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# Changing Pesticide Policies

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**I**n September 1993, the Clinton administration introduced a proposal to overhaul both the letter and spirit of the laws governing pesticide regulation. In unprecedented cooperation on this issue, the Environmental Protection Agency, U.S. Department of Agriculture, and Food and Drug Administration jointly developed the proposal. The proposal addresses the public concern that current regulation allows unacceptable health and environmental risks from pesticide use. Proposed policy changes would remove inconsistencies in the way government agencies regulate pesticides.

## Problems in the existing regulatory framework

At least three problems plague the current system of pesticide regulation: inconsistent statutes regulating fresh and processed foods, delays in reregistering old pesticides to ensure compliance with current health and environmental standards, and lack of consumer confidence in the ability of the system to limit health and environmental risks.

### *Inconsistent regulation of fresh and processed foods*

EPA regulates pesticides primarily through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA controls the sale and use of pesticides through product registration and labeling. EPA bases decisions to grant or deny registration on the pesticide's value in agricultural production, exposure levels for farmworkers and consumers (human health issues include cancer and other illnesses), and potential environmental and wildlife hazards.

The Federal Food, Drug, and Cosmetic Act (FFDCA) also guides pesticide regulation. FFDCA

requires that regulators (EPA) establish maximum acceptable levels (tolerance) of pesticide residues in foods and animal feeds. The FFDCA defines adulterated raw agricultural commodities to be those containing pesticide residues for which EPA has not set a tolerance or those which exceed the permitted tolerance. FDA can seize, condemn, and destroy adulterated commodities. Other legislation gives similar powers to USDA regarding pesticide residues in meat, poultry, or egg products.

Functionally, registration and tolerances go hand in hand to establish legal use of pesticides on food crops. EPA will not approve an application for a food-use registration under FIFRA until it specifies FFDCA tolerances for the residues that result from those uses. Most provisions of current law require that pesticide regulations for raw agricultural commodities balance the economic benefits of greater productivity against health and environmental risks. Thus, the law permits the presence of carcinogens in the food supply when regulators anticipate compensating benefits.

However, critical differences exist in the statutes regulating residues in processed foods. The Delaney Clause of FFDCA prohibits additions of any carcinogenic substances to processed food, no matter how small the risk. When a carcinogenic pesticide used on a raw commodity concentrates during food processing, EPA now classifies it as an additive and subject to the Delaney Clause. EPA cannot grant a tolerance for carcinogenic additives, and so will not register the pesticide for farm use on that crop.

In past years, EPA used a different interpretation of Delaney. Beginning in 1988, EPA interpreted the Delaney Clause to allow a *de minimis* risk, and permitted the use of negligible-risk carcinogenic pesticides that concentrate in processed food or feed. A challenge by the State of California, the Natural Resources Defense Council, Public Citi-

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zen, the AFL-CIO, and several individuals to the EPA's application of the *de minimis* exception to the Delaney Clause was upheld by the U.S. Court of Appeals in July 1992 and the Supreme Court in February 1993. The federal court rulings mean that EPA's *de minimis* interpretation of the Delaney Clause is not permitted by the law. EPA has revoked the processed food tolerances for the four pesticides named in the lawsuit.

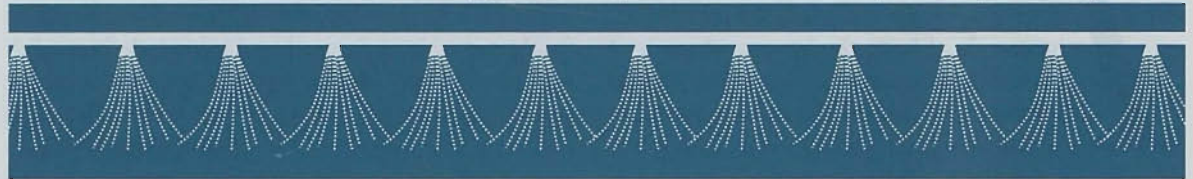
If the law is not changed, EPA could revoke tolerances for many other pesticides on processed and raw products. According to EPA, a literal interpretation of the Delaney Clause could require removal of over 100 tolerances on many different crops (see Kuchler and Ralston for discussion of the potential impacts). These tolerances especially affect apple, grape, and sugarcane production.

Different standards for fresh and processed foods could raise rather than reduce risks. Suppose, for

example, two equally effective pesticides are used on a crop, one being a higher-risk carcinogen than the other. If the weaker carcinogen concentrates in processed food and the other does not, the weaker carcinogen may fail the Delaney Clause but the higher-risk carcinogen would remain in use.

are not necessarily more risky, but simply unprofitable to register, and their disappearance has raised production costs for some commodities.

Because of the high cost of reregistration, pesticide manufacturers have voluntarily withdrawn registration of many pesticides with limited markets (so-called "minor use" pesticides). These products



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### *Delays reregistering older pesticides*

Before 1972, the government regulated pesticides primarily to protect agricultural producers from fraudulent claims (Reichelderfer and Hinkle). In 1972, FIFRA made new pesticide registrations subject to health risk and safety considerations. Congress also instructed EPA to reregister all products on the market registered prior to 1972. However, EPA made little progress in completing reregistrations. To further complicate matters, EPA adopted a new set of standards for registration in 1984, which reflected new scientific knowledge about pesticides' health and environmental effects.

Then in 1988, Congress required EPA to reregister older pesticides (those registered before November 1984) to ensure compliance with current health and environmental risk standards. Under this provision, registrants of the older pesticides must provide all of the environmental and health data required of newer pesticides. In addition, registrants are required to pay fees to cover EPA's costs of reregistration. The law requires completion of reregistration by 1997.

Reregistration has progressed slowly. As of late 1993, the EPA had completed only seventeen ini-

### *Lack of consumer confidence*

The scientific community raised concerns about pesticide regulation in two well-publicized National Academy of Sciences (NAS) reports. The first, *Regulating Pesticides in Food: The Delaney Paradox* (1987), examined the impact of the Delaney Clause on regulatory decisions and dietary risk. The report found that most of the cancer risks from pesticides in the diet arise from chemicals granted tolerances before 1978. The report recommended adoption of a single negligible risk standard for all pesticide residues in foods (raw and processed) and application of current safety standards to food tolerances for older chemicals.

More recently, the NAS report, *Pesticides in the Diets of Infants and Children* (1993), pointed out the vulnerability of children to health risks from pesticide residues in food. Children consume some foods in large amounts relative to their body weight (e.g., processed apple products), and, unlike adults, they may be at risk of developmental effects from some pesticide residues. The report recommended moving to a health-based standard with careful consideration of children's exposure and additional testing of pesticides for developmental toxicity.

Public sentiment reflects these scientific concerns. USDA's 1990 *Diet and Health Knowledge Survey* found that over one-half of the nation's consumers

believe that foods grown with pesticides are unsafe (Lynch and Lin). Most of those surveyed did not believe that current laws adequately protect the public from dangerous pesticide residues. This lack of consumer confidence creates difficulties for the food industry because consumers become easily alarmed about pesticide risks.

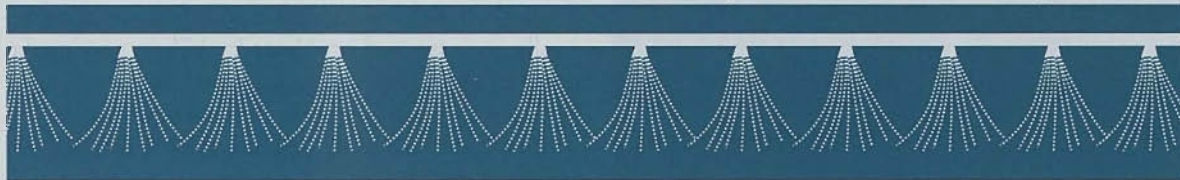
### Proposals for pesticide policy reform

The Clinton administration's pesticide policy proposal encompasses many issues, but we have chosen to focus on four major features: a unified health-based risk standard for pesticide residues on fresh and processed foods, new deadlines for review of tolerances to meet health standards, new registration procedures to encourage low-risk and minor use products, and encouraging integrated pest management (IPM) to reduce pesticide use.

these chemicals.

The proposed standard is narrative, and in contrast to a numeric risk standard, gives regulators the ability to base their decision on changing scientific knowledge about risks. However, it also means that some unspecified level of risk could be accepted by regulators. Alternatively, regulators could interpret "a reasonable certainty of no harm" as an absolute certainty and impose a very strict risk standard.

The administration proposal adopts some of the NAS (1993) recommendations. For example, EPA must account for differences between adults and children in terms of body weight, dietary patterns, and vulnerability to developmental toxicity. The proposal also recommends further study of the NAS recommendations. NAS recommended reducing the acceptable intake limits for pesticide residues when scientists question the data on developmental tox-



#### *A unified health-based risk standard*

The administration's proposal calls for a single health-based negligible risk standard for pesticide tolerances in both fresh and processed foods. The new standard would require "a reasonable certainty of no harm." It allows negligible risks for pesticide residues concentrating in processed foods, in contrast to the current zero-risk standard.

In another departure from current policy, EPA would no longer consider benefits in setting tolerances for raw agricultural commodities. However, EPA must allow a transition period if revoking a tolerance seriously disrupts domestic production.

The impact of changing from balancing risks against benefits to a risk-only standard will depend on how much benefits matter in current practice. Most commentators on EPA behavior assert that benefits usually matter very little (NAS, 1987, p.

icity, when nonfood sources add to residue intake, or when multiple pesticides with similar toxic effects exist. Each of these circumstances could reduce admissible residue levels set by tolerances.

Two alternative food safety reform bills pending in Congress also propose a unified risk standard to pesticides. While not as comprehensive as the administration's proposal, both bills require no more than negligible health risk from pesticide residues on both fresh and processed foods. The Kennedy/Waxman (S.331, H.R. 872) bill sets a specific numerical definition of negligible risk, identifies which populations must be considered in the risk assessment, and prohibits consideration of benefits. The Lehman/Blily/Rowland bill (H.R. 1627) requires that EPA consider pesticide benefits, and lets EPA define negligible risk in regulating pesticides.

#### *Deadlines for review of food-use tolerances*

To bring all pesticide residue tolerances in line with the administration's proposed health-based standards, all tolerances would be reviewed within seven years. Those pesticides which EPA believes likely exceed negligible risk would be reviewed within four years after enactment. Products which failed to complete the necessary testing within these time frames would automatically lose their tolerances.

This proposed review process could indirectly overcome the difficulties encountered in the ongoing reregistration of older pesticides. Automatic loss of food use tolerances, if adequate data are not

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*Different standards for fresh and processed foods could raise rather than reduce risks.*

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34). But a study by Cropper and others suggests the opposite, and the magnitude of productivity benefits has influenced how large a cancer risk EPA allows. Since much of the risk comes from older, widely used pesticides (NAS, 1987), ignoring benefits will more likely deny food-use tolerances for

provided by certain deadlines, would lead to losses of older pesticide registrations. To meet its deadlines, the proposal requires that registrants prove safety. Registrants that fail to comply automatically lose tolerances and the corresponding registrations for use on food crops.

If the unequal treatment of new and old pesticides discouraged development and use of safer pesticides, then equal treatment which eliminates uses of higher-risk pesticides will open the market to a variety of reduced-risk alternatives. However, if the real effect of unequal treatment was modest, farmers will have fewer pest-control options because of lost tolerances.

### *Reforming the registration process*

The administration's proposed changes in tolerance standards focus on food safety. In contrast, pesticide registrations under FIFRA will still balance

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*Most of those surveyed did not believe that current laws adequately protect the public from dangerous pesticide residues.*

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environmental and farm worker health risks against the production benefits of pesticides. The regulatory process for pesticides that cause only environmental risks, like toxicity to fish or birds, will not change. The ongoing reregistration process mandated by the 1988 FIFRA amendment would continue, and supplemental fees would be charged to cover the cost. However, under the administration's proposal, all pesticide registrations would be reviewed every fifteen years to ensure compliance with current health and environmental standards.

Under existing legislation, the high cost and long delays involved in registration discourage development of new pesticides. The administration's proposal creates a priority review process for both reduced-risk and minor-use pesticides. A pesticide meeting EPA's reduced-risk criteria, or having three or more minor uses, would be given priority review. The proposal offers a financial incentive to product development through lengthening the period when a developer can make exclusive use of data to support a product's registration. To encourage the development of biologically-based pesticides, EPA would allow time-limited conditional registrations prior to completion of all required tests.

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### *Encouraging integrated pest management to reduce pesticide use*

The administration wants to encourage IPM adoption, and USDA agencies are discussing ways to achieve this goal. Possibilities include expanded support for research, development and extension of new IPM techniques, market-based incentives to develop pesticide alternatives, and "prescription use" of certain risky pesticides needed for IPM systems.

The NAS report, *Alternative Agriculture*, defined IPM as "a pest control strategy based on the determination of an economic threshold that indicates when a pest population is approaching the level at which control measures are necessary to prevent a decline in net returns." In practice, IPM uses a variety of control measures, including pesticides, and applies controls only when the benefits from reduced crop damage exceed control costs. IPM relies on greater understanding of pest ecology. For example, routine application of pesticides may actually increase pest problems by killing pest predators. IPM techniques must match the individual needs of different crops and different locations.

The administration believes IPM will maintain productivity and reduce pesticide use, and that it could also overcome many of the difficulties inherent in product-by-product regulation. Promoting the judicious use of chemicals within a system of pest management may be a more effective way of reducing environmental damage and health risks than simply regulating individual chemical uses. However, many farms already practice IPM and it is not clear how much further promotion of this approach would reduce pesticide use.

### **Preparing for change**

Pressure is mounting to reform existing pesticide/food safety regulation. The federal court rulings which require that EPA enforce the Delaney Clause, and the concerns raised in the NAS study of children's exposure, have heightened interest in policy reform. The Clinton administration will soon present to Congress legislation supporting its pesticide/food safety reform package.

Some conventional pesticides will be removed through the reregistration process, regardless of any pesticide policy reforms. The agricultural establishment, including land-grant universities, needs to prepare for those changes. More substitute production practices, particularly for older high-risk chemicals, need to be developed so that a transition from current production practices to sustainable production can occur without significant disruptions in food markets. ■

## ■ For more information

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*The views expressed here are those of the authors and do not necessarily reflect USDA's position. The article has been reviewed internally by USDA.*



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The administration's proposal would promote Integrated Pest Management, which emphasizes monitoring pest levels in order to make decisions about pest control. It is hoped that IPM will reduce pesticide usage.