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Report to Congressional Requesters

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PESTICIDES

EPA's Formidable Task to Assess and Regulate Their Risks

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Resources, Community, and
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The Honorable Dave Durenberger, Chairman
The Honorable Max Baucus, Ranking
Minority Member
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate

As requested in your June 29, 1984, letter and subsequent discussions with your offices, we have reviewed the Environmental Protection Agency's (EPA) process for assessing and regulating adverse health and environmental effects of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. This report addresses EPA's activities in reassessing the risks of existing pesticides and their allowable residues on food; addressing potential risks of cancer-causing pesticides and inert pesticide ingredients; conditionally registering new pesticides; and reducing risks of pesticides of concern. This report is one of three companion reports. Another report deals with the nonagricultural use of pesticides (GAO/RCED-86-97). A future report will deal with monitoring and enforcing pesticide residue limits in the food supply.

As arranged with your offices, unless you publicly release its contents earlier, we will make this report available to other interested parties 14 days after the date of this letter. At that time, we will send copies to other appropriate congressional committees; the Administrator, EPA; the Director, Office of Management and Budget; the Chairman, Council on Environmental Quality; and other interested parties upon request.

J. Dexter Peach
Director

Executive Summary

Most of the 50,000 pesticide products registered (licensed) for use today have not been fully tested and evaluated in accordance with current testing requirements. These tests are required to determine, among other things, a pesticide's potential for causing chronic (long-term) effects in humans, such as cancer and reproductive disorders, birth defects, and environmental damage. In 1972, the Congress required EPA to reregister older pesticides in accordance with current requirements.

The Chairman and Ranking Minority Member, Subcommittee on Toxic Substances and Environmental Oversight, Senate Committee on Environment and Public Works, asked GAO to examine (1) EPA's progress in reassessing and reregistering older pesticides, (2) EPA's efforts to change existing pesticide registrations when it finds new evidence of potential unreasonable adverse effects, and (3) other emerging issues involving the safety and regulation of pesticides.

Background

Pesticide reregistration is regulated by the Federal Insecticide, Fungicide, and Rodenticide Act. In reregistering the 50,000 pesticide products EPA's approach is to assess the effects of the products' 600 active ingredients—those that destroy or control the pest. To do this, the act requires pesticide firms to perform health and environmental tests and submit the data as required by EPA.

If, at any time, new evidence on a pesticide raises a concern about a significant health or environmental risk, EPA may conduct a detailed analysis known as special review. This review is to quickly and comprehensively weigh the risks and benefits of potentially hazardous pesticides to determine if regulatory action, such as canceling or restricting a pesticide use or uses, is needed.

EPA is also responsible for assessing the amount of pesticide residue that can be safely left in foods; the risks of the inert ingredients that propel, dilute, or stabilize the active ingredients; and the cancer-causing potential of pesticides.

Results in Brief

At its current pace, EPA's reassessment and reregistration efforts will extend into the 21st century due to the magnitude and complexity of the tasks involved. Until EPA completes this effort, the health and environmental risks and benefits associated with older pesticides and their uses will not be fully known. GAO provides some options for the Congress to consider in accelerating this process.

EPA's special review has generally been a lengthy process affected by data not being readily available and the competing demands on EPA resources. EPA has recently implemented changes to speed up the process. GAO also provides some alternatives for congressional consideration.

EPA's reregistration effort is further complicated by such emerging issues as (1) the need for an efficient mechanism to obtain test data on the effects of some inert ingredients and (2) the apparent legal inconsistencies that prohibit, under some circumstances, the use of a cancer-causing pesticide while, under other circumstances, allowing the use of the same pesticide.

rincipal Findings

eassessment and eregistration Status

As of March 31, 1986, EPA had not completed a final reassessment on any pesticide active ingredient—the first one is due by the end of the year. EPA has, however, completed preliminary assessments of 124 of the 600 active ingredients. Preliminary assessment means that EPA has evaluated the data on file and identified additional areas where testing may be needed to complete reassessment. Based on this preliminary evaluation, EPA has required numerous studies from pesticide firms and imposed some restrictions on about 60 percent of the active ingredients preliminarily assessed. EPA plans to develop final reassessment after receipt and review of the required data.

Since beginning this process in 1978, EPA has increased its preliminary assessments to a point where 25 active ingredients are done each year. At this pace EPA estimates that it may take up to 20 more years to complete final reassessments. Reregistration of the thousands of pesticide products will extend past the year 2000.

EPA recognizes that reassessment and reregistration will take several decades to complete. Reasons cited include:

- The magnitude of the task with over 600 active ingredients and 900 inert ingredients needing evaluation and 50,000 individual pesticide products needing reregistration.

- The current lengthy and complex process under which EPA determines the acceptability of each piece of data, identifies data gaps, and makes scientific and regulatory decisions based on available data.
- The time necessary for pesticide firms to complete health and environmental testing, which may take up to 4 years in the case of chronic toxicity tests.
- EPA resource limitations which constrain, to some extent, the pace of reassessment. (See ch. 2.)

Special Review

From the inception of the special review program in 1975 through October 31, 1985, EPA completed 32 special reviews. As a result of the reviews, EPA canceled all uses of 5 active ingredients, canceled some use and/or imposed certain use restrictions on 26, and took no action on 1. However, EPA's special review process for dealing with pesticides where new evidence raises a concern about a significant health or environmental risk, has generally taken 2 to 6 years—contrary to EPA's goal of quickly making decisions on potentially hazardous pesticides. During this period, the public and the environment may be exposed to potentially hazardous pesticides. (See ch. 7.)

Emerging Pesticide Issues

EPA's reregistration effort is further complicated by emerging pesticide concerns. EPA has identified about 100 inert ingredients with known or suspected toxic concerns that need to be considered along with over 80(inerts for which EPA has insufficient data to determine potential hazards. EPA's ability to obtain data on inerts may be constrained by the pesticide law's restrictions on disclosing information on inerts, which are considered trade secrets. This legal constraint makes it difficult for interested chemical firms to avoid duplicative testing that may be required by EPA. (See ch. 5.)

Another issue is that EPA is faced with different legal requirements for allowing or prohibiting the same specific cancer-causing pesticide, depending on whether it is used on raw agricultural crops, as a food additive in processed food, or as an animal feed additive. (See ch. 4.)

Matters for Congressional Consideration

Given the program's current pace, EPA's accomplishment of reregistration will take a long time. To accelerate pesticide reregistration, the Congress may wish to consider the advantages and disadvantages of several alternatives which are discussed in this report, including:

- Amending the pesticide law to shift some of the regulatory burden to industry by requiring industry, rather than EPA, to identify data gaps and assess the adequacy of existing data prior to EPA's reassessment of the pesticide (see p. 48).
- Amending the pesticide law to establish reasonable deadlines for pesticide firms to submit complete test data and for EPA to review the data (see p. 50).
- Providing additional resources to EPA to accelerate the reregistration process, possibly through user fees (see p. 51).

GAO also presents some alternatives for the Congress to consider in providing EPA with direction or clarification in addressing (1) the pace of conducting special reviews of pesticides of concern (see p. 120) and (2) the consistent regulation of the use of cancer-causing, food-use pesticides (see p. 81).

Recommendations

GAO makes recommendations to the Administrator, EPA, on pesticide reregistration (see p. 58); the tolerance-setting for cancer-causing pesticides (see p. 82); and the means for obtaining test data on the effects of inert pesticide ingredients (see p. 90).

Agency Comments

GAO did not obtain official agency comments on this report. GAO did, however, discuss the contents of the report with EPA officials and has included their comments where appropriate.

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Abbreviations

CED	Community and Economic Development Division, GAO
CFR	Code of Federal Regulations
DBCP	dibromochloropropane
DDVP	2,2-dichlorovinyl dimethyl phosphate (dichlorvos)
EBDCs	ethylene bisdithiocarbamates
EDB	ethylene dibromide
EPA	Environmental Protection Agency
EPN	ethyl p-nitro phenyl thionobenzenephosphorate
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FTE	full-time equivalent
GAO	General Accounting Office
HRD	Human Resources Division, GAO
NRDC	Natural Resources Defense Council
OGC	Office of General Counsel
OPP	Office of Pesticide Programs
PCNB	pentachloronitrobenzene
PRZM	Pesticide Root Zone Model
RCED	Resources, Community, and Economic Development Division, GAO
RED	Resources and Economic Development Division, GAO
RPAR	rebuttable presumption against registration
TPTH	triphenyltin hydroxide
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

Introduction

Pesticides are chemicals or biological substances used to destroy or control weeds or unwanted plants, insects, fungi, rodents, bacteria, and other pests. Pesticides protect our food crops, non-food crops, ourselves, our homes, our pets and livestock. Pesticides are a mixed blessing: they contribute significantly to agricultural productivity and to improved public health through the control of disease-carrying pests, but they can adversely affect people, non-target organisms such as fish and wildlife, and the environment. Because pesticides are designed to kill and control living organisms, exposure to them can be hazardous. Some pesticides exhibit evidence of causing chronic health effects such as cancer or birth defects. Some pesticides persist in the environment over long periods of time and accumulate in the tissues of people, animals, and plants.

Approximately 50,000 pesticide products, derived from about 600 basic chemical ingredients, are registered for use by the Environmental Protection Agency (EPA). About 1.08 billion pounds of pesticides (excluding wood preservatives and disinfectants) were used in the United States in 1984—79 percent by agriculture, 15 percent by industry, and 6 percent by households. People are exposed to pesticides in the food they eat, the water they drink and swim in, the air they breathe, and in their homes and workplaces. In the home, pesticides are used in treated fabrics for wearing apparel, diapers, or bedding; in bathroom and kitchen disinfectants, such as common household bleach; in insect repellants applied directly to human skin; in pet flea collars; and in swimming pool additives.

Federal agencies that have to make decisions regarding the potential health hazards of chemicals are faced with several limitations and uncertainties. Data for assessing risk may be incomplete. Estimates of types, probabilities, and magnitude of health effects associated with a chemical are often uncertain. Determining the extent of current and possible future human exposures to specific chemicals and estimating the economic effects of a proposed regulatory action is also often surrounded by uncertainty. According to a 1983 National Academy of Sciences report,[1] there are

"no immediate solutions [to these problems] given the many gaps in our understanding of the causal mechanisms of carcinogenesis and other health effects and in our ability to ascertain the nature or extent of the effects associated with specific

[1] Risk Assessment in the Federal Government: Managing the Process, National Academy of Sciences, 1983.

exposures. Because our knowledge is limited, conclusive direct evidence of a threat to human health is rare."

Federal Pesticide Regulation Program

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.), and several sections of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.), authorize EPA to regulate pesticides and their uses. Under FIFRA, EPA is authorized to register pesticide products, specify the terms and conditions of their use prior to being marketed, and remove unreasonably hazardous pesticides from the marketplace. Under FFDCA, EPA must establish the maximum acceptable levels of pesticide residues in foods and animal feed, called tolerance levels, aimed at protecting human health while allowing for the production of an "adequate, wholesome, and economical food supply."

As originally enacted by the Congress in 1947, FIFRA required that pesticides be registered by the Secretary of Agriculture before being marketed to protect users from ineffective and acutely (immediately) dangerous pesticides. In the two decades following passage, pesticides became suspected of damaging the environment and causing more subtle, long-term (chronic) health problems, such as cancer and birth defects. In response, the Congress significantly amended FIFRA in 1972 to provide much broader regulatory coverage, thereby changing the law's emphasis from primarily consumer protection and product performance to public health and environmental protection. Further changes were enacted in 1975, 1978, and 1980. Earlier, authority for administering FIFRA was transferred from the U.S. Department of Agriculture to EPA, along with the responsible organizational elements, on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA.

Pesticide Registration

EPA is responsible for registering specified uses of pesticide products on the basis of both safety and benefits. Under FIFRA EPA can register a pesticide only if it determines that the pesticide will perform its intended function without causing "unreasonable adverse effects on the environment," that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide" (FIFRA Section 3(c)(5) and Section 2(bb)). Unlike most other environmental statutes, which focus on pollution abatement, FIFRA, as amended, focuses on balancing the inherent risks and benefits of substances that are generally

designed to be injurious to living organisms and deliberately introduced into the environment. This balancing of risks and benefits underlies all basic regulatory decisions under the act.

Under FIFRA, as amended, EPA generally must register a pesticide product before it may be sold, held for sale, or distributed in either intrastate or interstate commerce. Registrations are basically licenses for specified uses of pesticide products. For example, the use of a particular insecticide on corn is a registered pesticide use. A pesticide product registration sets the terms and conditions of the use of that product. EPA requires pesticide registrants to label their products as a primary means to regulate risks to people and the environment. For example, EPA may require that labels provide precautionary statements; restrict the use of a pesticide to applicators who are trained and certified; impose reentry intervals (a period after which individuals may reenter areas treated with pesticides); modify pesticide uses or formulations; and impose certain specific packaging limitations.

In order to evaluate the risks and benefits of pesticides and make regulatory judgments with respect to the safety of each pesticide proposed for use, EPA requires health and environmental effects data and information from pesticide producers. These data relate to such information as the potential for skin and eye irritation; hazards to non-target organisms, including fish and wildlife; the possibility of acute poisoning, tumor formation, birth defects, reproductive impairments, or other serious health effects; the behavior of the chemical in the environment after application, such as its groundwater contamination potential; and the quantity and nature of residues likely to occur in food or feed crops. As many as 150 different data/studies, which may take from a few months to several years to develop/complete, may be required to support the registration of a pesticide for use on food crops.

EPA has waived all requirements for pesticide firms to submit efficacy data, except for disinfectants and certain other pesticides, after determining that the marketplace is the best determinator of product performance. EPA does, however, require registrants to be able to show that their products are efficacious on demand for such data.

Reregistration

Under the 1972 amendments to FIFRA, the Congress mandated that EPA assess the safety of all of the then 35,000 (now about 50,000) pesticide products that had been previously registered by the federal and state governments. The Congress required that EPA reregister these pesticides

within 4 years using current health and environmental protection criteria because the data bases supporting these older pesticide registrations are incomplete or inadequate by present scientific standards. This reregistration process normally requires pesticide registrants to undertake and complete various tests that EPA then reviews to determine whether products may remain on the market. (EPA's data requirements, published in 1984, apply to both the registration and reregistration of pesticides.) EPA's early attempts to reassess pesticides were unsuccessful. In 1978, the Congress eliminated the deadline from FIFRA due to the uncertainty in predicting how many years this task would require. Instead, the Congress required EPA to reregister all pesticides as expeditiously as possible, giving priority to pesticides used on food.

In 1975, EPA issued regulations for the registration and reregistration of pesticides. However, their promulgation created a "double standard" in registration. Products registered after 1975 had to meet the new, more stringent data requirements of the regulations even though similar or even identical products registered prior to 1975 were generally supported by a much smaller data base. Thus, in 1977 EPA proposed, and in 1978 the Congress enacted, additional FIFRA amendments to attempt to relieve the inequities. The 1978 amendments permitted conditional registration of new products, under certain circumstances, even though the data base might not fully satisfy data requirements for registration. All registrants of like products would have to provide the missing data at a future time specified by EPA. The 1978 amendments also sanctioned a chemical-by-chemical rather than product-by-product approach to registration and reregistration; that is, EPA was allowed to assess first the approximately 600 basic chemicals that make up roughly 50,000 pesticide products currently registered, rather than having to reassess each of the pesticide products.

Members of Congress, GAO, industry trade representatives, environmentalists, and others have criticized the pace at which EPA is progressing toward the reregistration of all pesticides and the identification and removal from the marketplace of pesticides that pose unreasonable adverse effects.

Pesticide Tolerances

If a pesticide remains in or on food or on animal feed, FFDCA requires that EPA establish a tolerance (the maximum pesticide residue allowed in food) or a tolerance exemption on the basis of data submitted by a pesticide manufacturer. These data include the pesticide's toxicity (potential to cause adverse health effects) and residues (amount which may

remain in food). The establishment of a tolerance or an exemption from the requirement of a tolerance is a prerequisite to registration, and most of the data used in making a tolerance decision are also considered in deciding whether to register a pesticide product. Initially, tolerances were established by the Food and Drug Administration (FDA) of the Department of Health and Human Services, but that authority and responsibility was transferred to EPA when it was created in 1970.

FDA and Agriculture are responsible for enforcing tolerances. FDA is responsible for monitoring most of the nation's food supply to assure that consumers are not exposed to unsafe levels of pesticide residues in their food. Similarly, Agriculture has monitoring and enforcement responsibilities for pesticide residues in meat and poultry products. These agencies test 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.

Chapter 3 discusses EPA's activities relating to the reassessment of pesticide tolerances as part of EPA's efforts to reassess and reregister existing pesticides. In a companion report to be issued shortly, we report on the various roles, responsibilities, and activities of EPA and FDA in monitoring and enforcing pesticide tolerances to ensure the safety of the U.S. food supply.

Special Review of Pesticides of Concern

If, at any time, new evidence on a pesticide raises a concern about a health or environmental risk, EPA conducts a detailed risk/benefit analysis known as special review. At the conclusion of a special review, EPA may decide to continue, restrict, or cancel some or all uses of the pesticide under consideration. Chapter 7 discusses EPA's activities relating to the special review process and risk-reduction actions.

Prior GAO Reports

We have issued several reports on the regulation of pesticides (see app. I). Our most recent report on the pesticide registration and reregistration program was a February 15, 1980, report entitled Delays and Unresolved Issues Plague New Pesticide Protection Programs (CED-80-32), in which we reviewed EPA's programs for registration standards (reregistration) and special reviews (formerly called rebuttable presumption against registration). We concluded, in part, that

- the registration standards program, a costly and time-consuming program, was progressing slowly and had many basic unresolved policy and procedural issues that jeopardized the success of the program and
- the special review program's slow progress was resulting in public exposure to hazardous pesticides longer than necessary.

The report included several recommendations to EPA to improve EPA's administration of these programs.

Objectives, Scope, and Methodology

In a June 29, 1984, letter and at subsequent meetings, the Chairman and the Ranking Minority Member of the Subcommittee on Toxic Substances and Environmental Oversight of the Senate Committee on Environment and Public Works asked GAO to review the federal regulation of pesticides. This report, which concerns EPA's regulation of pesticides and their uses, addresses the following questions:

- What progress is EPA making in its efforts to reassess and reregister older pesticides as mandated by the Congress?
- What progress is EPA making in reassessing the tolerances and tolerance exemptions of pesticides undergoing reregistration?
- What are the issues surrounding EPA's policies for setting tolerances for cancer-causing pesticides used on food?
- What progress is EPA making in addressing the potential hazard of inert pesticide ingredients?
- How has EPA exercised its authority to conditionally register new pesticide active ingredients?
- What progress is EPA making in analyzing and regulating pesticides of concern through its special review process?

EPA's performance regarding the nonagricultural use of pesticides is covered in a companion report, Nonagricultural Pesticides: Risks and Regulation (GAO/RCED-86-97).

To address the above questions on pesticide regulation and to determine EPA's authority and procedures for implementing FIFRA, we reviewed appropriate laws, regulations, manuals, and agency policies and procedures concerning the various pesticide programs. We interviewed EPA headquarters officials to obtain their views on the matters discussed in this report.

To determine what progress EPA is making in its reassessment and reregistration of pesticides, we examined the Office of Pesticide Programs'

(OPP) Registration Standards and Data Call-In Programs; analyzed OPP's regulations for reregistering pesticides, standard operating procedures, policies, and other guidance on preparing registration standard reviews; reviewed several registration standards, including the administrative and scientific records supporting the standards; interviewed OPP officials responsible for preparing registration standards and for issuing data call-in letters, including product managers, scientists, and other Agency personnel; and obtained and analyzed OPP progress and tracking reports of the Registration Standards and the Data Call-In Programs.

To determine what progress EPA is making in reassessing pesticide residue tolerances, we examined the 92 interim registration standard documents of food-use pesticide chemicals available at the time of our review (EPA reported that interim registration standards had been completed for 95 food-use pesticides, but interim standards for 3 of these pesticides were unavailable) to determine whether EPA had reassessed the tolerances and what data were required; reviewed OPP standard evaluation procedures which provide guidance to Agency scientists on how to evaluate studies submitted by pesticide firms to EPA; and discussed the establishing of tolerances with OPP staff, including product managers, toxicologists, and residue chemists.

To identify the issues associated with EPA's policies and procedures for setting tolerances for carcinogenic pesticides, we analyzed relevant law, EPA guidelines for assessing carcinogens, recent tolerance rules, Registration Division files, and draft FDA criteria and procedures for evaluating carcinogens; interviewed OPP toxicologists regarding the tolerance assessment process for carcinogenic pesticides; and obtained the views of OPP management on the effect of the ban on carcinogens under FFDCA's Delaney Clause (Section 409(c)(3)(A)) on tolerance reassessment.

To determine what progress EPA is making in its efforts to review pesticide inert ingredients, we reviewed OPP documents, including its classification of inerts, procedures for inert exemptions, plans for the inert project, and records of meetings concerning inerts and discussed plans and issues with inert project staff and other OPP and EPA Office of General Counsel officials.

To determine how EPA has exercised its authority to conditionally register new pesticides, we examined the registration program. In doing so, we reviewed EPA's proposed and final regulations, policies, and procedures for registering new pesticides; interviewed pesticide product managers responsible for registering pesticides; analyzed OPP progress

reports, contractor evaluation reports, and other data on registration activities; and reviewed the registration files for six new registrations. We selected the registrations for review based on type of registrations, recency of EPA decision, volume of production, and pesticide use. Our data on the six pesticides cannot be projected to the universe of pesticide registration actions.

To determine what progress EPA is making in analyzing and regulating pesticides of concern, we looked at the special review process. In doing so, we reviewed pertinent documents including current, proposed, and final special review criteria and procedures (including public comments on the proposal), bi-weekly special review status reports, decision documents for 14 chemicals in special review, and Agency correspondence and discussed generically and on a chemical-specific basis the problems associated with doing comprehensive and timely special reviews with EPA officials and industry and environmental group representatives.

We attended, or reviewed the transcripts of, ten meetings of the Administrator's Pesticide Advisory Committee held between April 1984 and September 1985. The committee was disbanded on September 30, 1985. The committee was made up of a maximum of 18 representatives appointed by the EPA Administrator from groups such as the pesticide industry, state health or agriculture agencies, environmental groups, and labor unions. The committee reviewed major EPA pesticide programs, policies, and procedures and advised and made recommendations to the EPA Administrator on policy matters relating to registration, reregistration, and tolerance-setting responsibilities as mandated under FIFRA and FFDCA.

During our review, we attended several meetings of FIFRA's Scientific Advisory Panel. The panel, established by FIFRA, is made up of seven members of the scientific community. The panel's purpose is to provide comment to the EPA Administrator on EPA's pesticide related regulations, notices of intent to cancel or reclassify pesticide registrations, and guidelines for performing scientific analysis. We reviewed the panel's comments on special review issues and actions proposed by EPA on specific pesticides in special review. We also attended meetings of the States' FIFRA Issues and Research Evaluation Group. This group was established in 1978 as a means of obtaining input from the states on the administration of FIFRA.

To obtain input from the pesticide industry, we contacted officials of two major pesticide trade associations (the National Agricultural Chemicals Association and the Chemical Specialties Manufacturers Association) and representatives from selected pesticide firms referred to us during the course of the review. To obtain input from environmental groups, we contacted representatives from environmental groups involved in pesticide issues, including the Natural Resources Defense Council, the National Audubon Society, and the National Coalition Against the Misuse of Pesticides.

On January 15, 1986, we delivered a letter of inquiry to the Director of OPP soliciting EPA's official position on certain issues related to pesticide regulation and requesting confirmation and updates of certain data and policy information provided by officials in OPP during the course of our review. While partial response to this letter was made informally by EPA officials in meetings we held with them on March 28, 1986, and April 2, 1986, an official response was not received by the time this report went to publication in April 1986. Response to this letter would have provided additional information on EPA's programs for regulating pesticides.

Our review was made during a period of change in EPA's pesticide programs, and in some cases it is too early to evaluate the success of the changes made. We have made appropriate references in the report to any changes that may affect the matters discussed therein.

Our review was conducted from September 1984 through October 1985, with additional information obtained through April 1986. Our review was conducted in accordance with generally accepted government auditing standards. The views of directly responsible officials were sought during the course of our work and are incorporated in the report where appropriate. In accordance with the requesters' wishes, we did not request EPA to review and comment officially on a draft of this report.

The Formidable Task of Reregistering Pesticides Will Extend Into the 21st Century

People and the environment continue to be exposed to many pesticides that have not been fully tested and evaluated. Fourteen years after the Congress required EPA to reregister about 35,000 (now about 50,000) older pesticide products, the Agency has been unable to completely reassess the vast majority of the basic active chemical ingredients used in these products, although it is beginning to make some progress toward reassessment. On the basis of current resource and program projections, it appears that EPA's accomplishment of the task of reregistering all older pesticide products is uncertain, but extends into the 21st century. Until EPA completes reregistration it cannot fully assure that the public and the environment are adequately protected against possible unreasonable risks of older pesticides.

Until recently, EPA did not routinely follow up on data and labeling requirements imposed on registrants as a result of its preliminary reassessments of older pesticides. Registrants' compliance with these requirements is critical to the success of the reregistration program.

The expeditious reregistration of pesticides is, to some extent, constrained by the limited resources available to the pesticide programs, as well as by the time-consuming, resource-intensive nature of the tasks to be done. Concurrent with its efforts to reregister older pesticides, EPA conducts other important activities, such as assessing and registering new pesticides. While the Congress, EPA, the pesticide industry and environmental groups all agree that reregistration needs to be accelerated, it appears that few alternatives are available for accomplishing this objective. GAO presents several alternatives for the consideration of the Congress to accelerate reregistration and makes recommendations to the Administrator to improve the reregistration program.

Risks of Most Pesticides Remain Uncertain

Most pesticides used today have not been fully tested and evaluated in accordance with current testing requirements. These tests are required to determine a pesticide's potential for causing chronic (long-term) effects in humans such as cancer and reproductive disorders, birth defects, and certain damages to the environment. According to EPA, the ability to assess the risks associated with pesticide use has improved greatly through the expansion of the kinds of data required and improvement in the standards for conducting such testing. However, most pesticides, especially those registered prior to 1975, were registered before current data requirements were imposed. EPA's task is to gather and evaluate the necessary test data from pesticide firms and reevaluate older pesticides. Until this task is complete, the Agency

cannot fully assess the human health and environmental risks associated with older pesticides and their uses.

Between 1947, when FIFRA was first enacted, and 1972, the range of government concerns about the risks of pesticides expanded to include potential chronic health effects, adverse ecological effects, and the environmental fate of pesticides. For example, toxicology tests for chronic health effects, such as liver and kidney damage, were first required in 1963 and tests for potential genetic changes, in 1972. (See app. II.) However, as we have reported in the past,[1] new data requirements were applied primarily to new pesticides or new uses. According to EPA, there was no systematic process to impose requirements retroactively on previously registered pesticides. In addition, even for pesticides that have been tested for chronic and other effects, EPA has determined that certain of the studies were conducted using scientific standards that are no longer acceptable for decision-making today or that were invalidly conducted and will need to be replaced or repeated.

When FIFRA was amended in 1972, EPA was required, among other things, to formally establish pesticide registration regulations and data requirements and reassess and reregister all previously registered pesticides based on the newly established testing guidelines. In 1975, EPA established the basic requirements for registration of pesticide products. Between 1975 and 1981, EPA developed guidelines for registering pesticides which described the kinds of data that pesticide firms must submit to EPA to register products. In November 1982, EPA proposed the current data requirements for registering and reregistering pesticides which for the first time compiled all data requirements previously specified in proposed rules or draft guidelines. EPA's final rule on data requirements, published in October 1984 and effective in April 1985 (40 CFR Part 158), did not differ substantially from the proposal, according to the Agency. The standards for conducting acceptable tests are now published separately as pesticide assessment guidelines.

In our 1975 report, we concluded that the American consumer may not be adequately protected from the potential hazards of pesticide use because of the unavailability of information on pesticides to which much of the population is exposed daily. A 1983 staff report prepared for the Subcommittee on Department Operations, Research, and Foreign Agriculture of the House Committee on Agriculture, using a sample of

[1] Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately From Pesticide Hazards? (RED-76-42, Dec. 4, 1975).

60 active ingredients, estimated that 48 percent of federally registered pesticides lacked data to assess their potential to cause tumors; roughly 38 percent lacked data on birth defects; 48 percent lacked data on reproductive impairment; and 90 percent lacked data on genetic mutations. In the spring of 1985, EPA's Assistant Administrator for Pesticides and Toxic Substances stated that, ". . . the data bases for many of these [previously registered] pesticides are woefully inadequate and the existing data have not been evaluated by current standards."

Reregistration is the process of bringing the registrations of about 50,000 pesticide products into compliance with current requirements. This is a formidable task for EPA and the pesticide industry. EPA must gather and review essential health and environmental studies and make regulatory determinations on the risks and benefits of pesticides registered over the prior three decades. Industry must conduct the required tests for reassessment, some of which take up to 4 years to perform. In the interim, previously registered pesticides can continue to be sold and distributed under their existing registrations. Also, EPA may conditionally register (1) new pesticide products that are identical or substantially similar to those currently registered and (2) new uses of existing pesticides pending reregistration of all similar products already on the market as long as there is no significant increase in risk of unreasonable adverse effects on the environment.

While many more data are becoming available on major food-use pesticides through EPA's reregistration efforts, the risks of older pesticides remain uncertain because these pesticides have not been fully tested and evaluated against current requirements.

EPA's Approach to Reassessing Pesticides

Under the 1972 FIFRA amendments, the Congress required EPA to reregister all previously registered pesticides by October 21, 1976. In 1975, the Congress extended the completion date to October 21, 1977, because of inadequate resources and delays in EPA's development of a reregistration program, according to a 1976 Senate staff report on pesticide regulation. In 1978, the Congress reaffirmed the need for the expeditious reregistration of all pesticides but deleted the deadline requirement due to the uncertainty in predicting how many years the task would require, according to the House report accompanying the 1978 FIFRA amendment. The 1978 amendments added Section 3(g) to FIFRA, which provides:

"The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: Provided, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process." [7 U.S.C. 136a(g)]

Faced with the enormous task of reregistering almost 50,000 pesticide products and its unsuccessful prior attempts,[2] EPA proposed in 1978, and the Congress provided for, a generic chemical approach for registering and reregistering pesticide products and reassessing associated tolerances. Under this approach, EPA will make broad regulatory decisions at one time for all pesticide products containing the same generic chemical—active ingredient—rather than on a product-by-product basis.

Pesticide products generally consist of one or more active ingredients mixed with a number of inert ingredients. An active ingredient is that component in a pesticide product that is intended to specifically control a pest. An inert ingredient is not intended to have any pesticidal effect and is used to dissolve, dilute, deliver, or stabilize the active component(s) so as to enhance the effectiveness or to facilitate the use of a pesticide. (Inert ingredients are discussed in ch. 5.) Active ingredients, produced by manufacturers (manufacturing-use products), are formulated with inert ingredients by formulators for sale at the retail level (end-use products). EPA estimates that there are about 30 major manufacturers and 3,300 formulators of pesticides in the United States.

Under the generic approach, active ingredient data, which often are the most expensive and time-consuming to generate (e.g., chronic feeding and environmental fate), are generally required only of manufacturers. Formulators and others who purchase registered active ingredients generally are not required to submit these data. EPA concluded that reviewing the volume of toxicology, residue chemistry, environmental fate, and ecological effects data for each active ingredient, rather than for each pesticide use formulation, is the most efficient way to accomplish the reregistration mandate.

EPA has determined that there are about 600 active ingredients used in the approximately 50,000 products. EPA plans to systematically collect and analyze data relevant to each active ingredient registered before January 1, 1977, and then develop a document containing the Agency's regulatory position, called a registration standard, on each pesticide and

[2] For information on the early problems of reregistration see Delays and Unresolved Issues Plague New Pesticide Protection Programs (CED-80-32, Feb. 15, 1980).

its uses. The Agency conclusions reached with respect to an active ingredient would then serve as the basis for determining whether products containing that active ingredient meet the current statutory health and safety criteria and can be reregistered.

In addition to the efficiencies involved, EPA decided to focus its review on active ingredients because the Agency concluded that the long-term health and environmental safety effects of a product are largely a function of the active ingredient, rather than of the product formulation. EPA decided to generally assess the long-term effects of single active ingredients and not the effects of combining two or more ingredients (e.g., synergistic effects, etc.) because of scientific and economic limitations. However, EPA requires certain testing, particularly studies of acute effects, on the formulated product. About half of all pesticide products contain more than one active ingredient. In evaluating the possible long-term effects of these products, EPA plans to review the active ingredients separately and then regulate the products based on the combined regulatory positions developed on the active ingredients.

Since 1975 EPA has been pursuing a long-term strategy to gather and review the data necessary for reregistering pesticides and reassessing their associated tolerances. This strategy involves three related programs:

- The Data Call-In Program, begun in 1981, assists in collecting missing long-term health effects and certain other studies that may take up to 4 years to produce.
- The Registration Standards Program, begun in 1978, is EPA's major effort to reassess older pesticides and their associated tolerances. Under this program EPA plans to systematically develop comprehensive regulatory positions for each of the 600 active ingredients.
- The Special Review process, begun in 1975, is an informal review process to evaluate pesticides that may pose unreasonable adverse effects. (This process is discussed in ch. 7.)

Since 1983 EPA generally has been reviewing pesticides by clusters of similar-use active ingredients ranked according to production, potential human exposure, and potential ecological exposure, and giving priority to food-use pesticides, as required by the Congress.

Despite Progress, EPA Has a Long Way to Go to Reassess Older Pesticides

On the basis of current resource and program projections, EPA's accomplishment of the reregistraton of all pesticide products is uncertain but extends into the 21st century. This uncertainty is due to the number of active ingredients that EPA will have to review, the amount of data to be reviewed, the complexity of the regulatory decision-making, the actual reregistration of thousands of individual pesticide products, and other factors. EPA has made progress since our 1980 report, establishing a process to develop registration standards and calling in needed data. However, EPA is at a preliminary stage in the long-term reassessment process and has been unable to completely reassess most older pesticides because of data gaps. The Agency, in recent years, has accelerated the collection of needed data, but these efforts are incomplete. EPA plans to prepare final regulatory positions on older pesticides after receipt and review of required data and is planning to complete the first one in fiscal year 1986. In addition, EPA has reregistered pesticide products before completely reassessing the active ingredients used in certain of these products.

EPA Is at a Preliminary Stage in the Reassessment Process

The key to reregistration is the development of registration standards for each of the 600 active ingredients. Reviewing existing data and preparing the standards is taking longer than EPA initially anticipated. Although the Agency generally refers to them as registration standards, the 124 registration standards developed on pesticides through March 1986 have been interim, not final, standards. The standards are interim or preliminary because about one-third to one-half of the data needed for reassessment was nonexistent or inadequate at the time interim standards were prepared, according to EPA officials. The 124 registration standards are indicators of the Agency's progress toward reassessing pesticides, but they represent a preliminary step in the long-term reregistration process.

Rather than delay developing registration standards until a complete data base is available on a pesticide—something that takes time to achieve—EPA decided in 1979 to develop interim registration standards. An interim registration standard describes all the data available on a particular active ingredient; requires data to replace studies deemed inadequate, augment existing studies, or provide information that is lacking; addresses those regulatory and scientific issues for which sufficient data exist; and sets forth the conditions that pesticide products affected by the standard must meet to obtain or keep their registrations.

Developing interim registration standards is time-consuming and labor-intensive. On average, interim registration standards take about 18 months and cost about 5 staff years and $100,000 in extramural funds (i.e., contracts, cooperative agreements) to develop. Time and costs for development vary depending on the number of studies to be reviewed and complexity of regulatory issues. According to EPA, the single largest expenditure (both in time and resources) in the current Registration Standards Program is the scientific review of existing data, which includes evaluation of the adequacy of existing data, identification of data gaps, identification of data used to support the registration for data compensation purposes,[3] and documentation of reviews in a standard format. According to EPA, making a definitive determination about the data required for each older pesticide requires a reconsideration of the acceptability and utility of each piece of existing data for an active ingredient. This is the essence of EPA's current Registration Standards Program and a principal reason why it will take many years to complete.

As of March 31, 1986, EPA had developed 124 registration standards with interim regulatory positions for pesticides. As table 2.1 indicates, EPA has developed most of the interim registration standards within recent years—about 25 standards a year.

Table 2.1: 124 Interim Registration Standards Were Developed for Pesticides in Fiscal Years 1980-86[a]

	Number of standards developed	
Fiscal year	Annual	Cummulative
1980	6	6
1981	18	24
1982	18	42
1983	23	65
1984	25	90
1985	27	117
1986[a]	7	124

[a]As of March 31, 1986. A few of these registration standard documents are for recently registered active ingredients such as aliette, which was initially registered in 1983.

Source: Compiled from information supplied by EPA.

Since fiscal year 1983, EPA's interim registration standards have generally addressed higher volume pesticides. As of March 31, 1986, EPA estimated that the active ingredients reviewed in the 124 interim

[3] Under FIFRA, an applicant for registration or reregistration must offer to pay reasonable compensation for the right to cite another person's data to satisfy EPA's data requirements.

registration standards represent about 45 percent of the pesticide volume used in the United States.

EPA has not yet completely reassessed any active ingredient and issued a final regulatory position or standard. Because of data gaps, EPA has been unable to reassess tolerances or perform quantitative risk assessments for most active ingredients reviewed. The result is that the 124 registration standards developed are incomplete assessments that will have to be completed or possibly revised when the necessary data, which take time to generate, are received and evaluated by EPA. The Agency plans to develop final standards after all required data have been submitted and evaluated.

Several representatives from EPA, industry, and environmental groups have characterized the standards that have been developed as large data call-in notices, rather than as complete and comprehensive reassessments of a pesticide and its uses. A 1985 Hazard Evaluation Division pilot study of data requirements and data gaps for 15 registration standards estimated that 58 percent of required data were missing or invalid. The study estimated that 35 percent of the gaps were due to missing studies and 23 percent of the gaps due to invalid studies, with variances among the scientific disciplines. The 124 interim standards required affected registrants to submit about 6,700 studies. Approximately 80 percent of these studies are required to be submitted within 1 year; the longest of the remaining studies is to be submitted within about 4 years, according to EPA. Depending on the results of these studies and EPA's review of them, additional information may be needed to complete reassessment.

The data required by the interim standards demonstrate the actual extent of the data gap on older pesticides, EPA's efforts to collect the data, and the amount of work yet to be accomplished. Table 2.2 summarizes the data requirements on the active ingredients imposed by 74 interim registration standards for which data were available on OPP's Call-In Action Tracking System as of January 1986. Data requirements do not necessarily result in studies submitted to EPA because registrants may respond in several ways to the requirements, such as withdrawing product registrations, or amending registered product uses to eliminate the need to do a study. Further, registrants can and do negotiate with EPA concerning modifications to or waivers from specific items of data requested by the Agency. The significance and costs of conducting and reviewing studies submitted to EPA to meet these requirements vary by

requirement. For example, a chronic feeding study is much more costly to perform and review than a product chemistry study.

Table 2.2: Summary of 74 Interim Registration Standard Requirements Imposed by EPA[a]

Type of requirement[b]	Active ingredient requirements
Product chemistry	905
Residue chemistry	1,037
Environmental fate	785
Ecological effects	388
Reentry	69
Spray drift	7
Product performance	0
Toxicity	
Acute	162
Subchronic	109
Chronic	327
Mutagenicity	180
Other	57
Subtotal	**835**
Total	**4,026**

[a]Data on 74 interim registration standards entered into OPP's Call-In Action Tracking System as of January 22, 1986. We did not verify the information from this system. EPA has also imposed product-specific requirements on pesticide products covered by these standards.

[b]See app. II for descriptions of types of requirements.

Although data gaps exist for almost all active ingredients reviewed so far, roughly 60 percent of the interim registration standard reviews identified health and environmental concerns that necessitated additional restrictions, according to the Agency. The majority of the restrictions are for precautionary labeling, such as proper storage instructions, protective clothing requirements, reentry/post harvest intervals, crop rotation and restrictions on application, geographical use limitations, and product formulation. On the basis of available data reviewed in preparation of interim registration standards, EPA restricted the use of 16 pesticides to certified appplicators—individuals certified to use a pesticide under a federal/state program. EPA has also prohibited the registration of certain new uses of some active ingredients because the Agency lacks sufficient data to determine whether the additional uses would signficantly increase risk. Except for significant labeling changes, EPA imposes interim labeling changes only on single active ingredient manufacturing-use products. EPA will bring the labels of most other products containing the active ingredient (i.e., end-use products) into compliance

sometime in the future. (App. IV provides examples of the type of restrictions imposed on certain active ingredients as a result of EPA's interim registration standard reviews.)

In addition to imposing restrictions, since 1984 EPA has initiated special reviews of 12 active ingredients of concern because of actual or potential risk concerns based on data reviewed during the development of the 124 interim standards, according to EPA. (Ch. 7 discusses special reviews.)

To provide for greater public participation in the development of registration standards, EPA published a final rule in November 1985 to create and maintain a public docket for each standard developed and invite public comment on those registration standards where the chronic health effects data base of an active ingredient is substantially complete. EPA announced the availability of draft registration standards for five active ingredients in January 1986, the first standards on which public comment has been sought.

EPA Accelerates Data Collection, but Efforts Are Incomplete

To accelerate the collection of data needed for reregistration, EPA is requiring certain data from pesticide manufacturers before it begins to prepare a pesticide's interim registration standard. This effort is known as the Data Call-In Program; between 1981 and 1985, EPA reviewed 390 active ingredients to identify chronic toxicity tests missing from its files. EPA has also required data from registrants to address special concerns such as contamination of groundwater. Further, in fiscal year 1985 EPA initiated a pilot project to call in needed data on 31 non-food-use active ingredients; pilot project registrants are required to make the initial determination of what studies are needed for reassessment. EPA is planning to call in certain other needed data in fiscal year 1986.

While these Agency actions and plans will accelerate data collection in advance of initial reassessment, they are incomplete because EPA is not evaluating the adequacy of studies on hand under the Data Call-In Program. Certain of the data in EPA files are invalid or otherwise unacceptable for reregistration decision-making and will have to be repeated or replaced following interim registration standard review. Consequently, future initial registration standard reviews, while probably more complete because of incoming data, are likely to still be preliminary reassessments of older pesticides. On the other hand, calling in missing data may identify and clear inactive product registrations before EPA uses limited resources to review existing data.

In 1981, EPA initiated the Data Call-In Program to obtain chronic health data (chronic feeding, oncogenicity, reproduction and teratogenicity studies) missing from EPA files. The purpose of the program was to ensure that long-term toxicity tests, which take 3 to 4 years to produce, are available or under way when EPA begins to reassess an active ingredient. These tests are needed to reassess tolerances and evaluate a pesticide's potential for causing chronic health effects in humans. After accelerating the pace of the program in 1985, EPA has processed 390 active ingredients through the program, including all food-use pesticides, and notified registrants to submit about 1,400 studies. Since the longest of these studies takes 4 years to complete, EPA anticipates that it will have received all of the requested chronic studies by 1990. For the remaining 210 active ingredients, which are non-food-use chemicals, EPA may have registrants make the initial determination of what data are needed for reregistration, depending on the outcome of a pilot test of this approach discussed below.

Due to resource constraints, EPA decided not to review the scientific adequacy of studies already in its files during the Data-Call-In Program but to postpone such reviews until preparation of an interim registration standard. Consequently, an unknown number of existing studies will need to be repeated or replaced following registration standard review because EPA may determine that they are invalid or inadequate by today's standards. For example, in July 1982 EPA decided not to request any chronic toxicity studies for bentazon, a herbicide used on soybeans, under the Data Call-In Program, because existing studies were available. In 1985, EPA developed an interim registration standard for bentazon that identified existing studies as invalid and required replacement studies, some of which will take up to 4 years to complete.

In addition to calling in chronic toxicity data, EPA has required about 600 studies from registrants to address special concerns. These include

- product and residue chemistry and chronic toxicology data to evaluate existing tolerance exemptions for four chemical fumigant alternatives to ethylene dibromide (EDB) for insect control in stored grains,
- product chemistry and environmental fate data for 89 chemicals to assess their potential for contaminating groundwater,
- indoor air monitoring data on certain termiticides to assess human health risks, and
- reentry data on seven chemicals to determine the length of time required before a person can safely reenter a pesticide-treated site.

In fiscal year 1985, EPA initiated a pilot project to require registrants to identify and fill data gaps for two non-food-use chemical clusters. The two clusters include 31 active ingredients used in about 2,500 products—10 herbicides used on turf, lawns, ornamentals, golf courses, and public parks and 21 anti-slime chemicals used in pulp and paper mills, cooling towers, and sugar mills. Under the pilot project, registrants are required to make the initial determination of what studies are needed to satisfy all EPA data requirements in each scientific discipline and generate/submit any missing data. This procedure will not be expanded until it is evaluated this year, but according to the Director of OPP, preliminary results indicate it may be expanded in the future. This program is similar to the food-use data call-in—it identifies only missing studies and not the adequacy/validity of existing studies. In addition, EPA must eventually determine the completeness of the data submitted by the registrants.

To further accelerate the collection of studies needed for reassessment, EPA plans to call in human exposure data, such as residue chemistry data, for certain pesticides in 1986. In addition, EPA plans to call in updated confidential statements of formula and product chemistry data for all pesticide products in 1986. These data provide information on the formulation, identification, and quantification of intentionally added ingredients (both active and inert); impurities in pesticide products; and data on the chemical and physical characteristics of products and their components. Many of the existing data are obsolete, according to EPA. This call-in will involve approximately 6,000 registrants, 50,000 pesticide products, and 200,000 confidential statements of formula (several product formulations may be reported under the same registration number), according to the Agency.

One result of EPA's efforts to call in data has been to clear inactive registrations from Agency files. About 14 percent of the active ingredients reviewed have been suspended or voluntarily canceled because the pesticide is no longer produced or registrants decided not to pursue reregistration due to economic or other reasons.

Final Standards Are the Key to Reassessment

Final registration standards are for most pesticides the "key to the ultimate environmental pay-off from the entire reregistration effort," according to an OPP discussion paper. In preparing final standards, the Agency for the first time will be able to reassess its regulatory position

on older pesticide active ingredients based on complete data bases containing studies conducted in accordance with contemporary scientific standards.

According to a preliminary outline for final registration standards which the Agency refers to as Final Regulatory Standards and Tolerance Reassessment, these standards will

- make appropriate revisions to the regulatory position and rationale established by the interim standard,
- permit regulatory decisions that could not be made in the interim standard because of data deficiencies, and
- allow for reassessment of existing tolerances.

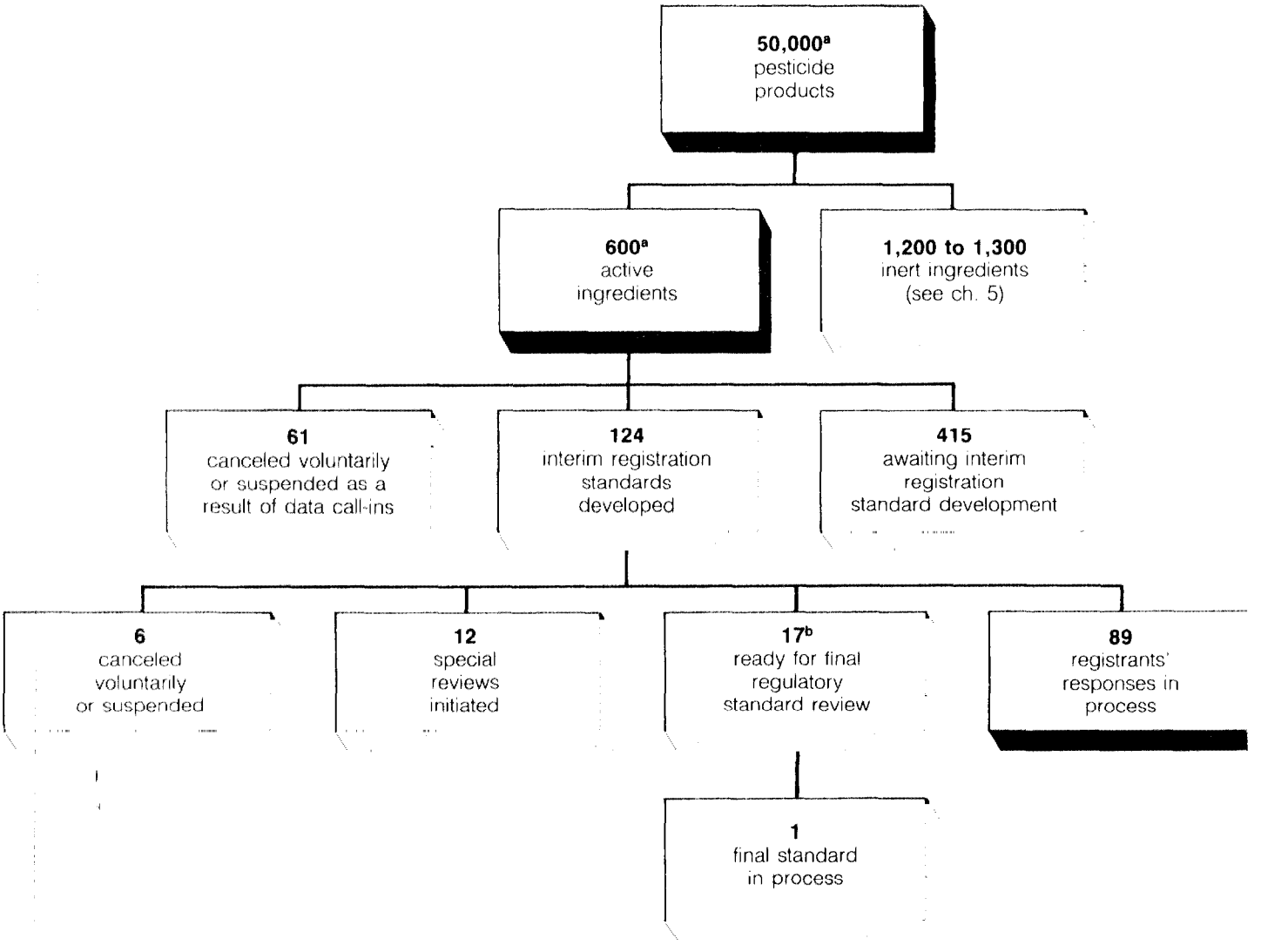
Final standards may also identify additional data the Agency needs to reassess an older pesticide. (App. III illustrates the current registration standards process.)

EPA anticipated that because of the time necessary to generate some of the data needed to conduct a full reassessment, the first reassessments based on complete data bases could not be conducted until fiscal year 1986. As of March 31, 1986, EPA is planning to complete the first final registration standard in fiscal year 1986, and 16 other active ingredients were ready for EPA's review to develop a final registration standard. Figure 2.1 provides the status of pesticide reassessments as of March 31, 1986. EPA has deferred developing final registration standards for 12 out of the 17 active ingredients because the interim standard identified minor data gaps and, based on review of the data required to fill these gaps, the Agency determined that it did not need to change its regulatory position, according to the Deputy Director of the Registration Division. EPA officials consider that reassessment is essentially complete for these 12 active ingredients and that preparing final registration standards for them would not be worth the resources. According to EPA, reassessment is essentially complete for warfarin, 4-amino-pyridine, methoprene, heliothiszea, butoxicarboxime, barium metaborate, isopropalin, OBPA, sulfur, hexazinone, chloroneb and chlorsulfuron.

Currently, EPA plans to conduct a pilot project on one active ingredient, metolachlor, in fiscal year 1986. Metolachlor, first registered in 1977, is a herbicide used on corn. EPA issued an interim standard for metolachlor in September 1980. EPA plans to use the metolachlor final registration standard to develop the tasks and procedures to prepare final registration standard and tolerance reassessments and to estimate resource

needs for future final standards. EPA plans to issue one final registration standard in fiscal year 1987 for one of the four other active ingredients (metalaxyl, phosalone, dimethoate, and aliette) that are ready for final registration standard review.

Figure 2.1: Status of Pesticides Undergoing Reregistration as of March 31, 1986



[a]Figures are approximate. EPA does not expect to review all older active ingredients or products because some are no longer produced or registrants may decide not to pursue reregistration.

[b]According to EPA, preparation of final standards has been deferred for 12 of these 17 active ingredients for which reassessment is essentially complete.

Source: Compiled from EPA information. We did not independently verify this information.

The number of final registration standards that EPA will have to prepare is uncertain but depends in part on how many interim standards it prepares. EPA anticipates that about 400 of the 600 active ingredients identified may require preparation of interim registration standards. The other 200 or so active ingredients (or about 35 percent) may not need to be reviewed because they are no longer produced or registrants may decide not to pursue reregistration of their products for economic and other reasons, according to the Deputy Director of the Registration Division, OPP. In these cases the product registration may be either voluntarily canceled by the registrant or suspended by the Agency thus eliminating them from final standard consideration. While a 35 percent drop-out rate is greater than the program's 14 percent experience to date, the Agency expects a higher drop-out rate in the future as the program begins to deal with lower volume or minor use pesticides, according to the Chief of the Program Coordination Staff, OPP.

EPA anticipates that it may conduct final registration standard reviews on two-thirds to three-fourths of the interim standards issued. The Agency expects that it may have to prepare fewer final standards because (1) a pesticide may no longer be produced due to market conditions and replacement with newer pesticides, (2) interim registration standards could result in canceled pesticides or uses, or (3) the special review of a pesticide of concern could result in final reassessment of that pesticide. The extent of this drop-off, however, is highly uncertain, according to EPA. Assuming that EPA prepares interim registration standards for about 400 to 600 active ingredients, the Agency would need to prepare final standards for about 260 to 450 ingredients.

The time frame for completing final registration standards also depends, in part, on how long it takes to complete interim standards. If EPA develops 25 interim standards a year as currently planned, then the Agency may issue interim standards for 400 active ingredients—assuming a 35 percent drop-out rate—in the mid to late 1990's. However, if EPA has to prepare interim registration standards for all 600 active ingredients, then the Agency may finish first round reviews around 2004.

Based on experience with tasks similar to those that will be required to do a final standard, EPA expects that each final standard may cost, in both time and resources, about as much as an interim standard. Later final standards may be less costly as interim standards are developed with more complete data bases as a result of the accelerated data call-in efforts. The time and resources required are subject to many variables,

including the amount and complexity of data to be reviewed, tolerance and other quantitative risk assessments, regulatory issues, and other factors.

Currently, EPA is planning to complete all final registration standards around 2005, depending on an anticipated increase in resources beginning in fiscal year 1988 to prepare these standards and on the Agency's experience in preparing final standards. EPA anticipates that the number of active ingredients ready for final registration standard review (i.e., all required data have been submitted) will accumulate at the rate of up to 20 per year. If additional resources are not made available beginning in fiscal year 1988, then EPA will have to balance resources between developing new interim standards for remaining active ingredients and completing final standards for already developed interim standards.

More to Do After Final Registration Standards

Although completion of final registration standards and tolerance reassessments may result in the culmination of pesticide reassessment, it does not complete the process of reregistering individual pesticide products. Following development of final standards, EPA will have to apply decisions reached on active ingredients to individual products containing these ingredients, including those containing more than one active ingredient, and take appropriate regulatory action such as reregistering products, imposing restrictions, or suspending and canceling registrations, if needed. In addition, EPA will have to update and revise the final standards, as needed, because of the dynamic nature of pesticide regulation and to preclude a costly reregistration-type effort sometime in the future. The time and resources needed to complete these tasks are unknown. However, according to EPA, it will be at least another 20 years before the Agency completes reregistration of all pesticide products.

The registration standards process will enable EPA to make judgments about the continued registrability of an active ingredient from a health and safety standpoint, but the licensing scheme of FIFRA requires EPA to reregister individual products. Registration standards are Agency position documents that do not in themselves constitute a final Agency determination pertaining to any particular pesticide product. When final standards have been completed, EPA will have to review the registrations of individual products to determine if they are in compliance with current requirements and, if not, impose necessary requirements, such as product-specific data requirements (i.e., acute toxicity and product chemistry data) and labeling restrictions/precautions.

While there are no firm estimates, EPA officials estimate that reregistering all pesticide products may take at least another 20 years or more to complete. In 1978 EPA initially estimated that the program would take 10 to 15 years to complete. The Director of the Registration Division, OPP, told us that he was not aware of any new estimates. The Director of the Program Management and Support Division, OPP, told us that with fixed resources the program may take until 2010 to 2015 to complete. However, the Chief of the Program Coordination Staff believes that EPA will essentially complete the reregistration program around the year 2005 when the Agency expects to complete all final registration standards for older pesticides.

Once EPA develops a final registration standard for a pesticide, the Agency may need to update and/or amend it to reflect changes in pesticide uses, composition, and formula not covered in the standard; advancements in science and technology; new data of a type not previously required; and new information, or a reinterpretation of data, which indicates significant human health or environmental concerns. In a sense, final standards will never be "final" per se. According to the Chief of the Program Coordination Staff, the need to maintain and update final registration standards will be a significant issue. Under EPA's proposed rules for registration, the Agency will revise registration standards on an as-needed basis. EPA concluded that reviewing registration standards every 5 years, to implement the renewal clause of Section 6(a)(1) of FIFRA, would be unnecessary and time-consuming. However, maintaining final registration standards will be a critical cost of doing business if EPA is to avoid costly and long-term efforts to periodically reregister pesticides to bring them into compliance with evolving requirements, science, and uses.

Reregistered Products Have Not Been Fully Reassessed

The term "reregistered" implies that an older pesticide product complies with all current registration requirements. However, the term, as defined and used by EPA, reflects merely a commitment by a registrant to comply with data requirements and amend product labels as required by interim registration standards. As of September 23, 1985, EPA had "reregistered" 145 pesticide products even though significant long-term data gaps are likely to still exist for certain of the active ingredients used in these products. EPA was using these "reregistrations" to measure progress but has discontinued this use, although the policies and procedures used to "reregister" these products remain in effect.

Under current EPA procedures the Agency may reregister pesticide products after issuance of an interim registration standard, but before EPA has received and reviewed all data required to complete pesticide reassessment. For example, EPA issued an interim registration standard for metolachlor in September 1980. EPA "reregistered" three metolachlor products in 1982. At the time EPA reregistered these products, several gaps existed in the data base for metolachlor, including studies of its potential chronic effects. According to the OPP product manager for metolachlor, the products were conditionally reregistered pending EPA's receipt and review of the required studies. As noted earlier, EPA is planning to use metolachlor as the pilot pesticide for preparing final registration standards and tolerance reassessments in fiscal year 1986. Thus, it will be about 4 years after EPA reregistered two metolachlor pesticide products before the Agency prepares a final reassessment of the active ingredient. Even so, the process may not be complete if EPA determines that it needs still further data to complete reassessment.

Agency officials we spoke to acknowledged that EPA's use of the term "reregistration" is a misnomer and said that OPP's definition of reregistration evolved from a need to show progress in a long-term program. Agency officials also told us that only Section 3(g) of FIFRA refers specifically to reregistration and the section neither defines the term nor specifies how it is to be carried out. However, since FIFRA defines registration to include reregistration under section 2(z), the Agency's review of pesticide product applications for reregistration encompasses the same considerations as for unconditional or conditional registrations of pesticide products, depending on whether additional data are required, according to EPA. EPA officials we spoke with believe that further congressional direction as to the requirements for reregistration would be desirable.

In September 1985, the Registration Division discontinued manually tracking the number of products reregistered. However, OPP's policies and procedures for reregistering pesticide products remain in effect. OPP officials could not tell us how many products the Agency "reregistered" through March of 1986. Consequently, EPA may be continuing to "reregister" pesticide products before completely reassessing the pesticides.

In fiscal year 1985 EPA adopted a new measure of progress—the implementation of an interim standard. Implementation—the extent to which the Agency has secured commitments from registrants and effected changes in pesticide registrations—is a more realistic measure of program progress, according to EPA officials. EPA considers implementation

of an interim standard complete when 80 percent of the products containing the chemical as an active ingredient are accounted for—that is, when either the registrant(s) has agreed to submit all studies required by EPA and has submitted an acceptable draft label, or the product(s) has been suspended or canceled. The Agency's goal is to complete implementation of an interim registration standard within 1 year of issuance. This time frame allows 6 months for registrants to comply with interim standard requirements (including commitment to satisfy long-term data requirements) and 6 months for EPA to process the necessary paperwork, review draft labels, and evaluate short-term studies—product chemistry and acute toxicity data. For fiscal year 1985, EPA was behind its schedule for implementing interim registration standards, implementing 16 of 20 targeted standards. EPA is behind in implementing interim standards because the Agency, until recently, did not follow up on registrant compliance with these requirements, according to the Deputy Director of the Registration Division. EPA's lack of follow-up is discussed in the next section.

Follow-Up Action on Registration Standard Requirements Needs Improvement

The success of EPA's reassessment of older pesticides, including the production of required data and the avoidance of unreasonable adverse effects, depends in part on timely registrant compliance with the data and labeling requirements of interim standards and on Agency efforts to enforce these requirements. Although compliance is a critical phase in successfully completing reregistration, EPA until recently did not routinely follow up on registrants' compliance with interim registration standard requirements. As of January 1986, about 50 percent of registrant responses to interim standard requirements were overdue. EPA is just beginning to deal with the administrative and legal issues involved in following up on—monitoring and enforcing—interim registration standard requirements.

Many Products Are Not in Compliance With Interim Registration Standard Requirements

EPA, until recently, did not know whether registrants were complying with interim registration standard requirements because the Agency was not following up on these requirements. Although EPA's follow-up action is incomplete, preliminary estimates, based on initial follow-up actions, indicate that many products are not in compliance with interim registration standard requirements. The extent of registrant compliance or noncompliance may not be fully known until EPA completes follow-up actions on all interim registration standards issued, according to EPA officials.

Initial reports indicated significant registrant noncompliance. For example, registrants' responses to almost half of the requirements imposed by 74 interim registration standards, for which data were available from the OPP Call-In Action Tracking System in January 1986, were overdue. Data supplied by EPA from the tracking system indicate that about 47 percent of registrant responses to active ingredient data requirements (i.e., chronic toxicity data on the active ingredient) were overdue. Further, about 54 percent of registrant responses to product-specific requirements were overdue. These latter requirements, which include acute toxicity and product chemistry studies, and revised labels, usually have to be submitted to EPA within 6 months of issuance of the interim standard.

According to the Deputy Director of the Registration Division, the tracking system overstates actual noncompliance because the system tracks noncompliance as an unresolved requirement and several requirements may relate to one action, such as submitting a study. The system also may overstate noncompliance because of lags in entering the results of recent OPP follow-up actions into the system. As part of its recent emphasis to follow up on interim standards issued, OPP has been manually updating its records. Although these efforts are incomplete, the Deputy Director estimated that as of March 1986 about 75 percent of the products covered in the 74 interim registration standards in the tracking system were in overall compliance with the requirements imposed; 80 percent of the products were in compliance (20 percent noncompliance) with the active ingredient data requirements; and 70 percent of the products were in compliance (30 percent noncompliance) with the product-specific requirements. The Deputy Director believes that the rates of compliance will continue to improve as the result of more recent follow-up actions are entered into the tracking system. (App. V illustrates the compliance status of pesticide products covered by the first 90 interim registration standards as of September 23, 1985.)

EPA Begins Follow-Up Actions

In fiscal year 1985 EPA began conducting a project to follow up on interim registration standard requirements. The project, which has been costly to develop according to the Chief of the Program Coordination Staff, has initially focused on developing a process to follow up on registrants' compliance with interim registration standards and catch up on the interim standards that have been issued.

Several EPA officials we spoke with told us that OPP did not routinely follow up on interim registration standards prior to fiscal year 1985

because the Agency was concentrating on developing the standards. According to the Director of the Registration Division, follow-up on interim registration standards is currently one of OPP's highest priorities. However, the Director has expressed concern that the follow-up process is behind schedule.

According to EPA's draft standard operating procedures on follow-up, developed in 1985, once an interim standard is developed, EPA must follow up on the requirements imposed. Follow-up involves

- maintaining records for all products covered by a standard;
- resolving registrant responses to requirements (i.e., challenges to data and label requirements, commitments, requests for test protocol reviews, requests for data waivers, requests for time extensions, voluntary cancelations of product registrations, etc.);
- monitoring registrants' compliance with requirements on a product-specific basis;
- initiating suspension actions against product registrations not in compliance with data requirements;
- recording receipt of new data and screening them for early review;
- reviewing draft labels; and
- changing and amending standards to reflect registrants' responses to requirements, new data, or proposed new uses.

EPA has not issued final follow-up procedures because the Agency is developing procedures for canceling product registrations not in compliance with labeling requirements.

Implementing and following up on interim registration standards (not including review of additional data) may cost as much as developing an interim standard, according to the Chief of the Insecticide/Rodenticide Branch. However, the cost is uncertain because of the limited actual data on this activity. Tracking individual products against requirements can require thousands of actions. For example, the interim registration standard for disulfoton affected 113 products and required, among other things, a total of 27 product-specific studies. However, EPA has to track about 1,162 product-specific requirements over a period of time to ensure that the registrants for the 113 products comply with the product-specific and administrative-type data requirements.

OPP product managers handle voluminous records and changes to records in monitoring registrants' compliance with data and labeling requirements. To assist them, OPP has been developing an automated

tracking system. Planned and designed in fiscal year 1984 and started in fiscal year 1985, the system, called the Call-In Action Tracking System, has experienced several startup delays. As of January 22, 1986, the data on 74 interim registration standards had been entered into the tracking system. Thirty-nine of the 74 standards had completed the system's quality control procedures to ensure correct data entry. The Registration Division has committed itself to process the other registration standards through the quality control steps by spring of 1986.

EPA is beginning to issue suspensions to enforce data requirements imposed by interim registration standards. According to OPP's draft follow-up procedures, the Agency may issue a Notice of Intent to Suspend (suspension notice) under authority of FIFRA Section 3(c)(2)(B) if it determines that a registrant is not taking appropriate steps to secure the required data in a timely manner or if a registrant does not produce the data or information when required. Suspension is effective 30 days after a registrant receives the notice unless a limited hearing is requested or EPA determines that the registrant has complied. A suspension, which may continue indefinitely, precludes a registrant from distributing a product until it complies with the data requirements that served as the basis for the suspension.[4] According to the Deputy Director of the Registration Division, OPP has issued several hundred suspension notices within recent months to enforce data requirements.

EPA must issue a separate suspension notice for each unmet data requirement, according to the Deputy Director. This means a product registration is subject to multiple suspensions for not complying with several data requirements. OPP is behind in issuing multiple suspension notices, according to the Deputy Director, and this is one reason for the high noncompliance statistics reported by the tracking system. EPA would like to cancel suspended registrations to clear the Agency's records, but (involuntary) cancelation procedures are difficult, according to the Assistant to the Director, Registration Division. Instead, EPA is encouraging registrants that decide not to comply with interim registration standard requirements to voluntarily cancel their product registrations by allowing the registrant to sell and distribute existing stocks of its product up to a year after the cancelation becomes effective.

[4] In order to enforce a suspension notice after it becomes effective EPA's Office of Compliance Monitoring (OCM) must issue a Stop Sale, Use or Removal Order (SSURO). OCM issued a compliance strategy for enforcing suspension notices on Sept. 3, 1985.

Problems in Enforcing Labeling Changes

Label requirements are the primary mechanism by which EPA regulates the use and misuse of pesticides. Labels specify the composition and packaging of a product and provide use directions, warnings, precautionary statements, and other needed restrictions to assure that proper use of the pesticide product poses no unreasonable risk. As noted earlier, EPA is imposing label restrictions on certain pesticide products through interim registration standards to update old product labels and to reduce risks to human health or the environment.

While most registrants may be complying with the labeling requirements imposed by interim registration standards, several are not. According to the Deputy Director of the Registration Division, currently, 175 pesticide products are not in compliance with interim registration standard labeling requirements and are subject to cancelation. According to EPA officials, OPP has not yet taken regulatory action against these products because FIFRA does not provide a simple procedure for canceling products for failure to meet label requirements. The problem EPA faces in enforcing labeling requirements demonstrates the difficulty it has in effecting changes in existing registrations.

EPA changes and enforces labeling requirements through the formal cancelation procedures under Section 6(b) of FIFRA. If a registrant fails to comply with these requirements, EPA may issue a Notice of Intent to Cancel (cancelation notice), which permanently revokes a registration. Before issuing a cancelation notice, EPA has to (1) analyze the risks and benefits and impact on the agricultural economy and (2) submit the analysis for review to the FIFRA Scientific Advisory Panel and USDA. Further, a registrant whose registration is threatened with cancelation is entitled to a full adjudicatory hearing on the merits of the Agency's decision to cancel the registration. These hearings provide an opportunity for the registrant to rebut the Agency's decision. Hearings of this type have been conducted in the past following special reviews of pesticides of concern and have been time-consuming—some have lasted several years. (See ch. 7.)

EPA has not yet issued any cancelation notices to enforce interim registration standard requirements, according to EPA officials. According to the Deputy Director, OPP, EPA has not taken this action because the Agency lacks the resources to carry out the required cancelation procedures on all products that could be subject to cancelation. According to EPA's Assistant General Counsel for pesticides, FIFRA provides sufficient authority for EPA to cancel pesticide registrations for failure to comply with labeling requirements but the process provided by the law is time-

consuming and resource-intensive. Alternatively, the Agency may elect to enforce required labeling changes through the misbranding provisions of FIFRA Section 12.[5] However, this might take as much work to do as processing a cancelation notice, according to this official.

Currently, EPA is planning to streamline the process for issuing cancelation notices to enforce labeling requirements. The Agency is planning to pilot-test these procedures on the chemical phorate, for which 6 of 32 product labels have not been submitted as required by the interim registration standard. The results of this attempt are as yet unknown.

Because cancelation proceedings are costly and time-consuming, EPA officials would prefer to use informal rule-making to more efficiently implement label requirements while providing an opportunity for a registrant to contest the Agency's decision. According to EPA's Assistant General Counsel, explicit statutory authority providing EPA with this option is needed and desired. On March 20, 1986, the Assistant Administrator for Pesticides and Toxic Substances testified before a House Agriculture subcommittee that the Agency thinks it should have the option to use the rule-making process to implement labeling changes and discussed a possible approach.

Pesticide Activities Compete for Limited Resources Available to EPA

Although EPA separately budgets registration and reregistration activities, competing demands for the limited resources available to OPP influences the programs' accomplishments. Concurrent with its efforts to reassess and reregister older pesticides, EPA must register new pesticides, approve new or experimental uses of pesticides, approve tolerances, amend product registrations, and perform other activities. While EPA's workload with respect to reregistration has increased, the resources available to the pesticide program are less than at their peak in 1980. Even with a recent emphasis on reregistration, EPA has determined that it will be unable to immediately review new studies required for reassessment. In addition, EPA must address emerging pesticide issues and concerns such as pesticide contamination of groundwater; toxicity of inert ingredients, impurities and contaminants; regulation of new, genetically engineered pesticides; and other issues.

[5] Generally, a product whose label or labeling does not contain the information required by EPA to protect health or the environment or which sets forth false or misleading information is misbranded. According to EPA, FIFRA establishes 12 specific situations in which a pesticide is misbranded, 7 U.S.C. 136(q).

To some extent, EPA's accomplishments with respect to regulating pesticides are a function of resources. The pace of reregistration is more a function of resources than process, according to the former Director of OPP, now the Acting Deputy Assistant Administrator for Water. The Acting Chief of the Program Coordination Staff told us that EPA has probably obtained maximum efficiency in the Registration Standards Program and any additional increase in output without a corresponding increase in resources would threaten the quality of the program.

The development of interim registration standards has been affected by the program's budget. In 1972, when the reregistration requirement was mandated, the pesticide program had 432 positions authorized and $11 million appropriated. The program reached its peak in fiscal year 1980 with 829 full-time equivalents (FTEs) and $45 million in actual expenditures. In fiscal year 1985 the program had 591 FTEs and $44 million in actual expenditures. These figures were not adjusted for inflation. EPA initially planned to develop 50 registration standards a year, but this was not possible because of program budget cuts, according to the Chief of the Policy and Special Projects Staff. Table 2.3 shows the Office of Pesticide Programs' budget history for fiscal years 1984, 1985, and 1986.

Table 2.3: Office of Pesticide Programs Budget and Staff History for Fiscal Years 1984-86

	1984[a]		1985[a]		1986[b]	
	(million)	(staff years)	(million)	(staff years)	(million)	(staff years)
Reregistration (Generic chemical review)	$19.8	207.5	$24.2	249.6	$21.4	274.3
Registration	9.7	220.0	14.8	217.9	13.0	207.3
Tolerances	2.4	65.9	3.1	78.5	2.8	73.8
Special registration	2.7	61.5	2.1	45.0	1.5	31.9
Total	**$34.6**	**554.9**	**$44.2**	**591.0**	**$38.7**	**587.3**

[a]Actual obligations and staff years.

[b]Estimated obligations and staff years.

Source: EPA.

In November 1985, EPA announced the Agency's number one priority for fiscal year 1987: the reduction of risks from exposure to existing pesticides and toxic substances. In February 1986 EPA announced that the President's fiscal year 1987 budget estimate includes $40.3 million for OPP. The estimate includes an increase of $1 million for OPP's generic chemical review program (reregistration) over fiscal year 1986 but no increase in staff years. Since fiscal year 1985 EPA has been shifting

resources from new pesticide registration activities to reregistration activities reflecting increasing Agency priority on reregistration.

Even with increased emphasis on reregistration, EPA has determined, because of resource constraints, that it will be unable to review immediately upon receipt the increasing volume of new studies it expects to receive. As a result of its reregistration efforts, EPA expects to receive an increasingly large number of studies requiring review. This has been characterized by EPA officials and others as the "data wave." While the number of studies to be received is uncertain and dependent on registrant compliance with requirements, EPA has decided that it generally will not review individual studies as they are received. Instead, the Agency will wait until all studies required for the final registration standard review of a specific pesticide are received. However, EPA will screen certain incoming studies for early reviews.

To assist EPA in screening and scheduling data reviews, EPA proposed on October 3, 1985, a rule to establish criteria by which pesticide applicants and registrants who submit certain types of toxicology, environmental fate, exposure assessment, or ecological effects data to identify—"flag"—a study if the results indicate possible adverse effects or demonstrate that the pesticide has characteristics of concern. In addition, under FIFRA Section 6(a)(2) EPA requires all registrants to submit to the Agency additional factual information regarding unreasonable adverse effects on the environment of registered pesticides if they possess, generate, or become aware of such information after registration. According to EPA officials, the flagging criteria will enable the Agency to focus on pesticides of greatest concern, but are not intended to define adverse effects. The actual number of studies that may be flagged by registrants and require immediate review by EPA is unknown but may be significant. OPP estimates, on the basis of a pilot study, that about 40 percent of incoming studies subject to the proposed flagging criteria may be flagged for immediate review. Further, a large number of studies, such as acute toxicology and mutagenicity studies, are not subject to the flagging criteria. If EPA is unsuccessful in screening incoming data for early review, then data in its possession, which may indicate a possible concern with an existing pesticide, may not be reviewed until EPA receives all required data for the pesticide and schedules the pesticide for a comprehensive review sometime in the future.

EPA is responsible not only for reregistering older pesticides but also for registering new ones. In fiscal year 1985 EPA conducted over 17,000 new

registration actions (multiple decisions on pending registration applications and tolerance petitions), including 354 reviews of new active ingredients, 4,209 reviews of similar pesticide product registrations, 9,749 reviews of registration amendments, and 596 tolerance petition reviews. In fiscal year 1985, these activities accounted for $20 million (45 percent of OPP's programs) and required 341 staff years (58 percent of OPP's programs). In fiscal year 1985, backlogs in OPP's new registration reviews grew in part as a result of the Agency's priority attention to reregistration.

In addition to these activities, EPA must address emerging pesticide regulatory issues. For example, one of the problems EPA is contending with is how to deal with actual or potential pesticide contamination of groundwater. Over half the population of the United States gets drinking water from groundwater, including 95 percent of rural residents. The extent of groundwater contamination by pesticides is generally unknown. However, 17 pesticides have been detected in groundwater in 23 states as a result of normal agricultural use. The concern is that people may be unknowingly exposed to high levels of pesticide residues by drinking water from contaminated groundwater and that a natural resource is being polluted. In addition to calling in environmental fate data on 89 active ingredients, EPA has taken specific actions to suspend, cancel, or impose restrictions on approximately 10 pesticides because of groundwater concerns.

EPA has made a start in addressing the issues surrounding groundwater protection, but the effort is a long-term one. It is too early to evaluate the success or effectiveness of these early groundwater protection effects. However, environmentalists, industry representatives, and others have urged EPA to act more quickly in providing federal leadership on this national issue. (App. VIII provides more information on how this issue is beginning to be addressed.)

Alternatives for Accelerating Reregistration Are Limited

A major criticism of EPA's Office of Pesticide Programs by members of Congress, the pesticide industry, environmental groups, and others is that reregistration is proceeding slowly and needs to be accelerated. However, the alternatives available for significantly accelerating this time-consuming and resource-intensive effort appear limited because of the tasks involved in technically reviewing a large volume of data and making complex regulatory decisions for a large number of pesticides. According to the Director of the Registration Division, there are no shortcuts to the current process.

Three alternatives discussed by different organizations which might accelerate the pace of reregistration are:

- Further shift the burden to industry to identify and submit all data necessary for reregistration, including replacement of previously submitted data that are no longer deemed scientifically acceptable.
- Impose statutory deadlines for the required generation, submission, and review of required data.
- Provide additional program resources, through general revenues or user fees, to accelerate the development of registration standards and data reviews.

These alternatives are neither all-inclusive nor mutually exclusive. Each has certain advantages and disadvantages. Our intent in discussing these alternatives is to show that there is no simple way to significantly accelerate the reregistration of older pesticides. We did not analyze the costs and other implications associated with these alternatives.

Shift Burden to Industry

One alternative for accelerating reregistration would be to shift more of the regulatory burden of reassessing older pesticides to industry. Under this alternative registrants could be expected to conform with different levels of responsibility. Registrants could be expected to determine and develop the complete data base necessary to reassess and reregister their pesticides. To do this, registrants would have to apply the published data requirements and guidelines to their own products, determine what data requirements apply, review existing data in support of their registrations, identify missing or invalid data, and develop any additional or replacement data that are necessary within certain time periods. If registrants failed to comply, EPA could suspend the product registrations.

Registrants could also be expected to review the studies supporting their registrations and take appropriate regulatory action to reduce risks. Using explicit EPA criteria, registrants would self-certify that all required determinations had been properly made to bring their products into compliance with current registration requirements. Registrants would be responsible for reviewing data and taking prompt and appropriate measures to reduce risks, including adding labeling precautions or notifying EPA should a risk concern be triggered. According to a preliminary discussion paper prepared by EPA's Office of Policy, Planning, and Evaluation, EPA would have to develop explicit certification criteria for

registrants to follow. In addition, the Agency would have to audit registrant certifications and data reviews and penalize registrants for noncompliance (i.e., suspend or cancel registrations) to ensure registrant compliance with certification criteria.

EPA discussed this alternative with its former Administrator's Pesticide Advisory Committee and is currently testing part of it. The pilot data call-in on 31 non-food-use active ingredients is testing the use of registrants to identify and submit missing data. EPA had considered expanding the call-in to require registrants to identify and replace invalid/inadequate data as well as missing data. However, according to an EPA analysis, the Agency's experience in having registrants judge the validity of existing data had been disappointing in the past, in part because the Agency did not develop explicit criteria for registrants to follow. For example, in the early 1980's EPA initiated a pilot project to determine the feasibility of having registrants assist in preparing registration standards—reviewing their own data, preparing study reviews, and identifying data gaps. Although registrants were cooperative, EPA found that registrant involvement cost OPP resources rather than saved them because of the need to instruct registrants on what to do and then to scrutinize carefully their work products, according to a 1984 OPP analysis of the registration standards process.[6]

EPA officials currently believe that shifting the burden to industry to develop a complete data base is possible because registrants are now more familiar with what studies are required to support pesticide uses. With the publication of the data requirements (Part 158) and pesticide assessment guidelines, new pesticide registration applicants are expected to be able to apply the guidelines and present the Agency with an application supported by all the required data. This same expectation could be extended to registrants of old pesticides, according to EPA officials. Further, these officials believe that with appropriate oversight of registrant data submissions through random and "for-cause" audits and the threat of suspension, the Agency could ensure registrant compliance.

This alternative may accelerate reregistration if registrants comply with EPA's criteria and the Agency is able to effectively oversee registrant data submission. However, based on EPA's past experience, questions

[6] EPA agreed to eliminate the preparation of industry-assisted registration standards as part of its September 1984 settlement with the Natural Resources Defense Council (NRDC). (Natural Resources Defense Council v. Ruckelshaus, No. 83-1509 (D.D.C. settlement approved, Oct. 14, 1984)). In 1983 NRDC and others sued EPA, challenging, among other things, the Agency's practice of developing industry-assisted pesticide registration standards.

remain on the likely success of this alternative. In addition, one other consideration is how such a process may be perceived by the public and whether public trust in EPA's regulation of pesticides would be eroded regardless of whether such a process was successful. EPA could pilot-test this approach on a sample of active ingredients and, if it were found successful, could expand the approach to other active ingredients to accelerate reregistration.

Impose Statutory Deadlines

Another alternative that has been widely discussed is the reestablishment of statutory deadlines for reregistration. On March 11, 1986, a bill was introduced in the Congress for completing reregistration of all active ingredients initially registered before September 30, 1978, within 7 years. Under the bill, H.R. 4364,[7] EPA is required to fully evaluate the existing data supporting registrations and notify registrants to submit required data, within 18 months of the effective date of the act, for a priority list of 300 active ingredients and, within 24 months of the effective date of the act, for the remaining chemicals. Pesticide manufacturers then have up to 4 years to complete the required studies. Following registrant submission of the studies, EPA has 1 year to reregister the pesticide. If the required data are not submitted, the registration would be suspended. The bill also provides for a one-time fee on active ingredients to financially assist, in part, EPA's efforts in meeting the reregistration deadlines. H.R. 4364, referred to as the compromise bill, reflects an accord reached between the National Agricultural Chemicals Association (NACA), a trade association representing 92 manufacturing companies, and the Campaign for Pesticide Reform (CPR), a coalition of 41 environmental, consumer, and labor groups. EPA and others have informally expressed concerns about the deadlines in H.R. 4364 and some have recently proposed alternate schedules for accelerating reregistration. We did not evaluate the feasibility or reasonableness of any of the proposed reregistration deadlines.

The compromise bill is similar to legislation enacted in the state of California in 1984 in setting a priority schedule for filling data gaps for pesticides posing the greatest risk. The California Birth Defects Prevention Act, a first-of-its-kind state law, seeks to fill critical data gaps for 10 chronic health effects tests on all pesticides registered by the state before July 1, 1983. The California act establishes time frames for the evaluation of existing data and submission of required data intitially targeted to the top 200 pesticides (those with the most significant data

[7] A companion bill, S. 2215, was introduced in the Senate on March 20, 1986.

gaps, widespread usage, and potential adverse health effects). All required health studies must be completed by March 1, 1991, according to a California state budget analysis.

According to the Special Assistant to the Director, Division of Pest Management, California Department of Food and Agriculture, the program will take about 10 years to complete because of the volume of data needing review. Further, the full cost of the program to the state is unknown because the number of studies that will indicate adverse effects and require risk assessments is unknown.

Establishing reasonable deadlines, perhaps with interim milestones, might accelerate reregistration even if a corresponding revenue generation scheme is not adopted. In September 1985 an EPA-funded study on the effectiveness of statutory deadlines in environmental laws, conducted by the Environmental and Energy Study Institute and the Enviromental Law Institute, concluded that although EPA misses most deadlines, statutory deadlines play an effective role in speeding action by EPA, states, and the regulated community. According to the researchers, deadlines that are perceived as realistic are more effective. The researchers recommended, among other things, that deadlines be realistic and that interim deadlines should be set for major, long-term undertakings. However, we are mindful of past deadlines on completing reregistration which were unattainable. In addition, although this alternative might accelerate the generation of data critical for reassessment, EPA would still have to monitor registrant responses to data requirements and review and evaluate the immense volume of data submitted.

Provide Additional Resources

A key controlling element in the reregistration process, as well as for all of EPA's pesticide work, is the resources—people and money—available to carry out the Agency's responsibilities. Accordingly, the most obvious and fastest way of expediting reregistration is to increase program resources.

Resources could be increased by hiring additional qualified employees or obtaining outside assistance. In October 1984 the House Committee on Government Operations, on the basis of a study of EPA's pesticide registration activities, recommended that EPA seek assistance from outside scientific organizations, such as the National Academy of Sciences/ National Resource Council, to assist in reviewing the volume of data required for reregistration. The Committee questioned whether EPA could ever complete reregistration without outside assistance because of

the magnitude of the task, limited personnel resources, and continuing budgetary constraints. In responding to the Committee's report, EPA concluded that the use of outside scientific panels would not significantly affect the pace at which reviews are being conducted. Further, according to an EPA analysis, while groups such as the National Academy of Sciences have high scientific expertise, reliance on them to conduct full science reviews would be inefficient because these groups would be unfamiliar with EPA's methodology for conducting reviews and are subject to high reviewer turnover rates.

Greater reliance on contractors to conduct full science reviews might also not significantly accelerate reregistration based on the Agency's reported experience with contractors. EPA already relies extensively on contractor support to conduct science reviews in support of registration standards; its experience with this practice has been highly variable, according to an internal EPA analysis of the Registration Standards Program. Further, contractor personnel turnover has delayed interim registration standard development in some cases, according to EPA's internal tracking records. Also, EPA would still have to monitor contracted reviews.

One possibility for increasing resources to accelerate reregistration is to charge user fees for pesticide registration and reregistration activities to recover the costs of these activities. For the registrants this would be a cost of doing business since they cannot market their products without being registered/reregistered. As noted above, recently proposed amendments to FIFRA provide for assessing fees to accelerate reregistration. We did not analyze the feasibility or implications of these fee proposals.

The basic authority for federal agencies to assess fees for services is contained in 31 U.S.C. 9701. This law, commonly referred to as the User Charge Statute, authorizes and encourages federal agencies to recover, to the fullest extent possible, costs attributable to special benefit services provided to identifiable recipients. Fees collected under this statute are deposited into the U.S. Treasury as miscellaneous receipts.

Currently, EPA charges user fees for its review of industry submitted tolerance petitions under authority of FFDCA Section 408(o). Unlike funds collected under the User Charge Statute, those collected for tolerance petitions are placed into a revolving fund to be used by EPA as is authorized by Public Law 88-136, an appropriation act for fiscal year 1964. The revolving fund is then charged as the fees are earned, i.e., as the petition reviews are completed.

EPA has considered assessing user fees to recover the costs of pesticide registration and reregistration activities. In 1980, after studying the issue at the request of the Congress, EPA found that establishing a fee schedule for registration actions would be both technically and administratively feasible.

EPA believes that it has sufficient legal authority to charge fees for registration and reregistration of pesticides under the User Charge Statute, but the Agency would prefer explicit authority under FIFRA to charge fees to avoid possible litigation which might delay assessing fees. Further, funds collected under the User Charge Statute would be deposited into the U.S. Treasury and would not be available to the program. EPA believes it needs statutory authority to be able to retain funds collected from user fees.

More recently, EPA has been considering a draft proposed rule that would establish a user-fee system to recover the costs of certain pesticide registration activities. The proposed rule also states EPA's belief that it could charge fees for reregistering products; therefore, the Agency intends to expand the proposed user-fee system to recover reregistration costs in the future. Issuance of this proposal has been postponed pending the issuance of findings/recommendations by an EPA task force formed to determine the feasibility of charging user fees for various EPA programs, including pesticides. The task force will also be considering the issue of making revenues from such fees directly available to the programs. The task force hopes to develop a preliminary report by the spring of 1986. The President's budget for fiscal year 1987 anticipates collecting $15 million from user fees for pesticide registration activities.

EPA's Latest Proposal to Expedite Reregistration

Although the Administration has not formally introduced legislation to amend FIFRA, EPA's Assistant Administrator for Pesticides and Toxic Substances, in testimony before the Subcommittee on Department Operations, Research and Foreign Agriculture, House Committee on Agriculture, on March 20, 1986, outlined a new two-staged approach to accomplish reregistration in 9 years. The new approach includes

- placing the burden on registrants to review existing studies for validity, identify data gaps, and commit to develop the data within specified time frames;
- setting a date for when current registrations would expire;

- immediately canceling product registrations for failing to comply with reregistration requirements; and
- assessing fees to assist the Agency in accelerating reregistration.

Because of the recency of the proposal, sufficient time was not available for us to evaluate EPA's proposed new approach to accelerate reregistration.

Conclusions

While much of the population is exposed daily to pesticides in food and the environment, EPA has limited assurance that human health and the environment are adequately protected from possible unreasonable risks of older pesticides. This is because most pesticides used today were initially registered before contemporary regulatory and scientific requirements were imposed. These older pesticides have not been fully tested to determine, among other things, their potential for causing long-term health effects, such as cancer and reproductive disorders, birth defects, and environmental damage. In the 1972 ammendments to FIFRA, the Congress required EPA to reassess the health and safety effects of all previously registered pesticide products and reregister only those that meet contemporary registration requirements. In the meantime, these products can continue to be marketed.

EPA faces a formidable task in reassessing the risks of pesticides registered over the past three decades. The task has proven to be a much more extensive and time-consuming effort than first envisioned, as evidenced by the initial 4-year deadline which the Agency did not achieve. Making a definitive determination on the acceptability of each piece of existing data, identifying data gaps, and making scientific and regulatory decisions are time-consuming tasks. In addition, the production of required new or replacement data takes time—up to 4 years in the case of chronic toxicity data.

The key element in the reregistration effort is EPA's Registration Standards Program. Under this program EPA plans to gather and evaluate data from pesticide manufacturers on about 600 active ingredients used in about 50,000 pesticide products. After a slow start EPA is beginning to make progress. As of March 31, 1986 EPA had developed 124 interim registration standards that state what is known about a pesticide, identify data gaps, and impose restrictions, where necessary, to reduce risks. In addition, the Agency has been calling in certain data missing from EPA files, notably long-term health effects data, in advance of preparing interim registration standards.

Despite this recent progress, EPA has been unable to completely reassess the vast majority of older pesticides because the necessary data are nonexistent or inadequate. EPA's efforts to accelerate the collection of data in advance of interim registration standards will improve the completeness of these standards but will fall short of providing a complete data base because EPA may determine that existing studies are invalid or inadequate when preparing an interim registration standard.

Based on current program and resource projections, it appears that reregistration will extend into the 21st century. EPA has been developing about 25 interim registration standards a year and expects to complete these preliminary reassessments around the year 1996. The Agency plans to complete final regulatory standards and tolerance reassessments after receipt and review of all required test data by the year 2005, assuming an increase in resources beginning in fiscal year 1988. The Agency expects that these final standards may cost as much to develop, in both time and resources, as interim standards. As of March 31, 1986, about 17 active ingredients are ready for the development of final registration standards, 12 of which have essentially completed reassessment, according to EPA officials. EPA plans to complete the first final standard in fiscal year 1986. Yet to be done is the reregistration of individual pesticide products following development of final registration standards. Further, EPA will have to maintain final standards to preclude another costly reregistration-type effort sometime in the future.

While EPA has stated it has "reregistered" about 145 pesticide products, the Agency reregistered certain of these products before having all data available and completely reassessing the active ingredients contained in these products. EPA officials acknowledge that this practice may be misleading, but its policies and procedures for effecting reregistration remain in force. EPA officials could not tell us whether it is continuing to "reregister" pesticide products. Thus, EPA may be continuing to reregister an undetermined number of products before completely reassessing the pesticides. EPA officials we spoke to believe congressional direction on the requirements for reregistration would be desirable.

To some extent, the success of EPA's reassessment of older pesticides, including the avoidance of unreasonable adverse effects, depends in part on timely registrant compliance with the data and labeling requirements imposed by interim registration standards and Agency efforts to enforce these requirements. Although EPA has been developing interim registration standards to identify and obtain needed data, the Agency, until recently, did not implement or follow up on interim registration

standards to obtain, monitor, and enforce registrants' compliance with these requirements. OPP has recently made registration standard follow-up a high priority—establishing draft procedures to follow up, developing an automated tracking system, and suspending product registrations not in compliance with data requirements. We believe that these are steps in the right direction and should be continued. However, the Agency has not yet canceled any pesticide product for noncompliance with labeling requirements imposed by interim standards because of the costly and time-consuming cancelation procedures under FIFRA. EPA is attempting to streamline the cancelation procedures, but the results of this effort are as yet unknown. EPA officials would like to have the option to use informal rule-making, that would provide an opportunity for registrants to contest certain Agency decisions, to more efficiently implement label requirements. EPA officials believe that explicit statutory authority is needed to make this option available to the Agency.

The Congress, the pesticide industry, environmentalists, and EPA all agree that the reregistration of older pesticides needs to be expedited. However, it appears that the alternatives available for accomplishing this feat are limited because greater resources would probably be needed to accelerate the resource-intensive and time-consuming task of reregistration. While EPA recently made review of older pesticides its number one priority and has requested additional funding for fiscal year 1987, reregistration will still extend past the year 2000. Some of the alternatives we have discussed in this chapter could accelerate the generation of necessary data but may still require additional resources for EPA to expedite review of data, prepare regulatory positions, and unconditionally reregister pesticide products. Shifting the burden to industry to identify and fill data gaps would be consistent with registrant responsibilities under FIFRA and accelerate production of missing data, but questions remain on the likely success of registrants' properly identifying and replacing existing studies that may not be adequate/valid by contemporary scientific standards. Setting reasonable deadlines for completing reregistration might expedite EPA's reregistration efforts even if the deadlines are missed. However, as past experience has indicated, setting deadlines without sufficient resources and without full appreciation of the task involved may not accomplish the objective.

In considering whether to provide additional resources to expedite reregistration, we believe a user-fee system could be considered. EPA is considering issuing a proposed rule which would institute a user-fee

system for pesticide registration activities. EPA has determined that collection of fees for these activities is both technically and administratively feasible, but the proposal has been delayed pending an EPA study of user fees. EPA believes that it has sufficient legal authority to charge fees for registration and reregistration of pesticides under the User Charge Statute, but the Agency would prefer explicit authority under FIFRA to charge fees to avoid possible litigation that might delay assessing fees. Further, funds collected under the User Charge Statute would be deposited into the U.S. Treasury and would not be available to the program. EPA would like to have the statutory authority to retain funds collected from user fees.

Matters for Consideration by the Congress

The Congress required EPA to reregister all older pesticides in the most expeditious manner practicable using current scientific knowledge about human health and environmental effects. In view of the current pace of reassessing the risks of older pesticides and the formidable task that lies ahead in accomplishing this objective, the Congress may wish to consider the advantages and disadvantages of alternatives for accelerating reregistration. Among some possible alternatives, the Congress may wish to consider:

- Shifting the burden to industry to identify and submit data missing from EPA files or no longer valid or adequate by contemporary scientific standards.
- Setting reasonable deadlines for the generation and review of health and environmental tests for older pesticides on the market.
- Providing EPA with additional resources to expedite the pace of reassessing older pesticides and reviewing the volume of industry-submitted health and environmental studies that EPA expects to receive in the coming years as a result of its efforts to call in needed data. User fees under consideration by EPA might be one method of funding the additional resources.

Recommendations to the Administrator, EPA

To reregister older pesticides in the most expeditious manner practicable, as required by FIFRA, we recommend that the Administrator, EPA:

- Cancel registrations of those products whose labels are not in compliance with registration standard requirements. Should the Administrator determine that statutory authority is needed to more efficiently implement label requirements, we further recommend that the Administrator

develop and submit to the Congress the appropriate legislative language to achieve this objective.

- Conduct a pilot test to determine whether registrants can successfully review existing data to identify and replace inadequate/invalid studies and the Agency's ability to successfully oversee registrant data submissions. Further, the Administrator should consider the results of the pilot study in determining whether and how to accelerate reregistration by further shifting the burden to industry to fill gaps in tests on existing pesticides.
- Discontinue reregistering individual pesticide products, by amending current policies and procedures, until the Agency has received and reviewed all data and completely reassessed the pesticides. Should the Administrator determine that congressional direction on the requirements for reregistering pesticide products would be desirable, we further recommend that the Administrator seek such clarification and direction from the Congress.

Health Risks Related to Pesticide Residues in Food Are Uncertain

While pesticides may protect the food supply from insects, weeds, and other pests, they may also leave residues that persist to the dinner plate. Some pesticide residues in food cannot be avoided by washing, peeling, and other food processing. Therefore, limiting the amount of residue is often critical to protecting the public from immediate health hazards and long-term health effects. EPA is responsible for setting limits (tolerances) on the amount of pesticide residue in food and for reassessing previously established tolerances. However, health risks related to pesticide residues in food are uncertain because for many pesticides with previously established tolerances, EPA lacks the data needed to determine safe residue limits.

EPA, FDA, USDA, and the states regulate the use of pesticides on food. Under FIFRA and FFDCA, EPA is responsible for registering pesticides and establishing tolerances. (Prior to 1970, USDA registered pesticides, and FDA set tolerances.) EPA and its predecessors have registered approximately 400 pesticides for food uses (about 390 of these are older pesticides that are being reassessed) and established about 6,000 tolerances for pesticide residues on numerous crops and processed foods. USDA monitors meat, poultry, and eggs, and FDA monitors other foods, to assure that consumers are not exposed to unsafe levels of pesticide residues in food. (We are preparing another report, to be issued in the near future, on FDA's program to monitor the food supply and enforce tolerances.) This chapter addresses EPA's progress in ensuring that previously established tolerances protect public health.

Many existing tolerances were established previously (older tolerances) without all the data EPA now requires to assess health risks of food-use pesticides according to current scientific standards. For example, some tolerances were set before tests for a pesticide's potential to cause cancer and genetic change were required. EPA plans to reassess tolerances and exemptions for about 390 older pesticides to determine whether they were set at levels which do not present a health hazard. We found that EPA has

- begun to obtain needed data and has established procedures for reassessing older tolerances,
- reassessed only a few older tolerances according to current scientific standards and will take many years to complete the extensive task of tolerance reassessment, and
- not yet resolved some scientific questions concerning how it assesses the safety of tolerance levels.

Until tolerance reassessments are completed, EPA cannot assure the public that many residue limits adequately protect health.

Overview of Tolerance Setting

EPA assesses potential health risks of pesticide residues in order to set tolerances at safe levels. To assess health risks, the Agency uses data submitted by pesticide registrants concerning pesticide toxicity (potential to cause adverse health effects) and residues (amount that may remain in food). Older tolerances were not always based on the testing methodologies and full set of data that EPA now requires.

EPA plans to reassess the tolerances or exemptions from tolerances for about 390 active ingredients. Most of the data used in making a tolerance decision are also considered in deciding whether to register or reregister a pesticide product. Accordingly, EPA plans to reassess tolerances as part of its Registration Standards Program. Although EPA establishes tolerances under the authority of FFDCA, rather than under FIFRA, the establishment of a tolerance or an exemption is a prerequisite to registration or reregistration of any pesticide with a food or feed crop use.

Description of Tolerances

A tolerance is the maximum limit of pesticide residue allowed in or on raw agricultural commodities, processed foods, or animal feed. The tolerance is also a level that will impose no health hazard within a practical certainty. It therefore represents both a pesticide residue level low enough to be safe and one high enough to cover residues that may be present if the pesticide is properly used. Every food-use pesticide chemical must have a tolerance or a tolerance exemption for each registered use on a crop or edible animal product. Pesticide registrants and others may submit a petition to EPA proposing that a pesticide tolerance level be established for each desired food use. EPA reviews the petition and its supporting documentation and decides whether or not to grant a tolerance or tolerance exemption.

EPA may establish tolerances with or without expiration dates. Also, FFDCA allows a pesticide chemical to be exempted from the requirement of a tolerance when a tolerance is not necessary to protect the public health. For example, EPA has exempted some naturally occurring substances not considered toxic to humans. Residues of exempted pesticides are normally allowed at any level.

If a pesticide is used according to instructions on its label, the tolerance represents the maximum level of residue that may be present on a commodity that is in commerce. FDA enforces tolerances by monitoring and testing food at the time it enters commerce. Subsequent food processing and preparation may result in an increase or decrease of the residue level.

Tolerance Risk Assessment

In order to determine whether tolerance levels proposed by pesticide registrants may present a health risk to the consumer, EPA requires registrants to submit toxicology and residue data. EPA's current toxicology data requirements include about 20 animal and microorganism tests for cancer, birth defects, genetic change, reproductive effects, and other chronic and acute health effects. Residue data requirements include studies to identify the nature and amount of residue that could occur with proper pesticide use and analytical methods that FDA can use to test the food supply for residues of the pesticide. (The major data requirements for registration and tolerance setting are listed in app. II.)

EPA toxicologists use toxicology and residue data to assess possible health risks of a pesticide's use on food and determine whether proposed tolerance levels would protect the public health within a practical certainty. The risk of pesticide residues depends on both the toxicity of the residues (i.e., their potential to cause adverse health effects) and potential human exposure to residues in the diet. EPA's risk assessment process for food-use pesticides has three steps: (1) determining the residue's toxicity, including a level of daily pesticide residue intake acceptable for humans (Acceptable Daily Intake), (2) determining the maximum potential dietary exposure to pesticide residues (Theoretical Maximum Residue Contribution), and (3) comparing potential dietary exposure to the acceptable level of human intake. (App. VI describes these concepts in more detail and provides an example of the risk assessment process for the herbicide chlorsulfuron.) Risk assessments involve an element of uncertainty because results of animal tests must be interpreted to determine toxicity to humans. Uncertainty occurs because animals are biologically different from humans and because higher doses are used in animal tests than are expected for human exposure.

Past Problems With Tolerance Assessement

Many existing tolerances and exemptions were established previously with fewer data than are now required, resulting in a need to reassess older tolerances according to current scientific standards. EPA published

its current data requirements (40 CFR 158) as a proposed rule in November 1982 and as a final rule in October 1984 which became effective in April 1985. EPA's Pesticide Assessment Guidelines contain scientific standards for conducting acceptable tests. Scientific advances in toxicology and residue chemistry were applied to new tolerances as the advances became available. According to EPA, the Agency has strengthened its ability to assess hazards associated with pesticide use by expanding the kinds of data required and upgrading the standards for conducting tests. For example, toxicology tests were first required in 1963 for chronic health effects; in 1970 tests were required for potential to cause birth defects. Also, residue analytical methods have advanced, allowing the detection of lower levels of pesticide residue. EPA's process for setting new tolerances incorporated these and other advances, but the Agency did not apply the advances when they became available to tolerances that were already established.

In 1975 we reported[1] that many tolerances were established without adequate toxicology and residue data and that EPA did not apply new data requirements to already established tolerances. This problem persisted, and we testified[2] in 1978 to the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce that EPA still lacked residue and toxicology data for many established tolerances. EPA had decided in 1977 that it would reassess tolerances for food-use pesticides through its program to reregister pesticides as required by FIFRA. FIFRA does not specifically require EPA to reassess tolerances, but it does direct the Agency to give priority to reregistering pesticides that leave residues in food.

EPA Has Not Yet Reassessed Most Prior Tolerances

EPA has not yet reassessed tolerances and tolerance exemptions for most pesticides undergoing reregistration because data were missing or inadequate. The Agency has made some progress, identifying data needed to assess the safety of approximately 90 food-use pesticides.

[1] Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately From Pesticide Hazards? (RED-76-42, Dec. 4, 1975).

[2] Testimony of Director of the Community and Economic Development Division, GAO, February 14, 1978, before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce.

EPA Prepares for Tolerance Reassessment

EPA has made some progress toward reassessing older tolerances by beginning to require needed data and establishing written procedures for reassessing tolerances. In reassessing tolerances EPA must determine whether tolerances and exemptions are appropriate by applying current data requirements and current scientific standards to the approximately 390 food-use pesticides registered prior to 1977. EPA is using its Data Call-In and Registration Standards Programs to require pesticide registrants to provide tests that are missing and to replace tests that do not meet current scientific standards.

In 1981 EPA initiated a data call-in of chronic health data (chronic effects, carcinogenicity, reproductive effects, and teratology studies) known to be missing for food-use pesticides and necessary for tolerance reassessment. (See ch. 2 for additional information on the Data Call-In Program.) By October 1985 the Agency had determined what chronic health tests were missing for the approximately 390 food-use pesticides undergoing reregistration and sent notices to registrants to require these data. As chronic studies may take up to 4 years to perform, registrants are scheduled to submit all required chronic tests by 1990.

In our 1980 review[3] of the reregistration program, we found that EPA was not prepared to reassess tolerances because it did not have formal procedures for tolerance review. In August 1981 the Agency established procedures for reassessing tolerances as part of the interim registration standard (a document stating what EPA knows about a pesticide at the time the standard is issued and identifying data needed to reassess the pesticide and its tolerances). (See ch. 2 for additional information on the Registration Standards Program.) The written procedures state that tolerances and exemptions will be reassessed if data are available and adequate. Reassessment follows certain steps:

- Scientists in EPA's Hazard Evaluation Division review tolerance-related data to determine whether they are still valid and adequate and whether tolerances are appropriate.
- The tolerance reassessment section of the interim registration standard is drafted. It is to state whether data are adequate to complete tolerance reassessment and, if so, what the result of that reassessment is (e.g., no change needed, tolerance levels to be increased or decreased).

[3] Delays and Unresolved Issues Plague New Pesticide Protection Programs (CED-80-32, Feb. 15, 1980).

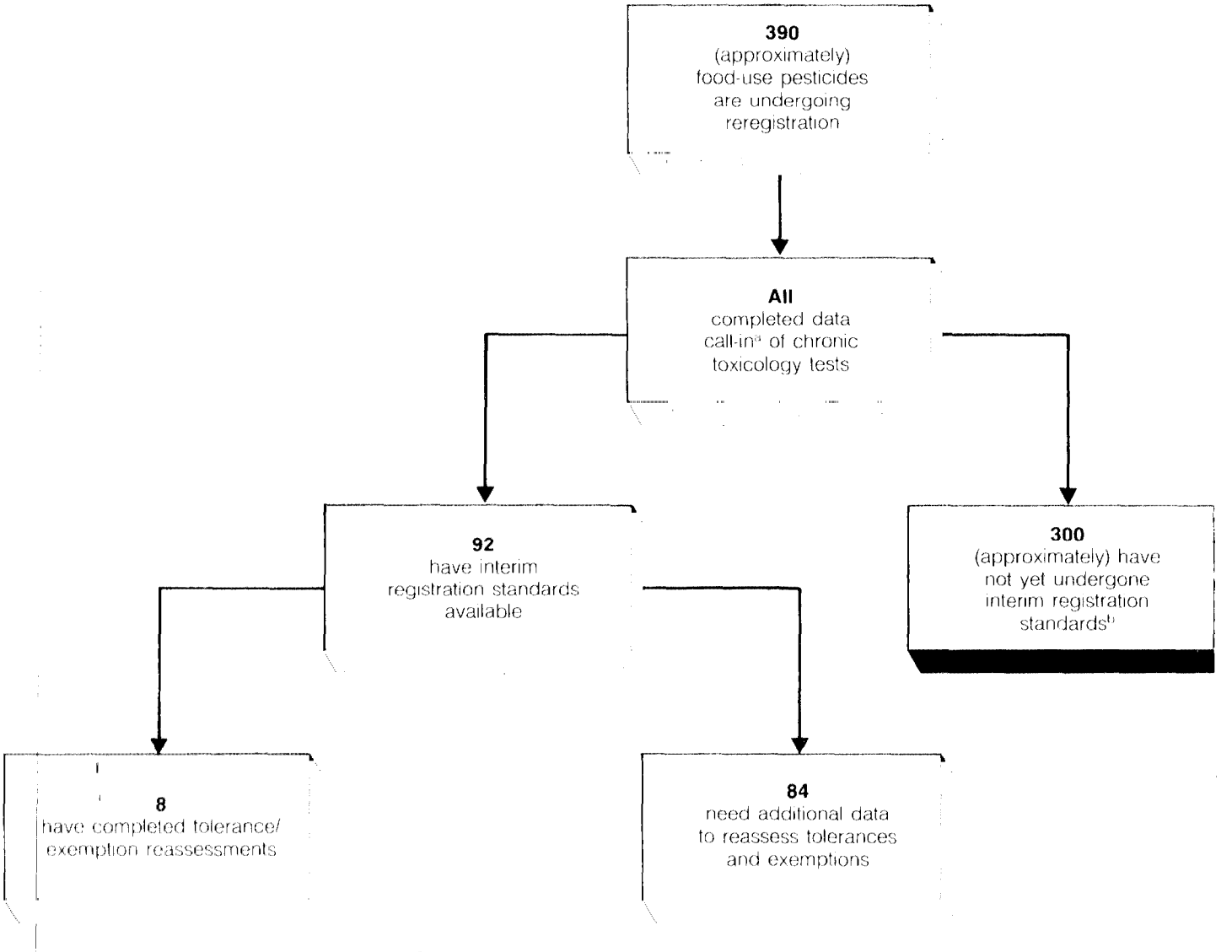
- If a tolerance must be changed, Registration Division staff are to draft a document for Federal Register publication to amend existing tolerance rules.

Few Tolerances Reassessed Due to Data Gaps

As of March 1986, EPA had reassessed tolerances and exemptions for 8 of the approximately 390 food-use pesticides undergoing reregistration. In most of the 92 interim registration standards for food-use pesticides we reviewed,[4] the Agency could not complete tolerance reassessments because additional data were required. EPA has not completed interim registration standards to determine data adequacy for approximately 300 food-use pesticides. Figure 3.1 illustrates the status of EPA's efforts to reassess tolerances.

[4] EPA reported completing 117 interim registration standards as of September 30, 1985. At least 95 of the standards were for food-use pesticides, but only 92 of them were available at the time of our review, for various reasons. For example, one interim standard was not available because the manufacturer had voluntarily withdrawn the pesticide's registration.

Figure 3.1: Status of Tolerance Reassessment (As of September 30, 1985)



[a]Completed Data Call-In — EPA has determined whether any chronic toxicology tests are missing and, if so, sent letters requiring registrants to submit the tests.

[b]EPA may not have to complete tolerance reassessments on all 300 as some may be voluntarily withdrawn, suspended, or canceled.

Source: GAO-prepared figure based on EPA information.

Data gaps have prevented EPA from fully reassessing tolerances and exemptions in most interim registration standards. Chronic toxicology

and residue chemistry data are essential to determining the safety of tolerance levels and exemptions. OPP's policy is that tolerances and exemptions will be reassessed in interim standards if data are available and adequate. Our review of 92 interim registration standards identified 8 food-use pesticides with tolerance/exemption reassessments based on complete data. The other 84 pesticides had gaps in chronic toxicology and/or residue data and therefore did not have complete reassessments.

Additional data may be needed either because EPA does not have certain tests or because it found existing tests inadequate. For example, EPA had no tests on the potential of anilazine (a fungicide used on fruits and vegetables) to cause birth defects or adverse reproductive effects. Additional data were also required concerning the amount of anilazine residue on various foods, including potatoes, strawberries, and processed tomato products. In another case, EPA could not reassess tolerances for the pesticide bentazon (a herbicide used on soybeans and alfalfa) because all existing chronic toxicology tests were unacceptable.

The data gaps identified in interim registration standards demonstrate both the size of the problem and EPA's progress in requiring data. Table 3.1 details tolerance-related data required in the 92 interim registration standards available at the time of our review; subsequent negotiations between EPA and registrants may reduce the amount of data required to some extent. Also, the table reflects any data requirements not yet met by registrants, including missing tests, inadequate tests which must be replaced, and additional information EPA needs regarding existing tests.

Our review of the 92 interim registration standards identified eight chemicals with tolerances or exemptions reassessed; the criteria we used were that the registration standard indicate (1) the results of the reassessment and (2) that no additional chronic toxicology and residue chemistry data were required. Interim registration standards for seven pesticides (calcium and sodium hypochlorite salts, 4-amino pyridine, heliothis zea, hexazinone, methoprene, phosalone, and sulfur) indicate that existing tolerances and exemptions are adequate. The reassessment of calcium and sodium hypochlorite salts also stated that additional tolerance exemptions were needed for additional post-harvest uses. Rules to establish the additional exemptions have not yet been published. An eighth pesticide (fosetyl-al) had no existing tolerances, but EPA decided that tolerances were needed for a new use of the pesticide and published a rule establishing them in 1983.

Table 3.1: Data Gaps Identified in Interim Registration Standards for 92 Food-Use Pesticides

Data type (purpose)	Number of pesticides needing additional data	Percent of pesticides needing additional data	Total number of data requirements not met[a]
Chronic toxicity (health effects from long-term exposure)	56	60.9	95
Oncogenicity (tumor effects)	57	62.0	96
Teratogenicity (birth defects)	67	72.8	106
Reproduction (reproductive effects)	39	42.4	39
Mutagenicity (genetic change)	67	72.8	175
Residue chemistry (nature and amount of residue, and residue analytical method)	70	76.1	1,129

[a]More than one data requirement of each type may not be met. EPA requires teratology tests in two animal species, for example, and a pesticide may be missing both tests, one, or none.

Final Tolerance Reassessments Will Take Many Years

After all needed data have been obtained and reviewed, EPA plans to reassess the safety of older tolerances and exemptions. The Agency plans to conduct final tolerance reassessments in conjunction with final pesticide reregistrations (discussed in ch. 2). It is apparent that it will be many years until EPA can complete final tolerance and tolerance exemption reassessments for all food-use pesticides undergoing reregistration. In the interim, health risks related to some pesticide residues in food will be unknown.

EPA expects to issue the first final registration standard and tolerance reassessment in fiscal year 1986. The first such document will concern metolachlor, a herbicide used on corn. OPP plans to continue its policy of reassessing tolerances in interim registration standards, if enough data are available. If more data are needed for a pesticide, its tolerances/exemptions will be reassessed in the final registration standard after EPA has obtained and reviewed the information.

According to EPA Registration Division officials, the Agency has not estimated how long it will take to complete tolerance/exemption reassessments for all food-use pesticides registered before 1977 because the Agency does not feel it has an adequate basis to do so. They expect to have a better basis for resource and time estimates after the first final reassessment is completed.

It is apparent that it will take many years to complete tolerance/exemption reassessment. As of March 1986, EPA reported it had fully reassessed tolerances and tolerance exemptions for 8 of the 390 older food-

use pesticides. Further, EPA has been issuing interim registration standards at the rate of approximately 25 a year, and about 300 food-use pesticides have yet to undergo review for development of interim registration standards.

The reassessment of tolerances and exemptions is critical to assuring that pesticide residue levels in food do not endanger human health, but potential health effects of many pesticides remain unknown. As table 3.1 shows, many pesticides lack data on chronic health effects. For instance, 62 percent of the 92 pesticides need additional data on their potential to cause tumors; 72.8 percent require further information on their potential to cause birth defects. Potential risks of residues of pesticides undergoing reregistration will be uncertain until missing data are obtained and reviewed and tolerances are reassessed according to current scientific standards.

Some Scientific Issues About Tolerance Assessments Remain Unresolved

EPA has resolved some, but not all, of the scientific issues raised in a 1979 review. EPA's Science Advisory Board drafted a study in May 1979 which addressed the scientific foundation of the tolerance-setting process.

EPA has developed a new automated system, known as the Tolerance Assessment System. This system is an analysis tool to help the Agency set tolerances. EPA believes the system will resolve some of the Science Advisory Board's concerns about calculating human exposure to pesticide residues. The board was concerned that EPA used 1965-66 data on average food consumption to estimate dietary residue exposure. The new system for analyzing pesticide dietary exposure uses more recent information on food consumption, based on a 1977-78 USDA study, including estimates of differing eating patterns of various U.S. subpopulations, such as ethnic and age groups. The new system will allow EPA to compare exposure estimates for population subgroups to results of toxicology studies, which may identify certain segments of the population at greater risk than others from pesticide residues. For example, because some children eat a smaller range of food than adults, their intake of pesticide residues on certain foods may be greater than adults' intake.

The Tolerance Assessment System is not yet fully implemented, but EPA estimates that the system will be fully operational in late fiscal year 1986. Before fully implementing the system, EPA plans to resolve certain issues, including how to use its capability to analyze exposure of population subgroups. In this regard, the Agency plans to establish an internal

policy concerning regulating pesticides that have differing levels of potential health risk for different subgroups.

EPA has not yet settled some of the Science Advisory Board's questions about how it assesses the safety of tolerance levels. Its assessments are based on (1) estimating human exposure to pesticide residues in food and (2) determining a level of daily pesticide residue intake considered safe (Acceptable Daily Intake). The board's 1979 study stated that there were no compelling scientific grounds for EPA's existing system for calculating Acceptable Daily Intake of pesticide residues. In particular, the board questioned EPA's use of a No Observable Effect Level and the standard safety factor of 100 to derive the Acceptable Daily Intake. (See app. VI for details.) In its response, EPA agreed with the board's position, listed some alternative methods for calculating Acceptable Daily Intake, and stated that it would establish committees to study alternatives. The Agency set up committees in 1984 to discuss Acceptable Daily Intake issues, but it was still using the old method as of March 1986.

Conclusions

EPA faces a very large task in reassessing tolerances for older pesticides. Missing and inadequate tests have prevented the Agency from completing many tolerance and tolerance exemption reassessments to date. Because tolerance reassessments are dependent on the data received and reviewed by EPA under the pesticide reregistration program, probably not until the 21st century will the safety of all older tolerances and exemptions have been reassessed according to current scientific standards. Until EPA obtains complete data and reassesses existing tolerances, the potential of many pesticide residues to cause genetic change, birth defects, cancer, and other chronic health effects cannot be fully determined.

Because tolerance reassessments are tied into the reregistration program, the recommendations and matters for consideration by the Congress dealing with expediting reregistration (see the end of ch. 2) could also affect the pace of tolerance reassessments.

Tolerance Decisions for Carcinogenic Pesticides Face Varying Legal Requirements

Federal law allows some food uses of carcinogenic pesticides and prohibits other uses. It therefore does not prevent all possible public exposure to carcinogenic residues in foods. As a result of the varying legal requirements, EPA uses different approaches to assess different types of proposed tolerances. Also, the varying legal requirements complicate EPA's efforts to reassess the tolerances of carcinogenic pesticides undergoing reregistration. Further, on the basis of new data, EPA has determined that some food-use pesticides with established tolerances are potential carcinogens. In addition, some scientists and governmental organizations have expressed differing opinions about both the law governing tolerances (FFDCA) and EPA's approaches to setting them. Alternatives to existing law could provide greater consistency in regulating the use of carcinogenic pesticides on food.

Legal Requirements for Pesticide Tolerances Vary

EPA sets tolerances for pesticide residues under the authority of FFDCA. The act's requirements, however, are different for raw agricultural commodities, food additives, and animal feed additives. Although FFDCA prohibits some food uses of carcinogenic pesticides, it does not prevent all sources of cancer-causing residues in food.

1. Raw agricultural products. FFDCA allows EPA to weigh risks to human health against benefits to food production in establishing tolerances for both carcinogenic and noncarcinogenic pesticides used on raw agricultural commodities. EPA has allowed some carcinogenic pesticides to be used on raw agricultural commodities because the benefits outweigh the risks. Thus, people who eat pesticide-treated raw foods may be exposed to carcinogenic residues up to the amounts allowed by the established tolerances.

2. Food additives. Under FFDCA, food additive tolerances are required when the pesticide residue level in processed food is greater than the tolerance level for the raw agricultural commodity. FFDCA's Delaney Clause (Sec. 409(c)(3)(A)) prohibits the establishment of tolerances for food additives found to induce cancer in humans or animals. (Without an established tolerance, the food additive pesticide cannot be registered under EPA regulations and therefore cannot be used on food.) However, carcinogenic pesticide residues may exist in processed foods when residues carry over from a raw agricultural commodity (soybeans, for example) to a processed food (soybean oil) at a level equal to or less than the established raw agricultural commodity tolerance level.

3. Animal feed additive. The Delaney Clause allows animal feed additive tolerances for carcinogens only in certain circumstances (see p. 75). Also, as with food additives, feed additive tolerances are required only when the pesticide residue level in animal feed (such as soybean hulls) is greater than the tolerance allowed for the raw agricultural commodity (soybeans). Thus, if animals eat feed treated with carcinogenic pesticides, some residues may carry over to meat, milk, and other animal products that people consume.

EPA Uses Different Approaches to Setting Tolerances

EPA has implemented the varying legal requirements by using differing approaches to assess proposed tolerances for carcinogens. EPA has used a risk-benefit approach in setting raw agricultural commodity tolerances for carcinogens. It recently defined an acceptable level of cancer risk (minimal risk approach) in setting animal feed additive tolerances.

EPA Uses Risk-Benefit Procedures for Raw Agricultural Commodities

Tolerances for pesticide residues on raw agricultural commodities are set under FFDCA Section 408, which requires EPA to consider whether the tolerance protects the public health (risk) and factors such as the production of an adequate, wholesome, and economical food supply (benefit). In determining whether to grant raw agricultural commodity tolerances for a pesticide suspected of causing cancer, EPA uses a four-step risk-benefit analysis. The activities undertaken by EPA in each of these steps are described below:

(1) Dietary exposure to pesticide residues is estimated by calculating the Theoretical Maximum Residue Contribution. (This estimate is discussed in app. VI.)

(2) EPA toxicologists extrapolate from animal tests to estimate human cancer risk associated with the Theoretical Maximum Residue Contribution. Estimated human cancer risk is usually expressed as the number of excess cancer cases over a lifetime of pesticide exposure. For example, a risk estimate might show that one more tumor case could occur among 1 million people than would occur if the pesticide were not used on food. (This is 1 excess cancer case in 1 million.)

(3) EPA considers the estimated number of excess cancer cases and the total weight of evidence for tumor effects to determine whether to grant a tolerance. The weight of evidence is the toxicologists' judgment about testing methods, recognizing that available data may not be clearly conclusive about human cancer risks and that knowledge about cancer is

still developing. Toxicologists may judge a pesticide to be a definite, probable, or possible human carcinogen, or to show inadequate or no evidence of carcinogenicity.

(4) If EPA considers human cancer risk to be significant, it may evaluate benefits of the proposed pesticide use and weigh benefits against risks. An EPA toxicologist told us that EPA has not formally defined what it considers a significant level of cancer risk, but that EPA reviewers commonly considered more than 1 excess cancer case among 1 million people to be significant enough to warrant a benefit assessment.

Unlike the risk assessment process used for other health effects of pesticides, EPA does not use an Acceptable Daily Intake in assessing carcinogenic effects. The Acceptable Daily Intake (discussed in app. VI) is a level of pesticide intake which is safe within a practical certainty. Scientists have been unable to determine whether a safe, threshold level exists for carcinogens because the mechanisms that produce cancer are not completely understood. Therefore, EPA uses dose-response models which assume that some risk of contracting cancer exists for even minute exposures to carcinogenic pesticide residues. Dose-response assessment defines the relationship between estimated dietary exposure to a carcinogen and the probability of carcinogenic effect.

Cypermethrin: Assessment of Dietary Risks and of Benefits

EPA's review of the proposed tolerances and registration for cypermethrin illustrates how risks and benefits are assessed. Cypermethrin was found to cause benign tumors in female mice. In June 1984 the Agency conditionally registered this insecticide for use on cotton. Because animals may eat cottonseed, raw agricultural commodity tolerances were needed for cypermethrin residues in cottonseed, various meat products, and milk. Through the four step risk-benefit assessment described below, EPA found that benefits of cypermethrin's use outweigh its risks and that its tolerances protect public health.

1. Dietary exposure estimate - EPA estimated maximum intake of cypermethrin residues by assuming tolerance level residues and an average diet. The Theoretical Maximum Residue Contribution is 0.0307 milligrams per day in a 1.5 kilogram diet.

2. Estimate of human dietary cancer risk - EPA applied a mathematical model to animal test data and extrapolated potential human risk. The upper limit of tumor risks related to the dietary exposure was calculated

to be 9.7 in 1 million. Over a lifetime of cypermethrin exposure, 9.7 tumor cases might develop among 1 million people.

3. Weight of evidence - EPA toxicologists classified cypermethrin as a possible human carcinogen, the weakest category for positive carcinogenicity evidence. The lung tumors found in an animal test were benign, not malignant. Furthermore, evidence of carcinogenicity was found only in one of two animal species tested, only in females, and only at the highest dosage tested.

4. Risk-benefit assessment - EPA found the risk to the general public from cypermethrin's use on cotton to be extremely small. The Agency did assess benefits of cypermethrin's use, finding that it could reduce cotton production costs by controlling insect pests with a lesser amount and fewer treatments than alternative pesticides. After weighing risks and benefits, EPA conditionally registered cypermethrin for use on cotton and, based on the low risk, established related tolerances for a specific time period.

Note: We did not independently evaluate EPA's risk-benefit analysis of cypermethrin.

EPA Used Minimal Risk Approach for Recent Feed Additive Tolerances

EPA based two recent animal feed additive tolerance actions (cyromazine and thiodicarb) on an FDA interpretation of the Delaney Clause and the conclusion that human cancer risk from these pesticides was minimal. Tolerances for both animal feed additive and processed food additive pesticides are established under FFDCA Section 409. Though the Delaney Clause of Section 409 prohibits carcinogenic food additives, it allows carcinogenic additives to animal feed in some instances. The Delaney Clause states that its prohibition does not apply to substances added to animal feed if (1) the additive does not adversely affect the animals and (2) no residue of the additive will be found (by prescribed residue analytical methods) in foods derived from the animal. EPA and FDA have interpreted the second point (no residue, etc.) to mean a residue level that would not significantly increase human cancer risk. They further defined a risk of 1 in 1 million over a lifetime as an acceptable level.

FDA issued a proposed rule concerning this interpretation of the Delaney Clause. As of March 1986, EPA had not issued an overall policy or regulation on setting tolerances for carcinogenic pesticides; it has used FDA's

interpretation in recent decisions establishing animal feed additive tolerances. In March 1979 FDA issued a notice proposing criteria for evaluating carcinogenic animal drugs and other additives, which also are affected by the Delaney Clause. The notice defined 1 in 1 million as an acceptable cancer risk level. On October 31, 1985, FDA issued a notice of proposed rule-making on this subject and plans to issue a final rule by the end of calendar year 1986. The FDA chemist handling the proposal told us that the Department of Health and Human Services took a long time reviewing the 1979 proposed rule because (1) very detailed scientific comments were received on the risk assessment method described in the proposed rule and (2) the Department of Health and Human Services debated internally because the proposal acknowledged that the government would approve a carcinogen in certain circumstances.

EPA used FDA's interpretation of the Delaney Clause in establishing a feed additive tolerance, effective in May 1985, for residues of cyromazine in poultry feed. Cyromazine (also known as Larvadex) is conditionally registered for use in chicken feed to control flies on chicken manure. It has a metabolite (chemical breakdown product) that caused bladder tumors in tested rats. EPA found that cyromazine's metabolite posed a lifetime cancer risk of less than 1 in 1 million. EPA's conditional registration notice stated that "the weight of the evidence strongly supports the thesis that the oncogenic [carcinogenic] risk to man is non-existent or, at worst, extremely low." EPA concluded that setting a feed additive tolerance was consistent with Section 409 of FFDCA, which includes the Delaney Clause and its animal feed additive provision.

Overall, 85 commenters responded favorably and 31 commenters opposed EPA's proposed registration decisions for cyromazine. Many of the positive commenters stated that cyromazine was effective and needed to control flies in poultry houses. Three commenters stated that the Delaney Clause bars approval of carcinogens as food additives. EPA responded that the commenters failed to note that the Delaney Clause provides an exception to its prohibition of carcinogens. Two other commenters stated that EPA should not adopt FDA's interpretation of the Delaney Clause provision for animal feed additives without first conducting rule-making concerning the appropriateness of the approach. EPA responded that it had not adopted FDA's approach as a general matter, but only for the cyromazine action, and that the notice and comment period for cyromazine rules was sufficient. Two comments indicated disagreement with FDA's interpretation of the Delaney Clause provision, and other commenters opposed EPA's decisions for other reasons.

Subsequent to its cyromazine decisions, EPA established feed additive tolerances for thiodicarb, which has a metabolite identified as a possible human carcinogen. EPA's risk assessment found that excess lifetime cancer risk of thiodicarb's metabolite would not exceed 1 in 1 million. EPA published a final rule establishing thiodicarb tolerances for cottonseed hulls and soybean hulls in October 1985, stating that it was adopting FDA's reasoning set forth in its 1979 proposed rule.

Varying Requirements Will Affect Tolerance Reassessment

As EPA requires additional data and begins to reassess prior tolerances, it is finding that some pesticides with food/feed additive tolerances may be carcinogenic. As of October 1985, EPA had identified 13 pesticides having FFDCA Section 409 tolerances which the Agency had either determined or preliminarily determined to have carcinogenic effects. EPA had data indicating carcinogenicity for some other pesticides with food/feed additive tolerances but had not completed its determinations. As of October 1985, EPA was taking the following actions to deal with the 13 carcinogenic pesticides with food/feed additive tolerances:

- Four have completed special review, with resulting actions ranging from label precautions to cancelation of some uses.
- Two were in special review.
- One has been voluntarily withdrawn by the registrant from its food additive use.
- Three were in registration standard review, with interim standard issuance planned for fiscal year 1986.
- Two were recently registered and feed additive tolerances established (cyromazine and thiodicarb, discussed above).
- One was still in the registration process, awaiting a new oncogenicity (tumor formation) study.

The Assistant Administrator for Pesticides and Toxic Substances stated that EPA expects to more frequently be confronted with legal and regulatory problems posed by the Delaney Clause as it reregisters pesticides. In an October 1985 letter to the Chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, EPA's Assistant Administrator for Pesticides and Toxic Substances noted the different standards of FFDCA Section 409 on the one hand and FFDCA Section 408 and FIFRA on the other. The Delaney Clause of Section 409 prohibits the establishment of food additive tolerances for carcinogens, while Section 408 and FIFRA allow a risk-benefit approach to pesticide regulation. Therefore, a single pesticide may confront different legal requirements for its various uses. For example,

captan has both raw agricultural commodity tolerances set under section 408 and a food additive tolerance set under Section 409. Since these tolerances were established EPA has identified captan as a possible carcinogen. The Assistant Administrator stated, "over the long term, changes to one or both statutes may be needed to permit logical, consistent, and fully protective administration of a Federal food safety program for pesticides." His letter did not endorse or specify any particular change.

Opinions on Establishing Tolerances for Carcinogenic Pesticides Vary

The regulation of carcinogenic pesticides used on food crops has become a very controversial issue, with organizations adopting various positions. For example:

- The House Subcommittee on Oversight and Investigations, in a 1978 report,[1] recommended (1) that the Congress consider banning the use of potentially carcinogenic pesticides on raw agricultural products, unless no pesticide residues remain on the food, and (2) that EPA cancel tolerances for pesticides that result in potentially carcinogenic residues in raw foodstuffs.
- In its 1979 draft report,[2] EPA's Science Advisory Board could not reconcile the opposing views of its study group's members on risk-benefit assessment. Some members of the board took the position that the process of carcinogenic risk assessment and risk-benefit analysis was invalid because no scientifically valid method exists for extrapolating human cancer risks from animal test data. Other board members took the position that human cancer risks can be validly assessed using animal test data.
- In a 1981 report,[3] GAO stated that the Congress should consider whether the Delaney Clause is still appropriate because of (1) advances in the ability to detect very low levels of substances and (2) uncertainties about the risk to humans of low levels of carcinogens.

The National Academy of Sciences/National Research Council's Board on Agriculture began a study in February 1985 to provide a scientific framework for assessing legal and regulatory issues concerning carcinogenic food-use pesticides. The board plans to assess (1) the effectiveness

[1] Cancer-causing Chemicals in Food, Report by the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, Dec. 1978.

[2] Review of EPA's Tolerance Setting System: Report of the Science Advisory Board Study Group on Pesticide Tolerances, Draft Report, May 1979.

[3] Regulation of Cancer-Causing Food Additives—Time for a Change? (HRD-82-3, Dec. 11, 1981).

of the Delaney Clause in protecting public health and fostering safe use of effective pesticides and (2) possible changes to existing laws and regulations. EPA is partially funding this study, which the board expects to complete in 1986. Specific issues planned for the study include

- inconsistencies in regulating carcinogenic pesticides under Sections 408 and 409 of FFDCA;
- the impact of carcinogenicity issues on tolerances undergoing reassessment;
- the advisability of the current law's emphasis on cancer as opposed to other health effects, such as neurotoxicity or reproductive effects;
- possible alternatives to the Delaney Clause; and
- the impact of the Delaney Clause and alternatives on dietary exposure to carcinogens and on the agricultural sector.

Legislative Alternatives

In our 1981 report on the Delaney Clause, we found that most food safety experts and regulatory officials believed the Delaney Clause should be changed, but there was no unanimity about how it should be changed. We also noted that consumer groups and some public opinion polls had shown concern about cancer-causing substances in food. Various opinions continue to exist about how EPA should regulate carcinogenic pesticides used on raw agricultural commodities, processed food, and animal feed. As the Congress considers amending pesticide provisions, three alternatives are possible: (1) leave the existing legislation unchanged, (2) amend FFDCA and FIFRA to prohibit all food uses of carcinogenic pesticides, or (3) lift the Delaney Clause's ban on carcinogens for food and feed additive pesticides.

Leave the Existing Legislation Unchanged

This alternative would require no action by either the Congress or EPA. EPA would continue to use different approaches to different types of tolerances for carcinogenic pesticide residues—a risk-benefit approach for raw agricultural commodity tolerances, a zero-risk approach (prohibition) for food additive tolerances under the Delaney Clause, and a minimal risk approach for animal feed additive tolerances. However, public controversy over whether EPA is setting tolerances at levels adequate to protect the public could continue. Furthermore, EPA will be confronted with difficult decisions relating to regulating carcinogens as more test data become available and as it reassesses prior tolerances.

Amend FFDCA and FIFRA to Prohibit All Food Uses of Carcinogenic Pesticides

This alternative would require the Congress to enact legislation requiring EPA to ban all carcinogenic food-use pesticides, revoke all associated tolerances, and cancel all associated pesticide registrations. This alternative would provide maximum protection to the public but would probably create economic uncertainty for both the agricultural and pesticide industries.

Lift the Delaney Clause's Ban on Carcinogens for Food and Feed Additive Pesticides

This alternative would require the Congress to enact legislation amending the Delaney Clause by lifting the clause's ban on carcinogens relating to food and feed additive pesticides. The Congress could consider specifying whether EPA is to use a risk-benefit or minimal risk approach in setting tolerances for carcinogenic pesticides. A risk-benefit approach considers benefits of pesticide use, and benefits might be found to outweigh risks greater than a "minimal" level. A minimal risk approach considers only risks. If risks exceed a defined level (such as 1 in 1 million), tolerances would not be allowed under a minimal risk approach, even if the pesticide had substantial benefits. In considering the risk-benefit and minimal risk approaches, the Congress should be aware that different mathematical models for estimating human risk can produce widely varying estimates. If the Delaney Clause were deleted, EPA's tolerance decisions for carcinogens would probably continue to be controversial, as these approaches would require assessing cancer risks based on animal tests, possibly assessing benefits of pesticide use and comparing risks and benefits, and allowing some public exposure to carcinogenic pesticide residues in food.

If it considers alternatives to existing legislation, the Congress may wish to require EPA to provide information on various alternatives and their likely impacts on the pesticide and agriculture industries, the nation's food supply, Agency resource needs, and public exposure to carcinogens. The National Academy of Sciences/National Research Council's current study may provide some of this information.

Conclusions

Although FFDCA prohibits some food uses of carcinogenic pesticides, it does not prevent all sources of public exposure to residues of these pesticides in food. The act allows EPA to set raw agricultural commodity tolerances (and allow use of the pesticide) if it finds that benefits outweigh risks from the use of a carcinogenic pesticide. On the other hand,

the act's Delaney Clause prohibits the establishment of food additive tolerances for carcinogenic pesticides. Further, EPA and FDA have interpreted the Clause to allow animal feed additive tolerances (and pesticide use) if human cancer risks are less than 1 in 1 million.

Federal laws and agency interpretation of them currently allow for different and sometimes inconsistent approaches to regulating the same carcinogenic pesticide. As a result, EPA is faced with a complicated and difficult task of regulating carcinogenic pesticides. FFDCA could be changed to provide greater consistency in regulating carcinogenic pesticides and to allow EPA to refine one approach and policy for regulating carcinogenic pesticides. Greater consistency could also simplify EPA's reassessment of prior tolerances as one pesticide may now face differing legal requirements for its different food uses. The Congress may wish to consider the legislative alternatives discussed above.

In addition, although the legal requirements allow different approaches to regulating carcinogenic pesticides, EPA does not have a policy on tolerance setting for carcinogenic pesticides. In the past, EPA's decisions have been on a case-by-case basis and it has relied on FDA's interpretation of the Delaney Clause regarding animal feed additives. Under this approach, pesticide registrants and the public may not have the benefit of being fully informed of EPA's policy and criteria regarding the setting of tolerances for carcinogenic pesticides. In light of deep-seated public concern over exposure to carcinogens, EPA should publish a policy on tolerance setting for carcinogenic pesticides. The policy should specify what approaches (e.g., risk-benefit and minimal risk) and what criteria are used to determine whether to grant tolerances. Such a policy statement would be useful to pesticide registrants, encourage public participation in the development of such a policy, and give EPA the benefit of interested parties' opinions and knowledge.

Matters for Consideration by the Congress

To provide consistent regulation of carcinogenic food-use pesticides, the Congress may wish to consider the advantages and disadvantages of the following alternatives for regulating carcinogenic food-use pesticides:

- Amending FFDCA and FIFRA to prohibit the setting of tolerances and all food uses of carcinogenic pesticides (in raw agricultural commodities and as food and feed additives) to require EPA to revoke the existing tolerances for carcinogenic pesticide residues and to cancel the pesticide registration of these uses.

- Amending FFDCA to lift the Delaney Clause's ban on carcinogens as it relates to pesticides and instead specify that either a risk-benefit or minimal risk approach be used for setting tolerances for all food uses of carcinogenic pesticides.

The Congress may want EPA to provide information on the possible impact of these various alternatives.

Recommendation to the Administrator, EPA

We recommend that the Administrator, EPA, develop and publish a policy concerning tolerance setting for carcinogenic pesticides, including criteria on how it decides whether to grant or deny such tolerances, and allow for public comment.

Issues Concerning Data Requirements for Inert Ingredients Remain Unresolved

EPA has identified some inert pesticide ingredients as potentially toxic to humans but knows little about the health risks of many inerts. Although EPA is beginning to reassess the safety of inerts, it has not determined how to obtain the data needed to review many of them. A major difficulty in requiring information relates to FIFRA's confidentiality provision, which prohibits EPA from disclosing information on inerts and on their registrants. The provision also makes it difficult for EPA to obtain the data needed to review the safety of inerts.

Although not active against targeted pests, inert ingredients may be used as solvents, thickeners, propellants, etc., to make pesticide products more effective or usable. Inerts range from innocuous substances such as water, sugar, and salt to highly toxic substances such as dioxane and formaldehyde. Approximately 1,200 to 1,300 chemicals are registered as inert ingredients in about 50,000 pesticide formulations. About 500 are registered for use on food. EPA and its predecessor exempted the 500 food-use inerts from the tolerance requirement because, when the exemptions were approved, they determined that tolerances were not necessary to protect public health.

EPA Recognizes the Need to Reassess Inerts

EPA realizes that it has little toxicology data for many inerts and that some inerts may be toxic. In 1975, we reported that EPA needed to require sufficient data on inert ingredients to ensure that they do not adversely affect man or the environment.[1] Also, according to a September 1977 EPA contractor report, 52 inert ingredients were found to have either (1) chemical, toxicological, or environmental characteristics requiring immediate attention or (2) available data indicating possible health hazards. The contractor found that a number of these inerts were used in agricultural pesticides and included strong carcinogens such as dioxane, phenarsazine oxide, and triethylamine.

EPA has little toxicology or residue data on most food-use inerts; thus, both their toxicity and the extent of public exposure to residues in food are unknown. While EPA routinely required registrants to test pesticide formulations, including inerts, for acute toxicity (health effects from short-term exposure), it rarely required registrants to test inerts for chronic toxicity (effects from long-term exposure, such as cancer and genetic change).

[1] Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately From Pesticide Hazards? (RED-76-42, Dec. 4, 1975).

In the past, EPA based most tolerance exemptions for food-use inerts on informal requests from chemical suppliers or pesticide registrants. These requests contained product chemistry information, a description of the proposed use of the inert, and some health and safety data. EPA processed inert exemption requests by checking existing toxicity data, if any, and by determining if the inert was (1) structurally similar to compounds known not to be hazardous, (2) not expected to leave residues at the time a crop was harvested, (3) allowed as a food additive, or (4) on FDA's "Generally Recognized As Safe" list. This list identifies substances (such as oils, spices, and natural extracts) generally recognized as safe for addition to foods when used in accordance with good manufacturing practice.

Although EPA was aware that some inert ingredients might pose health or environmental problems, its reregistration program has focused primarily on active pesticide ingredients. In 1978 the Congress accepted EPA's proposal to review pesticide chemicals rather than the thousands of individual pesticide formulations (active and inert ingredients formulated as a product). EPA's registration standard reviews through fiscal year 1985 have been of active ingredients.

EPA Begins Project to Reassess Inerts

In 1982 the Agency began a project on inerts, and in June 1985 it completed classifying them according to what is known about their toxicity. Based on information from the National Toxicology Program, the National Institute of Occupational Safety and Health, the International Agency for Research on Cancer, and other sources, EPA's task force classified inerts as of immediate toxicological concern, of suspected toxicity, of unknown toxicity, or as innocuous. Results of the classification are summarized in table 5.1.

Inert project plans for fiscal year 1986 include (1) initiating a data call-in of confidential statements of formulation and (2) beginning to address some of the 55 inerts identified as being of immediate toxicological concern due to health effects such as carcinogenicity, adverse reproductive effects, and liver and kidney damage. The Agency also plans to establish data requirements for new food-use inerts.

At the time of our review, EPA was developing but had not yet finalized a strategy for dealing with inerts in all classifications. The strategy was to include plans for assessing potential risks of the 51 inerts of suspected toxicity and the 800 to 900 inerts of unknown toxicity. The statements of formulation will identify which inerts are used in which products, but

EPA is also considering obtaining data on chronic health effects and residues in food crops.

Table 5.1: EPA Classification of Inerts

Classification	Immediate toxicological concern	Suspected toxicity	Unknown toxicological concern	Innocuous
Total number in classification	55	51	800-900	273
Characteristics of inerts in classification	28 are potentially carcinogenic, and 7 also had active uses which were or are being canceled;[a] 26 of the 55 have been approved for food use	These inerts have a chemical structure or other physiochemical properties suggesting toxicity; EPA gives them high priority for testing	Insufficient health and safety data exist for these inerts	This classification includes foodstuffs, natural products, inorganic salts, etc.

[a]A chemical may be an active ingredient in one pesticide product (i.e., act against the targeted pest) and an inert ingredient in another product.

Formulation Data Call-In

In fiscal year 1986 the Agency plans to send notices to all pesticide registrants requiring them to submit an updated confidential statement of formula for their products. These statements identify and quantify each active ingredient, each intentionally added inert ingredient, and all impurities in pesticide formulations. The data call-in will provide current information on the usage of inerts.

According to EPA, many formulation statements in its files are out of date or incomplete; the Agency therefore may not know precisely what inerts are in a given formulation. This problem arose for several reasons. First, some older statements are insufficient according to current data requirements. Second, EPA did not always require updates of formulation changes in the past. Third, EPA allowed registrants flexibility to use substitute inerts during the 1972 petroleum shortage.

Inerts of Toxicological Concern

To address the 55 inerts of toxicological concern, EPA initiated a survey of the pesticide industry to determine whether the inerts were still being used. The survey, completed in October 1985, showed that some inerts of toxicological concern may no longer be used. The National Agricultural Chemicals Association and the Chemical Specialties Manufacturing Association conducted the survey for EPA and found that

- 22 of the 55 inerts of toxicological concern were not used by their members who responded,[2]
- 6 seemed to be widely used, and
- 27 were used by fewer than 10 member companies.

EPA plans to use the survey results in setting priorities for reviewing inerts. The formulation data call-in will provide more complete information on inert usage.

EPA is planning several steps for reviewing the 55 toxic inerts of toxicological concern, including sending data call-in letters to registrants, preparing registration standards, and/or putting chemicals in special review, if warranted. (Special review is a process for reviewing risks and benefits of pesticides posing special concerns due to a specific perceived health or environmental risk. Chapter 7 discusses special review.) EPA plans a pilot project in fiscal year 1986 to (1) issue data requirement letters on a few inert chemicals and (2) develop a registration standard concerning inert uses of formaldehyde. As some inerts are widely used industrial chemicals, the Office of Pesticide Programs plans to consult with EPA's Office of Toxic Substances to ensure consistent risk assessments of these chemicals and to use data that may be required under the Toxic Substances Control Act (TSCA).

New Inerts

EPA plans to establish a minimum set of toxicology data that will be required for new inerts intended for food uses. According to the Director of OPP's Hazard Evaluation Division, tolerances rather than exemptions will be established for inerts of some toxicological concern, when appropriate. While any level of residue in food is normally permissible for exempted substances, tolerances set maximum residue limits. The Residue Chemistry Branch Chief told us 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 stated that tolerances should be established for those relatively toxic inert ingredients whose safe use is predicated on imposing a rigid use pattern to ensure that residues will be below a certain level.

[2] Responding members represent over 90 percent of the inert ingredient use in the pesticide industry.

Unresolved Issues Affect EPA's Ability to Require Data on Inerts

EPA has not yet resolved who is to be responsible for generating data on inerts and how data generation can be equitably accomplished. While FIFRA gives EPA certain authorities to obtain data, it includes provisions affecting EPA's ability to require data on inert pesticide ingredients. Although FIFRA's confidentiality provision (Sec. 10) is aimed at protecting trade secrets of pesticide formulations, it makes it difficult for the efficient development of needed test data on potential hazards of inerts and for pesticide registrants to share the costs of generating data on inerts, as they do for active ingredients undergoing reregistration. Some inerts with nonpesticidal uses may have data generated under TSCA, but EPA's authority to gather data under TSCA does not generally allow pesticide-related exposure data to be considered.

According to Hazard Evaluation Division officials, inerts are not necessarily made by pesticide manufacturers and may have extensive nonpesticidal uses. OPP recognizes that it needs to find a practical approach to assigning responsibility for providing data among pesticide active ingredient manufacturers, formulators of pesticide products, and suppliers of inert ingredients. Under FIFRA, pesticide active ingredient manufacturers (who make active chemicals that must be combined with inerts to make retail pesticide products) and product formulators (who produce end-use products) may register pesticides. Some inert ingredient suppliers are not registrants under FIFRA. Currently, manufacturers of active ingredients perform the extensive health effects and exposure testing required for active ingredients, while pesticide formulators are responsible only for acute testing of formulated products.

While active ingredient registrants may pool their resources to meet data requirements imposed by the reregistration program, FIFRA's confidentiality provision precludes EPA from letting registrants know which other registrants are using a specific inert. FIFRA Section 3(c)(2)(B) requires EPA to notify all registrants of a pesticide when it requires additional data and to allow the registrants to share the costs of performing tests. However, FIFRA Section 10 states that the identity and percentage of inert ingredients may not usually be disclosed. (It does not protect the identity of active ingredients from disclosure, and active ingredients are listed on pesticide product labels.) This confidentiality requirement makes it difficult for registrants to pool their resources to meet data requirements. If EPA requires data, either EPA would have to serve as a broker for various registrants using an inert who refuse to release their names to one another, or the registrants would have to perform duplicative tests. FIFRA's confidentiality provisions therefore affect EPA's ability to require data on inerts in a practical, equitable manner.

TSCA also gives EPA authority to require data on chemicals, but the act excludes chemicals manufactured or used as pesticides. The Congress enacted TSCA in 1976 to close gaps in existing statutes regulating some chemicals, provide for reviewing risks of chemicals, and regulate certain chemicals to protect human health and the environment. Some inerts with nonpesticidal uses are already listed for testing through the TSCA program. According to EPA's Office of General Counsel, EPA cannot use TSCA's authority to require inert manufacturers to provide data if the pesticidal use is the only justification for requesting data. Under TSCA, EPA must justify why data are required and undertake a rule-making process to obtain data. An attorney in EPA's Office of General Counsel told us that EPA could be legally challenged if the justification for a data request under this act was based on pesticidal uses of a chemical.

EPA needs to obtain further data in order to determine potential health risks of inerts about which little is known and protect the public from potentially hazardous residues in food. EPA's inert project could be hindered by unresolved issues concerning who is responsible for generating data and how to share the burden of generating data.

Conclusions

EPA has only recently begun to review inert pesticide ingredients, although some inerts were known to be hazardous to humans and insufficient information existed to determine the potential risks of many others. EPA needs to obtain further data in order to determine potential health risks of inerts about which little is known and to protect the public from potentially hazardous residues in food. It has made some progress by classifying inerts and surveying pesticide manufacturers. These steps may allow EPA to target its efforts to reassess inerts. However, current provisions of FIFRA may hinder EPA's review of the safety of inerts by making it difficult for the Agency to develop a practical and equitable means of obtaining data (who is responsible for generating data and how to share the burden of generating data).

Although FIFRA's confidentiality provision is aimed at protecting trade secrets of pesticide formulations of pesticide firms, the provision adversely affects the efficient development of needed test data on potential hazards of inerts. FIFRA's confidentiality provision could be changed to permit EPA to disclose which pesticide registrants are using a specific inert when data are needed to determine its safety. This would allow registrants to share the costs of developing data. To maintain some confidentiality, EPA need not disclose percentages of inerts in products. An inert's pesticidal use might be a relatively small portion of the

total market for some chemicals because some inerts are widely used industrial chemicals. However, allowing registrants to pool their resources would help lessen the burden of testing requirements.

Recommendation to the Administrator, EPA

In its current efforts to address the potential hazards of inert pesticide ingredients, we recommend that the Administrator, EPA, examine means to more readily obtain health and environmental effects test data on inerts. This should include examining an easing of FIFRA's confidentiality provision and requesting from the Congress any such additional authority needed to achieve this objective. This action may facilitate sharing the cost of generating data among pesticide registrants of inerts, while also providing some degree of continued protection of trade secrets of pesticide formulations.

EPA Conditionally Registered About Half of All New Pesticides Without Full Testing

Before a pesticide product is marketed in the United States, it must be registered with EPA; registration is a license or pre-market clearance based on EPA's review of data submitted by pesticide firms. The 1978 amendments to FIFRA allow EPA, under limited circumstances, to conditionally register pesticide products containing new active ingredients pending receipt of additional data. Upon receipt and review of required data and fulfillment of other conditions, EPA may convert a conditional registration to an unconditional registration or it may cancel the conditional registration.

On the basis of our review, it appears that, until recently, EPA had been lenient in granting conditional registrations of pesticide products containing new active ingredients without full testing and appears not to have routinely monitored registrants' compliance with conditions imposed. We were unable to readily obtain information on the status of the conditions imposed on the conditional registrations because EPA did not have a reliable information system to track the conditions imposed. Between fiscal years 1978 and 1984, EPA conditionally registered 44 out of 90 new active ingredients. Of the 44 conditionally registered, EPA has since converted 10 to unconditional registrations.

Beginning in October 1984, the Director of OPP initiated more stringent policies for conditionally registering new active ingredients. Further, in March 1986 EPA published a policy statement on conditional registration of new active ingredients. The intent of this policy is to more strictly apply the statutory requirements. EPA's action to tighten its policies and procedures with respect to granting and monitoring conditional registrations of new active ingredients is a step in the right direction. We did not determine the effectiveness of the new policy.

Statutory Requirements for Conditional Registrations

Under FIFRA, as amended in 1978, EPA may conditionally register pesticides in certain circumstances even though some of the test data required may not have been submitted to or evaluated by EPA. The Agency defines a conditional registration as "a registration for which the submission (or Agency review) of some supporting data has been deferred to a future date." EPA may grant three types of conditional registration:

- Under section 3(c)(7)(A), EPA may conditionally register pesticide products that are identical or substantially similar to those currently registered.

- Under section 3(c)(7)(B), EPA may conditionally register new uses of existing pesticides.
- Under section 3(c)(7)(C), EPA may conditionally register pesticide products containing new active ingredients.

In general, EPA issues conditional registrations for new pesticide products that are substantially similar to those currently registered and for new uses of existing pesticides if the Agency determines that these new registrations would not significantly increase risk to human health or the environment. Full review of the pesticides is deferred pending reregistration for all previously registered pesticide products containing the same active ingredient(s) in EPA's Registration Standard Program, discussed in chapter 2. This chapter addresses only conditional registrations of pesticide products containing new active ingredients.[1]

Under FIFRA Section 3(c)(7)(C), EPA can conditionally register pesticide products containing a new active ingredient not contained in any previously registered product in the absence of certain required test data, if EPA determines that

- insufficient time has elapsed since the imposition of the data requirements for those data to have been developed,
- use of the pesticide product(s) containing the new active ingredient during the conditional period would not cause any unreasonable adverse effects, and
- conditional registration of the pesticide product and its uses are in the public interest.

All three criteria must be satisfied before EPA may grant a conditional registration. The act does not define "in the public interest."

The Congress intended that the authority for conditional registration of new active ingredients strike a balance between the requirement for full pre-market testing of a new pesticide and the limited circumstance where the public interest would be served before full testing is complete. That is, the benefits of using a new pesticide before required tests are complete should outweigh the risk that some adverse effect might result from use during the conditional period. This authority also gives EPA the

[1] We note that EPA may conditionally register the initial pesticide product(s) containing a new active ingredient under authority of section 3(c)(7)(C). Subsequent registrations of new products or new uses of that active ingredient may be conditionally registered under fewer requirements of sections 3(c)(7)(A) and 3(c)(7)(B), respectively.

flexibility to permit use of a new pesticide that the Agency knows a relatively great deal about, as contrasted with permitting the expanded use of a previously registered pesticide awaiting reregistration that the Agency may know relatively little about.

The legislative history indicates that both EPA and the Congress intended that conditional registration of new active ingredients was to be for exceptional purposes to further the public interest. According to an April 1979 memorandum from EPA's Deputy Associate General Counsel, EPA proposed legislative authority for conditional registration of new active ingredients in 1977 for the rare situation where the public interest would be served by the conditional registration.

In reviewing the legislative history of conditional registrations of new active ingredients, EPA's Deputy Associate General Counsel concluded in 1979 that the public interest requirement imposed a stringent test. In a memorandum discussing the nature of the public interest requirement, the Deputy Associate General Counsel stated:

"Everyone whose views on the matter appear in the committee reports or floor debates stated that conditional registration under FIFRA 3(c)(7)(C) would be a relatively rarely-exercised authority, and each example of how it would be used that was put forward referred to serious pest problems for which the pesticide was needed.

"We believe that the [public interest] finding can be made only if the Agency concludes that there is a real and immediate need for the new pesticide for purposes of pest control or plant growth regulation, a need which cannot be met by use of other techniques or other chemicals on a reasonably acceptable basis."

In addition to the provision of section 3(c)(7)(C) for conditional registration, FIFRA Section 6(e) gives EPA authority to issue a notice of intent to cancel a conditional registration if the registrant fails to satisfy the statutory and EPA-imposed conditions. Further, under FIFRA Section 29, EPA must submit an annual report to the Congress on the conditional registrations of new uses of existing pesticides and pesticide products containing new active ingredients. We reviewed these EPA-submitted annual reports, which include information on the conditions imposed and the quantities of such pesticides produced. However, the act does not require EPA to submit information on the status of conditions imposed and on registrants' compliance with the conditions of the registrations.

EPA Lenient in Granting Conditional Registrations

On the basis of our review, it appears that, until recently, EPA was lenient in granting conditional registration of new active ingredients. When FIFRA was amended, EPA and the Congress anticipated that the authority for granting these conditional registrations would be rarely exercised. EPA has conditionally registered about 50 percent of all new active ingredients since 1978. According to the Director of the Registration Division and an internal OPP paper on conditional registration of new chemicals, OPP's application of the statutory requirements for conditional registration was less stringent in the past. EPA officials attribute this prior application to the evolving nature of pesticide data requirements and the general assumption that registration of a new pesticide active ingredient is in the public interest so long as the data on hand show no unreasonable adverse effects. Because the act does not define the public interest requirement, the granting of conditional registrations depends on EPA's definition of the public interest.

Between 1978 and 1984 EPA conditionally registered 44 and unconditionally registered 46 new active ingredients. The conditions vary from pesticide to pesticide but generally require the submission of certain studies by specific dates. The time frames for submission range from a few months to up to 4 years, depending on the amount of time needed to conduct the required studies; most data have had to be submitted within 1 year, according to the OPP paper.

In 1984 EPA first proposed rules for conditionally registering new active ingredients, but the proposal did not specify the requirements for meeting the public interest criterion. Generally, EPA reviewed these registrations on a case-by-case basis and tended to grant conditional registration pending receipt of more extensive test data. In analyzing a few conditional registrations, the OPP paper observed that "Although some data generally thought to be critical may be lacking, sufficient information is available to enable the Agency to make basic health and safety determinations." According to the OPP paper, the general assumption was that registration of a new active ingredient is in the public interest so long as the available evidence showed no unreasonable adverse effects.

Prior to 1985, OPP did not apply rigid standards to granting conditional registrations for new active ingredients. According to the OPP paper and product managers we spoke with, EPA did not impose rigid standards because:

- EPA considered the dynamics of the pesticide market (which emphasizes such factors as the need to replace obsolete pesticides and the search for new and better pesticide alternatives in terms of efficacy and cost) and
- EPA's revisions of pesticide data requirements contributed to uncertainty about what was required.

Although EPA's pesticide data requirements did not become effective until April 25, 1985, most data requirements had been imposed at least since 1982 and some before then (see ch. 2). EPA proposed the current pesticide data requirements on November 24, 1982. According to EPA, the final rule on data requirements, published on October 24, 1984 (effective Apr. 25, 1985), did not differ substantially from the proposal.

Conditional Registrations Not Routinely Monitored

EPA appears not to have routinely monitored the conditions imposed and enforced registrants' compliance with these conditions. According to EPA's proposed rules for conditional registrations of new active ingredients, these registrations are supposed to be limited to the period of time sufficient for generation and submission of the missing data. However, we were unable to readily ascertain the status of conditions imposed on conditional registrations, including whether EPA had formally extended conditional periods. Further, we were unable to determine whether the Agency has taken action to either cancel or suspend any conditional registrations of new active ingredients for registrants' failure to comply with conditions imposed. This is because EPA does not have a reliable information system that tracks the status of the conditions imposed.

According to the Chief of the Registration Support and Emergency Response Branch, OPP's on-line tracking system does not track the status of conditions imposed on conditional registrations. The Chief informed us that determining the status of conditions imposed on all conditional registrations of new active ingredients would require a time-consuming manual search of individual pesticide product registration files. Our discussions with four product managers confirmed that an extensive manual search of product registration files would be necessary to determine the status of conditions imposed on registrations.

Based on our analysis of EPA's annual reports to the Congress and information from OPP's Registration Support and Emergency Response Branch, we determined that the Agency has converted 10 out of the 44 conditional registrations of new active ingredients to unconditional

registrations since 1978. The other 34 active ingredients remain conditionally registered. Four out of the five new active ingredients conditionally registered in 1979 remain unconditionally registered as of February 1985, almost 6 years later. EPA could not provide us with the current information on what progress, if any, was being made by registrants to comply with the conditions of their conditional registrations. According to EPA officials, the Agency may not have routinely monitored conditional registrations of new active ingredients because of limited resources and competing priorities. Further, the Agency generally has many more data on new pesticides than on previously registered pesticides and hence knows a lot more about the risks of newer pesticides.

EPA Tightens Policy on Conditional Registration

Beginning around October 1984, the Director of the Office of Pesticide Programs initiated actions to tighten the policies and procedures in granting conditional registrations of new active ingredients. According to minutes of an OPP policy group meeting, the Director stated that OPP had not been stringent enough in its review of conditional registrations in the past. Further, he instructed the Registration Division to focus more on the process of following up on conditional registrations to ensure that conditions imposed are closely tracked, that required data are both submitted and reviewed, and that conditional registrations are converted to unconditional registrations or canceled, as appropriate. To this end OPP is developing procedures for reviewing applications for conditional registration and developing an automated system for tracking conditional registrations and the status of registrants' compliance with requested data. Further, OPP recently established policy and procedures to limit time extensions granted to registrants for meeting data requirement deadlines. According to a section chief in the Registration Support and Emergency Response Branch, conditional registrations of new active ingredients are becoming an endangered species.

In March 1986 EPA published a policy notice regarding approval or denial of applications for conditional registration of pesticide products containing new active ingredients under FIFRA Section 3(c)(7)(C). This notice establishes EPA's policies on the three statutory criteria for approval, the conditions of registration, and requirements for conversion from conditional to unconditional registration. Under the new policy, applicants for conditional registration of a new active ingredient will be expected to apply the EPA published data requirements themselves and submit a complete set of required studies. The Agency considers that most data requirements were imposed when EPA published the proposed requirements in 1982. In addition, the Agency considers

that since 1982 sufficient time has elapsed for most of the data required for registration to be generated. The Agency will consider granting conditional registration if a data requirement is clearly not foreseeable by the applicant before application, assuming that all other data requirements and the other two basic criteria are met.

In considering conditional registrations for new active ingredients, EPA will focus its analysis on the potential risks of using the pesticide during the conditional period while required studies are being generated. In recent years EPA conditionally registered three new pesticides—ethalfluralin, cyromazine, and cypermethrin—for which the data indicated that a certain risk criterion for initiating a detailed risk-benefit analysis may have been met. In analyzing these three new pesticides, EPA determined that the benefits outweighed the risks during the period of conditional use.

According to the policy notice, EPA will consider a number of factors to decide whether the public interest criterion for conditional registration is satisfied. In certain circumstances, EPA will presume that the use of a new active ingredient is in the public interest (e.g., to replace a relatively high-risk pesticide whose registration has been continued due to a lack of alternative pesticides). In reviewing all other new active ingredient applications, EPA will consider a variety of factors pertaining to the need for the chemical and its comparative benefits, risks, and costs. Applicants bear the burden of substantiating a public interest finding if requested by the Agency. If EPA grants a conditional registration, the registration will expire upon a date specified by the Agency, based upon the length of time to conduct the longest study required. Associated pesticide residue tolerances for the active ingredient will be issued to run concurrent with the conditional registration. These tolerances will expire a year after the scheduled expiration of the conditional registration to allow sufficient time for legally treated crops to move through channels of trade.

Conclusions

The Congress required EPA to regulate pesticides to ensure that pesticide use does not present any unreasonable adverse effects on health or the environment. FIFRA allows EPA to conditionally register new pesticide active ingredients with incomplete data, provided that the data are submitted at some future date, that using the pesticide during the conditional period will not present any unreasonable adverse effect, and that using the pesticide is in the public interest. Our review of the legislative

history indicates that both the Congress and EPA anticipated that conditional registration of new active ingredients would be for exceptional purposes. Since 1978 EPA has conditionally registered a large proportion—about 50 percent—of all new pesticide active ingredients even though some of the required health and environmental test data were not submitted to and evaluated by EPA. Since a conditional registration means that a new pesticide is registered for use with less than a full set of required test data, there is some uncertainty with regard to the risks of the pesticide's use.

Part of the problem is that FIFRA does not define "in the public interest." Also, in the past EPA used a broad interpretation of "in the public interest." EPA had not provided guidance on what constitutes "in the public interest" until March 1986 when it published its policy on conditional registration of pesticide products containing new active ingredients.

The FIFRA-mandated annual report to the Congress on conditional registration includes limited information and does not include information on the status of registrants' compliance with the conditions of their registrations. Such additional information would be more complete and useful to the Congress to monitor (1) EPA efforts to follow up on registrants' compliance in meeting requirements and (2) registrants' progress in meeting the conditions of their conditional registrations.

EPA is responsible for monitoring registrant compliance with conditions imposed, but it may not be doing so routinely because of limited resources and competing priorities. As a result, EPA may not fully know whether registrants are making reasonable progress in generating the test data on conditionally registered pesticides. EPA has recognized the need to more strictly apply the statutory requirements for conditional registrations of new pesticide active ingredients and recently published its policy on these registrations. EPA is also developing a tracking system that it believes will provide information on the status of conditions or studies that it requires of pesticide firms when it grants conditional registrations. We believe these recent actions, if properly implemented, are a step in the right direction primarily with future conditional registrations. Because of their recency, we were unable to determine the effectiveness of these new actions. However, we believe that EPA needs to follow up on past, outstanding conditional registrations to ensure that registrants are making reasonable progress in generating the required tests for pesticide products that were allowed to be used in commerce, on the condition that test data would be submitted later.

Recommendation to the Administrator, EPA

We recommend that the Administrator, EPA, review outstanding conditional registrations of new pesticide active ingredients, determine what progress is being made by registrants to develop and submit the required health and environmental effects test data, and take appropriate action, such as suspending or canceling the pesticide registration, in those cases where the registrant has not made reasonable progress to comply with the conditions imposed on the conditional registrations.

Matters for Consideration by the Congress

To ensure that EPA continues efforts to carry out its proposals to tighten up conditional registrations of new pesticides, the Congress may wish to consider the following alternatives:

- Requiring EPA, in its FIFRA-mandated annual report to the Congress, to include information on the status of registrants' compliance with the conditions imposed for each of the conditional registrations of new pesticides granted during preceding years. This additional information would provide the Congress with more complete information to monitor EPA's efforts to follow up on registrants' progress in meeting the conditions of their conditional registrations.
- Amending FIFRA to limit conditional registrations of new pesticide active ingredients without complete testing by defining "in the public interest" in a restrictive or limited manner.

Special Review—A Lengthy Process for Reviewing Pesticides of Concern

If, at any time, new evidence on a pesticide active ingredient (referred to as "pesticide" in this chapter) raises a concern about a significant health or environmental risk,[1] EPA may conduct a detailed risk/benefit analysis known as special review. Special review (previously known as Rebuttable Presumption Against Registration (RPAR)) is supposed to quickly and comprehensively weigh the risks and benefits of potentially hazardous pesticides to determine if regulatory action is necessary to protect the public and the environment.

From the inception of the special review program in 1975 through October 31, 1985, EPA has initiated special reviews for 51 pesticides; 19 were in the process and 32 have completed special reviews. The special review process has been lengthy, generally taking from 2 to 6 years or longer to complete. Although EPA has used the process to remove some dangerous pesticides from the environment and has identified others which it has regulated, the process is not meeting EPA's goal—to quickly make regulatory decisions on potentially hazardous pesticides. Because a pesticide of concern remains on the market while undergoing the lengthy special review process, the public and the environment may be exposed to a potential hazard.

EPA has taken or is considering several actions that it believes may help speed up or improve the efficiency of the special review process. Actions taken include (1) issuing special review data call-in letters to pesticide registrants, (2) integrating the registration standard and special review processes, and (3) issuing new special review risk criteria and procedures. Another action that EPA is pursuing is seeking legislative authority to use rule-making as the primary method for conducting special reviews.

Special Review—How It Works

EPA may conduct a special review of a pesticide if the Agency has a specific risk concern about it. During special review, EPA weighs the risks and benefits of a use or uses of a pesticide and decides whether to take regulatory action. Regulatory actions include canceling some or all uses, imposing use restrictions, and requiring labeling changes.

EPA created the special review process to facilitate the identification of pesticide uses which may not satisfy the statutory requirements for registration and to provide an informal procedure to gather and evaluate

[1] Significant health or environmental risks are defined by risk criteria triggers developed by EPA covering areas such as acute and chronic toxicity. These risk triggers are listed in app. VII.

information about the risks and benefits of these uses. Among the statutory requirements for registration is the provision that a pesticide must perform its intended function without causing "unreasonable adverse effects on the environment" (FIFRA Section 3(c)(5)). If a registered pesticide causes such unreasonable adverse effects, EPA may cancel its registration under authority of Section 6 of FIFRA.

The essence of the special review process is the preparation of an in-depth risk/benefit analysis. In this analysis EPA seeks to determine if the benefits of the continued use of a pesticide outweigh the risks associated with its use.

- The risk component of the analysis is determined both on the basis of toxicity and exposure to the pesticide. Toxicity (hazard) is the property of a pesticide that causes adverse health or environmental effects; exposure is the actual or expected degree to which human and other nontarget organisms come in contact with a pesticide. Exposure includes factors such as the magnitude, duration, and route of exposure and the size of the exposed population.
- The benefit component is defined as the dollar value, to the farmer or other users, of the continued use of the pesticide (i.e., benefits are the user's potential losses if EPA bans the pesticide). Benefits are estimated for control costs (the cost difference between the pesticide and alternative pesticides) and for revenues or productivity (the yield and revenue difference between using the pesticide and alternatives or no pesticide at all).

A pesticide must meet or exceed one or more risk criteria, also known as risk triggers, before it is put into special review. These risk triggers include those for oncogenicity (tumor formation), mutagenicity (heritable genetic effects), and other chronic (long-term) toxic effects; acute (immediate) hazards to humans and animals; and hazards to endangered species and other wildlife. If EPA determines that a pesticide meets or exceeds any of these risk triggers, it may initiate a special review of that pesticide. Special review is not intended to be an overall review of the pesticide, but rather is limited to the specific risk concerns indicated by the triggers involved. (EPA's special review risk criteria are listed in app. VII.)

The Special Review Process

The special review process has four major steps. Generally, as the process progresses from one step to the next, EPA gathers and evaluates

data and solicits comments from registrants and other interested parties. This section describes the four-step process.

Step 1. Pre-Special Review

In pre-special review EPA conducts an initial risk investigation involving an intensive review of the scientific study or studies of the pesticide in question that suggest that a risk trigger may have been met or exceeded. During this period, the registrant of the pesticide is notified that a risk trigger may have been met or exceeded. In most cases, EPA first determines, from review of laboratory data, the possible toxic effects associated with a pesticide use. If these studies are found to be valid, an effort is made to assess the significance of the risk posed by a pesticide use, considering both exposure and toxicity. If the Agency determines that a risk trigger has been met or exceeded, a special review will be initiated with the issuance of a notice of special review document.

Step 2. Notice of Special Review

The notice of special review document describes EPA's determination that a risk trigger (or triggers) has been met or exceeded and gives the affected registrant up to 45 days (with a possible 60-day extension) to rebut EPA's risk concern. Through a Federal Register notice, EPA advises interested parties of the availability of the document and solicits their comments. EPA continues to gather and analyze risk, exposure, and benefits data. With these data, EPA performs a risk assessment (based on toxicity and exposure) and a benefit analysis and combines them in a risk/benefit analysis. Also during this period, EPA may hold discussions with the registrant and other interested parties to try to determine ways in which the registrant can voluntarily reduce the risks associated with using the pesticide. For example, the registrant may voluntarily agree to make certain changes to the label instructions to reflect use restrictions, such as requiring that protective clothing be worn when applying the product.

If the registrant successfully rebuts EPA's risk concern, or if other data gathered alleviate EPA's concern, or if discussions with the registrant lead to sufficient voluntary reduction of risk, then EPA will terminate the special review process and issue a document describing its rationale in the Federal Register.

If EPA's risk concerns are not alleviated, the Agency will formulate a proposed regulatory position based upon what it considers to be the best balance of risks and benefits in the interest of public health and the

environment. EPA then issues this information in a preliminary determination document.

Step 3. Preliminary Determination

The preliminary determination document describes what regulatory action EPA proposes to take and details the various analyses that EPA performed before reaching its decision. Through a notice in the Federal Register EPA advises interested parties of the availability of the document and solicits their comments. The document includes EPA's assessment of any rebuttal offered by the registrant and EPA's risk assessment, benefit analysis, and risk/benefit analysis. Once EPA has analyzed any comments it has received, it formulates a final regulatory position and then issues a final determination document.

Step 4. Final Determination

The final determination document describes EPA's final regulatory position on what actions must be taken to reduce risks associated with a use or uses of a pesticide. This document also includes an analysis of any comments received, based on the preliminary position. A notice of EPA's issuance of the final determination is made in the Federal Register announcing the availability of the document. At this point the special review process has concluded, but implementation of EPA's regulatory decision may not necessarily occur immediately. Affected parties dissatisfied with EPA's decision may request an administrative hearing (as provided for under FIFRA Section 6(b)) and then, if not satisfied, may appeal through the federal court system. Implementation of EPA's regulatory decision is delayed during the administrative hearing and may be further delayed during an appeal in the federal court system if a stay is obtained.

According to EPA officials, while a pesticide is in special review, EPA will not approve any new major food uses of the substance that are likely to increase exposure to the pesticide; on the other hand, EPA may approve some new minor food uses and new non-food uses if anticipated exposure is low. After the special review has been completed, EPA will amend the pesticide's registration standard document to reflect the findings of the special review.

Special Reviews Are Lengthy

The special review program has been criticized for taking too long to complete reviews of pesticides. This criticism has been made not only by the pesticide industry and environmental groups but by EPA itself. Special reviews completed through October 1985 have generally taken 2 to

6 years or longer to complete. The Chief of EPA's Special Review Branch told us that, while special reviews take too long, it is difficult to speed up the special review process when EPA is dealing with so much uncertainty with respect to the quality of risk and benefits data, and with competing resource demands from other pesticide program activities. Table 7.1 shows the time in process and the results of special reviews for the pesticides amitraz (an insecticide used on pears), benomyl (a fungicide used on such crops as rice, cabbage, and wheat), and dibromochloropropane (a soil fumigant used on fruits and vegetables). (These pesticides were selected to show both a range of times and a range of results.)

Table 7.1: Sample of Special Review Process Times and Results

Chemical	Time in process[a]	Risk concern	Action taken
Amitraz	30 mos.	Oncogenicity	Conditional registration for restricted use pending receipt of data from registrants on benefits and oncogenicity
Benomyl	58 mos.	Mutagenicity Teratogenicity Reproductive effects Hazards to wildlife	Label change requiring wearing of mask for handling and mixing; registrants required to identify residues that may enter aquatic sites after use on rice
Dibromo-chloro-propane	86 mos.	Oncogenicity Mutagenicity	Voluntary cancelation of all registrations of end-use products, except the use on pineapples in Hawaii (this use was subsequently canceled)

[a]From issuance of the notice of special review document to culmination of the process by any of the aforementioned means.

According to EPA officials and records, a number of factors contribute to the length of time it takes to complete special reviews, especially with regard to obtaining and assessing data on pesticide toxicity and exposure. These factors include

- the complexity of issues and uncertainty in risk and benefits data;
- delays in getting needed studies and data, or studies having to be redone;
- limited resources—other special reviews and other pesticide program work compete for review time; and
- receipt of additional, unexpected data that must be reviewed and that may alter risk or benefit calculations, requiring EPA to consider different regulatory options.

EPA Resources for Special Review

Each of OPP's four divisions is involved in some part of the special review process.[2] OPP assigns a review manager and a team that includes scientists and economists from these divisions to each special review. Other participants in the process include the Department of Agriculture, EPA's Scientific Advisory Panel,[3] the pesticide industry, environmental groups, and the public.

EPA officials described the special review process as being very resource intensive. Agency resources allocated to special review for fiscal years 1980 through 1985 totaled about $54 million and 435 staff years. The following table shows how these resources were allocated by fiscal year.

Table 7.2: Resources Allocated to Special Review[a]

Dollars in Millions

Fiscal year	Intramural[b]	Extramural[b]	Total	FTEs[c]
1980	$3.8	$9.6	**$13.4**	112.9
1981	4.3	5.9	**10.2**	124.9
1982	2.8	6.6	**9.4**	68.7
1983	1.5	6.4	**7.9**	35.0
1984	2.0	5.3	**7.3**	45.4
1985	2.4	3.4	**5.8**	47.7

[a]The numbers in the table are not firm, but they represent the best data that EPA was able to provide. Data for fiscal years 1975-79 were not available.

[b]Intramural—internal agency expenditures; extramural—expenditures for contractors and consultants.

[c]FTE means full-time equivalent (staff year); an FTE is a personnel position representing one person for 1 year.

The Chief of EPA's Special Review Branch cautioned that the numbers in the table are not truly reflective of resources allocated to special review because of accounting differences from year to year. According to the Chief, the differences in accounting from year to year explain in part the reason for the sharp drop in full-time equivalents from fiscal year 1981 to fiscal year 1983. For instance, some activity formerly billed to special review is now billed to interim registration standard development. The Chief stated that other factors contributing to this drop were a reorganization, a lull in initiating new special reviews during 1982-83

[2] The Benefits and Use, Hazard Evaluation, Registration, and Program Management and Support Divisions.

[3] The Scientific Advisory Panel is a seven member panel provided for in FIFRA Section 25(d). The panel is appointed by the EPA Administrator and provides comment on EPA's pesticide-related regulations, notices of intent to cancel or reclassify pesticide registrations, and guidelines for performing scientific analysis.

when the Agency tried to clean up a backlog of special reviews in process, the availability of better data because of interim registration standard development, and increased efficiency on the part of the special review staff.

More Resources May Be Needed for Future Special Review Activity

According to the Chief of the Special Review Branch, more resources will be needed to handle anticipated increases in future special review program activity.

EPA expects in the near future that most special review pesticides will be identified through the registration standard process. In terms of future special review program activity, the Chief of EPA's Resource Management and Evaluation Branch estimated that 40 percent of the pesticide active ingredients for which interim registration standards will be prepared will be candidates for special review consideration. Other OPP officials estimated that 20 to 25 percent of the active ingredients for which interim registration standards will be developed will be put into special review. According to the Deputy Director of EPA's Registration Division, 12 of 124 chemicals (about 10 percent) for which interim registration standards have been developed had gone into special review as of March 31, 1986.

In February 1986 the Chief of the Special Review Branch told us that he expects the branch's workload to increase significantly throughout the remainder of fiscal year 1986 and during fiscal year 1987. The Chief estimates that up to 60 percent of the pesticides in the registration standard process will be considered as candidates for special review during this period. This is due primarily to two factors. First, EPA is having to reassess its previous special review decisions on 13 chemicals as stipulated in a settlement agreement reached with the Natural Resources Defense Council (NRDC), an environmental group, and others in September 1984 (see p. 111). These reassessments are coming due during 1986, with the last due December 31, 1986; some of them may lead to new special reviews of the chemicals concerned.

A second factor that will contribute to the escalating workload is receipt of data from the first wave of studies required in interim registration standards developed for food-use pesticides in 1980 and 1981. The Chief speculates that many of these study results will raise risk concerns necessitating risk assessments and, for an undetermined number of the pesticides involved, initiation of special reviews.

According to the Chief of the Special Review Branch, more resources will be needed to handle this anticipated workload. Accordingly, in February 1986 the Special Review Branch added six additional review managers (these staff were transferred from another EPA office). The Chief stated that these additional resources are needed for the Special Review Branch to meet its planned fiscal year 1986 special review workload. The Chief anticipates that he will need significantly more resources in fiscal year 1987, perhaps as much as 50 percent more staff over the fiscal year 1986 level, to meet an increasing workload that should begin to level off after fiscal year 1987.

Special Review Program Results

As of October 1985 EPA had completed special reviews for 32 of 51 pesticides for which reviews had been initiated. Most of the risk-reduction measures that have resulted from special reviews have been changes in how or what the pesticide could be used for, such as restricting the use of the pesticide to certain crops or geographical locations. In some cases EPA has canceled some or all uses of a pesticide. For the 32 pesticides that have completed special review, 5 have had all uses canceled, 12 have had some uses canceled, 23 have had use restrictions imposed, and no action was taken on 1 because risks were considered to be at acceptable levels (these numbers are not additive because more than one type of action was taken on some pesticides).

Some Pesticide Uses Have Been Retained for Lack of Alternative Pesticides

Some uses of certain special review pesticides of concern have been retained by EPA because no alternative pesticides were available, or, if available, the alternatives were not as efficacious or cost-effective. These uses were retained because benefits exceeded risks, but the risks were sufficient enough to cause continued concern. For example, several uses of the pesticides lindane and dimethoate have been retained because of a lack of suitable alternatives. Uses of lindane so retained include its use on ornamental plants and Christmas trees; alternatives exist for these applications but are either too expensive, ineffective, or more toxic than lindane. The use of dimethoate on grapes, citrus fruit, tomatoes, broccoli, and beans has been retained because effective alternatives do not exist.

EPA is circulating internally a draft paper addressing the question of what EPA could do to encourage the use of safer pesticides. This paper recommends that the Agency specifically identify, in concluding a special review, any significantly risky but beneficial pesticide uses left in

place solely because of the absence of satisfactory alternatives to those pesticides/uses. For such reluctantly retained uses, the Agency would

- publicly encourage the development of alternatives;
- accelerate the review of any such alternative pesticides proposed for registration; and
- when such alternatives are registered, automatically reconsider the continued registrability of the pesticide/use in question.

The paper further recommends that EPA compile a list of products/uses that are on the market today solely because of the absence of safer and reasonably effective alternatives; this list could be published to alert users to risks and to encourage producers to develop substitutes.

EPA is considering issuing, sometime in 1986, a notice in the Federal Register announcing a statement of proposed policy that would incorporate the recommendations discussed above.

EPA Agreed to Encourage Greater Public Participation and to Reassess 13 Special Review Decisions

In May 1983 NRDC and others sued EPA challenging the Agency's alleged use of closed-door meetings and protracted negotiations with industry to resolve special review proceedings. In September 1984 EPA and the plaintiffs executed a settlement agreement in which EPA agreed to develop procedures allowing for greater public participation in the pre-special review and special review decision-making processes. (Natural Resources Defense Council v. Ruckelshaus, No. 83-1509 (D.D.C. settlement approved, Oct. 14, 1984).) The Agency also agreed to reassess its RPAR (special review) related decisions on 13 pesticides.[4]

Most notably, EPA agreed to establish a public docket (a publicly available record of relevant documents) for each pesticide in pre-special review or special review that will include

- memoranda describing each meeting between Agency personnel and any person or party outside government that concerns a pending pesticide regulatory decision;
- all comments, correspondence, or other materials concerning a pending pesticide regulatory decision provided to the Agency by a person or party outside of government; and

[4] These were the RPAR or pre-RPAR decisions concerning lindane, benomyl, paraquat, the EBDCs (e.g., Amobam, Mancozeb, Maneb, Metiram, Nabam, and Zineb), EPN, PCNB, terbutryn, and DDVP. (See list of abbreviations on p. 9 for the meanings of EBDC, EPN, PCNB, and DDVP.)

- all documents, proposals, or other materials concerning a pending regulatory decision, provided by the Agency to any person or party outside the government.

For each pesticide in pre-special review, the docket will be made available to the public for inspection and copying after the pre-special review procedure has been completed. All materials in the docket for each pesticide in special review will be made available to the public for inspection and copying during the special review.

These new procedures providing for greater public participation are embodied in EPA's new Special Review Criteria and Procedures, issued on November 27, 1985. The new criteria and procedures are discussed later in this chapter (see p. 116).

As part of the settlement, EPA also agreed to reassess its pre-RPAR or RPAR decisions for 13 pesticides; the agreement includes deadlines for completing these reassessments.[5] In each reassessment, EPA agreed to independently review the full set of available health and safety data (not just the data available at the time the original assessments were done), assess applicable health and environmental risks, and reach an appropriate regulatory decision. Such decisions may include developing a registration standard, initiating a special review, proposing an appropriate regulatory action, and suspending or canceling the pesticide's registration.

EPA Has Acted to Speed Up the Special Review Process

EPA has taken actions that it believes may speed up the special review process. These actions include (1) issuing data call-in letters to fill data gaps on pesticides for which special reviews have been initiated and (2) integrating the registration standard and special review programs by completing interim registration standards before initiating special reviews.

EPA is issuing data call-in letters for special review pesticides to more quickly obtain data needed for decision-making. When EPA starts a special review, it identifies data gaps and then issues a data call-in letter to

[5] EPA completed its reassessment of lindane by September 30, 1985, as required by the settlement; as a result of this reassessment, EPA will special-review lindane based on two uses that are suspected of causing exposure related to irreversible kidney effects. EPA was to have reassessed its decisions for benomyl and paraquat by March 31, 1986, but did not meet this deadline (EPA expects to issue these reassessments in April 1986). EPA must reassess its decisions for the EBDCs, EPN, PCNB, DDVP, and terbutryn by December 31, 1986.

the registrant(s) indicating what studies/data are needed and imposing time frames for the submission of this information. The Chief of the Special Review Branch told us that in the past EPA was reluctant to ask a registrant to go to the expense of doing the studies needed because the Agency assumed that if it put a pesticide into special review, it was going to cancel that pesticide anyway. This official said that experience has shown that EPA in fact has not canceled many special review pesticides and therefore it is no longer reluctant to request data from the registrant. Special review data call-ins have been issued for several pesticides. (The use of data call-in letters is discussed in greater detail in ch. 2.)

EPA is trying to integrate the registration standard and special review programs by completing the interim registration standard for a pesticide prior to putting it into special review. By doing so, EPA believes it will have a more complete picture of the pesticide and will be aware of any and all special review risk criteria that may have been met or exceeded. EPA believes that this strategy of completing interim registration standards first will avoid the possibility of having already initiated a special review based on one risk trigger and then later finding that another risk trigger has also been met (perhaps even presenting a more urgent risk concern), requiring some pesticides to go through another special review. Also, the pesticide will potentially be in the special review process for less time overall if all risk concerns are identified at one time. In response to the House Committee on Government Operations' report, Problems Plague the Environmental Protection Agency's Pesticide Registration Activities (Oct. 1984), EPA's Assistant Administrator for Pesticides and Toxic Substances stated that:

"Generally, if the Agency is generating a [interim] registration standard for a pesticide, it does not initiate a Special Review until the [interim] standard is complete. By completing the standard we are often able to preliminarily assess exposure potential, which is vital to the decision whether to initiate a Special Review. In fact, the current [interim] standards development process does not delay Agency action on pesticide chemicals, but rather serves as a means of identifying chemicals for which action is necessary."

The Chief of the Special Review Branch told us that if EPA has a risk concern about a pesticide during the development of the interim registration standard, it will ask the registrant to expedite the completion of the studies addressing this concern. If, after reviewing these studies, EPA has a serious concern about the pesticide, it will put the pesticide into special review immediately without waiting to complete the interim registration standard.

In response to the aforementioned report to the House Committee on Government Operations, EPA's Assistant Adminstrator for Pesticides and Toxic Substances confirmed this policy by stating:

"... Special Reviews are initiated promptly on any chemicals of concern, regardless of whether [interim] registration standards are under development or have been completed, if the Agency has sufficient information concerning exposure and potential adverse effects. The Agency's recent initiation of a Special Review for dinocap is a case in point."

On the other hand, if EPA does not have serious concern about a pesticide, it will delay starting a special review until the interim registration standard is completed. The Chief told us that by delaying special review until interim registration standards are complete, EPA has a "comprehensive picture of that chemical in the absence of an imminent hazard."

EPA Is Proposing Rule-Making to Make the Special Review Process More Efficient

In addition to actions already taken, EPA is proposing another measure that it believes would make the special review process more efficient. This measure provides for establishing rule-making[6] as the primary method for determining whether pesticides cause unreasonable adverse effects on the environment and what regulatory steps should be taken to address such effects. EPA is currently working with the House Agriculture Subcommittee on Departmental Operations, Research, and Foreign Agriculture in developing appropriate legislative changes to FIFRA to expedite the special review process. EPA's proposal for rule-making is among the changes being discussed.

According to EPA officials, rule-making as proposed holds the possibility of significantly shortening the administrative hearing process that may be requested by registrants or pesticide users after EPA has completed its special review and announced its final regulatory decision. Currently, implementation of EPA's regulatory decision is delayed until the conclusion of this hearing; under rule-making, however, EPA's regulatory decision could be in effect even if a hearing were requested.

Currently, according to EPA officials, the special review process is essentially like an informal notice-and-comment rule-making, except that it has no binding effect if an adversely affected party objects to the

[6] As provided by the Administrative Procedure Act (5 U.S.C. 551 et seq.), rule-making is the agency process for formulating, amending, or repealing a rule (an agency statement of general or particular application and of future effect, generally designed to implement, interpret, or prescribe law or policy). An agency must provide public notice of proposed and final rules and an opportunity for affected parties to comment.

Agency's special review decision. If an affected party objects, it may request an administrative hearing. EPA's Assistant General Counsel for pesticide matters told us that the current hearing process can take 2 or more years and is an extremely resource-intensive undertaking in which the substantive risk/benefit issues decided upon in the special review process may be reexamined intensively through expert testimony and cross-examination.

EPA's Assistant General Counsel for pesticide matters told us that the hearing held on the pesticides 2,4,5-T and Silvex between March 1980 and February 1981 was an example of how resource-intensive these hearings can be. During this hearing, more than 100 witnesses appeared, over 1,500 exhibits were entered in the record, and more than 23,000 pages of transcript were made. This official also told us that of the 15 EPA attorneys working on pesticides matters, 8 to 10 may be working on the same hearing. In addition, the Chief of EPA's Special Review Branch told us that his staff can become very involved in hearing-related activities, such as helping to prepare background material and identifying witnesses. The Chief added that in the future the Director of OPP wants the branch to take a lead role in conducting negotiations to reach settlements in these hearings.

According to EPA officials, the Agency's proposal for rule-making involves combining desirable procedures from the current special review and hearing processes. Namely, EPA's proposal would add the benefits of cross-examination to the notice-and-comment rule-making process. According to these officials rule-making is an efficient way to collect information and make decisions that also provides the public and the regulated industry with extensive opportunities to participate. Cross-examination allows detailed scrutiny of controversial positions or ambiguous data. EPA's rule-making proposal would provide a limited period of cross-examination on any issue involved in rule-making, but cross-examination would occur before the final rule-making decision when the insights it provides would be most useful. According to these officials, the Agency's rule-making proposal would replace both the current special review and hearing processes.

After it has reached a special review decision by rule-making, if a hearing was requested, EPA is proposing that its scope be limited to (1) whether the pesticide product in question was covered by the regulation (i.e., the rule-making decision), (2) whether the product was in compliance with the requirements imposed by the regulation, and (3) whether significant information that could not have been presented in the rule-

making would make it unreasonable to require the product to comply with the regulation. The substantive risk/benefit issues decided upon in the special review process would not be subject to reexamination. The Assistant General Counsel for pesticide matters told us that under rulemaking, a hearing following special review would probably take no more than 6 weeks because of its limited scope.

Some Environmentalists and Industry Officials Support the Use of Deadlines

Both environmentalists and representatives of the pesticide industry have suggested that deadlines should be applied to the special review process in order to accomplish special reviews more quickly. These suggestions have ranged from applying an overall deadline to the entire special review process to applying deadlines for the completion of the individual steps in the process.

EPA does not believe that the use of deadlines for completing special reviews is realistic. According to the Agency, the time required to complete a particular special review is influenced by factors that are unique for each pesticide. These factors include, but are not limited to, the number and nature of use sites and application methods, the nature of the risks of concern, and the completeness of the data bases which may be required for the Agency to make a final regulatory judgment. The Chief of EPA's Special Review Branch told us that if deadlines were adopted, EPA would be forced to delay the initiation of special reviews until the Agency was sure it had enough data on hand to complete these reviews by the deadline; this would put the Agency in the position of knowing of pesticides for which it has significant adverse effects concerns, yet, because of the deadline requirement, not initiating special reviews immediately and, hence, not notifying user groups of EPA's concerns. Other EPA officials told us that if deadlines were imposed, it is imperative that they be reasonable in light of the complexities of special review. (See ch. 2 for further discussion on the usefulness of deadlines.)

EPA Has Issued New Special Review Criteria and Procedures to Make the Process More Efficient

On November 27, 1985, EPA published a final rule in the Federal Register (effective Apr. 14, 1986) outlining new special review risk criteria triggers for determining when to put a pesticide into special review, and new special review procedures that provide guidance on how special reviews should be performed. These new criteria and procedures replace those developed in 1975. EPA believes that these new criteria and procedures will provide for a more efficient special review process to thoroughly review and quickly resolve risk concerns from problem pesticides.

According to EPA, the new criteria and procedures are based primarily on revisions made to FIFRA by the Congress in 1978 and on the experience acquired by EPA in regulating pesticides under the previous special review criteria and procedures. The new procedures also incorporate changes to the special review process that were agreed to in the NRDC settlement agreement (see p. 111).

The New Special Review Risk Criteria

The new special review risk criteria triggers consider actual or projected human or wildlife exposures from the uses of a pesticide, along with the toxicological effects of the pesticide, in deciding whether to initiate a special review. Some of EPA's old risk criteria were based on toxicological effects only; specifically, the old acute toxicity criteria and the oncogenicity/mutagenicity criterion did not incorporate exposure considerations. As a result, the Agency believed that under the old criteria it was technically required to initiate special review of a pesticide in some cases even when it was convinced that exposures or risks were insignificant. (A comparison of EPA's old and new risk criteria appears in app. VII.)

According to EPA, the new criteria assure that the risk determination to decide whether to initiate a special review will be based on the toxic effects associated with a pesticide as well as on the exposure of humans and nontarget organisms to the pesticide. Exposure will include factors such as the magnitude and duration of exposure and the size of the exposed population. The significance of the risk will be determined according to the weight of the evidence of the toxicological information and the magnitude and scope of exposure.

EPA stated that it changed the risk criteria to comply with the 1978 amendments of FIFRA Section 3(c)(8). Under this section EPA may not begin a "public interim administrative review process" (i.e., special review) unless there is "a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment." In discussing this section, the conference report accompanying the legislation (S. Rep. No. 1188, 95th Cong., 2nd Sess. 35-36) directs EPA to consider exposure to a pesticide before initiating the special review process; hence, EPA is taking into account actual or projected human or environmental exposures from a pesticide use before a special review is initiated.

The Chief of the Special Review Branch told us that EPA had in fact been using the magnitude and scope of exposure along with toxicological data

in making decisions as to whether to initiate special reviews for almost 2 years prior to promulgation of the new criteria. According to EPA's Associate General Counsel for Pesticides and Toxic Substances, the Agency had undertaken this practice for several reasons. First, the legislative history for the 1978 FIFRA amendments directed EPA to consider "exposure to pesticides through any medium or pathway" in deciding whether to initiate a special review. Second, the same legislative history also directed EPA to notify registrants of its RPAR concerns by "private communication," in order to "ameliorate the indictment like characteristics of the [special review] process." As a result, the Agency began privately notifying affected registrants of its initial risk determination and affording them the opportunity to submit exposure information in rebuttal before EPA decided whether or not to initiate a special review.[7] (Provision for this prior notification is included in the new special review procedures discussed below.) Finally, EPA did not believe it was prudent to devote substantial public and private resources to a full-scale special review of a pesticide unless the exposure associated with its use presented a significant risk. EPA concluded that early consideration of exposure would enable the Agency to focus its available resources on those pesticides that may pose the most serious risks.

The New Special Review Procedures

EPA believes that its new special review procedures provide for a more efficient special review process that allows the Agency to more thoroughly and quickly perform special reviews of pesticides of concern. The new procedures also contain measures to assure accessibility to the process agreed to in the aforementioned settlement agreement reached with NRDC. The new procedures provide that EPA will

- notify registrants of the basis for Agency concerns prior to starting the special review process;
- provide for a risk assessment of the uses and exposures of concern prior to starting a special review;
- start a special review only if the risk assessment indicates the risks are significant;
- after starting the special review, foster discussions with registrants, user groups, and environmental groups to determine acceptable approaches to reduce risks, including holding informal public hearings

[7] In addition, according to the Associate General Counsel, unless EPA's own analysis of exposure indicated that the pesticide may present a significant risk, EPA did not initiate this notification-rebuttal process. In these cases, EPA believed that notification was unnecessary because EPA would almost certainly reach the same conclusion after submission of rebuttal information by a registrant.

to gather relevant information or otherwise assist the Agency's decision-making;

- assure equal access to the Agency's decision process for all parties potentially affected by the Agency's determination, including establishment of a docket (containing relevant memoranda, correspondence, and other documents) for each pesticide in special review that will be available for public inspection and copying; and
- issue a simultaneous notice of special review and preliminary determination document in cases where the need for expedited action to abate hazards outweighs the advantages of early public notification and participation afforded by the notice of special review document.

Conclusions

EPA, industry, and environmental groups all agree that EPA's special review process for addressing pesticides of concern is taking too long to complete, contrary to EPA's goal of doing these reviews quickly. Special reviews have taken from 2 to 6 years or longer to complete, and the hearing process which may follow a special review may take up to 2 years or longer. During this period of review and hearings, the public and the environment may be exposed to potentially hazardous pesticides.

Special review is also a resource-intensive process. Over the past 5 years, the special review process has cost EPA about $54 million and 435 staff years. To date EPA has completed 32 out of 51 special reviews initiated. Most of these reviews of pesticides of concern resulted in changes in use restrictions. Other reviews resulted in the cancelation of some or all uses of a pesticide.

One of the factors contributing to the length of time it takes to complete special reviews are competing demands on limited resources arising from other special review and pesticide program work. Moreover, EPA officials believe that the special review workload is going to increase significantly in the near future as special review pesticides are identified from both interim and final registration standard development. The Chief of EPA's Special Review Branch believes that more resources will be needed to meet this escalating workload.

Some environmentalists and industry representatives have advocated the imposition of deadlines on the special review process in order to accomplish special reviews more quickly. EPA does not believe that the use of deadlines for special review would be realistic because the time required to complete a particular special review is influenced by factors

that are unique for each pesticide. EPA officials told us that if deadlines were imposed, it is imperative that they be reasonable in light of the complexities of special review.

EPA hopes to speed up the special review process in several ways. First, EPA is issuing data call-in letters to pesticide registrants to obtain more quickly data needed for decision-making. Second, EPA anticipates that integrating the registration standard and special review processes should enable the Agency to complete special reviews more quickly because interim registration standard development will identify any and all risk concerns and generate much of the data that would be needed for a special review. Third, EPA proposes to improve the efficiency of the special review process by changing the criteria and procedures relating to special reviews. The new criteria provide for considering exposure as well as the toxicological effects of a pesticide. The new procedures provide for a more open and accessible special review process, in which EPA can benefit from the input of affected parties in determining ways to reduce risks. We believe these recent actions are a step in the right direction. Because of their recency, we were unable to determine the effectiveness of these actions.

EPA is also currently discussing with the Congress a proposal to make the special review process more efficient by establishing rule-making as the primary method for determining whether products cause unreasonable adverse effects on health and the environment and what regulatory steps should be taken to address such effects. After it has reached a special review decision by rule-making, if a hearing is requested, EPA is proposing that the hearing be limited in scope to avoid reexamining the substantive risk/benefit issues decided upon in the rule-making. EPA believes that this will significantly shorten the lengthy hearings that may occur now. Currently, these hearings can take 2 years or longer.

Matters for Consideration by the Congress

Because potentially hazardous pesticides remain on the market during sometimes lengthy special reviews, the Congress may wish to consider alternatives for accelerating the special review process. Among the possible alternatives the Congress may wish to consider the advantages and disadvantages of are:

- Providing EPA with additional resources to allow it to more quickly review studies and data related to on-going special reviews, and to meet future increases in the special review workload anticipated by the Agency. This alternative should be considered in conjunction with our

other suggestion on resources for accelerating pesticide reregistration discussed in chapter 2.

- Setting deadlines for completion of special reviews (or for some or all of the special review phases) which recognize the complexities of special review, and the resource requirements necessary to meet such deadlines.

GAO Reports on Pesticides

1. Better Coordination Is Needed Between Pesticide Misuse Enforcement Programs and Programs for Certifying and Training Individuals to Apply Pesticides (GAO/RCED-83-169, July 1, 1983).

2. Regulation of Cancer-Causing Food Additives—Time For a Change? (HRD-82-3, Dec. 11, 1981).

3. Stronger Enforcement Needed Against Misuse of Pesticides (CED-82-5, Oct. 15, 1981).

4. Need for Comprehensive Pesticide Use Data (CED-80-145, Sept. 30, 1980).

5. Need for a Formal Risk/Benefit Review of the Pesticide Chlordane (CED-80-116, Aug. 5, 1980).

6. Delays and Unresolved Issues Plague New Pesticide Protection Programs (CED-80-32, Feb. 15, 1980).

7. Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979).

8. Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues (HRD-79-10, Apr. 17, 1979).

9. Need for EPA to Improve Foreign Nation Notifications (CED-78-103, Apr. 20, 1978).

10. Special Pesticide Registration by the Environmental Protection Agency Should Be Improved (CED-78-9, Jan. 9, 1978).

11. Adequacy of Safety and Efficacy Data Provided to EPA by Nongovernmental Laboratories (RED-76-63, Jan. 26, 1976).

12. Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards? (RED-76-42, Dec. 4, 1975).

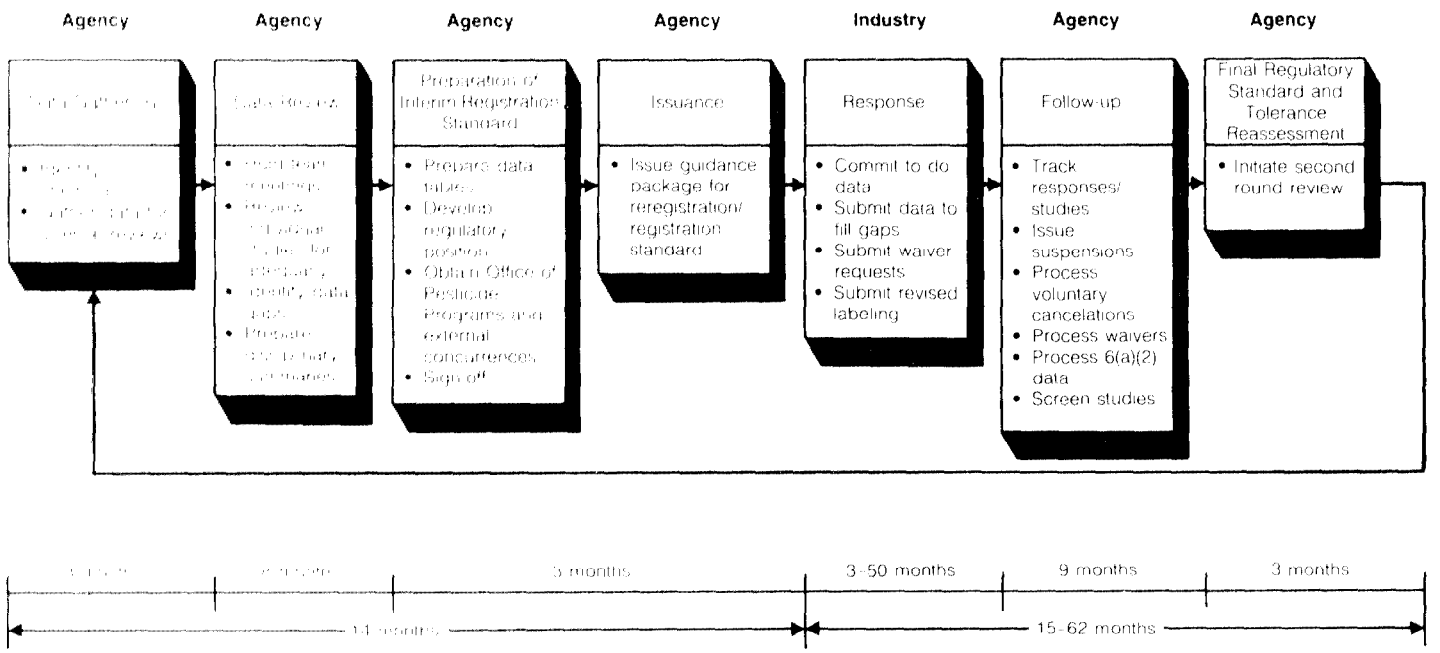
General Purposes of Major Pesticide Data Requirements[a]

Type of data	Purpose of data
Product chemistry	To provide information on product composition, and chemical and physical characteristics of a pesticide.
Residue chemistry	To provide information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of tests on the amount of residues remaining on or in the treated food or feed to support a finding as to the magnitude and identity of residues in food or animal feed as a consequence of a proposed pesticide usage. Data are used to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances.
Environmental fate	To demonstrate the fate of pesticides in the environment through degradation, metabolism, mobility, dissipation and accumulation.
Hazards to humans and domestic animals	
Acute toxicity	To determine health hazards likely to arise soon after, and as a result of, short-term exposure (oral, dermal, and inhalation). Data from acute studies serve as a basis for classification and precautionary labeling. First required in 1954.
Subchronic toxicity	To determine health hazards that may arise from repeated exposure over a limited period of time. These studies provide information on target organs and accumulation potential. First required in 1954.
Chronic feeding	To determine effects of a substance in a mammalian species following prolonged and repeated exposure, such as damage to liver or kidney. First required in 1954.
Oncogenicity	To observe test animals over most of their life span for the development of tumors. First required in 1963.
Reproduction	To determine effects of a substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. First required in 1963.
Teratogenicity	To determine the potential of a test substance to induce structural and/or other abnormalities to the fetus (birth defects) as a result of exposure of the mother during pregnancy. First required in 1970.
Mutagenicity	To determine the potential of a test substance to affect the mammalian cell's genetic components. First required in 1972.
Reentry protection	To calculate the length of time required before persons can safely enter a pesticide-treated site.

Type of data	Purpose of data
Pesticide spray drift	To evaluate the likelihood and extent of pesticide transport from the site of application to nontarget areas by aerial drift.
Hazard to nontarget organisms (ecological effects)	To assess potential adverse effects on nontarget organisms from basic laboratory and applied field tests on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants.
Product performance (efficacy)	To ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, such as disinfectants.

[a]Data Requirements for Pesticide Registration, 40 CFR 158, specifies the kinds of data and information that must be submitted to EPA to support the registration of each pesticide product and the tolerances for pesticide residues in food or feed.

Registration Standard Process



Time Line per Pesticide Active Ingredient

Source: EPA (March 1986)

Restrictions Imposed on Active Ingredients Reviewed Under the Registration Standards Program Through March 1985[a]

Active Ingredient	Manufacturing Process Restrictions	Formulation Restrictions	Labeling Restrictions	Restricted Use[c]	Special Review Initiated
Alachlor			Unique Labeling Required[b]	X	X
Alar (Daminozide)			Unique Labeling Required		X
Aldicarb			Protective Clothing	X	X
Al. Phosphide			Unique Labeling Required		
Amitrol			Unique Labeling Required	X	X
Anilazine		X	Protective Clothing		
Atrazine			Unique Labeling Required		
Aspon		X	Unique Labeling Required		
Avitrol	X		Unique Labeling Required & Protective Clothing		
Bifenox			Application Rate Restriction		
Bromacil			Unique Labeling Required		
Carbaryl			Unique Labeling Required		
Carbofuran			Unique Labeling Required	X	
Carbophenothion			Unique Labeling Required	X	
Captafol			Unique Labeling Required	X	
Chlorobenzilate				X	
Chloropicrin			Protective Clothing		
Chloropyrifos			Unique Labeling Required		
Chlorothalonil			Unique Labeling Required		
Coumaphos	X		Unique Labeling Required		
Cyanazine	X	X	Unique Labeling Required	X	X
Cycloheximide		X			
Demeton		X	Unique Labeling Required	X	
Dialifor			Reentry/Preharvest Interval		
Diallate			Unique Labeling Required		
Dicofol					X
Dicrotophos			Unique Labeling Required	X	
Dioxathion			Unique Labeling Required		
Disulfoton		X	Unique Labeling Required	X	
Endosulfan		X	Unique Labeling Required	X	
Ethoprop		X	Unique Labeling Required		
Ethoxyquin			Unique Labeling Required		
Fensulfothion		X	Unique Labeling Required	X	
Formenanate HCL		X	Unique Labeling Required		
Fonofos			Unique Labeling Required	X	
Fumarin			Unique Labeling Required		
Hypochlorite			Unique Labeling Required		

Active Ingredient	Manufacturing Process Restrictions	Formulation Restrictions	Labeling Restrictions	Restricted Use[c]	Special Review Initiated
Isopropalin		X	Unique Labeling Required		
Linuron			Unique Labeling Required		
MCPA	X		Unique Labeling Required	X	
Metalaxyl			Rotational Crop Restriction		
Methamidiphos			Unique Labeling Required		
Methomyl	X		Unique Labeling Required	X	
Mg Phosphide			Unique Labeling Required	X	
Methoprene			Unique Labeling Required		
Methidathion			Unique Labeling Required		
Naptalam		X	Unique Labeling Required		
Naphalene Acetic Acid		X	Unique Labeling Required		
Pendamethalin	X	X	Unique Labeling Required		
Phorate			Unique Labeling Required	X	
Phosalone			Unique Labeling Required		
Picloram	X	X	Unique Labeling Required	X	
Propachlor		X	Unique Labeling Required	X	
Simazine			Unique Labeling Required	X	
Sulprofos		X	Unique Labeling Required	X	
Terbufos			Unique Labeling Required		
Terrazole			Unique Labeling Required		
Thiram			Unique Labeling Required		
Trichlorofon			Unique Labeling Required		
TPTH			Unique Labeling Required	X	X
Warfarin		X	Unique Labeling Required		
Zn Phosphide				X	

[a]This information is taken, in part, from EPA's Evaluation Measures of the Registration Standards Program, January and July 1985. We did not verify the information contained in these reports.

[b]Unique labeling required includes such things as statements on use, restrictions, hazards, etc.

[c]A general EPA category indicating chemicals that may be classified for restricted use or classified for general use with certain restrictions imposed on use, such as do not allow in water.

Status of Pesticide Products Which Could Qualify for "Reregisration"[a]

		Total
1.	Number of registration standards [interim]	**90**
2.	Number of products covered under these standards	**3,709**
3.	Suspensions issued	**586**
4.	Cancelations [voluntary] issued	**485**
5.	Total submissions under review	
	a. Waivers and label disagreements	**630**
	b. Data under review	**83**
6.	Products reregistered	**145**
7.	Compliance status undetermined or dependent on pending decisions on related products reflected in No. 5 above[b]	**1,780**

[a]Reported by EPA as of September 23, 1985.

[b]According to the Acting Chief of the Program Coordination Staff, this category mostly includes formulated end-use products. Registrants of these products generally await EPA's disposition of manufacturing-use products before complying with a registration standard.

Tolerance Risk Assessment

This appendix defines the concepts generally used in assessing dietary risks of food-use pesticides and provides an example of how these concepts were used in establishing tolerances for the pesticide chlorsulfuron. Chlorsulfuron is a herbicide used to control certain weeds on wheat, barley, oats, and other crops. EPA has established 25 tolerances for chlorsulfuron and its metabolites (chemical breakdown products) on various grains, meat products, and milk.

Concepts	Example
Acceptable Daily Intake (ADI): A person's daily intake of a pesticide residue which, during a lifetime, is not expected to cause appreciable health risks on the basis of all facts known at the time. The ADI is based on the lowest No Observable Effect Level from the various toxicology studies, divided by a safety factor.	The Acceptable Daily Intake for the herbicide chlorsulfuron is 0.05 milligrams (mg) per kilogram (kg) of body weight per day. One could eat foods containing as much as the ADI level of chlorsulfuron residue daily, with a practical certainty that injury will not result even after a lifetime of exposure
No Observable Effect Level (NOEL): The NOEL is derived from toxicology studies and represents the highest level of pesticide fed to test animals which produced no toxic reactions or other signs. Effects observed at higher levels (whether adverse or non-adverse) are absent, and no significant differences exist between animals exposed to the pesticide and an unexposed control group.	The toxicology studies on chlorsulfuron were as follows: (1) 2-year feeding study on rats with a NOEL of 100 parts per million (ppm) showing weight reduction and hematological (blood) effects at higher levels, (2) 6-month feeding study on dogs with a NOEL of 2,500 ppm and no effects at highest level tested, (3) 2-year feeding study on mice with a NOEL of 500 ppm showing weight reduction at higher levels, and (4) a 3-generation rat reproduction study with a NOEL of 500 ppm showing slight fertility decrease at higher levels.
Safety Factor: A number intended to provide a margin of safety and account for inherent uncertainty in projecting the results of animal toxicology tests to humans. EPA toxicologists usually use a safety factor of 100, representing the difference in sensitivity between humans and test animals (one factor of 10) and the difference in sensitivity among different people (a second factor of 10). Safety factors from 10 to 1,000 may be used.	A 100-fold safety factor and the lowest NOEL from the animal studies were used to compute the ADI for chlorsulfuron. The lowest NOEL (100 ppm) equates to 5 milligrams per kilogram of body weight per day (mg/kg/day). NOEL of 5 mg/kg/day divided by safety factor of 100 = ADI of 0.05 mg/kg/day
Food Factor: An estimate of the portion of the total diet of an average consumer made up by a food or food group. Food factors were derived from a 1965-66 U.S. Department of Agriculture survey. Food factors estimate average consumption and assume a 60 kilogram average body weight and 1.5 kilogram per day average total diet.	For the foods and food groups for which chlorsulfuron has tolerances, the food factors are: Barley 0.0003 Red meat 0.1081 Milk and dairy 0.2862 Oats 0.0036 Wheat 0.1036

Concepts	Example
Theoretical Maximum Residue Contribution (TMRC): An estimate of the maximum daily dietary exposure to a pesticide's residues for a person consuming an average diet. Maximum dietary exposure (TMRC) of a pesticide used on potatoes, for example, depends on both the amount of pesticide residue that may be on potatoes (assumed to be the tolerance level) and on what proportion of the daily diet potatoes represent (estimated by the food factor). The TMRC for one food is computed by multiplying the tolerance by the corresponding food factor by the 1.5 kg average diet. The total TMRC for a pesticide is the sum of the TMRCs for existing and proposed tolerances. The TMRC assumes 100 percent crop treatment with the pesticide and tolerance level residues.	The TMRC for chlorsulfuron is the sum of the TMRCs for each food, computed as follows: Barley—0.1 tolerance X 0.0003 food factor X 1.5 kg = 0.00005 mg/day TMRC. Red meat—0.3 tolerance X 0.1081 food factor X 1.5 kg = 0.04866 TMRC. Milk & dairy—0.1 tolerance X 0.2862 food factor X 1.5 kg = 0.04292 TMRC. Oats—0.1 tolerance X 0.0036 food factor X 1.5 kg = 0.00054 TMRC. Wheat—0.1 tolerance X 0.1036 food factor X 1.5 kg = 0.01554 TMRC. TOTAL TMRC for chlorsulfuron = 0.1077 mg/day (sum of above).
Comparison: The potential exposure to pesticide residues (TMRC) is compared to the acceptable level of intake (ADI) to determine if tolerances are within an acceptable level for chronic effects. If the TMRC is less than the ADI (and the pesticide does not have carcinogenic or teratogenic effects), EPA considers the potential exposure to be safe and approves the proposed tolerances. Carcinogenic and teratogenic risks, if any, are assessed by different procedures. (Carcinogenic risk assessment is described in ch. 4.)	The ADI for chlorsulfuron is multiplied by 60 kg (average body weight): 0.05 mg/kg/day ADI X 60 kg = 3 mg/day. The total TMRC of 0.1077 mg/day is less than 3 mg/day, so chlorsulfuron tolerances are acceptable. The TMRC utilizes 3.6 percent of the ADI. Chlorsulfuron showed no carcinogenic or teratogenic concerns in animal tests.

Special Review Risk Criteria

Old Criteria	New Criteria
(40 CFR 162.11)	(40 CFR 154.7; effective and replaces old criteria on April 14, 1986)
Acute Toxicity	
Hazard to Humans and Domestic Animals:	
—Has an acute dermal LD_{50} dose (lethal dose at which 50 percent of animals tested die) of 40 milligrams per kilogram or less as formulated; or has an acute dermal LD_{50} dose of 6 grams per kilogram or less as diluted for use in the form of a mist or spray.	—May pose a risk of serious acute injury to humans or domestic animals.
	—Considers magnitude and scope of exposure.
—Has an inhalation LC_{50} concentration (lethal concentration at which 50 percent of animals tested die) of 0.04 milligrams per liter or less as formulated.	
Hazard to Wildlife:	
—Occurs as a residue immediately following application in or on the feed of animal species likely to be exposed to such feed in amounts of average daily intake of such species, at levels equal to or greater than the acute oral LD_{50} dose measured in mammals or subacute dietary lethal dose for birds.	—May result in residues of a pesticide in the environment of nontarget organisms at levels which are acutely toxic to such organisms.
	—Considers magnitude and scope of exposure.
—Results in maximum calculated concentration following direct application to 6-inch layer of water of more than 1/2 the acute LC_{50} concentration for aquatic organisms.	
Chronic Toxicity	
Hazard to Humans:	
—Induces oncogenic effects in test animals or in humans as a result of oral, dermal, or inhalation exposure; or induces mutagenic effects based on multitest evidence.	—May pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect; based upon demonstrated effects, expected exposure, and appropriate methods of evaluating data.
—Produces any other chronic or delayed toxic effect in test animals.	—Considers magnitude and scope of exposure.

Old Criteria	New Criteria
Hazard to Nontarget Organisms:	
—Can reasonably be anticipated to result in significant population reduction in nontarget organisms or fatality to members of endangered species.	—May result in residues of a pesticide in the environment of nontarget organisms at levels which are chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms. —Considers magnitude and scope of exposure to nontarget organisms. —May pose a risk to the continued existence of any endangered or threatened species. —May result in destruction or other adverse modification of any habitat designated as critical for any endangered or threatened species.
Lack of Emergency Treatment	
—No known antidote or first aid treatment for toxic effects in humans resulting from a single exposure.	—Criterion deleted; concern covered below implicitly in the risk criterion for acute toxicity.
Other Adverse Effects	
—None.	—The use of a pesticide may otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the pesticide offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

Pesticide Contamination of Groundwater Is Beginning to Be Addressed

EPA is taking several actions to determine the extent of the pesticide contamination of groundwater[1] problem and to decide on an appropriate regulatory response. EPA has initiated an agency-wide groundwater protection strategy that will outline a national approach to protecting groundwater resources from pesticides and other potentially hazardous substances. The strategy will also identify the goals and objectives for addressing the issue; how those goals will be implemented under statutory and regulatory authorities; and the roles of EPA offices, other federal agencies, and state and local governments. The strategy is a long-term national plan for dealing with the issue.

EPA has been addressing the question of pesticides in groundwater in the following ways:

Establishment of environmental fate data requirements. In October 1984 EPA published a rule requiring specific kinds of data that an applicant must submit to EPA to support the registration of a pesticide. One set of data required is on environmental fate—data on the fate of a pesticide in the environment, such as whether and how the pesticide moves, degrades, dissipates, or accumulates in the air, water, or soil.

Issuance of groundwater data call-in letters. In the spring of 1984 EPA sent data call-in letters to registrants of existing pesticides calling for environmental fate data on 89 pesticides that might have some leaching potential. EPA expects to begin receiving these data in late 1985.

Reporting requirements. In September 1985 EPA issued a rule consolidating its 1978 interpretation and 1979 statement of enforcement policy on FIFRA Section 6(a)(2). This section requires that pesticide registrants report to EPA information regarding unreasonable adverse effects on health and the environment due to pesticides. Among the kinds of reportable information, EPA is requiring that registrants report information on any amount of a pesticide residue appearing in groundwater. Such information must be reported to EPA within 15 working days after the registrant first possesses or knows of the information. EPA is currently reconsidering the September 1985 rule in response to comments it has received from registrants and others.

Use of models. Results of environmental fate studies can be entered into computer models to predict the movement of pesticides through the soil

[1] Groundwater is water that lies below the surface of the ground and can be drawn into a well. It can be found from just below the surface of the ground to thousands of feet down.

under various environmental conditions. OPP primarily uses the Pesticide Root Zone Model (PRZM) to predict how likely a pesticide is to leach in the upper levels of the soil. The model helps OPP compare the leachability of alternative pesticides; compare geographic regions; and indentify a need for additional data (i.e., monitoring data), label restrictions, etc. The model can assess the groundwater contamination potential of pesticides but cannot predict actual pesticide concentration in groundwater. EPA is funding a multi-year experiment to validate the results of PRZM under actual field conditions and is workng on the development of more sophisticated models for the future.

Development of a monitoring effort. To detect actual levels of pesticides in groundwater, EPA's Office of Pesticide Programs and Office of Drinking Water are designing a national survey of pesticides in drinking water from groundwater sources. The survey, scheduled to begin in fall of 1986, is being designed to allow national inferences to be made from the results and to target future monitoring and regulatory efforts.

EPA has also taken specific actions to suspend, cancel, or impose restrictions on approximately 10 pesticides because of groundwater concerns. For example, if a pesticide is found in groundwater and the risk is thought to present an imminent hazard, the Agency might immediately suspend all uses. This was done in the case of dibromochloropropane (DBCP) in 1979 and ethylene dibromide (EDB) in 1983. The Agency may also decide that the problem could be addressed through the restricted use provisions of FIFRA—either through restricting the use of the pesticide to certified applicators or through geographical limitations. As an example of the first type of restriction, the Agency has decided to restrict use of cyanazine to certified applicators and to put an advisory statement on the label alerting users to the potential for leaching to groundwater. An example of the geographical type of restriction is aldicarb, which may not be used at all on Long Island, N.Y., and is subject to various restrictions in other states because of the groundwater concern.

Addressing groundwater protection is complex because of a wide range of chemical characteristics, varied soil types and depth to groundwater, and a limited toxicological data base. Along with these complexities, EPA must answer the following questions:

- What effect do agricultural practices have on groundwater contamination and what changes should be made?
- What amount of pesticide residue in groundwater presents an unreasonable adverse effect?

- Can pesticide labels adequately deal with complex groundwater issues?
- What, if any, safe level of pesticide residue can be identified and how could that number be used or misused?
- How should state groundwater programs relate to pesticide regulations at the state and national levels?

Glossary

Acceptable Daily Intake	A daily intake level of pesticide residue which, during a person's lifetime, is not expected to cause appreciable health risk on the basis of all facts known at the time. It is based on the lowest No Observable Effect Level from animal studies, divided by a factor intended to provide a margin of safety.
Active Ingredient	An ingredient in a pesticide product that destroys or controls a pest.
Acute Toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism through a single exposure. The effect usually occurs shortly after the exposure.
Carcinogen	A substance or a mixture of substances that produces or incites cancer in a living tissue.
Chronic Feeding Study	A study of test animals involving multiple exposures to substances in their food over their lifetime. 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.
Chronic Toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism upon repeated or continuous exposure over a period of at least half the lifetime of that organism.
Data Call-In	An EPA program to notify pesticide registrants that they must submit certain missing long-term health studies.
Fungicide	A class of pesticide that prevents, destroys, or mitigates fungi (mushrooms, molds, mildews, rusts, etc.).
Herbicide	A class of pesticide that prevents, destroys, or mitigates unwanted plants or weeds.

Inert Ingredient	An ingredient in a pesticide product not intended to destroy or control a pest but rather used to dissolve, dilute, propel, or stabilize the active ingredient in the pesticide product.
Insecticide	A class of pesticide that prevents, destroys, repels, or mitigates insects.
Mutagen	A substance or mixture of substances that induces genetic changes in subsequent generations.
Nontarget Organisms	Those plants and animals (including humans) that are not intended to be controlled, injured, killed, or detrimentally affected in any way by a pesticide.
Oncogen	A substance or a mixture of substances that produces or incites tumor formations in living tissue.
Pesticide	A general term for chemical or biological products used to destroy or control unwanted insects, fungi, mites, rodents, bacteria, or other organisms.
Registration	Licenses for specified uses of pesticide products. A pesticide product registration sets the terms and conditions of the use of that product, including the directions and precautions for use outlined on the product label. All pesticides must be registered by EPA before they can be sold to the public.
Registration Standard	An EPA statement of what it knows, at a particular point of time, about a pesticide chemical and what its interim regulatory position is on the approvable uses.
Reregistration	A reassessment of previously registered pesticides according to current scientific standards.

Rodenticide	A class of pesticide that prevents, destroys, repels, or mitigates rodents and closely related species.
Special Review	A process for reviewing a pesticide's risks and benefits if the pesticide poses a special concern due to a specific perceived health or environmental risk (e.g., suspected of causing cancer, birth defects, or genetic effects). At the conclusion of a special review, EPA may decide to continue, restrict, or cancel pesticide uses under consideration.
Synergism	The simultaneous action of separate substances that, together, have a greater total effect than the sum of their individual effects.
Teratogen	A substance or mixture of substances that produces or induces birth defects.
Theoretical Maximum Residue Contribution	An estimate of the maximum daily dietary exposure to a pesticide's residues.
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.

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