# Apples, Kids and Core Science

*FQPA is the first U.S. environmental statute to direct regulations to use advanced risk assessment and management methods in dealing with "vulnerable groups."*

*By Charles M. Benbrook*

In its landmark 1993 report *Pesticides in the Diets of Infants and Children*, the National Academy of Sciences spelled out why existing pesticide tolerances might not be safe for pregnant women, infants and children (NAS). The report documented why babies and children are uniquely vulnerable to fetal and developmental effects from exposure to certain pesticides. The message from NAS to the Environmental Protection Agency (EPA) was that infants and children are not just little people, and current tolerances need to be revisited to assure that they are adequately protected.

If adopted, the major recommendations of the NAS report would resolve many long-standing pesticide tolerances problems associated with the application of the zero-carcinogen-risk Delaney Clause. Most public health, consumer and environmental groups embraced the report, as did most of the pesticide industry — at least initially. EPA promised speedy action and Congress pledged to do its part since new legislation would be required to implement several recommendations. The debate in public health circles and in Congress over how to fix the Delaney Clause had been an annual right of spring in Washington D.C. since 1981. Yet after just a few minutes of debate, Congress passed the Food Quality Protection Act of 1996 (FQPA) by unanimous votes in both houses. The endgame was stunningly fast and decisive.

## Importance of the FQPA

The FQPA is the most important addition to U.S. pesticide law since the modern Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was passed in 1972. It is the first U.S. environmental statute to direct regulators to use advanced risk assessment and management methods in dealing with the unique susceptibility of infants and children and other vulnerable groups.

What did the FQPA actually do for consumers? A tolerance can now be established only if it meets the health-based standard: "reasonable certainty of no harm." This change eliminated the role of pesticide benefits assessment in tolerance setting and in managing human dietary risks, although

pesticide benefits continue to play a role when EPA evaluates restrictions that are expected to impose higher short-run costs on farmers or society as a whole.

The law directed EPA to base safety findings on assessment of aggregate exposures to a pesticide from food, drinking water and beverages, in and around the home and in public places. It required EPA to impose an extra 10-fold margin of safety for pesticides shown to pose unique risks to pregnant animals or their offspring (the "10-X provision"). Finally, the act directed EPA to add together all exposures to pesticides that pose risk through a common mechanism of biological process in humans — arguably the FQPA's most important change in pesticide law.

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Unlike most laws, the FQPA was effective immediately. All new tolerances approved after August 3, 1996 had to meet the law's new safety standard. It took several months for EPA to specify testing, notification, and decision criteria and processes. New policies evolved piece-meal and big decisions were deferred. Applications for new lower-risk pesticides leading to minimal dietary exposure moved through the registration process with only modest delays, but those showing potential as a dietary risk-driver did not.

By mid-1997, several new risk policies for scientific assessment were published for comment in the Federal Register. At this same time, the agency published a schedule for review of old pesticides and announced that the organophosphate (OP) insecticides would be a top priority.

By mid-1998, consumer and environmental groups had carried out preliminary analyses of risks in the diet, drawing on the widely accepted residue data from the U.S. Department of Agriculture's Pesticide Data Program (PDP). The results showed that cumulative OP exposure from about two-dozen foods often exceeded a child's acceptable Reference Dose (RfD). (An "acceptable RfD" for a given day is the individual's weight in kilograms times the pesticide's Reference Dose, which is expressed in kilograms of pesticide per day. An RfD is the dose level below which EPA expects no adverse effects. It is typically based on a "No Observable Adverse Effect Level" in an animal study coupled with a 100-fold safety factor).

A variety of methods and models used by EPA, private groups and risk assessment experts showed that on a given day up to a million or more children are likely to consume more OPs than allowed by their personal Reference Doses just from residues in food . Despite empirical shortcomings and many unresolved technical risk assessment issues, the results confirmed that many fruit and vegetable crop uses of OPs would have to be cut back substantially in order to meet the FQPA's new safety standard.

## What Has the FQPA Accomplished?

Linda-Jo Scheirow's article in this issue of CHOICES (pp. 18-20) explains the three milestones for the FQPA review of old chemicals and all existing tolerances. Has the EPA met these milestones? The agency limped through the third-year milestone (August 1999) with little risk reduction to show for its efforts. While 1,500 tolerances had been revoked, all but about 10 covered obsolete, trivial crop uses, (that is, a use accounting for 2 percent or less of total acres producing the crop). With the exception of the ban on future methyl parathion applications on key children's foods, FQPA decisions as of August 1999 promised very little actual reduction in dietary risk.

Despite some early wheel-spinning, the EPA has made considerable progress in building the policy and risk assessment infrastructure required to make and defend the hundreds of decisions it faces. An enormous effort was required to work through the first stage of reassessment of some 30 organophosphate insecticides, and some solid and meaningful risk reduction actions have been negotiated with industry in the last year.

EPA has updated its toxicological reviews of most of the pesticides widely used on food, either affirming or adjusting chronic or acute Reference Doses (cRfD, aRfD). Of the approximately 250 food-use pesticides on the books when the FQPA was passed, the agency has:

- Raised cRfDs for about 5 percent of the pesticides, allowing greater exposure.
- Lowered cRfDs for about 15 percent of the pesticides.
- Left cRfDs unchanged for about 80 percent of the pesticides.

These RfD reviews are neither complete nor definitive, but the above pattern is likely to hold true. The FQPA will result in adjustments to RfDs in perhaps a quarter of cases, with RfDs being lowered much more frequently than they are raised.

The FQPA provision calling for a 10-fold safety factor has been used sparingly thus far. The agency has imposed the full 10-X safety factor in only about 10 cases. An added 3-X safety factor has been more common. Based on RfD decisions to date, more complete toxicological databases on pesticides, with emphasis on more sensitive human development studies, may lead to reductions in RfDs far greater than the law's 10-fold reduction provision.

## The Chlorpyrifos Decision

EPA has significantly reduced OP risk through actions impacting fruit and vegetable uses of two pesticides — methyl parathion and chlorpyrifos. Action against the former was taken in August 1999. The action was widely anticipated and not seriously contested. The chlorpyrifos decision in June 2000 was both bold and contested.

This OP, manufactured mainly by Dow AgroSciences (sold as Lorsban for farm use and Dursban for home and structural pest management uses), is the most widely used insecticide in America, with major farm and urban uses.

Dow has spent hundreds of millions defending the safety of chlorpyrifos. EPA, buttressed by compelling new evidence of developmental neurotoxicity, held its ground in the June 2000 decision. The agency has either banned or significantly cut back all urban and farm uses known to lead to significant exposure by infants and children. The key decisions involved three crops known to account for most exposures through the diet — apples, grapes, and tomatoes. The agency restricted use on apples to the pre-bloom period, resulting in about a 100 day "Pre-Harvest Interval" (PHI). Such a long PHI should assure no harmful residues on apples at harvest. In addition, EPA lowered the apple tolerance from 1.5 parts per million (ppm) to 0.01 ppm.

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The FQPA will help level the international market playing field since U.S. tolerances apply to all fresh and processed foods imported into the United States. Foreign growers shipping produce to the United States will have to abide by restrictions on chlorpyrifos application rates and timing similar to those applicable here. Growers and export companies that do not will risk serious consequences when the Food and Drug Administration detects over-tolerance produce or processed foods at a U.S. port of entry.

Comparable restrictions were imposed on grape uses, accompanied by a 100-fold tolerance reduction to 0.01 ppm. The tomato tolerance was revoked because of the availability of ample, proven pest management alternatives and the fact that, in recent years, fresh tomatoes imported from Mexico have had the highest residues of chlorpyrifos. If EPA had banned chlorpyrifos use on tomatoes in the United States without changing the tolerance, most of the risk from chlorpyrifos residues on tomatoes would remain, since in recent years Mexican tomatoes have accounted for most chlorpyrifos dietary risk from this crop.

As the agency works through the remaining high-risk OPs, it is likely to apply the same principles and decision criteria used in the chlorpyrifos decision. If EPA stays on course, most high-risk OP exposures will be either eliminated or dramatically reduced. The EPA should be able to reduce OP risks in major children's foods like apples, pears, grapes, peaches, green beans, and tomatoes by 98 percent or more by targeting actions against just a half-dozen higher-risk OP pesticides (Consumers Union, 1998).

EPA's decision brought good news for farmers and Dow AgroSciences. The agency imposed risk reduction measures only on those uses of chlorpyrifos that routinely result in risky food residues. The two biggest crop uses by volume — corn and cotton — were not impacted since these commodities do not usually lead to residues in food or exposures to children.

## Reducing OP Risks in Apples

Fresh and processed apples account for over one-half of total OP exposure and risk for children. Bringing apple-based OP risks down to the FQPA standard will require EPA to phase out residues of the five risk-producing OPs used in apple production: methyl parathion, azinphos methyl, chlorpyrifos, dimethoate, and diazinon. The agency has already taken the needed action limiting methyl parathion and chlorpyrifos. It is expected to follow suit with diazinon and dimethoate because of the risks these OPs pose to consumers, farmworkers, and wildlife. The remaining big decision will be when and how to cut back on the use of and risks associated with azinphos methyl (Guthion).

I projected changes in apple Integrated Pest Management (IPM) systems and insecticide use in a two- to five-year period after the phase-out of the above five OPs. Low risk alternatives include products like insect growth regulators, pheromones for insect mating disruption, and biopesticides like *Bacillus thuringiensis*. Major findings include:

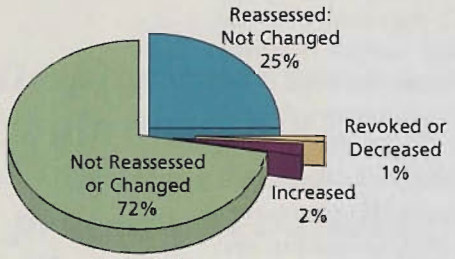
- The volume of insecticides applied to apples will drop as much as two-thirds, from over 7 pounds per acre in 1997 to around 2 pounds per acre.
- Less toxic OPs (phosmet and malathion) and carbamates (carbaryl and formetanate hydrochloride) will still account for about 30 percent of acre-treatments and about 80 percent of total insecticide pounds applied.
- Preferred alternatives will account for nearly 2 of every 3 acre-treatments.
- Grower pesticide expenditures will fall from about $140.00 per acre to $125.00, as biobased systems reduce secondary pest problems, especially late season mites.

Somewhat higher expenditures are likely on insect scouting and other IPM services. In good years, well-managed IPM systems can reduce total pest management expenditures to close to pre-FQPA costs. Larger, more robust savings are possible as competition drives down the price of newer pesticides and technology. In years with heavy pest infestations or in orchards new to IPM, total pest management costs are likely to rise, but not dramatically when compared to other episodic, unpredictable factors that impact production costs, yields, and crop quality.

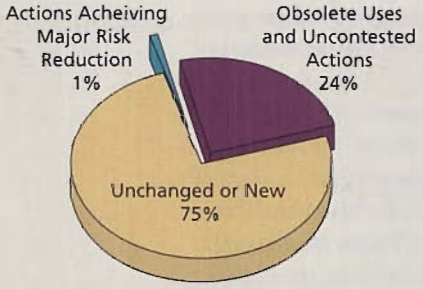
## Next Steps and Hurdles Ahead

The EPA faces a big task in completing and defending the core science policies required to implement the FQPA. Special attention must be directed to the cumulative risk assessment methodology, the provision of the FQPA that should have the biggest impact on high-risk families of chemicals. Toxicologists also face a major challenge in refining procedures used to estimate the effects of pesticides on human endocrine system development and function.

**EPA Tolerance Actions Through July 30, 1999**

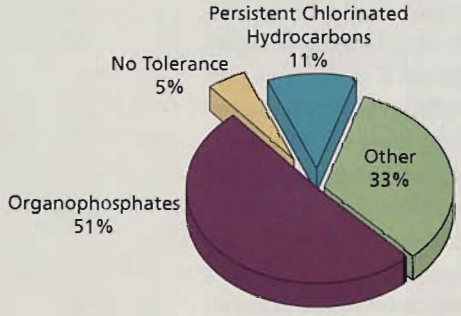



**EPA Pesticide Reassessments Fail to Reduce Risk From Organophosphate Use**




Based on 1,691 food-use tolerances

**Dietary Risk Tolerances Based on Pesticide/Crop Combinations.**




The global significance of the FQPA will come into focus as the EPA lowers some key tolerances on internationally traded foods. Tolerances in the United States are *de facto* world standards and can change how pesticides are applied in all countries exporting food to the United States. International tolerances, called Maximum Residue Limits (MRLs), are set within Codex, the international agreement governing food safety. In most cases Codex standards are higher than U.S. tolerances, so FQPA tolerance reductions will widen the divergence between the United States and Codex standards and make selling to the United States more difficult. An exporter's challenge before the WTO of an EPA tolerance decision would quickly emerge as a test of one consequence of globalization.

The EPA already faces lawsuits from both sides of the FQPA debate, and more are likely. An agriculture-industry coalition is trying to weaken the FQPA in Congress. Thus far, these efforts have not seriously affected implementation. In the past, registrants have been able to delay completion of contested EPA actions by five to 10 years by exercising administrative and legal appeals. The FQPA gives EPA powerful new tools to dissuade registrants from pursuing such a strategy. When challenged by a registrant, the EPA will be required to present and defend its risk findings in open proceedings — a process most corporate officers, producers, and food companies would just as soon avoid.

Congress foresaw the need for alternatives and included provisions in the FQPA designed to accelerate registration of reduced risk pesticides and encourage companies to expand R&D investments in search of biopesticides. These provisions have been implemented with a lack of imagination and effort.

EPA can and should do more to encourage the industry to shift attention toward highly specific, lower-risk biopesticides. Data requirements need to be clarified and streamlined and review periods need to be shortened. Reviews should be coordinated with states so that little or no time is lost between approval at the federal level and the granting of state registrations.

Hopefully, a new Administration and Congress will recognize the many good reasons why more public funding should be invested in FQPA-driven transitions toward prevention-based biointensive pest management systems. To the extent the FQPA fosters progress toward this longer-term goal, and in the short-run reduces exposures to known high-risk pesticides, this important statute will live up to its promise and serve the nation well. ■

## ■ For More Information


Benbrook, C., E. Groth, M. Hansen, J. Halloran, and S. Marquardt. *Pest Management at the Crossroads.* Yonkers, NY: Consumers Union, 1996.

Consumers Union. *Tolerance Tracking System and Tables.* Available at http://www.ecologic-ipm.com/CUTRT.html, April, 2000.

Consumers Union. *Worst First: High-Risk Insecticides, Children's Food and Safer Alternatives.* September 1998. Information on the history of the FQPA and all Consumer Union reports and comments related to this law are available at http://www.ecologic-ipm.com.

Groth, E., Benbrook, C., and K. Lutz. *Update: Pesticides in Children's Foods: An Analysis of 1998 USDA PDP Data on Pesticide Residues.* May, 2000.

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*The views expressed in this article are those of the author. Analytical findings are from consulting work done for Consumers Union. See the CU-FQPA website http://www.ecologic-ipm.com for official CU press releases, reports, comments, and methodological details.*