

# **A REPORT CARD FOR THE EPA**

**SUCSESSES AND FAILURES  
IN IMPLEMENTING  
THE FOOD QUALITY PROTECTION ACT**

Consumers Union of United States, Inc.  
101 Truman Ave., Yonkers, NY 10703-1057

February, 2001

# A REPORT CARD FOR THE EPA

## SUCCESSSES AND FAILURES IN IMPLEMENTING THE FOOD QUALITY PROTECTION ACT

### CONTENTS

#### PREFACE

#### OVERVIEW: INTRODUCTION AND SUMMARY

- A brief history of the FQPA
- Our Evaluations
- A Report Card for the EPA

#### PART 1. SCIENCE POLICIES

- The policies that frame EPA's implementation of the FQPA
- Our assessment of the policies and the process that produced them

List of Tables for Part 1

#### PART 2. DEFINING "REASONABLE CERTAINTY OF NO HARM"

- EPA's approach to defining safety under the FQPA
- EPA's reviews of safe doses of organophosphate insecticides
- Our assessment of EPA's performance in defining safe exposure

List of Tables for Part 2

#### PART 3. REDUCING DIETARY RISK

- Impact of EPA's reassessments of pesticide tolerances on residues in foods and relative risk of dietary exposure
- Risk reduction in terms of highest-risk pesticide uses; risk-driving chemicals; and key children's foods

List of Tables for Part 3

## PREFACE

This report is the latest in a series of analytical, policy-oriented studies related to the U.S. Environmental Protection Agency's implementation of the Food Quality Protection Act, produced by Consumers Union through our FQPA project.

For past reports, see our project web site, <http://www.ecologic-ipm.com>.

The Food Quality Protection Act of 1996 was probably the most important environmental legislation enacted during the 1990s. It markedly strengthened the safety standards that govern exposure to pesticides, elevated public-health protection to top priority in trading off health risk against benefits of chemical use, and made protecting vulnerable groups—especially infants and children—the explicit goal of Federal pesticide regulation.

Now, as the Clinton Administration leaves office, we have surveyed the progress EPA has made in the four years since the FQPA became law. The promise of enhanced public health protection through reduced exposure to pesticides has begun to be realized—but just barely begun. EPA has moved slowly and deliberately, choosing its steps with a lot of care, as it implements the FQPA. Recent decisions have eliminated some of the most obvious, largest risks posed by pesticides used around the home, and by dietary residues. These few initial steps have moderately reduced overall risk. But a great deal more work remains, and reducing risk farther will be more difficult, requiring decisions on a greater number of uses of many more chemicals that each contribute smaller, but collectively important, fractions of overall risk. As our earlier reports have, this one describes the relative risks of different pesticide uses in detail, mapping out priorities for future EPA attention.

Our research on FQPA implementation has been supported generously by Consumers Union, and by three charitable foundations who had the vision to understand that EPA efforts to implement the FQPA would be enhanced by the presence of an articulate and science-based consumer perspective. We gratefully acknowledge the support we have received for our FQPA project from the Pew Charitable Trusts, the Joyce Foundation, and the W. Alton Jones Foundation.

**Edward Groth III**, Senior Scientist and Project Director, CU/Yonkers, New York  
**Charles M. Benbrook**, Consultant, Benbrook Consulting Services, Sandpoint, Idaho  
**Karen Lutz Benbrook**, Consultant, Ecologic, Sandpoint, Idaho  
**Adam J. Goldberg**, Policy Analyst, CU/Washington Office

February, 2001

# 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 105<sup>th</sup> 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 all 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. Rumbblings 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](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 107<sup>th</sup> 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

<u>SUBJECT</u>	<u>GRADE</u>	<u>COMMENTS</u>
<b>Developing Science Policies</b>	C+	Some creditable work, substantially incomplete
<b>Defining Safe Exposure</b>	C	Sound use of science, too timid applying safety factors
<b>Reducing Home Exposures</b>	B	A slow but solid beginning
<b>Reducing Dietary Risks</b>	D	Slow progress, and much of the task incomplete
<u>Sub-tasks</u>		
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
<b>OVERALL AVERAGE:</b>	C-	Must stick to policies and continue hard work

# 1. SCIENCE POLICIES

## EPA'S PROGRESS IN DEFINING THE CRITICAL SCIENCE AND REGULATORY DECISION RULES THAT WILL GUIDE FQPA IMPLEMENTATION

The FQPA contains three critical new provisions designed to assure adequate margins of safety for infants and children in setting tolerances. The first requires EPA to impose an additional safety factor of up to 10-fold when establishing the acceptable daily intakes of pesticides (the 10-X provision). The second requires EPA to take into account all routes of exposure to a pesticide in judging the safety of any given use (often called aggregate exposure). The third requires EPA to consider as a group all pesticides that pose risks to human health through a common mechanism of toxicity, the so-called cumulative risk assessment (CRA) provision.

To implement these three innovative provisions, EPA has had to develop a series of new operating principles and science policies, a task the Agency started soon after the FQPA was signed into law, in August 1996. In a January 31, 1997 *Pesticide Regulation Notice*, EPA codified its interim decision rules. Since then, several meetings of EPA's scientific and advisory committees have reviewed many drafts of policies, and EPA has published more than two dozen technical papers supporting policy development. The process is still under way and more such work will be needed to finalize all the key policies.

### Core Implementation Issues in Nine Science Policy Areas

Within a few months of passage of the FQPA, EPA had articulated and sought advice on several core implementation issues:

- Whether, how and when to use human test data as the basis for establishing Reference Doses (RfDs). Before the FQPA was enacted, RfDs based on human data had been set for about a dozen pesticides, most of them organophosphate insecticides.
- How to integrate safety factors on the books prior to the FQPA with the FQPA's 10-X provision. About 50 active ingredients had additional safety factors embedded in their Reference Doses when the FQPA passed, several of which were triggered by concerns over pre- and postnatal toxicity.
- What constitutes evidence of "heightened sensitivity" following pre- and postnatal exposures to pesticides?
- What toxicological data gaps are significant enough to warrant imposition of an added safety factor under the FQPA's 10-X provision?

- When should limited exposure data and lack of precision in exposure assessments trigger an added FQPA safety factor?
- When EPA determines that an added safety factor is required, what level should it be set at between one and ten? If an added safety factor is deemed necessary for two or more reasons, can the combined added safety factor exceed 10?

As time passed and EPA had dialogues with stakeholders and its scientific advisory bodies, the list of issues grew and evolved. **Table 1.1** summarizes what eventually settled out as nine critical areas of science-policy needs.

We have assessed EPA’s progress in developing its critical science policies by reviewing the documentary history, including technical papers, Federal Register notices, records of advisory committee meetings, dockets with public comments on EPA’s proposals, and the Agency’s responses to those comments, for each of those nine key science policies. Our evaluation focused on timeliness—how effectively the EPA has kept to a schedule compatible with implementation deadlines in the FQPA itself—and quality of results, in terms of both EPA’s responsiveness to issues raised by stakeholders or public comments, and our judgment of how well the Agency’s policies address the intent of the statute. In addition, we have examined how closely EPA has followed its own policies in decisions it has made in reassessing safe exposure limits and tolerances under the FQPA.

**Table 1.2** summarizes the critical issues in each of the nine key policy areas. **Table 1.3** presents our grades for EPA’s progress in each policy area for timeliness, responsiveness to the statute and public comments, and consistency in adherence in the implementation process. Explanations of the basis for each grade follow.

### **Science Policy #1: Extra 10-X Safety Factor**

The 10-X provision of the FQPA directs EPA to impose an added safety factor of up to 10-fold when evaluating pesticide toxicity and establishing acceptable levels of exposure. In **Part 2** of this report, we examine EPA’s application of this provision in its decisions on the organophosphate family of insecticides. Here, we evaluate EPA’s policy outlining its judgments on how the 10-X provision should be applied.

The 10-X provision is of little consequence for pesticides posing modest risk because of low toxicity or lack of exposure, because there is already an adequately wide margin of safety between maximum “safe” doses and likely actual exposures. But for higher-risk pesticides, a ten-fold reduction in allowable exposure is both more obviously necessary in order to ensure “reasonable certainty of no harm,” and more likely to place pesticide uses in jeopardy because it will require risk-reduction steps.

From the beginning of the implementation process, EPA stated that it would, as a default position, initially impose the full 10-X in establishing allowable exposures. EPA states in

its May 1999, document, “The Office of Pesticide Programs’ Policy on Determination of the Appropriate FQPA Safety Factor(s) for Use in the Tolerance-Setting Process:”

“The FQPA Safety Factor provision, however, was not simply a codification of existing [safety factor] practice. It was both a codification and expansion. Prior to the enactment of the FQPA, OPP already considered both the observed adverse effects shown in studies and the completeness of the toxicology database in determining the appropriate composite uncertainty factor to be applied in calculating the RfD. It was only on rare occasions, however, that OPP found that an additional factor was needed.... Congress, by specifically including a reference to potential pre- and postnatal toxicity...has effectively expanded OPP’s pre-FQPA practice....An additional expansion of pre-FQPA practice was effected by Congressional reference to the completeness of the exposure database.” (page 13)

The Act allows EPA to reduce the additional safety factor or to remove it entirely if the Agency has sound data on exposure and ample toxicological data demonstrating that a given pesticide, as currently used, does not impose heightened pre- or postnatal risks. EPA has pledged that its decisions to reduce or remove the 10-X would be based on the “weight of the evidence.”

Congress enacted the 10-X provision in part to shift the burden of proof traditionally borne by EPA at least partly to pesticide registrants and users. Before the FQPA, EPA could take regulatory actions on pesticides only when it had “sufficient and verifiable data” showing that risks exceed benefits under real-world conditions. Under the laws governing pesticide regulation, registrants have multiple opportunities to interject new information, challenge EPA risk calculations, and raise doubts about the scientific basis for EPA’s actions. Prior to 1996, such challenges typically led to agreements between the EPA and registrants to develop better information, often through new toxicity tests or collection of exposure data. In the meantime, the pesticide stayed on the market. Even with EPA’s “Special Review” expedited procedures, such risk concerns sometimes were not resolved for a decade or more.

For years, public-health and environmental advocates tried to shift the burden of proof, to require registrants to provide more convincing evidence of a pesticide’s safety, before a product is introduced or allowed to remain on the market. This effort largely succeeded for new active ingredients and initial registration decisions, but not for already-registered products, which once on the market were traditionally “innocent until proven guilty.”

Many strategies were considered over the years to shift some measure of the burden of proof to pesticide manufacturers. As the FQPA took shape, Congress agreed some steps were needed in this direction. The 10-X provision emerged as the consensus solution. When EPA lacks solid information on toxicity to young animals and/or reliable exposure data, the FQPA requires EPA to impose an added safety factor of up to 10-X, without waiting for additional data. Such steps would be more likely to restrict pesticide uses, while registrants develop new data to resolve concerns. EPA’s decisions would be more

protective of public health in the interim and there would be incentives for companies to develop needed data as quickly as possible.

We regard the 10-X provision as the most important of several major policy innovations in the FQPA, and the EPA's performance in implementing this part of the law is central to our overall evaluation. The Agency's performance here is mixed.

For timeliness in developing its 10-X policy, EPA earns a **B**. Just weeks after the FQPA became law, the Agency advanced a Spartan but clear explanation of how it would apply the 10-X provision. At a series of meetings of its Food Safety Advisory Committee in the fall of 1996, EPA focused on 10-X issues and received general support for its policy direction. The Agency's Scientific Advisory Panel (SAP) also reviewed the interim 10-X decision logic at its October 1996 meeting and generally supported the EPA's approach, while asking for more details and concrete examples.

By early 1997, EPA had identified key scientific and policy issues in dispute and sought comments widely, from both its stakeholder advisory committees and scientific experts. This process took time, indeed more than was really needed. Multiple reviews did little to sharpen understanding of issues or strengthen the scientific case for one option versus another. Instead, the advisory process, particularly the Tolerance Reassessment Advisory Committee, provided a forum for interested parties to re-open debates about whether the 10-X provision was justified (a debate Congress had already resolved with its unanimous vote), rather than focusing on how to implement it. Eventually, by early 1999, EPA was finalizing detailed explanations of the process, criteria, decision-rules, and defenses of the ultimate judgments the Agency made, in applying the 10-X provision.

EPA also earns a **B** for responsiveness to public comments on its 10-X proposals. The Agency has generally done a good job in responding to questions and criticisms of its use of toxicological data. Its policy clarifies what constitutes "reliable" toxicological data and "heightened sensitivity."

The decision to require submission of developmental neurotoxicity (DNT) studies on all organophosphate and carbamate insecticides was sound and appropriate. But we disagree with the Agency's decision to impose at most a 3-X safety factor for pesticides lacking DNT data. We don't believe that DNT effects are sufficiently well understood currently to be certain that an extra 3-X safety margin is adequate to cover the range of possible differences in sensitivity to neurotoxicity in adult animals versus immature animals.

EPA has determined that it can impose up to an added 10-X safety factor for evidence of pre- or postnatal toxicity, and up to another 10-X safety factor for exposure data gaps. We agree with this approach and hope EPA will someday use this authority. However, as we explain below, EPA has chosen not to impose additional safety factors to compensate for lack of exposure data.

While EPA's science policy decisions on use of the 10-X provision have generally been sound, the Agency has too often fallen short of adhering to its own policies. As we show

in detail in **Part 2** of this report, EPA has reviewed its definitions of “safe exposure” for the organophosphate (OP) insecticides. In its 10-X policy, EPA defines DNT as a critical effect for OPs, and very few of them have been tested adequately for DNT. EPA has required manufacturers to submit DNT data for all members of this family of neurotoxic insecticides. However, although it lacks DNT data for most OPs, EPA has applied an added FQPA safety factor (10-X or 3-X) in setting safe exposure doses for just 13 of 44 OPs. It has cited lack of DNT data as a justification for the added safety factor in 10 of those cases. But for more than 20 other OPs that also lack DNT data, EPA has imposed no additional FQPA safety factor at all. We think lack of DNT data justifies an added safety factor for every OP inadequately tested for this effect. EPA’s failure to apply the 10-X provision consistently in this manner seems both an abandonment of the FQPA’s commitment to make public-health the top priority when data are lacking, and at odds with portions of the Agency’s own 10-X policy.

A second shortcoming in EPA’s 10-X policy lies in the way the Agency has chosen to address uncertainties on dietary exposure. EPA apparently decided early on not to take Congress seriously when it identified exposure data gaps as one reason to impose an added safety factor, and has budged very little from that stance in response to public comments and expert advice. When it lacks good exposure data, EPA has chosen to rely on “conservative models” and estimates of exposure that reflect “worst-case” scenarios, instead of applying an added safety factor. By doing so, the Agency retained the burden of defending its exposure estimates and default assumptions (which interested parties have often attacked as unreasonable). EPA has also failed to take full advantage of the key FQPA provision, which could provide a powerful incentive to develop better data on actual exposures to pesticide residues.

A recent review by the General Accounting Office concluded that EPA had produced a reasonably clear set of provisions governing 10-X decisions and had in fact followed them consistently. We largely agree on the toxicological side of the equation, but not in how the Agency has dealt with data gaps. Overall, for this inconsistent performance in following its stated policies, we grade EPA just a **C** for its responsiveness to the statute and adherence in implementation decisions in this policy area.

## **Science Policy #2: Key Choices in Dietary Exposure Assessment**

EPA has struggled for almost four years with the many highly technical and interrelated science policy decisions embedded in dietary exposure assessment. One area of intense debate has involved whether and how to use “Monte Carlo” probabilistic modeling as a tool for projecting likely exposures from existing food consumption and residue data. In the end, after lengthy consultations with its expert and stakeholder advisory bodies and exhaustive debate, the Agency outlined a scientifically sound and reasonable approach for using dietary exposure models.

There has been more consensus on some aspects. For example, EPA’s early judgment to rely heavily on the USDA’s Pesticide Data Program (PDP) as its main source of residue



data garnered wide support. Almost from its start in 1991, the PDP has been focused on children's foods and has measured residues in foods "as eaten," avoiding problems often encountered with older residue data. In certain other respects, however, reliance on the PDP data raised new problems that EPA needed to address (see SP Area #4, below).

EPA also had to decide where to draw the line that defines "excessive" exposures, based on the FQPA's "reasonable certainty of no harm" standard. In assessing short-term or acute risks, EPA chose to assure that the individual at the 99.9<sup>th</sup> percentile of exposure to a pesticide is not exposed over his or her personal "safe" dose (based on body weight and the EPA's definition of a safe dose). We support this decision as clearly protective of public health, but not excessively so. While exposures above the dose EPA defines as "safe" do not, based on the best available data, fall in the "reasonable certainty of no harm" range, exposures just marginally above the "safe" dose also clearly do not mean a "reasonable certainty of harm."

For timeliness in developing this policy, we give the Agency a **C+**. The process has taken almost four years, but the complexity of the issues warranted a deliberate approach. EPA earns an **A** for adherence to the statute and responsiveness to public comments in establishing its dietary exposure and 99.9<sup>th</sup>-percentile policies. To date the Agency has stuck reasonably close to the policy in decisions on individual chemicals, earning a **B+** for adherence in implementation. Since decisions so far have concentrated on the OPs and other pesticides for which acute dietary exposure is the central risk concern, it is not yet clear how EPA will address risks of chronic exposure, such as cancer risk.

### **Science Policy #3: Threshold of Regulation and Limits of Detection**

Complex issues arise in determining how to deal with the limits of analytical chemistry for detecting residues. EPA correctly recognizes that just because no residues have been detected, it does not necessarily mean none are present. To ensure that any "nondetects" are properly considered in risk assessment and risk mitigation, EPA has decided to set a default value of half the limit of detection (LOD) for commodities known to have been treated with pesticides, but on which no detectable residues are found.

We believe this is a reasonable assumption, which strikes a fair balance between other options (such as presuming zero, or presuming just less than the LOD). Obviously, as residue detection science improves, and tests can detect lower residue levels, this default assumption will more closely model actual residues found on any particular commodity. For its responsiveness to the statute and to public comments, we give EPA a **B+**. For adherence in implementing this policy, EPA earns an **A**, and for timeliness, a **B-**.

### **Science Policy #4: Dietary Residue Estimation**

In conducting risk assessments for particular uses of particular pesticides, EPA needs to know how much residue of the pesticide is in particular foods consumed by particular

populations. Sometimes, EPA has reliable residue test data; often, data are incomplete or absent, and certain key questions (such as highest residues likely to be encountered on a reasonably frequent basis) can't be adequately answered, and EPA must make estimates, based on existing information and reasonable assumptions.

One such problem is related to the composite nature of PDP samples. The PDP aims to measure representative average residue levels in foods, and tests composite samples made up of several pounds of food. While this is a sound way to estimate average (chronic) exposures, it tends to obscure variation in residues among individual servings, especially of fresh fruits and vegetables. In 1997, at the urging of its advisory bodies, EPA decided to regulate certain acutely toxic pesticides, including the OPs, on the basis of short-term (24 hour) exposures. This decision heightened the need to calculate exposures based on what children actually eat in a given day, rather than on "average" data. Outside experts and public comments warned EPA that composite data could significantly underestimate dietary exposure among children exposed to higher-than-average residues.

EPA scientists developed a sophisticated statistical algorithm to "de-composite" PDP residue levels from a single number to 10 or more values (the number reflecting how many individual apples or potatoes are included in the average composite sample). The algorithm produces a much bigger residue data set for acute dietary exposure estimation and improves the statistical reliability of the resulting estimates.

As part of this effort, EPA also asked the PDP staff to do some special single-serving surveys for apples, pears, potatoes and peaches. The results of these resource-intensive surveys have allowed EPA to compare the residue levels found in composite samples with the actual residue levels found in each individual fruit that made up the composites. EPA has tested and refined the performance of its algorithm compared to real world data. This process has made the valuable PDP data that much more useful and largely removed one source of downward bias in acute dietary exposure estimates.

The PDP has generated extensive pesticide residue data on only 40 foods out of hundreds eaten daily (25 or so fresh fruits and vegetables, and 15 or so processed foods). There are also, however, many foods not tested by PDP that are also important in the diets of some infants and children, particularly fresh fruits and vegetables sometimes consumed in large quantities, especially when in season. While the PDP may eventually test such foods, at this point they represent gaps in EPA's exposure data. We hope EPA and USDA will expand the scope of PDP testing to include another 10 to 20 key children's foods over the next few years.

Until such data can be obtained, dietary exposure science policies spell out how EPA develops exposure estimates for these additional foods. Just as in the case of a food tested by PDP, food consumption estimates for non-PDP foods are derived from the large food consumption databases compiled by USDA; residue data are developed from surveys by the Food and Drug Administration (FDA), from market basket tests, field trial data, and sometimes from other sources.

We think the procedures EPA has developed are sound and the Agency has made good use of available data. For these actions EPA earns a **B+** for its responsiveness to public comments and to the statute, and an **A** for consistency in application, but just a **C** for timeliness. The slow pace in finalizing dietary exposure assessment procedures set back all other aspects of implementation.

### **Science Policy #5: Drinking Water Exposure**

To date EPA has broken little new ground in the methodologies it proposes to use or the databases available to estimate drinking water exposures. It has also not completed risk assessments under the FQPA for any pesticide for which drinking water exposure is a major contributor to overall risk. The science policies set forth in this area codify past Agency procedures. Some refinements have been made in models used to estimate water-based exposures from, for example, farm ponds or drinking water from a municipal water district that uses various kinds of filtration systems. But any attempts to develop further policies needed to address FQPA mandates have been too tentative to evaluate.

For several widely used herbicides applied to millions of acres in the Midwest (such as atrazine and the other triazines), drinking water exposure accounts for virtually all human exposure. Residues are seldom if ever found in foods. If the FQPA will require actions to reduce risks from these herbicides, it will be because of drinking water exposure. We cannot predict how EPA will finalize and apply its science policies in this area, or what actions EPA might take to reduce drinking water exposures and risks. The only grade we can give the Agency in this area is an **“Incomplete.”** By the Clinton EPA’s schedule, at least, key decisions on the triazine herbicides are expected by the end of 2001.

### **Science Policy #6: Residential Exposure**

Some of the same pesticide chemicals used in agriculture that contribute to dietary risk are also used in pesticide products formulated and sold to consumers or professional pest control companies, for use in and around the home, in schools, in the workplace, and in other public places. While residential, lawn and garden, school and workplace exposures are an issue for a small subset of pesticides, such exposures can account for a large share of a pesticide’s aggregate risks, and for extremely high single-dose exposures, especially for children.

Unfortunately, EPA’s science policies in this area have broken little new ground; to date, the Agency has for the most part merely spelled out its current approach. In a few cases, when reviewing specific chemicals like chlorpyrifos and diazinon, EPA has negotiated withdrawal of many home use products from the market—often with a fairly long phase-out period. But the Agency has allowed pesticide registrants to move at a snail’s pace in fulfilling new residential exposure data requirements, a process that began early in the 1990s and has not markedly accelerated nor broadened since passage of the FQPA.

Still, EPA's actions on chlorpyrifos and diazinon set a strong precedent and raised the bar for new registrations. The Agency invested much time and effort in evaluating extensive data submitted by the manufacturer to defend residential uses of chlorpyrifos. It built a compelling case to end virtually all home uses, and the registrants ultimately accepted the Agency's view that such steps were necessary (albeit for different stated reasons). The maker of diazinon recently decided to voluntarily cancel all home uses, based on the risk assessment EPA had prepared to support proposed product cancellations, more to avoid the costs of contesting EPA's proposed actions than because it necessarily agreed with the EPA assessment. While the science policy process has done little to address key data gaps on residential exposure, EPA has effectively emphasized reducing such exposures in these two decisions. Its actions have demonstrated that an elaborate new science policy is not needed to address relatively clear-cut and straightforward risks. For these reasons EPA earns a **B** here for timeliness, responsiveness, and consistency in implementation.

### **Science Policy #7: Aggregate Exposure**

The FQPA requires EPA to consider all sources of exposure to a given pesticide when regulating any individual use of that chemical. For example, when setting safe limits for a residue on a food, EPA must consider residues of the same pesticide on all other foods, and must also examine exposure by other routes. The most common non-food routes of exposure to pesticides are contaminated drinking water and residential uses of the same agricultural pesticides that leave residues in foods.

Occupational exposure is a key source of pesticide doses for farmers, farm workers, and their children, as well as for professional pest control operators and others who handle and apply pesticides. The FQPA does not specifically require EPA to take occupational exposures into account, and EPA has to date not tried to include it in its assessments. We think EPA should identify any populations (such as farm children) at risk of heightened exposure because of their families' occupation. Such identifiable sub-populations also deserve to be brought within the FQPA's "reasonable certainty of no harm" standard.

EPA's models for estimating dietary exposure (See **Science Policies #'s 2 and 4**, above) address aggregate exposure across multiple foods. The Agency's policies for addressing drinking water and residential exposures were described under **Science Policies #'s 5 and 6**, respectively. A fundamental question, not yet fully resolved, is how best to aggregate exposures that occur on widely different scales of quantity and time—repeated low doses encountered daily in foods, and shorter-lasting but occasionally very large "spikes" of exposure from drinking water or residential treatments. EPA has (correctly, we think) established "safe" exposure limits for both acute exposure (spikes) and chronic exposure (most dietary residues); see **Part 2** for details. Ensuring that the "reasonable certainty of no harm" standard is met for a given pesticide is in effect ensuring that neither the acute nor the chronic safe dose is exceeded, regardless of the route(s) of exposure involved.

To date, in its decisions on a few individual chemicals, EPA has dealt with residential exposures and dietary exposures essentially as separate problems, but has addressed both

in the same review process, which we think meets the intent of the law. As noted above, EPA has not yet addressed drinking water exposure to any significant degree. EPA earns a **B+** for its responsiveness to the statute, and a **B** for responsiveness to public comments on this policy area. The slow pace that has left some core issues unresolved so far earns a **C** for timeliness, and the lack of actions affecting drinking water exposure to date make the grade for adherence to the policies an **“Incomplete.”**

### **Science Policy #8: Cumulative Risk Assessment**

Next to the “10-X” provision, perhaps the most important innovation in the FQPA is its requirement that EPA consider the cumulative effects of all pesticides with a common mechanism of toxicity as one problem. EPA can no longer regulate such pesticides “one at a time,” setting limits for each one as if it were the only residue children are exposed to; it must consider the combined effects of the multiple residues children (and everyone else) encounter, in foods and by other exposure routes.

This requirement has far-reaching effects. Until EPA can determine what cumulative dose of all pesticides combined meets the “reasonable certainty of no harm” standard, it cannot convincingly define the acceptable exposure limits for individual pesticides in a class that shares a mechanism of toxic action. In practice, working out how to do these cumulative risk assessments (CRAs) has been a substantial scientific and policy-making challenge. EPA could not afford to postpone all reviews of individual chemicals until it had figured out its CRA approach; the Agency has therefore completed its reviews of toxicity data and redefined the “safe doses” under the FQPA standard, for several dozen of the most toxic insecticides (see **Part 2**). It seems clear, though, that once it completes its CRA work, EPA will need to re-examine the limits it has set one-chemical-at-a-time, and probably will need to adjust many of those individual limits downward to ensure that cumulative risk does not exceed the FQPA safety standard.

EPA has worked hard for the last year or two, trying to develop its CRA policy, with an initial focus on the organophosphate insecticides (OPs). Seven meetings of the Scientific Advisory Panel have been devoted at least in part to discussion of CRA science policies, and the Agency recently produced its first “case study,” a CRA for a group of 24 OPs. While we generally support EPA’s efforts, as far as they go, the current approach needs substantial improvement (see our presentation at the December 7-8 2000 SAP meeting, at [http://www.ecologic-ipm.com/findings\\_CU.html#comments](http://www.ecologic-ipm.com/findings_CU.html#comments).) The work on this Science Policy area is also far from complete; it will require a great deal of additional work and is likely to undergo significant changes as EPA’s FQPA implementation evolves.

While developing CRA methodology may be the most complex challenge imposed on EPA by the FQPA, and we sympathize with the Agency on the difficulty of the task, the pace of work on this vital policy has been far too slow, earning EPA a **C** for timeliness. The Agency deserves a **B** for responsiveness to the statute. Public comment and response processes are still under way, and the issue of whether EPA’s decisions have adhered to its policy has not arisen yet. Grades for these components are **“Incomplete.”**

## **Science Policy #9: Common Mechanism of Toxicity**

In order to define classes that require cumulative risk assessments, EPA needed to spell out its definition of a “common mechanism of toxicity” (CMT). Several major pesticide families, including the OPs, carbamates and synthetic pyrethroids among insecticides, the triazine and acetanilide herbicides, the EBDCs and several other groups of fungicides, share toxic mechanisms in each case. So far, EPA has focused primarily on the OPs.

Pesticide makers and users have an interest in keeping the definition of such “common mechanisms” as narrow as possible, to limit the size of regulated classes and allow any given member of a class a slightly larger share of the acceptable risk. We think EPA has needlessly complicated policy in this area, and made more work for itself, by defining a common toxic mechanism too narrowly. In defining a common mechanism for the OPs, the Agency determined that for each chemical with a CMT there must be evidence of the same, very specific toxic endpoint, in the same species and sex of test animals, such as cholinesterase inhibition in brain cells of male rats. We believe this narrow definition will make it difficult to carry out meaningful cumulative risk assessments, whereas use of a broader criterion—such as any evidence of cholinesterase inhibition in an appropriate organ system of an appropriate test species—would better suit the need.

EPA also allowed debate over how to define CMT drag on for over three years, slowing development of related policies such as **Science Policy #8**, on CRA. A consensus has long existed that all OPs (plus the carbamates) inhibit cholinesterase and thus share a common mechanism of toxicity; in fact, recognition of this fact led to the CMT provision the FQPA. For that reason, EPA gets a **D** for timeliness on this policy; we can’t see any real excuse why it should have taken so long or been so difficult. The Agency chose not to heed much of the advice it got from its expert panels and public comments, so we’ve given it a **C** for responsiveness to comments. And the policy is still far from finished; EPA has thus far ducked the issue of whether OPs and carbamates share a CMT, and has not addressed several other classes of pesticides with a known CMT. For responsiveness to the statute and consistency in adherence, we give EPA an “**Incomplete.**”

### **Summary Assessment on “Core Implementation Issues”**

In the opening section of this Part of our report, we highlighted several core issues EPA raised at the beginning of the FQPA implementation process. Some of those issues cut across several of the nine “key areas” subsequently identified for development of science policies, and a few fall outside of the nine “key areas.” To supplement our assessment of the nine key science policies, we here briefly summarize EPA’s answers to the initial set of “core implementation issues.” Responses are drawn from more than two dozen major science policy papers EPA has produced.

*Whether, how and when to use human test data as the basis for establishing Reference Doses.*

This issue, which is not covered by any of the nine policies reviewed above, should have been the easiest to answer quickly and decisively. Given the clear ethical unacceptability of generating or using toxicological data on the effects of pesticides on pregnant women and babies, and the scientific inappropriateness of using data from exposures of healthy adults to assess risks of, say, effects on the developing nervous system, EPA could have resolved this issue immediately, simply by excluding the use of human data in setting Reference Doses. Instead, EPA allowed debate on this question to drag on for more than two years, using time at scientific and policy advisory committees that could have been better devoted to other, more equivocal issues.

In the end, EPA did determine that it will not request, nor generally use, human data in setting RfDs, but it left the door open for future reconsideration. We believe EPA should have stated much more forcefully and much sooner the sound scientific and ethical basis for concluding that human data contribute little if anything to the specific assessments of pesticide toxicity of greatest concern to the Agency and the public.

*How to integrate existing safety factors with the FQPA's 10-X provision.*

In developing both its 10-X policy and its CRA methodology, EPA has thoughtfully addressed and integrated the respective roles of the standard, pre-FQPA safety factor (typically 100-fold); additional safety factors used by EPA pre-FQPA, for weak databases or signs of exceptional toxicity; and the FQPA's additional 10-X provision. The Agency has used a clear, open process and achieved worthy final policy positions.

*What constitutes evidence of "heightened sensitivity" following prenatal and postnatal exposures to pesticides?*

EPA has developed detailed and generally appropriate guidance to determine evidence of heightened sensitivity from the Agency's standard battery of toxicology studies. The endpoints the Agency has chosen are sound, as far as they go, and the threshold defining a "heightened" effect is set at about the right level. But EPA has done a less satisfactory job of developing and using new data requirements to strengthen the overall toxicology database. In particular, not enough has been done to require tests with the sensitivity to identify subtle developmental effects. Nor has much progress has been made yet toward developing a pesticide-specific battery of tests on endocrine disruption, or on translating the results of such tests into new risk assessment methods.

*What toxicological data gaps are significant enough to warrant imposition of an added safety factor under the FQPA's 10-X provision?*

EPA has been tentative and equivocal in imposing the FQPA's 10-X provision in the face of toxicological data gaps. It decided to apply no greater than a 3-X added safety factor in setting organophosphate RfDs in the absence of developmental neurotoxicity studies,

despite ample evidence that studies of this type are most likely to lead to the lowest “No Observable Adverse Effect Level.” This timid policy seems to go against the intent of the law to require added safety margins in the face of critical data gaps.

EPA has also been excessively reluctant to impose added safety factors in cases of known endocrine disrupters, even though EPA scientists have done much of the critical research demonstrating pesticide perturbations of normal endocrine functions, with impacts on reproduction, development and the immune system.

The intent of the 10-X provision is clear: to reward pesticide manufacturers who do needed research on hazards like endocrine and developmental effects, and to penalize those whose weak data leave major uncertainties on these questions. By failing to use this authority more fully or assertively, EPA is missing a key opportunity to advance the science it needs to assure full protection of public health.

*When should limited exposure data, and lack of precision in exposure assessments trigger an added FQPA safety factor?*

In our judgment, the answer should be “often.” In practice, EPA has rarely done so, preferring instead to estimate exposure using conservative assumptions when either good residue data or verified exposure models are lacking. Instead of applying at least a 3-X routinely for exposure data gaps, the Agency has stubbornly insisted on continued use of outdated, unsophisticated models that sometimes lead to nonsensical results. Such results have been featured prominently in attacks on the Agency for its “unscientific” methods. Again, this policy decision undermines the intent of the FQPA to provide incentives to fill data gaps and resolve uncertainties.

*When EPA determines an added safety factor is required, what level should it be set at between one and ten? If an added safety factor is deemed necessary for two or more reasons, can the combined added safety factor exceed 10?*

EPA has set FQPA safety factors at just two levels: 3-X and 10-X. By thus limiting its choices, the Agency has avoided creating an unduly complex range of what might appear to be arbitrary choices, but has also lost degrees of freedom in matching the size of the added FQPA safety factor to unique issues raised by a particular pesticide’s toxicological profile and exposure patterns.

EPA has determined that added safety factors can exceed 10-X if warranted for two or more reasons, but has not yet applied greater than a 10-X FQPA added safety factor in any specific decisions.

Overall, the EPA has bypassed many opportunities to take full advantage of the FQPA’s key new provisions. In addition, during the lengthy debates that have helped to define and refine its science policies, the Agency has too often allowed participants to roam too



far afield, reopening the debate over the provisions themselves, rather than focusing on how to implement them.

Given how quickly the FQPA took final shape in Congress in 1996, the Agency did face the practical need to educate various constituencies on what the provisions meant and why they were included in the final bill. As the science policies took shape, the Agency certainly did reach out widely and often for both policy and scientific advice. Each round of review and comment led to a new, sharper draft.

The process has generally been transparent, exhaustive, and for many, exhausting. While all policy papers are termed “living documents” subject to further refinement, most are in close to their final form. On the whole, the Agency has made significant progress toward crafting a robust and well-grounded series of science policies and deserves an overall C+ for its efforts in this area. But much work still remains to be done to finalize many of the policies, and once they are completed, implementation is another hurdle. Nevertheless, in the past four years EPA has taken many positive steps that should, in the end, help ensure that the FQPA delivers on its basic promises.

## 2. DEFINING “REASONABLE CERTAINTY OF NO HARM”

### HOW HAS EPA DEFINED ACCEPTABLE EXPOSURE TO MEET THE SAFETY STANDARD OF THE FQPA, AND HOW WELL HAS EPA USED THE ACT’S INNOVATIVE SAFETY-FACTOR PROVISIONS?

To achieve the FQPA’s public-health protection goals, EPA will need to carry out a two-step process. First, it must carefully use the best available scientific data and appropriate “uncertainty” (or “safety”) factors to define exposure limits, i.e., maximum safe pesticide intakes for the populations needing protection. Then, EPA will need to review pesticide uses and take any needed steps to restrict uses that could result in exposures above those established safe limits. Here, we evaluate the EPA’s progress in reviewing and defining safe exposure limits, and especially how the Agency has used the “extra 10-X” provision.

#### Defining Safety

At the heart of EPA’s pesticide regulatory decisions lies a concept called the “reference dose,” or RfD. The RfD is an updated version of what used to be called the “Acceptable Daily Intake,” or ADI. RfDs have been established for both chronic exposure (repeated, low-level doses over the long-term) and acute exposure (a single, generally higher dose). A chronic RfD (cRfD) defines a dose that, in theory, a person could be exposed to day after day over an extended period (up to a lifetime) without appreciable risk of an adverse effect. An acute RfD (aRfD) defines safe short-term (24-hour) exposure; EPA uses the 24-hour period to encompass both single large doses and multiple smaller doses within a short period. Chronic RfDs have been established for most pesticide chemicals, but EPA has only recently begun setting acute RfDs, for those pesticides that pose particular risks of acute toxicity, such as the neurotoxic insecticides.

RfDs of either type are based on two components. The first is an assessment of existing toxicity data, mostly from animal tests. Based on these data, EPA determines the effects the pesticide has on exposed organisms, and which effects are “critical” (i.e., most likely to be observed at relatively lower dose levels, and of a serious enough nature to be the index of potential harm that standards need to protect against.) Dose-response data from animal studies usually define a “no observable adverse effect level” (NOAEL); when no well-designed study provides a NOAEL, the “lowest observable adverse effect level” (or LOAEL) is used instead as a lower boundary of toxic doses for critical effects in animals.

Once the lower limits of toxicity in animal studies have been determined, the second step is the application of “safety” or “uncertainty” factors. RfDs (limits for human exposure) are based on the NOAEL or LOAEL in animal tests, reduced by a wide margin, typically

100-fold. These safety factors serve as a hedge against known scientific uncertainties in extrapolating toxicity data from animals to humans.

The standard 100-fold uncertainty factor is based on scientific awareness that humans may be more (or less) sensitive to a particular toxic effect than lab animals are, and on a recognition that the genetically diverse human population contains individuals who are far more sensitive to toxic effects than average (while test animal populations are usually genetically homogeneous, to minimize this source of variability.) While it is recognized as a crude approximation, the normal 100-X safety factor is generally taken to include 10-X for interspecies differences and 10-X for variation in sensitivity among individual humans. The FQPA requirement for up to an additional 10-X safety factor to protect children is based on extensive evidence, which was reviewed in depth in a 1993 report by the National Research Council, *Pesticides in the Diets of Infants and Children*, indicating that the very young are likely to be more than 10 times as sensitive to certain toxic effects as average healthy adults, and so require a wider safety margin.

How large a safety margin is needed to ensure “reasonable certainty of no harm,” and to be sure infants and children are adequately protected? The answer must be informed by the best available scientific data on questions such as what effects are most sensitive and what populations are at greatest risk. But determining what is an adequate safety margin is also a subjective decision—an expert judgment that EPA must make, openly, based on the weight of the scientific evidence and with extensive input from “stakeholders,” and the associated political pressures.

The FQPA imposed a new safety standard, and requires EPA to review its limits for all pesticide chemicals with registered food uses when the law was passed, to be sure that they all meet the new standard. The sheer size of this task is daunting. Soon after the FQPA was enacted, EPA listed 552 pesticide chemicals that needed reassessment, to be sure that exposure limits and food tolerances meet the “reasonable certainty of no harm” standard for infants, children and other sensitive groups. Following the FQPA’s guidance to focus on the worst problems first, EPA sorted the 552 chemicals into three groups, representing high, medium and low priorities for reassessment. EPA’s “List 1” (high priorities) included 231 chemicals, still an overwhelming assignment.

Early in its FQPA implementation planning, EPA determined that the organophosphate (OP) and carbamate insecticides (two families of acutely neurotoxic chemicals, many of which are widely used on fruits and vegetables popular in children’s diets) should be top priorities. EPA focused first on reviewing and revising RfDs for these pesticide families, then concentrated even more narrowly on the more toxic members of the OP family.

The FQPA defines “safety” more broadly than just protecting against neurotoxicity in young children. To determine that pesticide exposures are “safe,” the law requires EPA to consider potential endocrine-disrupting effects of pesticides as well. And the FQPA certainly has not set aside classic concerns such as possible risks of cancer, birth defects and other pesticide hazards known from animal and epidemiological data.

But EPA cannot assess all risks of all pesticides simultaneously; priority choices have to be made. The Agency has decided that, in terms of protecting children, the most critical concern is potential for toxicity to the central nervous system during early development, and has focused its resources on reviewing the adequacy of RfDs for protecting against that risk. Without dismissing the importance of assessing endocrine effects, cancer risks and other aspects of pesticide toxicity in development and throughout life, we can accept the necessity of and the soundness of the EPA's priority choice. Our evaluation of EPA's work in this area therefore reflects the Agency's priority decisions. EPA has made little progress toward reassessing pesticides for endocrine disruption, cancer risk or many other attributes of their toxicity; the bulk of work on those challenges still lies ahead. We have not "penalized" the Agency for making essential priority choices, and have evaluated its progress solely on the areas on which EPA has chosen to focus.

### RfD Reviews of Organophosphate Insecticides

EPA made it a top priority to review its RfDs for the OPs, for good reason. There are 49 members of the OP family, about half of them used in economically important quantities on food crops in the U.S.

The OPs include several of the most toxic pesticide active ingredients, such as methyl parathion, chlorpyrifos, and methamidophos. All OPs share a common mechanism of toxic action (they inhibit the activity of acetyl cholinesterase, an enzyme that breaks down an important "messenger" chemical involved in transmitting signals from cell to cell within the nervous system.) The FQPA's requirement that EPA consider pesticides with such a common mechanism of toxicity in an integrated way adds another dimension to the task of defining safe exposure, and is one more reason why EPA chose to review the OPs first, and as a family.

**Table 2.1** lists 49 OPs, and displays the results of EPA's RfD reviews in each case. The table lists chronic RfDs EPA had established before the FQPA was enacted, and changes in the cRfDs that EPA has made since August 1996. The table also lists acute RfDs EPA has set for the OPs. Most aRfDs have been set only within the past four years, so there is no pre-FQPA column for aRfDs.

For completeness, **Appendix 1** of this section presents comparable information on all registered pesticide active ingredients reassessed under the FQPA. That Appendix lists 273 chemicals—about half of the 552 pesticides that EPA identified in 1996 as needing reassessment. Our focus here, though, is on EPA's highest-priority subset, the OPs.

At this point, we must introduce some new terminology. EPA felt a need to distinguish RfDs that had been reviewed to ensure that they met the FQPA "reasonable certainty of no harm" standard from those that had not been subject to such review. They invented a new term, the "Population Adjusted Dose," or PAD, to describe post-FQPA RfDs; quite simply, a PAD is an RfD that includes any additional safety factor required by the FQPA. If EPA has completed its review and retained no additional FQPA safety factor, the PAD

equals the (post-FQPA) RfD. PADs, like RfDs, are used to define acceptable limits for chronic (cPAD) and acute (aPAD) exposure.

If reviewing an RfD (or setting a PAD) were simply a matter of deciding when to apply the FQPA's "extra 10-X" safety factor, evaluating EPA's PAD decisions would be much simpler. But the process is more complex than that. There are myriad reasons that might lead EPA to revise an RfD. The reasons include:

- Toxicological research may provide evidence of new forms of toxicity;
- Such evidence may redefine the "critical effect" (e.g., developmental neurotoxicity may supplant other effects as the basis for limits);
- Toxic effects may be observed at lower doses than previously documented, or new studies may generate better dose-response data (raising or lowering the NOAEL);
- New policy guidelines may change the definition of what is acceptable exposure; for example, considering all pesticides with the same toxic mechanism as one problem can reduce allowable exposure to any one compound in such a group;
- An additional safety factor may be judged necessary; for example, when EPA has no good study that provides a NOAEL, it uses a LOAEL and applies an additional 3-X safety factor;
- Policy guidelines on how to weight human data may evolve, changing judgments of the appropriate safety factors to apply;
- Policy judgments on applicable safety factors may change (as the FQPA requires an extra safety margin to cover data gaps.)

As EPA has reviewed its RfDs for the OPs, several of these considerations could have come into play in any given case. For example, EPA has decided (wisely, we believe; see Part 1) not to use toxicity data from human studies in setting its cPADs. That led to changes in the cPADs for nine OPs whose previous cRfDs had been based on human data on cholinesterase inhibition (in healthy adults). As another example, where the best data on the critical effect come from a study with a LOAEL, EPA has applied an extra 3-X safety factor for that reason; in some of those cases, EPA has also retained either a 3-X or a 10-X FQPA extra safety factor. Each safety factor decision is independent of the other.

Early in its development of policies for implementing the FQPA, EPA determined that the Act unambiguously calls for the addition of an extra 10-X safety factor, unless EPA has reliable scientific data that can establish that such an added factor is not needed. That means that EPA's decisions with respect to the FQPA extra safety factor actually involve whether to reduce it or remove it—not whether to apply it. In cases where the Agency has judged that it lacks evidence to justify removal of the extra safety margin required by the law, it has "retained" an added FQPA safety factor, in EPA terminology.

#### Assessing EPA's Safety Decisions

**Table 2.1** shows that, among the 49 OPs, there are five for which EPA has set no PADs, because the chemicals are not registered for use in the U.S. Among the remaining 44, the

EPA set the chronic PAD lower than the pre-FQPA cRfD (tightened the chronic exposure limit) in 20 cases, or 45 percent. Two steps are involved in the process: First, EPA set an updated cRfD, based on a new review of the evidence. Then, EPA determined whether to retain the FQPA's added 10-X safety factor, retain a smaller safety factor, or retain none of the added safety margin. Thus, a cPAD lower than a pre-FQPA cRfD can result from a variety of decisions. In 14 cases, EPA lowered the cRfD; in 8 of those cases (acephate, fenthion, for example), no FQPA added safety factor was retained. In the other six cases, including chlorpyrifos and mevinphos, for example, the additional FQPA safety factor was retained, producing a larger, two-step reduction in the cPAD. There were four cases in which the cRfD was kept the same, but EPA retained an additional FQPA safety factor that lowered the cPAD. In one case (cadusafos), EPA had no prior cRfD, so it set one for the first time, then retained an FQPA 3-X factor in setting the cPAD. In one somewhat unusual case, (isofenfos) EPA *increased* the cRfD initially, but retained an FQPA safety factor, resulting in a cPAD that is slightly lower than the pre-FQPA cRfD.

As **Table 2.1** also shows, there are 21 cases (48 percent) in which the cPAD is the same as the pre-FQPA cRfD; i.e., EPA neither changed the cRfD based on its review of the evidence, nor retained an FQPA safety factor in setting the cPAD. In 3 cases (7 percent), EPA increased the cRfD, based on better toxicity data, and the cPAD is higher than the pre-FQPA cRfD. In one of these cases (S,S,S-tributyl phosphorothioate), EPA kept a full 10-X FQPA safety factor in the cPAD, but since it had increased the cRfD by 30-X, the cPAD still was higher than the pre-FQPA cRfD.

**Table 2.1** shows that EPA has established acute RfDs and acute PADs for 38 OPs. Most aRfDs were established after 1996 (in the post-FQPA toxicity data review), so the only distinction between an aRfD and an aPAD for a given OP is whether EPA chose to retain the added FQPA safety factor. The aPAD decisions are especially critical ones, because EPA has decided to base most of its dietary-exposure regulatory decisions on acute risks.

The table shows whether EPA retained an extra FQPA safety factor in its decisions on acute and chronic PADs for each OP. The Agency applied this key provision of the law in decisions on only 13 chemicals—13 of the 44 cPADs (30 percent), and 13 of the 38 aPADs (34 percent), 26 decisions in all. The full 10-X was retained in half the decisions, while the factor was reduced to an added 3-X in the other half of the decisions.

**Table 2.2** shows the reasons EPA cited for retaining an FQPA safety factor (either 10-X or 3-X), for those 13 chemicals where it did so. The most commonly cited reason is the absence of an adequately designed developmental neurotoxicity (DNT) study, for 10 of the 13 pesticides. Evidence of neurotoxicity (or sometimes of cholinesterase inhibition) and/or evidence of heightened sensitivity of offspring or prenatal/developmental toxicity were the next most frequent reasons EPA cited for retaining an extra safety factor.

But **Table 2.1** also suggests that EPA passed up innumerable opportunities to retain an extra FQPA safety factor. All OPs share the same common mechanism of toxic action on the brain. It is therefore reasonable to suspect all OPs of potential DNT, and EPA could quite fairly require DNT studies as the critical evidence it needs to establish “reasonable

certainty of no harm.” Very few OPs have been adequately tested for this effect, using up-to-date protocols (though tests are currently under way on several members of this pesticide family.) But in many cases, EPA has ignored this critical data gap and opted to retain no added FQPA safety factor in setting PADs.

Overall, EPA has retained a full 10-X added FQPA safety factor in only 13 of the 82 decisions (i.e., 44 cPADs and 38 aPADs) shown in **Table 2.1**, a mere 16 percent of its definitions of “safe” exposure to this family of very toxic insecticides. In another 16 percent of these decisions, EPA retained a 3-X added FQPA safety factor. Combining the two, just under one-third of EPA’s safety limits for OPs set under the FQPA to date have incorporated an extra safety factor designed to ensure “reasonable certainty of no harm” to children.

The FQPA presents the “extra 10-X” safety factor as a default position. EPA *must* apply the extra 10-X *unless* it has a reliable scientific basis for being reasonably certain there is no harm from currently permitted exposures. Yet, as **Table 2.1** shows, EPA has retained the FQPA extra safety factor inconsistently and infrequently. For every case where EPA did apply an extra safety factor for lack of DNT evidence, there are probably two others (including widely used OPs such as azinphos-methyl, acephate, dimethoate, parathion, diazinon and malathion) where the same criterion might have been applied but was not.

In its most prominent decision to date involving DNT evidence, the EPA retained the full FQPA “10-X” in the chlorpyrifos PADs, because the DNT studies showed clear evidence of adverse effects and heightened susceptibility in young animals. Certainly, the extra safety factor was justified in this case. But we believe EPA has generally been too timid in using the FQPA extra safety factor. By retaining this extra safety margin only where it had clear evidence of hazard, EPA has turned the precautionary intent of the FQPA on its head. The Agency had enough evidence to prove chlorpyrifos “guilty.” But the intent of the FQPA’s “10-X” provision is to shift the burden of proof, to require an extra safety margin when existing scientific evidence is sufficient to present a reasonable suspicion of a hazard, but insufficient to establish reasonable certainty of no harm. By choosing too often and too easily not to retain the FQPA safety factor in its PAD decisions for OPs, EPA has made inadequate use of the strongest public-health provision in the new law.

**Table 2.2** also shows that EPA has never cited inadequate exposure data as a reason for an additional safety factor in a PAD for an OP insecticide. The Agency has chosen not to use extra safety factors this way, but instead to rely on “conservative” exposure models as a basis for estimating the upper limits of plausible risk (see discussion in **Part 1**).

Overall, for its incomplete and inconsistent decisions in establishing new PADs under the FQPA, and for its timidity in using the “extra 10-X” provision, we award EPA a **C**.

### 3. REDUCING DIETARY RISK

#### HOW MUCH HAVE EPA'S TOLERANCE REASSESSMENTS REDUCED POTENTIAL PESTICIDE RESIDUES IN FOODS, AND THE ASSOCIATED RISKS TO CHILDREN?

The “bottom line” of EPA’s effort to implement the FQPA will be its impact in terms of reduced pesticide exposure. EPA can reduce children’s exposure in two primary ways: By eliminating pesticide uses around the home, and by restricting agricultural uses of chemicals that leave significant residues in children’s foods.

To date, EPA has aggressively addressed home uses of two major organophosphate insecticides. In June 2000, the agency negotiated the withdrawal from the market of home- and garden-use chlorpyrifos products with the manufacturer, and this December, EPA announced a phase-out of most home and garden uses of diazinon. Eliminating these products will remove a substantial number of potential sources of acute, high-dose exposure to two neurotoxic pesticides that pose particular risks for children.

Diazinon and chlorpyrifos are not the only high-risk chemicals used in home pesticide products; other home, lawn and garden products also contain additional organophosphate or carbamate insecticides for which EPA has not yet completed its reviews, and which are nearly as toxic as chlorpyrifos and diazinon. As these chemicals replace withdrawn products, more families will be exposed to them. But EPA’s actions on chlorpyrifos and diazinon should effectively eliminate risks from home exposure to the two most widely used chemicals, and we give the EPA a **B+** for these decisions. (It might have been an **A**, if EPA had been more assertive about getting existing stocks of these products off the market rapidly.) Overall, considering the work yet to be done and the need to prevent risks from products remaining on the market, EPA has still earned a **B**, overall, for its actions on non-food exposures.

While pesticide uses around the home pose risks of occasional very high exposures for a relatively small number of children on any given day, residues in foods expose millions of children to a shifting array of combinations of pesticides every day. We consider the management of dietary exposure and risks a much larger, more difficult, more important task, and EPA’s performance at reducing dietary risk has received the greatest weight in our assessment of their FQPA implementation.

To evaluate EPA’s success to date in reducing the risks associated with pesticide residues in children’s diets, we relied on our database of USDA Pesticide Data Program (PDP) data. CU has, over the last several years, built a large analytical model that incorporates data on residues in thousands of PDP-tested food samples, as well as EPA toxicity data on all registered pesticides. We have used data on the acute and chronic toxicity of each chemical and on the occurrence (the frequency of detection and mean concentration) of residues in various foods to calculate “Toxicity Index” (TI) scores for each chemical in



each food in which the PDP detected it. Our methodology for calculating TI scores has been described in detail in reports available on our FQPA web site ([http://www.ecologic-ipm.com/findings\\_CU.html#reports](http://www.ecologic-ipm.com/findings_CU.html#reports)). TI scores can be used in various ways to compare relative risks, rank problems, and identify priorities. See “*Do You Know What You’re Eating?*” (1999) and our “*Update*” (2000) on the web site for detailed examples.

For this analysis, we used our database to identify food/chemical combinations with relatively high TI scores. Each food/chemical pairing (e.g., azinphos-methyl on apples) is associated with an EPA tolerance. Pairings with high TI scores represent pesticide uses that contribute relatively more significant shares of dietary exposure and risk; we call these uses “risk drivers.” We did four separate analyses of risk-driving pesticide uses to assess the extent to which EPA’s FQPA tolerance reassessments to date have reduced dietary exposure and risk.

#### A. Risk-Driving Tolerances

From our database, we developed a list of all pesticide-food combinations detected by the PDP in test years 1994 through 1998. We eliminated duplication by considering only the most recent year in which a given pesticide was found in a given food. (For instance, if chlorpyrifos was detected on grapes in 1994, 1995 and 1996, we used only 1996 data.) We did separate analyses for U.S.-grown food samples and imported samples. The PDP in fact tests both, in proportion to the market share each holds for each tested food. For analytical purposes, however, it is difficult to assign values to residues in foods produced in two or more countries, because of different PDP sample sizes. We focused initially on U.S. samples. However, since the impact of EPA action on tolerances may occasionally be important with respect to imported foods, we did additional analyses of risk-driving food/chemical pairings in imported samples.

We also limited our analysis to data on chemicals for which the EPA has a current legal limit, or tolerance. Many residues detected by the PDP result from soil contamination by persistent pesticides banned years ago.<sup>1</sup> Some of these residues—for example, dieldrin, in winter squash and cantaloupe—have substantial TI scores in our previous analyses of the PDP data. But there is essentially nothing EPA can do to eliminate these exposures—tolerances for banned pesticides are already set at zero. We judged it inappropriate to expect EPA’s tolerance reassessments to affect TI values for old, banned chemicals, and excluded their residues and TI values from this analysis.

We also excluded TI values associated with illegal residues. Each year the PDP detects several dozen pesticide residues in foods on which the pesticides are not registered for use—for example, chlorpyrifos on spinach. Illegal residues rarely have high TI values, so excluding them has little effect on overall results. Here, too, the tolerance is already zero, and we would not expect EPA’s tolerance reassessments to affect TI scores.

---

<sup>1</sup> Our June 2000 report “Update: Pesticide Residues in Children’s Foods” contains a section on residues of old, banned organochlorine insecticides found in food. It is accessible on the website at the address noted above.

When duplications, old, banned chemicals and illegal residues are eliminated, there are 458 pesticide/food combinations in the five years of PDP data on U.S.-grown samples in CU's database, and 268 pesticide/food combinations in the data on imported samples. We ranked the combinations in order of descending TI, so that residue/food combinations posing the greatest relative risk are at the top of the list. There are 92 combinations with TI values >5.0 in the U.S. data, about 20 percent of the total. We chose this point (TI >5) as our cutoff between risk-drivers and less important uses. The sum of the TI scores for these 92 uses is about 97 percent of the total TI for all 458 uses; in other words, one fifth of all uses that leave residues account for nearly all the current risk, as measured by TI value for U.S.-grown samples. These 92 uses clearly should be the focus of EPA's risk-mitigation efforts. The 92 risk-driving U.S. pesticide uses are displayed in **Table 3.1**.

As noted earlier, each chemical/food combination corresponds to an EPA tolerance. To assess the effects of EPA's actions to date, we examined EPA's decisions on tolerances for the 92 risk-driving uses. **Table 3.1** shows the EPA tolerances that were in effect in August 1996 (when the FQPA was enacted), and shows the current EPA tolerances. If EPA has revoked a tolerance, "NT" appears in the "Current Tolerance" column. If EPA has lowered or raised the tolerance, the new limit is shown. If the tolerance is the same in both columns, it means either that EPA has reassessed the tolerance and left it unchanged, or that the Agency has not yet reassessed the tolerance.

To determine the effect of EPA tolerance decisions on residues and risks, we calculated an *estimated TI value* that we predict should result once the EPA action takes effect. For revoked tolerances, residues and the TI should drop to zero. For reduced tolerances, we estimated future residues from current residue data. If a lowered tolerance still exceeds the maximum residue detected by the PDP in recent years, we anticipate no change in use patterns for that pesticide as a result of the tolerance reduction, and thus we project no change in TI. For reduced tolerances that are significantly lower than current residues, we used the average ratio between current tolerances and recent mean residue values to calculate the expected mean residue under the lower tolerance, then recalculated the TI using that projected residue value. (See Appendix 1 for methodological details.)

**Table 3.1** shows anticipated changes in TI values produced by EPA actions for each of the 92 risk-driving uses. In a few individual cases (such as methyl parathion on peaches, apples, pears and green beans), EPA has eliminated significant potential residues and TI scores from the picture. However, the totals at the bottom of the table show that EPA's decisions have reduced overall TI score for the 92 uses by 37 percent. While EPA has effectively eliminated a few obvious high-priority risk-drivers, the Agency's actions in reassessing tolerances have not touched the bulk of the problem of dietary exposure and risk. For this muted overall impact, we award EPA a **D**.

Some pesticide/food combinations that contribute to overall risk are not listed in **Table 3.1**, because those chemicals are seldom used on those crops here in the U.S. But EPA actions on tolerances can still have important risk-reducing effects, by restricting legal residues in imported foods. Overall, imported samples account for about 15 percent of

the total PDP samples, which provides a rough index of the relative importance of effects of EPA actions on imported and domestically-grown foods.

We carried out the same analysis for imported samples in the PDP database, ranking all food/chemical/country combinations in descending order by TI and selecting those with TI >5 for analysis. There are 64 risk-driving uses on imported PDP samples, many of which also occur in U.S. samples, but a few are risk-drivers only on imports (such as the fungicide anilazine in strawberries). **Table 3.2** lists risk-drivers on imported foods, and shows the impacts of EPA's tolerance decisions on these uses.

EPA's actions have reduced the overall TI for the 64 risk-driving residues on imported samples by 33 percent, slightly less than the impact for domestic samples. Ironically, the biggest TI reduction occurred for anilazine, which is no longer registered for use in the U.S. Because there are no current domestic uses, EPA revoked all anilazine tolerances in 1998, not on the basis of a risk assessment but rather as part of a "housecleaning" effort to remove "obsolete" tolerances (and meet Congress's mandate to "reassess" 1/3 of all tolerances by August 1999). Facing a comparable situation on mevinphos, EPA left a number of tolerances in place even though all domestic uses of the insecticide have been cancelled, essentially to allow mevinphos residues on imported foods. Thus, EPA action eliminated TI values for mevinphos in domestic samples (**Table 3.1**) but not in imported samples (**Table 3.2**). EPA's decision on methyl parathion had little effect on imported foods (see discussion below), and if the anilazine tolerance on strawberries had not been revoked, the decline in TI score for imported samples would have been only 18 percent. Even at the 33 percent level, this achievement also deserves a **D**, in our judgment.

## B. Three Major Insecticides

EPA has thus far completed regulatory reviews of three major organophosphate insecticides that are among the most toxic pesticides widely used on children's foods—methyl parathion, azinphos-methyl and chlorpyrifos. Together, these three account for many high TI values in the CU database. They were clear top priorities for EPA action, and they were among the first chemicals the Agency thoroughly reassessed. We have evaluated the impacts of EPA's decisions in each case on dietary exposure and risk.

### 1. Methyl Parathion

In August 1999, on the day before the deadline specified by Congress for EPA's first major progress report on FQPA implementation, EPA Administrator Carol Browner announced "major" actions on both methyl parathion and azinphos-methyl. For methyl parathion, EPA banned use of this insecticide on 36 crops, including several (peaches, apples, pears, green beans, grapes) that have stood out as top risk-driving uses in CU's analyses of the PDP data.

**Table 3.3** lists 29 foods tested by the PDP for which EPA reassessed methyl parathion tolerances, and shows EPA's decisions on each tolerance and the impacts of the actions

on dietary exposure and risk, as measured by CU's TI values for U.S.-grown samples. The table lists only PDP-tested foods, which are just a subset of all the foods on which methyl parathion was registered for use. While foods not tested (so far) by the PDP are generally less important in children's diets, some (such as cherries, plums or nectarines) may occasionally contribute at least "spikes" of exposure. Our estimate of the impact of EPA's decisions on methyl parathion exposure, calculated for the foods in **Table 3.3**, is therefore not complete. Nevertheless, the results are striking. By banning just 10 of 113 registered uses of this pesticide (the 10 with reductions to 0 of TI scores in the Table), EPA has eliminated 99.7 percent of PDP-measured dietary exposure and risk. EPA left in place tolerances for applications to cotton and to many other food crops; collectively, these retained uses accounted for 83 percent of total pounds of methyl parathion applied in the U.S. in 1997 and 1998. In short, EPA has effectively eliminated dietary risk from methyl parathion, while requiring only a modest reduction in use of this economically important chemical. Although methyl parathion use has other adverse environmental impacts that might justify further restrictions, from the standpoint of the FQPA's mandate to protect children's health, EPA regulation of this chemical is a model of rational and efficient risk management, and earns the Agency an **A**.

Methyl parathion residues have seldom been detected on imported samples in PDP tests; food uses of this chemical are widely restricted outside the U.S. Therefore, our analysis of domestic samples captures essentially the entire impact of EPA's tolerance decisions on TI values in this case, and we did not do a separate analysis for imported samples.

## 2. Azinphos-Methyl

Administrator Browner announced EPA's decision on azinphos-methyl, another very toxic organophosphate used widely on fruits and vegetables, at the same press conference at which the Agency presented its decision on methyl parathion. But EPA's actions on these two chemicals, and their impacts on risk, could hardly be more starkly different.

**Table 3.4** lists 21 PDP-tested foods with tolerances for azinphos-methyl, and shows the estimated impacts of EPA's tolerance reassessment decisions on TI values for this residue in U.S.-grown samples. Just a handful of uses, on pears, apples, peaches and spinach, account for most of the Total TI for this insecticide in our PDP database. EPA cancelled none of these uses, but did lower the tolerances for apples and pears, from 2.0 to 1.5 parts per million in each case. We examined PDP residue data on all U.S. samples of pears and apples that tested positive for azinphos-methyl in the most recent test year. In no case did maximum detected residues exceed or even approach the new tolerance level of 1.5 ppm. We therefore expect EPA's moderate tolerance reductions to have no effect on azinphos-methyl use on these crops, and we estimate no reduction in TI values. **Table 3.4** shows that EPA actions will have no effect on 20 of the 21 TI values. EPA did revoke the tolerance for wheat, which will eliminate a TI value of 0.5—about two-tenths of 1 percent of the total. Overall, EPA's reassessment of azinphos-methyl tolerances left 99.8 percent of dietary exposure and risk untouched, and earned the Agency an **F**.

Azinphos-methyl is used in other countries on many of the same crops on which it is used in the U.S., and risk-driving uses on imported samples tested by the PDP are similar to those for U.S.-grown samples. **Table 3.5** shows estimated impacts of EPA's tolerance decisions on azinphos-methyl on TI values for imported foods, where the PDP has tested enough samples to generate a TI score. As for domestic samples, EPA actions will have essentially no impact on these TI values.

### 3. Chlorpyrifos

In June 2000, EPA announced its decisions on chlorpyrifos, another organophosphate and the most widely-used, economically important insecticide on the U.S. market. As noted above, the Agency negotiated the voluntary cancellation of all home uses of chlorpyrifos, eliminating serious risks of short-term, high-dose exposures for children, and earned a **B+** for that. Unfortunately, EPA's decisions on agricultural uses of chlorpyrifos were less consistently effective at eliminating risks.

**Table 3.6** lists 20 PDP-tested foods with chlorpyrifos tolerances covered by the EPA's June decision, and shows the impact of EPA's actions on TI scores for domestic samples. **Table 3.7** lists 12 foods with chlorpyrifos tolerances for which the PDP tested imported samples, and shows the impact of EPA's decisions in those cases.

EPA restricted chlorpyrifos uses (and revised the associated tolerances), on three key children's foods—apples, grapes and tomatoes. The Agency cancelled the tolerance on tomatoes, and reduced the limits on apples and grapes to 0.01 ppm. These dramatic reductions in tolerances—150-fold for apples, and 100-fold for grapes—were coupled with restrictions on chlorpyrifos use on the crops, which should eliminate any significant future dietary exposure. We estimate that EPA's actions on these three tolerances should reduce chlorpyrifos TI values for these three foods by 98 percent. For these selected foods, then, EPA has aggressively met the FQPA goal of protecting children's health.

However, chlorpyrifos is widely used on many other foods that children also eat, as **Table 3.6** shows. EPA left tolerances for most other uses unchanged and asked for public comment on the need for further action.<sup>2</sup> Collectively, the uses EPA has not restricted—or at least, the 17 on which we have PDP data that permit us to calculate TI values—account for about one-third of the Total TI score for chlorpyrifos residues in domestic samples. Overall, the tolerances EPA has eliminated or lowered should result in a 67 percent reduction in Total TI score for chlorpyrifos in PDP tested U.S. foods, leaving 33 percent of dietary exposure and risk still untouched. While we are impressed that EPA could eliminate almost two-thirds of chlorpyrifos TI value by restricting just three uses, the actions the Agency took fell far short of the potential risk reduction that could have been achieved. Overall, we awarded the EPA a **C** for this effort.

**Table 3.7** shows the effect of EPA's chlorpyrifos decision on TI values for imported PDP samples. Chlorpyrifos residues on imported apples, grapes and tomatoes have generally

---

<sup>2</sup> CU's comments entitled "Essential Steps in Mitigating Chlorpyrifos Risks" were submitted to EPA October 13, 2000 and are accessible at [http://www.ecologic-ipm.com/Chlorpyrifos\\_comments\\_2000.pdf](http://www.ecologic-ipm.com/Chlorpyrifos_comments_2000.pdf).

been higher than on domestic samples of the same foods, and those uses account for most of the total TI in **Table 3.7**. The reduction in total TI values for chlorpyrifos in imported samples is 86 percent—notably greater than for U.S. foods, and a testament to the value of tolerance reductions for limiting residues in imported foods. Considered in isolation, this achievement merits a **B+** -- but since imports are a small fraction of what American children eat, this does not offset the overall **C** that we've given EPA for the effects of its chlorpyrifos decision on dietary risk.

### C. Riskiest Chemicals

In its testing from 1994 through 1998, the PDP detected about 150 different pesticides and breakdown-products as residues in the foods it examined. Our PDP database allows us to identify individual pesticides that contribute most to overall dietary exposure and risk, and to rank those chemicals in order of their importance as risk-drivers. By adding up the TI values for all foods in which a particular pesticide was detected, we can get a Total TI for that chemical. **Table 3.8** lists the top risk-driving chemicals for U.S.-grown samples of PDP-tested foods. For this analysis, we drew a cutoff at a Total TI score of over 100; using that criterion, 14 individual chemicals qualify as top risk-drivers in U.S. PDP samples. Collectively, the sum of TI values for the top 14 chemicals is almost 90 percent of the Total TI value for all detected chemicals. I.e., roughly 10 percent of the chemicals account for 90 percent of the total risk. **Table 3.8** also shows contributions of residues in individual foods to the total for each chemical.

**Table 3.9** presents data on risk-driving chemicals in imported foods tested by the PDP. There are 10 chemicals with TI scores >100 for imported samples, including four not on the list for domestic samples (dimethoate, anilazine, endosulfan and benomyl).

We carried out the same analysis for risk-driving chemicals that we used to evaluate risk-driving individual pesticide uses. **Tables 3.8** and **3.9** display EPA's actions on applicable tolerances for each chemical/food combination, our estimate of the impact of the actions on expected TI values, and the sums of the impacts on each chemical's total TI value.

**Table 3.8** shows that EPA actions to date have reduced dietary risks associated with the top 14 risk-driving pesticides in U.S. samples by 40 percent. This percentage is slightly greater than that for the top 92 risk-driving food/chemical combinations shown in **Table 3.1**, reflecting the effect of our limiting this analysis to just the 14 riskiest chemicals. (At the same time, it suggests that EPA has not done much better within the narrower task of dealing with the riskiest chemicals, than on the somewhat more complicated list of all the riskiest food/chemical combinations.) Almost all reduction shown in this table resulted from decisions on a few uses of methyl parathion and chlorpyrifos. Aside from those few decisions, EPA's FQPA actions to date have had almost no effect on expected residues and TI values, and 60 percent of the total TI value for these 14 riskiest pesticides in U.S. children's foods remains undiminished. This effort earns EPA another **D**.

**Table 3.9** shows similar results for imported PDP foods. EPA actions have produced an estimated drop of 36 percent in total TI score for the 10 riskiest chemicals in imported PDP samples. As was true in **Table 3.2**, nearly half of the decrease in total TI score was due to the revoked tolerance for anilazine on strawberries; without that, the impact would have been just a 19 percent reduction. Nevertheless, despite the very modest amount of progress to date in risk reduction, we think **Table 3.9** does show the benefits of revoking tolerances, even when domestic use of a chemical does not pose much risk. By revoking tolerances, EPA can eliminate occasionally significant residues on imported foods.

A further example drives home this point. The organophosphate insecticide mevinphos appears in **Table 3.8** and **Table 3.9** as one of the top risk-driving chemicals in domestic and imported foods. All registrations for mevinphos use on U.S. crops were cancelled in 1994, before the FQPA was passed, when the manufacturer declined to respond to EPA's request for additional toxicity data to support reregistration. (The high TI score "Before EPA Action" for this chemical on U.S. samples reflects primarily the residues on lettuce, which was last tested by the PDP in 1994. And **Table 3.8** shows TI values for all uses of mevinphos in the U.S. dropping to zero, because those uses have been cancelled.)

In August 1999, in reviewing tolerances under the FQPA, EPA revoked 39 tolerances for mevinphos as a "housecleaning" step, because they applied to cancelled U.S. uses. One of those revocations (for peaches) produced the decreased TI values for mevinphos in imported samples shown in **Table 3.9**. But EPA left mevinphos tolerances in place for 13 foods on which the chemical was still registered for use in other countries, including grapes, spinach, strawberries, tomatoes and other foods often consumed by children. As a result, we project no decrease in the TI values for mevinphos in imported samples of foods other than peaches, as a result of EPA's action.

PDP tests have found virtually no mevinphos in foods tested since 1996. It appears there is no real need for the tolerances EPA left on the books, but the tolerances could permit mevinphos residues on imported foods to contribute significantly to children's overall risk. Here and in several similar cases, we think the Agency should revoke all tolerances when domestic uses of a high-risk pesticide are phased out. That way, growers exporting to the U.S. will have to meet the same safety goals EPA has set for domestic growers, and children will face no greater risk when they eat imported foods.

#### D. Riskiest Foods

From 1994 through 1998, PDP tested 25 different fresh foods and 15 processed foods. Our previous analyses of the PDP data have shown that the relative pesticide residue toxicity loads of different foods vary enormously. Some foods are essentially free of residues (TI scores <10), while a few have very high scores (TI >1,000), and many more have moderately high scores (TI >100). Using PDP data and knowledge of what children eat, EPA can readily identify the foods that contribute most to dietary exposure and risk.

We selected from our PDP database those foods that have TI scores >100 (the score for the food is the sum of the scores for the individual residues found on it). Excluding high scores associated with banned organochlorines like DDT, dieldrin and heptachlor, and excluding illegal residues, removes fresh and frozen winter squash, carrots, cantaloupe and potatoes from this category. Fourteen U.S.-grown and 7 imported foods (including pears from three countries) remain with TI scores greater than 100. **Table 3.10** displays the risk-driving U.S. foods, and **Table 3.11** displays the imported foods that meet this criterion. The tables show the applicable tolerances for each residue in each of the foods, before the FQPA and after EPA review, and the projected effects of EPA actions on the TI values for each residue, and on the foods' overall TI scores.

The impact of EPA actions has varied widely from food to food. For U.S. foods whose high TI scores were driven largely by methyl parathion residues, we project that future TI values will be dramatically lower. Peaches, the prime example, shows an 87 percent drop in TI score, while the decrease for pears is 39 percent, for frozen green beans 29 percent, and for apples, a modest 17 percent. (For the first three of these foods, the decrease in TI due to revocation of the methyl parathion tolerance accounts for essentially the entire decline in the food's TI value. For apples, EPA's methyl parathion decision contributes along with several other actions to a combined drop in TI score of 41 percent.)

EPA's restrictions of chlorpyrifos use on tomatoes, apples and grapes reduce TI scores for U.S.-grown samples of those foods by 12, 20 and 5 percent, respectively. The impact of the chlorpyrifos decision on TI values for imported samples is more substantial, with reductions of 33 percent for Mexican tomatoes, 68 percent for New Zealand apples, and 49 percent for Chilean grapes.

Actions EPA took on two other chemicals led to sharp reductions in predicted TI scores for two additional foods. These decisions were not risk-based; in 1994, the Agency and the manufacturer of mevinphos agreed to cancel all U.S. uses of that insecticide, and in 1999 EPA revoked the applicable tolerances. Similarly, in 1998 EPA revoked the legal limit for anilazine on strawberries, because the fungicide is no longer registered for this use in the U.S. The mevinphos action reduces the TI score for U.S. lettuce by 84 percent, and the anilazine revocation cuts the score for Mexican strawberries by 67 percent.

Beyond these few sharp reductions associated with limited actions on a handful of the most toxic chemicals, though, EPA's FQPA implementation effort to date has had little impact on the overall TI scores of many foods that contribute significantly to children's dietary exposure and risk. Four of the highest TI values among U.S. PDP-tested foods, for wheat, fresh strawberries, fresh green beans and fresh spinach, show essentially no changes from EPA actions thus far. Among imported foods, Chilean peaches and pears and Mexican spinach show essentially no drop in TI scores. Even after some reductions, TI scores for U.S. peaches, apples and pears, Chilean grapes, New Zealand apples, and Mexican tomatoes and strawberries remain high (all above 100, some above 200).

By failing to take effective actions on azinphos-methyl and on many chlorpyrifos uses, and because it has not yet completed its reviews of several other risk-driving chemicals,



EPA has reduced TI values for risk-driving children's foods much less than it needs to. **Tables 3.10** and **3.11** show that overall, EPA's actions have lowered the TI scores for the riskiest U.S. and imported PDP-tested foods by 37 and 35 percent, respectively. While some notable gains have been achieved, the work still to be done outweighs progress so far. EPA's grade for this still incomplete task is another **D**.

#### Conclusions: Some Achievements, But Much Work Still To Be Done

**Tables 3.8, 3.9, 3.10** and **3.11** present a clear picture of the EPA's "unfinished agenda" for FQPA implementation. While the Agency can be proud of some of its decisions so far, roughly 63 percent of overall risk, integrating our various measures of the reduction in TI values for PDP-tested foods, remains to be addressed. Many chemicals that account for significant shares of overall dietary exposure and risk, such as the organophosphate insecticides methamidophos and dimethoate; the carbamate insecticides methomyl and oxamyl; and the fungicides diphenylamine and iprodione, among others, have not yet been fully reviewed and reassessed. Clearly, the EPA still has a great deal of work to do to carry out the FQPA's mandates.

These unreassessed chemicals not only contribute to a large total TI value based on past uses; the importance of some of them as drivers of overall TI and risk might increase, if they replace cancelled or newly-restricted uses of methyl parathion and chlorpyrifos. In addition, another 19 pesticide chemicals that we consider "risk contributors" have Total TI values between 10 and 100 in our analysis of PDP data on U.S. samples. As higher-risk chemicals are gradually removed from foods by past and future EPA actions, some of the chemicals now farther down on the list may replace them, increasing their relative importance as risk-drivers.

Ultimately, we estimate that in order to meet the FQPA's safety standard for cumulative risk from all dietary residues, EPA will need to reduce overall exposure and risk by from 95 to 98 percent, as measured against our baseline total TI values. To achieve reductions on that scale, EPA will need to address almost all of the specific uses shown in **Table 3.1**, and additional pesticide uses we call "risk contributors" as well.

If future EPA actions follow the pattern of the best ones to date, the overall trend in total TI value should be downward, but EPA will need to be alert to "risk trading" associated with substitution of one chemical for another. EPA can't rest on its laurels until it has comprehensively assessed the combined exposure and risk from essentially all pesticide chemicals, and managed that collective risk to ensure a "reasonable certainty of no harm" for children, as the FQPA requires.

## **Appendix 1. Estimating Changes in Toxicity Index Scores Resulting From EPA Actions on Individual Pesticide-Crop Uses**

A major analytical challenge in implementing the FQPA is to develop ways to project, and then to monitor, impacts of changes in tolerance levels and pesticide use patterns on residues in food. Consumers Union has commented extensively on these methodological issues in response to draft EPA science policy papers (see [http://www.ecologic-ipm.com/findings\\_CU.html#comments](http://www.ecologic-ipm.com/findings_CU.html#comments)).

We strongly support EPA's reliance on USDA's Pesticide Data Program (PDP) as the principal source of residue data in key children's foods. Over time, changes in residue frequency and levels found by the PDP will provide a solid basis to project changes in actual dietary risk levels. We have suggested that EPA set clear, quantitative goals for reduction of OP residues and risks, and monitor annually achievement of those reduction targets when new PDP data are released. Whether EPA does so or not, CU will continue to compute and compare TI scores over time as one indicator of progress.

The analysis published here represents our first projection of impacts of EPA actions on expected residues and related TI scores. Here, we lay out in some detail the methods we used to estimate changes in residues likely to result from changes in EPA tolerances.

### Revoked Tolerances

When EPA has revoked a tolerance or scheduled it for phase-out, we simply project that residues will decline to zero. This may not happen immediately, as EPA sometimes has been slow to publish official tolerance revocation notices, even for high-risk OPs. In addition, the Agency sometimes phases tolerances down to zero in steps over a period of several years.

Projecting that the TI score associated with a revoked tolerance will decline to zero also assumes, of course, that there will be no illegal use of the pesticide. Given the prevalence of illegal residues in the PDP database (a few percent of detected residues each year), the validity of this assumption needs to be carefully monitored in the years ahead.

### Tolerance Reductions

When the EPA lowers a tolerance and/or alters the way and time when a pesticide can be sprayed on a given crop, several dietary risk-reduction outcomes could occur. In cases where the maximum residue level found in recent PDP testing is *below* the applicable, lowered tolerance level, we project no changes in Toxicity Index (TI) scores. EPA's reduction of the azinphos-methyl tolerance for apples from 2.0 ppm to 1.5 ppm is an example, since the maximum PDP residue was 0.44 ppm, far below the newly lowered tolerance of 1.5 ppm. In this case, growers have little need to alter how the pesticide is applied, and we project no meaningful change in residue frequency or mean levels.

In cases where the maximum residue detected by the PDP is *only slightly greater than* the newly lowered tolerance, we use a simple calculation to estimate the impact on TI scores. We calculate a TI adjustment factor equal to the ratio:

$$\frac{\text{(Lowered tolerance level in ppm)}}{\text{(Maximum residue found in ppm)}}$$

When the maximum residue value found by the PDP is *substantially greater than* the newly lowered tolerance (for example, the tolerances for chlorpyrifos on apples and grapes), we calculate the adjustment factor differently. We assume that growers will change their use of the pesticide such that the maximum residue found is no higher than the newly lowered tolerance level. For chlorpyrifos on apples and grapes, as examples, we assume the new maximum residue level will be 0.01 ppm.

Since TI scores are calculated using mean PDP residue levels, we need to estimate the likely mean residue value associated with a maximum of 0.01 ppm. We examined the ratio between maximum and mean residues for 50 major pesticide-food combinations in the 1997 PDP data, and calculated the average. The average maximum/mean ratio was 8.45. Accordingly, to estimate future mean residues for substantially lowered tolerances, we divide the estimated maximum (i.e., the tolerance) by 8.45. For the chosen example of chlorpyrifos on apples and grapes, the new tolerance of 0.01 ppm, divided by 8.45, produces an estimated mean residue value of 0.00118 ppm.

The ratio of the estimated new mean residue divided by the actual past PDP mean residue can then be multiplied by the TI value for past samples, to get the estimated TI value for samples subject to the new tolerance. (I.e., the TI is recalculated using the estimated new mean residue value.) In the current example of chlorpyrifos in apples,

$$\begin{aligned} & \frac{0.00118 \text{ ppm (estimated new mean residue)}}{0.0273 \text{ ppm (mean residue from PDP 1996)}} \quad \times \quad 87.1 \text{ (TI based on 1996 data)} \\ & = 3.8 \text{ (estimated new TI score)} \end{aligned}$$

The accuracy of projected reductions in TI scores will be tested in the years ahead as new PDP data become available. In the interim, we believe this is a reasonable method for estimating impacts of EPA's risk-mitigation actions.