United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

April 1991

PESTICIDES

EPA Could Do More to Minimize Groundwater Contamination

GAO/RCED-91-75

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

Resources, Community, and
Economic Development Division

B-243068

April 29, 1991

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request about the Environmental Protection Agency's activities concerning pesticides in groundwater. The report evaluates the adequacy of the agency's efforts to (1) assess pesticides' leaching potential, (2) regulate those pesticides that may leach into groundwater, and (3) consider human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Administrator, Environmental Protection Agency, and to other interested parties and make copies available to others upon request.

This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, (202) 275-6111. Major contributors are listed in appendix V.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

About 40 percent of the United States' population—over 90 percent in rural areas—depends on groundwater for its drinking water. Prior to the discovery of two pesticides in groundwater in 1979, it was generally believed that pesticides did not leach into groundwater as a result of normal agricultural use. By 1985, the Environmental Protection Agency (EPA) had identified 16 pesticides in groundwater, and by 1988, monitoring studies compiled by EPA had detected a total of 46 pesticides present in groundwater from normal agricultural use. Some of these can cause cancer or other health problems.

Cleaning up groundwater is extremely costly, difficult, and sometimes impossible. Therefore, EPA's policies advise acting before contamination reaches a level that could present health risks. Because of concerns about protecting public health and preventing contamination, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to review EPA's efforts to assess pesticides' leaching potential, regulate those pesticides that may leach into groundwater, and consider human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food. GAO's review generally concentrated on the 16 pesticides EPA had identified as groundwater contaminants by 1985.

Background

Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA evaluates the risks and benefits of pesticides before they are registered (licensed) for use and reevaluates (reregisters) older pesticides according to current scientific standards. EPA requires pesticide manufacturers (registrants) to submit studies so the agency can assess potential risks. When risks are found, EPA may take several types of regulatory actions, including (1) placing an informational advisory on the label; (2) restricting use of the pesticide to certified applicators; (3) limiting other conditions of the pesticide's use; and (4) canceling the registration, which removes the pesticide from the marketplace. When new information indicates a pesticide might present serious risks to health or the environment, EPA may conduct a risk-benefit assessment known as a Special Review to determine whether regulatory action is needed. In addition, under the authority of the Federal Food, Drug, and Cosmetic Act, EPA establishes tolerances, or maximum limits, for pesticide residues in or on food commodities.

Results in Brief

Five years after identifying 16 pesticides as groundwater contaminants, EPA has made limited progress toward fully assessing their leaching

potential or acting to protect groundwater. EPA has reviewed only about one-third of the studies it received to assess these pesticides' potential to leach. Some studies have been awaiting review as long as 5 years. Reasons for slow review include a shortage of staff and a policy that did not give priority to such studies. Of the studies EPA has reviewed, about 40 percent are unacceptable and will most likely have to be redone.

EPA could more fully utilize the regulatory measures available to reduce groundwater contamination by the 16 pesticides. EPA has used its strongest measure—cancelation of all uses of a pesticide—for 3 of the 16. For two of the three, the decision was based in part on the fact that groundwater contamination was occurring at levels presenting health risks. The agency has not consistently used less severe regulatory measures, such as placing advisories on labels, and has made little use of measures such as prohibiting use in specific geographic areas.

EPA could do more to account for human exposure resulting from pesticides' presence in groundwater when the agency assesses tolerances for residues in food. Although a person's health risk from a pesticide depends on the total amount ingested from food and water, the agency does not routinely account for exposure from pesticides in groundwater. For only seven pesticides in total has EPA incorporated in its tolerance risk assessments estimates of exposure from groundwater.

Principal Findings

EPA Is Slow in Assessing Pesticides' Leaching Potential

In order to assess the leaching potential of the pesticides EPA had identified by 1985 as groundwater contaminants, the agency imposed, through the reregistration process, a total of 100 data requirements on the registrants of these pesticides. These data are needed to identify factors such as soil types and climatic conditions that would promote leaching of a specific pesticide. This information could allow pesticide users to avoid its application under such conditions.

As of May 1990, registrants had submitted a total of 316 studies in response to EPA's data requirements. (In some cases, multiple studies were submitted for one data requirement.) EPA has reviewed only 110 of the 316 studies submitted, and about 40 percent of those reviewed are unacceptable and will probably have to be redone. When studies are

unacceptable, it is possible that 15 years could pass from the time a pesticide was initially found to contaminate groundwater until its leaching potential is fully assessed and it is reregistered. Reasons studies have been found unacceptable include registrants' not submitting all critical information or not following EPA's guidelines for studies. EPA recently provided registrants with additional guidance to help improve studies.

A shortage of staff and a policy under which studies addressing the potential for groundwater contamination were not a priority have contributed to EPA's lack of progress. EPA recently hired more staff to review studies. It is uncertain whether these resources are sufficient to review the backlog of studies and the influx of data expected over the next few years as the pace of reregistration accelerates.

EPA Could Do More to Regulate Groundwater Contaminants

While EPA has used the regulatory tools available in some cases, the agency could do more to ensure that groundwater contamination does not occur or worsen. Of the 16 pesticides, 3 have been canceled through the Special Review process, and at present, 4 more are undergoing Special Reviews. However, these reviews were initiated because the pesticide presented risks in addition to groundwater contamination; criteria for initiating Special Reviews do not specifically address a pesticide's presence in groundwater. In conducting these reviews, EPA has imposed measures to address groundwater contamination only when pesticide levels in groundwater presented health risks. The agency's approach may be inadequate because toxic effects of a pesticide could be discovered after groundwater has become contaminated, a situation that is extremely difficult to remedy. In initiating and conducting Special Reviews, EPA could consider the difficulty and high cost of cleaning up groundwater and its value as a resource for the future.

For the 13 pesticides that remain in use, EPA could take additional regulatory measures. For three of these pesticides, EPA has not required an informational advisory on labels, but could not state the reason it was not required. The agency has not imposed a restricted-use classification on any pesticide on the basis of its contamination of groundwater, except for one pesticide whose registrant volunteered this action. EPA's past attempts to impose this measure failed because the agency's regulations for imposing it lacked specific criteria addressing groundwater contamination. The agency is now developing such criteria. Four of these pesticides have had their use prohibited in areas where significant groundwater contamination has been found, but registrants volunteered these actions. Although data on these 13 pesticides' leaching potential

are not complete, regulatory measures such as an advisory, the restricted-use classification, and a prohibition on use in problem areas could be imposed on the basis of existing information.

Safety of Tolerances for Groundwater Contaminants Is Uncertain

EPA lacks assurance that it is setting tolerances for pesticide residues in food at safe levels because it does not routinely account for exposure from groundwater. EPA's Office of Pesticide Programs has considered exposure resulting from groundwater contamination in assessing only seven pesticides. In contrast to the Office of Pesticide Programs, EPA's Office of Drinking Water routinely accounts for multiple sources of exposure when it develops limits for contaminants in drinking water.

Recommendations

To help pesticide applicators avoid using groundwater contaminants under the conditions that promote leaching, GAO recommends that EPA expedite reviews of studies concerning pesticides' potential to leach and provide information on those conditions to applicators. Because a long time may pass between the discovery of a pesticide in groundwater and a complete leaching assessment, EPA should take further regulatory measures in the interim to help protect groundwater. This report includes recommendations for placing a groundwater advisory on pesticide labels and prohibiting pesticide use in designated areas, measures that GAO believes could be based on existing information.

In order to ensure preventive action before contamination reaches potentially hazardous levels, GAO recommends that EPA establish a criterion for initiating Special Reviews on the basis of groundwater contamination. Further, in conducting Special Reviews, EPA should consider the risks to water resources and consider even low levels of groundwater contamination to be a risk.

In order to ensure that total dietary exposure does not exceed safe levels, GAO recommends that in setting and reviewing tolerances for pesticides known to contaminate groundwater, EPA estimate and consider potential exposure from contaminated groundwater.

Agency Comments

GAO did not obtain official agency comments on this report, but did discuss its factual content with EPA officials, who generally agreed with the facts as presented. GAO included their comments where appropriate.

Contents

Abbreviations

ALISS	A List Inventory Support System
DBCP	dibromochloropropane
DCPA	dimethyl tetrachloroterephthalate
DRES	Dietary Risk Evaluation System
EDB	ethylene dibromide
EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
MCL	maximum contaminant level
ODW	Office of Drinking Water
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
PATS	Pesticide Action Tracking System
PEMD	Program Evaluation and Methodology Division
RCED	Resources, Community, and Economic Development Division
SMP	state management plan
USDA	U.S. Department of Agriculture

Introduction

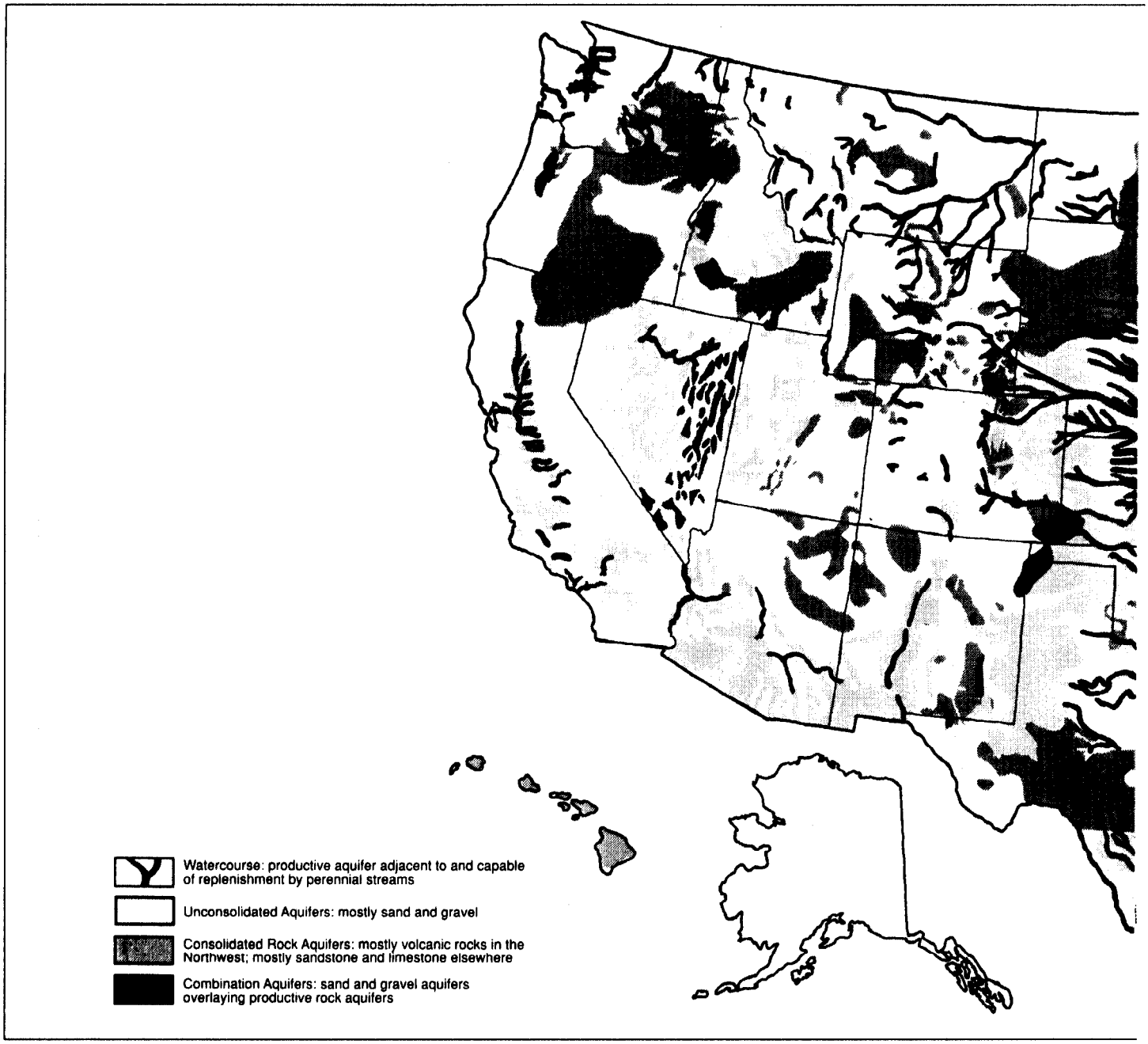
Since the first discovery of a pesticide in groundwater in 1979, 46 pesticides have been found to contaminate groundwater as a result of normal agricultural use, according to studies compiled by EPA. Some of these pesticides are known to cause cancer or other adverse health effects. As nearly half of the people in the United States depend on groundwater for their drinking water, groundwater contamination raises concerns about the potential effects on the health of many Americans. Because groundwater often discharges into surface water, groundwater contamination can also adversely affect wildlife, sensitive ecosystems, and people whose drinking water comes from surface water.

The Environmental Protection Agency's (EPA) policies advocate preventing groundwater contamination because cleaning up groundwater is very costly, difficult, and sometimes impossible. EPA is responsible for regulating pesticide use to prevent unreasonable risks to human health and the environment.

Pesticide Leaching Threatens a Valuable Natural Resource

A natural resource used for drinking water and other purposes, groundwater is found in small interconnected spaces between soil and rock particles. The underground areas containing a useful supply of water, called aquifers, may be near the surface or hundreds to thousands of feet underground. Groundwater has already been affected in many areas by pesticides that have leached downward through soil into it. Figure 1.1 illustrates the major aquifers in the United States and indicates whether groundwater occurs adjacent to streams, in sand and gravel, or in rock.

Figure 1.1: Map of Major U.S. Aquifers

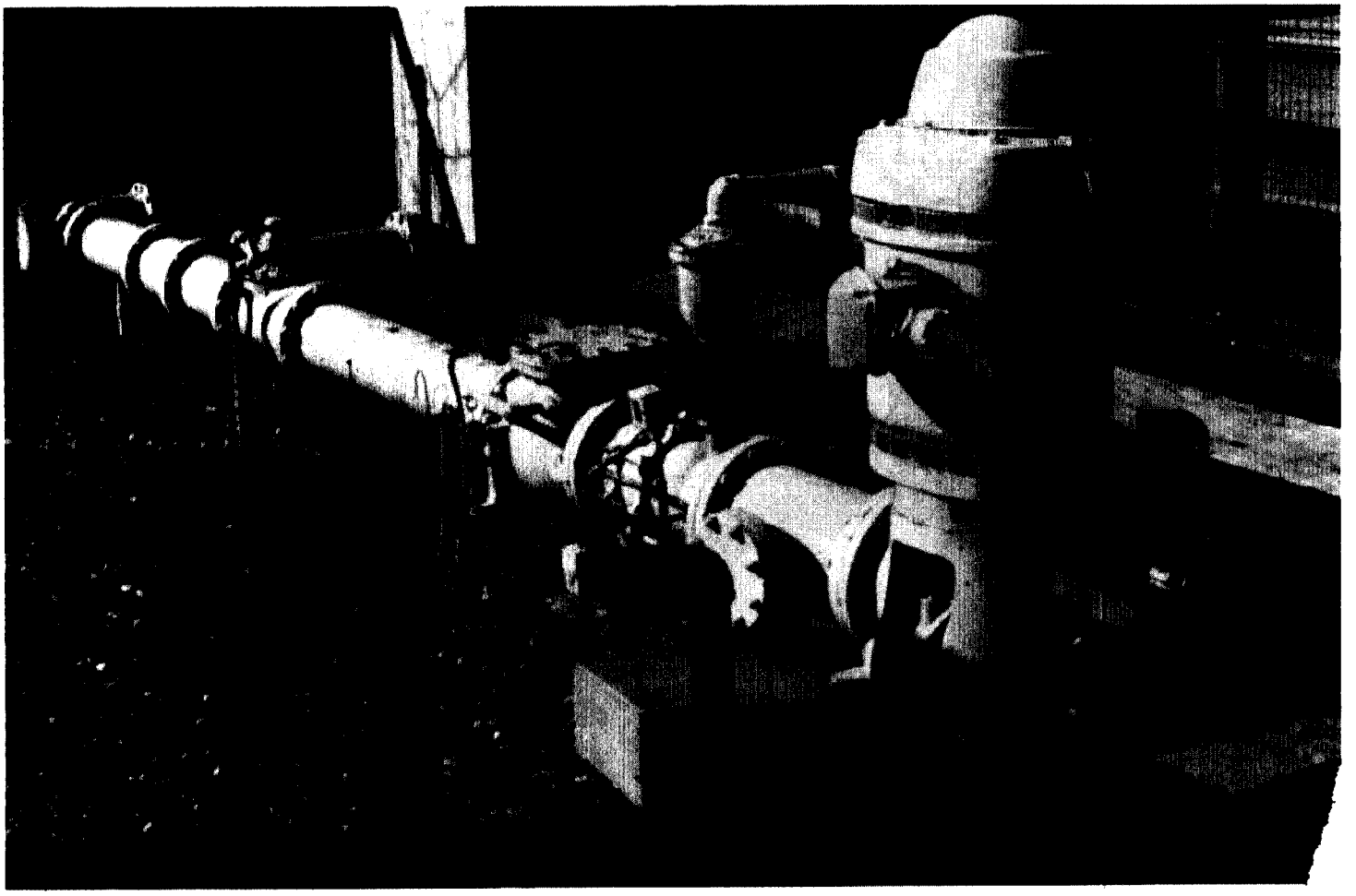


Note: The map indicates only those aquifers capable of yielding 50 or more gallons of water per minute to wells; white areas on the map are underlain by less extensive aquifers.

Source: Prepared by GAO from a map by the U.S. Geological Survey.

About 40 percent of the people in the United States—approximately 100 million people—use groundwater from private and community water system wells for their drinking water. In rural areas, the percentage is more than 90 percent. According to EPA staff responsible for maintaining statistics on drinking water systems, 44 of the 275 largest community water systems draw on groundwater. EPA estimates that there are 10.5 million rural private wells and 38,300 community water systems using wells. People depending on groundwater for drinking water are those who could be affected most directly by contamination by pesticides. Figure 1.2 shows a well field for a community water system.

Figure 1.2: Well Field for a Community Water System



Source: From an educational package for pesticide applicators, sponsored by EPA and the U.S. Department of Agriculture (USDA).

Groundwater is the source of about 55 percent of the water consumed by livestock and 40 percent of the water used for irrigation. Groundwater also recharges surface waters; about 30 percent of the water in rivers comes from groundwater. Because of the connection between surface water and groundwater, wildlife, sensitive ecosystems, and people whose drinking water comes from surface water such as lakes and rivers can be affected indirectly by groundwater contamination by pesticides.

Contaminated Groundwater Has Been Detected in Many States

Pesticides were first discovered in groundwater in 1979. Prior to that time, it was generally believed that they did not leach into groundwater as a result of normal agricultural use. In 1979, DBCP (dibromochloropropane) was found in wells in central California, and aldicarb was found to have contaminated wells on Long Island, in New York's Suffolk County. Groundwater monitoring (sampling water from aquifers and testing samples for various chemicals) over subsequent years has detected contamination by pesticides in over half the states.

A study completed in 1985 by EPA's Office of Pesticide Programs (OPP) identified 16 pesticides present in groundwater in 23 states as a result of agricultural practice.[1] (These detections excluded those attributed to poor disposal practices, pesticide mixing and loading operations, etc.) The study included results of studies by state agencies, the U.S. Geological Survey, and pesticide companies. The latest information available to us shows that these 16 pesticides have been found present in groundwater, as a result of normal agricultural use, in the states listed in table 1.1. Appendix I describes the uses of these pesticides.

[1]S.Z. Cohen, C. Eiden, and M.N. Lorber, Monitoring Ground Water for Pesticides, EPA, OPP (Washington, D.C.: American Chemical Society, 1986), was developed from a symposium held in 1985. The study listed 17 different pesticides, but as 2 of those listed are by-products of the same pesticide, we are considering the total to be 16 pesticides.

Table 1.1: States in Which the 16 Pesticides Have Been Detected in Groundwater

State	Pesticide															
	Alachlor	Aldicarb	Atrazine	Bromacil	Carbofuran	Cyanazine	1,3-Dichloropropene	DBCP	DCPA[a]	Dinoseb	EDB[b]	Fonofos	Metolachlor	Metribuzin	Oxamyl	Simazine
Arizona		X						X			X					
Arkansas		X														
California		X					X	X			X					X
Colorado			X													
Connecticut	X		X				X				X		X			X
Florida	X	X		X							X					
Georgia											X					
Hawaii							X	X								
Illinois	X		X										X	X		
Iowa	X		X			X						X	X	X		
Kansas	X		X											X		
Louisiana	X					X										
Maine	X	X	X							X				X		
Maryland	X		X		X	X	X	X								X
Massachusetts	X	X			X		X			X	X				X	
Nebraska	X		X			X						X				X
New Jersey		X	X													X
New York		X			X		X		X	X	X				X	
North Carolina		X														
Oregon		X														
Pennsylvania	X		X			X							X			X
Rhode Island		X			X										X	
South Carolina								X			X					
Texas		X														
Vermont			X			X										X
Virginia		X														
Washington		X					X				X					
Wisconsin	X	X	X		X								X	X		

Note: The information in this table draws on the previously cited study by Cohen et al., and on W. Martin Williams, Patrick W. Holden, Douglas W. Parsons, and Matthew N. Lorber, Pesticides in Ground Water Data Base: 1988 Interim Report, EPA, OPP (Dec. 1988). These pesticides may be present in groundwater in additional states. The table reflects results of monitoring studies, and monitoring has not been done in many agricultural areas, nor has each of the 16 pesticides necessarily been tested for in each of the states listed above. The table includes detections of by-products or breakdown products for some of the pesticides.

[a]dimethyl tetrachloroterephthalate

[b]ethylene dibromide

In December 1988, EPA reported that additional monitoring had revealed groundwater contamination by 74 pesticides in 38 states.[2] Of these pesticides, 46 had been detected in 26 states through scientifically confirmed studies in which contamination was attributed solely to normal agricultural use. The remaining pesticides were found through unconfirmed studies, or the pesticides' presence was attributed to misuse or spills. For 9 of the 46 pesticides, the maximum level detected exceeded EPA's current health advisory level (the level considered to be safe), and for 2 of the 9, the median level detected exceeded the health advisory level.[3] Appendix II summarizes information on the 46 pesticides present in groundwater from normal agricultural use.

According to EPA's November 1990 report, the agency's National Survey of Pesticides in Drinking Water Wells detected 16 pesticides or pesticide breakdown products, as well as nitrate (which can result from fertilizer use or other sources).[4] Samples from approximately 1,300 wells were tested for 126 pesticides and pesticide by-products and also for nitrate. The survey report estimated that approximately 10 percent of community wells and 4 percent of rural household wells contain detectable levels of at least one pesticide. Further, the report estimated that less than 1 percent of all wells—between 9,430 and 199,000 rural household wells and between 0 and 750 community water system wells—have concentrations of at least one pesticide above EPA's health-based standards for drinking water, indicating potential health risks.[5] That a substantial numbers of wells, particularly rural household wells, could be affected by the presence of one or more pesticides or nitrate indicates a need for continued attention to protecting groundwater, according to the report.

In comparison to the 1988 report, the National Survey of Pesticides in Drinking Water Wells reported fewer pesticides detected. According to the survey director, this is because the survey was designed to present a nationwide perspective of how many wells contain one or more pesticides, rather than to present a precise picture for any one pesticide. As a result, pesticides contaminating a less extensive area geographically

[2]Williams et al., Pesticides in Ground Water Data Base.

[3]EPA develops health advisories to provide risk information to state officials and water suppliers when contaminants are detected in water supplies.

[4]National Survey of Pesticides in Drinking Water Wells: Phase I Report, EPA, Office of Water and Office of Pesticides and Toxic Substances, Pub. No. EPA 570/9-90-015 (Nov. 1990).

[5]These estimates apply to those pesticides for which there are drinking water standards.

may not have been detected. In order to analyze the relationship of contamination to pesticide use, samples were taken from wells in areas with different levels of pesticide use, including areas with very little use of pesticides in general, and possibly no use of a particular pesticide. For example, according to the survey director, the approximately 1,300 wells sampled were in counties that account for less than 1 percent of the U.S. sales of aldicarb, which was not detected by the survey. Of the 16 pesticides detected by this national survey, 7 were also among the 16 reported in the 1985 study as having been detected.

In addition to developing national estimates of the frequency and concentration of pesticides and nitrate in drinking water wells, EPA's National Survey of Pesticides in Drinking Water Wells is designed to examine how contamination of wells by pesticides is related to the vulnerability of groundwater and the usage of pesticides. EPA expects to publish this analysis in the spring or summer of 1991. In the area of pesticide regulation, EPA plans to use results of its survey to (1) identify pesticides as candidates for regulatory measures, (2) set priorities for regulatory measures, (3) identify pesticides needing more monitoring or other studies to fully assess their potential to leach into groundwater, (4) identify factors that influence contamination of wells by pesticides, and (5) assist in the development of state management plans (SMP) for pesticides.

Contaminated Groundwater Is Difficult to Clean Up

Once contamination is detected, the nature of groundwater makes it difficult to clean up. Rehabilitating aquifers may be accomplished by (1) using biological or chemical agents to detoxify contaminants in the ground or (2) pumping groundwater to the surface for treatment and then returning it to the aquifer. Such remedies are not always feasible, and some are at the cutting edge of current technology. They can cost millions of dollars and take many years to complete. Therefore, cleaning up an aquifer may only be practical under certain conditions due to the time, cost, and complexity of the remedies.

Groundwater can also be treated at the surface, before use. While this protects public health, the contamination remains in the aquifer. For a household, the treatment could cost less than $1,000 for the installatior of one activated carbon filter, which would be effective against some, but not all, pesticides. If many households with private wells are affected by contamination, the cost of even simple treatments multiplies. For example, in the 7 years after aldicarb was found in Long Island groundwater, over $2.5 million was spent installing carbon 1

systems for affected household wells. Obtaining a new source of water is another alternative. Drilling a new well or hooking up to a public water supply can cost a household thousands of dollars. Also, public water systems may be able to dilute a contaminant by blending water from different sources, or the systems may need to install and operate treatment systems.

Many Factors Affect Whether a Pesticide Will Leach Into Groundwater

The geologic and climatic conditions where a pesticide is used, agricultural and pesticide use practices, and the nature of a pesticide can all affect whether it leaches through soil into groundwater in a particular situation. The vulnerability of groundwater to contamination varies greatly across the country. In general, aquifers close to the surface are more vulnerable than those at greater depths. Aquifers under sandy soil could be vulnerable because such soil permits the fast movement of water containing dissolved pesticides. Groundwater in areas with natural fractures in the earth, through which a pesticide could move, could also be vulnerable. Finally, groundwater in an area having heavy rainfall, which can accelerate a water-soluble pesticide's movement through the soil, could be susceptible to contamination.

Agricultural practices—both acceptable ones and accidents and misuse—also affect the potential for groundwater contamination. Heavy application of pesticides or overirrigation can increase pesticide leaching. Applying a pesticide in conjunction with irrigation water (chemigation) may increase leaching under some conditions, because some pesticides, dissolved in the irrigation water, move down through soil. Growing the same crop in the same location year after year may, over time, increase the likelihood of groundwater contamination, because more pesticide use may be needed to combat pests. In addition, carelessness in mixing, storing, or disposing of a pesticide may result in spills or leaks.

A pesticide's properties—solubility, persistence, and mobility of the pesticide—help determine its leaching potential. A more soluble pesticide (one that dissolves readily in water) is likely to move downward, dissolved in rainwater or irrigation water. A more persistent pesticide (one that breaks down slowly) has more time to move downward toward groundwater. A more mobile pesticide (one that tends not to be adsorbed onto soil particles) is more likely to move toward groundwater.

EPA's Policies Emphasize Prevention of Contamination and State Roles

EPA has adopted an overall strategy for all agency programs addressing groundwater. EPA's 1984 strategy and 1990 draft statement of principles apply to all agency programs affecting groundwater, including those pertaining to the cleanup of abandoned hazardous waste sites and to the regulation of hazardous waste disposal, drinking water, and pesticide use. The agency also has a strategy specific to the pesticide program.

EPA's Overall Strategy and Policy

In 1984, EPA published its first groundwater protection strategy applicable to all relevant agency programs and also established an Office of Ground Water Protection to oversee implementation of the strategy. The strategy establishes a policy of differential protection: Among the different aquifers, the strategy assigns the greatest level of protection to aquifers that provide irreplaceable sources of drinking water or support sensitive ecological systems, lesser protection to other aquifers that currently or potentially provide sources of drinking water, and the lowest level of protection to those that are not considered to be useful for providing drinking water. The 1984 strategy also emphasizes that states, with local governments, have the principal role in protecting groundwater, because EPA believes states are best suited to implement and enforce groundwater programs.

EPA's Administrator established a groundwater task force in July 1989 to develop principles to help ensure consistency among EPA's decisions affecting groundwater. The draft principles issued in September 1990 state that EPA's overall goal is "to prevent adverse effects to human health and the environment and to protect the environmental integrity of the nation's ground water resources." Because decontaminating polluted groundwater is extremely costly, difficult, and sometimes impossible, EPA's objective is to prevent such pollution wherever possible.

Pesticide Program's Strategy

To address the risks of groundwater contamination by pesticides, OPP has developed a draft strategy. Its goal is to "prevent contamination of ground-water resources resulting from the normal, registered use of pesticides that presents a risk of adverse effects to human health and the environment, by taking appropriate actions in vulnerable areas." Like the principles established by the Administrator's groundwater task force, OPP's strategy emphasizes prevention over remediation, focusin on the protection of groundwater currently used and reasonably expected to be used as drinking water and on the effects of interac between groundwater and associated surface water ecosystems. Th strategy also envisions a strong state role, through the developmen

SMPs to help prevent the contamination of groundwater by pesticides. SMPs could include elements such as the potential responses to contamination, planned methods to assess the vulnerability of groundwater, and explanations of state agencies' roles. These plans are described in chapter 3 and appendix IV.

EPA Has Legal Authority to Regulate Pesticides

EPA regulates pesticide use under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA gives EPA the authority to register (license) pesticides for use; establish terms and conditions of their use; review, under the reregistration program, the health and environmental effects of older pesticides; and remove hazardous pesticides from the U.S. market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA sets tolerances—maximum levels of pesticide residues allowed in food commodities. If a pesticide is used in accordance with the terms set by EPA and listed on product labels, residues in food should be lower than the tolerances.

Regulating Pesticides Under FIFRA

FIFRA, originally enacted in 1947, authorizes EPA to regulate pesticides and their uses. Pesticide products must be registered by EPA before they may be sold or distributed in U.S. commerce. A pesticide product consists of one or more active ingredients—ingredients intended to control or kill a pest, such as an insect or weed—and other ingredients needed to dilute it, propel it, stabilize it, etc. One active ingredient may appear in a number of different products. Under FIFRA, EPA has the authority to require data needed to evaluate the environmental and human health effects of pesticides, including data to evaluate pesticides' leaching potential. A pesticide product used according to the directions on its label must perform its intended function 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 authorizes EPA to restrict, cancel, or suspend an existing registration if the agency finds that a pesticide product presents an unreasonable risk to human health or the environment. If new evidence raises a concern about a significant health or environmental risk, EPA may conduct a risk-benefit analysis known as a Special Review.

Possible regulatory actions include canceling some or all uses, imposing use restrictions, and requiring labeling changes. For instance, EPA could

impose the restricted-use classification, which specifies that only applicators certified through state programs and persons under these applicators' supervision can apply the pesticide. Canceling all uses of a pesticide is a very severe action, as it removes the pesticide from the U.S. market.

Reregistering Older Pesticides

In 1972 amendments to FIFRA, the Congress directed EPA to reregister all pesticides to assess their safety in light of current, more extensive data requirements. Many pesticides had not been tested, for instance, for their potential to cause cancer, birth defects, and other chronic health effects. EPA established the Registration Standards program in 1978 to systematically review previously registered pesticide active ingredients, beginning with an evaluation of existing scientific data for each active ingredient. For each active ingredient case (a group of related active ingredients), the results of the review were set out in a document—an interim Registration Standard—in which EPA described the data available on the active ingredient case, identified data that were missing or inadequate, and addressed regulatory issues for which sufficient data existed. From 1980 through December 24, 1988, EPA issued interim Registration Standards for 194 active ingredient cases that the agency considered to have priority for review because of their high volume of use and/or use on food. These 194 active ingredient cases represented a significant proportion of the total volume of pesticides used in the United States. However, under the Registration Standards program, the remaining active ingredient cases had not yet had interim Registration Standards developed, and EPA had made little progress in reregistering the pesticide products containing the active ingredients.

Thus, despite progress under the Registration Standards program, EPA was at a preliminary stage in the formidable task of reregistering pesticides. The Congress amended FIFRA in 1988 to expedite the reregistration process. The 1988 amendments (known as FIFRA '88) generally required that EPA reregister within 9 years each pesticide product first registered before November 1, 1984, or take other appropriate action, such as canceling, suspending, or restricting the use of the pesticide. In addition, th act established a fee system to raise additional funding for the reregistration process.

There are currently approximately 420 active ingredient cases (rep senting about 690 active ingredients) and 23,000 pesticide products require reregistration under FIFRA '88. FIFRA '88 refers to pesticides which interim Registration Standards have been issued (the 194 ac

ingredient cases mentioned above) as being on List A.[6] All other pesticides that require reregistration are divided into three groups identified in the act as Lists B, C, and D. (Pesticides containing the active ingredients on the lists are referred to as List A pesticides, List B pesticides, etc.) For List B, C, and D pesticides, FIFRA '88 established five phases of reregistration duties for EPA and registrants and mandatory time frames for completing each phase. FIFRA '88 did not impose all of the phases and associated time frames for List A pesticides because some of the work required in the phases had already been done through the Registration Standards program. In addition, the act did not explicitly apply the final 9-year time frame to List A pesticides. However, in EPA's reregistration plan for List A pesticides, the agency states its intention to complete reregistration for these pesticides within the 9 years. EPA still considers List A pesticides to have a high priority for reregistration.

Requiring Data to Assess Pesticides' Leaching Potential

EPA requires pesticide manufacturers to submit environmental fate and chemistry data that are needed to assess a pesticide's potential to contaminate groundwater. Environmental fate data address what happens to the pesticide once it is introduced into the environment, including any potential runoff to surface water, dissipation into the air, and persistence in the soil. Some environmental fate studies are relevant to assessing a pesticide's leaching potential. The second type of data, chemistry data, address the pesticide's physical and chemical properties, some of which are relevant to its leaching potential. In the reregistration process, EPA currently permits registrants 1 to 4 years (depending on the type of study) to submit the studies relevant to assessing a pesticide's leaching potential. (In the past, EPA's time frames for these studies were 6 to 27 months.) Table 1.2 summarizes the purposes of the studies necessary to determine leaching potential. In addition to requiring the data described in this table, EPA requires studies to determine a pesticide's toxicity to people who apply pesticides and to people who eat treated crops; residue levels in food; potential effects on wildlife, and certain effects on domestic animals and ecosystems.

[6]Of the 194 active ingredient cases having interim Registration Standards, 166 are still registered and require reregistration; for the other 28, all products have been suspended or canceled.

Table 1.2: Data Required to Assess Pesticides' Leaching Potential

Data requirement	Determination made
Hydrolysis	Breakdown of pesticide in water through chemical processes, specifically, the rate of breakdown and identity of breakdown products
Photodegradation in soil and in water	Breakdown of pesticide by sunlight when pesticide is in soil and in water, specifically, the rate of breakdown and identity of breakdown products
Aerobic soil metabolism	Breakdown of pesticide due to microorganisms in the soil and to physical and chemical processes that occur in soil, specifically, the rate of breakdown and identity of breakdown products
Anaerobic soil metabolism	Breakdown of pesticide under conditions that can occur with flooding or waterlogging soil, specifically, the rate of breakdown and identity of breakdown products
Mobility in soil	Potential of pesticide to leach through soil or adsorb onto different types of soil particles
Dissipation in the field[a]	Persistence and mobility of pesticide under actual use conditions in the field
Water solubility	Tendency of pesticide to dissolve in water
Vapor pressure	Tendency of pesticide to dissipate into the air, rather than enter soil
Octanol/water partition coefficient	Rough indication of tendency of pesticide to adsorb onto soil particles

[a]EPA may also require a long-term dissipation study in some cases, depending on the results of certain other studies.

Setting Pesticide Tolerances Under FFDCA

Under FFDCA, EPA sets maximum allowable levels (tolerances) of pesticide residues in raw agricultural commodities, animal feeds, and processed foods. The act requires that tolerances protect public health, while allowing for the production of an adequate, wholesome, and economical food supply. For each active or inactive ingredient, a tolerance or tolerance exemption is established for each food commodity on which the ingredient is registered to be used. FFDCA also provides EPA with the authority to revoke existing tolerances.

EPA plans to reassess tolerances for previously registered pesticides through the reregistration program. The agency is in the process of requiring the toxicology and residue data needed to reassess tolerances. However, many gaps in the data remain. GAO testified that as of April 1989, EPA had reassessed tolerances and tolerance exemptions and completed all relevant actions for only 3 of the approximately 400 food-use pesticides that needed to be reregistered.[7]

In making tolerance decisions for new and existing pesticides, EPA assesses possible health risks from consuming food containing pest residues. The aim of these dietary risk assessments is to determine within a practical certainty, whether proposed or existing tolerance

[7]Reregistration and Tolerance Reassessment Remain Incomplete for Most Pesticides (GAO/T RCED-89-40, May 15, 1989).

protect public health. The risk of pesticide residues depends both on the toxicity of the residues (their potential to cause adverse health effects such as cancer and birth defects) and the potential human exposure to pesticide residues in food. EPA requires those petitioning for a tolerance, usually pesticide manufacturers, to submit data that allow the agency to determine what residue levels could result from a pesticide's use on a particular crop and to assess the toxicity of pesticide residues. Using these data, EPA determines whether potential exposure through food is at an acceptable level for human intake.

Objectives, Scope, and Methodology

Because of concerns about protecting public health from risks due to pesticides and preventing groundwater contamination, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to review EPA's efforts to regulate pesticides that contaminate groundwater. Specifically, the Chairman requested that GAO evaluate the adequacy of EPA's efforts to (1) assess the leaching potential of pesticides, (2) regulate groundwater contaminants through the pesticide reregistration and Special Review programs, and (3) consider human exposure to pesticides in groundwater when setting and reviewing tolerances for pesticide residues in food. In addition, we gathered information about, but did not assess, the agency's proposal to require SMPs for certain pesticides that leach into groundwater.

We focused our efforts concerning assessing pesticides' leaching potential and regulating groundwater contaminants on the 16 pesticides that EPA had identified by 1985 as groundwater contaminants because we considered it fair to gauge EPA's progress over the 5 years that have passed since these pesticides were detected in groundwater. These 16 pesticides are alachlor; aldicarb; atrazine; bromacil; carbofuran; cyanazine; 1,3-dichloropropene; DBCP; DCPA; dinoseb; EDB; fonofos; metolachlor; metribuzin; oxamyl; and simazine. All 16 pesticides are being or have been used on food crops, and several are among the agricultural pesticides with the highest volume of use in the United States. Because 3 of the 16 pesticides have been canceled, the information in chapter 2 that concerns the status of studies submitted in response to data requirements pertains to only the 13 pesticides that remain in use.

To determine EPA's progress in obtaining and reviewing studies necessary in assessing leaching potential, we obtained and analyzed printouts from EPA's A List Inventory Support System (ALISS) on the 13 known groundwater contaminants still in use. Chapter 2 presents information, drawn mainly from ALISS, on the status of studies as of May 1990, the

most recent information available to us. Because ALISS had little information on atrazine and simazine, we obtained information on most studies concerning their leaching potential from OPP's summaries of environmental fate information; we were unable to obtain accurate information on chemistry studies relevant to atrazine's and simazine's leaching potential, so information on their chemistry studies is not included in chapter 2. We interviewed OPP officials responsible for reregistration and study review.

To determine the adequacy of regulatory activities, we obtained and analyzed reregistration and Special Review documents for the 16 known groundwater contaminants. To verify whether regulatory actions stated in reregistration documents were taken, we reviewed labels for one or two major products containing each pesticide. We reviewed EPA's draft proposed rule for imposing the restricted-use classification on pesticides that leach, and we reviewed documents concerning the proposal for SMPs. We interviewed, within OPP, Special Review and reregistration officials, officials who manage product registrations, and officials who helped develop the proposal for SMPs.

To determine the adequacy of EPA's efforts to consider human exposure to pesticides in groundwater when setting or reviewing tolerances for residues in food, we interviewed scientists involved in exposure and risk assessments in OPP and the Office of Drinking Water (ODW). We reviewed how ODW accounts for multiple sources of exposure to pesticides when it develops health advisory levels and drinking water regulations and compared ODW's method with OPP's tolerance risk assessment methodology. Information in chapter 4, which addresses tolerance assessments, applies to all known groundwater contaminants. For the 16 pesticides EPA had identified as groundwater contaminants by 1985, we verified information on tolerance assessments by reviewing documentation of OPP's dietary risk assessments for the 16 pesticides. For other pesticides now known to contaminate groundwater, we relied on OPP officials for information and did not verify their statements that these pesticides' tolerance assessments did not incorporate exposure due to contamin tion in groundwater. We discussed the two methodologies used by O and ODW with knowledgeable National Academy of Sciences staff.

We limited our scope to EPA's activities, though other federal agenc and states also have a role in addressing the contamination of gro water by pesticides. Our work at EPA concentrated for the most pa the activities of OPP, which is responsible for pesticide registratio tolerances. Recent related GAO reports, included in the list on the l

page of this report, have addressed the Department of Agriculture's and state governments' activities to protect groundwater. GAO is also currently evaluating (1) state assessments of the vulnerability of groundwater and (2) EPA's policies for preventing groundwater contamination.

Our audit work took place from June 1989 through January 1991, primarily in the Washington, D.C., area. Our review was conducted in compliance with generally accepted government auditing standards. As agreed with the Subcommittee's office, we did not obtain official agency comments on a draft of this report. However, EPA officials did review and comment on the factual material in the report and generally agreed with the facts as presented. The EPA officials' comments have been incorporated where appropriate.

EPA Has Made Little Progress in Assessing the Leaching Potential of Groundwater Contaminants

EPA has made little progress in assessing the leaching potential of the 13 pesticides still in use that it had identified as groundwater contaminants by 1985.[1] The agency has reviewed about one-third of the relevant studies registrants have submitted in response to EPA-imposed data requirements for assessing leaching potential. Time frames for submission of studies have ranged from 6 to 27 months, but after submission, many studies have sat for years without review. Of the studies EPA has reviewed, many did not follow the agency's guidelines or contained incomplete information. Since some studies may have to be redone or additional information provided, it will be years before EPA has complete information to conduct a leaching assessment of these pesticides. Assessments of leaching potential are important because they provide information the agency needs to help pesticide applicators minimize groundwater contamination. In addition, complete data are needed to reregister pesticides.

Insufficient resources have been cited as one reason for EPA's slow pace of review. In response to an expected influx of studies, the agency created a review policy in 1984 that ranked data for review. Under this policy, many of the studies EPA received from registrants, including environmental fate studies needed for leaching assessments, were filed for review at a later time. Increased resources resulting from the 1988 amendments to FIFRA permitted OPP to hire more staff to review studies. However, competing priorities within OPP pushed reviews of environmental fate data for List A pesticides (which include the 13 we are reviewing) to the back of the review line.[2] Recently, EPA officials assured us that reviews of studies for List A pesticides are a priority for fiscal year 1991. Nonetheless, because of the large volume of studies EPA expects to receive for reregistration, the potential exists for the agency to fall further behind.

Not only has the pace of review been slow, but also EPA's system for keeping track of information has been unreliable; the agency lost track of the status of studies for some data requirements. With the accelerated pace of reregistration brought about as a result of FIFRA '88, da management is a critical component of a successful reregistration p gram. So that it can better manage the review process as the pestic

[1]EPA has canceled the registration of 3 of the 16 pesticides identified as groundwater contar by 1985. The data presented in this chapter will focus on the remaining 13 pesticides still in

[2]List A consists of pesticides for which interim Registration Standards have been issued. Th include most of the important food-use pesticides (those to which people and the environme most exposed) and represent 80 to 90 percent of the total volume of agricultural pesticides the United States.

progress towards reregistration, EPA recently initiated several projects to determine the status of studies in its files and to keep track of all of the data it will receive.

EPA's Pace of Review Has Been Slow

For the 13 pesticides, EPA has reviewed about one-third of the studies submitted for assessing leaching potential. According to reregistration officials, the slow pace of review has been due in part to a low level of staffing for review caused by insufficient resources and to a review policy that did not give priority to data necessary in assessing pesticides' potential to leach.

The data requirements needed to assess a pesticide's leaching potential constitute a subset of all environmental fate and chemistry data requirements EPA may impose on registrants for the purposes of reregistration. Eight environmental fate and three chemistry data requirements address a pesticide's leaching potential. EPA required registrants of the 13 pesticides to submit studies for a total of 100 environmental fate and chemistry data requirements.[3] Registrants were given time frames ranging from 6 to 27 months (depending on the time needed to conduct the study) within which to generate the required data. (EPA has since doubled the time frames for these studies to 1 to 4 years.) In some cases, registrants submitted multiple studies in response to one data requirement.

As of May 1990, registrants had submitted a total of 316 studies in response to the 100 data requirements. From EPA's data base, it appears that registrants generally have submitted studies on time. Once submitted, however, some studies have gone without a review for as long as 5 years. Of the 316 studies submitted, EPA has reviewed only 110. These 110 studies cover 41 of the 100 data requirements.

Reregistration officials cite insufficient resources as a reason that studies did not get reviewed. According to the Chief of the Reregistration Branch, resources were targeted for other tasks of higher priority, such as Special Reviews and the development of Registration Standards. EPA was expecting to receive an influx of studies in response to the interim Registration Standards, yet it had a shortage of staff to review the studies. Therefore, in 1984 the agency issued Policy Note #31 which ranked data for review. Only those studies meeting the review policy's

[3]One hundred forty-three data requirements could have been imposed (11 requirements times 13 pesticides), but all were not deemed necessary by EPA.

criteria were scheduled for a review as soon as they were submitted to the agency. All other studies required to be submitted under an interim Registration Standard were filed for examination at a later time as part of a comprehensive review of all of the data submitted for a pesticide. According to an OPP product manager responsible for managing data, environmental fate data generally did not meet the criteria in Policy Note #31 for immediate review. As a result, many of these studies were not reviewed. According to the EPA official responsible for drafting Policy Note #31, reviewing individual studies as they are submitted to the agency constitutes an inefficient use of resources because scientists need to look at the data on a pesticide as a whole to gain an understanding of that pesticide. As of September 1990, however, EPA had reviewed all of the data submitted for only 25 pesticides out of the 194 having interim Registration Standards.

Funding from the reregistration fees effected by FIFRA '88 has permitted EPA to hire more scientists for study reviews. Seven new reviewers were hired in 1989 and 1990 in the Environmental Fate and Groundwater Branch, so the number of people available to review environmental fate studies now totals approximately 15. Three more are expected to be hired in fiscal year 1991. These reviewers are responsible for reviewing not just the environmental fate data relevant to assessing leaching potential, but all environmental fate data for older pesticides on Lists A, B, C, and D and for new pesticides as well.

As of May 1990, a backlog of environmental fate data still remained. According to the Chief of the Environmental Fate and Groundwater Branch, not enough reviewers have been allocated to review studies for List A pesticides to eliminate the backlog during 1991. Although new reviewers have been hired, competing priorities within OPP had relegated reviews of studies that were submitted for List A pesticides (which include the 13 in our review) to a low priority. According to the branch chief, 50 percent of the reviewers' time in his branch had been allocated to reviewing studies submitted for pesticides on Lists B, C, and D because of the interim time frames FIFRA '88 established for these pe cides. List A pesticides, on the other hand, are not subject to the int time frames in FIFRA '88. Because of their importance, however, EP intends to reregister List A pesticides within the 9-year time fram completing reregistration. The other 50 percent of the staff's time been spent on all of OPP's other necessary activities, which include cial projects and reviews of data for new pesticides, as well as rev of studies submitted for List A pesticides. The agency is also expe to receive a large influx of new data in response to its requests fo

missing and inadequate studies not only for List A pesticides, but for those on Lists B, C, and D as well. The Deputy Chief of the Environmental Fate and Groundwater Branch expressed concern that a backlog of studies could develop 4 years from now when these studies start to come in to the agency.

In January of this year, senior OPP officials assured us that the agency's review policy for 1991 considers reviewing studies for pesticides on Lists A and B to be a higher priority than reviewing studies for pesticides on Lists C and D. Further, according to the Deputy Director of the Office of Pesticide Programs, OPP management would consider missing time frames for pesticides on Lists C and D if necessary to follow that policy.

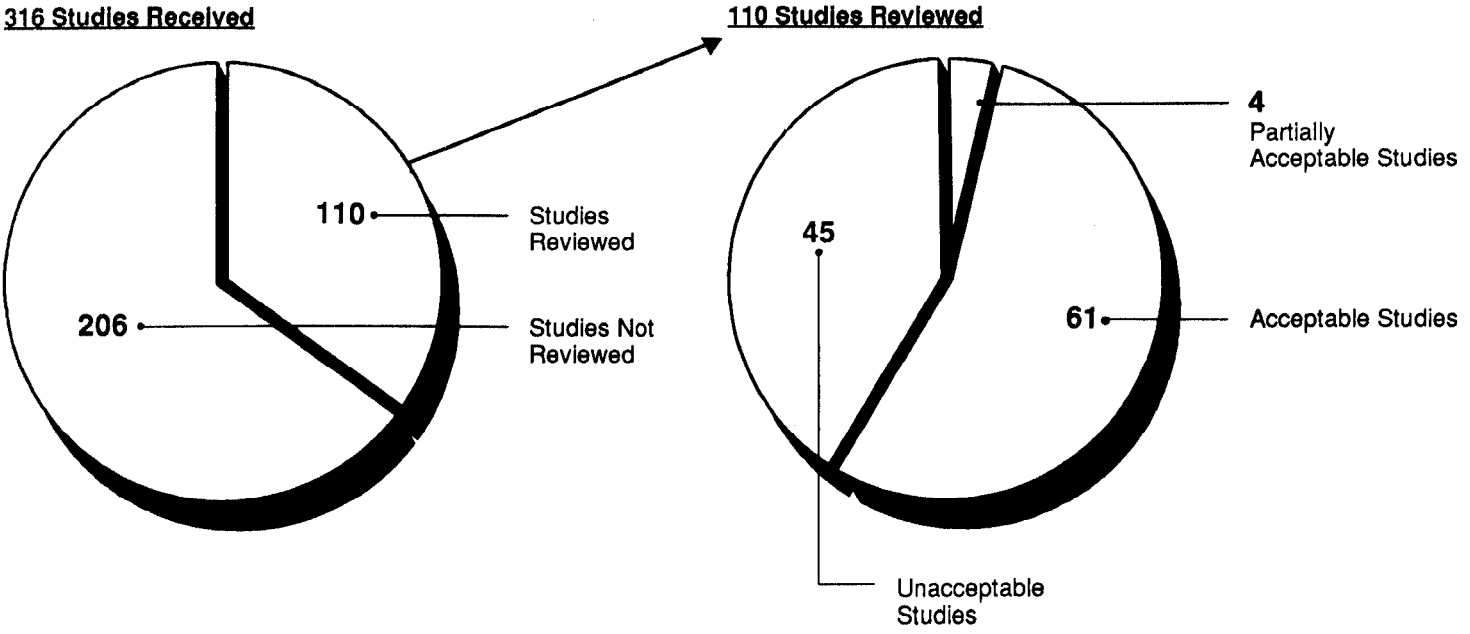
Many Reviewed Studies Are Unacceptable and May Have to Be Redone

Of the studies reviewed, about 40 percent are considered unacceptable. EPA found most of the chemistry studies acceptable, while it found many of the environmental fate studies unacceptable. According to the Deputy Chief of the Dietary Exposure Branch, chemistry studies are reviewed faster and are acceptable more often than environmental fate studies because the former studies are easier for registrants to generate and more straightforward to review. According to the Chief of the Environmental Fate and Groundwater Branch, the main reasons that environmental fate studies were found to be unacceptable are registrants' failure to follow EPA's guidelines for conducting studies and to report all critical information. This same official acknowledged, however, that EPA's guidelines for conducting studies are old and need to be updated. Moreover, according to the official, environmental fate studies involve many variables and are open to interpretation. These factors, he said, may cause a particular study to be found unacceptable. Recently, EPA issued a guidance document that gives registrants information about the agency's acceptance criteria for required studies. Reregistration officials have expressed hope that this document, coupled with EPA's feedback to registrants from reviews of submitted studies, will bring about the submission of more acceptable data in the future.

Of the 110 studies reviewed, EPA determined that 61 are acceptable, 45 are unacceptable, and 4 are partially acceptable. Figure 2.1 illustrates the status of studies received and reviewed as of May 1990. The 61 acceptable studies covered 23 of the data requirements. However, a nearly complete set of acceptable data exists only for one pesticide—cyanazine. Seventeen out of 18 studies submitted for cyanazine's 8 data requirements were reviewed and found to be acceptable. Even for

cyanazine, the agency is considering requiring groundwater monitoring studies to provide further information.

Figure 2.1: Status of Studies



Source: Prepared by GAO using EPA's data.

When studies are unacceptable, EPA must ask registrants to redo studies or submit additional information for the same data requirements imposed many years earlier. Such repetitive requests are necessary to obtain reliable data, but do delay some regulatory decisions and could delay the reregistration of pesticides. For two pesticides—atrazine and simazine—for which EPA has reviewed all of the environmental fate and chemistry studies submitted, the agency is requiring additional studies to fulfill almost all of the data requirements imposed earlier because most of the original studies are unacceptable.

In 1983, EPA imposed five environmental fate and one chemistry d requirements to enable it to assess atrazine's leaching potential. B November 1988, EPA had reviewed 24 studies that were submitted the five environmental fate data requirements. According to EPA d ments, 12 studies were acceptable, 11 were unacceptable, and 1 w tially acceptable. As a result, EPA asked registrants through a noti

issued in September 1990 to submit studies to meet four of the same five environmental fate data requirements it imposed in 1983. EPA also imposed a different environmental fate data requirement for which a previously valid study is no longer considered acceptable. We were unable to determine the number of studies submitted and reviewed in response to the chemistry data requirement. OPP requires new chemistry data if the registrant changes its manufacturing process for a pesticide. Because several years have passed since EPA asked for chemistry data for atrazine and because there may have been changes in the manufacturing process for the pesticide, the agency is requesting that registrants submit information on the three chemistry data requirements relevant to assessing leaching potential.

In 1984, EPA imposed five environmental fate and three chemistry data requirements to enable it to assess simazine's leaching potential. By July 1989, EPA had reviewed 25 studies submitted for the five environmental fate data requirements. All 25 were determined to be unacceptable. As a result, EPA is planning to ask registrants for studies to fulfill the same five environmental fate data requirements the agency imposed in 1984. As it did with atrazine, EPA is also planning to ask registrants to submit information on the three chemistry data requirements.

Obtaining complete and valid data for atrazine and simazine is likely to be a lengthy process. Time frames for the submission of studies concerning a pesticide's leaching potential now range from 1 to 4 years. After the new studies required for atrazine and simazine are submitted, EPA must again review them to determine their adequacy. If any studies are unacceptable, the process of asking for and reviewing more studies will have to be repeated. Moreover, results of some studies could trigger the need for a higher tier of testing, such as a longer-term field study or groundwater monitoring. If registrants submit studies on time, the earliest date that atrazine and simazine could be added to the queue for a reregistration decision would be 1994—about 10 years after these two pesticides were first detected in groundwater and these studies were first requested. If, however, studies need to be repeated or higher-tier testing is required, the date for a reregistration decision for these two pesticides could be extended several more years.

Many of the environmental fate studies already submitted for the other pesticides have not yet been reviewed. If these studies are unacceptable, as many were for atrazine and simazine, registrants then will be given another 2 or 4 years to submit acceptable data. Pesticides could go

through several rounds of requests for data before the agency has acceptable data to fully assess the pesticides' leaching potential.

Once EPA determines that it has acceptable data, a number of steps remain in order to reregister each of the List A pesticides, including the 13 pesticides in our review. The agency must (1) assess risks of each pesticide to determine if it is eligible for a reregistration decision or requires other regulatory action; (2) if the pesticide is eligible for reregistration, require and review data specific to the products containing the pesticide; and, (3) finally, reregister individual products if their risks do not exceed their benefits, making any necessary changes to product use directions. It is not improbable that more than 15 years could pass from the time a pesticide was first discovered in groundwater to the time a complete assessment of leaching potential and a reregistration decision could be made. The slow review of studies has delayed an already lengthy process.

The Review Process Lacked a Reliable Data-Tracking System

Until recently, EPA's system for keeping track of data requirements and studies was unreliable and as a result lost track of much of this information. A reliable data-tracking system will be a critical component of EPA's effort to manage data submission and review. This is particularly true now, because EPA is working under a 9-year time frame to accomplish the reregistration of pesticides, and over the next few years, the agency will be receiving a large volume of studies that it will have to track.

EPA's Pesticide Action Tracking System (PATS) was the means by which EPA attempted to keep track of studies in the past. PATS exhibited a high percentage of errors, however, and EPA officials in the Special Review and Reregistration Division expressed a lack of confidence in the system. PATS was not designed to hold some information necessary for keeping track of studies, such as the status or results of study reviews. In addition, information on waivers and time extensions often was not entered into PATS. Thus, over time, EPA lost track of the status of data requirements and studies and their due dates. Without a reliable data base on which it could depend, EPA did not have the information it needed to identify missing and inadequate data to progress towards the reregistration of pesticides.

In order to correct the situation, EPA began an inventory project in February 1989 to determine the current status of the data requirements and studies for List A pesticides. As a result of the inventory, EPA classified each List A pesticide by the degree to which its data base is complete.

For some pesticides, additional follow-up work beyond the inventory review was necessary because EPA could not determine if some data were overdue, or if waivers or extensions had been granted. EPA entered the results of the inventory into a computer data base—the A List Inventory Support System (ALISS). ALISS is designed to reflect the current status of studies as determined by the inventory and to facilitate the tracking of studies EPA will be receiving and reviewing in the future. EPA is still improving ALISS and still entering information as it proceeds with determining data requirements and the status of studies. EPA has had problems determining how to enter time extensions and waivers into ALISS. At present, the agency is in the process of validating the data in ALISS. Because the system is relatively new, we did not assess its adequacy.

Conclusions

EPA has made little progress to date in fully assessing the leaching potential of the 13 pesticides remaining in use among the 16 identified as groundwater contaminants by 1985. Many of the studies submitted by registrants have not been reviewed, and some have been awaiting review for as long as 5 years. Of the studies that have been reviewed, many are unacceptable.

Insufficient resources led to a review policy in which environmental fate data were not a priority for review. Funding from the 1988 amendments to FIFRA has permitted the hiring of new staff for reviews. Even though List A pesticides include most of the important food-use pesticides and represent 85 to 90 percent of the total volume of agricultural pesticides used in the United States, they are not subject to the same interim time frames and have not received priority for reviews. Recently, EPA officials assured us that reviews of studies for List A pesticides are a priority for fiscal year 1991. With the accelerated pace of reregistration brought about by the 1988 act, EPA expects to receive an increasing number of studies. Timely reviews of studies will be necessary to keep the agency from falling further behind. Whether EPA will be able to clear the backlog of studies and keep pace with incoming studies in the future cannot yet be determined.

EPA's past system for keeping track of the status of data requirements and studies was unreliable. The agency could not identify when data necessary for reregistration were missing or inadequate. EPA has since taken an inventory to determine the current status of data requirements and studies in its files and has entered the results in a computerized data base. This system is expected to track studies the agency will be

receiving in the future. Because these efforts are still in progress, it is too early to determine their adequacy to facilitate EPA's management of data submission and review.

It will be many years before EPA has complete, acceptable data necessary to conduct a complete leaching assessment of the pesticides it identified 5 years ago as threats to groundwater. EPA has just begun to issue new requests for missing and inadequate data for List A pesticides. Time frames for registrants to submit data concerning a pesticide's leaching potential are 1 to 4 years. As the agency reviews previously submitted studies, it most likely will find that some of them are unacceptable or do not meet current scientific standards, necessitating the submission of further information or replacement studies, as was the case for atrazine and simazine. It is possible that over 15 years could pass from the time a pesticide was first discovered in groundwater to the time a complete assessment of its leaching potential could be made. EPA's slow review of data extends what is already a long process.

Recommendation

To facilitate EPA's ability to assess the leaching potential of known groundwater contaminants, we recommend that the Administrator, EPA, review the relevant studies submitted by registrants for List A pesticides (which include the 13 groundwater contaminants in this report) on a priority basis.

EPA Could More Fully Utilize Regulatory Measures Available to Reduce Groundwater Contamination From Pesticides

Under FIFRA, EPA can take various regulatory measures to reduce groundwater contamination from pesticides. These measures vary in the degree to which they constrain pesticide use. They range from a groundwater advisory on the product label, which notifies the user of a pesticide's leaching potential and/or of its confirmed detection in groundwater, to cancelation of a pesticide's registration. Because groundwater is extremely difficult to clean up, prompt use of regulatory measures to minimize contamination by pesticides is critical.

However, EPA has not consistently used the regulatory measures available to protect groundwater from contamination by pesticides. Of the 13 pesticides still in use that EPA had identified as groundwater contaminants by 1985, 4 lack a groundwater advisory. EPA has not imposed a restricted-use classification, which restricts the use of a pesticide to certified applicators or persons under their direct supervision, on any of the 13 pesticides on the basis of concern about groundwater contamination.

EPA has made little use of other measures to minimize groundwater contamination, such as prohibiting use in specified geographic areas and prohibiting use within a specified distance from wells (well setbacks). In the few cases where such measures have been used, registrants have volunteered these restrictions. Although a lack of complete and acceptable data concerning leaching potential exists for many pesticides, other evidence, such as confirmed detections of pesticides' presence in groundwater from normal agricultural use, is now available on which EPA could base regulatory measures such as geographic use prohibitions and well setbacks. Assessments based on complete data would provide information on a pesticide's potential to leach under various soil and climatic conditions—information that could help pesticide users avoid application under conditions likely to increase leaching.

A pesticide's presence in groundwater is not a criterion for initiating a Special Review, which is a risk-benefit analysis EPA conducts when it is concerned about health or environmental risks that a pesticide poses. Such reviews may result in regulatory actions such as requirements for label warnings, the restricted-use classification, a requirement that applicators wear protective clothing, or cancelation of some or all uses of a pesticide. OPP's current Special Review practices are to (1) initiate reviews addressing threats to groundwater only if there are also risks to human health or wildlife and (2) take regulatory action to address groundwater contamination only if the levels of pesticides occurring in groundwater present health risks. Nevertheless, through Special

Reviews, EPA has canceled all uses of 3 of the 16 pesticides identified in 1985 as groundwater contaminants; in 2 of the cases, cancelation was partly due to concern about cancer risks resulting from contamination in groundwater. Concerns about groundwater contamination are being assessed in ongoing Special Reviews for 4 of the remaining 13 pesticides.

Under a new regulatory approach, EPA is proposing that states play an increased role in controlling certain pesticides by having state management plans (SMP). At present, this approach is still in the planning stage, so several relevant issues have yet to be resolved, and SMPs are still several years away.

Some Contaminants Do Not Have a Groundwater Advisory on Their Label

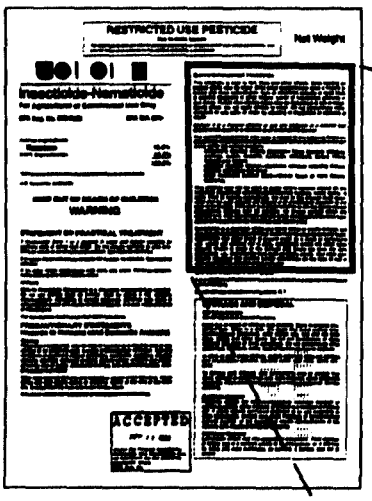
A groundwater advisory is a statement alerting users to the pesticide's previous detection in groundwater and/or its potential to leach in soil. An advisory may include advice that the pesticide should not be applied where the water table is close to the surface and where soils are permeable. EPA required an advisory on the product labels for 10 of the 13 pesticides, although labels for 1 of the 10 do not currently contain an advisory. For the remaining three pesticides—DCPA, 1,3-dichloropropene, and fonofos—no groundwater advisory was required, even though actual groundwater contamination or the potential for the pesticides to leach had been demonstrated. In addition, one of the three—1,3-dichloropropene—is classified by EPA as a probable human carcinogen. OPP officials did not know the reason an advisory was not required for these pesticides.

In some cases, a groundwater advisory may be the only indication on a label of a pesticide's potential to leach into groundwater. The labels for the three pesticides for which no groundwater advisory was required do not provide any other notice to the user of the pesticide's potential to leach from normal agricultural use.

On the labels for 9 of the 13 pesticides, advisories are included along with other information, under the general heading "Environmental Hazards" but are not always readily apparent. For only 3 of the 9 pesticides, the advisory appears under a prominent subheading that explicitly states "Groundwater Advisory." Given the amount of information contained in some labels, a subheading can make an advisory easier to locate. Figure 3.1 shows examples of two advisories from pesticide product labels.

Figure 3.1: Portion of Labels With a Groundwater Advisory

Advisory Without a Subheading



Environmental Hazards

This pesticide is toxic to fish, birds and other wildlife. Birds feeding on treated areas may be killed. Birds killed by [*] pose a hazard to hawks and other birds-of-prey; bury or otherwise dispose of dead birds to prevent poisoning of other wildlife. Cover or incorporate granules in spill areas. Runoff from treated areas may be hazardous to fish in neighboring areas. Do not apply directly to water. Do not contaminate wells, wetlands or any body of water by cleaning of equipment or disposal of waste.

Notice: It is a Federal offense to use any pesticide in a manner that results in the death of a member of an endangered species.

The use of [ ] may pose a hazard to the following Federally designated endangered/threatened species known to be found in certain areas within the named locations.

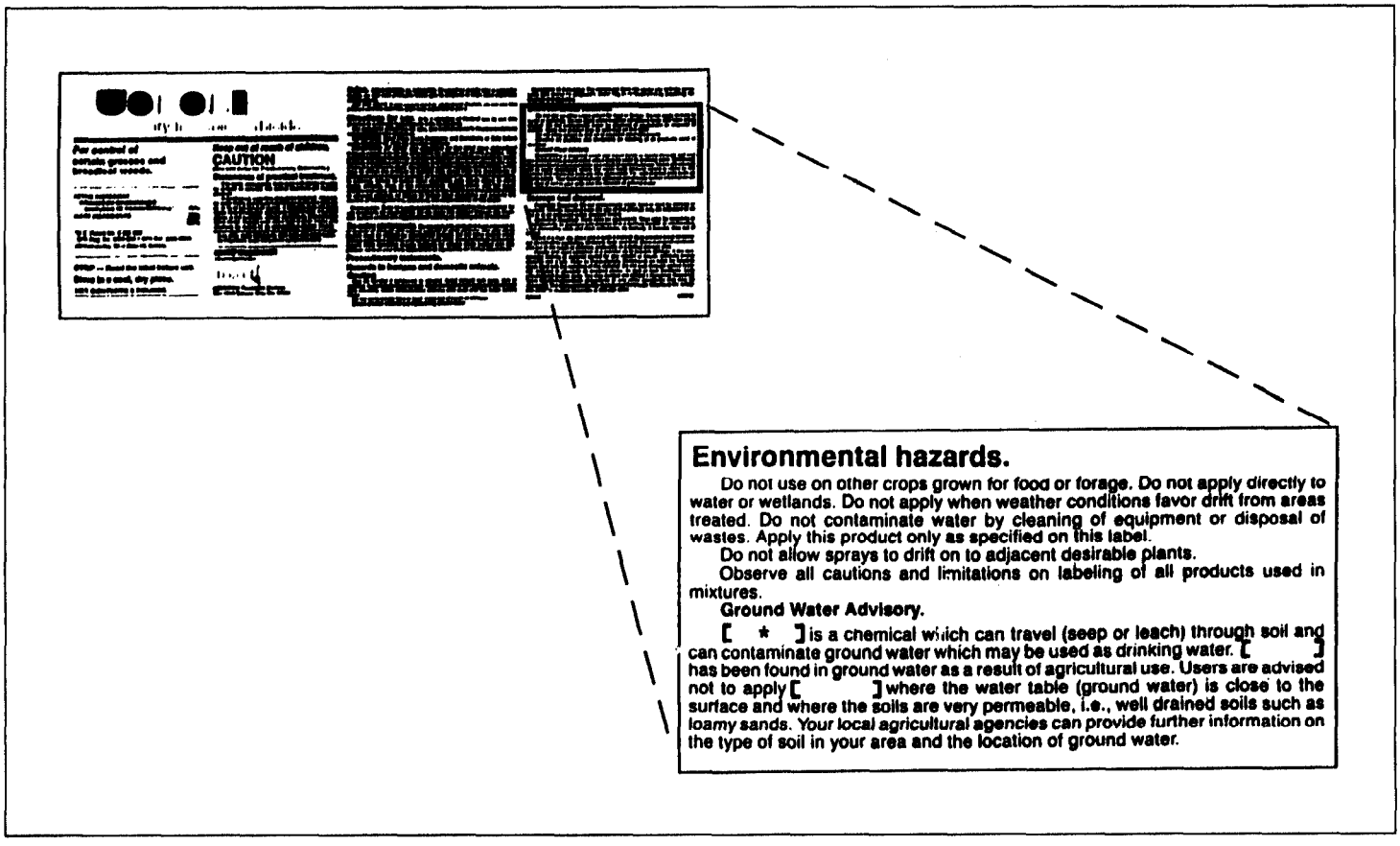
Attwater's Greater Prairie Chicken—Texas counties including: Aransas, Austin, Brazoria, Colorado, Galveston, Goliad, Harris, Refugio and Victoria
Aleutian Canada Goose—California counties including Colusa, Merced, Stanislaus and Sutter
Kern Primrose Sphinx Moth—Walker Basin of Kern County, California.

This product may not be used in areas where adverse impact on the Federally designated endangered/threatened species, noted above, is likely. Prior to making applications, the user of this product must determine that no such species are located in or immediately adjacent to the area to be treated. If the user is in doubt whether or not the above named endangered species may be affected, he should contact either the regional U.S. Fish and Wildlife Service office (Endangered Species Specialist) or personnel of the State Fish and Game office.

[ ] is a chemical which can travel (seep or leach) through soil and can contaminate ground water which may be used as drinking water. [ ] has been found in ground water as a result of agricultural use. Users are advised not to apply [ ] where the water table (ground water) is close to the surface and where the soils are very permeable, i.e., well-drained soils such as loamy sands. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water.

* Brackets indicate that pesticide name has been deleted.

Advisory With a Subheading



*Brackets indicate that pesticide name has been deleted.

The effectiveness of groundwater advisories to reduce the potential for contamination is not known. Because of the statement's advisory nature, it is not legally enforceable. Therefore, additional care in the use of the pesticide depends on the user's knowledge of the appropriate precautions necessary to reduce the potential for groundwater contamination and voluntary compliance with such precautions. Such a notification nonetheless is a minimum step that EPA can require of a registrant to bring attention to concerns about the effect of pesticide use on groundwater. According to one EPA official, a groundwater advisory does serve to raise the awareness of pesticide users to these concerns. Informing pesticide users could be beneficial because some of them are farmers who depend on groundwater for their drinking water and therefore may have an incentive to take additional precautions.

Restricted-Use Regulations Have Not Specified Groundwater Contamination

Pesticide products classified for restricted use under the authority of section 3(d) of FIFRA may be purchased and used only by certified applicators or individuals under their direct supervision. Because of the training that certified applicators are required to undergo, EPA believes that restricting use to certified applicators is an effective way to ensure that pesticides are used properly. OPP has been unsuccessful in imposing the classification on a single pesticide on the basis of concern about groundwater contamination, though 8 of the 13 pesticides are currently classified restricted-use for other reasons.[1] Currently, imposing the restricted-use classification on pesticides because of concern about groundwater contamination is authorized on a case-by-case basis under a general provision of EPA's regulation. However, this provision has proved difficult for EPA to implement because the criteria were not specific. Therefore, the agency is drafting a rule that will add specific new criteria to give the agency a clear basis for imposing the classification on pesticides that have the potential to contaminate groundwater on a widespread basis.

Attempts to Impose the Classification Have Been Unsuccessful

EPA's attempts to impose a restricted-use classification on 3 of the 13 pesticides on the basis of concern about their effect on groundwater failed because EPA's current regulation for imposing the classification did not provide specific criteria for doing so, according to an official in the Special Review and Reregistration Division. Because of particular concerns about the impact on groundwater of cyanazine, metribuzin, and simazine, EPA originally had proposed in their Registration Standards that they be classified restricted-use. EPA relied on the general provision of the regulation for imposing the restriction on that basis. The registrant for simazine successfully challenged its classification for restricted use, and EPA rescinded the requirement. EPA thereafter rescinded the requirement for metribuzin. While the requirement remained in effect for cyanazine because of concern about its toxicity, EPA deleted the rationale that was based on the pesticide's effect on groundwater.[2]

[1]Atrazine is currently classified restricted-use because of concern about groundwater contamination, but this action was volunteered by the registrant.

[2]Of the 13 contaminants, 5 are not classified restricted-use for any reason: bromacil, DCPA, metolachlor, metribuzin, and simazine.

EPA Proposes a New Restricted-Use Rule to Deal With Groundwater Contamination

As a result of EPA's lack of success in using the regulation's general provision to apply the restricted-use classification on these three pesticides on the basis of their effect on groundwater, OPP is drafting a new rule. Once final, the rule will add specific criteria to permit EPA to consider classifying a pesticide for restricted use if it has a potential to reach groundwater on a widespread basis.

The draft proposed rule contains two options on which EPA plans to solicit comments. Option one would contain two threshold triggers, either of which would be sufficient to consider classifying a pesticide for restricted use. These are (1) a pesticide's potential to reach groundwater, based on its measured persistence and mobility, and (2) the detection of the pesticide in groundwater in at least three different counties.

Option two would include two criteria for triggering consideration of the restricted-use classification: (1) the fact that the pesticide is persistent and mobile, and/or (2) the detection of contamination in three or more counties at levels exceeding 10 percent of the maximum contaminant level (MCL) (or health advisory level, if an MCL does not exist)[3] or contamination occurring in 25 or more wells in four or more states. For new and current registrations for which new data must be submitted, meeting either criterion would be sufficient to invoke consideration of the restricted-use classification. For currently registered pesticides for which no new data are required, meeting both criteria would be needed for EPA to consider restricting their use.

EPA proposed the second option in response to objections raised by the Office of Management and Budget (OMB) and USDA to an earlier draft of the proposed rule that contained only option one. Both OMB and USDA objected to EPA's criteria in option one that based consideration for the restricted-use classification only on the pesticide's potential for reaching groundwater on a widespread basis. Both agencies wanted EPA to consider whether a specific level of contamination poses an unacceptable risk to people who use groundwater before considering classifying a pesticide for restricted use. In its latest draft, EPA incorporated the agencies' concern in option two.

[3]EPA's Office of Drinking Water establishes both MCLs and health advisory levels. The former are enforceable standards for community water systems limiting the amounts of various contaminants sometimes found in drinking water. The latter are nonmandatory guidance for water suppliers and state officials to use when contaminants—especially those lacking an MCL—are detected in water supplies.

In the draft rule, EPA states two reasons for its preference for option one, which would permit the agency to consider restricting a pesticide's use without regard to the specific level of contamination that may occur or has occurred. First, EPA believes that considering a pesticide for restricted use when the pesticide has been detected at any level would allow the agency to reduce the likelihood of significant groundwater contamination at the earliest possible time. Second, option one is simpler to understand and administer and depends on less monitoring data than option two.

In our opinion, option one seems reasonable because pesticides meeting one of the criteria will be considered for restricted use, not automatically restricted. Moreover, option one would provide for more pesticides to be considered, at an earlier time, for this regulatory measure. Once a pesticide meets a criterion to be considered for classification, the agency is still required by FIFRA to consider the pesticide's risks and benefits before actually imposing the classification. At this stage, EPA would consider a number of factors, including, for example, the character of the toxicological concern and the risk associated with known levels of contamination. If after consideration of these and other factors, EPA determines that the pesticide presents an insignificant hazard, the agency would not restrict its use to certified applicators.

Additionally, as new information on the health effects of a pesticide becomes available, new concerns about previously acceptable levels of contamination may arise. If contamination is permitted to reach a level that is later determined to be too high, the only options would be to clean up or treat the contaminated water. We believe that the case of simazine supports the rationale for considering a pesticide for restricted use on the basis of its potential to reach groundwater on a widespread basis, without regard to the known toxicity of a specific level of contamination.

Toxic Effects of Simazine Discovered After EPA Rescinded Restricted-Use Classification

In 1984, EPA proposed through the interim Registration Standard for simazine that the pesticide be classified restricted-use because of concern about groundwater contamination. In the Registration Standard, EPA stated that available data were insufficient to assess fully the environmental fate of simazine and the exposure of humans and other nontarget organisms; EPA also expressed concern about the pesticide's contamination of groundwater and stated that simazine was known to leach through soil and had been found in groundwater. On the basis of

that concern, EPA proposed both a restricted-use classification and a groundwater advisory for simazine.

The registrant for simazine contested both the groundwater advisory and the restricted-use classification on the grounds that the registrant's studies indicated no widespread groundwater contamination from the normal use of the pesticide.[4] The issue of contamination by simazine was brought before the FIFRA Scientific Advisory Panel for review. Provided for in FIFRA, the Panel is composed of outside experts who advise EPA of the impact on health and the environment of various actions taken under FIFRA. The Panel concluded that detections of simazine in groundwater did not indicate that the pesticide was occurring extensively at levels warranting serious concern. Further, it concluded that existing toxicity data on simazine did not indicate it posed a toxic threat to humans. EPA thereafter rescinded the restricted-use classification. The registrant earlier had dropped its attempt to have the groundwater advisory deleted, and it remained on the labels.

Many gaps in simazine's toxicity data existed at the time the Panel conducted its review. More recent data indicate that simazine is a possible human carcinogen, increasing concern about the levels of simazine that have been detected in groundwater. According to EPA's 1988 report, one detection of simazine at 9.1 parts per billion was above EPA's health advisory level of 4 parts per billion that existed in 1988. Since these studies were published, however, EPA has lowered the health advisory level for simazine to 1 part per billion as a result of the agency's review of new studies of the pesticide's chronic health effects. Thus, the highest detection reported in 1988 was about 9 times the current health advisory level, and several other detections exceed the current health advisory level for simazine. OPP is beginning to consider possible regulatory actions for simazine.

Effectiveness of Restricted-Use Classification to Protect Groundwater Is Unknown

Restricting pesticides to use only by certified applicators is a minor weapon in EPA's arsenal to protect groundwater from contamination by pesticides that leach from normal agricultural use. The actual effectiveness of the restricted-use classification in reducing groundwater contamination is unknown. Though many pesticides are already restricted to use by certified applicators for reasons other than concern about their

[4]The registrant also claimed that the agency did not follow proper procedures for imposing the restricted-use classification on the pesticide. The procedural issue was resolved when EPA initiated cancelation proceedings under FIFRA.

effect on groundwater, an added benefit is gained from additionally classifying such pesticides restricted-use on the basis of their potential to contaminate groundwater, according to one EPA official. The additional rationale, the official stated, will alert users to the leaching potential of the pesticides. But for two of the eight pesticides that are currently classified restricted-use, the reason for such classification is not indicated on product labels. For pesticides that are already classified restricted-use, then, no additional gain would be evident unless the rationale appears on labels.

An EPA committee is recommending some changes be made in the placement and content of the restricted-use notice on labels to provide some consistency; this effort is in an early stage. According to a draft issue paper, the committee is advocating that the reason for the restricted-use classification be printed on the label. If EPA management approves such a requirement, the agency will issue a notice to registrants informing them of this change. We believe this policy would be beneficial because it would alert pesticide users to the need to take extra precautions to protect groundwater from contamination.

According to EPA's draft rule, the agency believes that the restricted-use classification can reduce groundwater contamination resulting from both misuse and spills at mixing, loading, or application sites. To the extent that these occurrences are responsible for pesticides' leaching into groundwater, the classification may be effective. According to EPA, certified applicators are more likely to follow label instructions than noncertified applicators because the former are better trained in techniques for pesticide mixing, loading, application, and disposal and are more aware that adverse environmental consequences may result if label instructions are not followed. The restricted-use classification will be all the more necessary, EPA believes, if the agency requires label changes for a pesticide. According to the draft rule, such changes are likely to require complex operations, equipment, or detailed knowledge, and the failure to follow changed directions on labels may result in a significant risk of groundwater contamination. EPA believes that certified applicators are more likely to have the required equipment and knowledge. In the absence of such label directions, the agency believes, the restricted-use classification can still reduce the potential for groundwater contamination because certified applicators are likely to exercise better judgment when contamination is a concern.

The restricted-use classification is a means by which EPA can ensure that applicators of pesticides with the potential to reach groundwater on a

widespread basis receive training on the proper use of pesticides. Although current regulations do not require that applicators be trained in techniques for protecting groundwater, the agency has proposed regulations that would require such training in the future and has prepared pertinent training materials. But even when applied properly, pesticides may still leach. Several pesticides that have been detected in groundwater are currently restricted to use by certified applicators because of EPA's concerns about their toxic effects. In such cases, the restricted-use classification would need to be used in combination with other specific types of limitations on pesticide use, or specific information would need to be provided to applicators, so that the potential for groundwater contamination is reduced further.

EPA Has Infrequently Utilized Specific Use Limitations to Minimize Groundwater Contamination

EPA has the regulatory authority to impose restrictions on a pesticide's use other than restricting its use to certified applicators. Such restrictions might include, for example, geographic use prohibitions and limitations on application near wells. In some cases, use restrictions have been imposed by EPA on pesticides for reasons other than concern about groundwater contamination, such as to prevent crop damage or prevent illegal residues on crops. In addition, specific instructions about factors that promote leaching can help pesticide users minimize the potential for groundwater contamination from pesticides, according to OPP officials.

In March 1987, EPA did take action to decrease one type of risk to groundwater, implementing a uniform label requirement concerning the use of pesticides through irrigation systems. Labels of agricultural-use pesticides applied through irrigation systems (in a practice known as chemigation) must include a requirement to use certain types of safety equipment. The safety equipment prevents fluid containing a pesticide from flowing backwards towards a well or other water source. For pesticides not intended to be applied through irrigation systems, a statement prohibiting such use must be included on the label. EPA believes that such a uniform label requirement is beneficial because it can be enforced to ensure compliance.

In some other cases in which EPA has not taken action, registrants have volunteered to impose specific types of restrictions on pesticides because of their effect on groundwater. EPA has approved some of these voluntary restrictions, incorporating them into labels as enforceable statements. While EPA has the authority itself to impose such restrictions, agency officials assert that unless EPA can convince the registrant that a restriction is necessary, implementation could take several years.

Current labels for 4 pesticides—aldicarb, carbofuran, DCPA, and oxamyl—among the 13 contain a geographic use prohibition against their use in certain counties on Long Island. According to EPA Registration Division officials, these restrictions were volunteered by the registrants as a direct result of extensive groundwater contamination that was discovered in that area, in some cases as early as 1979. The registrant for aldicarb also took action to prohibit use of the pesticide in several other counties in California and Oregon as a result of groundwater contamination, and further modified the use of aldicarb on potatoes in several other states.

Use of only 2 pesticides among the 13 is restricted by well setbacks, which prohibit the use of the pesticides within a specified distance from wells. These setbacks are specifically intended to allow time for the pesticide to dilute or degrade before it reaches the well. In one case, pesticide use is prohibited within 50 feet of any well. According to a director within the Office of Ground Water Protection, a 50-foot setback offers only minimal protection to the vulnerable area around a well. In the second case, pesticide use is prohibited within at least 50 feet of any drinking water well, but, in addition to this minimal setback, more stringent setbacks are also required based on factors that may influence permeability, such as the depth of the water table and the type of soil present.

EPA has not actively pursued other types of enforceable statements that would limit the use of pesticides under conditions that promote leaching—particular types of soils in combination with certain factors such as the expectation of rainfall and other climatic conditions. According to senior OPP officials, after discussing this issue with many interested parties, they believe such complex restrictions stated on labels would be difficult for applicators to understand and apply, and therefore would be impractical to enforce fairly.

However, such information might be useful to some pesticide applicators, who may be concerned about the safety of their own well water. Several OPP officials have expressed support for providing more specific statements about the soil and climatic conditions that promote leaching because such statements can give applicators the information they need to reduce the potential for groundwater contamination.[5] In addition,

[5]While groundwater advisories sometimes counsel against use when the soil is permeable and when the water table is close to the surface, these statements are not specific enough to provide the type of information applicators need to know in order to minimize groundwater contamination.

according to one EPA official, because the various pesticides have different characteristics, the agency needs studies on each pesticide's individual leaching characteristics to identify the conditions that promote its leaching. Therefore, EPA's slow review of submitted data may be precluding the agency from providing this information to pesticide users.

Imposing geographic use prohibitions and well setbacks, on the other hand, does not require such data. A geographic use prohibition could be imposed on the basis of groundwater monitoring studies showing the level of actual contamination in that particular location. According to a 1988 study, 9 of 46 pesticides known to leach from normal agricultural use have been detected in groundwater at levels greater than their health advisory levels. Five of the 9 are among the 13 pesticides in our review. Others have been detected at levels exceeding 50 percent of their current health advisory levels. (More information on the 46 pesticides detected in groundwater is in appendix II.) Contamination of groundwater above health advisory levels or maximum contaminant levels presents a potential health risk, yet EPA currently has no policy to prohibit further use of a pesticide within a limited geographic area under such circumstances. According to OPP's draft strategy for pesticides in groundwater, EPA will consider regulatory actions, including the possibility of prohibiting use of a pesticide in designated areas, when the level of a pesticide in groundwater is close to or exceeds a maximum contaminant level. However, senior OPP officials told us they would prefer to have states take such actions.

Well setbacks could also be imposed on the basis of general information the agency possesses about pesticide movement in various soil types. For example, use of any pesticide that is known to leach could be prohibited within a specified distance of wells in sandy soil, a soil type in which pesticides may leach more readily. EPA could impose well setbacks and geographic use prohibitions now, before conducting a complete assessment of a pesticide's leaching potential.

Groundwater Contamination Does Not Trigger Special Reviews

Special Reviews of eight pesticides have assessed these pesticides' presence in groundwater. Groundwater contamination at levels presenting cancer risks contributed to EPA's decisions to cancel the registrations of two pesticides that the agency had identified as groundwater contaminants by 1985. For pesticides undergoing reregistration, Special Review—a risk-benefit analysis—allows EPA to consider pesticides on a priority basis and act on serious concerns outside the usual, lengthy reregistration process. However, groundwater contamination is not among

the specific criteria in EPA's regulations for initiating Special Reviews. According to Special Review officials, EPA's current practice is to assess threats to groundwater through Special Review when a pesticide also presents health concerns. In completed Special Reviews, new regulatory measures have been imposed to address groundwater contamination only when the level of pesticide present in groundwater presented health risks. However, FIFRA would allow consideration of other types of risks in Special Reviews; EPA could consider groundwater's value as a resource and the cost of cleanup, for instance.

Special Review Criteria Do Not Specifically Address Groundwater

EPA's regulations that specify criteria for initiating Special Reviews (40 C.F.R. 154) do not specifically include groundwater contamination by pesticides. OPP's current practice is to assess groundwater contamination in Special Reviews if the pesticide also presents potential risks to human health or wildlife. In EPA's regulations, specific triggers for initiating Special Reviews are risks to human health, specifically acute and chronic health effects (such as cancer, gene mutations, and adverse effects to the reproductive system), and certain effects on wildlife. The regulations also include a general trigger that can be used to initiate Special Reviews on the basis of other significant risks to humans or the environment.

To date, Special Reviews that have addressed groundwater contamination also met one or more of the specific triggers. For instance, groundwater contamination was a factor in the review of EDB—a pesticide that was used to fumigate soil, stored grain, quarantined fruits and vegetables, and grain milling machinery—but EPA initiated EDB's Special Review on the basis of several chronic toxicity triggers. According to the Chief of the Special Review Branch, the general trigger in EPA's regulations for initiating reviews could also be applied to groundwater contamination, but, in her opinion, EPA would still need to demonstrate that data indicate a potential health risk from the pesticide's leaching into groundwater. To date, EPA has not applied the general trigger to contamination of groundwater by pesticides.

While OPP's current approach offers some consideration of potential groundwater contamination, it does not recognize that toxic effects of a pesticide could be discovered after groundwater has been contaminated. If EPA does not address groundwater contamination through Special Reviews because the levels of pesticides found in groundwater are not currently known to be toxic, contamination could continue to occur. If in the future, new toxic effects are discovered, EPA would have limited

recourse because, once contaminated, groundwater is very difficult to clean up.

Toxic effects not currently known could be discovered through the reregistration program or through new toxicity testing EPA is planning. The agency is still in the process of gathering data to meet existing data requirements through the reregistration program, and significant unknowns about possible health risks remain for many pesticides. Furthermore, EPA continues to add new toxicity testing as science advances. For instance, the agency currently requires limited testing for neurotoxicity (effects on the nervous system), but expects to propose new tests in 1991 covering previously unstudied potential risks to the nervous system. According to a recent report by the Office of Technology Assessment, pesticides are one of the most commonly encountered neurotoxins, which can adversely affect coordination, vision, learning, and memory.[6] EPA is also considering requiring tests for pesticides' effects on the immune system.

EPA has, in fact, discovered toxic effects of a pesticide after it was known to leach into groundwater. As discussed above, simazine's health advisory level was lowered recently because of new testing for chronic toxicity. A number of detections of simazine in groundwater are above the new health advisory level, though only one detection was above the previous health advisory level. Similar situations could occur in the future, with the pesticide DCPA, for instance. It was the most frequently found pesticide in the National Pesticide Survey of Drinking Water Wells. According to DCPA's interim Registration Standard, EPA did not feel that regulatory action was warranted because of DCPA's low toxicity and the low levels found in groundwater; the highest level of DCPA found in groundwater was less than one-third the pesticide's current health advisory level, which is based on the pesticide's potential to affect the kidney. At the time of DCPA's interim Registration Standard in June 1988, significant gaps in the data concerning DCPA's toxicity existed. EPA had no studies concerning carcinogenicity and effects on the reproductive system, for instance. If through new studies the pesticide is found to pose some other toxic effect at the levels already occurring in groundwater, EPA would have limited options for dealing with the contamination.

[6]Neurotoxicity: Identifying and Controlling Poisons of the Nervous System, U.S. Congress, Office of Technology Assessment (OTA-BA-436, Apr. 1990).

According to attorneys in EPA's Office of the General Counsel, FIFRA allows EPA to initiate Special Reviews and regulate pesticides on the basis of groundwater contamination regardless of the pesticide's toxicity. The agency could consider the value of groundwater as a present and future resource, the costs of cleanup, contamination of aquifers where there is no alternative drinking water source, and ecological effects. EPA's attorneys pointed out that the current approach of the Special Review Branch is a policy choice that is also consistent with FIFRA.

Eight Special Reviews Considered Groundwater Contamination

Of the 16 pesticides that EPA had identified as groundwater contaminants by 1985, 8 either are currently in Special Review or have been reviewed in the past. EPA has discussed potential groundwater contamination during each of the eight reviews. The four completed reviews have resulted in the cancelation of three pesticides and changes to the product labels for one pesticide. Four other pesticides are currently undergoing Special Review.

For all three canceled pesticides (EDB, DBCP, and dinoseb), groundwater contamination was considered during the Special Review. For two of the three (DBCP and EDB), groundwater contamination at levels presenting health risks was one of the factors leading to EPA's decisions to remove the pesticides from the market. Specifically, EPA's emergency suspensions of DBCP and EDB were based both on groundwater contamination occurring at levels EPA determined presented significant cancer risks and on risks, through occupational exposure or food, of carcinogenicity, mutagenicity, and adverse effects to the reproductive system. In 1979, EPA suspended and canceled all uses of DBCP except its use as a soil fumigant for pineapples grown in Hawaii; in 1985, EPA canceled this use.[7] Both actions were based in part on groundwater contamination; for the use on pineapples, EPA's major concern was possible toxic effects due to exposure through drinking contaminated groundwater. EPA suspended EDB's use as a soil fumigant in 1983, in part on the basis of the agency's finding that potential drinking water contamination from this use posed unacceptable risks and resulted in an imminent hazard. The agency suspended dinoseb—a herbicide, insecticide, and fungicide that was used on soybeans, peanuts, cotton, potatoes, and alfalfa—in 1986 on the basis of health risks to agricultural workers. However, groundwater contamination was mentioned as a minor issue in the suspension notice, and EPA determined that the levels of dinoseb found in groundwater

[7]DBCP was a fumigant used for cotton, soybeans, and a number of fruits, nuts, and vegetables.

were well below the level that the agency believed would present a health risk.

One other pesticide among the 16 known groundwater contaminants—cyanazine, a herbicide used on corn, cotton, and sorghum—was in Special Review in the past, but EPA dealt with the pesticide's risks to groundwater and pesticide applicators by measures other than cancelation. For the first risk, EPA decided that the existing groundwater advisory on product labels was sufficient to deal with potential groundwater contamination, because in monitoring studies, cyanazine was detected infrequently and at low levels. For the second risk, the agency required label warnings and protective clothing to reduce the risk of birth defects.

Four of the 16 groundwater contaminants identified in 1985—alachlor; aldicarb; carbofuran; and 1,3-dichloropropene—are currently in Special Review. All four Special Reviews have at least mentioned groundwater contamination, and it is a major issue in the review of aldicarb. These ongoing Special Reviews are summarized in appendix III.

The Special Review of aldicarb—an insecticide and nematicide[8] used on potatoes, peanuts, citrus fruits, soybeans, and cotton—focuses on its acute toxicity to people consuming residues in food and drinking contaminated groundwater. Aldicarb can affect an enzyme in the nervous system from short-term exposure (acute toxicity), with possible effects including gastrointestinal disturbances, blurred vision, seizures, and even death. EPA has proposed that aldicarb's potential to contaminate groundwater be addressed through EPA-approved SMPs. According to Special Review officials, aldicarb is likely to be the first pesticide regulated using these means. However, if EPA decides that SMPs for aldicarb are needed, they will take several years to be developed, approved, and implemented.

EPA Proposes State Management Plans for Pesticides That Leach

In a new regulatory approach, EPA plans to request that states develop SMPs, through which the states would regulate certain pesticides known to leach into groundwater. However, SMPs are still in the planning stage, and their implementation for any pesticide is several years away. In addition, EPA has not yet resolved several issues concerning the plans. For example, the agency has yet to clarify the relationship between nationwide regulatory measures and SMPs.

[8]A nematicide is a pesticide used to control or kill nematodes (roundworms).

EPA's Proposal Would Give States a Strong Role

Through an SMP for a pesticide, a state would have the responsibility to determine measures for minimizing groundwater contamination by the pesticide. This approach is consistent with EPA's overall principles regarding groundwater, which advocate a primary role for states in protecting groundwater. Through SMPs, EPA hopes to avoid overregulating in less vulnerable areas and underregulating in more vulnerable areas. SMPs would vary in content depending on pesticide use and the vulnerability of groundwater within individual states. EPA expects state plans to fall into three general categories: baseline, moderate, and full-scale. Appendix IV describes the elements of the three types of plans.

EPA anticipates that its role in the development of SMPs would include identifying pesticides needing the plans, providing guidance and technical information to states, and reviewing and approving the plans. EPA expects to choose pesticides needing SMPs on a case-by-case basis, by considering risks and benefits. EPA considers SMPs a relatively severe measure appropriate for pesticides likely to cause (1) unreasonable adverse effects through the contamination of groundwater and (2) risks that vary substantially at the local level. Therefore, not every pesticide that leaches into groundwater would have SMPs. EPA plans to issue guidance during fiscal year 1991 to assist states in developing the plans. The guidance would describe (1) the contents of the three categories of SMPs, (2) EPA's processes for evaluating and approving SMPs, (3) methods for developing groundwater monitoring programs and for using geographical data to identify areas for monitoring, and (4) appropriate state responses to detections of pesticides in groundwater.

FIFRA does not grant EPA the authority to require states to develop SMPs. Rather, the agency would regulate registrants by conditioning the use of certain pesticides on the existence of SMPs. According to OPP officials, the agency has decided to use the authority of section 3 of FIFRA to request SMPs in most cases, but in those cases where there are major risk factors in addition to concerns about groundwater contamination, EPA plans to use the authority of section 6 of FIFRA. If EPA uses section 3, which gives the agency the authority to impose the restricted-use classification and specific use limitations, SMPs would be imposed through a rulemaking procedure as a use restriction. If the agency uses section 6, which provides the authority to cancel the registration of a pesticide if its risks outweigh its benefits, SMPs would be imposed during cancelation procedures, and pesticide use would be allowed to continue in states with SMPs. In either case, use of the pesticide would be prohibited in states without an SMP. The label on the pesticide products would state that use is contingent upon the existence of an EPA-approved SMP.

The length of time that states will have to develop and implement SMPs is uncertain. An official in OPP's Field Operations Division estimates that the states may need about 2 years to develop their first SMP for a specific pesticide, with subsequent plans taking less time. In order to facilitate the process, EPA is encouraging states to begin developing generic SMPs (containing elements applicable to many pesticides) now and to submit them to the agency for preliminary approval before the 1992 growing season.

In order to encourage advance planning, OPP dispersed $5 million among the states in fiscal year 1990 to assist with the development of generic SMPs. States received total allocations composed of a base amount ($50,000 for each state) plus an amount based on need. States with heavy pesticide use and vulnerable groundwater, such as Iowa, Georgia, and Florida, received the highest percentage of the funding based on need. For fiscal year 1991, OPP has the same level of funding to encourage the development of SMPs.

The Office of Ground Water Protection also has grants available that states may use for developing SMPs. In fiscal year 1990, approximately $1.7 million was available under section 106 of the Clean Water Act for specific measures to protect groundwater from contamination by pesticides. For fiscal year 1991, this office has $2 million in funding targeted specifically to help develop SMPs.

EPA Has Yet to Clarify Some Issues

As SMPs are still in the planning stage, several issues have yet to be resolved. These include uncertainties about how states' and EPA's actions to prevent groundwater contamination would interrelate, whether states have adequate technical information for developing and implementing the plans, and how effective the plans would be in minimizing groundwater contamination by pesticides.

Questions remain about the relationship between states' actions to prevent groundwater contamination through the SMPs and EPA's actions to impose regulatory measures at the national level. The agency has indicated its intent to continue to address groundwater contamination at the national level by imposing some use restrictions. The draft Pesticides and Groundwater Strategy states that prior to imposing SMPs for a pesticide, EPA would determine whether national label restrictions and additional training required by the restricted-use classification adequately address concerns about the pesticide's leaching. However, it is unclear whether EPA would be willing to impose other national use restrictions

(such as well setbacks and geographic use restrictions) after SMPs are implemented for a certain pesticide or whether states would have most of the responsibility for imposing limitations to prevent groundwater contamination.

A practical issue that is unresolved is whether the states would have adequate technical information with which to develop and implement plans. GAO is currently reviewing one aspect of this issue—the quality of state assessments of the vulnerability of groundwater. EPA plans to provide technical assistance to the states, but the agency is unsure of the extent of information that will be available. The scientific community's understanding of groundwater contamination and the best means for addressing the problem are still developing. The agency also has yet to decide whether and how it would help states share information among themselves. EPA currently has no formal mechanisms set up to facilitate this task.

Finally, the effectiveness of states' actions to prevent groundwater contamination cannot be known for some time until after SMPs are implemented. With several questions unresolved, it may be several years before the first SMP is developed and implemented, and certain pesticides, if otherwise unregulated, will continue to leach into groundwater in the interim.

Conclusions

EPA's policies regarding groundwater call for the agency to protect the integrity of the resource and prevent contamination from posing unreasonable risks to people and the environment. Under FIFRA, EPA has a number of regulatory measures available to accomplish these goals, yet it has not consistently utilized them for the first 16 pesticides detected in groundwater. As a result, groundwater contamination by pesticides could continue unnecessarily, perhaps creating pollution that will prove difficult, costly, or even impossible to remedy and that may pose health and environmental risks as yet unknown.

A groundwater advisory, a minimal regulatory step, does not appear on the current approved labels for 4 of the 13 pesticides still in use. The inconsistent application of this measure could leave some users uninformed about potential threats to groundwater. For the 9 pesticides that currently have a groundwater advisory, its prominence on labels is not uniform.

Though 8 of the 13 pesticides have the restricted-use classification, not a single one has had this measure imposed by EPA because of concern about the pesticide's effect on groundwater. According to agency officials, EPA has been unsuccessful because its regulation does not include specific criteria for imposing the restriction on this basis. To rectify this problem, EPA is drafting a rule that will propose specific criteria to identify candidates for restricted use. OMB and USDA, which reviewed the proposal, commented that the toxicity of the contamination, as well as the pesticide's potential to reach groundwater on a widespread basis, should be included in the criteria. EPA prefers not to include the issue of toxicity in the specific criteria, a position that would provide for more pesticides to be considered for this regulatory measure. Because future health risks remain uncertain, criteria that do not take into consideration the known toxicity of the contamination seem reasonable. Moreover, FIFRA requires that EPA consider a pesticide's risks and benefits before actually classifying the pesticide restricted-use. If EPA determines that the pesticide presents an insignificant hazard, the agency would not restrict its use to certified applicators.

Except for implementing label requirements regarding chemigation, EPA has not actively pursued specific limitations, such as geographic use restrictions and well setbacks, on the use of the 13 pesticides still registered. Some registrants have volunteered to impose these restrictions on pesticide use, and EPA has approved these measures. We believe EPA could be more active in imposing these limitations on the basis of currently available knowledge. Specifically, geographic use restrictions could be imposed where contamination from normal agricultural use has been detected at a set percentage of the health advisory level. Setting a percentage well below 100 percent could help keep contamination in specific locations from worsening and presenting a potential health risk. Further, well setbacks could be imposed on the basis of general knowledge about the soils in which pesticides are most likely to leach. FIFRA would require that EPA consider risks and benefits before imposing such limitations on a pesticide's use.

The agency's slow review of the studies concerning the potential for groundwater contamination delays obtaining useful information about a pesticide's leaching potential in certain kinds of soils under various climatic conditions. Though EPA believes this information is too complex to place on pesticide labels as enforceable use directions, we believe that it would be useful to some pesticide users and should be provided to them once it is available. With increasing concern in rural areas about the safety of well water, pesticide applicators who rely on well water may

be willing to make extra efforts to protect it from contamination by pesticides. The information could be provided in several ways, such as through additional training about specific pesticides, informational mailings, or pamphlets distributed with pesticide products.

Groundwater contamination is not a specific trigger to initiate Special Reviews. While groundwater contamination has been assessed in a number of Special Reviews, they have been conducted only when the pesticide also presented other risks, and measures to address groundwater contamination have resulted only when pesticide levels occurring in groundwater presented health risks. However, knowledge of the possible toxic effects of pesticides is not complete, and new information could raise serious concern in the future about the health effects of a pesticide. If a pesticide has been allowed to contaminate groundwater in the meantime, risks to health and the environment may occur and options for cleaning up the groundwater will be limited and costly. When EPA initiates and conducts Special Reviews, the agency could consider, in addition to known health effects, factors such as the costs and difficulty of cleaning up groundwater, the importance of affected and threatened aquifers as sources of drinking water, potential effects to ecological systems and surface waters linked to affected aquifers, and groundwater's value as a resource for the future. When the SMP program is in effect, these factors may also be relevant in deciding whether to require SMPs for a pesticide.

As part of its regulatory scheme to protect groundwater, EPA plans to propose that states develop SMPs for some pesticides. As the concept is in an early stage of development, its impact on state and federal roles in protecting groundwater is unclear at this time. Because it will probably be several years before SMPs can be implemented for any pesticide and because EPA is unlikely to impose SMPs for all pesticides that leach, we believe national regulatory measures to minimize groundwater contamination will continue to be needed. If SMPs are implemented for a pesticide, EPA could reevaluate the appropriateness of federal regulations in light of states' activities.

Recommendations

To help prevent groundwater contamination, we recommend that the Administrator, EPA, promptly take the following actions on the basis of existing information:

- require a groundwater advisory for all pesticides known to leach into groundwater from normal agricultural use, to appear on labels under a

prominent heading such as "Groundwater Advisory," in order to alert the user to the problem;

- establish a percentage of the health advisory level as a criterion for prohibiting the use of a pesticide in any geographic area where the groundwater contamination from the normal agricultural use of that pesticide has reached that percentage; and
- establish a pesticide's potential to leach or actual detection in groundwater as a criterion for requiring well setbacks.

To minimize further groundwater contamination, we further recommend that after acceptable data are obtained and reviewed, the Administrator, EPA, conduct a complete leaching assessment of pesticides with a potential to leach, and provide specific information to applicators concerning the conditions that promote the leaching of these individual pesticides, including the soil characteristics and climatic conditions.

So that EPA can act preventively before contamination reaches potentially hazardous levels, we recommend that the Administrator establish a criterion for initiating Special Reviews on the basis of pesticides' potential to contaminate groundwater. We further recommend that during Special Reviews, the agency consider risks to water resources resulting from groundwater contamination, and even if levels of a pesticide found in groundwater are well below the level currently considered to present a health risk, the agency should consider the pesticide's presence in groundwater to be a risk.

EPA Lacks Assurance That Tolerances for Groundwater Contaminants Are at Safe Levels

A person's risk from a pesticide depends on its toxicity and the total level of exposure—from food, water, and other sources, such as use in the home. The Federal Food, Drug, and Cosmetic Act (FFDCA) allows but does not require EPA, when it sets tolerances (limits) for pesticide residues in food, to consider additional sources of exposure, such as water contaminated by pesticides. But in setting and reviewing tolerances for pesticide residues in food, EPA does not routinely take into consideration consumption of groundwater contaminated by pesticides as an additional source of exposure.[1]

To date, only for seven pesticides of all those now known to contaminate groundwater has OPP incorporated estimates of exposure resulting from groundwater contamination in risk assessments for tolerances. Generally, OPP's methodology for assessing proposed or existing tolerances does not consider exposure from contamination in groundwater. Thus, for many pesticides that leach into groundwater, OPP lacks assurance that it is setting tolerances at safe levels in light of possible additional exposure from contaminated water. Unlike OPP, EPA's Office of Drinking Water (ODW), in developing drinking water advisories and regulations, routinely accounts for sources of exposure in addition to water.

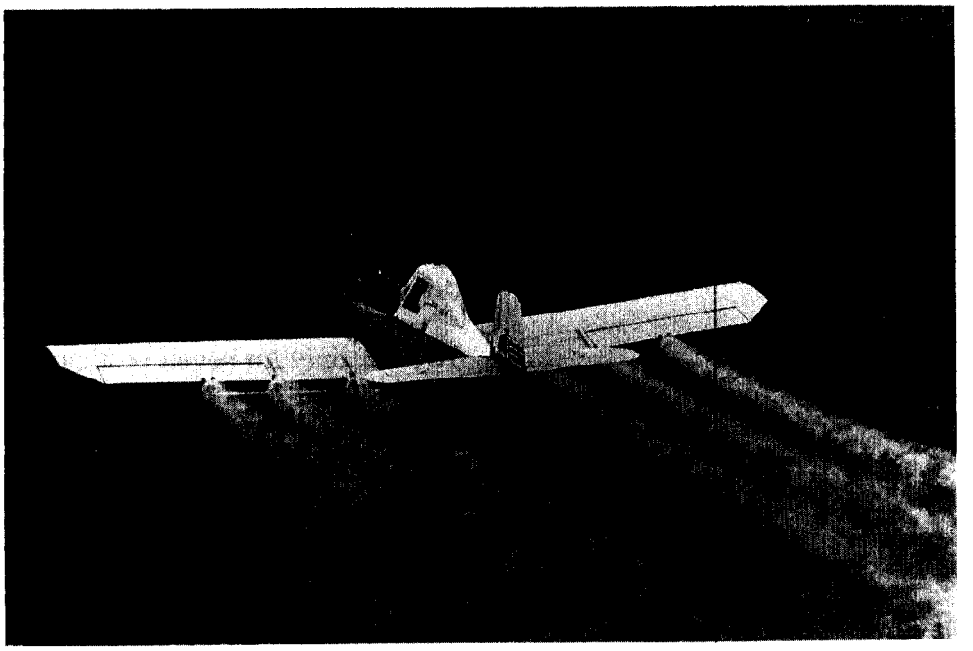
Health Risks From Pesticides Depend on Their Toxicity and Exposure to Them

The risk of pesticide residues depends on both their toxicity and potential human exposure to residues in the diet. Figure 4.1 illustrates routes of pesticide exposure.

[1]Information in this chapter applies to all pesticides known to contaminate groundwater, not just to the 16 pesticides EPA had identified as groundwater contaminants by 1985.

Figure 4.1: Pesticide Exposure Through Food and Groundwater

Pesticide Application to a Florida Orange Grove

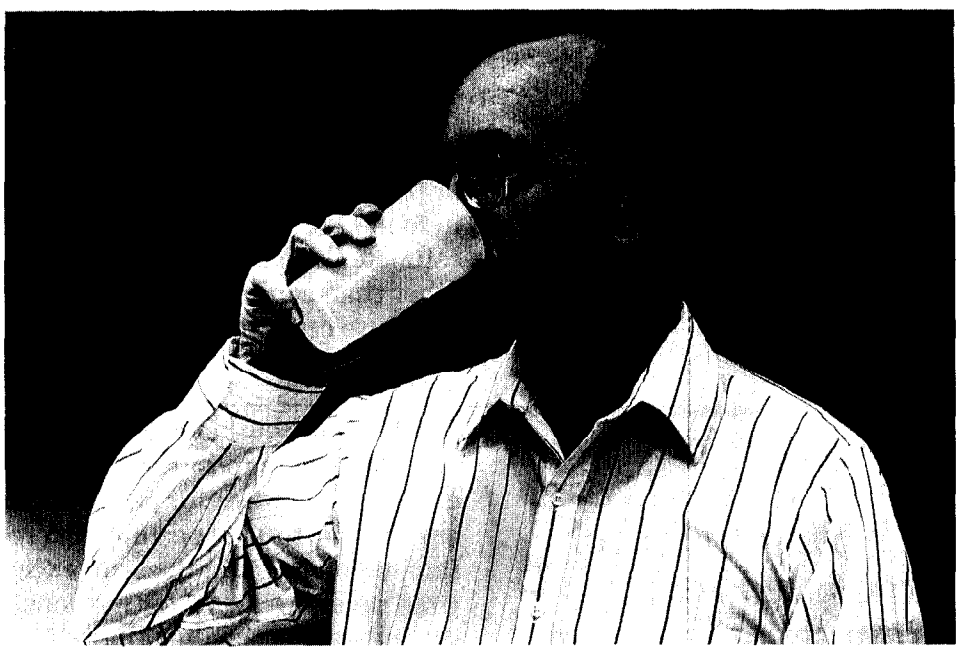


Source: USDA.

Exposure Through Food

Source: USDA.

Exposure Through Groundwater



To assess pesticide toxicity for effects other than cancer, EPA determines an acceptable daily intake (which EPA scientists now call a reference dose). This is a daily ingestion level of pesticide residue that is not expected, on the basis of all facts known at the time, to cause an appreciable health risk during a person's lifetime. The acceptable daily intake is derived from animal studies, submitted by registrants, that address a number of acute and chronic health effects, including birth defects and effects on the reproductive system.

EPA usually does not use an acceptable daily intake to assess cancer risk because scientists have been unable to determine whether a safe threshold level exists for carcinogens. On the assumption that some risk of contracting cancer exists for even minute exposures to the residues of a carcinogenic pesticide, EPA uses data from animal studies to assess the relationship between the dose of a carcinogen and the probability of inducing a carcinogenic effect.

Exposure to pesticide residues in food depends on (1) the level of pesticide residue in each food commodity on which a pesticide is used and (2) the amount of each food commodity consumed. Residue chemistry studies submitted by pesticide manufacturers provide information on the chemical identity and amount of residue in food commodities. OPP

has an automated system, the Dietary Risk Evaluation System (DRES), formerly known as the Tolerance Assessment System, which currently includes estimates of food and water consumption for the overall U.S. population and 22 population subgroups based on age, gender, race, region of residence, and season of the year. In all assessments of current or proposed tolerances, OPP uses DRES to compute exposure from residues in food.[2] For each subgroup addressed, a DRES analysis lists an exposure estimate for pesticide residues in food and calculates, for chronic effects other than cancer, the percentage of the acceptable daily intake the exposure estimate occupies.

Tolerances for Pesticides That Leach Do Not Account for Exposure From Groundwater

OPP does not routinely account for pesticides' presence in groundwater as a source of exposure when the Office sets new tolerances or reviews existing tolerances for pesticide residues in food. As a result, OPP cannot ensure that total exposure from residues allowed in food and from contamination in water does not exceed safe, acceptable levels. OPP officials cited several reasons for not considering exposure from pesticides in groundwater, including the difficulty of accounting for localized contamination in setting tolerances, which are nationwide regulations.

OPP's Usual Methodology Does Not Address Exposure Resulting From Groundwater Contamination

OPP's usual tolerance assessment methodology addresses only exposure from residues in food. To determine whether potential exposure is acceptable, for health effects other than cancer, OPP compares estimates of exposure from residues in food to the acceptable daily intake. If the estimated exposure from food is less than the acceptable daily intake, OPP concludes that tolerances protect public health. Thus, estimated exposure from food is allowed to utilize up to 100 percent of the acceptable daily intake, with no routine adjustment for potential exposure from pesticides in groundwater.

For at least two interim Registration Standards—for DCPA and oxamyl—OPP had available the information needed to include estimates of exposure due to contaminated groundwater, but did not do so. According to OPP staff who participated in developing the Registration Standard for oxamyl, a DRES analysis of dietary risk that incorporates exposure from contamination in groundwater was not done because such an analysis was not considered part of the Registration Standard process, though it

[2]More information on DRES and tolerance risk assessments can be found in Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food (GAO/T-RCED-89-35, May 17, 1989).

may be part of Special Review. (EPA officials could not tell us why such an analysis was not requested for DCPA.)

In fact, in assessing risks for existing tolerances, OPP has incorporated estimated exposure due to contaminated groundwater for only seven pesticides, in conducting Special Reviews or in considering additional regulatory actions for these pesticides. (These seven cases are discussed below.) In addition, in setting new tolerances, OPP has never estimated and considered exposure resulting from pesticides' presence in groundwater. According to officials of OPP's Health Effects Division, OPP has no plans to routinely account for exposure from groundwater when assessing tolerances.

OPP Cites Several Reasons for Not Routinely Assessing Exposure Due to Contaminated Water

OPP officials mentioned several reasons for not routinely incorporating estimates of exposure from drinking water when assessing tolerances for pesticides that leach into groundwater. One reason, according to officials in OPP's Health Effects Division, is that not every instance of groundwater contamination would need to be considered. The officials assert that if exposure from residues in food is well below the acceptable daily intake and pesticide levels in groundwater are low in comparison to the health advisory level, OPP does not need to estimate exposure resulting from a pesticide's presence in groundwater. According to these officials, the time involved in estimating exposure from groundwater and considering it in regulatory decisions would be warranted if extensive groundwater contamination exists and exposure from food is at or near a level causing concern about effects on health. However, because OPP currently does not routinely determine if pesticide levels in food and groundwater are high enough to warrant estimating exposure from groundwater, the office has not ensured that risk assessments incorporating exposure from groundwater are done for the more critical groundwater contaminants. We recognize that the degree of health risk varies for different pesticides, depending on factors including (1) the level of exposure from food in comparison to the level presenting concerns about toxicity and (2) the extent and levels of groundwater contamination. If OPP were to assess these factors, and take the further step of estimating exposure from contaminated groundwater, we believe more complete information about a pesticide's risks would be available for decisions about tolerances.

A second reason OPP officials have for not considering exposure resulting from groundwater contamination is that contamination is often a local situation, but tolerances apply nationwide. Officials of both the

Health Effects Division and the Special Review Branch stated that considering local situations in setting national standards is difficult. In the opinion of the Special Review Branch Chief, because groundwater contamination varies so much from area to area, it is more appropriate to deal with the problem through SMPs than through tolerances. People's exposure and risk will vary depending on whether they use well water and on whether or to what degree that water is contaminated. Tolerances (if based on valid data) would protect people not facing sources of exposure other than food. However, because EPA's drinking water standards for community water systems will allow pesticides in drinking water up to an established level, it seems reasonable that tolerances for food should account for that possible exposure. For people who live in areas where groundwater is contaminated by a pesticide and who rely on well water, we believe the combined exposure from food and water should be addressed to prevent a potential risk to their health.

A third reason for not including estimates of exposure resulting from contaminated water, according to the former DRES manager, was that problems existed with water consumption data in DRES. Analyses using DRES' data on water consumption have been done only when specifically requested by the Special Review and Reregistration Division, Health Effects Division, or others, and reports of DRES analyses have often included explanations of problems with the data. OPP does plan to correct problems with DRES' water consumption data when the system is updated with more recent information on the consumption of food and water. According to the head of the Dietary Exposure Section, the time frame for updating DRES is uncertain.

Finally, exposure from groundwater might not have been estimated in the past due to a lack of the data needed to reassess tolerances. Because many pesticides are undergoing reregistration to update and complete required studies, data needed to assess exposure from food and the toxicity of pesticides are not always available. For instance, for some pesticides, the data are insufficient to determine an acceptable daily intake or to determine whether the pesticides are carcinogens. Once necessary studies are obtained, risks resulting from pesticide exposure through food and water could be assessed.

Unlike OPP, ODW Routinely Accounts for Multiple Sources of Pesticide Exposure

In contrast to OPP's usual methodology, ODW's methodology routinely uses a standard factor to account for the multiple routes of exposure to pesticides. The National Academy of Sciences also has past and current studies relevant to exposure assessment methodologies.

Under the Safe Drinking Water Act, ODW establishes maximum contaminant levels (MCL) to be met by the nation's community water systems (public water supplies with at least 15 connections or serving 25 or more people). MCLs are limits on the amount of various contaminants that sometimes occur in drinking water. As part of its process for developing these standards for pesticides, ODW assesses exposure. As of January 1991, ODW had final MCLs promulgated or in effect for 15 pesticides and for a number of other substances, such as industrial pollutants.[3] Of the 16 pesticides EPA had identified as groundwater contaminants by 1985, 5 have final MCLs promulgated.

ODW also issues nonmandatory health advisory levels for pesticides and other contaminants, in order to provide risk information to water suppliers and state officials when contaminants—especially those lacking MCLs—are detected in water supplies. Health advisory levels are set for short-term, longer-term, and lifetime exposure to a contaminant. As of November 1990, ODW had issued health advisories for 71 pesticides and pesticide breakdown products, including the 16 identified as groundwater contaminants by 1985.[4]

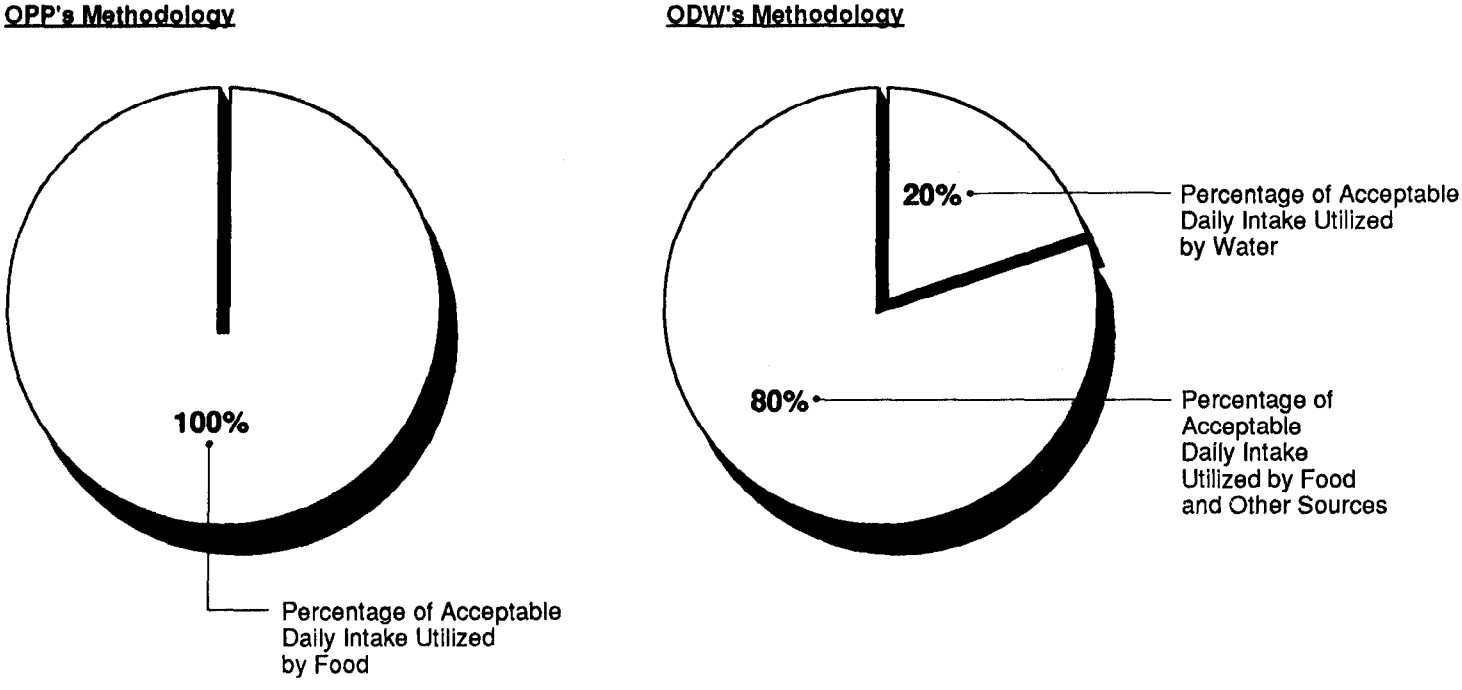
ODW's usual procedure to assess lifetime exposure involves using standard factors to account for the proportions of an individual's total exposure that result from contaminated drinking water and other sources (food, air, and others). This approach allows a margin of safety for multiple sources of exposure. ODW usually sets lifetime health advisories for noncarcinogens at 20 percent of the acceptable daily intake, assuming that 20 percent of a person's exposure to a pesticide comes from drinking water. This 20-percent assumption allows a margin (80 percent of the acceptable daily intake) for other sources of exposure so that the total is assumed to be within a safe, acceptable level.

Figure 4.2 summarizes the difference between OPP's and ODW's methods.

[3]Six pesticides have final MCLs in effect; five of these will be revised, effective July 30, 1992. Nine other pesticides had final MCLs promulgated January 30, 1991, that will take effect July 30, 1992.

[4]Of the 16, EPA has not established lifetime health advisory levels for 4 (alachlor; 1,3-dichloropropene; DBCP; and EDB) because they are probable human carcinogens, but has issued health advisory levels for shorter periods of time.

Figure 4.2: Comparison of OPP's and ODW's Methodologies



ODW's assessment process for developing MCLs also includes the 20-percent assumption, though EPA then takes other factors, such as the level at which a pesticide can be detected and the feasibility of water treatment, into account. In setting both MCLs and health advisories, ODW assesses carcinogens differently because some risk may exist even for minute levels of exposure.

ODW uses the 20-percent assumption unless it has specific data about the proportions of exposure resulting from various sources. The assumption is drawn from a 1977 National Academy of Sciences report that was mandated by the Safe Drinking Water Act of 1974. The report stated that because the calculation of acceptable daily intake values is based on the total amount of the pesticide ingested, the acceptable daily intake does not represent a safe level for drinking water alone. Therefore, in its assessments of certain pesticides, the Academy used 20 percent of total exposure as a hypothetical level for drinking water, and ODW has adopted this method. According to National Academy of Sciences staff, the report's authors did not intend for ODW to continue using the 20-percent assumption. Rather, it was intended as an interim measure until

ODW could obtain more precise data on the proportions of exposure that come from various sources. Staff in OPP's Health Effects Division similarly commented that using groundwater monitoring data would provide better estimates of actual exposure than the 20-percent assumption but added that the assumption is a reasonable way to reserve part of the acceptable daily intake for exposure from drinking water. According to staff of ODW's Criteria and Standards Division, ODW plans to continue using the 20-percent assumption in assessing most pesticides because data concerning the contribution of various sources to people's total exposure to pesticides are still rarely available.

As part of its ongoing study of the risks of pesticides to infants and children, the National Academy of Sciences/National Research Council plans to include several case studies addressing exposure to contamination in drinking water and the resulting risks, according to the study's project director. The Academy is conducting the study in accordance with a legislative mandate, and according to this official, the Academy expects to publish its results in the summer of 1991. In addition to estimating exposure from residues in food, the study committee plans to use groundwater monitoring data on several pesticides—if sufficient data are available—to estimate their levels in water and resulting exposure. The study committee hopes to estimate worst-case and average levels in groundwater, in order to present possible scenarios of exposure.

OPP Has Considered Exposure Due to Contaminated Groundwater in Risk Assessments for Only Seven Pesticides

OPP's risk assessments for seven pesticides (aldicarb, atrazine, carbofuran, DBCP, dinoseb, EDB, and simazine) did include estimates of potential exposure due to groundwater contamination. OPP did such assessments for these pesticides in conducting Special Reviews (of aldicarb, carbofuran, DBCP, dinoseb, and EDB) or in considering possible additional regulatory actions (for atrazine and simazine). The assessments for DBCP and EDB contributed to EPA's decisions to cancel these pesticides; in the cancelation of dinoseb, exposure resulting from groundwater contamination was not a key concern. Aldicarb and carbofuran are still undergoing Special Review, so OPP will use estimates of exposure from these pesticides' presence in water to assess the risks of these pesticides and decide whether to retain their tolerances and registrations. According to OPP officials, in Special Reviews, exposure due to pesticides' presence in groundwater has been included in risk assessments for pesticides presenting the worst health risks. For atrazine and simazine, OPP is using these exposure estimates as it begins to consider the need for regulatory actions.

Because more than one analysis was performed for some of the seven pesticides, there are 12 analyses in total that include exposure from groundwater. Two types of data are needed to assess exposure from a pesticide's presence in groundwater: an estimate of the amount of water a person consumes and an estimate of the level of the pesticide present in water. In estimating water consumption, EPA used water consumption data from DRES in eight analyses (for four pesticides) and other water consumption data for three analyses. For one analysis, we could not determine whether DRES' water consumption data were used. In estimating pesticide levels in water, OPP used groundwater monitoring data in five of the analyses and ODW's health advisory levels or MCLs[5] for six of the analyses, generally estimating exposure associated with ODW's level and one or more levels above and below ODW's level. For one analysis, we could not determine the type of data used to estimate the level of the pesticide in water.

Because EPA has limited data on pesticide levels in water, the resulting exposure estimates are uncertain. The analyses by DRES that estimate exposure to pesticides through water present hypothetical cases, according to DRES staff. It is not known if people are actually exposed to the pesticide levels in water used in the analyses, or whether such exposure, if it occurs, continues over time. In one analysis, the levels of exposure input to DRES were higher than people are likely to encounter because the levels were drawn from detections of aldicarb on Long Island, yet filtration systems have been installed there to reduce aldicarb levels in the tap water people drink. Health advisories and MCLs are not estimates of actual exposure, but are drinking water advisory and regulatory levels, respectively—levels above which exposure may present health risks. As a result, the DRES analyses of exposure resulting from water do not necessarily present expected or actual levels of exposure and risk. Rather, these analyses indicate what one's risk would be, if one is exposed to such levels of a pesticide in drinking water and also encounters residues of the pesticide in food. According to officials in OPP's Health Effects Division, using monitoring data, if available, would be preferable to using ODW's levels, because ODW's levels do not necessarily indicate levels of exposure that might actually be occurring. However, since pesticide levels are allowable in community water systems up to the MCL, an exposure at this level is possible.

[5]In one case, a maximum contaminant level goal was used to estimate the level of contamination in water. ODW uses such goals in developing MCLs.

The National Survey of Pesticides in Drinking Water Wells (described in ch. 1) provides additional information on the extent and levels of pesticides in well water. However, the usefulness of this information for exposure assessments is currently uncertain because survey results have not yet been analyzed fully. According to Health Effects Division officials, survey results will provide some information as to how contamination levels compare to health advisories. The director of the survey told us that because the survey did not target sites with known or suspected contamination, it would not provide useful data on the higher extremes of potential exposure.

OPP's Use of Anticipated Residue Data Makes Groundwater Exposure Estimates More Critical

OPP increasingly is using less conservative, more realistic estimates of pesticide exposure from food. This practice makes it more critical that OPP consider additional exposure resulting from pesticides' presence in groundwater because such estimates may not provide a margin of safety for sources of exposure other than food. OPP first makes an initial, conservative estimate of potential exposure from food by assuming the maximum allowable usage of a pesticide. If this estimate exceeds the acceptable daily intake or indicates a potentially significant cancer risk, OPP revises exposure estimates for food using anticipated residue data. OPP officials believe such data provide more realistic estimates of the residue levels consumers actually encounter than the initial, conservative estimates. If estimated exposure (from food only) using anticipated residue data is 100 percent or less of the acceptable daily intake, tolerances are considered acceptable. OPP does not routinely account for possible exposure due to contaminated water when anticipated residue data are used and has no plans to do so, according to Health Effects Division officials. OPP does, however, plan to continue using anticipated residue data.

OPP's initial estimates of exposure from food assume that residues are always at the tolerance level, the maximum amount allowed by law. Initial estimates thus assume that 100 percent of each crop on which a pesticide may be used is treated with the pesticide and that the pesticide is always applied at the maximum level and maximum number of times allowed by the label directions. Because exposure estimates assuming tolerance-level residues are conservative, they may provide a margin of safety for exposure from other sources such as contaminated groundwater. Exposure estimates using anticipated residue data are generally lower, according to OPP officials. This is because OPP uses these data to adjust for a pesticide's use on less than 100 percent of a crop, use at lower rates or less frequently than allowable, and reductions in residues

resulting from storage time, cooking, and processing. Although using anticipated residue data generally results in a lower estimate of residues in food "on the dinner plate," OPP does not lower the tolerances accordingly because tolerances are enforcement levels for food "at the farm gate," rather than "on the dinner plate."

Tolerances based on anticipated residue data do not necessarily provide a margin of safety for possible additional exposure from pesticides' presence in groundwater. Yet the agency has used anticipated residue data in assessing some pesticides that leach into groundwater. From January 1987 through mid-October 1990, EPA used anticipated residue data to assess 68 pesticides. Of the 68 pesticides, 5 (alachlor, aldicarb, atrazine, DCPA, and simazine) are among the 16 EPA had identified as groundwater contaminants by 1985. These 5 and 6 others (arsenic, chlorothalonil, diazinon, ethoprop, linuron, and methomyl) are among the 46 pesticides identified by the Pesticides in Ground Water Data Base as being present in groundwater from normal agriculture use. Of these 11 groundwater contaminants that OPP has assessed using anticipated residue data, OPP has incorporated estimates of potential exposure from contaminated groundwater in preliminary risk assessments for 3—aldicarb, atrazine, and simazine.

Conclusions

OPP is not adequately considering exposure due to contaminated groundwater when it sets tolerances for pesticide residues in food. The Office does not routinely account for exposure resulting from pesticides' presence in groundwater and has no plans to do so. OPP has included potential exposure from contaminated water in tolerance assessments for only a few of the pesticides now known to contaminate groundwater and has not always performed such assessments when it had necessary data available. As a result, whether tolerances for pesticides that contaminate groundwater are low enough to protect public health is uncertain. Although OPP officials assert that exposure due to groundwater contamination was incorporated in Special Review risk assessments for pesticides presenting the worst health risks, we believe OPP lacks assurance that all serious health risks have been addressed because the Office does not routinely assess whether exposure from food and groundwater is high in comparison to the level presenting concerns about toxicity.

We believe EPA lacks assurance that tolerances for groundwater contaminants provide an adequate margin of safety, particularly when anticipated residue data are used. EPA has used anticipated residue data in

exposure estimates for some of the pesticides that have been found in groundwater.

In contrast to OPP, ODW, when it sets advisory levels and standards for drinking water, accounts for multiple sources of exposure to pesticides. In setting health advisory levels, ODW accounts for people's exposure to pesticides through sources in addition to drinking water. At least two methods available to OPP could provide a margin of safety for potential exposure from pesticides in well water, namely, a standard factor such as the one ODW uses or the more detailed DRES methodology, which OPP has used for four pesticides. In light of comments by staff of the National Academy of Sciences and OPP's Health Effects Division, a more detailed assessment using monitoring data, if available, would probably be preferable to a standard factor.

Recommendation

In order to ensure that total dietary exposure does not exceed safe levels, we recommend that in setting and reviewing tolerances for pesticides found in groundwater and/or identified through studies as likely to leach into groundwater, the Administrator, EPA, assess and take into account potential human exposure from contaminated groundwater.

Sixteen Pesticides Detected in Groundwater and Their Primary Uses

Pesticide	Type	Uses
Alachlor	Herbicide	Corn, soybeans, and peanuts
Aldicarb	Insecticide, nematicide[a]	Potatoes, citrus fruits, soybeans, cotton, and peanuts
Atrazine	Herbicide	Corn, sorghum, wheat, and other crops
Bromacil	Herbicide	Pineapples and citrus fruits
Carbofuran	Insecticide, nematicide	Corn, rice, soybeans, sorghum, peanuts, and tobacco
Cyanazine	Herbicide	Corn, cotton, and sorghum
1,3-Dichloropropene	Nematicide	Tomatoes, potatoes, other vegetables, citrus fruits, and cotton
DBCP[b]	Fumigant	Cotton, soybeans, and a number of fruit, nut, and vegetable crops
DCPA[c]	Herbicide	Cotton, soybeans, field beans, vegetables, strawberries, lawns, and turfs
Dinoseb	Herbicide, insecticide, fungicide	Soybeans, cotton, potatoes, peanuts, and alfalfa
EDB[d]	Fumigant	Soil before planting, stored grain, quarantined fruits and vegetables, and grain milling machinery
Fonofos	Insecticide	Corn, peanuts, sugar beets, sugarcane, potatoes, and tobacco
Metolachlor	Herbicide	Corn, sorghum, cotton, potatoes, peanuts, soybeans, other beans and peas, certain fruits, and nuts
Metribuzin	Herbicide	Soybeans, potatoes, other vegetables, wheat, and sugarcane
Oxamyl	Insecticide, nematicide	Apples, potatoes, and tomatoes
Simazine	Herbicide, algicide	Corn and citrus fruits

[a]A nematicide is a pesticide used to control or kill nematodes (roundworms).

[b]dibromochloropropane

[c]dimethyl tetrachloroterephthalate

[d]ethylene dibromide

Forty-Six Pesticides Present in Groundwater From Normal Agricultural Use

Levels in parts per billion

Pesticide	Median level detected[a]	Maximum level detected[a]	Health advisory level[b]
Alachlor	0.90	113.00	
Aldicarb	9.00	315.00	10.00
Aldrin[c]	0.10	0.10	
Arsenic[c]			
Atraton	0.10	0.10	
Atrazine	0.50	40.00	3.00
BHC (Benzene hexachloride)[c]	2.70	4.30	
Bromacil	9.00	22.00	90.00
Carbofuran	5.30	176.00	40.00
Chlordane[c]	1.70	1.80	
Chlorothalonil	0.02	12.60	
Cyanazine	0.40	7.00	10.00
1,2-D (1,2-Dichloropropane)	4.50	550.00	
1,3-Dichloropropene	123.00	270.00	
2,4-D (2,4-Dichlorophenoxyacetic acid)	1.40	49.50	70.00
DBCP[c]	0.01	0.02	
DDT (Dichloro diphenyl trichloroethane)[c]	1.70	402.00	
DCPA	109.00	1,039.00	4,000.00
Diazinon	162.00	478.00	0.60
Dicamba	0.60	1.10	200.00
Dieldrin[c]	0.02	0.02	
Dinoseb[c]	0.70	36.70	7.00
Diuron			10.00
EDB[c]	0.90	14.00	
Endosulfan	0.30	0.40	
Ethoprop		12.60	
Fonofos	0.10	0.90	10.00
Hexazinone	8.00	9.00	200.00
Lindane	0.10	47.00	0.20
Linuron	1.90	2.70	
Malathion	41.50	53.00	200.00
Methamidophos	4.80	10.50	
Methomyl		9.00	200.00
Methyl parathion	88.40	256.00	2.00
Metolachlor	0.40	32.30	100.00
Metribuzin	0.60	6.80	200.00
Oxamyl	4.30	395.00	200.00

(continued)

Pesticide	Median level detected[a]	Maximum level detected[a]	Health advisory level[b]
Parathion	0.03	0.04	
Picloram	1.40	49.00	500.00
Prometon	16.60	29.60	100.00
Propazine	0.20	0.20	10.00
Simazine	0.30	9.10	1.00
Sulprofos	1.40	1.40	
TDE (Dichlorodiphenyl dichloroethane)[c]	4.80	6.20	
Toxaphene[c]	3,205.00	4,910.00	
Trifluralin	0.40	2.20	5.00

Note: The 16 pesticides identified in groundwater as early as 1985, which we addressed in our review, are in bold lettering.

[a]Detection levels are taken from W. Martin Williams, Patrick W. Holden, Douglas W. Parsons, and Matthew N. Lorber, Pesticides in Ground Water Data Base: 1988 Interim Report, Environmental Protection Agency (EPA), Office of Pesticide Programs (Dec. 1988). In this column, the absence of an entry indicates that the detection level related to normal agricultural use was not available in this report.

[b]Health advisory levels are current as of November 1990 and represent lifetime health advisory levels for a 70-kilogram adult. In this column, the absence of an entry indicates that no such health advisory level has been established for the pesticide.

[c]Most or all uses of this pesticide have been canceled.

Ongoing Special Reviews of Groundwater Contaminants

Pesticide	Special Review issues	Status of EPA's decision[a]
Alachlor	Carcinogenicity, presence in groundwater	EPA did not have enough data to resolve questions about groundwater contamination and has required additional tests. EPA completed its review of toxic risks, resulting in the restricted-use classification, a label warning, and new use directions.
Aldicarb	Acute toxicity, presence in groundwater	EPA proposed state management plans (SMP) to deal with leaching potential. EPA required additional data to resolve questions about risks from residues in food.
Carbofuran	Toxicity to birds, presence in groundwater	EPA found groundwater contamination not to be a serious concern and proposed amending an advisory on product labels. EPA proposed canceling granular products to prevent risks to birds.
1,3-Dichloropropene	Carcinogenicity, presence in groundwater	EPA did not yet have data to evaluate pesticide's risks fully. Review was at an early stage.

[a]Status as of November 1990.

Elements of State Management Plans

The contents and extent of an SMP would depend on pesticide use and the vulnerability of groundwater within the state. EPA expects state plans to fall into three general categories: baseline, moderate, and full-scale. The baseline SMP would be applicable in states with either no outdoor use of the pesticide or little outdoor use and only in areas where the vulnerability of groundwater is low. The moderate SMP would apply to states with pesticide use in areas where vulnerability is low to moderate, but no use in highly vulnerable areas. The full-scale SMP would be appropriate in states where a pesticide is used in highly vulnerable areas.

The baseline plan would include the following components:

- a statement of philosophy,
- a description of the means for giving public notice and receiving comments on the decision that no higher-level SMP is required,
- a commitment to report any future contamination to EPA,
- a commitment to develop a more extensive SMP if contamination is detected in groundwater at higher levels, and
- evidence of adequate legal authority to carry out the plan's elements.

A moderate plan would include the preceding components as well as the following two:

- a description of the means for monitoring and
- an explanation of the technical expertise, costs, and funding needed to carry out the plan.

A full-scale plan would incorporate the following additional components:

- an explanation of state agencies' roles and responsibilities;
- a description of the means for enforcing requirements;
- an explanation of the geographic planning methods used to assess vulnerability, contamination, and measures to prevent pollution;
- a description of the means for disseminating information; and
- identification of the potential actions in response to contamination.

Major Contributors to This Report

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

Peter F. Guerrero, Associate Director, (202) 252-0600
J. Kevin Donohue, Assistant Director
Rachel J. Hesselink, Evaluator-in-Charge
Therese C. Nelson, Staff Evaluator
Kristen G. Burnham, Staff Evaluator
Deborah L. Eichhorn, Staff Evaluator
John H. Skeen, III, Writer-Editor

Related GAO Products

Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (GAO/RCED-91-52, Mar. 7, 1991).

Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, July 23, 1990).

Drinking Water: Compliance Problems Undermine EPA Program as New Challenges Emerge (GAO/RCED-90-127, June 8, 1990).

Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food (GAO/T-RCED-89-35, May 17, 1989).

Reregistration and Tolerance Reassessment Remain Incomplete for Most Pesticides (GAO/T-RCED-89-40, May 15, 1989).

Groundwater Protection: The Use of Drinking Water Standards by the States (GAO/PEMD-89-1, Dec. 20, 1988).

Fighting Groundwater Contamination: State Activities to Date and the Need for More Information From EPA (GAO/T-PEMD-88-7, May 17, 1988).

Groundwater Standards: States Need More Information From EPA (GAO/PEMD-88-6, Mar. 16, 1988).

Groundwater Quality: State Activities to Guard Against Contaminants (GAO/PEMD-88-5, Feb. 2, 1988).

Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986).

Ordering Information

The first five copies of each GAO report are 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.

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20877

Orders may also be placed by calling (202) 275-6241.

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

Official Business
Penalty for Private Use $300

First-Class Mail
Postage & Fees Paid
GAO
Permit No. G100