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Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

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PESTICIDES

Better Data Can Improve the Usefulness of EPA's Benefit Assessments

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December 31, 1991

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

A recently introduced food safety bill calls for the Environmental Protection Agency (EPA) to base regulatory decisions about pesticides solely on the potential risks they pose to human health and the environment and to discontinue the practice of estimating their benefits. To aid the Subcommittee in evaluating the merits of benefit assessments for pesticides used on food, you requested that we review EPA's practices for conducting them.

In a previous report, Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (GAO/RCED-91-52, Mar. 7, 1991), we described (1) the means by which EPA defines and quantifies the benefits of food-use pesticides and (2) the role benefit assessments play in establishing maximum allowable pesticide residues (tolerances) and registering pesticides for particular uses. As agreed with your office, this report evaluates EPA's methods for conducting benefit assessments. Specifically, we examined the role of benefit assessments in EPA's special reviews—in-depth analyses of the benefits and risks of already registered pesticides that new evidence suggests may pose an unacceptable risk. We also determined the extent to which benefit assessments are based on adequate data, make clear any limitations, and adequately consider alternative means of controlling pests.

Results in Brief

By design, EPA makes risk assessments the primary consideration in special review, with benefit assessments playing a secondary role. Even this secondary role is limited, however, because EPA often cannot accurately forecast the economic impacts that pesticides or their alternatives have on farmers and consumers.

Specifically, quantitative estimates of pesticides' benefits are generally (1) imprecise because some data on which they are based are frequently of poor quality or missing altogether, (2) potentially misleading because the analyses frequently do not acknowledge their limitations, and (3)

incomplete because the analyses seldom use promising chemical and nonchemical alternatives.

Although benefit assessments can be an important part of regulatory analysis, EPA's pesticide benefit assessments are often based on inadequate data, resulting in imprecise estimates. We found few sources of reliable data on the quantity of pesticides used on food crops and, most importantly, the effect of various alternatives on crop yields. EPA must collect and piece together information for benefit assessments from many sources, including commercially available data bases of pesticides' usage, scientific literature, and experts. This process results in data of inconsistent quality and quantity.

The problem of poor or missing data is compounded when EPA does not document its data's limitations or when it produces analyses that do not follow its guidance. Because these limitations are often not acknowledged, benefit estimates can appear more precise than they really are and, therefore, can be misleading. If benefit assessments misrepresent the cost-effectiveness of alternative pesticides, EPA could make misguided regulatory decisions.

Even though EPA's benefit assessments usually list alternatives to registered pesticides, the agency normally bases benefit estimates on differences between special review pesticides and other registered alternatives. This approach seems to counter the agency's guidelines that call for promising alternatives (chemical and nonchemical) to also be used as points of comparison.

According to officials in EPA's Office of Pesticide Programs (OPP), one reason for focusing on registered alternatives is that data are frequently unavailable for new alternatives. While we recognize that these data may not be readily available, developing sources for such data would allow EPA to include in its quantitative analyses the broader range of alternatives that its guidelines envisioned. Moreover, when developing these data is not cost-effective, qualitative analyses of new, promising alternatives could provide more information for decision-makers than the current approach. Including this wider range of alternatives as a basis for benefit estimates could also help EPA register safer pesticides and cancel higher-risk chemicals more quickly than is now possible.

Background

In regulating pesticides, EPA balances the risks they pose to human health and the environment against their benefits. The Federal Food,

Drug, and Cosmetic Act gives EPA the authority to weigh risks to human health against economic benefits when establishing tolerances for pesticides used on agricultural products. The Federal Insecticide, Fungicide, and Rodenticide Act authorizes EPA to formally examine pesticides' benefits when it registers pesticides prior to their sale or use in the United States.

EPA's major use of risk-benefit analysis in regulating pesticides is during special review, which the agency initiates when it receives new information suggesting that a pesticide's risks may exceed established standards. Currently, EPA uses benefit assessments in this process to help guide risk-reduction measures.

EPA's benefit assessments attempt to compare the economic impacts—on farmers, consumers, and food processors and distributors—of alternative pest control methods in preventing crop losses. There are three basic components to EPA's quantitative analysis of a pesticide's benefits: (1) the per-acre difference between the cost of using the pesticide (its price and the cost of its application) and using its main alternatives; (2) the per-acre difference in crop yield resulting from using the pesticide and using its alternatives (comparative product performance evaluation); and (3) the extent to which the pesticide is used. The result of this analysis yields an overall monetary impact of the pesticide's use. EPA's quantitative analyses are guided and supplemented by qualitative insights from EPA officials and other experts. According to senior agency officials, these insights play a critical role in the agency's final assessment of any pesticide's benefits. (See app. I for more details on background.)

We analyzed the benefit assessments, completed between June 1985 and December 1990, for five food-use chemicals: the herbicides alachlor and cyanazine; the insecticides carbofuran and aldicarb; and a family of fungicides, ethylene bisdithiocarbamates (EBDC). We examined 39 different pesticide-crop combinations.

Benefit Assessments' Role Is Limited

Because EPA considers the need to protect human health and the environment paramount, the agency's regulatory decisions reached through special review are based primarily on risk assessments, with benefit assessments playing a secondary role. This secondary role may involve using benefit estimates to help EPA choose which uses of a pesticide to cancel or restrict in order to reduce overall risks, or to help EPA decide whether to cancel or restrict a particular use that poses a borderline

risk. Currently, benefit assessments are not meeting their full potential to help refine the agency's regulatory decisions primarily because of limitations in the data used.

EPA's special review of EBDCs provides an example of a role benefit assessments currently play in special review. EPA began its special review of EBDCs in July 1987 after receiving data indicating that the upper bound of the carcinogenic dietary risk to the public from the cumulative exposure over a lifetime to three of the five fungicides was 4 in 10,000, well above the agency's informal criterion of 1 in 1 million for such risks. In other words, these data indicated that the use of EBDCs could increase the odds of getting cancer by 4 in 10,000 for people exposed over a 70-year lifetime. At that time, EBDCs were being used on 55 different crops.

EPA had information on EBDCs' risks and benefits broken out by the crops on which EBDCs were used. The information compared EBDCs' risks and benefits with those of alternative registered chemical fungicides. EPA's goal was to eliminate enough uses of EBDCs to reduce the cumulative risk to an acceptable level. EPA decided to propose cancellation of most of the high-risk uses regardless of benefits. Certain other uses had similar lesser risk estimates but greatly different benefit estimates. For example, EBDCs' use on lettuce presented a lifetime carcinogenic risk of 3 in 1 million and estimated economic benefits of $40 million to $204 million. Thus, according to EPA's estimates, the use of these pesticides on lettuce would increase the odds of getting cancer by 3 in 1 million, and canceling EBDCs' registrations and using the chief alternatives would cost society $40 million to $204 million. Similarly, EBDCs' use on watermelons and lima beans presented carcinogenic risks of 2 in 1 million, but the benefits were far less than for lettuce—only $800,000 for watermelons and $700,000 for lima beans.

According to EPA officials, the agency decided to propose canceling EBDCs' use on watermelons and lima beans primarily because these uses yielded low benefits. The officials also told us that despite the similar carcinogenic risk of EBDCs' use on lettuce, EPA would continue to allow this use because of the comparatively large benefits. Because of the large uncertainty surrounding benefit estimates, it is only when estimated benefits vary greatly, as with EBDCs' uses cited above, that benefit assessments can play a role in helping to identify which uses to cancel or restrict.

Benefit Assessments Rely on Questionable Data

EPA's benefit assessments could be improved with more and better data on pesticides' usage and comparative product performance. Although the agency's guidelines for benefit assessments call for determining pesticides' specific uses on crops and specific effects on crop yields, this information is often unavailable. In the absence of reliable survey data on usage and quantified field testing, which would demonstrate the effect of the pesticides on crop yields, the agency obtains whatever information it can on a case-by-case basis. The resulting data are inconsistent in quantity and quality.

Sources of data for the agency's benefit assessments include submissions from manufacturers, published reports in scientific journals, reports from the U.S. Department of Agriculture (USDA) and state agriculture departments, and commercial surveys of pesticides' use. EPA also relies on the expert opinion of scientists, extension agents, farmers, and state agriculture department personnel. According to EPA officials, reliable data on the cost of purchasing and applying the pesticides being assessed have been available, but acquiring reliable data on usage and especially on comparative performance has been more difficult.

Usage Data Are Imprecise

Our review showed that the precision of the agency's usage data varied somewhat. For example, EPA's estimates of the overall usage of alachlor had a range of uncertainty of about 2 percent, while the estimates for EBDCs had a range of about 20 percent. According to senior agency officials, EPA would like to have more precision in its usage estimates, but there have been few sources of statistically valid and reliable data. In addition, these officials noted that there is greater uncertainty in the estimates for less frequently used pesticides or for pesticides used on smaller-volume crops and that uncertainty in usage data also reflects variability in the amounts of pesticides used from year to year.

The quality of usage data may be improved by two recent developments. First, in October 1990 USDA began expanding the scope of its usage surveys to cover more pesticides and more crops. As a result of budgetary constraints, the number of pesticides and crops included in these surveys had shrunk since 1971. Second, the Food, Agriculture, Conservation, and Trade Act of 1990 (Food and Agriculture Act, P.L. 101-624) requires that USDA, in consultation with EPA, require all certified applicators to keep records of applications of pesticides whose use is restricted and that USDA and EPA conduct surveys of certified applicators' records to develop a comprehensive annual report to the Congress on agricultural and nonagricultural pesticides' use. While these requirements

could help improve the quality of EPA's usage data, senior EPA officials maintain that any improvements may be limited because the use of most pesticides is not restricted.

Comparative Performance Data Are Imprecise and at Times Absent

The agency's information regarding pesticides' impact on crop yields is usually considerably more imprecise than usage data. In the absence of reliable field studies, which the agency maintains are the best way to generate performance data, EPA has sometimes excluded the consideration of performance from benefit analyses or has attempted to estimate yield differences on the basis of expert opinion. We found that the imprecision introduced by these omissions and substitutions may be equal to or greater than the agency's benefit estimate.

The benefit assessment for aldicarb's use on peanuts exemplifies this problem. Because performance data were not available for one of aldicarb's alternatives—telone II (a fumigant)—the agency assumed no difference in yield resulting from using aldicarb as opposed to telone. EPA, therefore, excluded telone from the quantitative analysis because of the higher costs of purchasing and applying the pesticide. EPA then estimated that aldicarb's use on peanuts resulted in benefits of $17 million to $33 million over the use of other alternatives to aldicarb. We noted, however, that a fumigant similar to telone had proved to be 4 to 14 percent more effective than aldicarb on potatoes. For the purpose of illustrating how benefit assessments can be misleading when comparative performance data are not available, we estimated the effect on the benefit assessment of aldicarb's use on peanuts had telone proved to be more effective than aldicarb. Our analysis showed that aldicarb would be about $1 million less expensive than telone if using telone resulted in a 10 percent greater peanut yield; however, aldicarb would be $19 million more expensive than telone if using telone resulted in a 14 percent greater yield. EPA's benefit assessment did not document this omission of performance data and its potential to triple the uncertainty in the estimate of aldicarb's benefits.

Because comparative performance data are frequently either unavailable or highly imprecise, replacing EPA's current sources of this information with more reliable ones will help benefit assessments achieve their full potential in special review. EPA recognizes the need for better performance data and, according to agency officials, is considering requiring manufacturers to submit these data at the time products are registered. Other options include exploring the cost-effectiveness of developing more comprehensive sources of performance data by (1)

entering into voluntary agreements for conducting field tests with other federal and state agencies, particularly USDA and state agriculture departments; (2) sponsoring these tests by agricultural colleges and universities; or (3) having manufacturers of pesticides and/or pesticide users sponsor these tests. (See app. II for more details on the data for benefit assessments.)

Assessments Often Do Not Acknowledge Data's Limitations

EPA's guidelines emphasize the importance of identifying the limitations of the data underlying benefit assessments. In practice, the analyses often do not acknowledge the uncertainties they contain. When data are absent, EPA, often without acknowledgement, either omits key variables or substitutes assumptions for the missing data.

In its 1986 analysis of cyanazine's use on field corn, for example, EPA found no available published performance data. However, through informal contacts with agricultural experts, EPA was told that "up to a 10-percent yield loss due to uncontrolled broadleaf weeds" could be expected without cyanazine's use on the crop. EPA used this information as a single, absolute estimate rather than using a range to estimate cyanazine's benefits. Thus, the assessment conveyed an image of precision that did not exist.

At times, EPA does not perform the kind of quantitative benefit analyses—called for in the agency's guidelines—that would provide estimated overall benefits and impacts on consumers, farmers, and others. For example, we found that EPA quantitatively estimated overall economic benefits in only 30 percent of the benefit assessments we examined. Similarly, in only 25 percent of the assessments we reviewed did EPA estimate the impact on the incomes of farmers who did not use the pesticide in question. Not estimating these and other specific economic impacts contributes to the imprecision in benefit assessments. Poor or unavailable data account at least in part for the agency's inability to quantify some important benefits. EPA officials said that the agency's guidelines for quantifying benefits are meant to be flexible, not necessarily applied to every benefit assessment. Thus, officials noted that the impact on consumers is usually quantified only when a preliminary examination of available information indicates that a regulatory action would substantially affect crop yields.

In addition to having problems introduced by poor or unavailable data, benefit assessments sometimes do not conform to the agency's guidance. For example, EPA's guidelines specify that when the cancellation of a

pesticide could result in making a crop prohibitively expensive to produce, benefit assessments should take into account adjustments farmers might make—such as shifting to other crops. In the analysis of alachlor's use on soybeans, EPA estimated that canceling alachlor would make soybeans too expensive to grow on roughly one-third of the acreage on which they were being grown. In its benefit estimate, EPA assumed some farmers would continue to grow soybeans at a loss and did not allow for those farmers switching to other crops. This made alachlor's benefits appear greater than they would have otherwise. According to senior officials, such limitations in data are usually conveyed to decision-makers in oral briefings. (See app. III for more details.)

Assessments Do Not Use Promising Chemical or Nonchemical Alternatives to Estimate Benefits

EPA's guidelines for benefit assessments specify including promising developmental pesticides and nonchemical means of controlling pests. Although nonchemical alternatives were frequently described in the benefit assessments included in our review, EPA actually used these alternatives in estimating benefits in only two minor cases—for carbofuran's use on cranberries and alachlor's use on beans. According to senior EPA officials, limitations in their data usually preclude a broader analysis of alternatives. EPA usually compares the special review pesticide to pest control methods that the agency believes farmers will adopt if the review pesticide is canceled. In most instances, EPA believes the most likely alternatives are other registered chemicals.

In its benefit assessment for carbofuran's use on rice, EPA reported that carbofuran was the only available chemical effective against the rice water weevil. However, EPA's assessment indicated there were 10 promising chemicals that in limited test trials controlled weevils as well as or better than carbofuran. None of the noted chemicals, however, was registered with EPA either because manufacturers were not convinced of a viable market or because environmental concerns existed. In addition, EPA's assessment indicated that as alternatives to carbofuran, there were nonchemical methods of controlling pests, such as manipulating planting dates, managing the use of water, and eliminating nearby foliage where weevils spend winters, but the agency concluded that these methods were more costly than carbofuran and therefore were not viable alternatives.

Acquiring the necessary data and including promising chemical and nonchemical alternatives in benefit assessments would support EPA's

"safer pesticides policy" proposal—a plan to encourage the development and use of less risky pest controls, which may lead to the cancellation of higher-risk pesticides. According to this proposal, the agency plans to routinely reconsider the registration of high-risk pesticides when safer substitutes become available. If EPA used promising chemical and nonchemical alternatives to assess benefits during special review, the balance between the review pesticide's risks and benefits might be significantly altered. When alternatives are safer or more beneficial, according to the proposal, the agency could speed their registration and cancel the higher-risk uses more quickly than under the current system. (See app. IV for more details.)

Conclusions

Uncertainty in EPA's benefit estimates currently limits their role in special review. At present, imprecision in the agency's data results in imprecise benefit estimates, allowing the agency to differentiate only between pesticides having greatly different estimates. This imprecision in the data prevents EPA's benefit estimates from fulfilling their appropriate role in regulatory decision-making.

The agency compounds the problem of poor data by often failing to (1) disclose the data's limitations in its analyses, (2) use ranges rather than single values in the analyses, and (3) check on conformance to the agency's guidance. These practices make the agency's benefit estimates appear more accurate than they are in reality and thus could impair the integrity of special review decisions. Incorporating in the internal reviews of benefit assessments specific checks to ensure the disclosure of the data's limitations, inclusion of ranges, and conformance to guidelines could provide decision-makers with more realistic appraisals of pesticides' benefits.

For the results of benefit analyses to be more precise, better comparative performance data are needed, including data for new and promising pest controls—chemical and nonchemical. The current approach of generally including only registered chemical alternatives in estimating benefits does not encourage the development of safer, cost-effective pesticides and other alternatives. When developing data is not cost-effective, a comparative qualitative analysis would provide more information than the current approach, allowing EPA to consider a broader range of alternatives, and could enable the agency to remove higher-risk pesticides more quickly than currently possible.

Recommendations

So that benefit assessments can be more useful in regulatory decision-making, we recommend that the Administrator of EPA

- develop, where cost-effective, ways to secure adequate and reliable comparative performance data for alternatives (chemical and nonchemical) to be used in benefit analyses and
- develop procedures to ensure that the agency's benefit assessments (1) fully disclose the limitations of data and the effect of those limitations on potential regulatory decisions; (2) where appropriate, conform to EPA's guidance and document any deviations from that guidance; and (3) use alternative pest controls beyond registered chemicals to estimate benefits.

Agency Comments

As requested, we did not obtain written agency comments on a draft of this report. However, we discussed the facts contained in this report with EPA officials and incorporated their comments where appropriate. Their comments are summarized below.

EPA agreed with many of our findings. OPP officials acknowledged that limitations in data compromise the precision of benefit estimates, that the agency needs to develop cost-effective ways to secure better performance data, and that these limitations could be better acknowledged in benefit analyses.

However, EPA did not agree that benefit assessments should necessarily include analyses of nonchemical pest controls and promising unregistered pesticides. Officials noted that despite the agency's guidance calling for benefit estimates to be based on such alternatives, they consider the requirement impractical because comparative performance data are generally not available for these alternatives, and farmers are unlikely to adopt these pest control measures if the special review pesticide is canceled. The officials also said that they were not obliged to follow the agency's guidance on this matter because the guidance was meant to serve only as a model for benefit analyses and not to establish binding requirements.

We believe that EPA's guidance for including nonchemical pest controls and promising unregistered pesticides in benefit assessments outlines a sensible and important approach. In fact, the guidance supports OPP's strategy for 1993 to 1996, which encourages the development and use of pesticides that pose fewer adverse effects than current pesticides. The

strategy statement recognizes the need for additional research on alternative pesticides; this research could supply the performance data needed for benefit assessments. We believe that when the necessary data are unavailable, EPA should explore cost-effective ways to develop them to base benefit estimates on alternative and potentially safer pesticides, as well as registered alternatives. However, even in cases when data cannot be developed cost-effectively for new and nonchemical alternatives, EPA should still use these alternatives to estimate benefits qualitatively. Until the agency establishes the relative benefits of these alternatives, we believe that judging which alternatives farmers are likely to adopt if EPA cancels the special review pesticide is difficult.

EPA also commented that our report overemphasizes quantitative analysis without sufficiently emphasizing the qualitative work that usually accompanies benefit assessments. Officials said that expert opinion from EPA and USDA, as well as opinions from experts outside government, guides quantitative research, helps interpret its results, and helps fill in gaps in the data.

We believe that when reliable data are available, performing quantitative analyses of pesticides' benefits is the ideal approach for weighing the relative benefits of using alternative pest controls on food crops. Qualitative analyses that address missing data and describe alternative pest controls do not provide the verifiable results that we believe are the best means to weigh risks and benefits. However, when reliable data are not available and cannot be developed cost-effectively, we believe that EPA should continue to depend on qualitative insights.

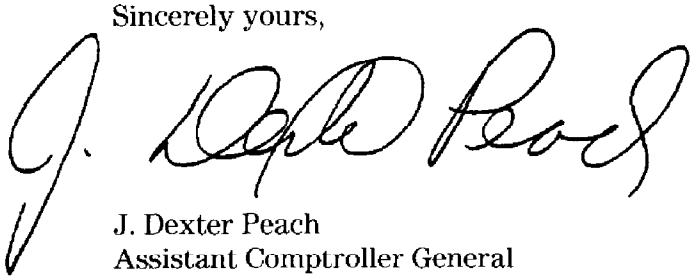
To evaluate EPA's method for conducting benefit assessments, we analyzed the benefit assessments done for five of the eight chemicals for which special reviews were begun between June 1985 and December 1990. We reviewed the agency's regulations, policies, and guidelines and interviewed current and former EPA officials who either are or were involved in carrying out benefit assessments. We also interviewed environmental, scientific, and industry groups interested in this issue. We performed our work from November 1989 through August 1991 in Washington, D.C., and vicinity, in accordance with generally accepted government auditing standards.

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, EPA; the Director,

Office of Management and Budget; and other interested parties. We will also make copies available upon request.

This work was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, who can be reached at (202) 275-6111. Other major contributors to this report are listed in appendix V.

Sincerely yours,



J. Dexter Peach
Assistant Comptroller General

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Abbreviations

EBDC	ethylene bisdithiocarbamates
EPA	Environmental Protection Agency
ERS	Economic Research Service
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
NAPIAP	National Agricultural Pesticide Impact Assessment Program
OPP	Office of Pesticide Programs
USDA	U.S. Department of Agriculture

Background

Pesticides—chemical or biological substances designed to destroy or control unwanted organisms—have come to play a dominant role in agriculture. American farmers use an estimated 700 million pounds of pesticides annually at an approximate cost of $4.1 billion to control a wide variety of pests. Roughly 69 percent of these agricultural pesticides are herbicides, 19 percent are insecticides, and 12 percent are fungicides.

Balancing Pesticides' Benefits and Risks

Using pesticides has advantages and disadvantages. On the one hand, pesticides may contribute directly to agricultural productivity by helping to control weeds, insects, fungi, nematodes, rodents, and other pests that compete with crops. Greater crop yields may result, which can increase profits for farmers and the agricultural economy, depending on the extent to which increased yields affect the prices farmers receive. Increased yields can also lower retail food prices for American consumers. The United States' seemingly unlimited agricultural potential also permits vast amounts of food to be exported—on average, about 125 million metric tons of grain per year over the past 4 years—thus helping to reduce the U.S. trade deficit. Pesticides can also aid public health by helping to control disease-carrying pests. And some pesticides, particularly herbicides, may allow growers to employ farming techniques, such as reduced tilling, that lessen soil erosion and improve the quality of surface water.

On the other hand, because pesticides are designed to kill or otherwise control living organisms, exposure to them can be hazardous. Pesticides have been found to adversely affect people, fish and wildlife, and the environment. Some pesticides may cause chronic health problems, such as cancer and birth defects, while others may produce acute effects, including death. Not only do pesticides inadvertently kill fish and wildlife, but they also sometimes kill pests' natural enemies, thereby eliminating natural controls and creating a need for additional pesticidal treatments, which in turn lead to further exposure. The widespread use of pesticides has also contaminated the soil at varying levels and polluted surface water and groundwater.

To balance the advantages and disadvantages of pesticides, the Congress has charged the Environmental Protection Agency (EPA) with the responsibility to weigh the relative benefits and risks of using pesticides. According to senior agency officials, one of EPA's main goals in special reviews—in-depth analyses of registered pesticides' benefits and

risks—is to minimize risks by canceling or reducing the uses of pesticides that appear to offer few benefits. To pursue this objective, EPA now examines pesticides' benefits and risks at varying levels of detail during different parts of the regulatory process.

EPA's Examination of Pesticides' Benefits and Risks

EPA's authority to balance pesticides' benefits and risks derives from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and from the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. Under FIFRA, EPA is authorized to register pesticides for specific uses, considering both safety and benefits. In fact, EPA can register a pesticide use only if the agency determines that the pesticide will perform its intended function without causing unreasonable adverse effects to the environment (FIFRA section 3(c)(5)). EPA must determine that the pesticide does not cause "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of the pesticide (FIFRA section 2(bb)). Under FFDCA, EPA establishes the maximum acccptable levels of pesticide residues in foods and animal feed—termed tolerance levels—to protect human health while allowing for the production of an "adequate, wholesome, and economical food supply" (FFDCA section 408).

EPA conducts risk-benefit analyses for a number of different purposes and at varying levels of detail, as explained in a previous GAO report, Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (GAO/RCED-91-52, Mar. 7, 1991). The main role of benefit assessments, however, is to provide input for special reviews. A special review is initiated when new evidence—from sources such as pesticide manufacturers, the National Cancer Institute, National Institutes on Health, or independent testing facilities—suggests that a pesticide poses an unacceptable risk. The purpose of special review is to provide senior decision-makers with the information necessary to balance the benefits and risks of the pesticide being reviewed, in order to help guide regulatory decisions.

EPA's Assessment of a Pesticide's Risks During Special Review

Although we did not evaluate the quality of EPA's risk estimates or data, agency officials told us that EPA's basic approach to estimating risks in special review includes four steps. EPA first identifies the hazard(s) arising from the pesticide's use on specific crops; second, EPA estimates

the dose required to produce adverse effects in people or the environment; third, EPA assesses the extent to which people and the environment are exposed to that hazard; and fourth, EPA attempts to describe how much risk individual uses pose.

The hazard identification step is designed to assess the nature of any adverse health effect of the pesticide under review. Hazards are identified primarily on the basis of laboratory animal studies. Among the factors EPA examines are the potential for skin and eye irritation; the possibility of acute poisoning, the formation of tumors, birth defects, impairment to reproductive systems, and other serious health problems.

The second part of EPA's risk assessment is a dose/response assessment, which explores the relationship between a level of exposure and an adverse effect on people or the environment. Since epidemiological studies with reliable quantitative data on human exposure are rarely available, EPA relies on the results of experimental animal studies to estimate dose/response relationships. The agency extrapolates from animal studies to predict potential effects on humans. For almost all toxic effects, EPA determines the highest dose that does not produce the adverse effect, then applies a safety factor to establish a level of human exposure that theoretically will eliminate all risk to humans.

Once EPA identifies the pesticide's hazard(s) and develops a dose/response assessment, the agency begins an exposure assessment. This involves estimating the level, duration, frequency, and route of exposure. EPA must consider pesticide exposure at harmful levels that may occur among people who mix and apply pesticides or among people who consume foods and drink water containing pesticide residues. EPA also examines hazards to organisms not targeted by the use of the pesticide, including fish and wildlife, and the behavior of the pesticide in the environment after application, such as the tendency to leach into groundwater.

The final step in EPA's risk assessment process is risk characterization. Integrating the above factors, EPA characterizes the pesticide's risk to humans for each use under review. To regulate carcinogens, for example, EPA requires that a lifetime of exposure to a pesticide in the diet generally should not increase the overall risk of contracting cancer by more than 1 in 1 million.

EPA's Assessment of a Pesticide's Benefits During Special Review

Recognizing that some losses in the quantity (yield) and/or quality of crops are inevitable even when pesticides are used, in most cases EPA compares the effectiveness of the pesticide being reviewed in preventing crop losses with that of its main alternative(s) and then estimates the dollar value of the difference(s) in crop losses. EPA also recognizes that pesticides vary in cost, so the agency compares the costs of purchasing and applying the pesticide being reviewed and its alternative(s). The sum of these two factors—the value of an enhanced crop yield and difference in cost—is multiplied by the total acres treated with the pesticide to estimate the overall economic benefit of the pesticide's use. EPA's guidance also calls for the agency to estimate total and regional impacts on farmers and consumers, as well as effects on inflation, unemployment, and international trade. Although senior agency officials believe that quantifying a pesticide's benefits is an important part of EPA's regulatory program, the officials pointed out that quantitative analysis should be guided by the judgment of EPA managers and should not be used independently of expert opinion to help interpret its results.

EPA's Use of Risk-Benefit Analyses

The agency has no formula to guide the balancing of a pesticide's benefits and risks in special review. According to EPA's Director of the Office of Pesticide Programs (OPP), special review decisions center on reducing risks by focusing, to the extent practicable, on restricting and canceling the pesticide's uses that appear to offer the least benefits. For example, EPA reduced the overall risk posed by a family of fungicides, ethylene bisdithiocarbamates (EBDC), by focusing its regulatory attention on uses that offered relatively few benefits. In addition, a pesticide's aggregate benefits are sometimes used to offset otherwise significant risks. For example, EPA noted that alachlor's total benefits of $400 million to $500 million outweighed its estimated carcinogenic risk of 6 in 1 million. In making special review decisions, senior policymakers rely on both quantitative estimates of benefits and risks and the judgment of senior officials. Short of outright cancellation of some or all uses, regulatory options available to EPA include requiring labeling changes, reducing the number of pesticide applications allowed on food crops, reducing the allowable quantity of the pesticide used per application, and requiring protective equipment and clothing.

EPA's Data for Benefit Assessments

According to EPA's guidance, three basic types of data are required before benefits can be estimated: the costs to purchase and apply the pesticide, usage data, and comparative performance data. The costs to purchase and apply the pesticide are determined on a per-acre basis. Usage data include the total amount of an active ingredient applied to a crop, the rate and frequency of application, and the total number of acres treated nationwide. Performance data measure the quantity and sometimes the quality of the per-acre yield obtained by treating a particular crop with the pesticide. The precision in EPA's benefit assessments depends on the quality of these data.

According to EPA officials, reliable data on the costs of purchasing and applying pesticides have been available, but usage and performance data have been much more difficult to obtain. This view was documented in a 1988 report based on a survey of EPA, the U.S. Department of Agriculture (USDA), state agriculture departments, and others. The survey, initiated by USDA and conducted by the Ohio State University, asked respondents for their views on the benefit assessment process. The survey disclosed that limitations in data constituted a pressing problem with benefit assessments. According to the survey, applicable data are frequently either unavailable or unreliable.

Usage Data

EPA selects its usage data for special review on a case-by-case basis from whatever sources are available. Sources include manufacturers, state agriculture departments, commercial data services, and USDA. For minor crops on which usage data are scarce, EPA informally contacts personnel of state and local farm associations, county extension agents, and individual farmers and pesticide applicators to develop estimates. EPA also conducts in-house literature searches.

Sources of Usage Data

From manufacturers, EPA obtains FIFRA-required proprietary submissions, which identify the quantities of pesticides produced and shipped to distributors. FIFRA, however, does not require manufacturers to develop information on pesticides' actual use. Thus, EPA can learn generally from manufacturers where pesticides are shipped, but it cannot find out from manufacturers which pesticides are used or the extent of usage (pounds applied and acreage).

EPA also obtains estimates of usage from state agriculture departments. However, according to EPA, data from these sources vary substantially in quality and availability because current laws and regulations do not

establish requirements for reporting usage data. Despite these limitations, EPA usually relies to some extent on state-supplied usage data.

In addition, EPA obtains some usage data from commercial data services that survey farmers regarding the types and amounts of pesticides used on various crops. However, information available from these sources is limited. These services' surveys usually provide more complete information on heavily used pesticides and pesticides used on major crops such as corn and wheat. According to agency officials, surveys of this type obtain usage data on fruits and vegetables about every 2 years, but do not cover all specialty crops.

EPA also obtains usage data from USDA. For four of the five special review pesticides we studied, EPA relied to some extent on USDA. Although USDA is recognized as a major source of usage data, USDA officials told us that until recently, the Department's data had been fairly weak. According to these USDA officials, usage surveys historically conducted by USDA had been scaled back since 1971.

USDA's Economic Research Service (ERS) conducted national surveys of usage for 1964, 1966, 1971, 1976, and 1982. These surveys provided national and regional estimates of pesticide usage. However, budgetary constraints reduced the scope of latter studies. The 1982 survey was restricted to 33 states and considered usage only on major crops and livestock. USDA performed limited surveys of usage on some specialty crops during 1978 and 1979 and some partial surveys for other crops during the 1980s, but because of further budgetary constraints, USDA conducted no further national surveys of usage until last year.

In addition to having ERS' national surveys, USDA has generated usage data through Department-funded programs at the state level, such as the National Agricultural Pesticide Impact Assessment Program (NAPIAP), a coordinated USDA-state effort that collects many types of data from a variety of state and local sources. EPA officials have questioned the reliability of data generated by NAPIAP and have noted that the program has had difficulty providing timely usage data for special review. In the past, usage data collected by NAPIAP have been based primarily on expert opinion; however, recently NAPIAP has begun funding state efforts to conduct usage surveys.

When formal reports or surveys of usage data do not already exist, EPA may survey experts, such as county extension agents, university agriculture professors, farm bureau personnel, and/or farmers. Estimates of

carbofuran's use on rice, for example, were compiled primarily from personal contacts with experts.

Our review of benefit assessments revealed uncertainty in EPA's usage estimates. Table II.1 displays the ranges of the uncertainty in EPA's usage data.

Table II.1: Range of Uncertainty in EPA's Estimates of Pesticides' Usage

Pesticide	Estimated use (1,000 lbs. of active ingredient)	Percentage variation from mean estimate
Alachlor	80,040–83,848	2.3
Carbofuran	5,954–8,763	19.1
Aldicarb	5,212–5,757	4.9
EBDCs	12,000–18,000	20.0
Cyanazine	22,000–24,000	4.3

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

The variation in EPA's estimates of usage ranged from 2.3 percent for alachlor to 20 percent for EBDCs. According to EPA officials, the agency would like to have more precision in these estimates, but because usage data vary from year to year depending on weather, pest infestation, acres planted, tillage practices, and so forth, uncertainty has been hard to avoid. Still, EPA officials consider the usage data to be better in quality than performance data, and significantly better than most other EPA programs' data.

Obtaining Reliable Usage Data

The Food and Agriculture Act directs USDA, in consultation with EPA, to require that all certified applicators keep records of restricted-use pesticide applications. The act also directs USDA and EPA to use this information to develop and maintain a data base sufficient to publish annual comprehensive reports on pesticide usage. Thus, the Food and Agriculture Act provides some reporting requirements that could allow EPA to gather usage data that are more reliable. Senior agency officials believe, however, that this survey provision may provide only limited benefits because most uses of pesticides are not restricted.

EPA and USDA have not completed the arrangements necessary to develop the data base called for in the act. EPA and USDA officials told us that work has been under way for several months and that the agencies believe the data base should be available by about 1993.

Comparative Performance Data

As with usage data, EPA identifies sources of performance data on a case-by-case basis. No centralized data base exists for these data, and EPA does not conduct or sponsor its own tests to produce them. Rather, EPA relies on studies published in agricultural literature and on information obtained from experts, especially agricultural researchers at state agriculture schools. Occasionally, the agency obtains data from other sources. For example, EPA used performance data from corn seed companies for the benefit assessment of alachlor. The seed companies had kept detailed records of differences in yields when corn was grown with the use of alachlor and of its alternatives. As a result, the quality of the comparative performance data EPA used in this benefit assessment was much better than the quality of the data used in the other assessments we analyzed. According to OPP officials, comparative performance data are much more available for major crops such as corn than they are for other crops such as fruits and vegetables.

EPA is concerned about the quality of its performance data. According to senior agency officials, current performance data are often inadequate to make accurate and legally defensible benefit assessments. As a result, the agency is considering requiring manufacturers to submit comparative performance data when their products are registered. These data would be used to compare the performance of one pesticide to that of other pest control methods (chemical, biological, and cultural), measured in terms of the resulting yield differences for agricultural crops. In order to ensure that EPA receives the needed performance data under these new provisions, the agency has begun work on revising guidance on how to conduct comparative performance studies.

According to an agricultural research and testing firm that performs commercial studies, it could cost from a few hundred thousand dollars to several million dollars to perform the kind of analysis to generate the performance data EPA needs for one special review. The cost of such studies, the firm explained, would be determined by the number of crops for which testing had to be performed, the number of different regions in which it had to be done, the number of alternatives considered, and the number of targeted pests. For the pesticides included in our review, the number of specific field tests would have varied considerably. For example, EBDCs were used on 55 crops, and these uses involved multiple conditions, regions, and application rates. Field tests would likely have cost several million dollars. Conversely, alachlor had only two major uses. Tests for alachlor, therefore, would probably have cost considerably less.

Our review of EPA's benefit analyses showed that performance data were often unavailable or highly imprecise. In the absence of reliable field studies, the agency commonly excluded performance data from its benefit calculations (as in the case of aldicarb's use on sweet potatoes, sugar beets, and soy beans) or attempted to estimate performance on the basis of expert opinion (as in the case of cyanazine's use on field corn).

Determining Specific Economic Impacts

EPA's guidance directs agency analysts to estimate the comparative costs of using the special review pesticide and its alternative(s). The resulting estimate is a key part of the benefit assessment because it determines which alternatives would be economically viable, and preferred by farmers, should EPA ban the pesticide being reviewed. EPA's guidance also calls for estimates of the economic benefits for farmers, as well as for consumers. In addition to estimating the impacts on agricultural markets, benefit analyses are to examine macroeconomic effects such as inflation and employment, as well as effects on local communities. The analyses should, according to the agency's guidance, take into account other variables that could affect dollar estimates, including market distortions (e.g., price supports and acreage controls) and international trade issues.

The level of quantitative analysis called for in EPA's guidance is not possible to achieve, given the current state of usage and comparative performance data. These data, together with data on the costs of purchasing and applying pesticides, are essential for accurate quantitative estimates of benefits because they anchor the agency's benefit assessment methodology. For example, data on anticipated yields (which should vary with the efficacy of pest control methods), as well as approximations of farming costs (including the cost of pest control), are needed to estimate the impact on farmers' income. Expected changes in food prices for consumers also depend, to some extent, on crop yields and the elasticity of demand, as greater supplies can lead to lower retail prices. According to EPA officials, when quantitative analysis is impossible because of shortcomings in the data, the agency relies on qualitative analyses and expert opinion to help estimate benefits.

Our review of benefit assessments indicated that EPA has had difficulty conforming to its internal guidance on analyzing economic impacts in special review. Table II.2 illustrates the extent to which EPA complied with some of the key components of its guidelines.

Table II.2: Extent to Which EPA's Economic Analyses Conform to Agency's Guidance

Economic effects EPA's guidance says should be estimated	Percentage of analyses with quantitative estimates	Percentage of analyses with qualitative estimates
Overall economic estimate of benefits	30	15
Immediate effects on consumer prices	65	20
Long-term effects on consumer prices	5	5
Effects on income of farmers who use the review chemical	95	0
Effects on income of farmers who do not use the review chemical	25	20

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

As shown in table II.2, EPA does not always perform the quantitative analyses called for in the agency's benefit assessment guidance. According to EPA officials, the guidance is meant to be flexible, and thus not all benefit assessments are expected to follow the guidelines exactly. In addition, senior officials asserted that the facts of individual special reviews also help determine the extent benefit assessments conform to the agency's guidelines. According to these officials, an elaborate benefit assessment similar to that described in the agency's guidance is sometimes unnecessary. For example, EPA believes that a sophisticated benefit assessment is not needed when the agency and pesticide manufacturers reach an agreement on reducing risks early in the special review process.

EPA's Documentation of Data's Limitations

EPA's guidelines for benefit assessments emphasize the importance of identifying the limitations of the data underlying the estimates. According to the guidelines, these limitations are to be stated not only when the data are entered into the analyses, but also when the results are finally presented. The guidelines also call for statements of uncertainty to be expressed in nontechnical language.

In practice, EPA's benefit analyses often do not acknowledge the uncertainties they contain. In the benefit assessments we examined, when EPA estimated or assumed a value for performance, the agency often introduced a specific number into its calculations instead of a range that would show the uncertainty. The resulting estimate of benefits appeared more certain than they were in reality. Similarly, when performance data were unavailable, EPA often calculated benefits solely on the basis of the costs of purchasing and applying the pesticide and its alternative(s), without acknowledging the omission. In so doing, the agency effectively assumed there was no difference in the yields resulting from the use of the pesticide being reviewed and its alternative(s). This practice not only employs a potentially questionable assumption (because likely differences in yield could affect the benefit estimate), but it also conveys an image of precision in the analysis that may not be present. In its analysis of cyanazine's use on field corn, for example, EPA found no available performance data and therefore assumed, on the basis of telephone contacts, that the herbicide would prevent "up to a 10-percent yield loss due to uncontrolled broadleaf weeds." Because EPA accepted the upper bound of the estimate as an absolute value, and did not use a range of possible values, the benefit estimate not only appeared more precise than it was in reality, but it also maximized the benefits of cyanazine; thus, the estimate may have misled EPA's decision-makers.

Because performance data were not available for EPA's analysis of aldicarb's use on peanuts, the agency assumed no difference in the performance of aldicarb and one of its four alternatives—the fumigant telone II. EPA, therefore, excluded telone from the analysis because it was more expensive to buy and use than aldicarb. Comparing aldicarb to the other alternatives, EPA estimated that aldicarb's use on peanuts resulted in benefits of $17 million to $33 million. We noted, however, that a fumigant similar to telone had proved to be 4 to 14 percent more effective than aldicarb when used on potatoes. For the purpose of illustrating a possible effect of omitting performance data from an analysis, we estimated benefits that reflect these differences in yield if telone performed similarly on peanuts. If the use of telone resulted in a 10 percent greater peanut yield, aldicarb's benefits would be about $1 million. If telone

resulted in a 14 percent greater yield, using aldicarb would be roughly $19 million more expensive than using telone. EPA's benefit assessment did not document this omission of performance data and its potential to triple the uncertainty in the estimate of aldicarb's benefits.

EPA's Consideration of Alternative Pest Controls

EPA's benefit assessments compare the value of the pesticide being reviewed with the value of alternative pest controls. Despite the agency's guidance calling for the consideration of promising unregistered chemicals and nonchemical pest controls, EPA largely limits its comparisons to other registered chemicals. Our review of benefit assessments showed that in all but two minor cases—carbofuran's use on dry-harvested cranberries and alachlor's use on dry beans—the agency limited its quantitative analyses to other registered chemicals.

Agency's Guidance for Considering Alternative Pest Controls

EPA's guidance for performing benefit analyses in special review specifies that a range of alternatives to the pesticide under review should be considered in estimating benefits. Among the alternatives that EPA's guidance recommends for consideration are other registered chemicals, promising unregistered chemicals, nonchemical controls, and agricultural practices that minimize the use of pesticides.

In addition to the pesticide(s) registered for use on a given crop, many other chemicals may be effective in controlling the pests that attack that crop. Though some of these chemicals could be less risky than the registered chemical, these chemicals may not have been registered for a variety of reasons. Some may simply be new, and their manufacturers may not have had time to register them yet. Others may be effective for uses that are not extensive enough, in the manufacturers' eyes, to justify the expense of registration.

Nonchemical controls include a variety of biological controls. Sometimes, a pest's natural enemies or other predators are applied to crops as a control. At other times, pest-resistant crops can be bred.

Agricultural practices that minimize the use of pesticides, such as integrated pest management and low-input sustainable agriculture, combine the use of pesticides with the use of other controls (natural predators to control insects) or alternative farming methods (increased tilling to control weeds). The goal is to apply pesticides only when they are needed.

Consideration of Alternative Pest Controls in Benefit Assessments

EPA's quantitative analyses for the special reviews we examined generally did not include any of the alternatives called for in the agency's guidance except other registered alternatives. We found discussion, at varying length, of unregistered chemicals, nonchemical controls, and/or integrated pest management as alternatives, but—except in two minor cases—we found only registered chemicals considered as alternatives in

the product comparisons on which benefit estimates are based. Agency officials told us that although some unregistered alternatives showed promise, they were excluded from the quantitative analysis because the agency's standard practice was to include only those alternatives farmers are likely to use if the pesticide in special review is canceled (almost always registered chemicals) and because performance data were largely unavailable for unregistered alternatives.

In EPA's analysis of carbofuran—the only registered chemical for use against the rice water weevil—EPA discussed unregistered chemicals and nonchemical alternatives under development, but did not include any of them in its benefit estimate. EPA cited 10 unregistered chemicals that in limited tests had performed as well as or better on rice than carbofuran. Although the comparative risks of these 10 pesticides were not available, 7 are of pesticide classes that tend to be less risky than carbofuran. However, according to EPA, since no manufacturer was supporting these chemicals for registration on rice, the agency did not consider them viable options. Hence, EPA did not quantify these chemicals' potential effects. In addition, EPA discussed alternative farming techniques, such as draining fields and manipulating planting dates, and it discussed several nonchemical controls, including the use of the water weevil's natural enemies, such as a dragonfly and a nematode.

We found two minor instances in which EPA did quantify nonchemical alternatives and used them as a basis to estimate pesticide benefits. In estimating the benefits of alachlor's use on dry beans—which represents only 0.2 percent of the pesticide's total use—the agency's main alternative was hand weeding. And for the agency's analysis of carbofuran's use on dry-harvested cranberries, which are about 3 percent of all cranberries grown in the United States, EPA considered the use of a parasitic nematode as the primary alternative. Although these analyses focused on relatively small uses, they represent a distinct departure from the agency's usual practice of quantifying the benefits of only registered alternatives, and they are a step toward including potentially safer alternatives in EPA's quantitative benefit estimates.

EPA officials noted that their choices of alternatives for comparison with pesticides in special review were based on recommendations from state agriculture agencies, agricultural colleges and universities, county extension services, and others. According to EPA officials, these sources usually believe that other pesticides are the most likely alternatives to pesticides in special review. Most farmers are less familiar with integrated pest management and nonchemical methods and consequently

prefer to continue using chemical pesticides and farming practices that are better tested.

EPA's Strategy Emphasizing Use of Safer Pesticides

The Office of Pesticide Program's (OPP) strategy for 1993 to 1996 encourages the development and use of pesticides that pose fewer adverse effects than current pesticides. The strategy states that new agricultural practices, such as integrated pest management and low-input sustainable agriculture, can reduce reliance on chemical pesticides, thereby supporting EPA's goal of reducing risks. As a result, according to the strategy, ". . . the agency also needs to encourage both additional research and application of these technologies." EPA's Assistant Administrator for Pesticides and Toxic Substances has voiced support for expediting the registration of pesticides deemed safer than those currently in use, and, in fact, the agency has a draft "safer pesticides policy" proposal.

According to this proposal, when the agency registers an effective and safer substitute, EPA will reconsider the registration of high-risk pesticides by reinitiating special reviews or taking other actions. The proposal states that the availability of safer chemical alternatives or safer agricultural practices would significantly alter the results of the risk-benefit analyses and lead directly to the cancellation of or more stringent limits on the higher-risk use(s).

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