GOODBYE PESTICIDES?

THE FOOD QUALITY PROTECTION ACT OF 1996

by Daniel M. Byrd

THE COMMERCE COMMITTEE DELIVERED a bill that was to become the Food Quality Protection Act (FQPA) to the House floor on 3 August 1996. The *Washington Post* and the *New York Times* immediately ran favorable editorials. Three days later, at nine in the morning, the House passed the bill by voice vote. The bill never went to a House-Senate conference. Instead, the Senate debated it for twenty-eight seconds before passing it by unanimous consent. President Clinton promptly signed it into law.

The bill averted the demise of a few agricultural chemicals, pleasing some companies. It also tightened the regulatory screws on many other pesticides, pleasing many environmentalists.

Unintended or not, the FQPA could drive more than half of all agricultural pesticides from the market, driving up food prices and worsening the diets of poorer Americans.

A complicated interplay of ideas and interests propelled the rapid passage of the FQPA. It included publicity about a new environmental fear called "endocrine disruption;" Congressional misreading of a National Research Council report; the political adroitness of Rep. Henry Waxman (D-Calif.); and industry desires to keep certain pesticides on the market.

THE NEW CHEMICAL THREAT

In 1996, many policymakers felt confident that the Environmental Protection Agency had built so many layers of safety into regulations that no human health effects could possibly result from pesticides in food. That confidence was shaken by the publication that year of *Our Stolen Future* by Theo Colborn, Diana Dumanoski, and John Peterson Myers. It claimed that tiny amounts of pesticides and other manufactured chemicals behaved as "endocrine disrupters" or "environmental estrogens." Accused of interfering with hormone-regulated biochemical pathways, the chemicals were blamed for certain types of cancers, decreased sperm counts, developmental problems, and other adverse consequences in humans and developmental abnormalities in wildlife.

The wide publicity given to *Our Stolen Future* set off a contest on Capitol Hill between various legislative committees to see which would first enact provisions for endocrine disrupter testing.

A few months later, in May 1996, members of Congress and committee staffs heard rumors of discoveries at Dr. John McLachlan's laboratory at Tulane University. Reportedly he had shown that certain pesticides, which lacked notable toxicity when tested individually, interacted synergistically when tested for estrogenic activity.

At that time, the EPA was known to have a draft of the Tulane paper, and EPA experts seemed to spend more time than usual on Capitol Hill. But they declined to answer questions about the Tulane experiments. Silence only heightened concern. In mid-June, the paper by McLachlan and his coauthors appeared in the prestigious journal, *Science.*

The experimental method used by the Tulane researchers did not actually measure any toxic effect directly, but the results seemed frightening. The researchers tested several pesticides for activation of estrogen receptors, early events in biochemical pathways that may cause some toxic effects. When tested individually, at low concentrations, the pesticides displayed little activity. But mixtures of two pesticides were reported to be more than one thousand times as potent for activating estrogen receptors. No elaborate laboratory methods or statistical manipulations were necessary to demonstrate the potential significance of the thousand-fold increase.

The Tulane results underlined the concerns raised in *Our Stolen Future*. Synergism fears heightened anxiety about the already complex process of pesticide regulation for foods. Members of Congress saw a political and public health risk in not acting quickly on the information. There seemed to be no time to check the authenticity of the Tulane experiment by trying to reproduce it in other labs. Although other factors contributed, to the rapid passage of the FQPA, the Tulane results certainly had an effect.

LEGISLATIVE FORCES

Usually, three groups battle over pesticide issues and cancel each other out. The first group, agricultural interests and many members of Congress from farm states—both Republicans and Democrats—believe pesticides are essential for the profitable production of quality food that will sell at reasonable prices. The second group, moderate members of Congress from both

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major parties, favor tight restrictions, but no outright bans. Finally, many environmentalists feel that all pesticides should be eliminated and replaced with "organic" farming methods. Concerns about endocrine disrupters and other events that preceded the FQPA upset that traditional balance.

Passage of the FQPA must be understood in light of 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which satisfied none of the aforementioned groups. In the 1988 amendments, Congress raised user fees on pesticide manufacturers. The EPA collected $2 million in annual fees and Congress promised faster reviews of new pesticide registration applications in exchange. Swift review never materialized. Further, the EPA continued failing to meet many regulatory deadlines imposed by the 1988 amendments.

The amendments provided pesticide manufacturers no relief from one of their worst burdens, the Delaney Clause of the Federal Food, Drug, and Cosmetic Act of 1957 (FFDCA). That clause forbids the addition of any cancer-producing chemical to food. The application of Delaney has been problematic at best. Today's technology can detect extremely small traces of many chemicals that pose no danger to human health. Nevertheless, food additives that have been shown to cause cancer in any animal test are banned from foods.

That interpretation of the Delaney clause created a problem for pesticide manufacturers and food processors. Although the FFDCA does not directly apply to pesticides such as fungicides, the Food and Drug Administration difines any substance in a food that concentrates during processing a food additive. For example, if a pesticide on apples is concentrated in the manufacturing of applesauce, it is labeled a food additive. If the pesticide induced cancer in animals, it had to be banned from applesauce, even if the risk of human cancer was so low as to be nonexistent.

The EPA tried to allow carcinogenic pesticides in processed foods when risks were extremely low. But in 1992, the Ninth Federal Circuit Court, in *Les v. Reilly*, ruled against that approach. As part of the settlement, the EPA agreed to phase out some fungicides as of 1996. That set the stage for change. Food processors, facing the impending elimination of fungicides crucial to their business, sought congressional relief from the application of Delaney to pesticides in processed foods. They recognized that they would probably have to give up something in exchange. Nothing had come from earlier efforts to persuade Congress to amend or repeal the Delaney clause. Defenders of Delaney had only to indicate that politicians supporting repeal favored more cancer, a frightening accusation for an elected official.

When Bill Clinton took office in 1993, he did not assign a high priority to food safety. But much of the White House staff came from environmental groups. Thus, the Administration's food safety bill materialized in 1994. Most observers regarded it as a wish list for environmentalists and bureaucrats, without support even from the important Congressional committees; committees then controlled by Democrats.

In 1995, rather than proposing amendments to the Administration's bill, the House Agriculture Committee drafted a new bill, H.R. 1627, which addressed many FIFRA and pesticide issues but not the Delaney problem. It did not reach the House floor for a vote.

THE PASSAGE OF THE FQPA

The publication of *Our Stolen Future* and the Tulane study caused Congress to place food safety high on its agenda. Representative Tom Bliley (R-Va.) chaired the House Commerce Committee that wrote the final version of the FQPA and specifically drafted the parts that amended the FFDCA. Despite its general responsibility for the FFDCA, the changes in the FQPA barely affected the FDA. Instead, the FFDCA amendments required major changes in operations at the EPA because they changed the application of Delaney to pesticides.

Bliley, who represents an agricultural constituency, was not well disposed to consider the interests of food processors. He felt that he had received unfair criticism about the demise of H.R. 1627. During a visit to California, the farm community reproached him at every turn for appearing to block the reform legislation. Further, Bliley believed that the food processing industry improperly bypassed his committee by trying to repeal Delaney through regulatory reform bills and the appropriations process.

Most observers thought that food protection legislation would go nowhere in 1996, but Bliley's committee assembled a small drafting team to attempt compromise legislation. The participants represented the EPA's Office of General Counsel; the EPA's Office of Pollution Prevention, Pesticides, and Toxic Substances; the FDA; the ranking Democrat member of the Commerce Committee, Representative John Dingell (D-Mich.); Bliley; Waxman, the ranking minority member on the Health Subcommittee; and two lobbyists, one from an environmental group and one from industry. Although billed as a consensus work group, Waxman heavily influenced the team.

Under pressure, the team often retrieved specific wording from the old Administration bill. After several weeks, the FQPA emerged from the room as it appears today. It eliminated the application of Delaney to pesticides but changed the criterion for legal pesticide use. The previous criterion required the EPA to balance risks and benefits. The new criterion requires that pesticides meet the "reasonable certainty of no harm" standard before they can be registered for sale and use. That means the EPA is allowed to consider only risks. Few pesticide companies in 1996 seemed to appreciate the impact of that new principle or other changes. Instead, they rejoiced at the apparent relief from burdens imposed by the 1988 version of FIFRA.

The accomplishments of the FQPA drafting team now appear equivocal. Had the FQPA gone through more of the traditional congressional checks and balances, a better bill surely would have emerged, but it might not have passed. Now, the adverse effects of hasty policy and bad science are emerging.

TOLERANCE SETTING

To evaluate the folly of the FQPA, it is necessary to under-

stand how the federal government deals with pesticide and food safety issues. As applied to pesticides, "tolerance," means the maximum level of pesticides on food that toxicologists and policymakers consider safe. Setting those levels involves consideration of analytical chemistry, toxicology, similarities and differences between test animals and humans, and food consumption. The theory, however, requires only general comprehension of three subjects: thresholds, safety factors, and exposures.

The basis for all chemical regulations is animal tests. The results of those tests are interpreted differently depending on whether the test is for cancer or another health defect. For noncancer effects, the highest test dose that does not cause disease is the threshold dose. Regulators typically divide the threshold dose by a safety factor of one hundred to set the maximum permitted human exposure. The safety factor of one hundred comes from a factor of ten to allow for the possibility that humans are more sensitive to the toxic effects of the pesticide than animals, multiplied by another factor of ten to allow for more sensitive groups or individuals in the human population. Both the FDA and the EPA follow that procedure to set acceptable chemical levels in food.

UNLESS REGULATORS INTEND TO BAN A PESTICIDE OUTRIGHT, THEY HAVE TO DECIDE THAT SOME LEVEL OF CANCER RISK IS ALLOWABLE.

The EPA sometimes will use what it regards to be incomplete or ambiguous test data when registering a pesticide. When it does, it multiplies the standard uncertainty factor of one hundred by another factor of two, five, or ten to allow for the greater uncertainty. The FDA, on the other hand, generally rejects ambiguous data and denies regulatory approval unless more complete or less ambiguous data are submitted. The EPA also applies safety factors larger than one hundred when a substance causes developmental effects of unusual severity, such as deaths soon after birth in animal tests, or irreversible conditions, such as malformations. The FDA similarly applies an additional safety factor when the observed toxic effect is irreversible. Both agencies apply extra safety factors when a human subpopulation may have greater sensitivity.

The EPA uses the term "reference dose" or RfD to refer to the amount of a pesticide that it calculates can be consumed without ill effects. Others, including the FDA, call the same quantity the "acceptable daily intake" or ADI. Both the EPA and the FDA standard for pesticides are calculated on the basis that a person can consume food for a seventy-year lifetime at the RfD or ADI level without experiencing a chronic, noncancer health effect. Consumers probably could ingest higher levels without adverse effects, but the federal agencies think that those levels are assuredly safe.

The procedure is different for carcinogenic effects. Under current federal policy, no level of exposure to carcinogenic substances is considered risk-free. Although controversial within the scientific community, the policy holds that risk decreases with decreasing exposure but does not reach zero until exposure is zero.

Unless regulators intend to ban a pesticide outright, they have to decide that some level of cancer risk is allowable. By convention, a lifetime cancer risk of one additional case in one million individuals is considered the allowable risk or "virtually safe dose" (VSD). A federal agency can permit lifetime consumption at that level of risk or less as a negligible risk. But that practice was moot for pesticides in processed foods after the EPA lost in court in 1992, because of the prohibition under the Delaney clause.

Once a RfD or an ADI is available for a noncarcinogenic pesticide or a VSD is available for a carcinogenic pesticide, another step is necessary to determine what level of the pesticide on a crop will be tolerated. Tolerances vary from crop to crop, because people consume, for example, different amounts of apples, pineapples and so on. The EPA decides what levels of pesticide residues will be tolerated on fruits or vegetables in the marketplace. The FDA inspects foods and enforces the EPA-established standards, seizing foods and food products with levels of pesticides higher than tolerances and penalizing the producers.

THE DELANEY PARADOX

The concentrations of pesticides on most raw fruits and vegetables are well below the allowed tolerances, and processing such foods seldom results in a concentration greater than the tolerance allowed on raw crops. However, Delaney forbids any amount of carcinogenic pesticide in processed foods, regardless of its concentration. Thus arises the Delaney paradox. Pesticide concentrations that are acceptable on raw fruits and vegetables can be unacceptable in processed foods made from the same crops.

Another perverse effect of the Delaney clause is that it sometimes blocks the introduction of less risky pesticides. A National Research Council report in 1987, *Regulating Pesticides in Food: The Delaney Paradox*, noted that some potential new pesticides had measurable but trivial carcinogenic risks, yet were safer overall than the products they would replace. But food processed from fruit and vegetables treated with those pesticides would be banned, growers are forced to use older pesticides of overall greater toxicity. The EPA tried to get around the Delaney paradox by allowing carcinogenic pesticides in processed foods, even when they concentrated during processing, if the amounts still posed negligible risks. As noted above, in 1992, the Ninth Circuit Court decided that approach was illegal.

The Clinton Administration has justified some of its stricter regulatory policies through an appeal to protect children. Not surprisingly, Dr. Lynn Goldman, the EPA Assistant Administrator for Pollution Prevention, Pesticides, and Toxic Substances, advocated the addition of provisions to the FQPA to protect children. The emphasis had the political dividend of placing any member of Congress voting against the FQPA "against kids."

In drafting the FQPA, the Commerce Committee relied heavily on a 1993 National Research Council (NRC) report, *Pesticides in the Diets of Infants and Children*, concerning the differential effects of pesticides on infants and children. Says the report:

> Because there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the tenfold factor traditionally used by the EPA and the FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when toxicity testing relative to children are incomplete.

Children have significantly higher exposures to some pesticides than adults because children have higher metabolic rates and consume more food in relation to their body weights. In addition, children consume a higher proportion of certain foods in their diets, such as apple juice and orange juice, on which pesticides are used.

Most scientists expected that the EPA would deal with the problem of higher childhood exposures by setting lower tolerances for certain, targeted products. Thus, if a pesticide used on apples turned up at six times higher levels in baby diets than adult diets, the EPA could lower the tolerance for that pesticide on apples by that amount. The Agriculture Committee transcribed that approach in a draft bill, H.R. 1478. But the bill went nowhere.

The NRC recommended that an additional safety factor be considered, leaving open the possibility of making decisions on a case-by-case basis. The Commerce Committee went further. The FQPA mandates that:

> an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.

The EPA has responded to the requirement for an extra tenfold safety factor by asserting that test data already on hand will justify a factor smaller than ten for many pesticides. In a formal policy paper issued in September 1996, the EPA essentially ignored the Congressional requirements, retaining most of its pre-FQPA policy. But it seems unlikely that the EPA will be able to get away with such a policy. If nothing else, environmental organizations will sue the EPA attempting to force it to adhere to the FQPA.

REGULATORY POLICY AND SCIENCE

The language of the FQPA reflects Congressional fears about the underestimation of exposure to pesticides. One worry is that a pesticide may reach the typical consumer through pathways other than food. For example, if the pesticide runs off fields after spraying and gets into the water supply, people may drink the water, adding to their exposure to the pesticide.

The FQPA deals with multiple pathways by requiring the EPA to estimate consumers' "aggregate" exposures. Reasonable as the requirement might appear, the problem is that nonfood exposures are usually trivial. Under the FQPA, the burden of proof falls on manufacturers to show that total exposures are within acceptable safety levels. But gathering and evaluating the data to prove that the contribution is minor will be costly and time consuming. For example, a pesticide might be used in cosmetics as well as on crops, and an aggregate exposure analysis or "multiple pathway assessment" involves adding together the two exposures.

The estrogenic testing provisions in the FQPA look increasingly troublesome. While the FQPA is clear about the deadlines for establishing a testing and screening program, the methods and tests are left to the discretion of the EPA. Achieving a practical consensus among stakeholders about a testing and screening program will prove extremely difficult, if not impossible. Since there is serious scientific doubt about adverse health effects resulting from exposure to tiny amounts of endocrine disrupters, testing will achieve no direct public health utility. Instead, test results that finger a chemical as having estrogenic activity simply will generate demands to apply other toxicology tests for health effects such as potential reproductive and developmental effects. Manufacturers have already conducted those tests on pesticides.

DISCREDITED SCIENCE

Science got walloped in the FQPA. Congress responded to the NRC's recommendation by mandating an additional tenfold safety factor. The EPA and the regulated community will now have to struggle with the FQPA's new criteria.

The FQPA seems to direct the EPA to determine the adverse effects of synergism in mixtures of several pesticides that individually pose no health threat. To do so, the EPA will seek "common mechanisms" of toxicity, defined broadly as ways that substances could be toxic in combination. But there is great uncertainty among toxicologists about how to translate that concept into something that makes sense operationally. Mechanisms of toxicity are often not known, making it impossible to discuss "common mechanisms." Some toxicologists have suggested the term might refer to effects at the same anatomical site or even to substances having similar structures. But the truly bizarre thing about the requirement is that it is based on discredited science—the Tulane University results published in June 1996. In meetings during the fall of that year, several scientists reported that they had been unable to replicate the results. In early 1997, both Science and Nature published reports by scientists who could not duplicate the Tulane results. Initially, Dr. McLachlan, head of the Tulane laboratory, defended the work, but in July 1997, he acknowledged that neither his own nor any other laboratory had been able to repeat the experiments.

Yet, the EPA will interpret "common mechanisms of toxicity" somehow, and pesticide manufacturers will have to test their new products accordingly. The EPA ignored McLachlan's withdrawal of the synergism claim. According to James Aidala, an agency official, the EPA assumes, as a matter of policy, that synergy occurs.

The FQPA uses another clause, "cumulative effects," that has

stumped everyone. Does it mean the effects observed after cumulative exposure to a pesticide or after exposure to several pesticides? Was it an attempt to emphasize chronic effects over acute effects? Did the Commerce Committee think that certain biological outcomes add to or interact with each other? Those and other unresolved terms in the FQPA promise work for scientists and policymakers at the EPA , in trade associations, and in various companies. They also promise contracts to academics and other testing laboratories, and to consultants of all kinds. What they do not promise is an improvement in public health. None of the writings and discussions that led up to the passage of the FQPA mentioned a method for measuring the harm those food pesticides may cause to any population, including children. Those effects, if they occur at all, are too rare or too subtle to detect.

THE EPA HAS LOST MUCH CREDIBILITY, AT LEAST AMONG SCIENTISTS WITH AN INTEREST IN A SAFE AND NUTRITIOUS FOOD SUPPLY.

EFFECTS ON PESTICIDES

How many pesticides will the new tenfold safety standard eliminate from the market and, by extension, harm America's food supply? Such a calculation is only hypothetical since no one knows how the courts will allow the EPA to apply the statutory language. In one such effort, the author and his staff examined the uses of forty-one active ingredients present in agricultural pesticides. For each ingredient, on average, about fifty tolerance levels exist covering various crops. To approximate the effects of the new tenfold increase in the safety factor, the current tolerances for various crops were divided by ten. Those new tolerances were compared to the levels of pesticide currently found on crops. For example, let us say that the current tolerance level for a certain pesticide on corn is 150 units. The measured level of the active ingredient in the pesticide is fifty units, well below the tolerance level. Under the new FQPA standards, the tolerance level of 150 is divided by ten, resulting in a new tolerance of fifteen units. Under that standard, growers would not be allowed to use a pesticide containing that active ingredient on corn.

Of the forty-one active ingredients checked, thirty-two—approximately 80 percent—had at least one tolerance that an extra tenfold safety factor would place below the current measured concentration on a crop. For many of the forty-one pesticides, all of the new tolerances were below the actual amounts on crops, meaning that pesticides containing those ingredients could not be used at all. Another toxicologist estimates that 50 percent of pesticides would be eliminated.

On 4 August 1997 the EPA published a schedule for reassessing food tolerances, using the "most risky first" principle, a different approach. The Agency placed 33 percent of all tolerances in the first, most risky group. Many of the reviewed forty-one active ingredients fall into this "most risky" category of pesticides.

WINNERS AND LOSERS

Besides the scientific community, the FQPA had highly disproportionate outcomes for other stakeholders. Representatives of industry and agriculture who think that the FQPA substitutes a "reasonable certainty of no harm" for the Delaney clause should look again. But Delaney remains a part of the FFDCA. It just no longer applies to processed foods in the same way.

Pesticide manufacturers will probably suffer tremendous losses. At best, some of their products will spend years in regulatory limbo. First, the EPA will have to decide on the appropriate tests to satisfy the requirements of the FQPA and how those tests will be interpreted. Laboratories and consultants will then run the tests, produce the results, and send them to Washington for review. Finally, the EPA will have to decide if the tests provide the information it requires. Time and money will be lost, and the pesticides involved will lose sales. At worst, manufacturers might lose approximately half of their products.

In contrast, environmental advocates achieved a fantastic victory at little cost. To groups that think that decreased risk strictly depends on smaller amounts of pesticides in the environment, the potential elimination of many currently marketed pesticides is an awesome triumph. Further, environmental groups have given up little, if any leverage. They gave up Delaney's blanket rejection of carcinogenic pesticides on processed foods, but they can continue to petition the EPA to cancel the use of pesticides with carcinogenic effects one at a time, using standard regulatory notice and comment procedures. The action simply shifts the fight over pesticides from one big battle to many little skirmishes.

The EPA has lost much credibility, at least among scientists with an interest in a safe and nutritious food supply. Its political appointees displayed a serious lack of leadership and veracity during the construction of the FQPA. While some officials, including Dr. Goldman, have taken credit for the FQPA, the EPA has responded to the law as if struck by a meteorite. Although offered a chance to participate in drafting the legislation that radically changed pesticide regulation, the EPA did not even insist on a transition period. As a result, the FQPA's provisions became effective on the date of passage. The FDA fared better than the EPA. FDA officials had already sought the minor changes that the FQPA imposed on them, such as new enforcement procedures. The nightmarish implementation of the FQPA surprises only the EPA's leadership.

No one knows how the requirement for an additional tenfold safety factor will play out. Understanding will lag behind the inevitable legal challenges and actions.

Unless the endocrine testing requirements yield unexpected discoveries of risky substances, the entire program simply amounts to a camouflaged tax on industry, not an advance for public health. The impact of the tax—reduced pesticide availability and higher costs—will not become apparent for several years.

The ultimate casualty of the FQPA likely will be the health of Americans, especially the poor. As pesticide use decreases,

the negligible health risks from pesticides on foods, if any, will decrease. The far more certain health risks are more expensive food, diminished food availability and poorer food quality. The middle class will not starve or even significantly reduce its consumption of fresh fruits and vegetables when the food supply gets expensive, but disadvantaged groups will suffer. Thus, the ironically named FQPA may well protect us some of us from quality food.

SELECTED READINGS

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