstrated by inaccurate juxtapositions of new and old material. This was most evident in the discussion of data requirements, in which it was assumed incorrectly that the conditions under which certain studies are required by the new regulations (effective August 4, 1975) were the same as the conditions of requirement in the past. Another result of the changes is that several of the problems identified by GAO have been corrected. While it is obviously too soon to evaluate the success of all the changes made, in the interests of accuracy they should at least have been mentioned.

The remainder of these comments are directed to the specific recommendations made in the draft report. Because of considerable overlap among some of the chapters, the recommendations, while identified by page and number, are grouped for purposes of discussion under headings summarizing GAO's findings.

Specific Comments:

1. Defficiencies in Supporting Data

Findings:

Many registrations and tolerances are supported by less than complete sets of data, in terms of current requirements. When requirements have changed, EPA has not pursued missing data aggressively.

Recommendations:

a) Notify registrants and petitioners of gaps in supporting data, and cancel registrations or tolerances when such data are not submitted within a reasonable time (p. 28, 1 and p. 59, 1).

b) Require the full range of data to support reregistration and future renewals (p. 28, 2).

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Response:

Several steps have been taken to correct this problem. First, in accord with the requirements of amended FIFRA at Section 3(c)(2), guidelines have been developed "specifying the kinds of information which will be required to support the registration of a pesticide..." These guidelines, published for comment June 25, 1975, represent the first systematic compilation of registration data requirements. Second, in preparation for reregistration, the data base supporting the safety of each registered active ingredient has been reviewed, and any gaps have been identified. If there are gaps which require studies of short duration, products containing an affected chemical will not be reregistered until the gap is filled. If missing data require long-term studies, affected products will be granted non-renewable reregistration for a period reasonable to allow development and review of the missing data.

If the data are not submitted, the registrations involved will lapse. If data are submitted, then the acceptability of the registration will be judged on the basis of the data.

While neither the Guidelines nor the reregistration program affect tolerances directly, another recent change was the inclusion among the data requirements for registration of full long-range effects testing whenever a tolerance is required. Thus many of the gaps in tolerance-supporting data will be filled in the course of reregistration.

On the question of requiring the full range of data to support reregistration, we considered and rejected this approach. In spite of its obvious attractions, as GAO points out elsewhere in the report, we are faced with severely constrained resources and time for reregistration. The industry, both in manufacturing and testing, is similarly constrained. Thus we determined to concentrate resources in the area of highest priority, which is potential human hazard. A double standard was created in the regulations, limiting the scope of data requirements for reregistration to safety data; including hazard to fish and birds, chronic mammalian effects, oncogenesis, teratogenesis, and reproduction studies; while requiring the full range of data to support new registrations.

The remaining less critical gaps in efficacy and environmental data will be addressed in the course of future renewals, at which time all products will be subject to all data requirements current as of the renewal date.

2. Applicability of Data Requirements

Findings:

Inert ingredients are not required to be tested as rigorously as active ingredients, although they may pose significant hazards.

Little is known about long-term effects of exposure to combinations of active ingredients, and the potential for synergistic effects is cause for concern.

Recommendations:

a) Require complete testing of inert ingredients which may present hazards (p. 29).

b) Consider requiring testing of pesticides as marketed (p. 28, 3).

Response:

Three points need to be made concerning testing requirements for pesticidally inert ingredients. First, many substances that appear as inert ingredients in pesticides are extremely common in other uses as well, and there is a potential interface with other existing regulatory programs which must be considered. If Toxic Substance legislation is passed, it may well provide the most appropriate mechanisms for regulating many substances which occur as inert ingredients in pesticides. There is, in any case, a possibility of significant regulatory overlap.

Second, as GAO points out in the report, funding requests by the Office of Pesticide Programs for a general study of inert ingredients in pesticides have been repeatedly denied.

Finally, the Agency has the authority to require, on a case-by-case basis, testing of inert ingredients which may be hazardous. This authority has been exercised frequently, and during just the past six months, in connection with the following inert ingredients, among others:

p-hydroxybenezenesulfonic acid-formaldehyde condensate and its sodium salt
copper phthalocyanine
diphenyl oxide sulfonate
sodium xylene sulfonate
sodium 1,4-dicyclohexylsulfosuccinate
sodium 1,4-hexylsulfosuccinate
sodium 1,4-diisobutylsulfosuccinate
sodium 1,4-dipentylsulfosuccinate
sodium 1,4-ditridecylsulfosuccinate
dodecylbenzene
N-methyl-2-pyrrolidone

As for considering a requirement for testing products as marketed, rather than simply their individual ingredients, we did consider this in the development of the new regulations and guidelines. Certain testing requirements of the regulations, particularly studies of acute effects, can only be satisfied by tests performed on the formulated product. We rejected the approach that all required safety testing be performed on the formulated product, because of the awesome economic impact that would result. Compliance with such a requirement, because of limited testing facilities, would take years, and would cost several billions of dollars.

It is also worth pointing out in this context that combinations of ingredients in formulated products are by no means the only combinations of pesticide chemicals to which man and the environment are chronically exposed. As soon as a pesticide is released into the environment, complex processes of chemical combination and transformation begin. As is stated in the National Academy of Sciences 1975 publication, Principles for Evaluating Chemicals in the Environment, "there are so many different possibilities for potential interactions that it is unrealistic to demand that all of them be tested in advance." In general, the state of the art is not developed to the point of confident prediction and detection of interactions. Granting that present knowledge is cause for concern, until more is known about mechanisms of interaction, it is difficult to determine what regulatory or testing requirements would be most effective.

3. Labeling Deficiencies

Findings:

Many labels do not meet requirements, and when labeling requirements have changed, EPA has not pursued compliance aggressively.

Recommendations:

Establish procedures to ensure that all pesticides are adequately labeled, with consideration of:

(a) Label reviewer checklists

(b) Follow-up on final printed labeling when registration is granted pending its submission

(c) More emphasis on upgraded reference compendia

(d) Follow-up review of affected product labels when requirements change (p. 42).

Response:

Many changes have been made in the course of preparing for reregistration which should result in correction of most current labeling problems identified by GAO. Most important is the batch approach to reregistration, which has the following characteristics:

(a) Before reregistration applications are solicited from the registrants, EPA reviews a group of products similar in chemistry and use.

(b) This review considers the sufficiency of supporting data, the use classification, required precautionary statements, and any required changes in other labeling elements.

(c) The product of this review is a "Label Guidance Package", specific to the particular batch, itemizing label text and format requirements.

(d) The Label Guidance Package for each batch will be sent to all registrants of affected products, to aid them in developing acceptable labels for submission.

(e) The Label Guidance Package will also be provided to the reviewers to use as a reference standard in considering applications for products in each batch.

Another significant change has been made in the regulations, which now require submission of final printed labeling prior to acceptance of the application, whether for new or amended registration. This should eliminate altogether the problem addressed by GAO's second recommendation.

4. Tolerance-setting Criteria

Findings:

Interim tolerances have been granted in the absence of complete data on safety and on residues, when a question of safety was known to exist.

Permanent tolerances for certain chemicals have been granted such that total dietary exposure may potentially exceed the estabished Acceptable Daily Intake.

Registrations have been granted for some food or feed uses in the absence of required tolerances.

Recommendations:

(a) Evaluate total human exposure to each pesticide residue to ensure that total residues do not exceed the Acceptable Daily Intake (p. 59, 2).

(b) Periodically review all tolerances and revise as necessary.

(c) Evaluate the need for interim tolerances, and if they are essential, provide guidelines for their establishment (p. 79, 1).

(d) Cancel registrations of food or feed uses for which no tolerances exist (p. 79, 2).

Response:

GAO's criticisms are well-founded, and we are very much concerned about tolerance-setting problems. In the recent past our emphasis on the implementation of FIFRA has allowed for insufficient attention to the problems identified here. Now that the necessary regulations for registration have been promulgated, we can turn more of our attention to review of the tolerance regulations and procedures, to reassessment of tolerances already regulated, and to a comprehensive evaluation of the whole scientific basis for tolerance setting. We accept and will implement GAO's recommendations in this area.

5. Resource Deficiences

Findings:

EPA's workload increases have outpaced staff and funding increases; resources are now inadequate to carry out responsibilities.

EPA has moved slowly to implement the reregistration provisions of amended FIFRA, and thus will not meet the statutory deadline.

Recommendations:

Determine and present to Congress Agency needs both to meet the deadline for reregistration and to carry out the full pesticide program effectively and efficiently (p. 91-92, 1).

Response:

While the workload burden of reregistration is admittedly great, we are less certain than GAO that the statutory deadline of October 1976 cannot be met, or at least closely approached. It remains to be seen whether or not our planning projections concerning Congressional appropriations for FY 1976, volumes of activity, productivity and registrant cooperation are sound.

As for resource needs after the workload peak of reregistration is past, we are actively working on projecting them, and will certainly bring them to the attention of Congress.

APPENDIX I

6. Renewal Program Deficiencies

Findings:

The five-year renewal program has been ineffective, and has contributed to deficiencies in labeling and supporting data.

Recommendations:

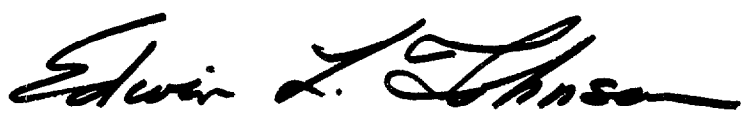
After completion of reregistration, reinstate five-year renewals (p. 91-92, 2).

Response:

We agree with GAO's findings, and accept their recommendation. We will reinstate the five year renewal program after completing reregistration, with the following changes from past practice:

(a) Each product will be required at the time of renewal to meet the same standards for supporting data and labeling as would a new product registered at that time; and

(b) The renewal anniversary date will not be reset by amendments approved during the five-year period.



Edwin L. Johnson

APPENDIX II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C 20201

SEP 19 1975

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report to the Congress entitled, "Federal Pesticide Registration Program: Is it Adequately Protecting the Public and the Environment from Pesticide Hazards." They are enclosed.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX II

DEPARTMENT COMMENTS ON THE DRAFT GAO REPORT TO CONGRESS ENTITLED "FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT ADEQUATELY PROTECTING THE PUBLIC AND THE ENVIRONMENT FROM PESTICIDE HAZARDS?"

GAO RECOMMENDATION:

The Secretary, HEW, through the Commissioner, FDA, [should] expand its market surveillance program so that over a period of years all pesticides with tolerances are tested for in the surveillance program.

DEPARTMENT COMMENT:

We do not concur with the proposed expansion of the pesticide surveillance program at this time. In essence, we do not believe there is a significant need for surveillance of all pesticides since there are means other than residue testing for ensuring the safe use of pesticides and our current assessments of the total food supply do not indicate the presence of excessive pesticide levels.

In assessing FDA's surveillance program, it is essential to understand that the control of pesticides in food encompasses more than merely testing samples of food for the presence of illegal residues. The relationship of good agricultural and manufacturing practices to the regulatory control of pesticides in food is an equally, if not more important consideration. It is generally recognized that if food is treated with a pesticide in a manner consistent with its labeled directions, there is only a very remote possibility that violative levels of residues would occur. It is for this reason that FDA, EPA, State and local agencies conduct establishment inspections to make certain that pesticides are being properly used.

This preventive approach of FDA and EPA has been augmented by a Memorandum of Understanding on Pesticide Enforcement which was published in the Federal Register of June 12, 1975. Among other things, this cooperative agreement calls for EPA to immediately notify FDA whenever that agency encounters an incident of pesticide misuse in which food may be implicated and provides for the coordination of the agencies' investigation and surveillance of pesticide practices. Similarly, officials of most State and local agencies advise FDA of improper pesticide practices encountered in their inspections. In addition, USDA, EPA, FDA and State extension agencies have on-going educational and advisory programs for the agricultural community and the food industry regarding the safe and proper use of pesticides in food production.

APPENDIX II

Additionally, we do not believe that the recommended action is commensurate with the relative seriousness of pesticide residues in food. Each year, FDA samples about 7000-8000 shipments of food and feed for pesticide residues. As indicated in the GAO report, less than 3% of these shipments contain residue levels in excess of established tolerances. The incidence of pesticide residues in most raw agricultural commodities is generally of a low order and their levels are frequently well below established tolerances. In addition, the results of the FDA total diet studies each year for the past 10 years indicate the consumer's average daily dietary intake for over 90 of the more persistent and toxic pesticides (or their metabolites) is well within acceptable daily intake limits established for these pesticides by the World Health Organization and the Food Agricultural Organization of the United Nations.

It is acknowledged that the present FDA Surveillance Program and the Total Diet Studies place emphasis on organochlorine and certain organophosphate pesticides and chlorophenoxy acid herbicides, and the above findings primarily relate to these pesticides. However, these pesticides are, or have been widely used, and they are persistent in the environment and bioaccumulate in living organisms such that their residues occur in milk, eggs and meat. Therefore, these findings should serve as an indication of the relative seriousness of the overall pesticide residue problem. FDA believes that on the basis of the findings for these pesticides, there is little reason to expect that residues of less persistent pesticides are occurring to any significant degree at violative levels in the nation's food supply. This conclusion is further supported by the fact that in fiscal year 1974, FDA examined approximately 500 selected food samples for 32 pesticides other than those not recovered by analytical methods employed in the routine surveillance program and only 4 samples were found to contain residues above tolerance.

In summary, we believe that a comprehensive assessment of the regulation of pesticides does not support the need for the periodic testing of all pesticides that have tolerances. Although it might be reassuring to extend testing to pesticides that have a low toxicity, rapid dissipation rates or a small volume of usage, we do not foresee any significant benefit to the public that would justify the additional costs of the expansion.

APPENDIX II

GAO RECOMMENDATION:

The Secretary, HEW, through the Commissioner, FDA, [should] coordinate with EPA on all future efforts to sample pesticide residues in food.

DEPARTMENT COMMENT:

We agree with this recommendation. In fact, the June 12, 1975 Memorandum of Understanding on Pesticide Enforcement contains provisions along these very same lines. Accordingly, it is FDA's intention to formally request that EPA review and comment on the scope and overall adequacy of the FDA surveillance program and total diet studies including the types of foods and pesticides covered by these activities. FDA would then modify these programs as appropriate, based on EPA suggestions.

PRINCIPAL OFFICIALS OF EPA AND HEW RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office From	To
EPA (note a)		
ADMINISTRATOR:		
Russell E. Train	Sept. 1973	Present
John R. Quarles, Jr. (acting)	Aug. 1973	Sept. 1973
Robert W. Fri (acting)	Apr. 1973	Aug. 1973
William D. Ruckelshaus	Dec. 1970	Apr. 1973
ASSISTANT ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS:		
James L. Agee	Aug. 1974	Present
James L. Agee (acting)	Apr. 1974	Aug. 1974
ASSISTANT ADMINISTRATOR FOR HAZARDOUS MATERIALS CONTROL (note b):		
Charles L. Elkins (acting)	Oct. 1973	Apr. 1974
David D. Dominick	June 1971	Sept. 1973
ACTING COMMISSIONER OF PESTICIDES:		
Raymond E. Johnson	Dec. 1970	May 1971
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDES PROGRAMS:		
Edwin L. Johnson	Mar. 1975	Present
Edwin L. Johnson (acting)	Dec. 1974	Mar. 1975
Dr. Henry J. Korp (acting)	Oct. 1974	Dec. 1974
Dr. Henry J. Korp	Dec. 1972	Oct. 1974
Dr. William M. Upholt	May 1971	Dec. 1972
HEW (note a)		
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
David Mathews	Aug. 1975	Present
Caspar W. Weinberger	Feb. 1973	Aug. 1975
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
Robert H. Finch	Jan. 1969	June 1970
Wilbur J. Cohen	Mar. 1968	Jan. 1969
John W. Gardner	Aug. 1965	Mar. 1968

APPENDIX III

	Tenure of office	
	From	To
ASSISTANT SECRETARY FOR HEALTH:		
Theodore Cooper	May 1975	Present
Theodore Cooper (acting)	Jan. 1975	May 1975
Charles C. Edwards	Mar. 1973	Jan. 1975
Richard L. Seggel (acting)	Dec. 1972	Mar. 1973
Merlin K. Duval, Jr.	July 1971	Dec. 1972
Roger O. Egeberg	July 1969	July 1971
Philip R. Lee	Nov. 1965	Feb. 1969
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Alexander M. Schmidt	July 1973	Present
Sherwin Gardner (acting)	Mar. 1973	July 1973
Charles C. Edwards	Feb. 1970	Mar. 1973
Herbert L. Ley, Jr.	July 1968	Dec. 1969
James L. Goodard	Jan. 1966	June 1968
Winton B. Ranking (acting)	Dec. 1965	Jan. 1966

[a]All pesticide functions in the Department of Agriculture and the pesticide tolerance-setting function of HEW were transferred under Reorganization Plan No. 3 of 1970 to EPA on December 2, 1970.

[b]Before July 24, 1973, the title of this position was Assistant Administrator for Categorical Programs.

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