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 phosphorothrthioate), 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). 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.[1] 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.

[1] 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.[2] 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

[2] 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.

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>).

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,

$$\frac{\text{0.00118 ppm (estimated new mean residue)}}{\text{0.0273 ppm (mean residue from PDP 1996)}} \times 87.1 \text{ (TI based on 1996 data)}$$

$$= 3.8 \text{ (estimated new TI score)}$$

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.