

Regulating Pesticides: The "Delaney Paradox"

The "crazy quilt" of regulations governing pesticide use needs overhaul, says an Academy committee; strict enforcement of the Delaney amendment would not be the best approach

THANKS to a brief amendment that was approved by Congress almost three decades ago, a New York congressman named John J. Delaney has secured for himself a lasting place in the nation's food and drug laws. The Delaney amendment, as the provision is universally known, in essence bans the addition to processed foods of any compound that causes cancer in test animals. Few people have argued against the sentiment behind Delaney's amendment, but over the years it has been the focus of a great deal of controversy. Now a committee of the National Academy of Sciences has added a new twist.

Strict application of the Delaney amendment to the regulation of pesticides would not be the surest way to reduce cancer risks, says the committee. Indeed, a consistent policy that would permit some weakly carcinogenic pesticide residues in processed foods would actually result in a lower cancer risk. Hence the title of the report: "Regulating pesticides in food: The Delaney paradox."

The committee argues that there is currently a "crazy quilt" of regulations governing pesticides, which results in different rules for raw and processed foods and different standards for old pesticides and newer compounds. As a consequence, the cancer risk from some pesticide uses may be too high, while other chemicals are being kept off the market when they pose very little hazard. A uniform approach to pesticide regulation, based on reducing cancer risk to a "negligible" level rather than the zero-risk standard of the Delaney amendment, would be far preferable, the committee argues.

The Environmental Protection Agency (EPA), which is charged with implementing the nation's pesticide laws, likes this advice. However, John Moore, EPA's assistant administrator for pesticides and toxic substances, says the legal basis for anything other than strict adherence to the Delaney clause is shaky at best. Moore would like to see Congress change the Delaney amendment, but acknowledges that such a step is unlikely. The issue, he says, is "political dynamite."

In the meantime, EPA is facing a mounting problem. New toxicological data indicate that many pesticides that have been on the market for years could be carcinogenic, at least in animal tests, and new detection techniques make it possible to pick up trace amounts of these compounds in food. Strict application of the Delaney amendment would require many uses to be canceled.



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So far, EPA has not invoked the amendment to remove a single "old" pesticide from the market, but it may be forced to do so soon. As many as 20% of these pesticides could have a problem, Moore says. Two years ago, EPA turned to the Academy for advice on what to do.

The Academy appointed a committee under the chairmanship of Ray Thornton, a former congressman who is now president of the University of Arkansas. It has concluded that the nation's pesticide laws are not working well, and the problem is not just the Delaney amendment.

First, the law itself sets a double standard for raw and processed foods. In short, EPA

can permit pesticide uses that leave residues in or on raw foods, even if the chemicals have been shown to cause tumors in test animals. The agency can use its own judgment on whether the dietary risk is acceptable, and it is explicitly permitted to take into account the benefits from using the pesticide.

A different set of rules applies to processed foods, however. If pesticide residues concentrate during processing, these new levels must be proven safe, or that particular use of the pesticide must be banned. No risk-benefit judgment is permitted. Moreover, the Delaney amendment also kicks in: if a pesticide raises tumors when fed to test animals at any level, and its residues concentrate when a food is processed, that use of the pesticide must be prohibited.

What this means in practice is that an oncogenic pesticide cannot be applied to a crop if any portion of the crop is processed in a way that will concentrate the pesticide residues. However, if the food is not processed, use of the pesticide may be permitted. The committee said it could find "no scientific reasons" for the different treatment of raw and processed foods.

EPA does not appear to be applying the law with undue rigor, however. The committee found 31 cases in which the agency allows a pesticide to be used on crops that will be processed, even though the chemical is suspected of causing cancer in test animals and is believed to concentrate during processing. "All of these appear to conflict with the Delaney Clause," it says. It also identified another 778 pesticide uses that pose a potential, but less clear-cut conflict. "Hence," the committee concludes, "over the next few years, the EPA will face bringing several hundred additional pesticide uses into compliance" with the law.

There is also a dual standard for pesticides registered before 1978 and those that have come up for approval more recently. Recent applicants have had to go through a battery of tests that were not required before 1978, and EPA has enforced the Delaney amendment strictly in its review of these new compounds. As a result, the Academy committee says 90% of the total cancer risk from pesticides in the diet comes from "old" compounds.

This more rigorous review of new compounds has sometimes had the ironic effect of prohibiting use of some pesticides that would have replaced potentially more hazardous old compounds, the committee says. For example, it cites a case in which EPA denied use of a fungicide on hops because its residues would have posed a theoretical risk of causing one additional cancer for every 100 million people exposed. However, it

would have replaced an older fungicide which has an estimated risk of one in 10,000.

EPA is now reviewing many of the older pesticides, and it will soon be faced with applying the Delaney amendment to many commercially important compounds that have been in use for a long time.

The Academy committee is recommending that it use a uniform "negligible risk" standard for suspected carcinogens that would apply to all pesticides and all forms of food. In essence, it suggests that EPA should cancel uses of a pesticide on a particular crop when the combined estimated cancer risk from the residues on both raw and processed foods exceeds 1 in 1 million. The committee points out that the overall lifetime cancer risk in the United States is now about 1 in 4, or 0.25. Adoption of the negligible risk standard for pesticides would raise the risk to 0.250001. Hence its use of the term negligible.

Such a strategy applied to 28 pesticides that the committee regards as potentially the most troublesome would reduce the total estimated cancer risk by 98%, but it would result in cancellation of only 32% of the uses. In contrast, adoption of a consistent "zero-risk" strategy would remove the remaining 2% of the estimated cancer risk but require cancellation of all uses of the pesticides that leave any residues on raw or processed foods, while continued application of Delaney just to processed foods would reduce the total risk by only 55%.

Whether EPA could legally adopt such a strategy is unclear. Moore says EPA will respond to the report with a policy paper, outlining its proposed strategy, within 90 days. The agency will, however, soon have to take action on several old pesticides that are in apparent conflict with the Delaney amendment. Whatever EPA does is likely to be challenged in the courts, which means that it would be years before the legality is finally determined.

A suit filed last year against the Food and Drug Administration (FDA) could, however, pave some legal ground. The suit, filed by Ralph Nader's Public Citizen, challenges FDA's approval of two food dyes that are believed to be weak carcinogens and therefore potentially fall foul of the Delaney amendment. FDA approved the dyes on the grounds that their use poses negligible cancer risk (*Science*, 23 August 1985, p. 739). The case is expected to go all the way to the Supreme Court, and is unlikely to be decided before the summer of 1988.

Congress could always amend the Delaney amendment, but in the past it has been extremely reluctant to tamper with it. ■

COLIN NORMAN

PHS Revitalization Plan Stirs Up NIH

The Surgeon General would like Public Health Service officers to wear uniforms and be reassigned every few years; NIH officials say the service works fine as it is

SURGEON General C. Everett Koop wants to "revitalize" the commissioned corps of the Public Health Service—a project that, he says, will help the PHS respond more effectively to national emergencies as well as day-to-day health problems. But many of the 700 Public Health Service officers at the National Institutes of Health, including the director of NIH, are upset by Koop's plans.

At issue is the question of what the commissioned corps of the Public Health Service should be. Koop argues that it should be more of a military organization that responds efficiently to the country's health problems, especially in an emergency such as the AIDS epidemic. A number of the Public Health Service officers at NIH reply that the corps is functioning fine at NIH just as it is and that the revitalization plans are not just unnecessary, they are detrimental.

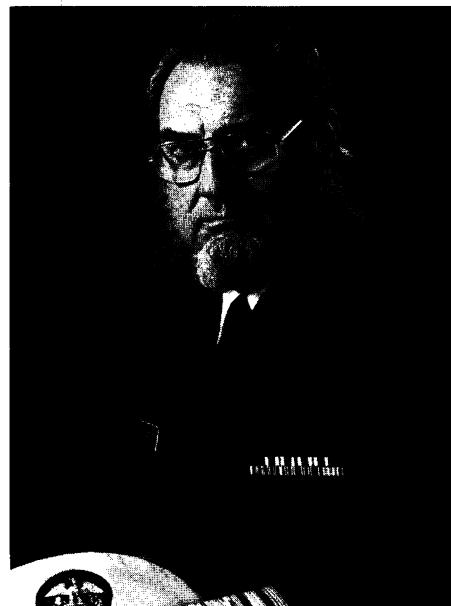
The NIH critics say that if Koop's revitalization project goes through, it will seriously disrupt research and the collegial atmosphere of the NIH. In particular, many excellent senior scientists would be forced to

retire, other key researchers would be relocated, and NIH scientists and clinicians would have to wear uniforms—a requirement that, the commissioned officers argue, would seriously disrupt professional relationships at NIH.

Koop, who declined through a spokesman to be interviewed for this article, has reportedly told NIH director James Wyngaarden that his plans are not set in stone—the rules may be bent a bit, he said. So far, however, all the NIH officers have to go on is Koop's written proposal, which does not include any specific plans for flexibility.

Public Health Service officers at NIH have been feeling uneasy ever since Koop announced his revitalization project this spring, but matters came to a head on the afternoon of 18 May when commissioned officers jammed the NIH's 500-seat Masur auditorium for a meeting with Koop. Many left the meeting feeling hostile and demoralized. "Koop could have reassured us, but he didn't," says one scientist who asked that his name not be used.

The Public Health Service was established



The uniform question. NIH director James Wyngaarden (left) does not own one, but Surgeon General C. Everett Koop (right) says Wyngaarden and all other Public Health Service commissioned officers should own and wear them.