OVERVIEW: INTRODUCTION AND SUMMARY

A Brief History of the FQPA

When Congress passed the Food Quality Protection Act (FQPA) in August of 1996, a number of remarkable things happened:

First, its passage broke a decade-long deadlock in Congress over pesticide-policy reform. The combination of skillful management by the bill's sponsors and election-year politics helped the FQPA sail through both houses of Congress. It was approved *unanimously*—without a dissenting vote on either side of Capitol Hill. Stakeholders on all sides of the pesticide debate welcomed passage of the bill. Environmentalists and other public-health advocates praised the new emphasis the FQPA puts on protecting children from pesticide risks. Chemical industry and farmer groups rejoiced that the FQPA repealed application of the anti-cancer Delaney Clause to pesticide residues, replacing that reviled "zero-risk" standard with a more science-based standard of "reasonable certainty of no harm." The scientific community welcomed the FQPA's adoption of key recommendations from two major studies on pesticides by the National Academy of Sciences, published in 1987 and 1993, respectively.

Also remarkable was the way the FQPA transformed a key element of federal pesticide regulation, tolerance setting, from its long-standing function of registering chemicals for use on foods, based on balancing risks and benefits, into a more explicitly health-based mission. The FQPA's requirement that EPA ensure that every pesticide exposure have a "reasonable certainty of no harm" also replaced the Agency's previous mandates, which had allowed already-approved pesticide uses to remain on the market unless EPA could show that their risks outweighed their benefits.

The new law addressed a chronic problem, lack of scientific data on pesticide toxicity, which for decades had slowed the regulatory process to a standstill. The FQPA requires EPA to add up to a 10-fold safety factor in setting limits for pesticide exposure, when it cannot be "reasonably certain of no harm." This so-called "10-X" provision gives public health the benefit of the doubt when data are insufficient to assess risks adequately, and creates an added incentive for pesticide makers and users to carry out needed testing to fill critical data gaps.

The FQPA contains two other innovative provisions designed to ensure adequate margins of safety for infants and children in setting tolerances. The first calls for EPA to take into account all routes of exposure (such as foods, drinking water and residential exposure) to a pesticide in judging the safety of any given use. The second requires EPA to consider together pesticides that share a common mechanism of toxicity, so that cumulative risks of pesticides with additive effects can be assessed. Under the FQPA, even the cumulative risks of a whole family of pesticides with the same mechanism of toxic action must meet the "reasonable certainty of no harm" standard.

When President Clinton signed the FQPA into law in August 1996, the focus shifted to implementation. It was immediately obvious that the new law imposes enormous new responsibilities on the EPA. The FQPA requires EPA to review, or "reassess," all of its current pesticide limits, and to ensure that they meet the new "reasonable certainty of no harm" standard. There are more than 500 pesticide chemicals registered for use on food crops, and the EPA must review the toxicity of all of them, determining what level of exposure to each, and to groups that share a mechanism of toxicity, is safe for children under the terms of the FQPA. Making those determinations will require innovative scientific and decision-making approaches, tools the Agency has needed to create afresh in most cases. To frame those policies, EPA also needed a process that gave interested parties and the public a chance to participate and to comment on policy proposals.

Once EPA has defined "safe" exposure by FQPA standards, the law requires the Agency to reassess all tolerances—the legal limits for pesticide residues in foods—and to adjust or eliminate tolerances (and associated pesticide uses) as necessary, to make sure dietary exposure to residues is within safe limits. There are roughly 9,600 pesticide tolerances—each defining the permitted level of one residue on one food—and EPA must reassess all of them.

Congress recognized the size of the mandate it was imposing, and instructed the Agency to set priorities, and tackle the most serious hazards first. And as Congress is wont to do, it specified deadlines in the Act. The FQPA requires the EPA to have reassessed the first one-third of all tolerances—those posing the greatest risks to children's health—by the third anniversary of the Act (August, 1999). EPA has another three years, until August 2002, to complete reassessments of the second third of all tolerances, and until August of 2006—ten years in all—to finish the entire job.

After the 1996 elections, as the 105th Congress settled in, the pesticide industry, grower interests and others concerned with the economic impacts of pesticide regulation began a campaign to slow or stall implementation of the FQPA. Groups taken by surprise by the Act's swift passage launched a protracted effort (which continues today) to keep the EPA from pursuing the new law's public-health goals too aggressively.

The American Crop Protection Association (the pesticide industry trade association) and the American Farm Bureau Federation (the national political arm of grower organizations across the country) began spreading the rumor that the EPA was planning to ban <u>all</u> of the organophosphate and carbamate insecticides—two major families of economically important pesticides that all farmers (except organic growers) rely on to some extent. The Farm Bureau ran ads in farmers' magazines, with a picture of a flyswatter, and a message that said, in effect, "A flyswatter is all you'll have left to combat pests, unless you help us stop the EPA!"

This fear campaign succeeded in stirring up anxiety among farmers, which was rapidly translated into anxiety among Members of Congress from rural districts. Rumblings on Capitol Hill accused EPA of being "out of control," of ignoring science, of putting the

livelihoods of thousands of farm families in jeopardy. Some conservative commentators warned that if the EPA actually *implemented* the FQPA, food prices would skyrocket, the economy would be plunged into a recession, and millions of children would starve. The kinds of rhetoric often used to block legislation were in this case aimed at government's effort to carry out the mandates of a law Congress had just passed unanimously.

This anti-FQPA hysteria stirred up by the pesticide industry and anti-regulation political activists raised concerns in the White House that the Democrats were in danger of losing votes in farm states in the 1998 and 2000 elections. Vice President Gore intervened and sent a letter to the EPA, instructing Administrator Browner to pursue implementation deliberately, and to ensure that all interests with a stake in the outcome—and especially farmers—had the opportunity to be heard in the Agency's decision-making process.

In response, the EPA and the USDA jointly established the Tolerance Reassessment Advisory Committee (TRAC), with representation from various stakeholders: Pesticide manufacturers, growers, food processors, farm workers, consumer and environmental organizations, and more. EPA then poured substantial time and resources into TRAC meetings at which industry members fought with the Agency over the legitimacy of its FQPA mandates. Ultimately, all of the public-interest members of TRAC (including Consumers Union) resigned *en masse*, noting that TRAC was stalling implementation, not helping to guide it. EPA took a more sanguine view, pointing out that it needed to educate the various affected interests about the nature of the FQPA's requirements, and that TRAC had been a useful forum for that purpose.

Between the political climate of resistance and the difficulty of the tasks imposed by the FQPA, EPA moved ahead with implementation very slowly and cautiously. Most of the work done during 1997 and 1998 was preparatory in nature: Setting priorities, developing drafts of needed new policies, educating constituencies and Congress about what FQPA requires and how EPA was planning to attack the challenges.

August 1999 arrived almost before EPA knew it. The Agency owed Congress a report, showing that it had complied with the law's first major deadline. In point of fact, EPA had accomplished very little in the way of actually reassessing tolerances by mid-1999, and had done nothing remotely approaching reassessment of the one-third of tolerances that posed the highest risks. But the Agency took one dramatic step—on August 2, it announced a ban of major food uses of methyl parathion, an organophosphate insecticide that is among the most intensely toxic chemicals used on food crops. Consumers Union (and no doubt, EPA itself) had analyzed USDA pesticide residue data and had flagged methyl parathion as the riskiest single pesticide detected in the U.S. food supply (See *Do You Know What You're Eating?*,http://www.ecologic-ipm.com/Do_You_Know.pdf.)

The methyl parathion ban affected just 36 tolerances, out of 113 permitted food-crop uses of methyl parathion, and out of the roughly 3,200 tolerances EPA was supposed to have reassessed by August 1999, but it was a major risk-reduction step. The Agency cobbled together a list of another 3,000 or so tolerances it said had been "reassessed," which was enough to persuade a none-too-critical Congress that adequate progress was being made.

In fact, most of the 3,000 tolerances were obsolete or redundant standards that EPA had revoked or combined in "housecleaning" operations; those actions had little or no risk-reducing impact, and the affected tolerances were hardly top priorities. (See our analysis of the EPA's August 1999 announcement, http://www.ecologic-ipm.com/tolerance.html.)

But in the political climate of 1999, it appeared that EPA's effort to steer its way through the rocks was at best a limited success. Whatever unanimity had existed in August 1996 was now a distant memory, and the hue and cry of ancient pesticide debates resounded through the Capital again. Although the methyl parathion ban had shown environmental and consumer advocates that EPA could assert itself to eliminate an obviously excessive risk, public-health advocates generally complained that EPA had accomplished too little, and clearly had failed to curb the worst one-third of all tolerances. Pro-pesticide factions were even more vocally critical of the Agency. Despite EPA's effort to show that it was proceeding carefully, giving proper weight to science and the views of affected parties, Members of Congress who claimed the Agency was "out of control" held a hearing the day after the EPA's announcement, at which witnesses hostile to the EPA were invited to testify. EPA was berated for its "reckless" action and Members used the hearing as a pep rally to announce their sponsorship of a bill designed to strip the EPA of most of its new FQPA-conferred public-health mandates.

EPA's Recent Progress and Our Evaluations

In the year and a half since August of 1999, EPA has moved into a more active phase of implementation. The groundwork has largely been laid, and the Agency now has begun the long process of case-by-case reassessments of individual chemicals, starting with the consensus top-priority category, the organophosphate insecticides.

In this report, we review EPA's decisions and assess their progress. How much has the Agency achieved? Have decisions been consistent with the FQPA's intent, and based on sound science? Is the food supply less contaminated with pesticide residues now than it was in 1996, and if so, how much of that is because of EPA actions? What other steps EPA has taken have reduced pesticide risks for children?

EPA's work in implementing the FQPA to date has fallen into three general areas:

(1) Science Policies. EPA has had to define numerous scientific and regulatory decision rules to guide FQPA implementation. Many of these policies address new tasks that the Agency previously did not perform—applying the FQPA's "10-X" provision, and doing cumulative risk assessments for groups of chemicals that share a common mechanism of toxicity, for example. In developing these "science policies," EPA has drafted more than two dozen technical papers, has repeatedly consulted with its (peer-review) scientific advisory committees, and has followed an open, public process in which affected parties and the public have had extensive opportunities to participate, comment and criticize.

In **Part 1** of the accompanying report, we review EPA's progress in developing nine key "science policies." We have reviewed the documentary history of each policy, and offer our assessments of the degree of progress made to date, the timeliness of EPA's actions, the soundness of the current policy, its responsiveness to the statute, and the soundness of the process EPA followed, including its responsiveness to public comments. When EPA has applied the new policy in reassessing tolerances or related actions, we have assessed how well the Agency has adhered to its own policy in its FQPA decisions.

(2) Reference Doses. At the heart of EPA's FQPA decisions are its definitions of safe exposure, the level of intake of individual pesticides (or groups with a common toxic mechanism) that EPA determines have a "reasonable certainty of no harm" to children and other exposed populations. Prior to the FQPA, EPA established "Reference Doses" (RfDs), defining exposures judged "safe" for pesticides and other toxic chemicals. RfDs may be established for both acute (short-term, often high) and chronic (repeated, long-term, typically lower) exposure. In implementing the FQPA, EPA has developed new terminology: when it has reviewed an RfD and adjusted it if necessary to ensure that it meets the FQPA safety standard, EPA calls it a "Population Adjusted Dose," or PAD.

Part 2 of this report examines EPA's work to date reviewing its RfDs and establishing PADs for pesticides under the FQPA. EPA has focused first on the organophosphate insecticides, a high-priority family of nerve poisons. We compare RfDs for members of this family before the FQPA was passed with EPA's current PADs, and we assess how EPA has used existing science, how it has treated critical data gaps, and how effectively it has used the FQPA's "10-X" provision in defining safe exposure limits for 44 members of the OP family.

(3) Reducing Dietary Risk. The "bottom line" of EPA's implementation effort is actual reduction of risk, from actions on pesticide uses and tolerances. To ensure that children are not exposed to more than the PAD for a given pesticide, EPA may need to revoke or reduce tolerances for the pesticide on certain foods. It may also need to restrict or ban certain uses of the chemical, to keep dietary exposures below the PAD, prevent serious contamination of drinking water, or protect children from excessive exposures around the home, associated with residential and garden applications. EPA has so far completed its reviews of just a handful of important pesticides (with more decisions in the pipeline). Some of those decisions, such as the ban of selected crop uses of methyl parathion, have significantly reduced risks. Other decisions have had less impact on exposure and risk.

In **Part 3** of this report, we look at the impact of EPA's tolerance reassessments on risk reduction, focusing on dietary residues. Our analysis of dietary exposure relies on our database of pesticide residues in children's foods, compiled from tests by the USDA Pesticide Data Program. We compare tolerances with actual residues and compare the tolerances before the FQPA with EPA's "reassessed" or current tolerances. Where EPA has reduced or revoked a tolerance, we project the effect that action will have in terms of reduced dietary residues. Using the "Toxicity Index" approach we have developed in previous reports, we estimate changes in overall dietary risk measured in various ways.

A Report Card for the EPA

Our assessments show that EPA has made some progress in each of these areas, but that most of the work of implementing the FQPA still lies ahead.

In **Part 1**, we show that EPA has completed or nearly completed only three of nine key science policies, while others are still far from finalized. Since some of the policies are sequential—that is, others must be ready before they can be completed—the delays in finishing critical science policies have greatly slowed overall implementation. Most of the work EPA has done in developing these policies is sound—with a few exceptions noted in our review. Creating sound policy is just the first step, and EPA has not always adhered to its policies as it has made decisions on specific chemicals.

In **Part 2**, our review of EPA's decisions on PADs for the organophosphates shows that the Agency has been highly inconsistent and has failed to use the FQPA's "10-X" rule effectively. For more than half of the OPs it has reviewed to date, EPA has set the PAD for chronic exposure at the same level as the pre-FQPA RfD or higher. PADs have been set at lower doses than the old RfD in 20 of 44 cases. More significantly, while EPA has concluded that developmental neurotoxicity (DNT) is a "critical effect" for determining "reasonable certainty of no harm" for infants and children, and the Agency has required manufacturers to submit developmental neurotoxicity test data for all OPs, such data are currently unavailable for most members of this insecticide family. Yet EPA has rarely cited lack of DNT data as a reason for increasing the margin of safety in an RfD.

In all, EPA has applied the FQPA's "extra 10-X" safety factor in just 16 percent of its PAD decisions on OPs. In another 16 percent, EPA has applied an extra 3-X safety factor. In more than two-thirds of its OP PAD decisions, however, EPA has ignored the FQPA's explicit requirement that when critical toxicity data are unavailable, the Agency must incorporate a wider safety margin in exposure limits. We believe EPA has failed to use the "10-X" provision as Congress intended, and has in effect abandoned the FQPA's commitment to give children's health the benefit of the doubt when critical toxicity or exposure data are unavailable.

In **Part 3**, our projected impacts of EPA's tolerance decisions on dietary exposure and risk (as measured by CU's Toxicity Index) show moderate success to date. By banning just 10 food uses of methyl parathion, EPA eliminated at a single stroke 29 percent of the total TI score for all residues in all foods tested by the USDA. Actions on a handful of other specific pesticides have had more modest impacts. Collectively, the effect of all of EPA's tolerance reassessments to date has been to reduce dietary risk by slightly more than a third. Several measures of Toxicity Indices for key foods, high-risk chemicals and highest-risk crop/chemical combinations indicate that EPA's decisions have eliminated about 37 percent of the overall risk—leaving 63 percent or so still to be addressed.

Consumers Union is expert at rating products and services, and to aid in communicating our assessment of the EPA's progress, we have summarized our evaluations in the form

of a "Report Card," with letter grades for each major task (see next page). Grades for the individual activities range from an "**A**" to an "**F**," with an overall average of "**C-**." EPA has had some successes—but its FQPA work leaves a lot of room for improvement. In the sections that follow, we explain the basis for each grade in detail.

What Next for the EPA and the FQPA?

Our conclusion that EPA has achieved about a 37-percent reduction in dietary pesticide exposure and risk suggests that the FQPA has begun to yield the public-health benefits Congress hoped it would. So far, those gains have come about with minimal adverse economic effects. Sales of a few very toxic pesticides have been reduced, but farmers have access to alternative pest control weapons, and the fantasies of food shortages and sky-high prices for fruits and vegetables have not materialized. All this is good news.

But there is also some bad news. Eliminating the first third of dietary risk was the easy part—EPA has in effect "cherry-picked" some of the biggest and ripest targets for risk-reduction. We believe that meeting the public-health goals of the FQPA will ultimately require a 95 to 98 percent reduction of dietary exposure and risk from the pre-FQPA baseline level. To achieve that, EPA still needs to address 100 or so uses of about 20 key chemicals, and to address the cumulative risks of chemical families with a common toxic mechanism. Once it completes methods for cumulative risk assessment, EPA may need to further reduce exposure limits for individual members of such chemical families.

EPA also will need to take steps to prevent "risk-trading." As more high-risk pesticide uses are banned, EPA must avoid letting almost-as-toxic chemicals replace those uses, or it will achieve little net reduction in risk.

We believe these goals can be met, and can even be met within the 10-year horizon set by Congress in the FQPA—if EPA maintains its commitment to implementation, in the new Republican Administration, and if Congress leaves the FQPA intact and gives EPA the resources it needs. In 1999, pro-pesticide Members of Congress introduced an industry-drafted bill that would have repealed the essence of the FQPA. The bill, the so-called "Regulatory Fairness and Openness Act," introduced by Congressman Richard Pombo (R-CA) and Senator Chuck Hagel (R-NE), did not get far in the last Congress, but it will probably arise again, in one form or another, in the 107th Congress.

We hope Congress will not be swayed by fear campaigns, and will look dispassionately at the facts presented here. Congress had good scientific and policy reasons for passing the FQPA in 1996. The Act was a superbly-crafted and long-overdue upgrade of federal pesticide law. It has properly committed the government to ensuring that pesticide uses don't endanger public health. As President Clinton said when he signed the bill, we can both protect crops from pests *and* protect children's health; we do not need to sacrifice one to achieve the other. After four and a half years, EPA has shown that it can markedly reduce risks without harming farmers or the food supply. What Congress demanded in 1996, EPA can deliver, today, if the political climate allows it.

Report Card

for Pesticide Regulation

STUDENT NAME: **U.S. EPA** MAJOR: **FQPA IMPLEMENTATION**

SUBJECT	GRADE	COMMENTS
Developing Science Policies	C+	Some creditable work, substantially incomplete
Defining Safe Exposure	C	Sound use of science, too timid applying safety factors
Reducing Home Exposures	B	A slow but solid beginning
Reducing Dietary Risks	D	Slow progress, and much of the task incomplete
Sub-tasks		
92 Riskiest Tolerances	D	Only 37% of work complete
14 Riskiest Chemicals	D	Only 40% of work complete
14 Riskiest Foods	D	Spotty performance
3 Major Decisions		
Methyl Parathion	A	Excellent, solid work
Azinphos-methyl	F	Complete failure
Chlorpyrifos	C	Good start, more to do
OVERALL AVERAGE:	C-	Must stick to policies and continue hard work