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

March 1991

PESTICIDES

EPA's Use of Benefit Assessments in Regulating Pesticides

GAO/RCED-91-52

GAO

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

Resources, Community, and
Economic Development Division

B-242523

March 7, 1991

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

Dear Mr. Chairman:

You requested that we review the Environmental Protection Agency's (EPA) current practices for considering the benefits of pesticides used on food. The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provide EPA with pesticide regulatory powers. Under FFDCA, EPA establishes tolerance levels, or the maximum levels of pesticide residue allowed in food. FFDCA authorizes EPA to consider pesticide benefits when setting tolerances for raw food. However, when a pesticide is suspected of causing cancer, EPA is not allowed to set processed food additive tolerances, regardless of anticipated benefits. FIFRA authorizes EPA to register pesticides prior to their sale or use in the United States. Under FIFRA, EPA is to take into account economic, social, and environmental costs and benefits of pesticide use. Pesticides must have valid tolerances before they can be registered for use on food products. Further discussion of the legislation governing pesticides appears in appendix I of this report.

As agreed with your office, this interim report summarizes the information we have gathered to date in response to your request. Specifically, this report will describe

- how EPA defines and quantifies the benefits of food-use pesticides and
- the role benefit assessment plays in tolerance and registration decisions.

A subsequent report will present more detailed technical information regarding EPA's use of benefit analysis. It will also evaluate the agency's internal guidelines for quantifying benefits and its adherence to such guidance.

Results in Brief

EPA considers the value of increased crop yields attributable to the use of one chemical pesticide over another as the primary measure of pesticide benefits. The agency's benefit assessments include two parts: a biological analysis and an economic analysis. In its biological analysis, the

agency gathers information about differences in crop yield and quality resulting from the use of a number of pest control methods. The analysis takes into account factors other than pesticide use, such as weather variations, that could also affect crop yield and quality. Any effect on yield or quality attributable to a specific pesticide is considered that pesticide's biological impact, or benefit. To determine economic benefits, the agency assigns dollar values to biological benefits, taking into account factors other than pesticides, such as pesticide costs, government subsidy programs, and regulatory actions, that could affect crop prices.

Thus far, our analysis indicates that EPA bases initial tolerance and registration decisions primarily on perceived risks to health and on environmental considerations. Benefits play a larger role when EPA reviews already established pesticide tolerances and registrations, although risks are still of primary importance. For example, the principal role of benefit analysis is to inform EPA decisionmakers during special review—EPA's administrative process for reviewing already-registered pesticides in the light of new data indicating health or environmental concerns—about the extent of the benefits associated with a specific pesticide's use. EPA also assesses benefits, albeit less systematically than during special review, when it moves to suspend a pesticide's registration on an emergency basis and when it considers granting exemptions or waivers from standard registration requirements.

Defining and Quantifying Benefits

EPA's pesticide benefit assessments include two sequential steps. First, the agency performs an analysis to determine biological benefits, such as enhanced crop yields and quality, taking into account factors other than pesticides that could play a role. Second, EPA's economic analysis of pesticide benefits attempts to express biological benefits, principally crop yield, in dollar terms.

Biological analyses are to contain information on pesticide usage; target pest(s) for each crop, including pest population; effectiveness of chemical and nonchemical control alternatives; and pests' geographic distribution. EPA analysts judge the relative effectiveness of a pesticide by comparing the results of its use on crop yield and quality with the results of using other forms of pest control (chemical and nonchemical). In performing this analysis, EPA takes into account weather variations, geographic considerations, and other relevant factors. Identified improvements in yield and quality represent EPA's estimate of the biological "benefit" of using the pesticide rather than its available alternatives.

The principal objective in EPA's economic analyses of pesticide benefits is to express biological effects, particularly yield differences for each crop, in economic terms. During special review, agency economists typically assign a dollar amount to the identified differences in crop yield resulting from the use of the pesticide under review and its most likely registered alternative, adjusting for pesticide costs and variables that could affect commodity prices.

In the benefit analyses we examined, EPA economists used two methodologies to estimate the dollar value of biological benefits: partial budgeting and a large-scale agricultural model. Partial budgeting equates pesticide benefits to the value of lost yield plus changes in pest control costs resulting from the use of alternative control methods. Agricultural models attempt to measure changes in crop prices while taking into account market factors that may affect crop yield and the value of production. In all of the benefit assessments we examined, EPA used partial budgeting; however, in one study—an analysis of alachlor on corn—the agency supplemented its partial budgeting findings with an agricultural model. EPA's guidance and methods for estimating the dollar value of differences in crop yield and quality are described in appendix II of this report.

Benefit Assessment Role

According to EPA, the agency bases initial tolerance-setting and registration decisions primarily on potential risks to human health and to the environment. Risk considerations also dominate EPA's review of already established tolerances and registrations, but benefit considerations may also affect these decisions. For example, when EPA initiates a special review, the agency may conduct a rigorous benefit assessment. The agency also examines benefits, albeit less systematically, when it reviews applications for exemptions or waivers from registration procedures or when it attempts to suspend or cancel pesticide registrations on an emergency basis.

If the risk analysis EPA conducts during the registration of new pesticides reveals that risks are negligible, the agency assumes that benefits exist on the basis of manufacturers' willingness to bear the considerable costs of registration. However, when risks appear greater than negligible, the agency requires applicants to develop a risk reduction strategy and/or demonstrate that benefits outweigh risks. In practice, however, agency officials said that most manufacturers either try to reduce risks or they abandon the registration altogether when the agency questions the risks associated with new products.

During special review EPA formally estimates and compares the benefits and risks of the suspect pesticide and tries to determine whether (1) its benefits outweigh its risks and (2) regulatory action is required. Regulatory options available to EPA include cancellation of some or all uses, restriction of uses, and labeling changes. According to EPA, if the agency cancels a pesticide's registration(s), then it usually revokes its tolerance(s), as well. Thus, special review serves as EPA's means to review registrations and tolerances. Through December 31, 1989 (the date of EPA's most recent estimate), about 30 of 390 pesticides with food uses were undergoing or had completed benefit assessments as part of special review. Further information regarding special review appears in appendix III of this report.

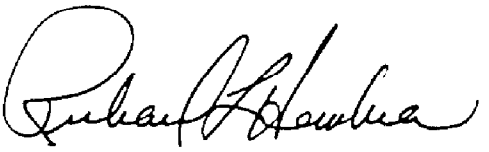
FIFRA allows EPA to suspend a pesticide's registration on an emergency basis if the pesticide poses an imminent hazard. In these cases EPA conducts a risk-benefit analysis to help agency decisionmakers decide whether to suspend the registration. According to EPA analysts, benefit analyses conducted as part of these time-critical emergency proceedings are less detailed than special review analyses and rely more heavily on benefit data submitted by manufacturers. EPA staff review and frequently supplement manufacturer-supplied information with in-house data.

EPA also grants exemptions and waivers from standard registration requirements in response to requests from chemical manufacturers, federal agencies, or state authorities. EPA officials noted that such exceptions, which include conditional registrations, waivers from some data submissions, and emergency exemptions, are usually granted on condition that they are in the public interest and pose no overriding risk concerns. Normally a public interest finding requires, among other things, that proposed uses be beneficial. These benefit studies are much less detailed than those conducted for special review, concentrating only on anticipated impacts for growers of those crops under review and taking no account of potential effects on food transporters or distributors. Further discussion of situations in which EPA requires applicants to establish pesticide benefits is contained in appendix IV of this report.

To determine the types of benefits EPA considers, the role of benefit assessment, and how the agency quantifies benefits, we reviewed 5 pesticides analyzed in 18 specific benefit analyses completed in special review since 1986. We also examined legislative background materials,

as well as pertinent agency policies, guidance, and regulations. We discussed the material contained in this report with EPA officials, and they generally agreed with our presentation of the facts. We incorporated their comments where appropriate. However, as agreed with your office, we did not obtain official agency comments. 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 make copies available to other interested parties. If you have any questions, please contact me on (202) 275-6111. Major contributors to this report are listed in appendix VI.

Sincerely yours,



Richard L. Hembra
Director, Environmental Protection
Issues

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Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
OPP	Office of Pesticide Programs
USDA	U.S. Department of Agriculture

Legislation Governing Pesticide Registration and Tolerances

The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provide the Environmental Protection Agency (EPA) with pesticide regulatory powers. Under FFDCA, EPA establishes the maximum levels of pesticides allowed in food—termed "tolerance" levels—aimed at protecting human health while allowing for the production of an "adequate, wholesome, and economical food supply." FIFRA authorizes EPA to register pesticides prior to their sale or use in the United States and to remove unreasonably hazardous pesticides from the marketplace. Food-use pesticides must have valid tolerances before being registered for food uses in the United States.

FFDCA

If a pesticide remains in or on food or in animal feed, FFDCA requires that a tolerance (the maximum pesticide residue allowed in food) be established. EPA may establish tolerances, or determine that the pesticide is exempt from having an established tolerance level, on the basis of data pesticide manufacturers submit. These data include pesticide toxicity (potential to cause adverse health effects) and residue (amount that may remain on food). In most cases, pesticide manufacturers propose tolerance levels, and EPA evaluates whether these residue levels may present a risk to consumers. EPA's assessment of risk includes three steps: (1) determining residue toxicity, including a level of daily intake acceptable for humans (Acceptable Daily Intake); (2) determining the maximum potential dietary exposure to pesticide residues (Theoretical Maximum Residue Contribution); and (3) comparing potential dietary exposure to the acceptable daily intake. The goal of this process is to assess whether proposed tolerances would protect public health within a practical certainty.

Tolerances for raw agricultural products are established under authority in Section 408, while food additive tolerances for processed food are established under Section 409. FFDCA requires a food additive tolerance when a pesticide's residue in processed food is greater than the tolerance level for the raw commodity. Under FFDCA, EPA sets tolerances for pesticide levels in food, while the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the states monitor and enforce tolerances.

Federal pesticides law allows some food uses of carcinogenic pesticides and prohibits others. For example, FFDCA requirements relating to potential carcinogens differ for tolerances established for raw agricultural

commodities and food additive tolerances for processed food. These differences are important because legislative authority to examine pesticide benefits also varies along these lines. FFDCA prohibits establishing tolerances for food additives found to induce cancer in humans or animals, regardless of benefits. And although FFDCA allows EPA to weigh risks to human health against economic benefits in establishing tolerances for carcinogenic and noncarcinogenic pesticides used on raw agricultural products, EPA told us that these decisions are based primarily on risk.

FIFRA

EPA is responsible for registering pesticides for specified uses on the basis of both safety and benefits before they may be sold, held for sale, or distributed in commerce. Registrations are essentially licenses for specified pesticide uses. Under FIFRA, EPA can register a pesticide only if it determines that the pesticide will 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." Thus, FIFRA focuses on balancing the inherent risks and benefits of pesticide use.

To support the regulatory process and to evaluate pesticide benefits and risks, EPA requires that pesticide manufacturers submit health and environmental effects data. The agency may require manufacturers to complete as many as 150 different studies to support a food-use pesticide registration. The data requirements for these analyses are expensive, in some cases costing millions of dollars. Although FIFRA authorizes formal examination of pesticide benefits before registration, in practice EPA assumes that benefits exist on the basis of manufacturers' willingness to bear the considerable cost of registration. Thus, the agency has largely waived requirements for manufacturers to submit comparative product performance data, which would be most useful to formally examine benefits. EPA does, however, require registrants to be able to demonstrate product effectiveness on demand. Typically, EPA formally examines benefits primarily during its special review process, designed to assess risks and benefits of registered pesticides suspected of posing unreasonable adverse effects. Special review is detailed in appendix III.

In the 1972 amendments to FIFRA, the Congress directed EPA to reregister all pesticides to assess their safety in light of more extensive data requirements legislated at that time. Although the agency has made some progress in this formidable task, EPA's progress has been slow. Office of Pesticide Programs (OPP) officials believe that amendments to

FIFRA enacted in 1988, which provided EPA with additional resources for reregistration and established time frames to complete the task, should quicken the pace of reregistration.

Agency Guidance and Methods for Estimating Pesticide Benefits

Guidance

EPA's guidance for the biological section of its pesticide benefit analyses calls for the agency to examine and summarize control methods that are recommended by pest management authorities and professionals and are actually used to control the pest(s) for which the review chemical is registered. Alternatives to be considered include other chemicals, integrated pest management (IPM) practices, and nonchemical concepts, such as ridge tilling, that are likely to be available for future use.

Comparative evaluations of the performance of the alternatives, chemical and nonchemical, are to be made, both in terms of pest control efficacy and of crop yield/quality over a range of both pest infestation and pesticide application levels. The guidance calls for attention to situations for which no alternative control method is available, to problems with pests developing resistance to pesticides, and to differences arising from the influences of geography, weather, timing, and pest population dynamics.

Guidelines for the economic analysis part of EPA's pesticide benefit analyses direct the agency to estimate dollar values for differences in crop yield and quality identified in the biological analysis. In so doing, economists are instructed to estimate impacts on users, distributors, and consumers. To help ensure accuracy, EPA's guidance also specifies that economic analyses take into account a range of factors that could affect dollar estimates, including market distortions (e.g., price supports, acreage controls, and marketing orders) and international trade issues.

Methods

EPA uses two primary methodologies to formally estimate the economic benefits of pesticides: partial budgeting and agricultural modeling. EPA applies formal pesticide benefit assessment methods principally during special review. Benefit analyses performed during other regulatory actions are usually much less detailed. EPA's main objective is to determine the dollar value of biological differences between pesticides, i.e., to measure the value of the variation in crop yield and quality attributable to the pesticides in special review and to selected alternatives.

In basic terms, EPA begins with biological estimates of the change in crop yield and quality resulting from the use of the chemical in special review and its most likely alternatives, controlling for other factors, such as weather, that could also affect yield and quality. EPA usually reports these differences as average per acre losses.

Once EPA determines the biological impacts of the pesticide under special review, the agency attempts to quantify the dollar value of the forgone agricultural production, controlling for factors that could affect crop prices. For each use under review, EPA first estimates the acres treated with the pesticide under review, and then multiplies the per acre difference in yield between the pesticide under review and its primary alternative, controlling for regional variations in yield effects. This calculation provides an aggregate estimate of the total biological effect of using one pesticide over another. Next, the agency multiplies the total biological effect by an average price per unit, accounting for regional price differences. This estimate is typical of EPA's measurement of pesticide benefits, although not all analyses follow this approach. Sometimes EPA adjusts this estimate to account for changes in the amount that consumers pay for the affected commodity and changes in government agricultural subsidies.

Partial Budgeting

Generally speaking, partial budgeting equates pesticide benefits to the value of production lost plus the change in pest control costs incurred by switching to alternative pest control mechanisms. If prices remain constant, partial budgeting can usually estimate the value of lost production fairly accurately. Partial budgeting assumes that changes in pest control alternatives constitute the primary factor in production.

Partial budgeting does not account for different commodity market interactions, nor does it account for other mitigating actions that may be taken by producers (e.g., crop switching) faced with the cancellation of a pesticide. Partial budgeting estimates normally become less accurate when production losses are large enough to induce significant price changes. Production losses or cost increases, or both, associated with changes in pest control techniques can cause price increases, which can affect farmers' planting decisions.

Agricultural Modeling

In contrast to partial budgeting, large-scale agricultural modeling attempts to factor in market variables that may affect crop yields and the value of production. Hence, modeling approaches may add an extra measure of precision to results obtained from partial budgeting methods. Examples of market variables that can be found in models include changes in market price, USDA crop support programs that could entice farmers to devote more acres to certain crops than otherwise would be the case, and crop switching. In addition, large-scale models of the agricultural sector allow EPA to account for interactions and impacts

across multiple markets, not just for the market of the commodity directly affected. For example, cancellation of pesticide uses could influence farmers to switch crops, thereby affecting other markets. In our sample of 5 pesticides involving 18 special reviews, EPA used a large-scale model to estimate the benefits of alachlor on corn. The agency relied on partial budgeting for all other pesticides in our sample.

EPA's Special Review Process

The main role of benefit analysis in EPA's pesticide regulatory scheme is to provide input for special review. The purpose of special review is to systematically and extensively compare the risks and benefits of pesticides whose risk estimates exceed pre-established criteria, also known as risk "triggers."[1] EPA's comparison of risks and benefits comprises the principal focus of special review because suspect pesticides' benefits must outweigh their risks to avoid cancellation or restriction of some or all uses. According to EPA, if the agency cancels a pesticide's registration(s), then the agency usually revokes its tolerance(s), as well. Hence, EPA uses the process to review both registrations and tolerances.

Special review generally follows four sequential stages. As the process moves from one stage to the next, EPA gathers and evaluates information on risks and benefits, as well as solicits comments from registrants and other interested parties.

In the first stage, known as pre-special review, EPA reviews scientific analyses of the pesticide in question that suggest risk criteria may have been met or exceeded. EPA's risk analysis includes estimates of toxicity and exposure. Pesticide toxicity causes adverse health effects; exposure is the actual or expected degree to which human and other nontarget organisms come into contact with the pesticide. In most cases, EPA reviews laboratory data for possible toxic effects associated with pesticide uses.[2] If EPA finds these studies valid, then it tries to assess the significance of the risk posed.

During this first stage, EPA notifies registrants that a risk criterion may have been met or exceeded. This notification, known as Grassly-Allen, is not part of the public record. Registrants have 30 days to respond. If registrants successfully rebut EPA's concerns, then the agency announces in the Federal Register that a special review had been considered but rejected and requests comments from interested parties. If registrants do not successfully rebut the Grassly-Allen notification, EPA publishes a Federal Register notice initiating a special review.

The second phase of a special review begins with an official announcement in the Federal Register (known as Position Document-1 or PD-1).

[1]Risk criteria (triggers) appear in 40 C.F.R. 154.7 and include oncogenicity (tumor formation), mutagenicity (heritable genetic effects), other chronic (long-term) toxic effects, acute (immediate) hazards to humans and animals, and hazards to endangered species and other wildlife.

[2]Data are normally submitted to the agency from manufacturers fulfilling FIFRA data submission requirements, other governmental agencies, such as the National Cancer Institute and the National Institutes on Health, independent testing facilities, and interested groups.

This notice describes EPA's determination that a pesticide has met or exceeded a risk criterion (or criteria), advises interested parties of the special review, and solicits comments. Affected registrants have up to 45 days to rebut the agency's risk concern, but may apply for an extension. During this period EPA gathers and analyzes risk, exposure, and benefits data on the review pesticide. On the basis of these data, EPA performs individual risk and benefit assessments and combines them in risk-benefit analyses for each use or category of use. During this period the agency may also hold discussions with registrants and other interested parties to determine ways in which risks associated with the review pesticide can be reduced voluntarily.

EPA collects risk-benefit data from a variety of sources. For example, at times EPA uses portions of the information FIFRA requires manufacturers to submit in support of individual pesticide registrations. In addition, EPA conducts literature searches regarding the relative effectiveness of competing pesticides. The agency also fosters communications with growers, farm associations, applicators, and extension agents in attempting to develop these data. Since 1976 EPA has had a memorandum of understanding with the U.S. Department of Agriculture (USDA) to cooperate in developing data required for pesticide risk-benefit assessments.

If the registrant successfully rebuts EPA's risk concern, or if other data alleviate EPA's concern, or if discussions with the registrant lead to sufficient voluntary risk reductions, then the agency will terminate the special review and issue a document describing its rationale in the Federal Register. If EPA's concerns are not alleviated at this stage, the agency will formulate a proposed regulatory position based on its perception of the best balance of risks and benefits. EPA issues this information in a preliminary determination document.

The Notice of Preliminary Determination (PD-2/3) represents the third stage of special review. This document describes EPA's proposed regulatory action and details the various analyses the agency performed before reaching its decision, including summaries of EPA's risk-benefit estimates. Through a notice in the Federal Register EPA advises interested parties of its proposed decision and solicits comments. The document includes EPA's assessment of any rebuttal offered by the registrant and a discussion of risks and benefits. Once EPA analyzes public comments, it formulates a final regulatory position and then issues a final determination document. Regulatory options range from no changes in the review pesticide's registration(s) to cancellation of some or all uses.

The final determination document (PD-4) describes EPA's final regulatory position on actions required to reduce risks associated with the review pesticide. This document also includes analysis of comments on the preliminary determination. A Notice of Final Determination is published in the Federal Register, concluding the special review. Affected parties dissatisfied with EPA's decision may request an administrative hearing and may then appeal through the federal courts. The regulatory decision becomes effective in 30 days unless a hearing is requested within that time. If a hearing is requested, the decision does not become effective until the hearing is completed.

Other Situations in Which EPA Examines Pesticide Benefits

EPA usually uses special review to analyze the risks and benefits of pesticides thought to present unacceptable risks, although the agency does examine benefits under other circumstances as well. For example, when EPA receives information leading it to believe that a registered pesticide poses an immediate risk, the agency can move to cancel or suspend that pesticide's registration on an emergency basis. EPA normally performs risk-benefit analyses to support these regulatory actions.

FIFRA authorizes EPA to grant exemptions from normal registration procedures. In addition to estimating the risks associated with such exemptions, EPA requires petitioners to document their benefits because the agency wants assurances that use of the pesticides at issue will prove to be in the "public interest."

Emergency Exemptions

"Emergency exemptions" represent one type of exception that FIFRA authorizes. In an emergency exemption, other federal agencies, states, and/or U.S. territories petition EPA for exemption from registration procedures based on FIFRA Section 18. EPA estimates that such requests may number 200 per year, of which the agency usually grants about 80 percent. According to EPA, some of the requests involve petitioners' claims that a recent pesticide cancellation may cause substantial economic losses for a specific crop. EPA also entertains petitions for emergency exemptions to control pests new to the United States and to control pests that may cause significant risk to human health. For example, EPA reported that a number of emergency exemptions have been justified because the Colorado potato beetle developed resistance to many common insecticides. Agency guidance specifies that decision criteria for granting emergency exemptions include a determination that an emergency condition exists (or will exist), and consideration of pesticide residue levels and the risks/benefits likely to result from the proposed use.

Conditional Registrations for New Active Ingredients

FIFRA authorizes EPA to grant conditional registrations when manufacturers submit incomplete data. EPA considers conditional registrations interim measures issued with specific limitations and for specific periods of time. According to OPP officials, EPA grants fewer than 10 conditional registration requests for new active ingredients per year. According to agency operating guidelines, successful applications depend on EPA's determining that each of the following conditions is present:

- applicants have had insufficient time since the imposition of the data requirement to generate necessary data,
- the pesticide's use will not cause unreasonable adverse effects, and
- the pesticide's use is in the public interest.

According to agency operating procedures, EPA may presume public interest when the pesticide

- will be used on a minor crop,
- can replace a particularly risky pesticide currently in use,
- has a FIFRA Section 18 (Emergency Exemption) registration because effective alternatives for a given pest are not available, or
- is used against a public health pest.

When these conditions are not present, however, petitioners must substantiate that the conditional registration serves the public interest by

- filling a need not being met by currently registered alternatives, or
- offering less risky alternatives to available products, or
- achieving benefits that outweigh those from registered alternatives or non-chemical control measures.

Minor Use Data Waivers

EPA also considers minor use data waivers from some testing requirements when manufacturers claim that insufficient economic incentives exist to perform all necessary tests. When such claims are made, EPA determines the extent to which sufficient economic incentives exist for manufacturers to undertake required testing. If the agency finds insufficient incentives, then EPA analyzes potential risks and benefits associated with the proposed use(s) and determines whether registered products could fulfill the perceived need. EPA estimated that it receives less than 100 data waiver requests per year.

EPA officials told us that benefit analyses conducted in support of exemptions and waivers are normally less detailed than those conducted for emergency cancellations/suspensions and are much less rigorous than those done during special review. EPA normally requires petitioners for exemptions or waivers to submit benefit data, which agency staff evaluate and frequently supplement. These analyses typically include only anticipated impacts on those crops under review, with no accounting for potential effects on other crops.

Objectives, Scope, and Methodology

The Chairman of the House Subcommittee on Health and the Environment requested that we review EPA's current practices for considering the benefits of food use pesticides. As agreed with the Chairman's office, this interim report summarizes the information we have gathered to date in response to that request. Specifically, this report describes

- how EPA defines and quantifies food use pesticide benefits, and
- the role benefit assessment plays in tolerance and registration decisions.

A subsequent report will present more detailed technical information regarding EPA's use of benefit analysis. Our later report will also evaluate the agency's internal guidelines for quantifying benefits and its adherence to such guidance.

To determine the legislative authority surrounding EPA's use of pesticide benefit assessments we reviewed the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act. We also discussed these laws with EPA's Office of General Counsel. In addition, we reviewed the Congressional Record and various background memoranda and documents.

To assess the role benefit assessments play when EPA sets or reviews tolerances, we reviewed agency regulations, policies, and guidelines concerning benefit assessments. We interviewed current and former EPA officials who are or were involved in setting and reviewing tolerances in the agency's Office of Pesticide Programs and Office of Policy, Planning, and Evaluation, as well as environmental (Natural Resources Defense Council and Audubon Society), scientific (National Academy of Sciences), and industry (National Agricultural Chemicals Association) groups involved in this subject area.

To determine how EPA defines and quantifies benefits, we examined in depth 18 benefit assessments completed since 1986. These included alachlor on corn and soybeans; carbofuran on rice; aldicarb on peanuts, sugarbeets, soybeans, pecans and potatoes; ethylenebis[dithiocarbamates] (EBDCs) on lettuce, celery, peanuts, mushrooms, and bananas; and fungicides on peaches, tomatoes, cucurbits, sweet corn, and cole crops. We selected post-1986 benefit studies to analyze because agency officials told us that the 1986 assessment of alachlor constituted one of EPA's better efforts in this area. Thus, we concluded that the agency's work from that point to date would fairly represent its current practices for assessing pesticide benefits. We also

reviewed EPA's technical guidelines for conducting benefit studies and interviewed agency officials who conduct such analyses.

We performed our work from November 1989 through September 1990 in Washington, D.C., in accordance with generally accepted government auditing standards. During the course of our work, we sought the views of agency officials and incorporated their comments where appropriate. However, as requested, we did not obtain official agency comments on this report.

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