● 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: if a pesticide offers enough economic benefits, it can be registered, no matter how threatening its hazards. 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 develop and implement alternative pest management techniques.

UPDATED BY CAROLINE COX

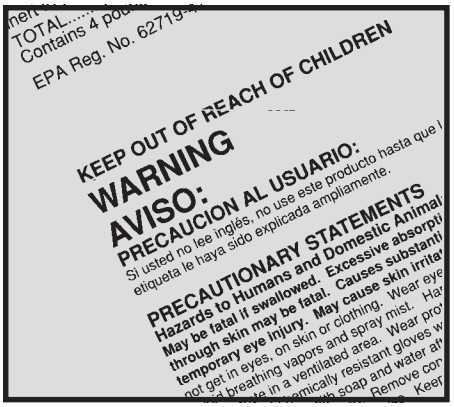
Following some complaints about the herbicide program along your county's roads, county officials set up a public hearing. Stories are told about how you and your neighbors have seen the sprays' damage. The answer? "We're sure that the pesticides we use don't cause problems," officials say. "They've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

A new insecticide is used at your children's school. Parents and teachers ask questions. A chemical company representative responds, "It costs millions of dollars to complete the tests required by EPA. We can 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 as a guarantee of safety. In fact, EPA regulations specifically prohibit manufacturers of pesticides from making claims like "safe," "harmless," or "nontoxic to humans and pets" with or without accompanying phrases like "when used as directed."[1] NCAP believes that no 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 environmental concerns to be included in registration. In addition to registering new

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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.

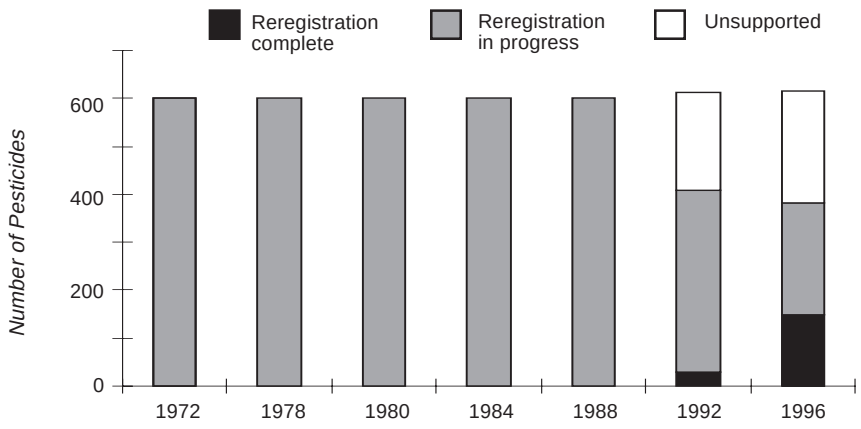
The way in which the 1972 FIFRA amendments mandated that health and environmental concerns be evaluated is fundamentally different from the way that our laws deal with other environmental hazards. FIFRA requires EPA to register pesticides if they do not pose "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." (FIFRA Section 2(bb)). 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.

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.[4] This omission automatically inflates the calculation of benefits.

By the late 1980s, little progress had been made in reregistering pesticides.[2] In 1986, a 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.[5] By December 1988, EPA had evaluated 194 of the 604 active ingredients needing reregistration[5] and decided what data was missing or inadequate. However, no products had completed the reregistration process.

Figure 1
Reregistration's Slow Progress



Sources:
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U.S. EPA. Prevention, Pesticides and Toxic Substances. 1996. Office of Pesticide Programs annual report for 1996. Washington, D.C. (Nov.)

Congress passed FIFRA amendments again in 1988 (called FIFRA '88), this time requiring a strict time line for industry submission of registration tests. All tests for pesticides registered before November 1, 1984 were to be completed and submitted to EPA within nine years (by 1997).[5]

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.[5]

However EPA has fallen behind in meeting FIFRA 88's scheduled goals. As of March 1997, 380 of the 604 active ingredients requiring reregistration were still being supported by pesticide manufacturers. (Supported pesticides are those for which the manufacturer pays registration fees and submits reregistration data to EPA.) Of these 380, only 148 had completed the reregistration process. (See Figure 1.) EPA now estimates that the reregistration process will take until 2002.[6]

In 1996, Congress passed new pesticide legislation (the Food Quality Protection Act) that contained amendments to both FIFRA and the Federal Food, Drug and Cosmetic Act. 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 registrations will be reviewed every 15 years.[6] Given that reregistration is now estimated not to be finished until 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.) The new law allows EPA to waive data requirements and to extend testing deadlines. (FQPA Sec. 210(c)) Also, Congress appropriated 10 million dollars to help pay for testing "minor use" pesticides. (FQPA Sec. 32) These provisions added to a waiver of annual registration fees provided by the 1990 Farm Bill for

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.

minor use pesticides.[7] In simple terms, these pesticides receive outright subsidies.

Flaws in Reregistration

Reregistration does not mean that a 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.[8] It is the second most widely used herbicide in U.S. agriculture.[9] EPA classified it as a "possible human carcinogen" because it caused liver tumors in female rats. It is absorbed through skin with "significant bioaccumulation." It has adversely affected the growth and development of juvenile fish at concentrations close to 1 part per million. It is persistent and mobile in soil, 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.[8]

• **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. Children every day are consuming between 85 and 231 percent (depending on what assumptions are made) of what EPA believes is an acceptable amount of chlorpropham.[10]

• 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."[11]

• EPA's Ecological Effects Branch (EEB) characterized the herbicide **picloram** as having "extreme phytotoxicity."[12] EEB also noted that it had significant persistence under typical conditions, and "extreme propensity to leach into groundwater."[12] Both EEB and the Environmental Effects and Groundwater Branch recommended against the reregistration of picloram.[12,13] However, the reregistration process was completed in 1995, with only small requests for additional data.[14]

Flaws in New Registrations

Since 1984, an average of over 16 new products (ranging between 8 and 40 per year) have come on the market annually.[9,15-17] These pesticides are not subject to the reregistration process set up by FIFRA '88 for older pesticides. (FIFRA Sec. 4 (a))

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 (FIFRA Sec. 3(c)(7)) because requiring completion of all the tests would put new products at an economic disadvantage to older pesticides.

Even pesticides with full (not conditional) registrations may not have complete testing. For example, the herbicide glufosinate was registered in 1993 although acceptable tests of its ability to cause cancer have not yet been received by EPA.[18]

Problems with Testing

In addition to the problems with the fundamental concept on which FIFRA is based, and the way that the requirements of the law are slow in being met, there are problems with the tests used to evaluate pesticides. 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-ways, and turf. Assuming that exposure will be minimal since humans will not get these pesticide residues on their food, 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.[19]

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 exposure data and usage information to determine "significant" exposure.[20] 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.[21] Therefore, adverse health effects of the formulated pesticide product are untested and unknown.

For example, xylenes, solvents used as "inerts" in almost 2,000 pesticide products,[22] are known to cause eye, nose, and throat irritation; impaired memory; hearing loss; and reduced fertility and decreased fetal weight gain. In people exposed occupationally to xylenes, the frequency of leukemia is increased.[23] 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.[24] As new problems with pesticides are documented, they are 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).[19]

• No chronic neurotoxicity tests are required of most pesticides,[19] no neurotoxicity tests of "inert" ingredients,[21] and no tests for effects on learned behaviors.[19]

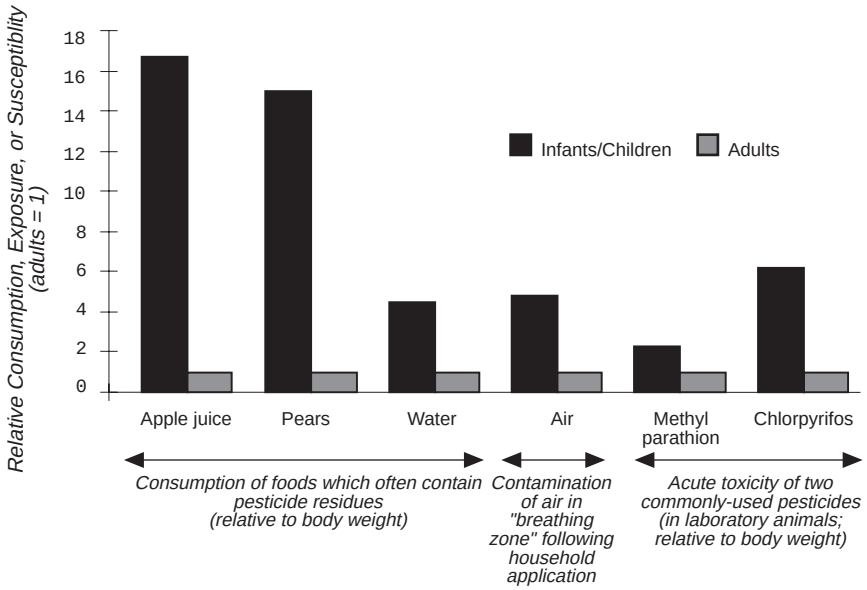
• No tests are required to determine if pesticides affect plant reproduction, as has been documented for sulfonylurea herbicides.[19]

• Under the Food Quality Protection Act, pesticides are required to be tested for their ability to disrupt the normal functioning of hormone systems (endocrine-disruption), but protocols are just being developed and it will be years before testing is completed.[25,26]

• No tests of the effects of a pesticide on sperm production are required, 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

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



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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 pesticide contaminated. 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.

FOOD TOLERANCES

Food tolerances are set as part of the pesticide registration process to specify the concentrations of pesticides that can legally be present on food.

Tolerance-setting procedures are currently changing because of the recently-passed Food Quality Protection Act (FQPA) However, a brief outline is as follows:

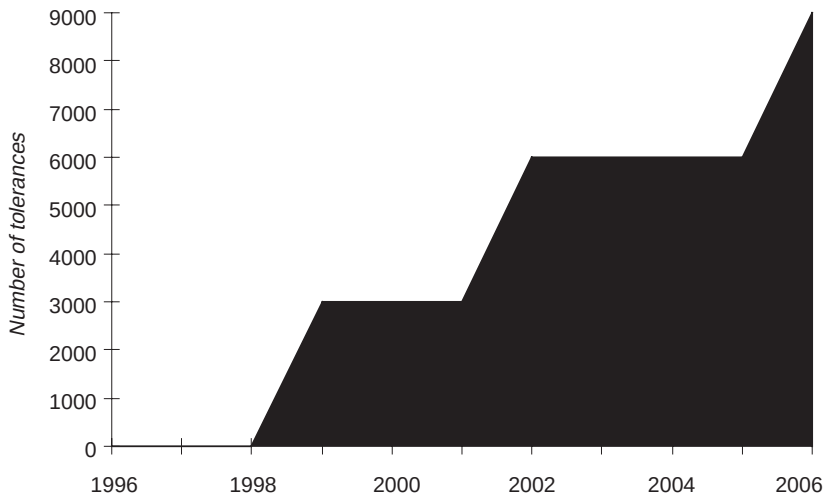
• First, field tests are conducted to determine how much of a pesticide and related chemicals is present on a crop following application. Based on this information, the manufacturer proposes a tolerance.[1]

• For most types of adverse health effects that are caused by pesticides, EPA then sets a reference dose (or acceptable daily intake) of the pesticide. The reference dose is based on the lowest "no observable effect level" (NOEL), the dose at which no adverse effects were observed during acute or chronic toxicity studies. The NOEL is divided by an uncertainty factor of 100: 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.

EPA then uses the field residue data and information about food consumption to calculate how much of the pesticide an average person would consume. This amount is not supposed to exceed the reference dose.

FQPA requires an additional (up to 10-fold) safety factor to account for the special susceptibility of children unless "reliable data"[1] suggests a different factor will be "safe for infants and children."[2] However, EPA so far has not used this additional safety factor when establishing a tolerance, even for a pesticide like the herbicide oxyfluorfen which had "severe" developmental effects in laboratory animals.[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.

• 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.[1] This is the level that EPA calls a "negligible risk." EPA is not interpreting this standard strictly; estimated cancer risks that are almost double are acceptable.[3] Also, economic benefits can be used to justify cancer risks that are up to ten times higher.[2]

Problems with Tolerances

There are three major problems with the food tolerance setting process. First, the food consumption database is not up-to-date, nor does it take into account people's individual food preferences. In 1986, EPA began using a 1977-1978 food consumption survey. Although it is now twenty years old, that database is still in use because a newer consumption survey doesn't provide accurate information about sensitive groups such as nursing infants and pregnant mothers.[3] Even if up-to-date information were used, many people (those who eat mushrooms regularly, for example) will consume very different amounts of residues than the database average.

Second, the tolerance setting process generally considers only one pesticide at a time. Tolerances are usually set for each chemical separately, without consideration of the amount of other pesticides that may be present on a particular food. FQPA requires that tolerance-setting consider cumulative exposure to pesticides with similar mechanisms of toxicity if such information is available. However, EPA does not have the data it needs to determine which pesticides have similar mechanisms of toxicity and is not requiring the submission of any new data to meet FQPA standards. EPA has not even accounted for cumulative exposures when it evaluated an

insecticide like cyfluthrin, which is chemically related to dozens of other insecticides.[4] Also, it will be ten years before all existing tolerances are reassessed under FQPA standards and existing tolerances were set without consideration of cumulative exposure.[1]

Finally, food tolerances generally do not account for any other type of exposure to a pesticide. Although FQPA now requires that exposures to pesticides in drinking water and from home uses be considered when setting a tolerance, EPA does not have the data and models it needs to estimate these exposures. The agency is not yet requiring new data to meet this requirement, and, as above, reassessment of existing tolerances will take 10 years.[1]

Are Tolerances "Safe"?

Under FQPA, pesticide residues in food must be "safe."[1] However, the legal definition is very different from a common-sense definition. For example, EPA recently (April 1997) set a "safe" tolerance for the herbicide oxyfluorfen on strawberries in 6 states. Tests submitted to EPA show that oxyfluorfen causes liver tumors and cancers in mice. When fed to pregnant rats, it caused an increase in fetal loss, as well as an increase in the frequency of a blood vessel abnormality and several bone abnormalities in the offspring.[2] To intentionally apply this kind of chemical to a food like strawberries seems far from "safe."

1. U.S. EPA. Prevention, Pesticides and Toxic Substances. 1997. 1996 Food Quality Protection Act: Implementation Plan. Washington, D.C. (Mar.)
2. U.S. EPA. 1997. Oxyfluorfen; Pesticide tolerance for emergency exemption. *Fed. Reg.* 62(80):20104-11.
3. U.S. General Accounting Office. 1991. Pesticides: Food consumption data of little value to estimate some exposures. Washington, D.C.
4. U.S. EPA. 1997. Cyfluthrin; pesticide tolerance. *Fed. Reg.* 62(90):25518-24. (May 9.)

insecticides, have demonstrated toxicity to the immune system.[27] However, EPA is only now finalizing a protocol for testing pesticides for immunotoxicity.[28]

Tests Look at "Average" Individuals

Some important parts of the human population (sensitive individuals,[29] children,[30] people with illnesses, 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.[30] Infants breathe in more pesticides following household pesticide treatments than do adults.[31] They are also more vulnerable to some pesticides.[30] (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 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.[32] These differences are ignored by standard test protocols.

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.[33] 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.[34] However, current EPA registration procedures do not require testing for possible synergistic effects.

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.

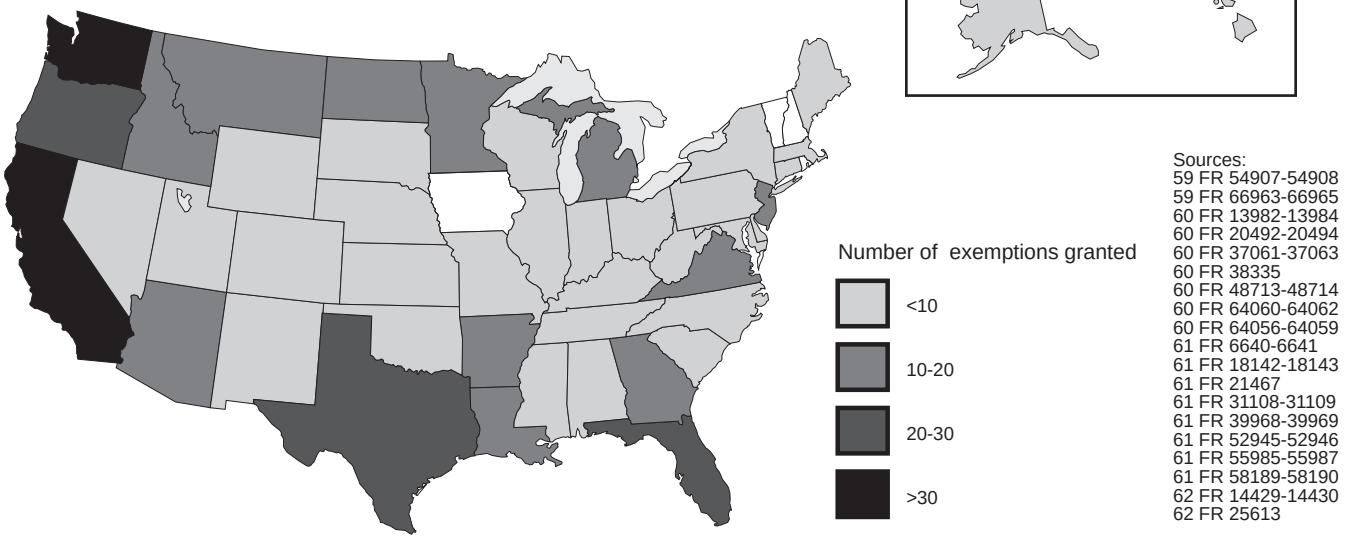
A good example is the herbicide alachlor, the third most widely used pesticide in U.S. agriculture. In 1984, when alachlor was found to be contaminating drinking water in Iowa, EPA asked Monsanto to do a monitoring study. The wells Monsanto selected for testing were deep wells in clay soils where alachlor was unlikely to be a problem. Richard Kelley, 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."[35]

Outright fraud has also occurred. In 1983 three toxicologists were convicted of mail fraud after faking toxicity studies of drugs and pesticides, bringing test fraud into the headlines of U.S. newspapers.[36] The three were top officials at Industrial-Biotest Laboratories, one of the largest and oldest of the independent testing laboratories that conduct toxicity tests for pesticide manufacturers.[37] An EPA review showed that over 800 significant toxicity tests for 140 pesticides had been done by this company.[38] EPA then began an audit program to help ensure that this kind of situation would not occur in the future.[38] 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.[39]

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

Figure 3
Emergency Exemptions
(1994-1996)



Emergency exemptions bypass normal pesticide registration procedures. They are widely used by almost every state in the country.

18 authorizes exemptions 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 200 Section 18 emergency exemptions per year were granted to 46 states during a recent three year period (1994-1996). Almost 10 percent of these exemptions were granted repeatedly, for all three years. Some states frequently use emergency exemptions: California, Oregon, and Washington, for example.[40-62] (See Figure 3.) Since state agencies (usually the agriculture department) apply for emergency exemptions,[63] FIFRA Section 18 provides another government 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 Reviews are initiated when EPA has data to show that the use of a pesticide is causing unreasonable damage.[64] 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 seven years to complete[64] and the hazards of the pesticide in question continue during that period. Only 45 Special Reviews have been completed by EPA.[64]

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.[65] 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[66] at least in part because the study had not been identified as a 6(a)(2) study.[67] 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.[68]

The Bottom Line

The 2,4-D Task Force, an industry group formed to support the reregistration of the herbicide 2,4-D, recently reported that the reregistration process for 2,4-D required spending 25 million dollars and conducting 270 tests.[69] 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." (FIFRA Section 2(bb)) 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 develop and implement alternatives to their use.

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