United States General Accounting Office

GAO

Report to the Chairman, Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, House of Representatives

December 1994

PESTICIDES

Reducing Exposure to Residues of Canceled Pesticides

GAO/RCED-95-23

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-258289

December 28, 1994

The Honorable Mike Synar
Chairman, Environment, Energy, and
Natural Resources Subcommittee
Committee on Government Operations
House of Representatives

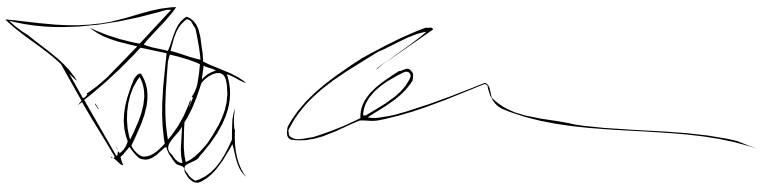
Dear Mr. Chairman:

This report responds to your request that we (1) determine whether marketed foods contain unsafe levels of residues from canceled pesticides and (2) evaluate the Environmental Protection Agency's (EPA) procedures for revoking tolerances for canceled food-use pesticides. The report contains recommendations aimed at ensuring that EPA and the Food and Drug Administration (FDA) develop appropriate standards for regulating the residues of canceled pesticides in fish and that EPA revokes the tolerances for canceled pesticides in a timely manner.

We are sending copies of this report to the Administrator, EPA, and the Commissioner, FDA. We will also make copies available to others upon request.

Please contact me on (202) 512-6111 if you or your staff have any questions about this report. Major contributors to this report are listed in appendix V.

Sincerely yours,



Peter F. Guerrero
Director, Environmental
Protection Issues

Executive Summary

Purpose

Since its creation in 1970, the Environmental Protection Agency (EPA) has canceled the registrations (licenses) for hundreds of pesticides, often because it has found that the pesticides pose unreasonable health risks. Many of these pesticides were once used in food production. A few of them, such as DDT, whose registrations were canceled about 20 years ago, persist in the environment and continue to appear in certain foods. In addition, hundreds of tolerances—or allowable limits on residues of pesticides in food—remain in effect for other pesticides whose registrations have been canceled.

Concerned that canceled pesticides may pose a health risk for U.S. consumers, the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked GAO to (1) determine whether marketed foods contain unsafe levels of residues from canceled pesticides and (2) evaluate EPA's procedures for revoking tolerances for canceled food-use pesticides.

Background

Federal responsibility for protecting U.S. consumers from exposure to unsafe pesticides is shared by EPA, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). EPA registers pesticides for use on specific crops and, because pesticides may remain on crops, sets tolerances to limit human consumption of their residues. EPA sets tolerances at levels that it believes will pose no unreasonable risks to consumers. A single pesticide may be registered for multiple food and nonfood uses; each registered use on a food crop must have a tolerance or an exemption from a tolerance. FDA and USDA use tolerances to monitor residues of pesticides in foods and animal feed sold in interstate commerce. States may monitor residues in foods that are not sold in interstate commerce.

EPA may cancel a pesticide's registrations for some or all uses if it finds that the pesticide does not meet current standards. After a pesticide's registration for a specific use has been canceled, the pesticide may no longer be sold or distributed for that use in the United States. However, as long as the pesticide's associated tolerances stand, foods containing allowable amounts of the pesticide's residues may be sold in the United States. Tolerances are not automatically revoked when registrations are canceled. Instead, EPA takes a separate action to revoke a canceled pesticide's tolerances.

In the course of revoking a pesticide's tolerances, EPA assesses the pesticide's persistence in the environment. If EPA determines that the pesticide persists and is unavoidable in certain foods, EPA recommends action levels to FDA or USDA. Action levels are enforcement standards that are used (1) in place of tolerances that have been revoked or (2) in regulating residues of pesticides that have never been registered for use on certain foods, such as fish, but have inadvertently contaminated these foods.

During the late 1960s and early 1970s, FDA established action levels for the residues of certain chlorinated pesticides in fish. These pesticides, for which tolerances had been set for other foods, were appearing in fish because they were being transported in agricultural runoff to the nation's streams and lakes and fish were accumulating the residues in their tissues. Although EPA canceled the registrations for nearly all uses of these pesticides during the 1970s and revoked most of their tolerances in 1986 (see app. I), the pesticides have persisted in the environment—that is, they have remained in the soil and water—and action levels are still required to regulate their residues in foods, especially in fish.

In 1982, EPA adopted a policy in which it stated that, in recommending action levels, it (1) would assess both the health risks and the extent to which residues were unavoidable in foods and (2) would lower action levels periodically as residues declined in the environment. In this policy, EPA also stated that a pesticide's tolerances should logically be revoked when the pesticide's registrations for food uses have been canceled. FDA and USDA concurred with EPA's policy.

Results in Brief

Because the residues of most pesticides do not persist in the environment, EPA officials believe that most marketed foods do not contain unsafe levels of residues from canceled pesticides. However, the residues of a few long-canceled chlorinated pesticides have persisted and continue to appear, especially in fish. Both EPA and FDA believe that the levels of these residues in fish have generally declined since the action levels for regulating them were established about two decades ago. Nevertheless, a study conducted by EPA shows that, under the action levels for five canceled chlorinated pesticides, consumers of some fish may be exposed, over a lifetime, to health risks that exceed the agency's standard of negligible risk (under which the risk of an additional case of cancer does not exceed 1 in 1 million). On the basis of this study, EPA proposed lower action levels to FDA in 1991 for residues of the five canceled pesticides in

fish. These proposed action levels reflected EPA's weighing of both health risks and the extent to which the residues were unavoidable in fish. FDA agreed that the action levels for the five pesticides should be lowered to reflect declines in residues but believed that EPA had not given sufficient weight to the residues' unavoidability. Although both agencies believe that the existing action levels should be lowered, neither has taken further steps to reach agreement on the appropriate reduction.

EPA does not revoke a pesticide's tolerances at the same time as it cancels the pesticide's registrations for food uses. On average, the agency has taken over 6 years to revoke the tolerances for canceled pesticides. EPA officials acknowledge that the agency's current process for revoking tolerances takes too long and makes inefficient use of scarce resources. The establishment of procedures linking revocation to cancellation would provide for more efficient revocation actions. It would also reduce the potential for consumers to be exposed through imported foods to residues of pesticides that EPA no longer considers acceptable for use on food crops.

Principal Findings

Unsafe Residues May Be Present in Some Fish

According to EPA officials, most marketed foods do not contain unsafe levels of residues from canceled pesticides because most pesticides break down fairly quickly in the environment. Furthermore, EPA officials do not believe that residues of the few canceled chlorinated pesticides that have persisted in the environment are present at significant levels in most foods. In 1985, when EPA published its intention to revoke the tolerances for three of these pesticides—DDT, chlordane, and dieldrin—in foods other than fish, EPA did not receive comments expressing concerns about health risks. Therefore, in 1986, EPA revoked the tolerances and recommended action levels for residues of these three pesticides in foods other than fish.

When EPA proposed action levels for residues of DDT, chlordane, and dieldrin in foods other than fish, it also proposed to retain the action levels that FDA had been using since the late 1960s and early 1970s for residues of these pesticides in fish. In response to these proposed action levels, EPA received some comments expressing concerns about health risks. EPA responded to these comments by conducting a multiyear study of health risks and residue levels in fish for these three pesticides, plus two

others—heptachlor and mirex. This study showed that, under the existing action levels, consumers of some fish could be exposed, over a lifetime, to health risks exceeding the agency's standard of negligible risk. EPA believed that health risks could be higher for consumers who eat either large quantities of fish or more highly contaminated fish. On the basis of this study, EPA sent a draft letter to FDA proposing lower action levels. Unlike the earlier action levels, these took health risks into account as well as actual residue levels, which EPA believed had generally declined since the earlier action levels were established.

Although FDA agreed that the action levels for fish should be lowered to reflect the decline in actual residue levels, it maintained that EPA had not adequately assessed the extent to which residues of the canceled pesticides were unavoidable in fish. According to FDA, EPA had not sufficiently demonstrated the need to lower action levels as much as EPA had proposed. FDA asked EPA for more data to explain to consumers and commercial fisheries the basis for stricter standards and their potential economic impact. However, EPA considered its data adequate and conducted no further studies. EPA has never formally recommended the lower action levels to FDA.

In addition to providing FDA with enforcement standards for regulating fish in interstate commerce, federal action levels provide states with standards for regulating fish caught locally by recreational and subsistence fishermen. According to an EPA study, most states use the federal action levels as their basis for monitoring residues and for advising consumers of any health risks. As long as actual residue levels do not exceed the federal action levels, these states are unlikely to advise consumers of the potential health risks they may incur in eating the fish.

EPA Has Been Slow to Revoke Tolerances for Canceled Pesticides

EPA has not instituted standard procedures for revoking a pesticide's tolerances after it has canceled the pesticide's registrations for food uses, and when it has revoked these tolerances, it has taken, on average, over 6 years to do so. Typically, the agency has allowed about 2 years for remaining stocks of the pesticide to be used and for products legally treated with the pesticide to move through commerce. The balance of the delay has occurred because EPA has assigned low priority to revocation and has not established guidelines linking revocation to cancellation. Establishing such guidelines would be consistent with EPA's 1982 policy on revoking the tolerances for canceled pesticides, would streamline EPA's process for revoking tolerances, and would eliminate the inconsistency

that now allows residues of the same pesticides that EPA has deemed unacceptable for use on crops to appear legally in food.

EPA has recently made progress in revoking tolerances and, as of July 1994, had done so for 50 canceled food-use pesticides. Nevertheless, a potentially large but unknown number of pesticides still have tolerances awaiting revocation. (EPA's data bases do not contain the information needed to determine this number.) As additional cancellations occur, this backlog can be expected to grow. An EPA official estimated that 100 or more canceled food-use pesticides may still have tolerances awaiting revocation. GAO identified 10 high-priority pesticides whose registrations for food uses were canceled from 3 to 13 years ago but whose 185 associated tolerances had not yet been targeted for revocation.

Recommendations

To protect consumers from unreasonable exposure to the residues of canceled pesticides, GAO recommends that the Administrator of EPA and the Commissioner of FDA work together to determine, on the basis of the most recent data, the appropriate action levels for residues of the five canceled chlorinated pesticides in fish. GAO also recommends that the Administrator of EPA periodically reevaluate and lower recommendations for action levels to reflect decreases in environmental residue levels. In addition, GAO recommends that the Administrator establish procedures for concurrently conducting tolerance revocation and cancellation actions and, when necessary, set an effective date for revocation that gives growers enough time to use existing stocks of the canceled pesticide. Finally, GAO recommends that the Administrator identify the pesticides whose registrations for food uses have already been canceled and revoke their tolerances.

Agency Comments

GAO discussed the facts and analysis presented in this report with responsible officials from EPA—including the Deputy Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances—and from FDA—including the Deputy Associate Commissioner for Regulatory Affairs. These officials generally agreed with the information presented but suggested a number of technical and editorial changes that GAO incorporated where appropriate. In particular, EPA officials believed that GAO's presentation of EPA's data on the health risks posed by residues of canceled chlorinated pesticides in fish overstated the health risks. GAO agreed and revised its presentation of EPA's data to point out the uncertainties in the data and to include only the

information that EPA considered to be the most valid. EPA agreed with GAO's revised presentation of the data.

GAO also discussed the potential effectiveness of the actions recommended in this report with EPA and FDA officials. The EPA officials agreed that such actions are necessary to resolve the problems that GAO identified in connection with both action levels and tolerance revocations. The FDA officials agreed with the thrust of GAO's recommendations on action levels. As requested, GAO did not obtain written agency comments on a draft of this report.

Contents

Figure

Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
ppm	parts per million
USDA	U.S. Department of Agriculture

Introduction

Pesticides are used extensively in agricultural production throughout the world to control or kill insects, fungi, or other pests and to increase crop yields. But pesticides can also harm human health and the environment. As the types and number of pesticides have grown over the past 30 years, their effects on health and the environment have come under closer scrutiny. And as scientific evaluation has shown that certain food-use pesticides can cause cancer, birth defects, and other disorders, the use of some of these pesticides has been banned, or canceled, in the United States.

But canceling a pesticide may not eliminate all of its risks, particularly if its residues persist in the environment or appear on imported foods. Hence, federal food safety agencies must decide not only which pesticides to cancel but also how to regulate the residues of canceled pesticides that continue to appear in foods. These decisions made after a pesticide has been canceled can have important health and economic implications.

Federal Agencies Share Responsibility for Ensuring Pesticide Safety

Federal responsibility for protecting public health and the environment from unsafe pesticides is shared by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). Broadly speaking, EPA sets standards for pesticide safety, which FDA and USDA monitor and enforce.

EPA Registers Pesticides and Sets Tolerances for Their Residues

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers (licenses) pesticide products for use on specific crops grown in the United States. EPA may register a pesticide if it determines, among other things, that the pesticide will perform its intended function without causing "unreasonable adverse effects on the environment." FIFRA defines this term to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of the pesticide's use. EPA may register a single pesticide for multiple food and nonfood uses.

Residues of a pesticide used on a food or feed crop can remain on the food or feed and be ingested with it. EPA is required under the Federal Food, Drug, and Cosmetic Act (FFDCA) to establish a tolerance—or an exemption from a tolerance[1]—for any registered use of a pesticide on food or animal feed. A tolerance specifies the maximum amount of the pesticide's residue

[1]EPA may exempt a registered food-use pesticide from the requirement for a tolerance when residues of the pesticide remaining in food appear to pose no hazard to public health.

that may legally remain in or on the food or feed. A single pesticide registered for multiple food or feed uses must have multiple tolerances.

FDA and USDA Monitor Residues and Enforce Tolerances

FDA and USDA monitor pesticides' residues in foods and feed sold in interstate commerce using the tolerances established by EPA. If food or feed products contain residues of pesticides that have not been granted tolerances (or exemptions from tolerances) or if residues exceed tolerances, foods are considered adulterated and are subject to seizure. FDA monitors most foods sold in interstate commerce except meat, poultry, and certain egg products, which are monitored by USDA. States are responsible for monitoring foods that are not sold in interstate commerce.

EPA Cancels Registrations for Unsafe Pesticides

After registering a pesticide, EPA continues to evaluate its safety, principally through two major programs—reregistration and special review. If EPA finds that a pesticide poses unreasonable risks to humans or the environment, the agency may cancel the registrations for some or all of its uses. A manufacturer may also voluntarily cancel a pesticide's registrations.

Under amendments to FIFRA, enacted in 1972 and 1988, EPA is reevaluating and reregistering thousands of previously registered pesticide products on the basis of current scientific standards. In implementing this mandate, EPA is focusing primarily on about 600 active ingredients that are the main components of the individual pesticide products. Although, as we reported in May 1993,[2] EPA will not complete its reregistration program for many years, many manufacturers have already canceled the registrations for thousands of pesticide products containing hundreds of active ingredients rather than pay the fees or develop the data required to support the products' reregistration.

When new evidence indicates that a registered pesticide may pose a significant health or environmental risk, EPA conducts an extensive analysis, known as a special review, to determine whether the risks to human health or the environment exceed the benefits of continued use. Through this process, EPA has determined that a number of active ingredients—and the products containing these active ingredients—pose unreasonable risks to human health or the environment and has therefore canceled some or all registrations for the use of these pesticides. In many

[2]Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

cases, a manufacturer facing special review has voluntarily canceled a pesticide's registrations.

EPA Takes a Separate Action to Revoke Tolerances

In general, after a pesticide's registration for a specific use has been canceled, the pesticide may no longer be sold or distributed for that use in the United States. However, as long as the pesticide's tolerances remain in effect, foods containing residues of the pesticide may be sold in the United States. FDA and USDA may not classify such foods as adulterated and may not seize and remove them from commerce.

Neither FIFRA nor FFDCA requires EPA to revoke a pesticide's tolerances after it has canceled the pesticide's registrations. However, in 1982, after consulting with FDA and USDA, EPA adopted a policy on revoking the tolerances for canceled pesticides in which it stated that "when a pesticide's registration for a food or feed use is canceled because of a concern about the safety of the pesticide, the associated tolerance . . . is no longer justified and logically should be revoked." EPA added that "the agencies are concerned that having formal tolerances remaining in effect for canceled pesticides may serve to condone use of these pesticides in this country and/or in or on commodities imported from foreign countries."

EPA May Recommend Action Levels for Monitoring Unavoidable Residues

Although most pesticides break down fairly quickly in the environment, some pesticides degrade very slowly and persist in the environment long after their use has ended. Hence, residues of these pesticides may be unavoidable in certain foods. To provide standards for regulating these unavoidable residues in foods, EPA recommends action levels, which FDA and USDA have agreed to establish for use in monitoring and enforcement, in accordance with EPA's 1982 policy. In recommending action levels, EPA's policy requires the agency to assess health risks as well as the extent to which residues are unavoidable in foods and to periodically lower action levels as residues of canceled pesticides decline in the environment.

Like a tolerance, an action level specifies the maximum amount of a pesticide's residues that may be allowed in or on a food or feed. However, an action level is established only for residues that are considered unavoidable in a certain food. An action level may be established to take the place of a tolerance that has been revoked. An action level may also be established for a pesticide's unavoidable residues in a food for which a tolerance was never set because the pesticide was never registered for use

on that food. FDA issued a notice in the Federal Register (55 Fed. Reg. 14359, Apr. 17, 1990) explaining how the agency would use action levels. FDA stated that, according to FFDCA, "in the absence of a tolerance, any amount of a pesticide residue in a food or feed is unsafe and therefore renders the food or feed adulterated." But when a food or feed is unavoidably contaminated with certain persistent pesticides that do not have tolerances, FDA said that it would use action levels to provide guidance for determining when enforcement action was warranted.

Most of the action levels that EPA has proposed or recommended have been for a group of chlorinated compounds—including DDT, chlordane, and dieldrin—that were widely used in U.S. agriculture during the 1950s and 1960s. Because these compounds were later found to pose unacceptable chronic health risks to humans and to affect reproduction and cause birth defects in wildlife, most of their registrations were canceled during the 1970s. However, unlike most pesticides, these compounds have not readily broken down. Today, they are still found in soil, sediment, and water.

Chlorinated compounds are not highly concentrated in plants, but they are accumulated in other organisms, particularly in fish, which are at or near the top of the aquatic food chain. Unlike the herbivorous land animals eaten by humans, fish are often predators. When they prey on other aquatic animals, they may ingest and accumulate compounds that their prey have already accumulated. According to EPA, aquatic organisms may accumulate environmental contaminants in concentrations up to 1 million times greater than are found in the surface water from which the organisms are taken. Although these chlorinated pesticides were never registered for use on fish, they have been found in fish for decades, largely because agricultural runoff transported the pesticides to the nation's rivers and lakes. Since these pesticides did not have tolerances for fish, FDA established action levels as guidelines for determining when enforcement action was warranted.

According to EPA, most foods and feeds either contain no detectable residues of these canceled pesticides or contain residues that are well below the recommended action levels. Therefore, EPA believes that the dietary risk from these canceled pesticides in most foods is low. But because of the relatively high potential for these persistent pesticides to be concentrated in fish, health risks from dietary exposure to these canceled pesticides are greater in fish than in other foods.

EPA Has Established a Process for Revoking Tolerances and Recommending Action Levels

When EPA decides to revoke a pesticide's tolerances, it first verifies that all of the registrations associated with these tolerances have been canceled. It then reviews monitoring data to determine whether and to what extent residues of the canceled pesticide remain in foods and whether action levels are needed to replace the existing tolerances. EPA also analyzes the economic impact of revoking tolerances on domestic food producers and on imported commodities. Then, EPA prepares and issues a preliminary notice in the Federal Register stating its intent to revoke certain tolerances and requesting comments from interested parties. If action levels are needed, EPA specifies what levels it intends to recommend to FDA or USDA. After the 60-day comment period has expired, EPA issues a final notice in the Federal Register announcing the effective date of the tolerances' revocation and, if necessary, the final recommended action levels.

Objectives, Scope, and Methodology

Concerned that residues of canceled pesticides in food continue to pose a health risk to U.S. consumers, the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked GAO to (1) determine whether marketed foods contain unsafe levels of residues from canceled pesticides and (2) evaluate EPA's procedures for revoking tolerances for canceled food-use pesticides.

To determine whether marketed foods contain unsafe levels of residues from canceled pesticides, we focused on health risks from fish contaminated with residues of five canceled pesticides—DDT, chlordane, dieldrin, heptachlor, and mirex. We focused on these five canceled pesticides because—unlike most other pesticides—they are highly persistent in the environment and because EPA, the National Academy of Sciences, and other organizations agree that they pose significant health risks through dietary exposure. We focused on fish because fish are more likely than most other foods to accumulate residues of these canceled pesticides. In addition, data on the health risks of residues from other canceled pesticides on food commodities are sparse. But data on the health risks of residues from these five canceled pesticides in fish were readily available because EPA had assessed these risks in response to concerns expressed by Members of Congress, EPA regional officials, and environmental organizations.

To evaluate EPA's basis for proposing action levels for the residues of five canceled pesticides in fish, we reviewed EPA documents and Federal Register announcements on establishing action levels. We also reviewed EPA's study of residue levels and health risks for these pesticides, as well

as EPA's analyses of the economic impact of lowering the action levels for residues of the five canceled pesticides in fish.

To determine the trends in residue levels for these canceled pesticides, we reviewed FDA's pesticide monitoring data for fish and fishery products and FDA's total diet studies for all food commodities, from 1984 through 1992, for detections of DDT, chlordane, and dieldrin. We compared the current action levels with the actual residue levels detected in fish tested by FDA. Specifically, we compared the current action level for dieldrin residues in whitefish with the average dieldrin residues that FDA detected in testing domestic whitefish from 1984 through 1992.

To demonstrate the effect of federal action levels on consumers of fish that are not tested by FDA because they do not enter interstate commerce, we interviewed EPA Office of Water officials and reviewed EPA studies on (1) the basis that states use to establish fish advisories, (2) the levels of contamination from pesticides and other chemicals that are found in fish nationwide, and (3) the guidance that the Office of Water provides to states on establishing fish advisories. We also examined a 1991 National Academy of Sciences study of seafood safety, which discusses the extent to which fish are contaminated by pesticides and other chemicals and the actions that are needed to better inform consumers of the potential risks of eating certain fish. In addition, we contacted several state health and environmental officials to find out how federal action levels affect their regulation of pesticides in fish and to determine the extent of their efforts to monitor these pesticides.

To evaluate EPA's process for revoking the tolerances for canceled pesticides, we interviewed key EPA officials who either were or had been involved in the revocation process, and we collected documents explaining EPA's revocation policy and procedures and showing the status of EPA's revocation efforts. We also examined the Federal Register notices for all pesticides whose tolerances had been revoked as of July 1994 to determine how many tolerances had been revoked and how much time had elapsed between cancellation and revocation. In addition, we reviewed EPA documents and information systems to determine how many canceled pesticides still have tolerances. When we reviewed data from EPA's information systems on canceled food-use pesticides, we found that much of the information was unreliable and, therefore, could not be used. To identify canceled food-use pesticides that still have tolerances, we examined EPA planning documents and reregistration status reports and asked EPA officials to verify the information. In addition, we examined FDA

fiscal year 1992 monitoring data to determine whether some canceled pesticides that still had tolerances were appearing in the U.S. food supply.

We conducted our review between April 1993 and September 1994 in accordance with generally accepted government auditing standards.

We discussed the facts and analysis presented in this report with responsible officials from EPA—including the Deputy Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances; the Deputy Director, Office of Pesticide Programs; and the Director, Policy and Special Projects Staff, Office of Pesticide Programs—and from FDA—including the Deputy Associate Commissioner for Regulatory Affairs; the Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition; and the Director, Contaminants Policy Staff, Office of Regulatory Affairs. These officials generally agreed with the information presented but suggested a number of technical and editorial changes that we incorporated where appropriate. As requested, we did not obtain written agency comments on a draft of this report.

Unsafe Residues May Be Present in Some Fish

According to EPA, most pesticides break down fairly quickly in the environment and therefore do not appear at significant levels in most foods. But a few pesticides whose registrations were canceled about 20 years ago have persisted in the environment. EPA believes that residues of these pesticides are present at low levels in most foods. However, they are found in some fish at levels that exceed EPA's usual negligible risk standard. The action levels currently used to regulate residues of these canceled pesticides in fish do not meet criteria in EPA's 1982 policy because they (1) are not based on an assessment of health risks and (2) have never been adjusted to reflect declines in residue levels that have occurred since FDA first set the action levels in the late 1960s and early 1970s.

In 1991, after conducting a study that evaluated health and economic effects and more recent residue data, EPA proposed lower action levels to FDA. While FDA agreed that action levels should be lowered to reflect declines in residues of these pesticides in fish, it believed that EPA's proposed levels would represent too great a reduction. Despite their shared belief that action levels should be lowered, neither agency has since taken any action to reach agreement on appropriate lower action levels.

EPA's Policy Requires Assessment of Health Risks and Declines in Residues

In its 1982 policy on revoking the tolerances for canceled pesticides, EPA established principles for recommending action levels to FDA and USDA that emphasized the importance of assessing health risks and actual residue levels in food. Under the policy, action levels would "be set limiting the quantity of a pesticide in or on food commodities to the extent necessary to protect the public health." Although action levels would "tak[e] into account the extent to which the contaminant is unavoidable," they would be "sufficient to protect the public health." In some instances, according to the policy, the health risk for a given pesticide could be so great that no residue level would be acceptable. In these instances, the policy calls for EPA to recommend action levels that do not exceed levels that FDA can detect using its current testing methods. Finally, the policy stated that EPA would periodically review action levels and lower them as residues of canceled pesticides in food declined.

Current Action Levels Are Not Based on EPA's Policy Criteria

In 1985, EPA placed preliminary notices in the Federal Register announcing its intention to revoke the tolerances for DDT, chlordane, and dieldrin, whose registrations for food uses it had canceled during the 1970s. Because these pesticides' residues persisted in the environment, EPA, in

accordance with its 1982 policy statement, also proposed action levels to replace the revoked tolerances. For fish, EPA proposed to retain the action levels that FDA had been using since the late 1960s and early 1970s.

EPA Based 1985 Action Level Proposals on Old Residue Data

In developing the action levels that it proposed for DDT, chlordane, and dieldrin in 1985, EPA primarily reviewed residue data from the 1970s, which indicated that residue levels in fish had not declined much since the action levels were originally established. In addition, EPA did not assess the health risks posed by these residues, as directed in its 1982 policy. In response to concerns about DDT expressed in a 1986 congressional hearing, EPA said that it had not assessed health risks when it proposed action levels to replace the tolerances or existing action levels for this pesticide. Instead, EPA reviewed FDA's pesticide monitoring data and proposed action levels that reflected the actual levels of DDT residue found in foods monitored during the late 1970s.

EPA officials told us that the proposed action levels for DDT and other chlorinated pesticides were set at a level high enough so that most—about 95 percent—of the residues found in foods would be at or below the action levels. EPA reasoned that the residues of these canceled pesticides were unavoidable and had not entered the food supply through the misuse of pesticides. Therefore, the agency did not want to penalize food producers for past legal uses of the pesticides.

In response to its preliminary notices, EPA received no significant comments on the adequacy of the action levels it had proposed for foods other than fish. But a number of commenters—including two EPA regions—questioned the safety of the action levels proposed for fish. EPA's Region VII noted that EPA apparently had not reviewed available health effects data, as required by its 1982 policy, to assess the safety of the proposed action levels. Similarly, EPA's Region V commented that EPA had not assessed the effects of the proposed action levels on human health. According to several commenters, the risk of cancer under the proposed action levels was far greater than the agency's risk standards usually allowed. For example, although EPA typically applies a negligible risk standard for cancer when regulating pesticides in food,[3] EPA's Region VII stated that the risk of cancer under the proposed action level for chlordane was 1 in 22,000, and the National Wildlife Federation estimated that the risk of cancer for dieldrin was 1 in 1,000.

[3]In practice, EPA has generally defined negligible risk from dietary exposure to pesticides as an incremental increase of 1 in 1 million or lower in the lifetime risk of cancer as calculated according to a conservative risk-assessment methodology.

In commenting on the proposed action levels for fish, FDA maintained that the existing action levels might need to remain in effect because high levels of DDT residue were still being found in fish from at least one part of the United States. But FDA also said that EPA needed to study the health effects of these pesticides in light of the comments it received on its proposed action levels.

In 1986, EPA issued final notices in the Federal Register in which it revoked the tolerances for DDT, chlordane, and dieldrin in foods other than fish and recommended action levels to replace the tolerances. But in response to concerns over the level of risk that would still be allowed under the proposed action levels for residues of these three canceled pesticides in fish, EPA announced that it would wait to recommend action levels for fish until it could obtain updated residue data and assess the health effects of alternative action levels. Later, EPA added two other canceled pesticides—heptachlor and mirex—to its study of action levels for fish (see app. I).

EPA Conducted a Study to Assess Recent Residue Data, Health Risks, and Economic Effects

To determine whether action levels should be revised, EPA conducted a study in which it reviewed recent residue data and evaluated health risks, as prescribed in its 1982 policy. In addition, EPA evaluated the economic effects of lower action levels.

To conduct its study, EPA obtained recent exposure information by collecting national and regional data on residues of DDT, chlordane, dieldrin, heptachlor, and mirex in fish and compiled a data base from tests of about 11,000 samples conducted between 1983 and 1987 by FDA, EPA regions, state agencies and other federal agencies. Using these data, EPA estimated the risk of cancer to consumers of fish at various action levels.

To assess the economic effects of alternative action levels for fish, EPA projected the percentage of the fish catch that would exceed lower action levels and estimated the costs to commercial fisheries of not being able to sell these fish.

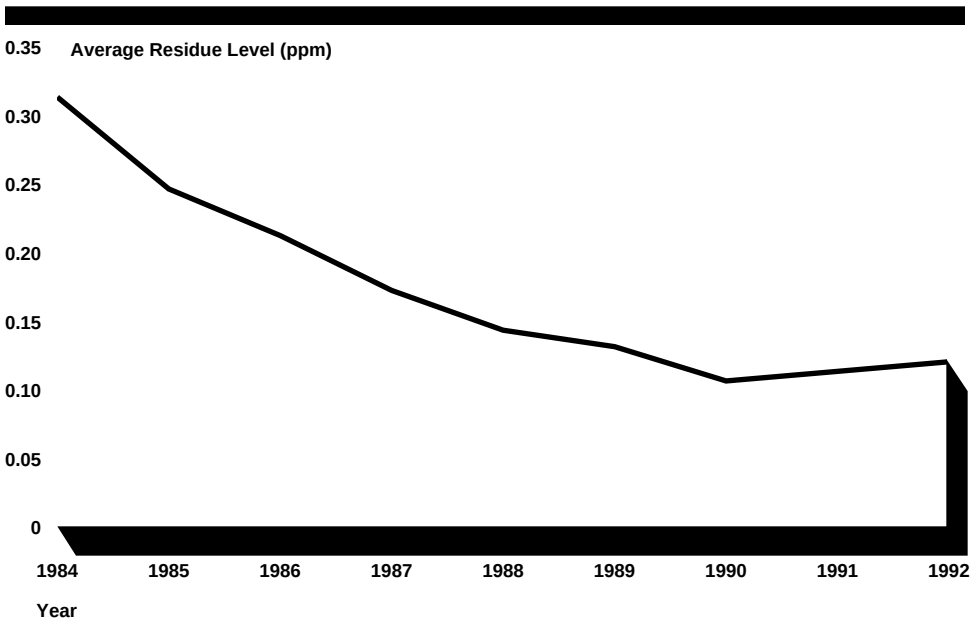
EPA's Study Showed Lower Residue Levels

EPA's analysis of the monitoring data showed that, for the five canceled pesticides, residue levels in fish generally appeared to be declining. However, in certain locations, residue levels appeared to remain constant or to increase over time. EPA attributed the apparent increases in residue levels in fish to the occasional stirring up of sediment and releasing of residues from the sediment into the water or to methodological issues,

such as variation in the size of the fish sampled and nonrepresentative sampling. But EPA said that action levels could be lowered to reflect the generally declining levels of these pesticides' residues in fish.

We examined FDA's records of dieldrin detections in whitefish from 1984 through 1992 to determine the trends in residue levels. As shown in figure 2.1, FDA's records indicate that residue levels declined from an average of 0.313 parts per million (ppm) in 1984 to 0.120 ppm in 1992. Since 1984, average dieldrin residue levels have been consistently below the current action level of 0.3 ppm. However, FDA's records also show that between 1990 and 1992 residues of dieldrin in fish have remained steady or have increased slightly. According to EPA officials, this slower rate of decline indicates that despite the general decline in residues of canceled chlorinated pesticides in fish, these residues may continue to appear at significant levels in some fish for a number of years to come.

Figure 2.1: Average Dieldrin Residue Levels in Domestic Whitefish, 1984-92



Source: GAO's presentation of FDA's data.

EPA's Study Indicated Health Risks Exceeding the Agency's Usual Standard

EPA's Office of Pesticide Programs calculated the risks of cancer at current action levels to consumers of average amounts of fish that are sold in interstate commerce and that contain average levels of the five canceled

pesticides' residues. These calculations, presented in table 2.1, were based on national and regional data collected by EPA from federal agencies, states, and EPA regions. EPA's analysis of the data showed that, at current action levels for the five pesticides, the dietary risks of cancer exceed the agency's usual standard of negligible risk (1 in 1 million).

Table 2.1: Estimated Risks of Cancer at Current Action Levels

Pesticide	Risk of cancer at current action level[a]
Dieldrin	100 in 1 million
Heptachlor	39 in 1 million
Chlordane	16 in 1 million
DDT	9 in 1 million
Mirex	2 in 1 million

Note: To calculate these risks, EPA used the average level of residue in fish containing these pesticides at or below the current action levels. Three species of fish—tuna, cod, and salmon—account for most of the calculated risk either because consumption of these fish is high or because the level of residue in these fish is high. The data analyzed were not representative of national fish consumption and were derived, to a great extent, from fish that were likely to be more contaminated. For samples containing no detectable residues, it was assumed that residues were present at the limit that can be detected using current testing methods.

[a]Number of additional cases of cancer expected per 1 million persons assuming consumption of 15 grams per day for 70 years and an average body weight of 70 kilograms.

Source: GAO's presentation of EPA's data.

According to EPA, the figures shown in table 2.1 could either overestimate or underestimate risks, depending on the extent to which actual exposure differs from the assumptions used in the calculations (see note following table 2.1). For consumers of average amounts of fish sold in interstate commerce, the figures may significantly overstate risks. For example, for dieldrin, EPA said that if it had used less conservative assumptions for samples in which no residues were detected, the risks calculated for this pesticide would have been only 2 in 1 million rather than 100 in 1 million. According to EPA, more accurate estimates of risk were not possible using available data.

But EPA also noted that the actual risks could be considerably higher than the average risks shown in the table for consumers of larger amounts of fish or of fish that are more highly contaminated with residues of these pesticides. For example, although the calculations of risk in table 2.1 assume consumption of 15 grams of fish per day, EPA has estimated that

typical recreational fishermen consume 30 grams per day and subsistence fishermen consume 140 grams per day, on average. These levels of consumption are about two to nine times greater than the levels EPA used to calculate the risks shown in table 2.1. Because risks are proportional to consumption, consumers of larger amounts of fish could be exposed to proportionately higher risks than are shown in the table.

EPA Estimated the Economic Effects of Lower Action Levels

EPA computed the economic costs to commercial fisheries of implementing lower action levels, taking into account the estimated loss of nationally and regionally important fish species. The agency calculated a potential annual economic loss to commercial fisheries of either $74.3 million or $272.7 million, depending upon the action levels considered and assuming that FDA would identify and remove from commerce all fish that exceeded the action levels. For fish species considered to have national or local economic importance, EPA also estimated the percentage of fish that would exceed the current action levels and the lower action levels. These estimates indicated that a significantly greater percentage of fish would exceed the proposed lower action levels than would exceed the current action levels. For example, although none of the herring catch would exceed the current action level for dieldrin, 17 percent of the catch would exceed the lower action level for dieldrin that EPA proposed in 1991. Similarly, while 17 percent of the sablefish catch would exceed the current action level for DDT, 25 percent would exceed the proposed lower action level.

EPA's Study Indicated Lower Action Levels

In 1991, after reviewing its data on residues of the five pesticides in about 11,000 fish samples, assessing the health risks of each pesticide, and calculating the economic costs to commercial fisheries of implementing alternative action levels, EPA sent FDA a draft proposal to lower the action levels for residues of DDT, chlordane, dieldrin, heptachlor, and mirex in fish. These lower action levels are presented in table 2.2 along with the current action levels used by FDA. EPA officials told us that these action levels represent the agency's balancing of health and economic effects, taking into account the unavoidability of these residues in fish.

Table 2.2: Comparison of Current and Proposed Action Levels

Action levels in parts per million (ppm)

Pesticide	Action level	
	Currently used by FDA	Proposed to FDA in 1991
DDT	5.0	0.50
Dieldrin	0.3	0.10
Chlordane	0.3	0.10
Mirex	0.1	0.05
Heptachlor	0.3	0.02

Source: GAO's presentation of EPA's data.

EPA and FDA Have Not Agreed on Lower Action Levels for Fish

One year after EPA sent the draft proposal, EPA and FDA officials met to discuss these action levels. According to EPA's Deputy Assistant Administrator for Prevention, Pesticides, and Toxic Substances, staff from both agencies believed that residues of the five pesticides had been declining in the environment and that lower action levels would therefore be appropriate. FDA agreed to review its pesticide monitoring data to see how much residues had declined and whether its data could support the lower action levels proposed by EPA.

In September 1992, FDA concluded, after reviewing its monitoring data for 1989 to 1991, that EPA's lower action levels would greatly decrease the allowable catch from the Great Lakes and a number of southern and western states. FDA said that EPA would therefore have to demonstrate and document the need for the lower action levels to protect consumers and show that the lower levels took into account the unavoidability of residues in fish.

In May 1994, the Director of FDA's Contaminants Policy Staff told us that EPA did not justify its proposed action levels to FDA. He said that FDA believes that residues of canceled chlorinated pesticides in fish have generally declined since the action levels were originally established and that the action levels should be lowered to reflect this decline. But, according to the official, EPA's proposed lower action levels were significantly lower than they would be if they were based only on declines in residues in fish. Therefore, FDA needed adequate justification to explain to consumers and commercial fisheries the basis for the stricter standards and their potential economic impact.

In May 1994, the Director of EPA's Pesticide Registration Division told us that because of budgetary constraints, EPA has no foreseeable plans to obtain additional documentation to satisfy FDA's concerns. He said that EPA considers its data sufficient to justify the lower action levels. However, EPA has not formally recommended the lower action levels to FDA. Hence, despite their agreement that the action levels should be lowered, neither agency has taken the initiative to reach agreement on appropriate lower action levels.

Many States Use Federal Action Levels to Regulate Fish

Although federal action levels are based on national rather than regional or local data, many states use the federal action levels as their basis for determining when to issue fish consumption advisories.[4] In 1990, EPA's Office of Water reported that two-thirds of the states (34) were using federal action levels as their basis for evaluating the safety of chemical contaminants in fish. Other states were using a risk-assessment approach derived from EPA's criteria or had developed their own approach.

According to a 1991 National Academy of Sciences report on seafood safety, fish caught for recreation or subsistence may pose greater health risks than fish sold in interstate commerce because such fish are more likely to be caught near areas contaminated with hazardous chemicals (including pesticides)[5] and may be consumed in greater quantities by certain subpopulations. The Academy reported that recreationally harvested fish may represent over one-fifth of the fish consumed in the United States and that these fish are caught by an estimated 17 million recreational fishermen.

The Academy noted that state regulatory agencies are almost exclusively responsible for issuing seafood health advisories. But it said that states depend heavily on federal guidance in regulating seafood, and this guidance may not take into account specific regional variations in seafood safety. The Academy suggested that "a more consistent and focused effort in the determination and communication of public health risks from contaminated seafood should be developed" and that "a more pronounced and consistently defined federal role in the risk characterizations leading to these [seafood health] advisories would be [beneficial]."

[4]Fish consumption advisories are issued by many states to provide information to the public about contaminated fish from particular bodies of water that may have unacceptable effects on health if consumed above certain levels.

[5]According to EPA, most recreational fishing is done in freshwater where contamination of fish with pesticides is generally greater than in saltwater.

In 1992, EPA's Office of Water completed a study of chemical residues in fish that revealed widespread contamination by pesticides and other chemicals in fish. Concerned about this contamination and about states' inconsistent procedures for sampling fish and issuing fish consumption advisories, the Office of Water issued guidance to the states in 1993 and 1994 to assist them in developing a risk-based approach for monitoring fish and determining when fish advisories should be issued (see app. II for more detailed information on the study and guidance). Office of Water representatives told us that it was too soon to evaluate the impact of this guidance. They did not know of any states that had used the guidance to strengthen their monitoring standards for pesticides' residues in fish.

An Office of Water official also said that a number of states are not active in monitoring fish and issuing fish advisories, principally because they lack funding. He said that other states, such as New York, recognize that the federal action levels are designed for FDA's regulation of fish in interstate commerce but nevertheless continue to use the federal action levels in their own regulatory programs.

A New York State environmental health official told us that although her agency believes that a risk-based monitoring approach would protect consumers' health better than action levels, the agency is reluctant to move toward risk-based monitoring. The official explained that New York has a number of commercial fisheries whose catches are subject to FDA's monitoring. Because pesticides and other chemicals in these fish do not generally exceed the federal action levels, the fish are sold legally in interstate commerce. The official said that, in view of FDA's monitoring, the state believes that it would face an untenable position if it were to adopt more stringent risk-based monitoring standards for fish caught and consumed within the state. At the same time as the state was trying to justify stricter standards for fish that would be caught and consumed within New York, the official said, FDA would be allowing the same species of fish, with the same levels of chemical contamination, to be sold nationwide without any warnings or advisories.

EPA's Region V also noted that a number of states are reluctant to apply different state and federal standards in monitoring the safety of pesticides' residues in fish. The region is concerned that if the action levels for pesticides' residues in fish are not lowered, then the states will not issue more protective fish consumption advisories.

The Director of FDA's Contaminants Policy Staff agreed that states might have difficulty explaining differences between federal and state monitoring levels to local consumers and commercial fisheries. Nevertheless, he said that FDA could not set enforcement limits for local conditions because the action levels enforced by FDA apply nationwide to fish in interstate commerce. The Director noted that a state or locality might issue guidance on the amount of contaminated fish that consumers might eat without appreciable risk to their health.

Conclusions

Although EPA believes that residues of the five persistent pesticides that it studied do not appear in most foods at significant levels, it has found that they appear in some fish at relatively high levels. The current action levels for these pesticides in fish, which FDA established about two decades ago, are based on residue levels found in the environment at that time. They have not been adjusted to reflect health risk assessments or subsequent declines in residue levels. Consequently, they are not consistent with the 1982 policy that calls upon EPA, when recommending action levels, to assess health risks as well as unavoidable residues and to revise its recommendations periodically as residue levels decline.

The action levels that EPA proposed to FDA in 1991 are based on EPA's assessment of residue data, health risks, and economic effects. Hence, these action levels were developed in accordance with the requirements of the 1982 policy. Both EPA and FDA agree that the action levels should be lowered but disagree on the extent to which they should be lowered on the basis of available data. We do not believe that the differences between EPA and FDA over the sufficiency of EPA's data should block attempts by the agencies to reach agreement on appropriate action levels. Reaching agreement on appropriate action levels would help to ensure that consumers of both federally monitored and state-monitored fish are being adequately protected.

Recommendations

To protect consumers from unreasonable exposure to the residues of canceled pesticides, we recommend that the Administrator of EPA and the Commissioner of FDA work together to determine, on the basis of the most recent data, the appropriate action levels for residues of the five canceled chlorinated pesticides in fish. We also recommend that the Administrator of EPA periodically reevaluate and lower action level recommendations to reflect decreases in environmental residue levels.

Agency Comments

EPA and FDA officials generally agreed with the information presented in this chapter but suggested a number of technical and editorial changes that we incorporated where appropriate. In particular, EPA officials believed that our presentation of EPA's data on health risks posed by residues of canceled chlorinated pesticides in fish overstated the health risks. We revised our presentation of EPA's data to highlight the uncertainties in the data and to include only the information that EPA considered to be the most valid.

We also discussed with these officials the potential effectiveness of the actions that we recommend in this report. The EPA officials agreed that actions such as we recommend are necessary to resolve the problems we identified in connection with action levels. The FDA officials agreed with the thrust of our recommendations on action levels.

EPA Is Slow to Revoke Tolerances for Canceled Pesticides

In canceling the registrations for many food-use pesticides during the past two decades, EPA has not concurrently revoked the related tolerances for these pesticides. Although EPA has recently taken action to revoke the tolerances for some older canceled pesticides, an undetermined but potentially large number of canceled pesticides still have tolerances.

On average, EPA has taken over 6 years to revoke a pesticide's tolerances after canceling the pesticide's registrations. Although part of this delay is intended to allow food treated with remaining stocks of a canceled pesticide to clear the channels of trade, a greater part is attributable to the low priority that EPA has assigned to revocation and to the absence of procedures linking revocation to cancellation.

As long as the tolerances for canceled pesticides remain in effect, foods containing allowable amounts of these pesticides' residues can legally enter the U.S. food supply. FDA and USDA cannot consider such foods adulterated and cannot take enforcement action against them.

Many Tolerances Have Been Revoked, but Many More Remain

Over the past few years, EPA has stepped up efforts to revoke the tolerances for pesticides whose registrations for food uses were, for the most part, canceled during the 1980s. As of July 1994, EPA had revoked the tolerances for 50 canceled pesticides[6] and had formally proposed to revoke the tolerances for 31 canceled pesticides (see apps. III and IV). According to EPA officials, these revocations have dealt with the major pesticides that pose a dietary risk to the public, such as DDT, chlordane, and toxaphene. Most of these revocation actions occurred during the past 2 years.

EPA has not been able to determine how many more canceled pesticides have tolerances that should be revoked because its data bases do not identify all pesticides whose registrations for some or all food uses have been canceled. But an EPA official responsible for revocations estimated that over 100 pesticides may fall into this category and that hundreds of associated tolerances remain in effect for these canceled pesticides. This official believes that the food-use registrations for most of these pesticides have been canceled for over 2 years.

[6]In addition to these revocations, EPA had, as of July 1994, revoked the tolerances for 27 other pesticides for reasons other than the cancellation of their food-use registrations or for reasons that could not be determined because of the pesticides' uncertain regulatory history. EPA had also revoked the tolerance exemptions for seven inert ingredients used in pesticide products.

In the past, EPA tried to define the universe of canceled pesticides that still had tolerances to be revoked. For example, in early 1992, EPA identified 98 pesticides whose tolerances it considered "probable" candidates for revocation. Over 2 years later, EPA has not begun to revoke the tolerances for nearly half of these pesticides, and the agency is again attempting to identify the canceled pesticides that still have tolerances to be revoked.

Though difficult to determine because of deficiencies in EPA's data bases, the number of canceled pesticides that still have tolerances may be sizable. From EPA's List A—the group of pesticides assigned the highest priority for reregistration—we identified 10 pesticides whose registrations for food uses were all canceled between 3 and 13 years ago. There are 185 tolerances that remain in effect for these canceled pesticides. For one of the pesticides, cyhexatin, all of the registrations were canceled voluntarily by its manufacturers in 1987 after EPA considered initiating a special review in response to concerns over the pesticide's potential to cause birth defects. However, as of July 1994, EPA had not begun to revoke cyhexatin's tolerances.

As of April 1994, EPA had evaluated approximately 100 out of about 600 active ingredients that are undergoing reregistration. As it continues its evaluations through reregistration and special review, the registrations for other pesticides are likely to be canceled and their tolerances will then need to be revoked.

EPA Assigns Revocation a Low Priority and Has No Procedures Linking Revocation to Cancellation

Since 1982, when it issued its policy on revoking tolerances, EPA has taken over 6 years, on average, to revoke a pesticide's tolerances after canceling the pesticide's registrations. Typically, the agency has allowed some time—usually about 2 years—for remaining stocks of a pesticide to be used and for products legally treated with the pesticide to move through commerce. But most of the delay in revocation can be attributed to both the low priority that EPA has assigned to revocation and the absence of procedures linking revocation to cancellation. The regulatory history of the pesticide bufencarb illustrates this pattern: Although EPA had canceled all registrations for food uses of bufencarb by April 1986, it did not propose to revoke the related tolerances until August 1992, and it did not complete their revocation until June 1993, over 7 years later.

EPA Assigns Low Priority to Revocation

EPA assigns low priority to revoking tolerances, in part because revocation is not required by law. When the agency first canceled registrations for

food-use pesticides during the 1970s, it had no mandate or guidance directing it to revoke the related tolerances. Although EPA's 1982 policy established the principle that revocation should coincide with cancellation, it created no time frames for revocation or impetus for linking revocation to cancellation.

EPA officials told us that the agency assigns low priority to revoking tolerances because many of the food-use pesticides have been canceled voluntarily or pose little or no dietary risk. But the fact that a pesticide has been canceled voluntarily does not necessarily mean that it poses no dietary risk. In addition, EPA has delayed revocation for almost all pesticides, including those considered to pose dietary risks. For example, long-term exposure through the diet to the pesticide heptachlor could cause cancer in humans, according to EPA, yet the agency revoked the tolerances for this pesticide more than 11 years after canceling its registrations for food uses.

The low priority assigned to revocation is reflected in the limited resources allocated to it. The EPA official responsible for revocation said that none of the 13 staff in her unit works full-time on revocation actions and slightly fewer than 3 full-time-equivalent staff per year are allocated for such actions. According to this official, her unit has so many other higher-priority responsibilities that it can handle only a limited number of revocation actions at one time. While recognizing that the tolerances for many other canceled pesticides still required revocation, she said that she currently did not have the time available to identify these pesticides. Most of the EPA personnel involved in revocation told us that revocation activities have a lower priority than their other responsibilities.

To conserve the limited resources that it has allocated to revocation, EPA usually delays the revocation of a pesticide's tolerances until it has canceled all of the pesticide's registrations for all of its food uses. Thus, it avoids taking multiple revocation actions for a single pesticide. For example, EPA canceled all registrations for insecticidal uses of the pesticide sodium arsenite in 1988 because of concerns about the pesticide's toxic effects on workers and the general public. But the agency did not propose to revoke the tolerances for these uses until the registration for one remaining food-use—as a fungicide on grapes—was canceled in 1992, about 4 years later.

EPA Does Not Have Formal Procedures for Linking Revocation to Cancellation

Despite its policy supporting a link between revocation and cancellation, EPA has not developed written procedures or guidelines specifying when it should revoke a pesticide's tolerances for canceled food uses. As a result, the agency has taken anywhere from a few months to over 14 years to revoke the tolerances for individual pesticides. Without such procedures, EPA is under no pressure to revoke tolerances in a predictable or consistent way.

In addition, EPA has no written procedures or guidelines requiring the officials responsible for handling cancellations to notify the officials responsible for revoking the related tolerances of any cancellations. Consequently, the personnel responsible for revocations often do not receive information about cancellations on a timely and consistent basis and in a standard format that provides all of the information needed to revoke tolerances. Without reliable channels of information and communication between the personnel responsible for cancellations and the personnel responsible for revocations, EPA cannot effectively implement its policy linking revocation to cancellation.

EPA officials acknowledge that the agency's current process for revoking tolerances takes too long and is inefficient. According to the officials, the establishment of a process linking revocation to cancellation would help ensure that the tolerances for canceled pesticides are revoked in a timely manner. Furthermore, the officials said that taking revocation and cancellation action concurrently would generally result in the more efficient use of EPA's resources than the current revocation process. They emphasized that although the revocation action could occur at the same time as the cancellation action, EPA would need, when establishing an effective date of revocation, to give growers enough time to use exisitng stocks of the canceled pesticide.

Enforcement Agencies Cannot Take Action Against Foods Containing Residues of Canceled Pesticides

As long as the tolerances for residues of canceled pesticides remain in effect, FDA and USDA can do nothing to prevent foods containing allowable amounts of these chemicals from entering the U.S. food supply. Although a pesticide's residues usually decline or disappear in domestic foods within a few years after the pesticide's registrations have been canceled—except when the pesticide persists in the environment—the pesticide's residues may continue to appear in imported foods. U.S. and foreign manufacturers may continue to sell the canceled pesticide for use on crops abroad, and the food grown abroad may be sold in the United States as long as the pesticide's residues do not exceed the tolerances.

Determining the extent to which canceled pesticides that still have tolerances appear in foods is difficult, not only because EPA has not identified all of these pesticides but also because FDA monitors residues selectively. Nevertheless, in reviewing FDA's 1992 monitoring data, we found that FDA had detected demeton, a pesticide whose registrations were canceled nearly 5 years ago, seven times on four different food commodities that still had tolerances. Because the tolerances for demeton had not been revoked, FDA did not consider the foods containing the pesticide to be adulterated.

Similarly, assessing the health risks posed by canceled pesticides that still have tolerances is difficult. Information on the health risks of many canceled pesticides is limited because EPA's data bases are incomplete or because the registrant voluntarily canceled the registrations before EPA finished assessing the pesticide's health risks. For example, after the registrations for food-uses of the pesticide tetrachlorvinphos (a possible human carcinogen) were canceled in 1987, EPA stated that it did not have sufficient scientific data to evaluate the safety of the pesticide's tolerances—which were established under less stringent scientific standards in the early 1970s. Despite this uncertainty about the pesticide's dietary risks, EPA did not propose to revoke the pesticide's tolerances until 1994—about 7 years after the associated food-use registrations were canceled.

For some canceled pesticides that still have tolerances, available data indicate a potential to harm humans. For example, the pesticide monocrotophos is a potent cholinesterase inhibitor (linked to nervous system problems) and is toxic to fetuses. Another pesticide, captafol, is classified by EPA as a probable human carcinogen. Both of these pesticides were voluntarily canceled 6 or more years ago, but EPA has not yet revoked their tolerances, although it proposed to do so in June 1993.

Conclusions

Because EPA has not consistently or expeditiously revoked the tolerances for many canceled pesticides, residues of these pesticides have been allowed to appear legally in the food supply, often for many years after the pesticides' domestic uses were prohibited. Although EPA believes that it has revoked the tolerances for most of the older, higher-risk canceled pesticides, it still needs to identify and revoke the tolerances for a substantial number of other canceled pesticides.

By revoking the tolerances for canceled pesticides and, in the future, conducting revocation and cancellation actions concurrently, EPA would be acting consistently with its 1982 policy statement. In addition, it would be streamlining its process for revoking tolerances and eliminating the potential for residues of the same pesticides that it has deemed unacceptable for use on crops to appear legally in food.

Recommendations

To expedite the revocation of tolerances for canceled pesticides and make more efficient use of scarce resources, we recommend that the Administrator, EPA,

- establish procedures for concurrently conducting tolerance revocation and cancellation actions and, when necessary, set an effective date for revocation that gives growers enough time to use existing stocks of the canceled pesticide and
- identify the pesticides whose registrations for food uses have already been canceled and revoke their tolerances.

Agency Comments

EPA officials generally agreed with the information presented in this chapter but suggested a number of technical and editorial changes that we incorporated where appropriate. The officials agreed that actions such as we recommend are necessary to resolve the problems we identified regarding tolerance revocations.

Six Canceled Pesticides With Action Levels for Fish

Pesticide	Regulatory action	Effects
Aldrin/ Dieldrin[a]	Registrations for all food uses of both pesticides canceled by EPA in 1975.	Classified as probable human carcinogens. Neurotoxicity observed in humans with chronic exposure. Adverse effects on the liver and the reproductive system indicated by animal studies.
Chlordane	Registrations canceled by EPA in 1978 for all but a few food uses, which were phased out by 1980.	Classified as a probable human carcinogen. Adverse effects on the immune and nervous systems, particularly during prenatal exposure, indicated by animal studies.
DDT	Registrations for all food uses canceled by EPA in 1972.	Classified as a probable human carcinogen. Adverse effects on the reproductive system, liver, and immune system indicated by animal studies. Chromosomal damage also indicated.
Heptachlor	Registrations for most food uses canceled by EPA in 1978; remaining food uses phased out by 1983.	Classified as a probable human carcinogen. Increased chromosomal aberrations, blood disorders, decreased fertility, and decreased survival of newborns indicated by animal studies. Exposure in humans associated with stillbirths.
Mirex	Registrations for all uses canceled by EPA in 1976.	Classified as a probable human carcinogen. Adverse developmental effects including heart defects, decreased fertility, undescended testes, and decreased brain and liver weights indicated by animal studies.

[a]Because the breakdown product of the pesticide aldrin is dieldrin, residues of the two pesticides cannot be distinguished.

Office of Water's Study of Chemical Residues in Fish

In September 1992, EPA's Office of Water issued a study of chemical residues in fish that revealed extensive contamination by pesticides in fish. Because this study followed up on a national dioxin study, the Office of Water sampled fish from waters near many sites that had been targeted as likely sources of dioxins. Samples were taken from waters near 388 sites, 314 of which were point and nonpoint sources of pollution, such as pulp and paper mills, and Superfund sites. The study found the following:

- DDT residues were found in fish at 99 percent of the sites. For example, catfish from the Alamo River, sampled near Calipatria, California, had DDT levels yielding an estimated cancer risk of 8.9 in 100,000, and lake trout from Lake Michigan, sampled near Waukegan, Illinois, had DDT levels yielding an estimated cancer risk of 6 in 100,000.
- Chlordane residues were found in fish at 64 percent of the sites. For example, lake trout from Lake Michigan, sampled near Waukegan, Illinois, had chlordane levels yielding an estimated cancer risk of 9.3 in 100,000, and catfish from the Delaware River, sampled near Torresdale, Pennsylvania, had chlordane levels yielding an estimated cancer risk of 3.5 in 100,000.
- Dieldrin residues were found in fish at 60 percent of the sites. For example, lake trout from Lake Michigan, sampled near Waukegan, Illinois, had dieldrin levels yielding an estimated cancer risk of 6.0 in 10,000, and carp from the Mississippi River, sampled near Quincy, Illinois, had dieldrin levels yielding an estimated cancer risk of 2.8 in 10,000.
- Mirex residues were found in fish at 38 percent of the sites. For example, chinook salmon from Lake Ontario, sampled near Olcott, New York, had mirex levels yielding an estimated cancer risk of 3.8 in 100,000, and brown trout from Lake Ontario, sampled near Rochester, New York, had mirex levels yielding an estimated cancer risk of 2.2 in 100,000.
- Heptachlor residues were found in fish at 16 percent of the sites. For example, lake trout from Lake Michigan, sampled near Waukegan, Illinois, had heptachlor levels yielding an estimated cancer risk of 3.4 in 100,000, and carp from the Mississippi River, sampled near Quincy, Illinois, had heptachlor levels yielding an estimated cancer risk of 2.2 in 100,000.

In June 1994, the Office of Water issued a guidance document for states entitled Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume II - Risk Assessment and Fish Consumption Limits. This document was designed to assist states in developing risk-based consumption limits for 23 high-priority chemical contaminants in fish. For the five pesticides included in the Office of Pesticide Programs' study, the guidance document indicated that consumers who eat slightly

less than 1/2 pound of fish per month and who desire no more than a negligible risk of cancer (1 in 1 million) should not eat fish when fish contain pesticides at or near the action levels proposed by EPA to FDA in 1991.

The Office of Water's guidance document presented alternative consumption rates and risk levels for states to consider. Table II.2 shows the number of meals per month that the document considers acceptable when (1) fish contain pesticides at (or near) EPA's proposed action levels, (2) the meal size varies from 4 ounces per month to 16 ounces per month, and (3) the risk of cancer varies from 1 in 10,000 to 1 in 1 million. For example, when fish contain chlordane at the proposed action level (0.1 ppm), consumers can eat 14 4-ounce fish meals per month if they are willing to incur a cancer risk of 1 in 10,000, but they cannot eat any fish meals if their standard of safety is negligible risk (1 in 1 million).

Table II.2: Office of Water's Monthly Consumption Limits for Fish Containing Residues at or Near Proposed Action Levels

Pesticide/Action level	Meal size	Number of meals per month that can be eaten without exceeding a cancer risk of:		
	Ounces	1 in 10,000	1 in 100,000	1 in 1 million
Dieldrin				
0.10 ppm	4	1.0	None	None
	8	0.5	None	None
	16	None	None	None
DDT[a]				
0.50 ppm	4	13.0	1.0	None
	8	6.0	0.5	None
	16	3.0	None	None
Chlordane				
0.10 ppm	4	14.0	1.0	None
	8	7.0	0.5	None
	16	3.0	None	None
Heptachlor epoxide[b]				
0.02 ppm				
	4	10.0	1.0	None
	8	5.0	0.5	None
	16	2.0	None	None
Mirex[c]				
0.05	4	Unlimited	2.0	None
	8	13	1.0	None
	16	6.0	0.5	None

[a]The Office of Water did not calculate consumption limits for fish containing DDT residues at the proposed 0.5 action level but instead calculated limits at the 0.4 and 0.6 residue levels. In this table, we used the limits calculated at the 0.4 residue level. Consumption limits at the 0.5 residue level (the proposed EPA action level) would be expected to be equal to or lower than the limits at 0.4.

[b]Heptachlor epoxide is a metabolic breakdown product of heptachlor. Action levels set for heptachlor also apply to heptachlor epoxide.

[c]The Office of Water did not calculate consumption limits for fish containing mirex residues at the proposed 0.05 action level but instead calculated limits at the 0.04 and 0.06 residue levels. In this table, we used the limits calculated at the 0.04 residue level. Consumption limits at the 0.05 residue level (the proposed EPA action level) would be expected to be equal to or lower than the limits at 0.04.

Canceled Pesticides Whose Tolerances EPA Had Revoked as of July 1994

Delay in years

Pesticide	Date of cancellation action[a]	Date of final revocation action	Delay in revocation[b]
Acetic acid	January 1991	September 1993	2.6
Aldicarb	March 1992	June 1993	1.2
Aldrin	May 1975	December 1986	11.6
Arsenic acid	May 1993	January 1994	0.7
BHC	July 1978	July 1986	8.0
Bufencarb	April 1986	June 1993	7.1
Calcium arsenate	June 1988	April 1991	2.8
Captan	February 1989	August 1992	3.5
Carbon disulfide	December 1986	February 1989	2.1
Carbon tetrachloride	November 1986	February 1989	2.2
Carbophenothion	October 1989	July 1994	4.7
Chlordane	March 1978	December 1986	8.8
Chlordimeform	February 1989	October 1991	2.7
Chlordimeform	As of 1978	October 1989	10.8
Chlorobenzilate	February 1979	March 1986	7.1
Chloroform	October 1983	February 1989	5.3
Copper arsenate	April 1977	May 1988	11.1
Crufomate	October 1988	June 1993	4.7
Daminozide	November 1989	March 1990	0.3
Daminozide	August 1984	July 1987	2.9
DBCP	September 1978	January 1986	7.3
DDT	July 1972	December 1986	14.5
Diallate	January 1991	January 1994	3.0
Dichlorvos	October 1989	June 1991	1.7
Dieldrin	May 1975	December 1986	11.6
Dinoseb	October 1986	September 1993	6.9
EDB	October 1983	January 1985	1.3
EDB	October 1983	December 1993	10.2
Endrin	As of December 1970	June 1993	22.5
EPN	July 1987	June 1993	5.9
Ethylene dichloride	December 1986	February 1989	2.1
Fensulfothion	October 1988	November 1993	5.1
Glyphosine	March 1984	May 1988	4.1
Heptachlor	March 1978	August 1989	11.4
Isopropalin	As of August 1981	June 1991	9.9

(continued)

Delay in years

Pesticide	Date of cancellation action[a]	Date of final revocation action	Delay in revocation[b]
Lead arsenate	June 1988	April 1991	2.8
Mirex	December 1976	December 1986	10.0
Nitrapyrin	January 1986	June 1993	7.4
Nitrofen [TOK]	September 1983	September 1985	2.0
Oryzalin	July 1984	June 1991	6.9
Perfluidone	July 1984	June 1993	8.9
Pirimicarb	As of December 1981	May 1988	6.3
Profluralin	April 1984	June 1993	9.1
Ronnel	January 1986	March 1994	8.2
Schradan [OMPA]	May 1976	January 1986	9.6
Silvex	January 1985	June 1993	8.5
Sodium arsenite	June 1988	July 1993	5.1
Sodium diacetate	January 1991	September 1993	2.6
Strobane	June 1976	January 1986	9.6
Tetrasul	January 1984	May 1988	4.3
Thionazin	As of December 1971	May 1988	16.4
Toxaphene	November 1982	September 1993	10.8
Zineb	January 1991	December 1992	1.9
Average delay between cancellation and revocation			**6.6**

[a]Not all of the pesticide's food uses may have been canceled by the action. Some pesticides may have had more than one cancellation action.

[b]This delay represents the time elapsed between cancellation and final revocation. When the day of the month could not be determined for a cancellation or revocation action, the last day of the month was used in calculating the delay. When the month of the year could not be determined for either of the actions, the last month of the year was used in the calculation.

Canceled Pesticides Whose Tolerances EPA Had Proposed to Revoke as of July 1994

For the following pesticides, EPA has issued a notice in the Federal Register proposing the revocation of tolerances associated with their canceled uses and requesting comments on the proposed actions. But the agency has not yet taken final action to revoke these tolerances.

Delay in years

Pesticide	Date of cancellation action[a]	Delay in revocation as of July 1994[b]
1,2,4,5-Tetrachloro-3-nitrobenzene [TCNB]	October 1989	4.8
2-Chloroallyldiethyldithio-carbamate [Sulfallate]	October 1989	4.8
Alachlor	March 1988	6.3
Barban	October 1989	4.8
Bifenox	January 1991	3.5
Captafol	April 1987	7.2
Chlorfenvinphos	January 1991	3.5
Chlorobenzilate	December 1988	5.6
Crotoxyphos	January 1991	3.5
Cyclohexamide	October 1989	4.8
Demeton	October 1989	4.8
O,O-Dimethyl O-p-(Dimethylsulfamoyl)phenyl. [Cythioate]	October 1989	4.8
Dinitramine	January 1991	3.5
Dipropetryn	December 1989	4.6
Flucythrinate	January 1991	3.5
Hexachlorophene	January 1991	3.5
Mancozeb	March 1992	2.4
Maneb	March 1992	2.4
Metiram	March 1992	2.4
Monocrotophos	July 1988	6.0
Norea	October 1989	4.8
Perthane	June 1980	14.1
Phenothiazine	January 1991	3.5
Pirimphos-ethyl	January 1991	3.5
Sodium trichloroacetate	October 1989	4.8
Sulfur dioxide	December 1991	2.5

(continued)

Delay in years

Pesticide	Date of cancellation action[a]	Delay in revocation as of July 1994[b]
Terbutryn	As of October 1989	4.8
Terrazole	Mid-1980s	6.5
Tetrachlorvinphos	August 1987	6.9
Tetradifon	January 1990	4.5
Tributylphosphorotrithioite [Merphos]	January 1991	3.5
Average delay between cancellation and revocation		**4.7**

[a]Not all of the pesticide's food uses may have been canceled.

[b]Because EPA has not yet finally revoked the tolerances for these pesticides, this delay represents the time elapsed between the date of cancellation and the date we obtained these data—July 1994. The delay for these pesticides can be expected to increase until EPA finally revokes their tolerances. When the day of the month could not be determined for a cancellation action, the last day of the month was used in calculating the delay. When the month of the year could not be determined for a cancellation action, the last month of the year was used in the calculation.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.

J. Kevin Donohue, Assistant Director
Robert J. Tice, Evaluator-in-Charge
Mark Trapani, Staff Evaluator
Richard A. Frankel, Senior Scientist/Evaluator
Elizabeth R. Eisenstadt, Communications Analyst

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Mail
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested