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Resources, Community, and  
Economic Development Division

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December 20, 1995

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

Dear Ms. Collins:

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) is responsible for registering new pesticides and ensuring that they will perform their intended functions without causing unreasonable adverse effects to the environment. Also under FIFRA, EPA is required to reassess and reregister older pesticides on the basis of current scientific data.

This report responds to questions that you asked about various aspects of EPA's responsibilities in regulating the use of pesticides. Specifically, you requested information on (1) whether EPA maintains a ranking of the highest-risk cancer-causing food-use pesticides, (2) what the reregistration status is of certain pesticides appearing in a 1995 study of pesticides in drinking water,<sup>1</sup> (3) whether certain high-risk cancer-causing food-use pesticides appeared in the 1995 study, (4) the extent to which EPA uses outside contractors to assist in reviewing studies submitted by the pesticides' registrants--generally producers, (5) what procedures EPA follows when canceling uses of a pesticide, and (6) what an "import tolerance" is (a tolerance is the maximum amount of a pesticide residue permitted to remain on food) and when one is needed. The enclosure to this report contains background material, the questions you posed, and our responses.

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<sup>1</sup>Weed Killers by the Glass: A Citizens' Tap Water Monitoring Project in 29 Cities, Environmental Working Group (Washington, D.C.: 1995). The Environmental Working Group is a nonprofit environmental research organization. The group is a project of the Tides Foundation, a California Public Benefit Corporation that provides administrative and program support services to nonprofit programs and projects.

## SCOPE AND METHODOLOGY

In preparing this report, we contacted officials from EPA's Office of Pesticide Programs and reviewed appropriate laws, regulations, and previous GAO reports on pesticides.

We conducted our review from September 1995 through December 1995 in accordance with generally accepted government auditing standards.

## AGENCY COMMENTS

We provided a draft of this report to the Administrator of EPA for review and comment. In responding to the draft, the Director, Office of Pesticide Programs, generally agreed with the responses given in the report and provided some technical comments. We made changes to incorporate these comments as appropriate.

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Major contributors to this report were Susan D. Kladiva, Raymond M. Ridgeway, Jennifer W. Clayborne, and Phyllis Turner. If you or your staff have any questions, please call me at (202) 512-9692.

Sincerely yours,



Lawrence J. Dyckman  
Associate Director, Environmental  
Protection Issues

**BACKGROUND, QUESTIONS, AND RESPONSES ON  
VARIOUS PESTICIDE-RELATED ISSUES**

*In 1987, the National Research Council assessed the risk of 28 cancer-causing food-use pesticides.<sup>1</sup> The Council selected the 28 pesticides from a list of 53 pesticides that EPA had preliminarily determined either caused cancer or had the potential to cause cancer. On September 29, 1995, we reported on EPA's progress in reregistering the 10 pesticides posing the highest such risk, as identified in the National Research Council's report.<sup>2</sup>*

**Question 1:** Does EPA maintain a current ranking of the highest risk cancer-causing food-use pesticides?

**Response:** EPA does not maintain lists of pesticides ranked for risk by their potential to cause cancer or other toxicological factors. EPA's Office of Pesticide Programs (OPP) said that in the past, EPA has developed, for very specific purposes, limited lists of pesticides ranked by risk, but those lists are not maintained or updated. EPA believes that doing so would be costly, of little use to the program, and inappropriate. For example, the agency believes that a list of pesticides ranked only for dietary cancer-causing properties might be misleading, particularly when other toxicological factors (such as the effect on the nervous system) might be equally or more compelling. Also, nondietary risk, such as the risk to workers or adverse effects not related to human health (ecological effects, for example) may be more significant. In general, EPA believes that ranking pesticides for risk is not useful in providing overall direction or setting priorities for the agency's efforts.

*In 1995, the Environmental Working Group published a report on the results of its project to monitor tap water in 29 cities. The group reported that two or more pesticides or metabolites--products resulting from the chemical breakdown of pesticides--had been found in the tap water of 27 cities.*

**Question 2:** What is the reregistration status of the pesticides appearing in the Environmental Working Group's 1995 drinking water study?

**Response:** The following table shows the reregistration status of the pesticides in the study.

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<sup>1</sup>Regulating Pesticides in Food: The Delaney Paradox, National Research Council (Washington D.C.: 1987). 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>2</sup>Reregistration Status of Cancer-Causing Pesticides (GAO/RCED-95-276R).

Pesticide	Year reregistration began	Year reregistration eligibility document is expected to be issued <sup>a</sup>	Notes
Metolachlor	1980	Issued on May 23, 1995	
Metribuzin	1985	1996	
Alachlor	1984	1996	A decision resulting from a special review <sup>b</sup> of the pesticide's carcinogenicity, published in December 1987, required, among other things, restricted use and warnings on the labels. Data on toxicology to support a request to reevaluate the pesticide's cancer classification are currently under review.
Atrazine	1983	No date established	Atrazine was placed in special review in November 1994 because of concerns about cancer and about residues in water. The Environmental Working Group also found two metabolic breakdown products of atrazine--desethylatrazine and desisopropylatrazine--in tap water.
Simazine	1984	No date established	This pesticide was placed in special review in November 1994 because of concerns about cancer and about residues in water.
Cyanazine	See notes	N/A <sup>c</sup>	Although this pesticide was placed in special review, along with atrazine and simazine, in November 1994, a phaseout has been negotiated with the registrant. The use of cyanazine will no longer be allowed after 2002.

Acetochlor	N/A	N/A	This pesticide was registered in 1994 and is thus not subject to reregistration. According to EPA, this pesticide was registered with standards for protecting groundwater and surface water that establish clear criteria for triggering voluntary suspension or cancellation if the water quality is adversely affected.
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<sup>a</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. Through the reregistration eligibility document, EPA requests any needed product-specific studies and revised labeling. Once such data and labeling are received and accepted by EPA (about 14 to 24 months after the eligibility document is issued), the pesticide products are reregistered.

<sup>b</sup>If significant concerns about adverse health or environmental effects arise either before or during the reregistration process, EPA may initiate a special review. A special review is a separate process for reviewing a pesticide's risks and benefits if the pesticide is suspected of posing an unreasonable risk to health or the environment (e.g., suspected of causing cancer, birth defects, or genetic effects). At the conclusion of a special review, EPA may decide to continue, restrict (through labeling changes and other means), or cancel certain uses of the pesticide.

<sup>c</sup>N/A = not applicable.

*The 10 cancer-causing food-use pesticides identified as riskiest by the National Research Council in 1987 were, in ranked order, linuron, zineb, captafol, captan, maneb, permethrin, mancozeb, folpet, chlordimeform, and chlorothalonil.*

**Question 3:** Do any of the 10 riskiest cancer-causing food-use pesticides identified by the Council in 1987 appear in the Environmental Working Group's 1995 study?

**Response:** Although none of the 10 riskiest cancer-causing food-use pesticides identified by the Council in 1987 appeared in the Environmental Working Group's 1995 study, two pesticides in that study--alachlor and metolachlor--were ranked 15th and 17th in risk among

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the 28 cancer-causing pesticides examined by the Council in 1987. The reregistration status of alachlor and metolachlor is shown in the table responding to Question 2 above, along with the status of the other pesticides that appeared in the Environmental Working Group's study.

*The reregistration process is lengthy and complex, as pesticide registrants--generally the producers--conduct numerous health and environmental studies for EPA's review. Over 100 studies may be required to provide the information EPA needs to assess a food-use pesticide. EPA is required to review the registrants' studies and identify gaps in the information.*

**Question 4:** To what extent does EPA use outside contractors to assist in reviewing the studies submitted by the pesticides' registrants?

**Response:** EPA uses outside contractors to assist in reviewing the health and environmental studies submitted by the pesticides' registrants. The use of contractors to review studies varies from office to office within EPA and also depends on the availability of a current contract. For example, within OPP's Ecological Effects Branch, approximately 75-80 percent of all the studies submitted to the Branch were reviewed by a contractor during the period December 1990 to March 1994--the period the contract was in effect. The total number of reregistration studies reviewed by the contractor for the 40-month period was 1,310. From March 1994 to August 1995--when a new contract became effective--all studies were reviewed by staff within the Ecological Effects Branch.

In other science branches within OPP, the percentage of studies on environmental fate, chemistry, and exposure reviewed by contractors in fiscal year 1995 ranged from 18 to 25 percent. Within the Environmental Fate and Groundwater Branch, for example, contractors reviewed 58 of 320 studies, or about 18 percent of the studies reviewed. A contractor typically reviews a study to determine if the data collected are valid and can be used to characterize the environmental exposure and hazards of the pesticide, while EPA's reviewers

use the data to characterize the pesticide's risk and hazard. According to EPA, all the work done by contractors is also reviewed by EPA for quality assurance.

*If EPA finds that a pesticide poses unreasonable risks to humans or the environment, the agency may cancel the registration for some or all of its uses. A manufacturer may also voluntarily cancel a pesticide's registration.*

**Question 5:** What are EPA's procedures for canceling a pesticide's uses?

**Response:** To cancel a pesticide's registration, EPA must first issue a notice of its intent to do so. The registrant has 30 days after receipt of the notice or publication in the Federal Register, whichever is later, to make any corrections identified in the notice or to request a hearing. Any other person adversely affected by the cancellation may also request a hearing within the same 30 days. If the registrant fails to make the required corrections and no hearing is requested, the cancellation becomes effective after 30 days from the date the notice of intent to cancel is received by the registrant or published in the Federal Register, whichever is later.

Instead of issuing a notice of intent to cancel, EPA may also hold a hearing on its own initiative to decide whether to cancel a pesticide's registration. If a hearing is held to challenge the cancellation, and thereafter the cancellation is sustained, or if EPA holds a hearing in which it concludes that a registration should be cancelled, the cancellation is effective immediately upon the issuance of the final order resulting from the hearing.

After a pesticide is cancelled, its sale and distribution for the previously registered uses are generally prohibited. However, EPA may allow existing stocks of the pesticide to be sold, distributed, or used under conditions that it specifies. If the registrant requests a hearing on the cancellation order, a review of the decision begins and the product may continue to be

marketed. However, EPA may immediately stop the sale and use of a pesticide because of an imminent hazard to the environment by suspending the pesticide under its emergency authority. Suspension takes place as part of the cancellation process.

*The Federal Food, Drug, and Cosmetic Act prohibits adulterated food from moving in interstate commerce.<sup>3</sup> Food containing a residue of a pesticide is generally considered adulterated unless EPA has issued a tolerance (the maximum residue level permitted in or on the food) and any residue does not exceed that tolerance.<sup>4</sup> EPA must establish tolerances to the extent necessary to protect the public health, taking into account other relevant factors, including the need to produce an adequate, wholesome, and economical food supply.<sup>5</sup> Under its regulations, EPA will not register a food-use pesticide unless all necessary tolerances, or exemptions from tolerances,<sup>6</sup> have been issued.<sup>7</sup>*

**Question 6:** What is an import tolerance and when is one needed?

**Response:** According to EPA, "import tolerance" is a term commonly used to refer to a tolerance established for foods that are not grown in the United States (bananas or cacao, for example), or for pest problems not encountered in the United States and for which no U.S. registration is involved. The data needed and the standard for establishing and maintaining a food or feed tolerance are the same as they are for domestically produced and imported food.

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<sup>3</sup>21 U.S.C. 331(a-c).

<sup>4</sup>21 U.S.C. 342(a)(2); 346a(a).

<sup>5</sup>21 U.S.C. 346a(b).

<sup>6</sup>EPA may exempt a food-use pesticide from the requirement for a tolerance when such a tolerance is not necessary to protect the public health against the pesticide's residue (21 U.S.C. 346a(c)).

<sup>7</sup>40 C.F.R. 152.112(g).

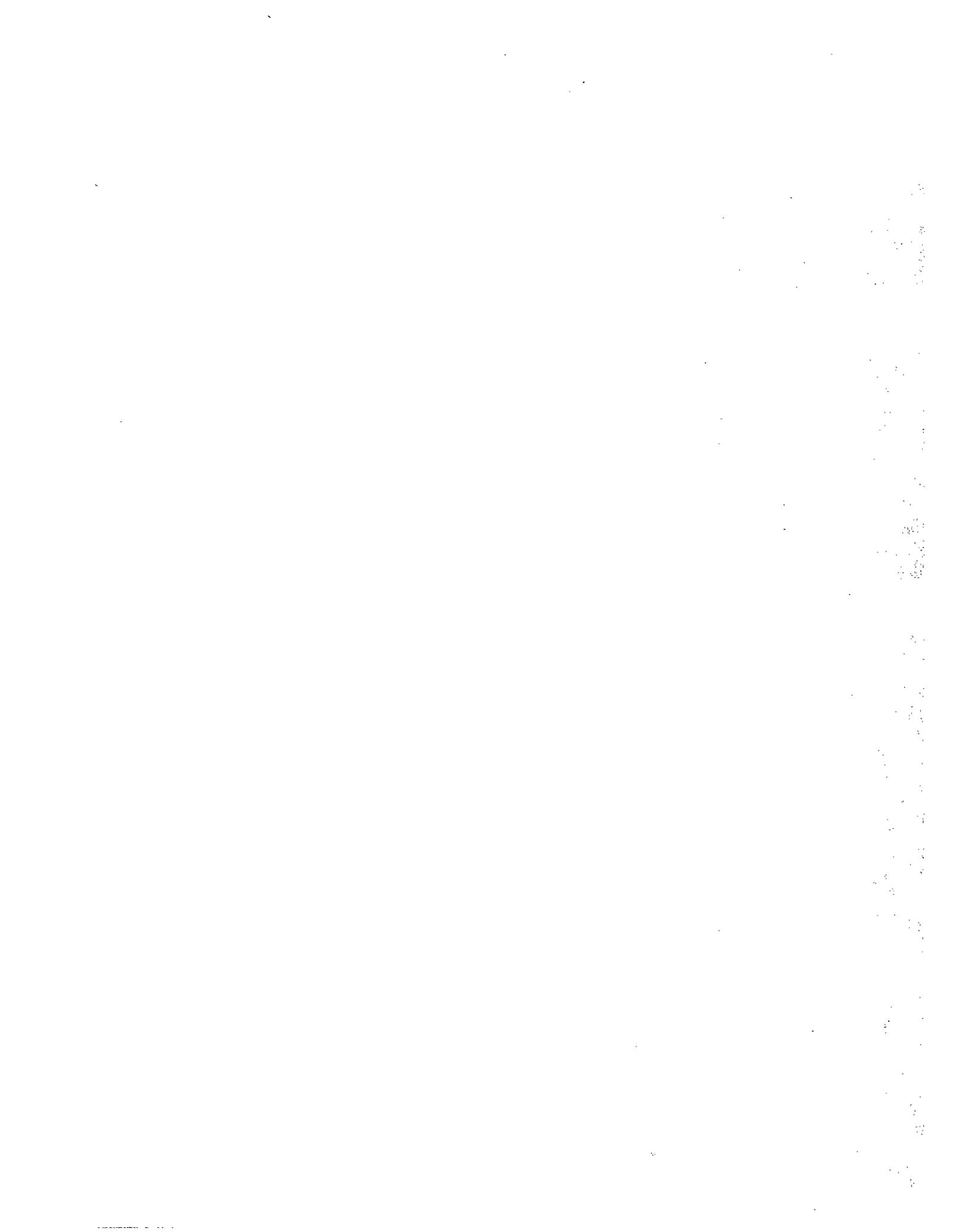
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According to EPA, an import tolerance is no different from a tolerance that would be established for a crop such as tomatoes, which is both grown domestically and imported.

A U.S. tolerance is generally established as part of the registration of the pesticide for use in the United States, and the tolerance covers imported foods. In the reregistration process, EPA reassesses all the tolerances established for a pesticide, including so-called import tolerances. According to EPA, if it determines that the tolerances continue to pose no dietary risk, the tolerances are retained.

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