How to Report Pesticide Adverse Effects & Get Access to Reported Adverse Effects Information

by James Handley

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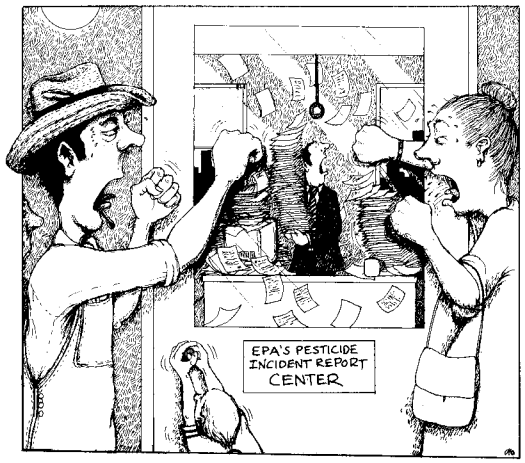
James Handley was the attorney in an EPA enforcement action against DowElanco in 1995 for its failure to report to EPA adverse effects reports, as required by law, which it received on the insecticide chlorpyrifos. His work resulted in a fine of $876,000, the largest in the program's history. DowElanco's violation of Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) came to light after the National Coalition Against the Misuse of Pesticides advised Connie Chung's CBS program Eye-to-Eye to ask EPA whether it had received reports from DowElanco on poisonings. Specifically, the program was reporting on a lawsuit involving a West Virginia boy, Joshua Herbst, whose parents sued DowElanco for his injuries that they attributed to prenatal exposure to chlorpyrifos. EPA had no report of the poisoning. And, after further investigation, it was found that DowElanco had failed to report hundreds of incidents, most of which involve its product Dursban (containing chlorpyrifos), but some also involving other DowElanco pesticides. Dursban™ is an organophosphate pesticide, the effects of which include chronic delayed neuropathy (numbness and tingling in the hands and feet) as well as other neurological symptoms. As a result of EPA's review of heretofore unreported incidents, DowElanco agreed to withdraw registration for Dursban when used in total-release foggers. (Ordinarily registrants do not withdraw registrations unless EPA cancellation seems at least probable, and that generally occurs when there is serious concern that the risks of a given use outweigh the benefits.) All other uses of Dursban are unaffected by this action. The story does not end here; Dursban adverse effects continue to be reported. In July 1999, EPA filed an action against Dow AgroSciences (successor to DowElanco) for late reporting of adverse effects involving termite application to a house in Overland Park, MO. The reported adverse effects include neurological symptoms. —Editor.



Adverse Effects Reporting Supplements Registration Data from Registrants

EPA's pesticide registration process involves the submission by pesticide registrants of data about the products that they seek to register. To support claims of safety, EPA may require registrants to perform animal and other laboratory studies. *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA) section 6(a)(2) provides a window on the real world and an after-the-fact check on registration decisions by requiring registrants to report to EPA "additional factual information about unreasonable adverse effects." This information may come in the form of studies that the registrant undertakes or learns about or information about exposure incidents, for instance, where individuals become ill or die as a result of pesticide exposure. EPA has developed a regulation (62 FR 49369, September 19, 1997) describing what is to be reported, which explains that registrants must report information about persons or non-target organisms that suffer adverse effects after exposure. No proof of a "cause and effect" relationship is required for an incident to be reportable because EPA uses the reports to look for patterns; spurious reports are sifted out in this process. Adverse effects information may lead the Agency to change the label, limit the approved uses of a pesticide, or even cancel a registration. (*See sidebar*)

Adverse effects reports are therefore an important supplement to the data generated by registrants in support of registration and perhaps this is particularly true now as EPA reassesses pesticide registrations and food tolerances. This article is intended to give consumers and public interest organizations suggestions on how to report these adverse effects and, in addition, how to get access to the information that has already been reported to EPA.

EPA Eliminates Requirement to Report "chronic or delayed" Adverse Effects

The FIFRA 6(a)(2) rule describes what information pesticide registrants are required to report. The rule was promulgated after public notice & comment in the *Federal Register* and went into effect in the summer of 1998. EPA's Office of Pesticide Programs conducted a series of meetings that spring with registrants (chemical companies) to answer questions and gain their cooperation in reporting under the new rule. A group of trade organizations representing registrants petitioned EPA to eliminate the requirement that they report incidents where a person "may suffer a delayed or chronic adverse effect in the future." Registrants expressed concern that this would require them to report whenever someone *thought* he or she *might* later get sick. EPA agreed to eliminate this requirement, and issued a pesticide registrant notice (Pesticide Registrant (PR) Notice 98-4) eliminating the requirement on August 4, 1998. Unfortunately, eliminating this requirement may also hinder EPA's ability to track incidents of chronic or delayed neuropathy which are adverse effects associated with organophosphates. Dursban (chlorpyrifos) is one of the most widely used organophosphates and large quantities are very commonly used to treat soil around homes and other buildings for termites (see related story on DowElanco and Dursban). *See the text of the PR notice at http://www.epa.gov/pesticides/fifra6a2.htm.*

Action Item: It is important that EPA collect as much information about all possible illnesses related to pesticide exposure. Write a letter to EPA Administrator Carol Browner *(401 M Street, SW, Washington, DC 20460)* to reinstate the reporting requirement for chronic and delayed effects immediately. *—Editor*

First, it should be emphasized that the *requirement* to report is borne by the *registrant* (chemical company). That is because the registrant is, in effect, being issued a license by EPA to distribute and sell a pesticide. Reporting adverse effects to EPA is a condition of the registration. Consumers typically report problems to registrants or their agents or to poison control centers and this information is often organized and reported to EPA. EPA has contracts with several universities that collect and assemble data from poison control centers and provide it to the Agency. Registrants (at least those in compliance with the law) also have a process for collecting and summarizing data to EPA. Except for more severe incidents (e.g., involving deaths) registrants may accumulate data about several incidents before submitting it, and reports of the least severe incidents are submitted as summaries.

How to Report Pesticide Adverse Effects

When a pesticide adverse effect involving human health occurs, obviously the first priority is to obtain first aid and medical assistance. Refer to the label and call a poison control center and/or a hospital. Provide as much specific information about the product and the exposure as you can so they can respond with appropriate first aid instructions (or bring the proper antidotes in the ambulance). Another resource for medical and toxicological advice, funded by EPA, is the National Pesticide Telecommunication Network at 1-800-858-7378 which operates between 6:30 and 4:30 PM Pacific Standard Time. (It collects and reports data to EPA but it doesn't go into the 6(a)(2) data base.) You should also contact the pesticide registrant both for emergency advice and to report the incident. Many companies put toll free numbers on their labels that are staffed to provide assistance, often 24 hours a day. In an ideal world, a call to the poison control center or to the registrant would be enough to assure that the incident was reported. The registrant or the poison control center would report the information to EPA. But for various reasons that does not always happen. Individuals who want to be sure their reports are received by EPA can submit information themselves. Similarly, organizations of people who are routinely exposed to pesticides (such as farm workers or pesticide applicators) may be able to collect and submit useful adverse effects information that presently is not being reported.

Submitting information to EPA is straightforward. EPA decided not to develop a required form for reporting (because this would have required justification for information collection under the Paperwork Reduction Act), but the pesticide industry, with EPA advice, has developed a standard form (with instructions) for reporting which can be found on the Internet at www.fifra6a2.com. (Other information about the FIFRA 6(a)(2) program, including the text of the 6(a)(2) rule can be found at www.epa.gov/pesticides/fifra6a2.htm. For instance, this site includes the text of Pesticide Registrant Notice 98-4 which eliminated until further notice the requirement that registrants report incidents where "a person may suffer a delayed or chronic adverse effect in the future.") (*See Sidebar*)

A report on a human health incident should generally include:

1. Who was injured? (Name, address, contact phone number, age, gender, pregnant?)
2. When did the injury occur and when did the symptoms arise?

3. What was the product and registration number? How much was involved?
4. What were the circumstances? (E.g., was there a spill or leak? Were the label instructions followed? Was the product being mixed, sprayed, transported, etc.?)
5. What was the route of exposure? (E.g., breathing fumes, contact with skin, eyes, eating contaminated food, etc.)
6. Was the exposure intentional? (E.g., attempted suicide or homicide.)
7. Medical care sought and obtained? Any medical opinions?
8. List of symptoms and adverse effects, including when they started.
9. Results of any lab tests performed.

Reports can be supplemented later if more information is obtained after the original report.

For incidents involving fish, wildlife, plants and other non-target organisms, the information is somewhat different, but follows similar logic. Reports should include:

1. The species affected and number of individuals per species.
2. Symptoms or adverse effects, including description of severity.
3. Magnitude of effects (e.g., square feet or land or miles of stream).
4. Pesticide application rate (per acre).
5. Results of lab tests.
6. Circumstances and description of habitat.
7. Distance from treatment site.
8. Name of the pesticide product and registration number.

For incidents involving domestic animals, reports should include:

1. Type of animal, including species and breed.
2. Exposure route.
3. Adverse effects, including severity.
4. Treatment.
5. Lab test results.
6. Name of the pesticide product and registration number.

In addition to incidents involving adverse effects to humans and non-target organisms, EPA requires incidents involving contamination to groundwater and surface water and of unauthorized residue in food or feed to be reported. All incidents should be reported to:

Document Processing Desk, 6(a)(2)
Environmental Protection Agency
Office of Pesticide Programs (7504C)
401 M Street, SW
Washington, D.C. 20460

Federal Pesticide Regulation under FIFRA & FQPA

The primary laws that regulate pesticides in the United States are the *Federal Insecticide Rodenticide Act* (FIFRA) and the *Federal Food Drug and Cosmetic Act*, both of which were amended by Congress with the 1996 *Food Quality Protection Act* (FQPA). FIFRA established EPA's program for registration and labeling of pesticides. In order to register a pesticide, EPA must determine that when used in accordance with widespread and commonly recognized practice, the product will perform its intended function without causing *unreasonable adverse effects on the environment* (which in this context is construed to include human health). When EPA registers a pesticide, it reviews and approves a label submitted by the registrant. The label contains the legal restrictions on the pesticide's use; misuse is a violation of federal law.

Many pesticides have been registered for decades without a comprehensive review of their risks and benefits. When Congress enacted FQPA in 1996, it mandated that EPA review all food tolerances for pesticides (and implicitly, all registrations) over the subsequent 10 years. Congress instructed the Agency to develop a schedule within the first year prioritizing this review, focusing first on the pesticides that pose the greatest risk to public health and to complete its review of the first one-third of these pesticides within 3 years. The deadline for review of the first third is August 16, 1999. Congress provided that the schedule setting the *priority* in which EPA will review pesticides cannot be challenged in court but once the schedule is established, *"failure to take final action pursuant to the schedule"* is subject to judicial review. FQPA also instructed EPA to take special account of the effects of pesticides on children and of endocrine-disrupting effects. It also set up a default "ten-fold margin of safety" that is to be applied where there is inadequate data to assess risk. At present, EPA's Office of Pesticide Programs is busily working to meet the August deadline. The process has been controversial, and EPA set up a "Tolerance Reassessment Advisory Committee" to involve "stakeholders" and make the reassessment process more "transparent" to registrants and the public. (Several environmental groups eventually withdrew from this advisory committee, complaining of the slow pace and their perception that the agricultural chemicals industry wielded disparate influence on the Committee.)

Some states (notably California) have their own pesticide adverse effects reporting systems, so you may also want to report to your state so it is aware of the situation. Additionally, some public interest groups, such as Beyond Pesticides/NCAMP, compile information about pesticide incidents and you may want to provide information to them to assist in their advocacy. (*See box)*

Adverse Effects Data at EPA

When EPA's Office of Pesticide Programs receives adverse effects information, it reviews, summarizes, and enters it into a computer data base for EPA to use in performing its regulatory function over pesticide registrations. The FIFRA 6(a)(2) data base is organized by pesticide category and registrant. Because of concerns about privacy, it generally does not contain specific information about individuals, including names and medical data. Although the data base was not set up to inform the public, the information may be of interest to individuals or organizations that want to know about reported problems. For instance, if you are deciding whether to use a particular product or if you were injured or are an attorney representing (or considering representing) a person who feels he or she was injured by pesticide exposure, you may want to check for reports of similar incidents involving the same pesticide or active ingredient.

Information about pesticide adverse effects can be obtained by the public through the Freedom of Information Act (FOIA). The Office of Pesticide Programs has a web page on how to obtain information at www.epa.gov/opppmsd1/PR_Notices/pr94-3.html. FOIA requests should be submitted to:

Freedom of Information (1105)
U.S. Environmental Protection Agency
401 M Street, S.W.,
Washington, D.C. 20460
Fax (202) 260-0295

FOIA requests should be as specific as possible. For instance if you are interested in a particular pesticide and a particular type of adverse effect, specify those as much as possible including the active ingredient. OPP has very limited staff, which limits the number of requests they can handle and the speed with which they can respond. It's not unusual for a response to take several months. To speed the process along, you may want to do a "piggy-back" FOIA, which means you ask for the documents that have previously been released under FOIA on your subject. The Agency can more quickly send you a copy of what was already released to another person. At the same time you may want to supplement this request by asking for any new documents that were created or submitted after the prior request. This will generally take longer. Keep in mind that FOIA does not require the Agency to create any new documents or to even summarize existing documents. The EPA person responding to your request may call you to clarify the request. This person may be willing to describe what documents exist and are available. For instance, for a particular pesticide, you may simply want the summary information from the 6(a)(2) data base. After reviewing that, you may decide that for certain incidents or studies you want the supporting documents that were submitted. Keep in mind that FOIA exempts from disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." Thus, in responding to your request, the Agency is likely to "redact" portions of some documents in order to protect individuals' privacy.

As you can see, FOIA and FIFRA §6(a)(2) are imperfect tools for members of the public who want to know more about pesticide adverse effects. Answering information requests from the public is one of many important responsibilities of the Office of Pesticide Programs, and FQPA has placed new and urgent responsibilities on OPP staff. Therefore, they would appreciate your efforts to coordinate and consolidate information requests. Perhaps this is an area that deserves increased resources. Under the *Government Performance and Results Act* (GRPA), EPA was required in 1997 to submit to Congress a 5-year Strategic Plan which will be updated in 2000. One of EPA's ten Strategic Goals is "Expansion of American's Right to Know About Their Environment." This goal is explained as follows:

"Easy access to a wealth of information about the state of their local environment will expand citizen involvement and give people tools to protect their families and their communities as they see fit. Increased information exchange among scientists, public health officials, businesses, citizens, and all levels of government will foster greater knowledge about the environment and what can be done to protect it."

Should information about pesticide risks and benefits, including adverse effects information, be part of this "right to know"? Could additional resources be provided to the Office of Pesticide Programs to make 6(a)(2) data more accessible to the public so it can play a more informed role in the reassessment of pesticide risks mandated by FQPA?

Beyond Pesticides/NCAMP's Toxic Warning Signals Project

Beyond Pesticides/NCAMP:

- collects data on incidents through its Pesticide Incident Report (PIR). Contact us for a copy.
- maintains a step-by-step guide, "How to Avoid Pesticide Poisoning and What to Do if You Can't," on its website www.ncamp.org.
- will publicize the tragedies associated with daily pesticide use, share them with regulatory officials and the media, help people find more facts, litigate, and build a base of political power to turn the situation around.