●PESTICIDE REGISTRATION

NO GUARANTEE OF SAFETY

Our national pesticide law is not a health- or safety-based law. Instead, it is based on risk-benefit analysis: hazardous pesticides can be registered as long as they offer enough economic benefits. It is nearly impossible to do a sound risk-benefit analysis. There is no satisfactory way, for example, to weigh the costs of two million dead birds, or 100 children born with birth defects, against the profit margins of chemical manufacturing companies.

The registration process is cumbersome and expensive, but it misses or ignores many important effects. Pesticides are registered while important health and safety data are still being generated; reevaluations of old pesticides mandated by laws passed in the 1970s are still incomplete; pesticides may continue to be used after evidence of their hazards is given to EPA; and pesticides may never be required to be tested for certain kinds of hazards.

True resolution of these problems will come only when we prevent pest problems and implement alternative pest management techniques.

UPDATED BY CAROLINE COX

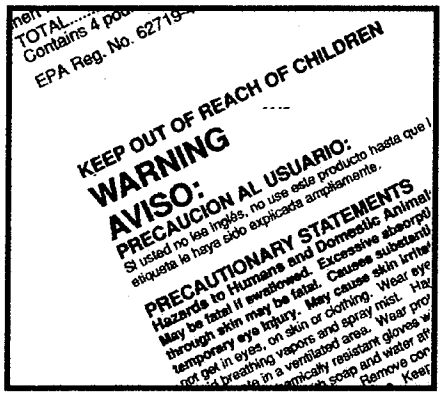
Following some complaints about the herbicide program along your county's roads, county officials set up a public hearing. Stories are told about how you and your neighbors have seen the sprays' damage. The answer? "We're sure that our pesticides don't cause problems," officials say. "They've been approved by the U.S. Environmental Protection Agency (EPA)."

A new insecticide is used at a local school. Parents and teachers ask questions. A chemical company representative responds, "It costs millions of dollars to complete the tests required by EPA. We assure you that this product won't harm you or your children."

Sound familiar? These kinds of remarks are heard repeatedly in communities across the country. How can we respond to these kinds of comments? What does the EPA registration process actually do or not do? How well does it work?

No Guarantee of Safety

As a starting place, it is crucial to understand that EPA does not view registration, the process that allows a pesticide to be legally sold in the U.S., as a guarantee of safety. In fact, EPA regulations specifically prohibit manufacturers of pesticides from making claims like "safe," "harmless," or "non-toxic to humans and pets" with or without accompanying phrases like "when used as directed."[1] NCAP believes that neither manufacturers nor pesticide users should make these kinds of claims. Pesticides are poisons, most of which are designed to kill. Claims to the contrary are misleading and should be challenged.



The Regulatory Framework

Several flaws built into the pesticide registration process make it impossible to guarantee the safety of a pesticide.

First, the law regulating pesticides is not a health- or safety-based law. Instead, it is based on a risk-benefit standard. This allows pesticides to be used even if they pose hazards to humans and the environment as long as the benefits outweigh the hazards.

Second, the regulatory process has never been able to cope with the huge number of products used as pesticides, so that many of the pesticides in use today do not meet the requirements of the law.

A brief look at the history of U.S. pesticide regulation illustrates these flaws.

Fifty Years of Legislation

Our national pesticide law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was enacted in 1947 as a product reliability law designed to assure farmers that pesticides would actually perform their intended function and that they were not acutely toxic.[2,3] Put another way, the law was not intended to protect human or environmental health.

The 1970s brought two important changes to pesticide regulation: (1) In 1970, the administration of the law shifted from the U.S. Department of Agriculture to the newly formed Environmental Protection Agency; and (2) the 1972 FIFRA amendments, for the first time, required chronic toxicity and

Caroline Cox is the editor of NCAP's magazine, the *Journal of Pesticide Reform.* This article, written in April, 2002, updates "No Guarantee of Safety" (JPR 17(2):2-9).

environmental concerns to be included in registration. In addition to registering new products, EPA was to "reregister" the 50,000 products that were already on the market.[2,3] Reregistration involves bringing all health and safety testing up to current standards.

The way in which the 1972 FIFRA amendments mandated that health and environmental concerns be evaluated is fundamentally different from the way that our laws deal with other environmental hazards. FIFRA requires EPA to register pesticides if they do not pose "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[4] Any health or environmental hazards of a pesticide can be acceptable if their estimated benefits (increased crop yields or decreased agricultural production costs) are believed by EPA to outweigh the hazards.

The risk-benefit standard can seem logical at first glance, but it actually is seriously flawed. Pesticide use mainly benefits the pesticide industry. The risks, however, are mostly borne by entirely different groups: the animals, plants, microorganisms, and humans who are exposed to the chemical. EPA is supposed to balance these risks and benefits, but it is nearly impossible to do this task well.

In addition, benefits of pesticide use have traditionally been calculated based on limited information. In general, calculations of benefits are done by comparing the cost of the pesticide in question with the cost of other pesticides or with the costs (reduced yields) of doing no pest management at all. Nonchemical management techniques are usually not considered. For example, when the U.S. General Accounting Office (GAO) analyzed benefit assessments done by EPA for five agricultural pesticides, GAO found that EPA had considered nonchemical alternatives for only two minor cases.[5] This omission automatically inflates the calculation of benefits.

By the 1980s, little progress had been made in reregistering pesticides.[2] In 1986, a General Accounting Office survey of EPA data on 92 food-use pesticides showed that 62 percent lacked required cancer tests, 73 percent lacked required birth defects tests, and 73 percent lacked required mutation tests.[2] By December 1988, EPA had evaluated the data that the agency had received for 194 of the over 600 active ingredients needing reregistration[6] and decided what data were missing or inadequate. However, no products had completed the reregistration process.

Congress again passed FIFRA amendments in 1988 (called FIFRA '88), this time requiring a strict time line for industry submission of reregistration tests. All tests for pesticides registered before November 1, 1984 were to be completed and submitted to EPA within nine years (by 1997).[6]

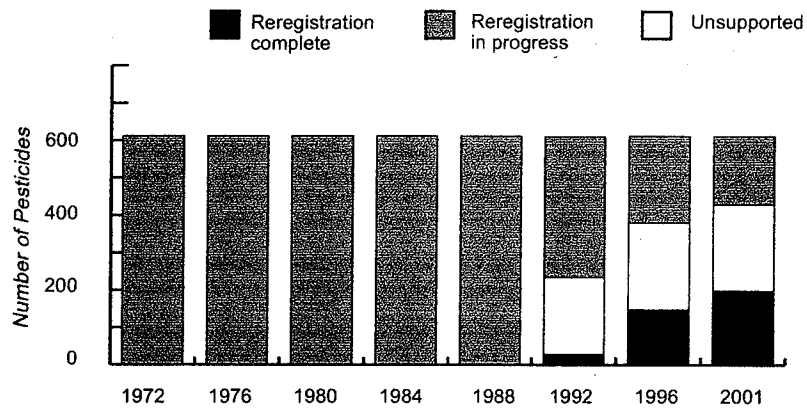
When all these tests have been evaluated by EPA and the agency determines that the pesticide does not cause unreasonable adverse effects when used according to the label, EPA issues a reregistration eligibility decision.[7]

However EPA has fallen behind in meeting FIFRA 88's scheduled goals. As of September, 2001, only 34 percent of the active ingredients requiring reregistration had completed the process.[8] (See Figure 1.) EPA estimates that reregistration will not be complete until 2006.[8]

In 1996, Congress passed new pesticide legislation (the Food Quality Protection Act; FQPA) that contained amendments to both FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA). Many of the provisions of the law affect the way pesticide residues on food are regulated. (See "Food Tolerances," p.6.) The most important change in pesticide regulation is that all registrations will be reviewed every 15 years.[9] Since reregistration is will not to be finished until more than 30 years after it started, this is an ambitious goal.

In addition, EPA's authority to preserve so-called "minor-use" pesticide registrations was expanded. ("Minor-use" is the term used to describe the pesticides used on most vegetable, fruit, and nut crops, those grown on less than 300,000 acres in the U.S.[10]) The new amendments allow EPA to waive data requirements,[11] extend testing deadlines,[12] and offer exemptions from registration fees for these pesti-

Figure 1
Reregistration's Slow Progress



Sources:
U.S. EPA. Prevention, Pesticides and Toxic Substances. 1992. Pesticide reregistration progress report. Washington, D.C. (Oct.)
U.S. EPA. Prevention, Pesticides and Toxic Substances. 1996. Office of Pesticide Programs annual report for 1996. Washington, D.C. (Nov.)
U.S. EPA. 2001. Office of Pesticide Programs FY 2001 annual report. Partners and stakeholders: working together to protect public health and the environment. www.epa.gov/pesticides.

Reregistration, the process of evaluating old pesticides according to current standards, although mandated in 1972, is proceeding slowly and is only half finished.

TABLE SALT, ASPIRIN, AND PESTICIDES

One of the most commonly used measures of the toxicity of a pesticide is the LD_{50}, the dose of the chemical that will kill 50 percent of a population of test animals. Proponents of pesticide use often use the LD_{50} to state that a pesticide is less toxic than aspirin or table salt.

There are several important ideas to keep in mind when evaluating such statements. First, LD_{50}s measure only the dose that causes death immediately. They don't include many serious health problems. The ability to cause cancer, birth defects, or neurotoxic effects, for example, is not measured by the LD_{50}. Individual differences in susceptibility are not considered; LD_{50}s do not measure the dose that kills the first animal, or ten percent of the animals. In addition, humans might be more sensitive to the pesticide than the test species. LD_{50}s are based on only one route of exposure (most commonly eating the pesticide) and don't consider the multiple ways in which people are exposed to pesticides. We can drink or bathe in contaminated water, for example, be exposed through our skin, or breathe contaminated air.

Writing about these kinds of comparisons, New York's attorney general stated, "This type of comparison is generally based on so many simplifying and limiting assumptions as to be meaningless."[1] As consumers, and as residents in areas where pesticides are used, we are entitled to more useful and less misleading information.

1. Abrams, R. 1987. Lawn care pesticides: A guide for action. Albany, NY: State of New York Dept. of Law.

USDA/Tim McCabe

EPA is in the process of reevaluating (reregistering) all older pesticides in order to bring their health and safety testing to current standards. However, even pesticides that have completed this process pose significant hazards to human and environmental health.

cides.[13] Also, Congress appropriated 10 million dollars to help pay for testing "minor use" pesticides.[14] In simple terms, these pesticides receive outright taxpayer subsidies.

Flaws in Reregistration

Even when reregistration for a pesticide is complete, there is no assurance that the pesticide is "safe" in the common-sense meaning of the term. A few examples from recent reregistrations show that pesticides are reregistered in spite of clear evidence of hazards.

- The herbicide **metolachlor** was reregistered in 1995.[15] It is the second most widely used herbicide in U.S. agriculture.[16] EPA classified it as a "possible human carcinogen." It has adversely affected the growth and development of juvenile fish at concentrations close to 1 part per million. It has been found in the groundwater in 20 states, and is among the top five pesticides detected in surface and drinking water in the Midwest.[15]
- **Chlorpropham**, reregistered in 1996, is a sprout inhibitor used on about 60 percent of the potatoes eaten in the U.S. In laboratory studies, it caused anemia in both dogs and rats. In pregnant rabbits, chlorpropham caused fetal loss. The average child's daily diet is contaminated with between 85 and 231 percent (depending on what assumptions are made) of what EPA believes is an acceptable amount of chlorpropham.[17]
- The organochlorine insecticide **heptachlor** was reregistered in 1992 although fifteen years previously EPA had negotiated cancellation of almost all registered uses because of its "demonstrated carcinogenic and developmental effects in mice and rats, as well as its persistence in the soil for many years and bioaccumulation throughout the food chain."[18]
- EPA's Ecological Effects Branch (EEB) characterized the herbicide **picloram** as having "extreme phytotoxicity."[19] EEB also noted that it had significant persistence under typical conditions, and "extreme propensity to leach into groundwater."[19] Both EEB and the Environmental Effects and Groundwater Branch recommended against the reregistration of picloram.[19,20] However, the reregistration process was completed in 1995, with only a few requests for additional data.[21]
- The herbicide **bromoxynil** was reregistered in 1998. It causes liver cancer in laboratory animals. In addi-

tion, pregnant animals fed bromoxynil have more miscarriages and more offspring with skeletal abnormalities than unexposed animals. It reduces egg production in birds, and is "very highly toxic" to some fish.[22]

• **Chlorothalonil**, a fungicide reregistered in 1999, is a likely human carcinogen and causes kidney tumors in laboratory animals. It also is corrosive to eyes. It reduces eggshell thickness when fed to birds, and is "very highly toxic" to fish and other aquatic animals.[23]

• The fungicide **vinclozolin**, reregistered in 2000, causes testicular cancers in laboratory tests, and disrupts the normal activity of androgens, male sex hormones. Testicular effects have also been reported in birds.[24]

Flaws in New Registrations

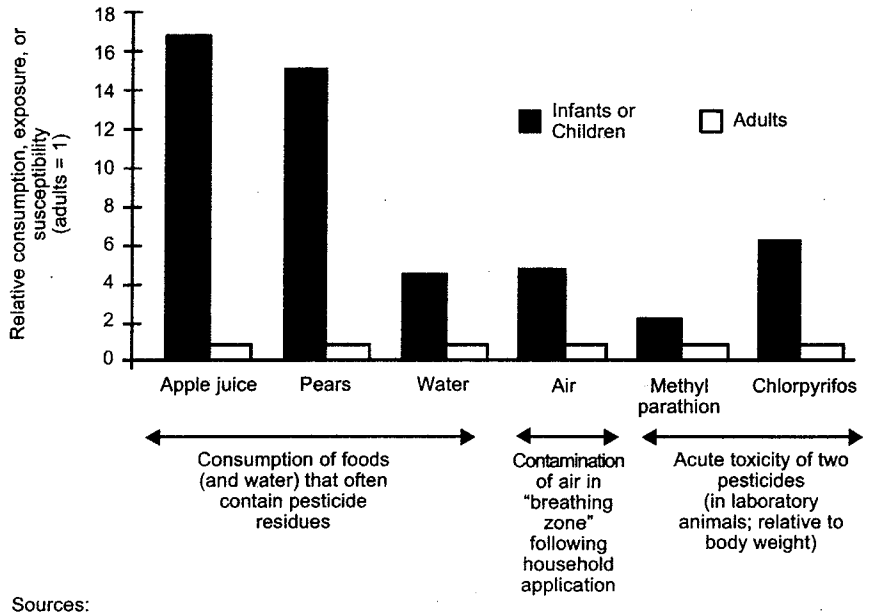
Since 1984, an average of over 18 new products (ranging between 6 and 38 per year) have come on the market annually.[25] These pesticides are not subject to the reregistration process set up by FIFRA '88 for older pesticides.[26]

This doesn't mean, however, that health and safety testing is complete. Under FIFRA, EPA can allow "conditional registration" of new pesticide products even though health and safety tests are missing[27] because requiring completion of all the tests would put new products at an economic disadvantage to older pesticides.

NCAP surveyed 41 new conventional pesticides registered between 1997 and 2001; over half were conditionally registered. Even pesticides with full (not conditional) registrations do not always have complete testing. In NCAP's survey, over half of the pesticides with full registrations were incompletely tested at the time they were registered.[28]

Whether conditionally registered or not, new pesticides often have significant hazards. NCAP's survey of new registrations found that almost 20 percent were classified by EPA as carcinogens; over one-third had caused genetic damage in laboratory tests submitted as part of the registration process; over three-quarters had caused birth defects, miscarriages, or other reproductive problems in laboratory tests; and over 20 percent were neurotoxic.[28] Ecological hazards were also common; NCAP's survey found that almost a quarter of newly registered pesticides adversely affected birds, almost half were moderately or highly toxic to fish, and EPA believed almost 20 percent had chemical characteristics that made them likely to contaminate water.[28]

Figure 2
Relative Exposure of Infants and Children to Pesticides and Their Relative Susceptibility



Sources:
National Research Council. Commission on Life Sciences. Committee on Pesticides in the Diets of Infants and Children. 1993. *Pesticides in the diets of infants and small children.* Washington, D.C. National Academy Press.
Fenske, R.A. et al. 1990. Potential exposures and health risks of infants following indoor residential pesticide applications. *Am. J. Pub. Health.* 80: 689-693.
C.N. Pope et al. 1991. Comparison of in vivo cholinesterase inhibition in neonatal and adult rats by three organophosphorothioate insecticides. *Toxicol.* 68:51-61.

Children can be more susceptible to pesticides than adults, and are more heavily exposed. For their size, they eat more food and drink more water than adults. Both are potentially contaminated with pesticides. Children also spend more time close to the floor where pesticide concentrations in the air they breathe are higher following pesticide applications in a home. In addition, for several widely used chemicals the amount that causes death in laboratory animals is smaller in newborns than in adults.

Problems with Testing

The hazards described in the preceding two sections are hazards that have actually been documented during the registration process. However, even though a large number of tests are required, registration leaves many important questions about pesticide hazards unanswered. The next six sections of this article describe some of those unanswered questions.

Important Tests Are Waived

While many pesticides are used on food crops, some are registered only for nonagricultural uses like homes, rights-of-way, and turf. Assuming that exposure will be minimal since humans will not eat residues of these pesticides, EPA can waive all chronic toxicity tests for nonagricultural pesticides. These include tests of whether the pesticide causes cancer, genetic damage, birth defects, and other reproductive problems.[29] The agency has said it will not require chronic toxicity tests unless there will be significant human or environmental exposure, but a 1986 General Accounting Office report pointed out that EPA lacks both

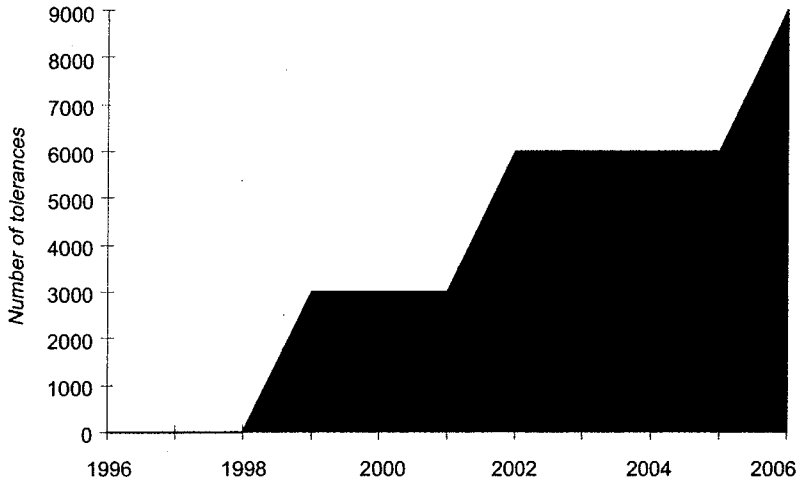
FOOD TOLERANCES

Food tolerances specify the concentrations of pesticides that can legally be present on food. Although tolerances are not a new concept, EPA's tolerance evaluation procedures changed significantly in 1996 because of the Food Quality Protection Act's (FQPA's) amendments to the Federal Food, Drug and Cosmetic Act.

Under FQPA, EPA is reassessing over 9,700 tolerances that were in place at the time FQPA became law. As of September, 2001, EPA had reassessed about 40 percent of these tolerances. In addition, any new tolerances must comply with FQPA.[1]

To establish a tolerance, EPA first sets the acceptable daily consumption of the pesticide (often called the reference dose). This acceptable amount is based on the lowest "no observable effect level" (NOEL), the dose at which no adverse effects were observed during toxicity studies. The NOEL is divided by an uncertainty factor of 100 to calculate EPA's acceptable daily consumption: a factor of ten to account for differences between the laboratory animals tested and humans, and another factor of ten to account for individual differences in sensitivity.[2]

Figure 1
Tolerance Reassessment Schedule Under the Food Quality Protection Act



Source: U.S. EPA. Prevention, Pesticides and Toxic Substances. 1997. 1996 Food Quality Protection Act: Implementation Plan. Washington, D.C. (Mar.)

If tolerance reassessment proceeds according to the schedule set up in the Food Quality Protection Act, it will not be finished until 2006.

USDA/Ken Hammond

FQPA requires food tolerances to be set with a special safety factor to protect children unless "reliable data" suggest otherwise.

FQPA requires an additional (up to 10-fold) safety factor to account for the special susceptibility of children unless "reliable data"[3] suggest a different factor will be "safe for infants and children."[3]

EPA then uses information about food consumption collected by the U.S. Department of Agriculture (USDA) to calculate how much of the pesticide an average person would consume if the proposed tolerance were adopted. The tolerance is set so that this amount does not exceed the reference dose.[5]

If a pesticide causes cancer in laboratory animals, a different calculation is made. The tolerance is set so that estimated exposure will be less than the amount calculated to cause one extra cancer case per million people.[4] This is the level that EPA calls a "negligible risk." Economic benefits can justify cancer risks that are up to ten times higher.[3]

Prior to FQPA, tolerances were set for each chemical separately, without consideration of the amount of other pesticides that may be present on a particular food. FQPA now requires that tolerance-setting consider cumulative exposure to pesticides with similar mechanisms of toxicity if such information is available.[3]

Food tolerances also did not account for exposure to a pesticide other than through food until FQPA was passed. FQPA now requires that exposures to pesticides in drinking water and from home uses also be considered when setting a food tolerance.[3]

Problems with Tolerances

There are two major problems with the tolerance setting process. First, the food consumption database averages, and thus the tolerances, do not take into account

people's individual preferences. Many people will consume different amounts than the database average. If you eat more than a quarter of an ounce of green beans in a day, for example, or more than two-thirds of an ounce of apples, you are eating more than the average person.[6]

Second, FQPA improvements are slow. In response to a lawsuit filed by the Natural Resources Defense Council, the first cumulative risk assessment was scheduled to be completed in December, 2001,[7] but EPA did not meet that deadline.[8] As of September, 2001, over 5,800 tolerances were still based on only dietary exposure.[1] Reassessment of all existing tolerances will not be complete until 2006.[9]

Are Tolerances "Safe"?

Under FQPA, pesticide residues in food must be "safe."[3] However, the legal definition is very different from a commonsense definition. For example, EPA recently (January 2002) set a tolerance, and made a "determination of safety," for the fungicide fenbuconazole on bananas, pecans, peaches, apricots, and cherries.[10] Tests submitted to EPA show that fenbuconazole causes liver cancer in mice and thyroid cancers in rats. When fed to pregnant rats, it caused an increase in fetal loss and stillbirths.[10] To intentionally apply this kind of chemical to foods like peaches or bananas seems far from "safe."

1. U.S. EPA. 2000. Pesticide reregistration performance measures and goals. *Fed. Reg.* 65:37375-37383, June 14.
2. U.S. EPA. Integrated Risk Information System (IRIS). 1999. Glossary of IRIS terms. Washington, D.C., Oct. www.epa.gov/iris.
3. FFDCA Sec. 408(b).
4. U.S. EPA. Prevention, Pesticides and Toxic Substances. 1997. 1996 Food Quality Protection Act: implementation plan. Washington, D.C. p. 22.
5. U.S. EPA. Office of Pesticide Programs. Available information on assessing exposure from pesticides in food: A user's guide. Washington, D.C., June 21. www.epa.gov/oppfead1/trac/science.
6. U.S. Dept. of Agriculture, Agricultural Research Service. 1997. Data tables: Results from USDA's 1994-96 continuing survey of food Intakes by individuals and 1994-96 diet and health knowledge survey. Available on CD-ROM (NTIS Accession Number PB98-500457) or from www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html#anchor 164107.
7. Natural Resources Defense Council v. Whitman. C-99-3701. Partial consent decree.
8. U.S. EPA. Office of Pesticide Programs. Undated. Cumulative risks of pesticides. Assessing cumulative risk. www.epa.gov/pesticides/cumulative/.
9. FFDCA Sec. 408(q).
10. U.S. EPA. 2002. Fenbuconazole: Pesticide tolerance. *Federal Register* 67:1880-1888, Jan. 15.

USDA/Keith Weller

exposure data and usage information to determine "significant" exposure.[30] Your child can roll around in your neighborhood park, for example, on grass treated with a pesticide that will never be tested for chronic toxicity.

Pesticide Products Are Not Fully Tested

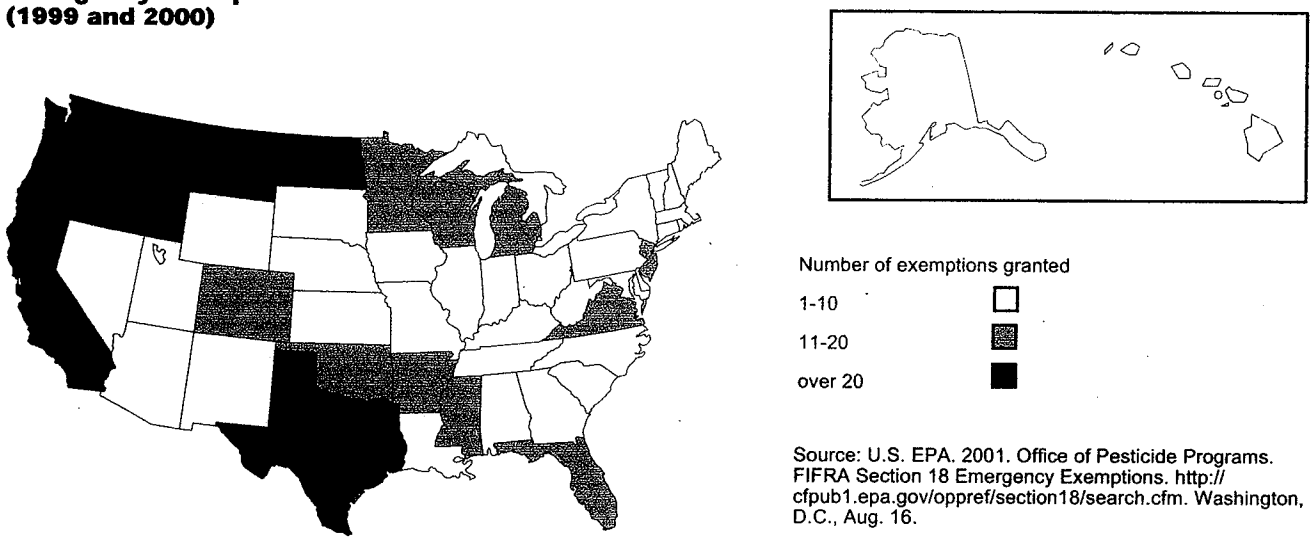
Almost all pesticide products are composed of "active" ingredient(s), whose identity must be listed on the label, and a number of "inert" ingredients, most of whose identities manufacturers claim are trade secrets. "Inerts" are added to the pesticide to make it more potent or easier to use, and are not necessarily chemically or toxicologically inactive. Most chronic toxicity testing required for EPA registration is done on the active ingredient only.[31] Therefore, adverse health effects of the complete pesticide product are untested and unknown.

For example, xylenes, solvents used as "inerts" in almost 900 pesticide products,[32] are known to cause skin, eye, nose, and throat irritation, impaired memory, and decreased mental ability. In laboratory tests, xylene exposure has caused hearing loss; reduced fertility, and increased fetal loss. In one study of people exposed occupationally to xylenes, the frequency of leukemia is increased.[33] However, xylenes are not included in the chronic toxicity testing for the pesticide products that contain xylenes.

Tests Are Not Required for Many Important Hazards

Pesticide testing requirements are a process of "locking the barn door after the horses have been stolen." EPA requires tests for effects that have been already identified as problems, but the tests miss potential new and important hazards. Tests for cancer, genetic damage, and effects on reproduction were not required until the 1960s and 70s, after these problems had been documented in pesticides first used in the 1940s and 50s.[2] Tests for the potential to contaminate ground and surface water were "very limited" until after this contamination had become widespread.[34] As new problems with pesticides are documented, they are

Figure 3
Emergency Exemptions
(1999 and 2000)



Source: U.S. EPA. 2001. Office of Pesticide Programs. FIFRA Section 18 Emergency Exemptions. http://cfpub1.epa.gov/oppref/section18/search.cfm. Washington, D.C., Aug. 16.

Emergency exemptions bypass normal pesticide registration procedures. They are used by almost every state in the country, particularly in Texas and in the Pacific Northwest.

almost never quickly incorporated into pesticide testing protocols.

Examples are numerous:

- No registration tests are required to determine if a pesticide causes depletion of the stratospheric ozone layer (as has been shown with the soil fumigant methyl bromide).[29]
- No chronic neurotoxicity tests are required of most pesticides,[29] no neurotoxicity tests of "inert" ingredients,[31] and no tests for effects on learned behaviors.[29]
- No tests are required to determine if pesticides affect plant reproduction,[29] as has been documented for sulfonylurea herbicides.[35]
- Under FQPA, pesticides are required to be tested for their ability to disrupt the normal functioning of hormone systems (endocrine disruption),[36] but EPA is still determining high-priority chemicals and establishing test protocols. (The protocols are scheduled for completion between 2001 and 2005; testing will follow.)[37]
- No tests of the effects of a pesticide on sperm production are required,[29] although effects on male reproduction have been documented for over 60 currently-used pesticides. (See JPR 16(2): 2-7 for a list of the 60 pesticides.)
- Since the 1970s studies of certain pesticides, particularly organophosphate insecticides, have demonstrated toxicity to the immune system.[38] EPA has finalized a protocol for testing pesticides for immunotoxicity,[39] but these tests are not required for pesticide registration.[29]
- Tests for effects on wildlife are inadequate. Only a few species are tested. No tests are required to see if a pesticide damages food resources or important habitat. No tests look for effects on significant behaviors, such as avoiding predators, homing behavior, or parenting.[29]

Tests Look at "Average" Individuals

Some important parts of the human population (sensitive individuals,[40] children,[41] and the elderly, for example) are more susceptible than the average person to pesticides' adverse effects. However, most pesticide tests are done with uniform strains of laboratory animals rather than particularly sensitive individuals.

For example, children consume more food and water (for their size), and eat different kinds of food than do adults. This means that they can be exposed to more pesticides in their diet.[41] Infants breathe in more pesticides following household pesticide treatments than do adults.[42] They are also more vulnerable to some pesticides.[41] (See Figure 2.) However, most testing is done on adult animals.

People other than children also have special susceptibilities to pesticides. For example, one of the enzymes that detoxifies organophosphate insecticides in humans exists in two forms. These forms were first identified in 1976. One form detoxifies some insecticides more quickly than the other form; researchers have estimated a 13-fold difference. Individuals who have the slow form of the enzyme may be much more sensitive to organophosphate poisoning.[43] These differences are ignored by standard test protocols.

In addition, standard toxicology tests generally ignore stresses, like poor nutrition or illness, that may make people more susceptible to pesticide hazards.[44]

Tests Ignore Synergy

For decades, scientists have known that combinations of chemicals can be more potent than when acting alone.

These are called synergistic effects. For example, in the 1950s, scientists reported that the combination of two organophosphate insecticides, malathion and EPN, was over 50 times more potent than either used alone.[45] Similar synergistic effects in herbicides were reported in 1966; the combination of picloram and 2,4-D was more toxic to sheep than either used alone.[46] However, current EPA registration procedures still do not require testing for possible synergistic effects.

Tests Focus on Food Exposure

Most pesticide testing involves feeding a pesticide to laboratory animals. This kind of test ignores other kinds of exposure that may be important, and cause different problems than exposure through food. People can be exposed to pesticides through drinking or bathing in contaminated water, breathing contaminated air, or touching contaminated surfaces or objects.[44]

Test Fraud Occurs Too Often

FIFRA requires that pesticide manufacturers provide the data needed for registration. There is an inherent conflict between EPA's need for unbiased data and the manufacturers' need for data that show their products are not hazardous.

A good example is the herbicide alachlor, the third most widely used pesticide in U.S. agriculture. In 1984, when alachlor was found in drinking water in Iowa, EPA asked Monsanto to do a monitoring study. The wells Monsanto selected for testing were deep wells in clay soils where alachlor was unlikely to be a problem. Richard Kelley, then a researcher with the Iowa Department of Water, Air, and Waste Management described the study this way: "The study was systematic — it was systematically designed not to find the product."[47]

Outright fraud has also occurred. In 1983 three toxicologists were convicted of mail fraud after faking toxicity studies of drugs and pesticides, making the headlines of U.S. newspapers.[48] The three were top officials at Industrial-Biotest Laboratories, one of the largest of the independent laboratories that conduct toxicity tests for pesticide manufacturers.[49] An EPA review showed that over 800 significant toxicity tests for 140 pesticides had been done by this company.[50] EPA began an audit program to help ensure that this kind of situation would not occur in the future.[51] However, test fraud again made headlines in 1994, when Craven Laboratories was fined over 15 million dollars and its president sentenced to five years in prison for falsifying residue data.[51]

Amy Mosher

EPA's reviews of hazardous pesticides have taken an average of five years to complete, and the pesticide can be sold and used all during the review process. Voluntary phaseouts negotiated with pesticide manufacturers can be equally slow.

Regulatory Loopholes

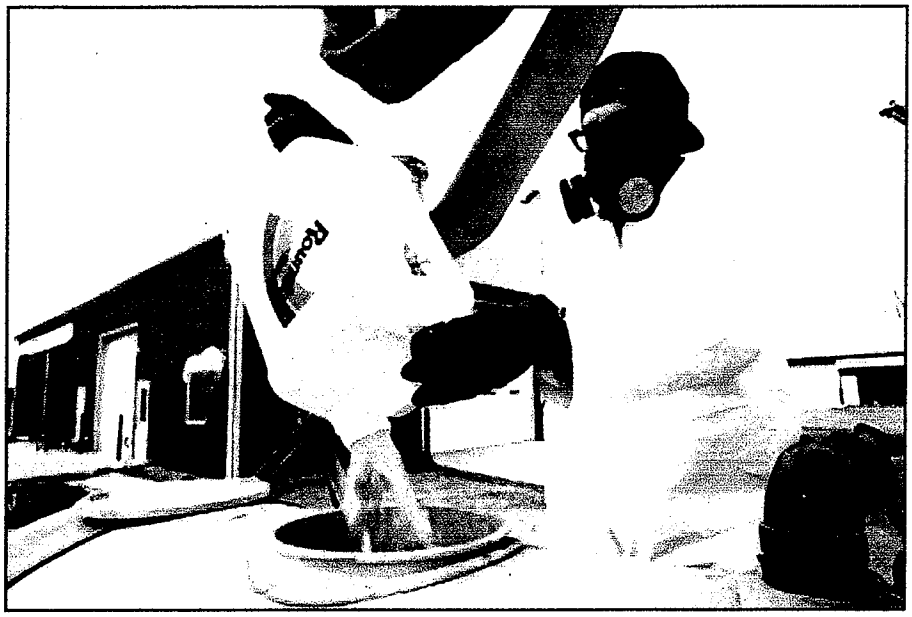
FIFRA specifies several alternative registration processes that allow a pesticide to bypass most of FIFRA's standard registration requirements. Section 5 allows EPA to issue experimental use permits for new, unregistered, pesticides. Section 18 authorizes exemptions for state and federal agencies from any provisions of FIFRA if "emergency conditions exist." Section 24(c) authorizes a state to register additional (not federally registered) uses of a pesticide to meet "special local needs."

These alternative registrations are both widely and routinely used. For example, about 500 Section 18 emergency exemptions were granted to 49 states during 2001. Some states frequently use emergency exemptions: California, Oregon, Washington, and Texas, for example.[52] (See Figure 3.) Since public agencies (usually a state agriculture department), apply for emergency exemptions,[53] these exemptions provide another taxpayer subsidy of the pesticide industry.

Hazardous Pesticides Stay on the Market

The lengthy regulatory process called Special Review provides a loophole for hazardous pesticides. Special

USDA/Tim McCabe



Pesticide registration is cumbersome, time-consuming, and expensive. Yet the process has not been protective of human or environmental health. The only true resolution to this problem will come when the money now being spent to register and regulate pesticides is spent to promote the prevention of pest problems and the implementation of alternatives to pesticide use.

Reviews are initiated when EPA has data to show that the use of a pesticide is causing unreasonable damage.[54] During Special Review, the pesticide product continues to be sold and used while EPA conducts a risk-benefit analysis and explores possibilities for "risk reduction" measures. Special Reviews should evaluate hazardous pesticides and remove them from the marketplace. In fact, the process is slow and unwieldy.

The average Special Review takes over five years to complete[54] and the hazards of the pesticide in question continue during that period. Only 45 Special Reviews have been completed by EPA since the 1972 FIFRA amendments passed.[54]

In addition, EPA may not even evaluate the information necessary to begin a Special Review. After the massive 1991 spill in northern California of the fumigant metam sodium, California officials discovered a study showing that the pesticide caused birth defects.[55] Under Section 6(a)(2) of FIFRA (a 1972 amendment), pesticide manufacturers are required to inform EPA about "factual information regarding unreasonable adverse effects." In the case of metam sodium, EPA had neglected to take action on the adverse effects reported[56] at least in part because the study had not been identified as a 6(a)(2) study.[57] Pesticide manufacturers have also simply withheld information about adverse effects. For example, in 1995 EPA fined DowElanco over 730,000 dollars for failing to report several hundred incidents of adverse effects resulting from exposure to the organophosphate insecticide chlorpyrifos and other pesticides.[58]

Following a Special Review or other assessment, EPA often uses what the agency calls "voluntary cancellations" (negotiated agreements with pesticide manufacturers) to remove hazardous pesticides from the market. While this process avoids the lengthy process FIFRA requires for an EPA-mandated cancellation,[59] the agreements often allow sale of hazardous pesticides for extended periods. For example, the recent (2001) voluntary cancellation agreement for the insecticide diazinon has a four-year long phaseout for some uses.[60]

The Bottom Line

The 2,4-D Task Force, an industry group formed to support the reregistration of the herbicide 2,4-D, has reported that the reregistration process for 2,4-D required spending 25 million dollars and conducting 270 tests.[61] There can be no question that pesticide regulation is cumbersome, time-consuming, and expensive.

And yet, over and over again the process has not been protective of human health or the environment. Pesticides are registered for use while important health and safety data are still being generated; they may continue to be used after evidence of their hazards is given to EPA; they may be registered through alternative processes that bypass important tests; and they may never be required to be tested for certain kinds of hazards.

The failures of the regulatory process result from many causes, but most important is probably the basic assumption on which registration is based: the requirement that regulation of pesticide use must take "into account the economic, social, and environmental costs and benefits."[4] There is no satisfactory way, for example, that any government agency can weigh the costs of two million dead birds, or 100 children born with birth defects, against the profit margins of chemical manufacturing companies.

The only true resolution to this problem will come when the money now being spent to register and regulate pesticides is spent to promote the prevention of pest problems and the implementation of alternatives to pesticide use.

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