

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

Resources, Community, and Economic Development Division

B-265923

September 29, 1995

The Honorable Cardiss Collins
Ranking Minority Member
Committee on Government Reform
and Oversight
House of Representatives

Dear Ms. Collins:

In 1987, the National Research Council<sup>1</sup> assessed the dietary cancer-causing risk of 28 pesticides.<sup>2</sup> Under the Federal Insecticide, Fungicide, and Rodenticide Act, these pesticides, like many others that were registered before 1972, are subject to reregistration by the Environmental Protection Agency (EPA) to ensure that they meet the current, more stringent scientific standards.

This report responds to your request that we determine the reregistration status of pesticides posing cancer-causing risk. We agreed with your office to provide an update on the 10 pesticides posing the highest dietary cancer-causing risk as identified in the National Research Council's 1987 report.

GAO/RCED-95-276R, Reregistration Status of Cancer-Causing Pesticides

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<sup>&</sup>lt;sup>1</sup>The National Research Council is the principal operating agency of the National Academy of Sciences, a private, nonprofit organization that advises the federal government on scientific and technical matters.

<sup>&</sup>lt;sup>2</sup>The Council selected the 28 pesticides from a list of 53 pesticides that EPA had preliminarily determined were either cancer causing or potentially cancer causing.

In summary, we found that, as of August 31, 1995,

- 3 of these 10 pesticides had been canceled voluntarily by the registrants--generally producers--before the reregistration process began and
- 7 were pending reregistration, including 3 pesticides that had some of their uses on food crops canceled.

For five of the seven pesticides pending reregistration, EPA is reviewing and/or awaiting various studies it required from the registrants. For the remaining two pesticides, EPA has received but not reviewed the required studies. EPA expects to issue reregistration eligibility documents for four of the seven pesticides by 1997; dates have not yet been established for issuing eligibility documents for the remaining three pesticides.<sup>4</sup>

#### BACKGROUND

In 1985, EPA asked the Board on Agriculture of the National Research Council to study the agency's methods for setting tolerances (the legal limit of a pesticide residue allowed to remain in or on foods) for pesticide residues. The Council estimated the dietary cancer-causing risk for 28 pesticides. The 10 ranked highest by the Council were--in descending order of risk--linuron, zineb, captafol, captan, maneb, permethrin, mancozeb, folpet, chlordimeform, and chlorothalonil. According to the Council, these 10 pesticides accounted for 80 to 90 percent of the total estimated dietary cancer-causing risk from the 28 pesticides it analyzed.

<sup>&</sup>lt;sup>3</sup>The pesticide is no longer an active ingredient—the component that destroys or controls the pest—in any registered pesticide product.

<sup>&</sup>lt;sup>4</sup>Issuing a reregistration eligibility document means that EPA has evaluated the information submitted on the pesticide and determined that the pesticide poses no unreasonable risk to humans and the environment when used under the terms and conditions EPA has established. Generally, products containing the pesticides are reregistered about 14 to 24 months after a reregistration eligibility document is issued.

<sup>2</sup> GAO/RCED-95-276R, Reregistration Status of Cancer-Causing Pesticides

EPA's process for reregistering these and other older pesticides is both lengthy and complex because the pesticides' registrants must conduct numerous health and environmental studies for review by EPA during its risk assessment. Over 100 studies may be needed to provide the information EPA requires to assess a pesticide's use on foods. The studies, some of which take up to 4 years to complete, include information on the chemical and physical characteristics of the pesticides as well as their potential to cause adverse effects on human health and/or the environment. EPA reviews the registrants' studies, identifies gaps in the information, and, when necessary, issues data call-in notices to formally require additional data.

If significant concerns about adverse health or environmental effects arise either before or during the reregistration process, EPA may initiate a special review of a pesticide's risks and benefits. Because the registrants may be required to submit additional data under such a review and EPA must review these data before making reregistration decisions, the process can take many years to complete. As a result of a special review, EPA may continue, restrict (through labeling changes and other means), or cancel some or all pesticide uses. For example, after a special review ending in 1992, EPA proposed the cancellation of certain pesticide uses, including the use of maneb and mancozeb on the following food crops: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. All of these uses except the use on collards and mustard greens were canceled. Since a hearing was requested on the pesticides' use on collards and mustard greens, these uses have not been canceled.

Once EPA determines that a pesticide poses no unreasonable risk to humans and the environment when used according to the directions, the agency issues a reregistration eligibility document and requests the registrant to submit product-specific studies and revised labeling for each product containing the pesticide. Generally, once EPA has received and accepted these studies and any labeling revisions and determined that the uses of the pesticide are eligible, individual products may then be reregistered. At any time during the reregistration process, the pesticide's registrants may also voluntarily cancel their registered products.

## REREGISTRATION STATUS OF 10 HIGHEST-RISK DIETARY CANCER-CAUSING PESTICIDES

As shown in the enclosure to this report, all uses of zineb, captafol, and chlordimeform have been voluntarily canceled by the registrants; some food-crop uses of captan, maneb, and mancozeb have been canceled, and their remaining uses are pending reregistration; folpet is pending reregistration for only one food-crop use in the United States; and all uses of linuron, permethrin, and chlorothalonil are pending reregistration.

Five pesticides--captan, captafol, maneb, mancozeb, and zineb--had some or all food-crop uses canceled during or after a special review. The amount of time that elapsed between the start of a special review and the cancellation of any food uses ranged from 3 to 9 years. For example, captan was in special review from 1980 until 1989, when some of its food uses were canceled.

For those pesticides pending reregistration, EPA is generally reviewing studies and/or awaiting studies, except for two pesticides for which the agency has received but not yet reviewed studies. The enclosure to this report also shows the dates on which EPA expects to issue reregistration eligibility documents for four of the seven pesticides. EPA has not established the expected dates for issuing these documents for the remaining three pesticides.

The enclosure to this report contains more detailed information on each of the 10 pesticides.

### SCOPE AND METHODOLOGY

To determine the reregistration status of the 10 food-use pesticides identified by the National Research Council in 1987 as posing the highest cancer-causing risk, we obtained and reviewed documentation from EPA and interviewed officials from EPA's Office of Pesticide Programs.

We conducted our review between July 1995 and September 1995 in accordance with generally accepted government auditing standards.

#### AGENCY COMMENTS

We provided a draft of this report to EPA for its comments. On September 22, 1995, EPA provided some technical comments on the enclosure of our report, and we have made changes to incorporate these comments.

4 GAO/RCED-95-276R, Reregistration Status of Cancer-Causing Pesticides

If you or your staff have any questions, please call me at (202) 512-6111.

Sincerely yours,

Peter F. Guerrero

Director, Environmental Protection Issues

Enclosure

ENCLOSURE ENCLOSURE

# REREGISTRATION STATUS OF 10 HIGHEST-RISK DIETARY CANCER-CAUSING PESTICIDES

Pesticide	Year reregistration began	Year reregistration eligibility document is expected to be issued	Notes
Linuron	1984	1995	This pesticide was first considered to be cancer causing in 1982. A special review begun in 1984 and completed in 1989 concluded that the pesticide's ability to cause cancer was weak, and no uses of this pesticide were canceled. In April 1995, EPA issued a reregistration eligibility document requiring additional studies to confirm its regulatory assessments and conclusions.
Zineb	N/A <sup>a</sup> The registrant voluntarily canceled all uses in 1991, before the reregistration process began.	N/A	This pesticide was first considered to be cancer causing in 1970. Zineb underwent two special reviews. The first, which began in 1977 and ended in 1982, resulted in measures designed to reduce risk. EPA also required additional data, which included information on carcinogenicity. During the second special review, which began in 1987 and ended in 1992, the registrant voluntarily canceled all uses.
Captafol	N/A  The registrant voluntarily canceled all uses in 1987, before the reregistration process began.	N/A	This pesticide was first considered to be cancer causing in 1984. A special review begun in 1984 ended after the registrant voluntarily canceled all uses.

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Captan	. 1986	1996	The pesticide was first considered to be cancer causing in 1980 as part of a special review that began the same year. The special review resulted in the cancellation of some registered uses in 1989. As part of the reregistration process for other uses, EPA is currently reviewing four residue studies.
Maneb	1988	No date established	This pesticide was first considered to be cancer causing in 1970. A special review, which began in 1977 and ended in 1982, resulted in risk-reduction measures. As a result of a second special review, which began in 1987 and was completed in 1992, EPA canceled uses on some crops. For the remaining crop uses, EPA has received but not yet reviewed numerous studies (ecological effects, environmental fate, exposure, and residue chemistry).
Permethrin	1989	1997	This pesticide was first considered to be cancer causing in 1986. The cancer risk has not been considered high enough to warrant a special review. EPA is currently reviewing numerous studies (toxicology, ecotoxicity, occupational/residential exposure, and residue chemistry). EPA is also waiting to receive overdue and outstanding studies on environmental fate and ecological effects.
Mancozeb	1987	No date established	This pesticide was first considered to be cancer causing in 1970. A special review, which began in 1977 and ended in 1982, resulted in some risk-reduction measures. As a result of a second special review, which began in 1987 and was completed in 1992, EPA canceled uses on some crops. For the remaining crop uses, the agency has received but not yet reviewed numerous studies (ecological effects, environmental fate, exposure, and residue chemistry).

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Folpet	1987	To be scheduled after the last study (due in May 1996) is received	The pesticide was first classified as cancer causing in 1986. The level of risk has not been considered high enough to meet the criteria for initiation of a special review. Use on avocados is the only U.S. crop use being considered for reregistration. EPA is awaiting three studies, and is currently reviewing 22 others (including environmental fate and residue chemistry studies).
Chlordimeform	N/A  The registrant voluntarily canceled all uses in 1989, before the reregistration process began.	N/A	The pesticide was first classified as cancer causing around 1985. Although EPA planned to put chlordimeform into special review, the registrant voluntarily canceled all uses of the pesticide before the review formally began.
Chlorothalonil	1984	1996	The pesticide was first classified as cancer causing in 1987. Chlorothalonil has not been in special review because EPA has determined that the risk associated with its use is acceptable. EPA is currently reviewing some studies (including data on occupational and residential exposure). A groundwater monitoring study is due in August 1996, and EPA is also awaiting data from field trial studies regarding crop uses.

 $<sup>^{</sup>a}N/A = not applicable.$ 

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